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National Health  
and Nutrition  
Examination Survey

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LABORATORY  
PROCEDURES  
MANUAL



January 2004

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# **1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY**

This chapter provides a general description of the health examination surveys conducted by the National Center for Health Statistics (NCHS) and the current National Health and Nutrition Examination Survey (NHANES). It also provides an overview of the tasks that staff perform during the survey.

## **1.1 History of the National Health and Nutrition Examination Programs**

This NHANES is the eighth in a series of national examination studies conducted in the United States since 1960.

The National Health Survey Act, passed in 1956, gave the legislative authorization for a continuing survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. In order to fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) the people themselves by direct interview; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) places where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, between 1960 and 1984, the National Center for Health Statistics (NCHS), a branch of the U.S. Public Health Service in the U.S. Department of Health and Human Services, has conducted seven separate examination surveys to collect interview and physical examination data.

The first three national health examination surveys were conducted in the 1960s:

1. 1960-62 – National Health Examination Survey I (NHES I)
2. 1963-65 – National Health Examination Survey II (NHES II)
3. 1966-70 – National Health Examination Survey III (NHES III)

NHES I focused on selected chronic disease of adults aged 18-79. NHES II and NHES III focused on the growth and development of children. The NHES II sample included children aged 6-11, while NHES III focused on youths aged 12-17. All three surveys had an approximate sample size of 7,500 individuals.

Beginning in 1970 a new emphasis was introduced. The study of nutrition and its relationship to health status had become increasingly important as researchers began to discover links between dietary habits and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutrition Surveillance System was instituted by NCHS. The purpose of this system was to measure the nutritional status of the U.S. population and monitor nutritional changes over time. A special task force recommended that a continuing surveillance system include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutrition Surveillance System was combined with the National Health Examination Survey to form the National Health and Nutrition Examination Survey (NHANES). Four surveys of this type have been conducted since 1970:

1. 1971-75 – National Health and Nutrition Examination Survey I (NHANES I)
2. 1976-80 – National Health and Nutrition Examination Survey II (NHANES II)
3. 1982-84 – Hispanic Health and Nutrition Examination Survey (HHANES)
4. 1988-94 – National Health and Nutrition Examination Survey (NHANES III)

NHANES I, the first cycle of the NHANES studies, was conducted between 1971 and 1975. This survey was based on a national sample of about 28,000 persons between the ages of 1-74. Extensive data on health and nutrition were collected by interview, physical examination, and a battery of clinical measurements and tests from all members of the sample.

NHANES II began in 1976 with the goal of interviewing and examining 28,000 persons between the ages of 6 months to 74 years. This survey was completed in 1980. To establish a baseline for assessing changes over time, data collection for NHANES II was made comparable to NHANES I. This means that in both surveys many of the same measurements were taken in the same way, on the same age segment of the U.S. population.

While the NHANES I and NHANES II studies provided extensive information about the health and nutritional status of the general U.S. population, comparable data were not available for many of the ethnic groups within the United States. Hispanic HANES (HHANES), conducted from 1982 to 1984, produced estimates of health and nutritional status for the three largest Hispanic subgroups in the United States—Mexican Americans, Cuban Americans, and Puerto Ricans—that were comparable to the estimates available for the general population. HHANES was similar in design to the previous HANES studies, interviewing and examining about 16,000 people in various regions across the country with large Hispanic populations.

NHANES III, conducted between 1988 and 1994, included about 40,000 people selected from households in 81 counties across the United States. As previously mentioned, the health status of minority groups is often different than the health status and characteristics of nonminority groups, so black Americans and Mexican Americans were selected in large proportions for NHANES III. Each group comprised 30 percent of the sample. NHANES III was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. To obtain generalizable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate than previously. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure levels of pesticide exposure, presence of certain trace elements in the blood, and amounts of carbon monoxide present in the blood. A home examination was incorporated for those persons who were unable or unwilling to come to the exam center but would agree to an abbreviated examination in their homes.

In addition to NHANES I, NHANES II, Hispanic HANES, and NHANES III, several other HANES projects have been underway since 1982. These projects have been a part of the HANES Epidemiologic Follow-up Survey, a multiphase survey conducting follow-up interviews with the NHANES I population in order to provide longitudinal data on the health of the U.S. population.

## **1.2 Overview of the Current NHANES**

This NHANES follows in the tradition of past NHANES surveys, continuing to be a keystone in providing critical information on the health and nutritional status of the U.S. population.

The major difference between the current NHANES and previous surveys is that the current NHANES is conducted as a **continuous, annual survey**. Each single year and any combination of consecutive years of data collection comprises a nationally representative sample of the U.S. population. This new design allows annual statistical estimates for broad groups and specific race-ethnicity groups as well as flexibility in the content of the questionnaires and exam components. New technologic innovations in computer-assisted interviewing and data processing result in rapid and accurate data collection, data processing, and publication of results.

The number of people examined in a 12-month period will be about the same as in previous NHANES, about 5,000 a year from 15 different locations across the nation. The data from the NHANES are used by government agencies, state and community organizations, private researchers, consumer groups, companies, and health care providers.

### **1.2.1 Data Collection**

Data collected on the current NHANES survey began early in 1999 and will continue for approximately 6 years at 88 locations (stands) across the United States. The survey was preceded by a pretest in the spring of 1998 and a dress rehearsal was conducted in early 1999.

Approximately 40,000 individuals of all ages in households across the U.S. will be randomly selected to participate in the survey. The study respondents include whites as well as an oversample of blacks and Mexican-Americans. The study design also includes a representative sample of these groups by age, sex, and income level. Adolescents, older people, and pregnant women are also oversampled in the current NHANES.

The overall goals of the NHANES are to:

- Estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factor;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposure;
- Analyze risk factors for selected diseases;

- Study the relationships between diet, nutrition, and health; and
- Explore emerging public health issues and new technologies.

Selected persons are invited to take part in the survey by first being interviewed in their homes. Household interview data are collected via computer-assisted personal interviewing (CAPI) and include demographic, socioeconomic, dietary, and health-related questions. Upon completion of the interview, respondents are asked to participate in a physical examination. The examination is conducted in a specially equipped and designed Mobile Examination Center (MEC), consisting of four trailers. The MEC houses the state-of-the-art exam equipment and is divided into rooms to assure the privacy of each study participant during the exams and interviews. The examination includes a physical and dental examination conducted by a physician and a dentist, laboratory tests, a variety of physical measurements, and other health interviews conducted by highly trained medical personnel.

The household interviews and MEC exam combined will collect data in the following important health-related areas:

- Cardiovascular and respiratory disease;
- Vision;
- Hearing;
- Mental illness;
- Growth;
- Infectious diseases and immunization status in children;
- Obesity;
- Dietary intake and behavior;
- Nutritional status;
- Disability;
- Skin diseases;
- Environmental exposures;
- Physical fitness; and
- Other health-related topics.

### **1.3 Sample Selection**

A sample is defined as a representative part of a larger group. Since it is impossible to interview and examine everyone in the U.S. for NHANES, a representative sample is taken of the U.S. population. By studying a representative sample of the population, it is assumed that the findings would not have been too different had every person in the U.S. been studied. Because generalizations about the population will be made, it is extremely important that the sample be selected in a way that accurately represents the whole population. Statisticians calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population, such as age, gender, race, and income.

An introductory letter is sent to each household in the sample. A few weeks after the letter goes out, interviewers visit each listed household and use carefully designed screening procedures to determine whether any residents are eligible for the survey. If eligible residents are present, the interviewer then proceeds to introduce the study, presents the Sample Person (SP) a survey brochure, and obtains a signed consent for the household interview. The brochure contains detailed information on the survey, the household interview, and the MEC examination.

A signed consent form must be obtained from each eligible individual before the household interview can be conducted. A refusal to sign the consent form is considered a refusal to participate in the survey. After the interview is completed, the interviewer then explains the MEC exam, obtains another signed consent form for the MEC exam, and contacts the field office to schedule a MEC appointment for the SP. All SPs aged 12 years and older must sign the Examination Consent forms to participate in the MEC examination. Parental consent is also required for SPs under 18 years of age. SPs aged 7-11 years old are asked to sign the Examination Assent Form. An additional consent form is required for consent to future general research for both adults (ages 18+) and parents of children under 18 years. This consent form gives permission to store a small sample of blood and urine for future specimen testing. A refusal to sign the MEC consent or assent form is considered a refusal to participate in the examination phase of the survey. Examinations will not be performed on sample persons who do not sign a consent form.

## 1.4 Field Organization for NHANES

There are two levels of field organization for this study - the home office staff and the field staff.

- **Home Office Staff from Westat** – Project staff from Westat are responsible for overseeing the field teams and field work.
- **Field Office (FO) Staff** – For this survey, an office will be opened at every survey location (stand). Each field office will have a Study Manager (SM), Office Manager (OM), a Field Manager (FM), and one Assistant Office Manager (AOM).
  - The **Study Manager (SM)** is responsible for the overall management of operations at a stand.
  - The **Office Manager (OM)** is responsible for the stand office operations and is the main conduit for the flow of work and information between the MEC and the household interviewing staff. S/he will supervise one or more local office clerks hired to assist with office activities. The OM reports to the SM.
  - The **Field Manager (FM)** has primary responsibility for the supervision of the household interviewers. The FM also assists the SM and supervises the activities of the Assistant Office Managers. S/he will deal with administrative issues, ISIS problems, and preparations for the next stand.
  - The **Assistant Office Managers (AOMs)** are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. The AOMs report to the FM and also work closely with the OM.
- **Household Interviewers** – This staff is primarily responsible for identifying and enrolling the survey participants, conducting the household interviews, and appointing the study participants for the MEC exam. Specifically, household interviewers will locate occupied residential dwelling units, administer the Screener to select eligible sample persons, obtain signed consents to the household interview, conduct the interviews, set up examination appointments, obtain consents for the MEC exam, conduct field reminders for MEC appointments, and assist in rescheduling broken, cancelled, and no-show appointments.

Several times a week, household interviewers visit the field office and report to the field manager. During the course of the study, interviewers also interact on a daily basis with other field office staff and home office staff.

- **MEC Staff** – This staff of health professionals conducts the health exams. The survey includes two exam teams.

There are 16 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 1 licensed dentist, 3 medical technologists, 4 health technologists, 2 MEC interviewers, 2 dietary interviewers, and 1 phlebotomist. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff. A data manager also travels with each team.

The following section describes the steps that are always completed prior to the opening of a stand and an overview of the tasks that interviewers are expected to perform. Highlighted items are basic concepts critical to the conduct of the study.

Steps completed prior to interviewing include:

- Statisticians scientifically select certain segments in the sampling area. A segment is an area with definite boundaries, such as a city block or group of blocks containing a cluster of households.
- Twelve weeks before data collection begins, NHANES staff list the segments. Listing is the systematic recording on special forms of the address of every dwelling unit (DU) located within the segment. Commercial buildings and other structures not intended as living quarters are not listed.
- A sample of dwelling units is selected from the listing forms. This sample is the group of addresses that interviewers visit in order to conduct interviews.
- Immediately before data collection begins, an advance letter is sent to each dwelling unit with a mailing address. This letter briefly describes the study and inform the household that an interviewer will contact them in the near future.

The tasks interviewers perform when they arrive at a stand include:

1. After the successful completion of training, interviewers are given an assignment of sampled dwelling units to contact. Each assignment consists of pre-labeled Household Folders, pre-labeled Neighbor Information Forms, and the appropriate Segment Folder.
2. Using addresses on the Household Folders and listing/mapping materials in the Segment Folder, interviewers locate these dwelling units.
3. If a selected address is not a dwelling unit or is not occupied, interviewers complete the “Vacant/Not a DU Section” on the Screener Non-Interview Form.
4. In an occupied residential dwelling unit, interviewers contact an adult who lives in the selected household and administer the Screener using a laptop computer.

The Screener is an interview that lists all the individuals who live in the household, divides the household into families, and collects all the demographic characteristics necessary to immediately determine if there are persons in the household eligible for further interviewing.

All instructions necessary to determine eligibility and to select sample persons (SPs) are programmed in the CAPI Screener.

5. If all persons in a household are ineligible, no further work is done with the case. When eligible household members are identified, interviewers continue to conduct all the necessary tasks associated with the case.
6. In eligible households, the interviewer obtains a signed interview consent form prior to completing the medical history and/or the family questionnaire.
7. Next, the appropriate medical history CAPI interview is administered to eligible respondents. The questions asked depend on the age of the SP.
8. In each household containing children aged 1-5, floor and window sill dust samples are obtained. These samples provide information on lead levels in the household environment.
9. A Family questionnaire is also administered to one adult family member from each eligible family in the household.
10. Next, an appointment is scheduled for each SP, coordinating the MEC schedule and the SP schedule.
11. Interviewers then obtain signed consent form(s) for each SP for the examination, call the field office to confirm the examination appointment(s), and give each SP an appointment slip.
12. If there is more than one eligible family in a household, this process is repeated with each additional family.
13. Interviewers record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.
14. Interviewers also support the survey by conducting field reminders prior to MEC appointments and reschedule broken, cancelled, or no-show MEC appointments.
15. If an interviewer is unable to complete any of the questionnaires or procedures for any SP, an SP Card is completed. This card documents the problems encountered in completing one or more tasks.
16. Interviewers check for missed DUs and/or structures when instructed to do so. If any are found, the Missed DU or Missed Structure Procedures is implemented and appropriate forms will be completed.

17. When an interview has been completed, interviewers edit their work, carefully reviewing all forms for completeness and legibility.
18. Interviewers report in person to the FM at the stand office for regularly scheduled conferences, usually every other day. During these conferences, interviewers discuss completed cases, discuss problems with incomplete cases, receive new case assignments, and report time, expenses, and production.
19. To insure the accuracy and completeness of the survey, all interviewer work is edited by the field office staff, and then validated by recontacting respondents. After this review, supervisors provide interviewers with feedback concerning the quality of the work.
20. At the end of each stand field period, interviewers return all interviewing materials to the supervisor.

## **1.5 Exams and Interviews in the Mobile Examination Center (MEC)**

Examinations and interviews are conducted in a mobile examination center (MEC), which is composed of four specially equipped trailers. Each trailer is approximately 48 feet long and 8 feet wide. The trailers are set up side-by-side and connected by enclosed passageways. During the main survey, detachable truck tractors drive the trailers from one geographic location to another.

Exhibit 1-1 shows a floor plan for the MEC. The interior of the MEC is designed specifically for this survey. For example, the trailers are divided into specialized rooms to assure the privacy of each study participant during exams and interviews. Many customized features have been incorporated including an audiometry room that uses a soundproof booth, a wheelchair lift, and a wheelchair-accessible bathroom available to assist participants with mobility problems. Exhibit 1-2 shows the locations of the various exams within the MEC.

### **1.5.1 Exam Sessions**

The MEC operates 5 days a week and includes weekday, evening, and weekend sessions. Two 4-hour sessions are scheduled each day with approximately 10-12 SPs per session. During a stand, work weeks rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

Exhibit 1-1. Floor plan of the MEC

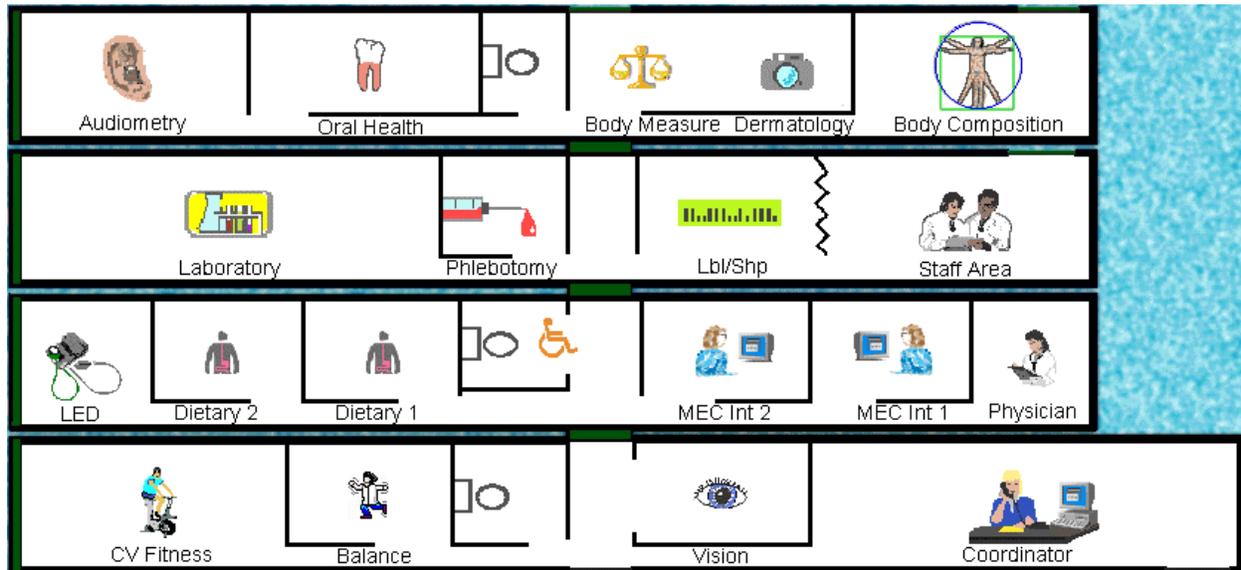


Exhibit 1-2. MEC exams and rooms

<u>Trailer</u>	<u>Room</u>	<u>Room Use</u>
Trailer 1	Reception area	Welcoming and waiting area for SPs
	Vision room	Vision tests
	Balance	Balance test
	Fitness	Cardiovascular fitness
Trailer 2	Physician	Physical examination
	MEC Interview	Health interview
	MEC Interview	Health interview
	Dietary Interview	Dietary interview
	Dietary Interview	Dietary interview
	Lower Extremity Disease	Testing for lower extremity pulses and sensitivity
Trailer 3	Venipuncture	Drawing of blood samples, MRSA collection and physical activity monitor
	Laboratory	Processing of urine and blood samples
	Label/shipping area	Lab area for labeling and shipping specimens
	Staff lounge	Staff area that houses main computer system
Trailer 4	Total Body Composition	Total body composition scans and bioimpedance
	Body Measures	Body measurements and dermatology
	Dental	Dental exam
	Audiometry/Tympanometry	Hearing tests

## 1.5.2 Exam Team Responsibilities

There are 16 individuals on each exam team. In addition, a local assistant will be hired to assist the staff in managing examinee flow. One data manager also travels with each team. The duties of the exam team members are summarized below:

- One MEC manager supervises the exam staff, manages the facility, and supports exam operations.
- One coordinator directs the flow of SPs through the MEC examination process. The coordinator manages all SP appointments, verifies that all components are completed for each SP, and exits SPs from the MEC.
- One physician conducts the medical examination and records results, reviews the results of the complete blood count and pregnancy test, and serves as the safety officer for the MEC.
- One dentist conducts the dental exam and calls the results to a health technologist who records the findings.
- Two health (MEC) interviewers administer questionnaires for physical and mental health information.
- Two dietary interviewers administer the dietary questionnaire. The interviewers record a 24-hour dietary recall of the types and amounts of foods consumed by the SP in the last 24 hours.
- Four health technologists with radiologic technology or other health training take and record body measurements, perform balance tests, vision tests, cardiovascular fitness tests, muscle strength assessments, lower extremity measures, total body composition (DEXA) scans, bioimpedance (BIA) tests, administer hearing tests, and collect skin images. In addition, the technologists record findings for the dental examiner.
- Three medical technologists conduct clinical laboratory tests on biological and environmental specimens, record the results of the tests, and prepare and ship specimens to various laboratories.
- One phlebotomist administers the phlebotomy questionnaire draws blood from SPs, and recruits SPs for special studies.
- The data manager (DM) assists in the setup and testing of computer systems and telecommunications hookups at the FO and MEC. S/he also coordinates the maintenance and repair of computer systems at the FO and MEC with the home office and external vendors and acts as the FO and MEC systems “help desk” person. The data manager reports to the SM on administrative matters and the HO for ISIS-related matters.

Each staff member is part of a team of professional persons with specific assignments that must be completed in order to accomplish the overall objective of the survey. Each individual must be aware of and respect the job demands placed upon other staff members, maintain an attitude of tolerance and consideration for fellow members of the team, and willingly perform extra tasks that may be assigned to support other staff members in the performance of their duties. MEC staff members may be requested to perform tasks not directly related to their specific professional skills in order to implement the overall data collection plan.

### **1.5.3 Examination Components**

The full examination for an adult takes approximately 3½ hours, but the actual length depends on the SP's age. Some exams are done only on certain age groups so the exam profiles vary, even among adult SPs. The exam components are described briefly below and summarized in Exhibit 1-3:

- **Anthropometry**

The purpose of the anthropometry component is to provide: (1) nationally representative data on selected body measures, (2) estimates of the prevalence of overweight and obesity, (3) data to study the association between body measures and such health conditions and risk factors as cardiovascular disease, diabetes, hypertension, and activity and dietary patterns, and (4) data to monitor growth and development in children. A total of 11 body measurements are collected, but the number and type of measures varies with the age groups.

- **Balance**

Balance disorders, disequilibrium, and dizziness from vestibular disorders constitute a major public health problem. Primary disorders may be hidden by their consequences, such as falls, while subtle dysfunction may underlie difficulties in learning, writing, reading, and in everyday activities. The main objectives of the balance test are to obtain prevalence data, examine the relationship between balance disorders and other factors, and to characterize normal and disordered balance and spatial orientation. The standard Romberg test is used to measure postural sway.

- **Bioelectrical Impedance Analysis (BIA)**

The purpose of the BIA exam is to monitor secular trends in overweight prevalence, describe the prevalence of obesity, and examine the relationship between overweight and obesity and other examination measures. BIA measures the electrical impedance of body tissues and is used to assess fluid volumes, total body water, body cell mass, and fat-free body mass.

Exhibit 1-3. Examination components

<b>Component</b>	<b>Ages</b>
Anthropometry	All
Audiometry/Tympanometry	20-69 (half-sample)
Balance	40+
Bioimpedance (BIA)	8-49
Cardiovascular Fitness	12-49
Dermatology	20-59
Dietary Interview	All
Lower Extremity Disease	40+
MEC Interview	8+
Mental Health	8-19 years (also includes parents of 8-15-year-olds); 20-39 years (half-sample)
MRSA sample collection	1+
Oral Health	2+
Physical Activity Monitor	6+
Physician Exam	All
Total Body Composition	8+
Urine Collection	6+
Venipuncture	1+
Vision	12+
Volatile Organic Compounds (VOC)	20-59 (random subsample)

■ **Cardiovascular Fitness**

Evaluation of physical fitness provides nationally representative data on measures of physical fitness, and estimates of the prevalence of persons at risk due to sedentary habit and poor physical fitness. Cardiovascular fitness is assessed with a submaximal treadmill test on examinees aged 12 through 49 years.

■ **Dermatology (Skin Disorders)**

The specific aims of this component are: (1) to monitor the prevalence, secular trends and impact of selected skin conditions that were last assessed in NHANES I (1971-75); (2) to identify risk factors for selected skin conditions that can be used to increase understanding of disease etiology and prevention; and (3) to create a data resource that can be used to develop a CDC National Skin Cancer Prevention and Control Agenda. The MEC dermatology exam involves standardized photography of selected sites on the body. This component will focus on two specific skin diseases: psoriasis and hand dermatitis. The major goal is to determine the prevalence of these two conditions.

- **Dietary Interview**

The goal of the dietary component is to estimate total intake of foods, food energy and nutrients, nonnutrient food components, and plain drinking water by the U.S. population; and assess dietary behaviors and the relationship of diet to health. Quantitative dietary intake data is obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system. A second 24-hour recall will be conducted on all SPs by telephone through a phone center operation at the home office. In 2003, a self-administered form, the Food Frequency Questionnaire, will be offered to SPs who complete the MEC dietary interview. It will be mailed from and returned to the home office.

- **Hearing**

The goals of the hearing exam are to obtain normative data on the hearing status of the adult U.S. population, and to evaluate certain covariates that may be related to hearing loss, such as occupational exposure. The hearing component tests adults by performing pure tone audiometry and tympanometry. Because pure tone screening by itself may not be sensitive enough to detect middle ear disease, tympanometry is conducted to provide an estimate of tympanic membrane compliance.

- **Laboratory**

The laboratory component includes the collection and processing of various biological and environmental specimens including blood for subjects 1 year and older, urine for subjects 6 years and older. On-site pregnancy testing excludes pregnant women from other examination components such as DEXA, BIA, and cardiovascular fitness testing. Complete Blood Counts (CBCs) are also performed in the MEC laboratory. All other specimen testing is performed by Federal, private, and university-based laboratories under contract to NCHS.

- **Lower Extremity Disease (LED)**

The purpose of this component is to determine the prevalence of LED and its risk factors. Simple and reproducible measures of lower extremity arterial disease are obtained. Peripheral neuropathy is evaluated by measurement of cutaneous pressure sensation in the feet. Foot deformities permit the estimation of prevalence of those at high risk for the late-stage complications of LED.

- **MEC Interview**

The MEC Interview consists of questionnaire sections designed to obtain information on health behaviors, specific conditions, medical history, and risk factors. The information collected in the interview is intended to assist researchers in analyzing the data collected in the other examination components. The interview is administered to all age-eligible subjects, or a suitable proxy, using computer-assisted interviewing software.

- **Mental Health**

The mental health assessment is used to estimate the prevalence of selected disorders in the U.S. and to describe the degree of comorbidity between mental health disorders and other medical conditions and biological risk factors. Assessments are made during the MEC Interview using relevant portions of the Diagnostic Interview Schedule for Children (DISC) and the Composite International Diagnostic Interview (CIDI) for adults.

- **Methicillin-Resistant *S. Aureus* (MRSA) Sample Collection**

A nasal swab specimen collection for Methicillin-Resistant *Staphylococcus aureus* (*S. aureus*) is obtained on SPs aged 1+ years for the purpose of estimating the prevalence of MRSA in the population. Antimicrobial resistance to *S. aureus* has increased so dramatically, particularly in the hospital setting, that currently only one treatment option exists for this organism. NHANES is the first population-based prevalence study of MRSA. No other population-based studies or national surveillance efforts are available to provide reliable national estimates for this problem.

- **Oral Health**

This component monitors oral health status, risk factors for disease, and access to preventive and treatment services. The exam consists of a series of subcomponents which assess dentition and periodontal disease.

- **Physical Activity Monitor**

The purpose of physical activity monitor component (PAM) is to assess the physical activity levels of NHANES examinees 6+ years of age. NHANES examinees wear a physical activity monitor (PAM) to examine physical activity patterns over a 7-day monitoring period and then mail it back to the home office. The monitors detect locomotion-type activities such as walking or jogging. The monitors provide a means of capturing non-structured activities that are often difficult for survey respondents (SPs) to self-report. Physical activity data are linked to other household interview and health component data and are used to track changes that occur in body weight, functional status, bone status, and health status over time.

- **Physician Exam**

Blood pressure assessment and discussion of testing for sexually transmitted disease are the primary elements of the physician's exam. The purpose of assessment of blood pressure is to monitor prevalence and trends in major cardiovascular conditions and risk factors and to evaluate prevention and treatment programs targeting cardiovascular disease. The physician discusses the purpose of STD testing and arranges for SPs to select a unique password with which to phone NCHS and obtain test results.

- **Total Body Composition**

This component is composed of the BIA and Dual Energy X-ray Absorptiometry (DEXA). The purpose of the DEXA scan is to gain insights into age, gender, and racial/ethnic differences in the skeleton relative to other measures of body composition such as total muscle and fat mass, as well as behavioral factors such as diet and activity. A total body scan using dual energy X-rays is performed to provide measures of bone mineral content, bone mineral density, muscle and fat mass.

- **Vision**

The vision examination consists of a near vision acuity test, a distance vision acuity test, an eyeglass prescription determination (when appropriate), and an automated refraction measurement. Information from the component may be used to estimate the prevalence of visual acuity impairment and distribution of refractive error in the U.S. population. Data are also used to evaluate screening strategies for visual impairment and eye disease, and evaluate functional impairment related to vision.

- **Volatile Organic Compounds (VOC)**

Information on levels of exposure to a selected group of volatile organic compounds is collected on a subsample of the survey population to assist in determining whether regulatory mechanisms are needed to reduce the levels of hazardous air pollutants to which the general population is exposed.

#### **1.5.4 Sample Person Remuneration**

All examinees receive remuneration for the MEC visit as well as payment for transportation expenses. The MEC visit remuneration is age-related and includes an extra incentive if the SP fasts prior to the exam. SPs who complete the physical activity monitoring component also receive an incentive. In addition, remunerations are offered to SPs who complete the dietary phone interview and the Food Frequency Questionnaire.

#### **1.5.5 Report of Exam Findings**

Examinees receive the results of many of the tests and exams conducted in the MEC, though some results are used only for research and are not reported.

One report, a Preliminary Report of Findings, is produced for the SP on the day of their examination and includes results that are immediately available and require no further evaluation or

interpretation. Just prior to the examinee's departure from the MEC, the coordinator prints a report that includes height, weight, and body mass index, complete blood count, blood pressure, and results from the audiometry, cardiovascular fitness, lower extremity disease, vision, and dental exams. The MEC physician reviews the blood pressure and complete blood count test results for abnormalities and discusses any problems with the SP (or their parent). The dentist also discusses the dental recommendations with the SP. Approximately 12-16 weeks after the exam, NCHS mails the remainder of the examination results to the SP after appropriate clinical or quality reviews are completed. Seriously abnormal results are reported to the SP via telephone by NCHS before the remaining findings are mailed.

Certain tests, such as those for sexually transmitted diseases (chlamydia, gonorrhea, syphilis, Herpes simplex 1 and 2, bacterial vaginosis, and Trichomoniasis) and human immunodeficiency virus (HIV) are released only to the sample person using a specially devised procedure requiring a unique password.

To further assist sample persons, an in-house NCHS survey response team is available to answer calls from NHANES participants regarding the results from the Report of Finding System. The response team effort works both as a triage mechanism and a surveillance system. A receipt and control record is kept on all sample person inquiries. Also available at no cost to sample persons is an 800 toll-free telephone number which can be accessed during regular scheduled business hours. The response team members include a physician, a nurse with a doctorate degree, and other staff who are trained to answer specific questions.

Tests and procedures conducted in the MEC are not considered diagnostic exams and are not a substitute for an evaluation by a medical professional. No clinical treatments or health interventions of any type are performed in the MEC. If a health problem is discovered during the course of the MEC exam, the physician offers to contact the examinee's personal healthcare provider or recommend a local physician or clinic for follow-up care. If a sample person is found to have a serious condition requiring immediate attention, the local rescue squad may be summoned or the SP will be advised to seek immediate medical treatment.

### **1.5.6 Dry Run Day**

At the beginning of the examination period, one-half day is devoted to calibrating instruments, practicing MEC procedures, and collecting biological specimens that serve as blind quality control samples. A dry run day is scheduled immediately prior to the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. Any problems are corrected quickly before the “real” examinations begin. All procedures in the dry run are completed as though the actual exam session was being conducted. The only difference is that the examinees are actual volunteers who are not part of the sample for the survey. Volunteers may include local residents, local officials, or field employees or guests of NCHS.

### **1.6 Integrated Survey Information System (ISIS)**

The Integrated Survey Information System (ISIS) is a computer-based infrastructure designed to support all survey operations including sample management, data collection, data editing, quality control, analysis, and delivery of NHANES data. With a collection of customized subsystems, the ISIS links the Field Office, Mobile Examination Center, Westat home office, and NCHS during field operations. Each component in NHANES such as Dietary Interview has a computer application for direct data entry. Data collected in the Dietary Interview room of the mobile examination center is directly entered in the ISIS system computers. In addition, data from biomedical equipment such as the blood pressure monitor in the CV Fitness room is directly downloaded to the ISIS system where it is displayed on the computer screen and stored in the system database.

### **1.7 Confidentiality and Professional Ethics**

All information regarding this study must be kept strictly confidential except as required by law. This includes location of survey sites. Since this study is being conducted under a contract with the National Center for Health Statistics, the privacy of all information collected is protected by two public laws: Section 308(d) of the Public Health Service Act (42 U.S.C.242m) and the Privacy Act of 1974 (5 U.S.C. 552a).

Each person working on the study must be continuously aware of the responsibility to safeguard the rights of all the individuals participating in the study. Each participant should be treated courteously, not as a sample number. Never divulge names or any other information about study participants except to the research team. Refrain from any discussions about study participants, in or out of the MEC, which might be overheard by people not on the survey staff. All of the members of the research team are under the same legal, moral, and ethical obligations to protect the privacy of the SPs participating in the survey. No participant names will be included in any reports prepared about the survey and neither NCHS nor the contractor is allowed to release information that would identify study participants without the consent of the participants.

Cooperation from the public is essential to the success of survey research. A great deal of effort is expended in obtaining cooperation from many national, regional, state, and local officials and the general public. It is the responsibility of every field employee to build on the integrity of the survey to encourage continued access to study participants during current and future surveys. Professional conduct, both on and off the job, is extremely important.

Each staff member has a responsibility for promoting good public relations. The Public Health Service and the contractor will be judged by the actions of the staff both on and off duty; consequently staff must be discreet in speech and action. Personal appearance and behavior must be governed by these same considerations. Please be aware of the audience at all times and avoid statements or actions that could shed an unfavorable light on the survey.

Staff will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that they are prohibited by law from disclosing any information while working on the survey to anyone except authorized staff of NCHS and the contractor, and that they agree to abide by the contractor's Assurance of Confidentiality.

## 2. OVERVIEW AND LABORATORY TEAM RESPONSIBILITIES

### 2.1 Overview

The laboratory component of NHANES includes the collection, processing, storage, and shipping of blood, urine, and other biological and environmental specimens. Collectively, these specimens provide data about the health status of the U.S. population.

The blood collection (venipuncture) procedure consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw. The phlebotomist also collects one additional blood tube and administers a questionnaire to SPs selected for the VOC (volatile organic compounds) special study, collects a nasal swab to test for Methicillin-Resistant *Staphylococcus aureus* (MRSA), and recruits SPs to wear a physical activity monitor for 7 days.

The purpose of urine collection and processing is to collect sufficient urine from participants aged 6 years and older to be able to (1) perform a pregnancy test on selected females aged 8 to 17 years and all females aged 18 to 59 years to exclude pregnant participants from other components that could put the participant at risk; (2) allocate urine into 12 vessels for storage and transport to seven laboratories for analysis; (3) allocate urine into two vessels for future studies; and (4) hold and process urine as a backup for the HIV blood test when the amount of blood collected was insufficient.

The purpose of blood processing is to (1) perform a complete blood count; (2) allocate blood into 42 vessels for storage and transport to 17 laboratories across the United States for analysis; and (3) allocate plasma and serum into vessels for future studies.

The purpose of collecting and processing lead dust wipes and vaginal and nasal swabs is to be able to store and transport these samples to various laboratories for analysis. One vaginal swab is used to prepare a slide for gram stain and to determine pH.

The purpose of performing a complete blood count on blood specimens is to provide a study of blood cells and coagulation.

The purpose of pregnancy testing is to exclude pregnant women aged 8-59 years from participating in the dual-energy x-ray absorptiometry (DXA) and bioelectrical impedance analysis (BIA) sections of the Body Composition component of the MEC exam.

The purpose of conducting the special Volatile Organic Compounds (VOCs) study is to determine the prevalence of exposures to certain chemicals.

## **2.2 The Laboratory Team**

Each laboratory team includes three ASCP (American Society of Clinical Pathologists) certified medical technologists or medical laboratory technologists who have experience in all aspects of laboratory practice and a certified phlebotomist who has experience in venipuncture.

The chief medical technologist is the most senior member of the team. The chief medical technologist is responsible for overseeing all the activities of the medical technologists and phlebotomist in the MEC, and also quality control, equipment calibration, and maintenance. On a routine basis, the chief medical technologist performs the same duties as the other medical technologists.

## **2.3 Tasks**

The phlebotomist's tasks include performing MEC equipment QC activities and recording the results, conducting the venipuncture, administering the VOC questionnaire, recording collection of the VOC tap water sample, collecting nasal swabs, recruiting SPs to participate in the physical activity monitor study, printing laboratory labels and labeling blood processing racks, recording oral health and body measures results, assisting the medical technologists as needed, and managing the component inventory.

The medical technologist's tasks include performing MEC equipment QC activities and recording the results; printing labels and labeling vessels; performing complete blood counts (CBCs); conducting pregnancy tests; processing blood, urine, nasal, and vaginal swabs; lead dust wipes; lead dust QC specimens; tap water samples; and shipping specimens to contact laboratories. On a routine basis the medical technologists assist the phlebotomist as needed and manage the component inventory.

## 2.4 Organization of the Laboratory

The laboratory consists of three areas—the phlebotomy room, the laboratory (biological and environmental sample processing/hematology/pregnancy testing) area, and the label/shipping area. The phlebotomy room and laboratory area are located in the back half of trailer #3. The label/shipping area is located in part of the front section of trailer 3.

The phlebotomist collects blood, administers the VOC questionnaire, records collection of the VOC tap water sample, collects nasal swabs, and recruits SPs to participate in the physical activity monitor study in the phlebotomy room. The medical technologist processes, stores, and ships biological and environmental samples, runs CBCs, and performs pregnancy testing in the laboratory area. They print labels, label blood processing racks, and prepare shipping documents in the label/shipping area.

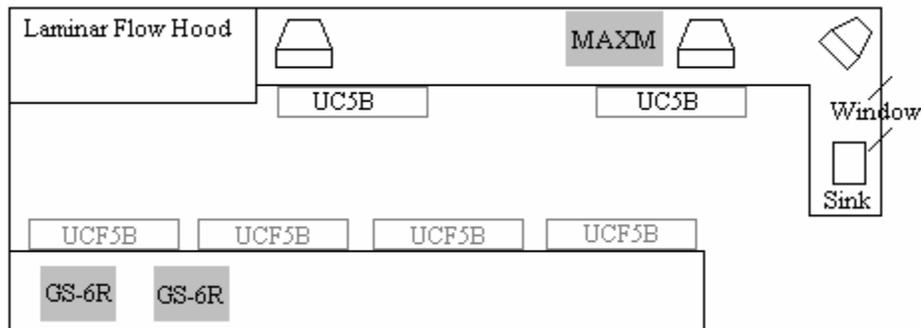


Figure 2-1. Laboratory area

### Laboratory Area Floor Plan

The laboratory area contains two workstations designated workstation 1 and workstation 2. Blood processing, storage, and HIV urine processing occurs at workstation 1. Urine collection, urine processing and storage, pregnancy testing, running CBCs, lead dust and VOC specimen processing, nasal and vaginal swab specimen processing, and routine quality control activities occur at workstation 2.

Workstation 3 is located in the label/ship area of the laboratory. Printing labels, labeling vials for each SP's blood-processing rack, and shipping activities occur at this workstation. Packing specimens in shippers may also occur at workstations 1 and 2.

## **2.5 Tasks – Phlebotomy Room**

- Set up supplies and check expiration dates of Vacutainer® tubes.
- Maintain the Supply Use Control Log.
- Conduct the venipuncture interview, administer the fasting questionnaire, perform the venipuncture, collect tap water samples for selected participants, administer the VOC questionnaire, collect nasal swabs, and recruit SPs to participate in the physical activity monitor study.
- Enter blood, tap water, nasal swab collection results, and recruitment results.
- Label and transfer all blood tubes, tap water samples, and nasal swabs to the laboratory area.
- Fit the physical activity monitor on each recruited SP.
- Disinfect all the counters at the beginning and end of each day.
- Record the QC readings.
- Maintain the appearance of the venipuncture area and the equipment.
- Monitor the inventory and restock supplies.
- Conduct the start and end of stand inventory counts.
- Clean the phlebotomy room at the start and end of each stand.
- Assist in printing laboratory labels and label and assemble blood-processing racks.
- Serve as the backup oral health and body measures recorder.

## **2.6 Tasks – Workstation 1**

- Stock blood processing and storage supplies.
- Receive blood specimens.
- Select the correct pre-labeled rack and age appropriate template.
- Set the red top blood tubes aside to clot.

- Pipette whole blood into separate 2-mL cryovials for vessel 1 (Lead/Cad/HG), vessel 2 (Ery Proto), vessel 3 (RBC Folate), vessel 4 (Glycohem), vessel 5 (Mercury), vessel 6 (CD4), and vessel 88 (Acrylamide) from the 3-mL or 4-mL lavender tube.
- Transfer the 3-mL or 4-mL lavender tube to the workstation 2 technologists for hematology.
- Make the dilution for vessel 3 (RBC Folate).
- Centrifuge the remaining whole blood in the 3-mL lavender tube on SP age 3-5 and centrifuge the 4-mL lavender tube on SPs age 6+ in the refrigerated centrifuge.
- Pipette the plasma from the 3-mL or 4-mL lavender tube into 2-mL cryovials for vessel 81 (Vitamin B6), vessel 7 (Homocys/MMA), and vessel 8 (Xtra Plasma).
- Centrifuge the 2-mL gray tube.
- Pipette the plasma from the 2-mL gray tube into a 2-mL cryovial for vessel 9 (Glucose).
- Centrifuge the red top tubes.
- Pool the serum from the 7-mL and 15-mL red top tubes for each SP and mix well.
- Aliquot serum into separate 2-mL cryovials for vessels 70, 12, 13, 14, 87, 99, 11, 17, 21, 85, 77, 79, 16, 19, 20, 18, 23, 22, 24, 74, 75, 15, 26, and 32-37.
- Make the dilution for vessel 79 (Vitamin C).
- Pour serum from one of the 10-mL red tubes into a 5-mL cryovial for vessel 29 and the serum from the second 10-mL red tube into a 5-mL cryovial for vessel 89.
- Enter the blood processing results.
- Refrigerate or freeze the processed vessels.
- Access the HIV urine processing module and record HIV urine (vessel 53) processing results.
- Check contents of blood and HIV urine storage boxes (containers) using the box map module at the end of each session.
- Disinfect all the counters and the laminar flow hood at the beginning and end of each session.
- Maintain appearance of the blood processing area and the equipment.
- Monitor the inventory and restock supplies.

- Conduct the start and end of stand inventory counts.
- Clean the laboratory at the start and end of each stand.
- Assist in printing laboratory labels and label and assemble blood-processing racks.

## **2.7 Tasks – Workstation 2**

- Perform start of stand, start of session, end of session, weekly, and end of stand quality control checks on laboratory equipment and record results.
- Maintain the Supply Use Control Log.
- Prepare the ascorbic acid.
- Prepare the 6% MPA (metaphosphoric acid).
- Stock supplies for urine processing, hematology, pregnancy and pH testing, and gram stain slide preparation.
- Enter the urine collection results.
- Label urine vessels and aliquot urine into 2 or 5-mL cyrovials or 14-mL Falcon snap cap tubes for vessels 45, 46, 69, 86, 48, 49, 62, 50, 65, 66, 67, 51, 52 and 53.
- Enter the urine processing results.
- Store the urine vessels.
- Run the pregnancy test controls.
- Conduct the pregnancy test and enter results.
- Perform start-up procedures and run quality control materials on Coulter® MAXM.
- Run specimens on the Coulter® MAXM and enter results.
- Print the lead dust and lead dust QC labels.
- Process lead dust, lead dust QC samples, nasal and vaginal swabs, and VOC (blood and water) specimens.
- Check contents of urine, lead dust, nasal and vaginal storage boxes and bags using the box maps module at the end of each session.
- Disinfect all counters at the beginning and end of each session.

- Maintain the appearance of the urine processing/hematology area and the equipment.
- Monitor the inventory and restock supplies.
- Assist the phlebotomist with venipuncture.
- Conduct the start and end of stand inventory counts.
- Clean the laboratory at the start and end of each stand.
- Assist in printing laboratory labels and label and assemble blood-processing racks.

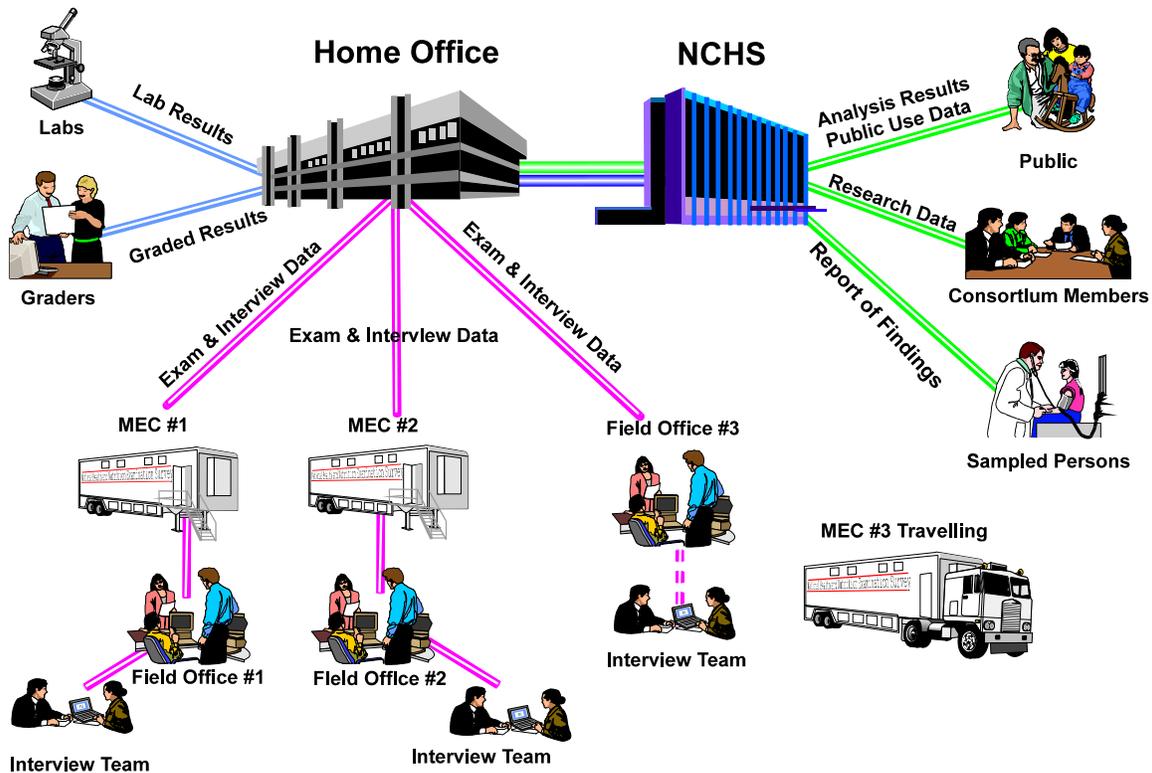
## **2.8 Tasks – Workstation 3**

- Print blood, urine, vaginal swab (lab and physician), and pregnancy testing labels.
- Pre-label the vials for each SP's blood-processing rack.
- Generate container IDs at the start of stand.
- Assign a container ID number to one container for each vessel.
- Close all open containers, create air bills, and assign containers to shippers.
- Prepare shipping manifests and send electronic files.
- Prepare blood (whole blood, serum, and plasma), urine, nasal swab, vaginal slide and swab, special study samples, and lead dust specimens for shipping.
- Pack, weigh, label, and ship shippers.
- Open all new containers after shipping.
- Run FedEx tracking.
- Maintain appearance of the label/ship area and the equipment.
- Monitor inventory and restock supplies.
- Assist phlebotomist with venipuncture.
- Conduct start and end of stand inventory counts.
- Clean the laboratory at the start and end of each stand.

### 3. INTEGRATED SURVEY INFORMATION SYSTEM (ISIS)

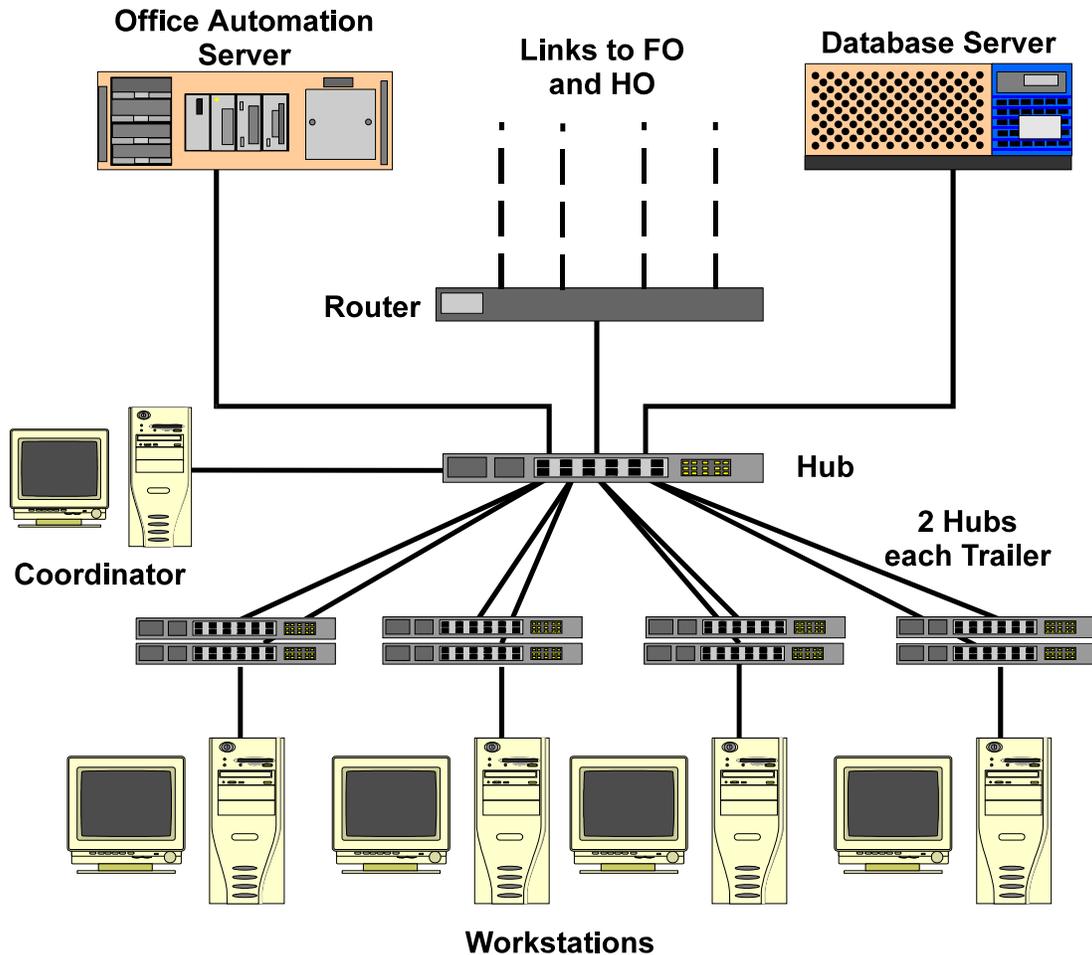
#### 3.1 Network Overview

The illustration below depicts how the MEC subsystems are connected to the field office (FO) and the home office (HO) to supply the SP data necessary to conduct the multitude of examinations. The field office manages the interview teams that conduct the footwork of identifying and gathering detailed data on prospective SPs and transmit the information to the FO and HO for processing. This information is stored in databases and retrieved by the MEC subsystems in preparation for examinations. The results of FO surveys and MEC examinations are collected, analyzed, and prepared for dissemination for research purposes.



Each ISIS workstation is an integral component of a sophisticated network that links the MEC workstations together with utility and database servers, and the home office. Continual status communications between the workstations and the coordinator station enable orchestration of activities and personnel flow.

A simplified Intranet schematic is illustrated below:



Each workstation connects to both the office automation server (NT Server) and the database server (Sybase) through a series of hubs. These hubs connect the servers and workstations (operating on Windows NT) within the MEC trailers to form part of the ISIS system. The MEC network communicates with both the Field Office (FO) and Home Office (HO) using primary and backup data links. The data links synchronize operational activities and transfer examination and other data as scheduled.

### **3.2 MEC Coordinator Overview**

The MEC coordinator subsystem is designed to orchestrate the flow of sample persons (SPs) throughout the MEC examination process. Continual interaction between each workstation and the coordinator enables smooth passing of SPs from one workstation to another. Each component examination program automatically transmits the status of the examination to the coordinator to assist in synchronizing the next component assignment. Exams cannot be performed without specific assignment of a technologist and a SP.

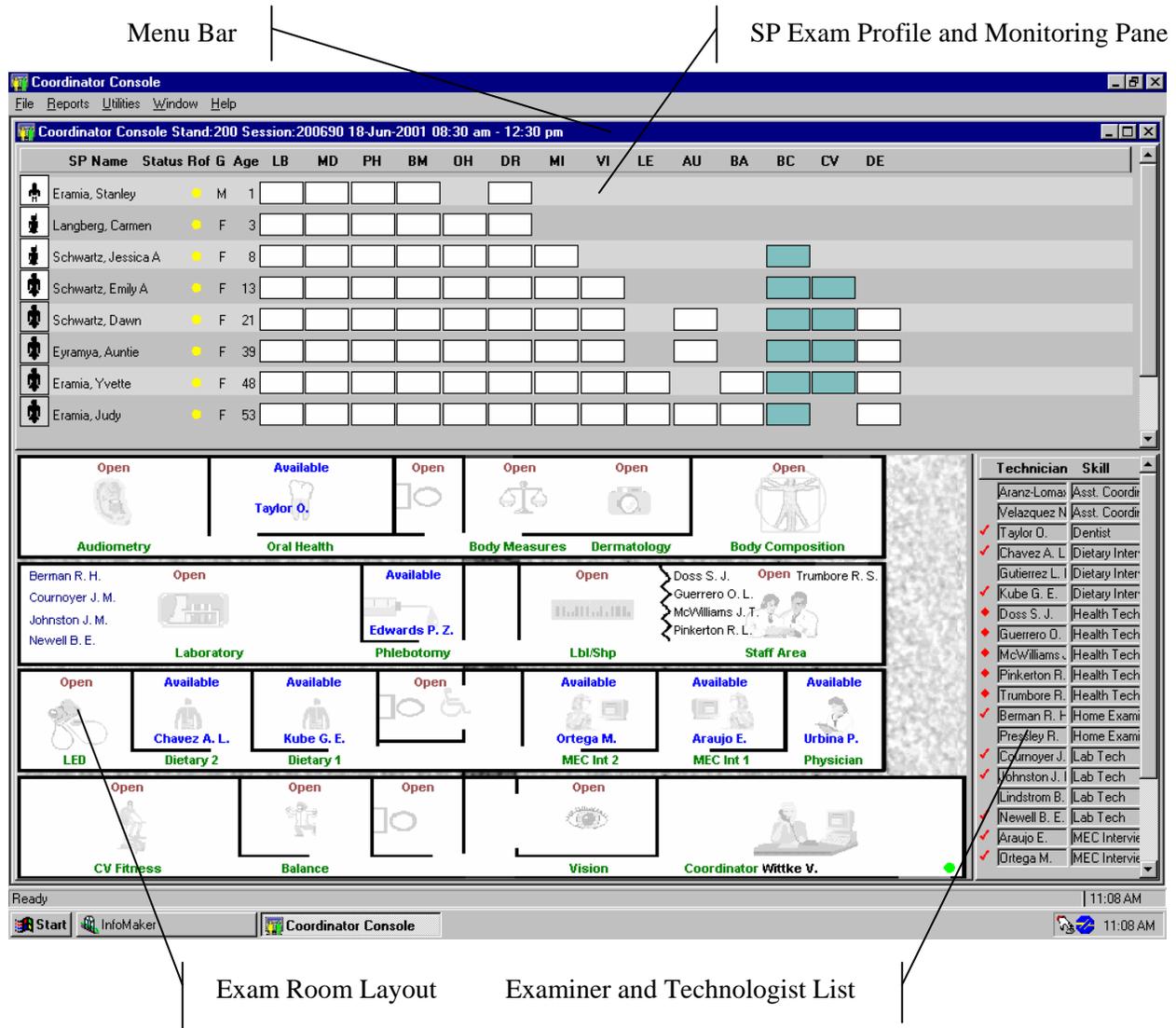
The MEC coordinator subsystem receives appointments scheduled by the field office's Appointment Management Subsystem (AMS). The coordinator application determines the appropriate examination program, called a 'profile,' based on gender and age at the time of the household interview.

During the conduct of the session operations, the coordinator application provides a graphical representation of the location of SPs in the MEC, the status of exam components, the availability of examiners, and the availability of exam stations.

The coordinator subsystem is the nerve center for the MEC. All functions of the coordinator are executed with the graphical interface designed to assign, monitor, and manage all activities within the MEC. The coordinator tracks each SP through the MEC using the coordinator system. This system tracks the SP throughout the exam, including arrival, location during the session, and exit. The coordinator uses this system to direct the SP to the appropriate workstations in the MEC and to determine if all the appropriate examinations are complete. The MEC coordinator monitors exam component status using responses from examination stations.

Each SP receives a bar-coded ID bracelet when they arrive at the MEC. The bracelet remains on the SP throughout the session. This bracelet contains the SP's ID number in bar code and eye-readable format. The examiner "wands" the bracelet bar code with a bar code scanner (wand) to log the SP into the exam component. If necessary, the ID number can be entered manually by reading it from the bracelet and entering it using the keyboard keys.

The coordinator screen, illustrated below, is organized into three major panes and a menu bar:



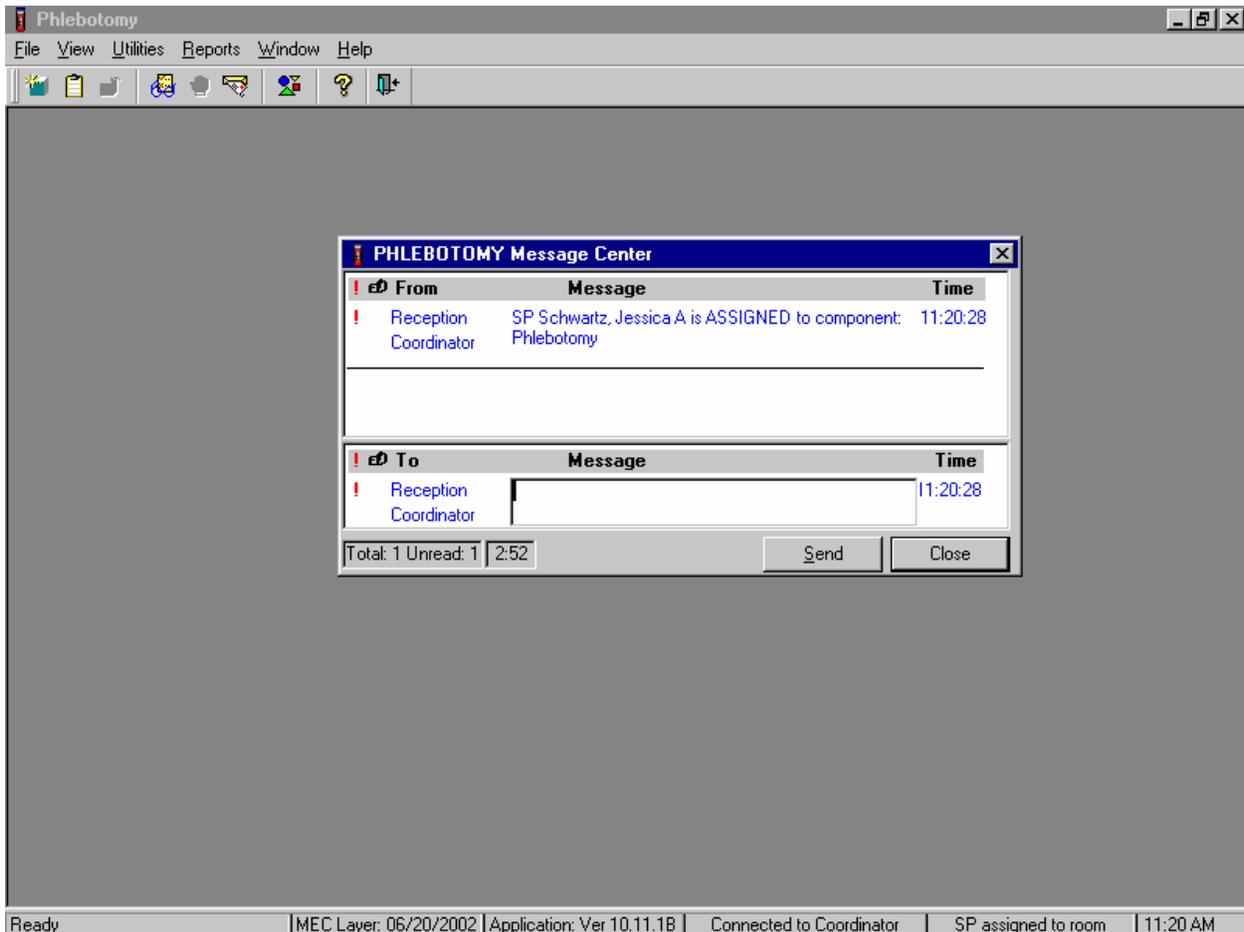
- The Menu Bar provides access to options detailed in the following section.
- The SP Exam Profile and Monitoring pane displays each SP exam profile, current status, and examination progress. (The actual screen shows all three scheduled SPs and three VIP guests). The Examination Profile pane is designed to assist the coordinator to assess the availability of examination components against the required examination profiles for each SP, and to manage the movement of SPs and staff.

- The MEC Examination Rooms Layout visually portrays the floor plan of the MEC, availability of each examination room, assigned examiner and technologist, the location of SPs, and examination status for each room.
- The Examiner and Technologist List shows available examiners and technologists along with their status.

### 3.2.1 Assigning an SP to an Exam

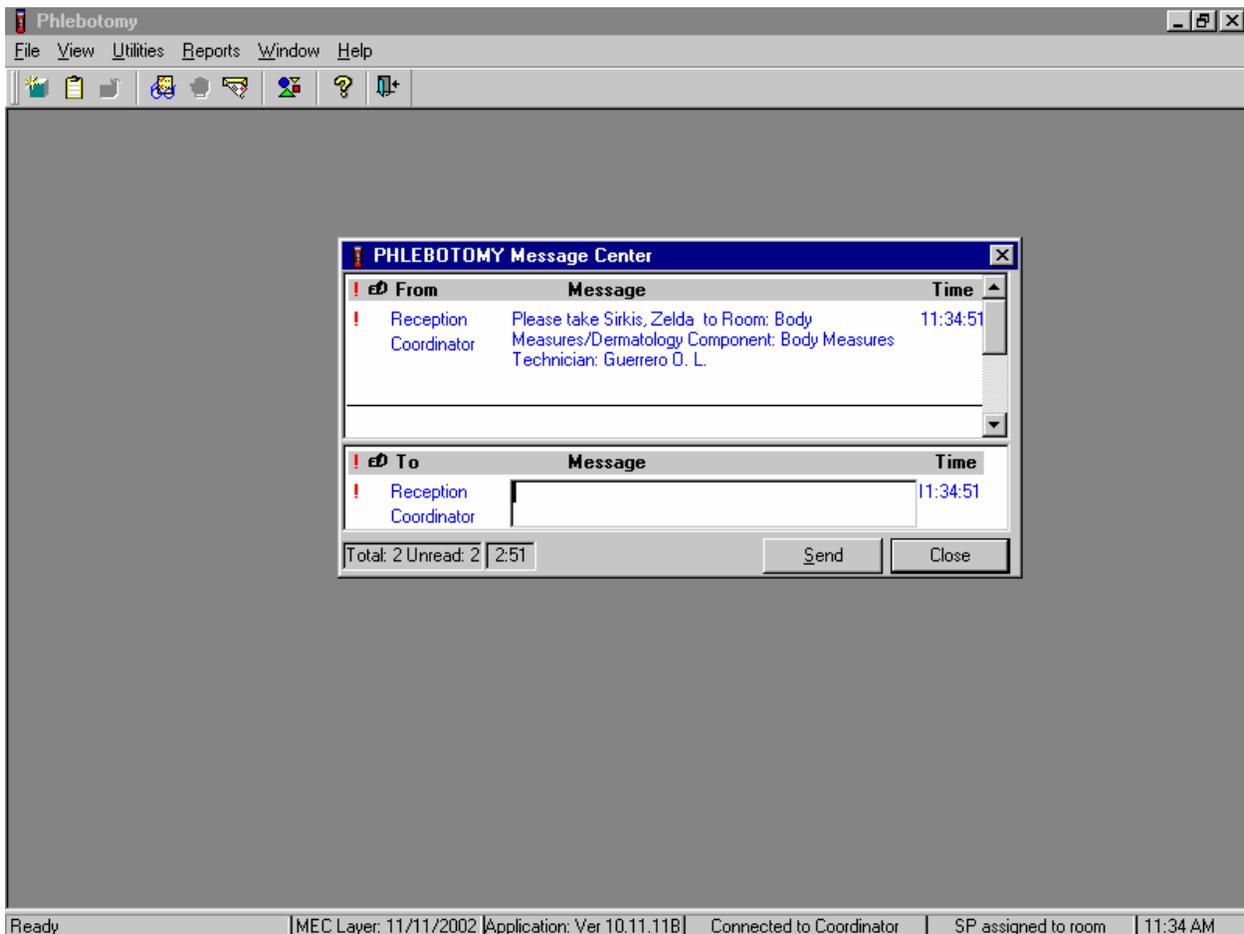
After check-in and after completion of individual examinations, the MEC coordinator assigns the SP to new components. Assignments are based on a list of the SP's remaining required exams, available examiners, and available exam components.

Examiners are notified by a system-generated message when a SP is assigned to their component.



A Message Center message text box containing a message from the coordinator indicating the name of the SP who is assigned to the component displays. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the Send button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the Close button and left click, or select [Enter].

When the examination is complete, the coordinator system advises the examiner of the SP's next component.



Review the instructions in the Message Center text box and follow the directions. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the Send button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the Close button and left click, or select [Enter].

### **3.2.2 System Blocking and Exclusions**

Specified examinations are “blocked” or excluded for SP assignment or continuation of an examination due to medical, SP nonconsent, or safety considerations. Some examinations become “unblocked” when medical conditions are verified, such as a negative pregnancy test result from the lab.

### **3.3 MEC Workstation Startup**

The workstation start-up procedures are rarely necessary since the workstations will remain powered and running the Windows NT operating systems for the stand duration. However, at times the workstation must be completely shutdown and restarted to resolve connectivity and other operating issues.

In the event that a workstation requires a startup, follow these procedures:

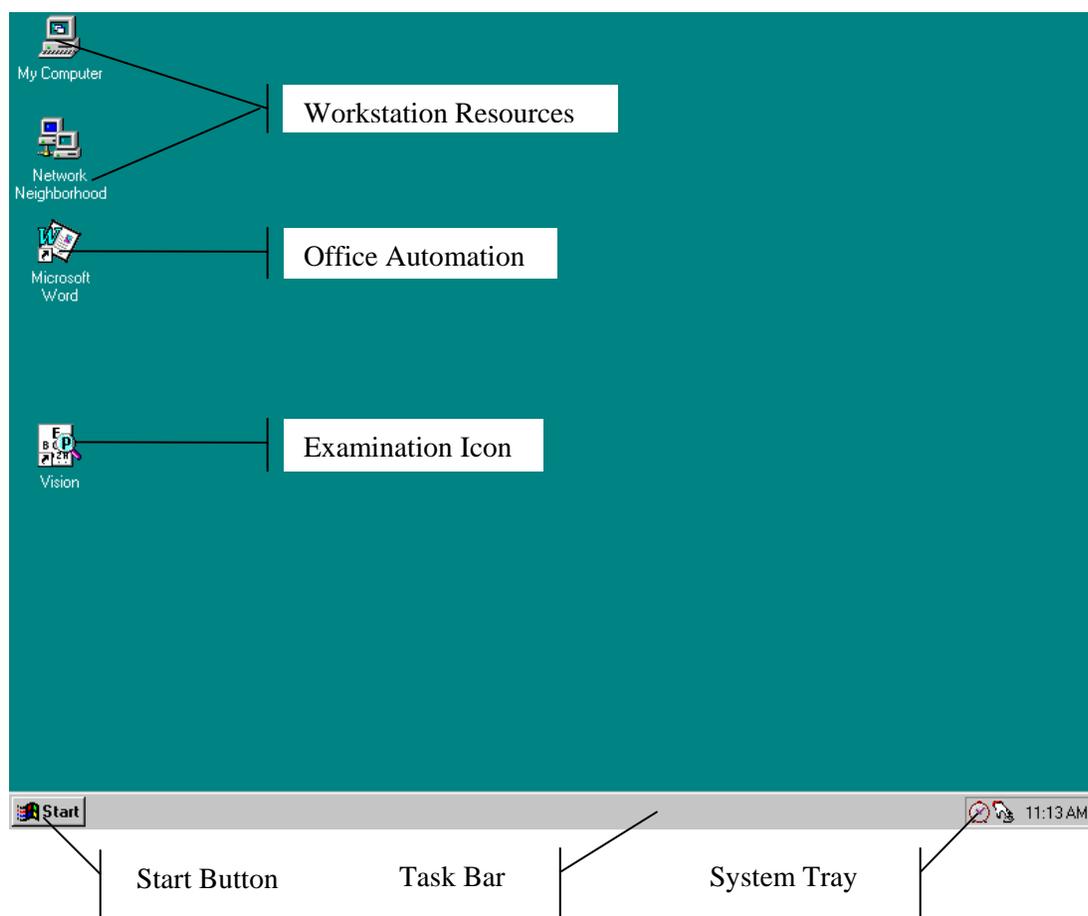
1. Locate and press the power button on the hard drive.
2. Turn on the monitor.
  - a. Locate and press the power button.
  - b. A small green light located near the power button will light if the monitor’s power line is connected.

### **3.4 Workstation Desktop**

After workstation startup, the MEC desktop appears. The desktop is specially tailored to support the specific MEC examination or station.

The desktop is similar to a real desktop. The desktop holds “shortcuts” to frequently used programs, such as the examination programs. Shortcuts are icons that represent a file or program located within the computer or network. The shortcuts provide a rapid means to open the program or file it represents. When an application opens, it displays on the desktop, as well as most other system activities.

Descriptions of the items that appear on all examination workstations are below.



**Workstation Resources** = My Computer and Network Neighborhood

- My Computer icon views and manages the files. Double-clicking the icon will open a window view of the computer and connected resources.
- Network Neighborhood provides a view of all available resources on the network.

**Office Automation** = Word processing program

**Examination Icon** = Phlebotomy, Laboratory, Vision, Physician, LED, etc.

- Examination program icons (with shortcut indicators) reside on the desktop to start an examination. Each examination has its own tailored icon. Double-click on the icon to open the examination program.

**Start Button** = Displays a menu containing Windows files

**Task Bar** = Displays the Start button and the System Tray

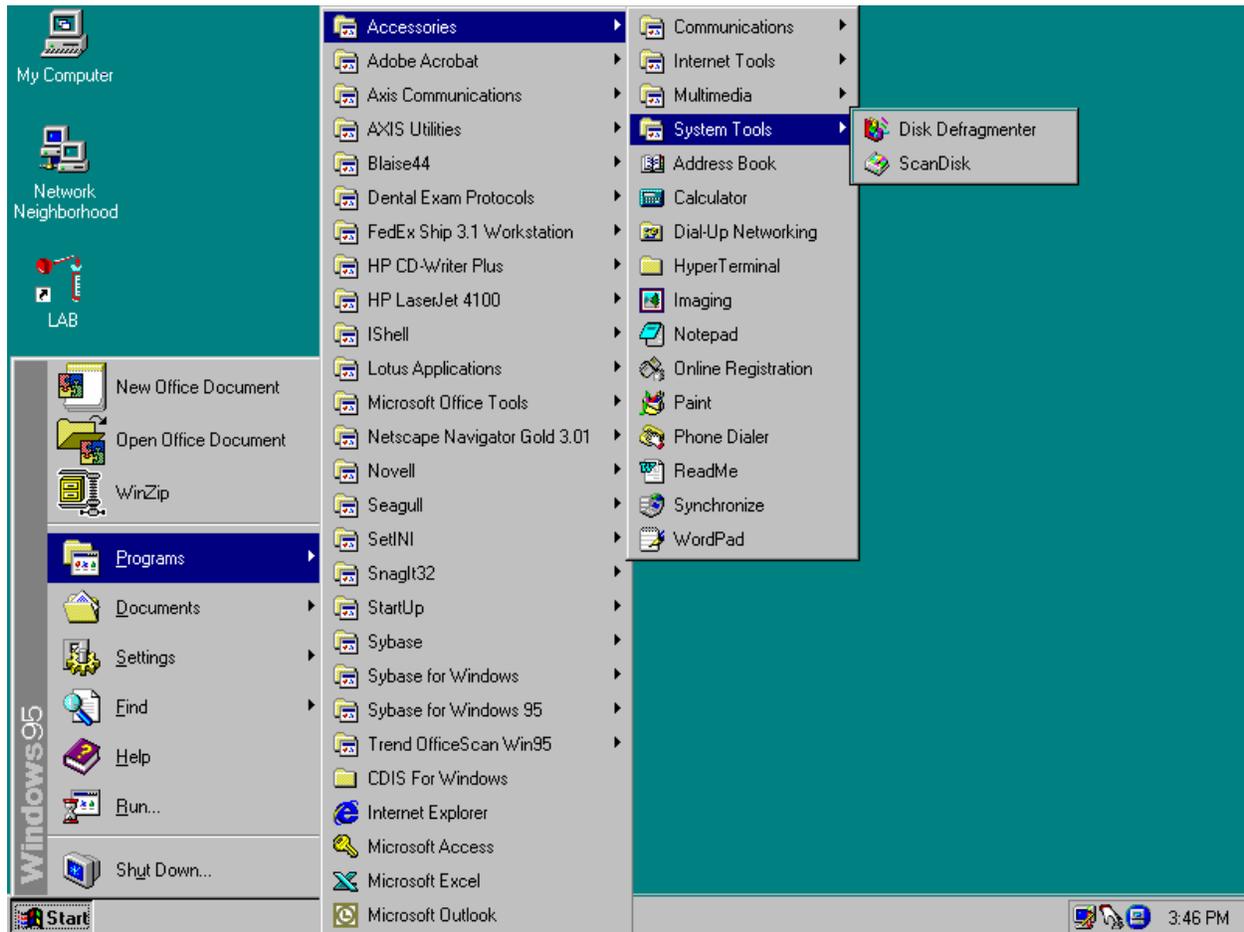
**System Tray** = Holds icons that represent programs for displaying time and a screen capture utility

The **Taskbar**, located at the bottom of the Desktop, displays the Start button on the left side and the System Tray on the right side of the bar. By default, the system tray displays the current time and shows special system icons for programs that run in the background. Programs running but minimized are also shown as a button on the Taskbar.

The **System Tray** holds icons that represent the programs for displaying time and a screen capture utility, PrintKey. The PrintKey screen capture utility operates automatically in the background. This feature enables you to capture items for documentation and database or program error messages.

### 3.4.1 The Start Button

The **Start** button, when clicked, displays a menu containing everything needed to begin using Windows.

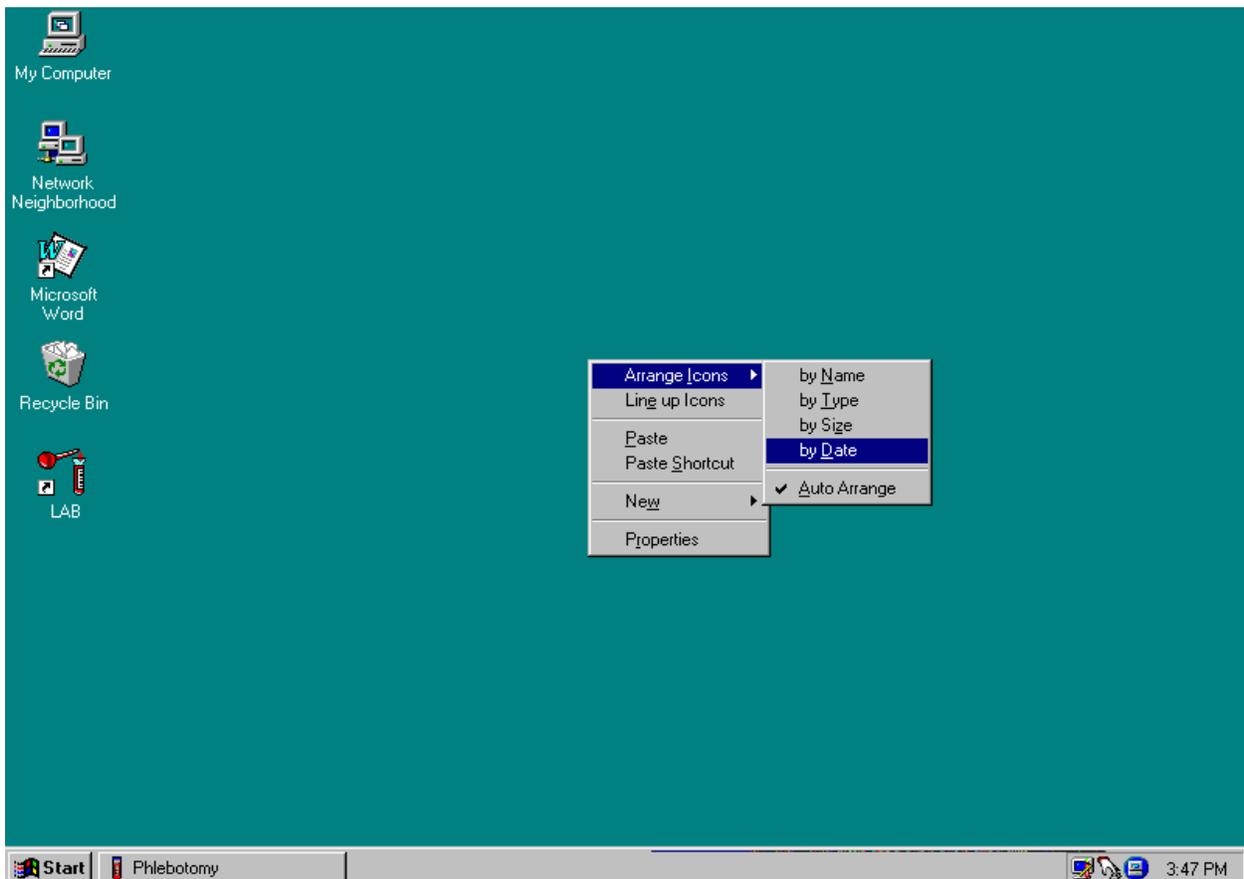


The menu options include:

- **Shut Down** – Shuts down menu options
- **Help** – Starts Windows NT Help
- **Find** – Searches for and locates files
- **Documents** – Displays a list of previously opened documents
- **Programs** – Displays a list of programs

The Start button menu expands as programs are added to the system. Note the highlighted selections. The menu expands when a small black arrow is shown on the right margin of the menu. The development team sets the main Start menu, the menu with the Windows NT banner on the first menu's left margin.

### 3.4.2 Right Mouse Button Menus



The right mouse menu for the Desktop appears when right-clicked anywhere on the desktop, as shown below:

- Arrange Icons provides options to display the icons.
- Line Up Icons automatically rearranges your desktop in a disruptive manner. Use of this icon is not recommended.

- Paste will place the contents of the clipboard onto the desktop.
- Paste Shortcut places a shortcut of the item in the clipboard on the desktop.
- New provides a menu of items from which to create, such as a new folder or document.
- Properties displays the Display Properties window to view and change several properties, such as window appearance, background, and colors. Some, if not all properties, will be disabled to ensure consistent appearance of all MEC workstations.

### **3.4.3 End of Day Procedures**

The current procedure is to leave the workstation operational when departing the MEC. Examinations are closed and the programs in the system tray left running.

The system can malfunction, such as when it demonstrates a failure to respond to keyboard or mouse commands. Contact the data manager who will provide further instructions.

To Shut Down or Restart the Workstation:

- Click on the *Start* button on the Taskbar.
- Select *Shutdown* from the Start Menu.
- The dialog box, shown below, appears.
- To shut down the system completely, select *Shut down the computer*.
- Wait for the message indicating that it is safe to turn off the computer.
- To restart the system without shutting down, select *Restart the computer*.
- The system will restart automatically.

### **3.5 MEC Exam Application's Common Features**

MEC applications are custom built for each specific component but share a common design. This commonality provides all component applications the same “look and feel” which minimizes

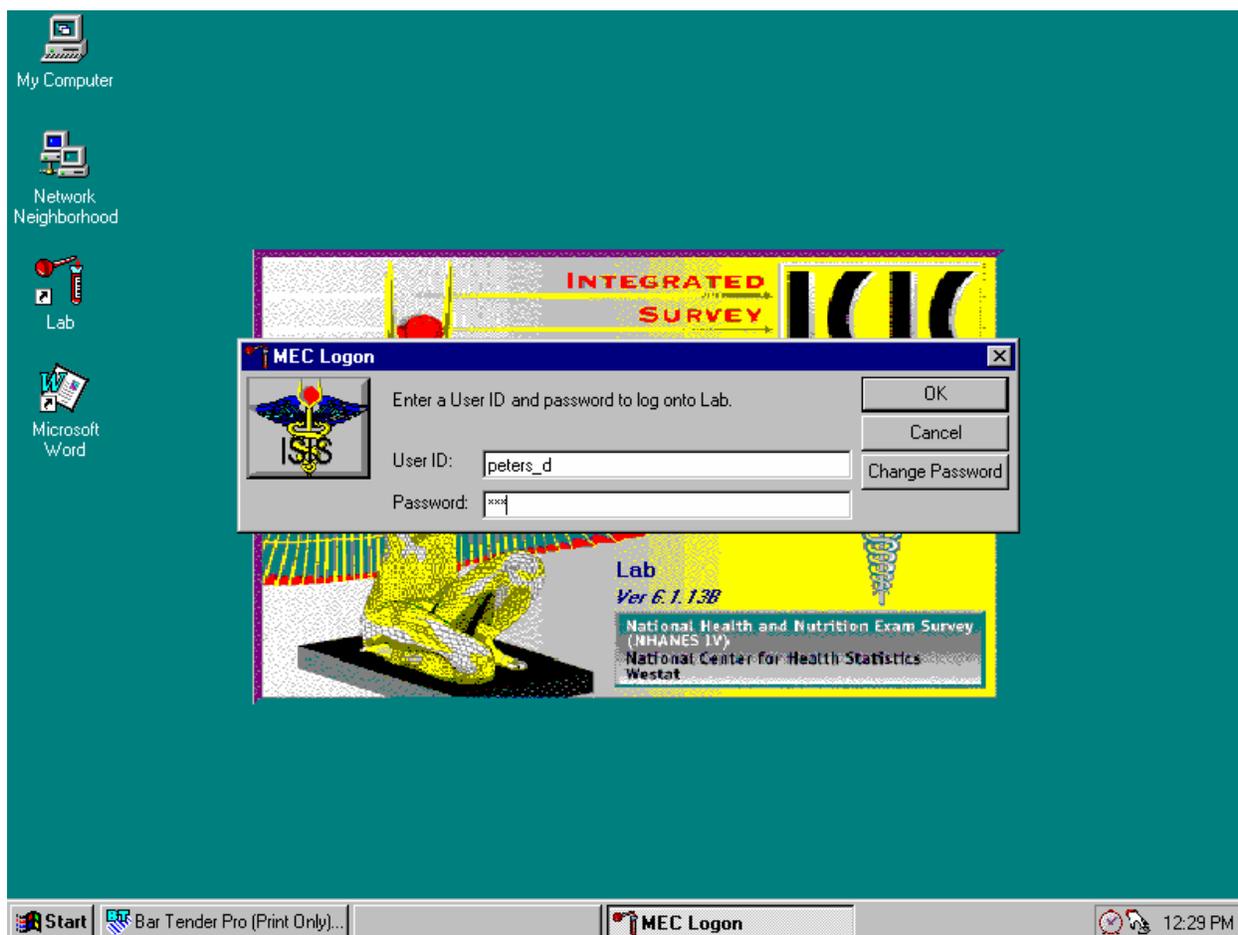
reorienting technologists that rotate from component to component. These features and characteristics are described below.

### **3.5.1 Examiner Logon**

There are currently several types of examiner logon procedures. The logon procedure for an examination component is determined by whether the examiner is *static* or *rotates* through other components throughout a session. Static examinations include components such as Physician, Phlebotomy, Dietary, and MEC Interviewers that remain logged on throughout the session. Health technologists are not assigned to rooms but rotate through several examination components such as Vision and CV Fitness. These technologists are required to logon and logoff for each examination. Other examinations, such as Dental and Body Measurements, have slightly different requirements and are addressed in their specific user's manuals.

## Static Examiner Logon

The logon screen, shown below, appears after the coordinator assigns the examiner to the component and the assigned examiner starts the examination program.

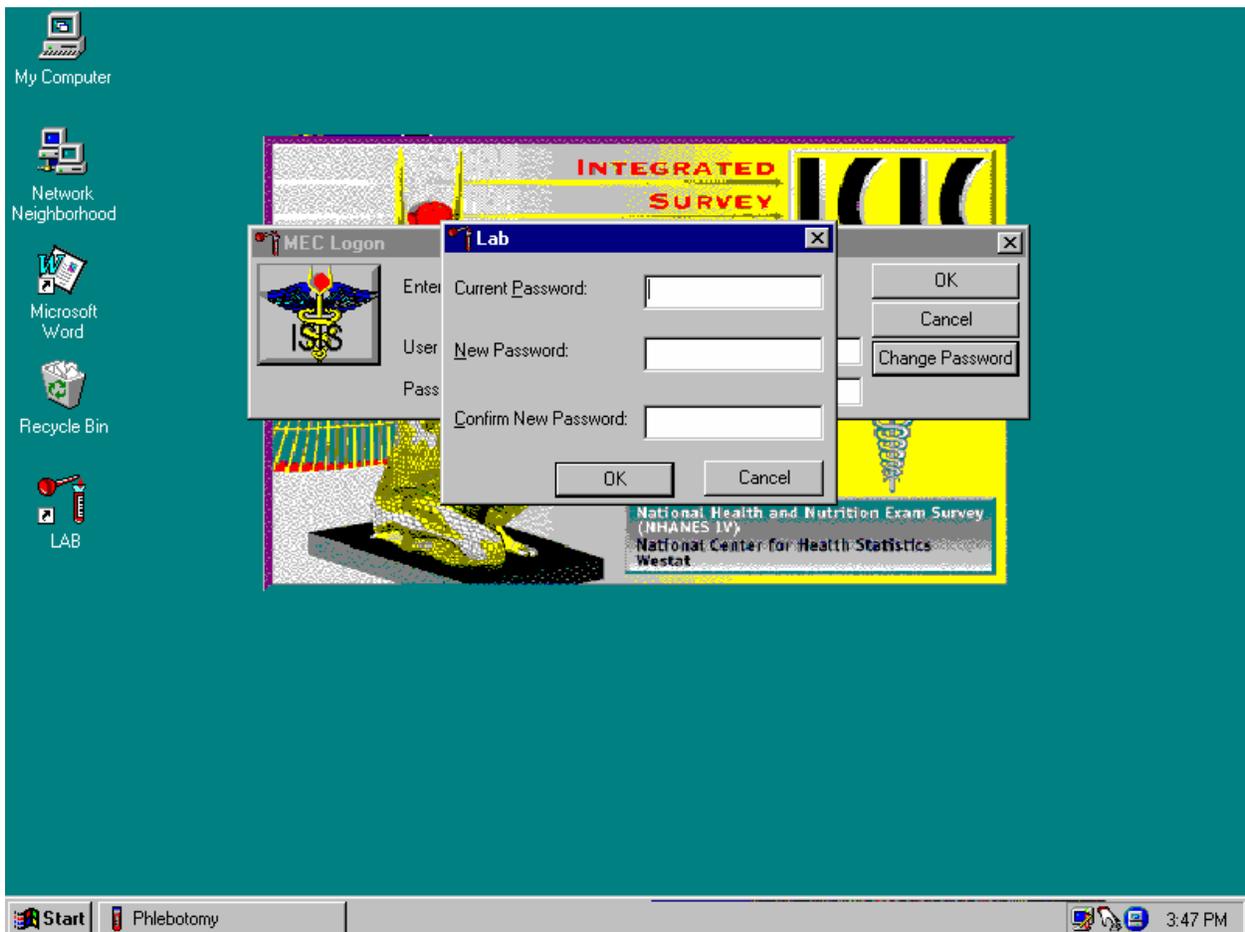


The MEC Logon window displays. The **User ID** (Last Name\_First Initial) will automatically appear and cannot be changed. Type last name, underscore, first initial in the User ID space, and [Tab] or [Enter]. Enter the password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the OK button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the Cancel button and left click. Examiner logoff is automatic at the end of the session.

### 3.5.2 Changing Personal Passwords

All examination actions within the MEC are traced with the Logon User ID and Password. Protecting personal passwords prevents unauthorized entry and malicious actions to the ISIS system. Do not share passwords for any reason as this could jeopardize much more than study data.

After entering the password and before pressing OK, change the password by clicking on the Change Password button. The Change Password dialog box appears.

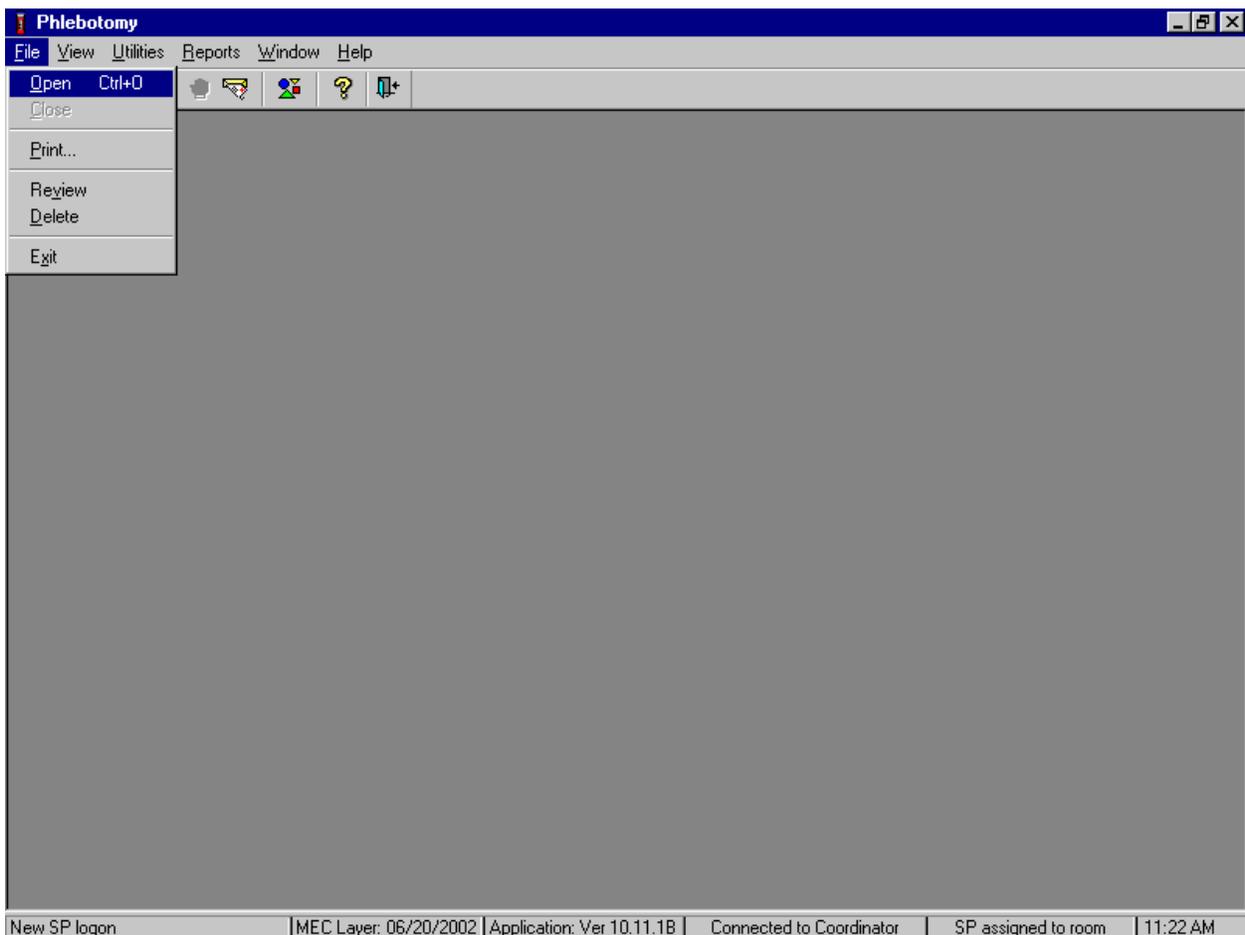


Enter the current password for access verification, followed by the new password. Confirm the new password and press OK.

### 3.5.3 Open an Exam

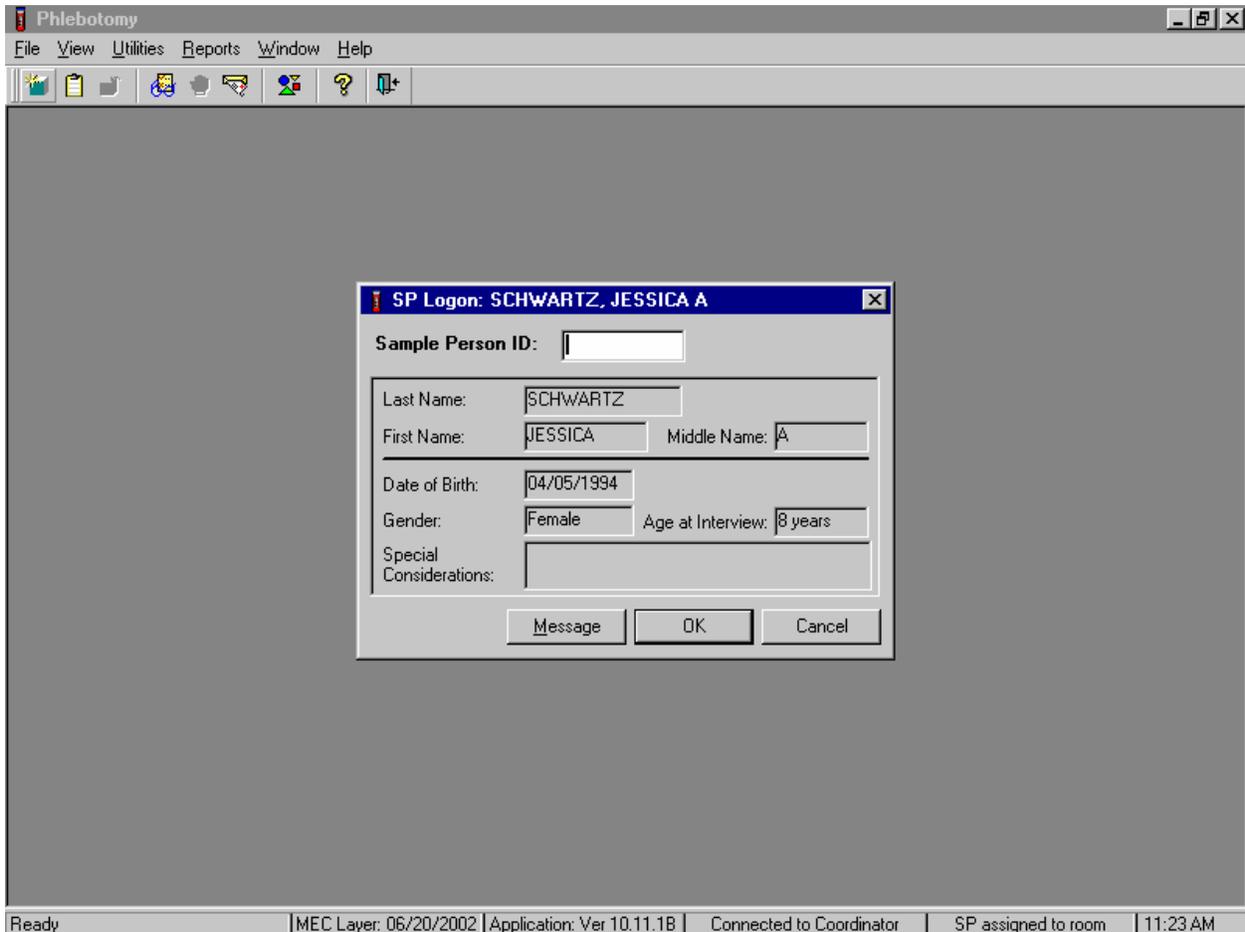
The MEC coordinator checks in each SP upon arrival and assigns the SP to an initial examination component. The action of assigning the SP to a component automatically triggers a message from the coordinator to alert the technologist that a SP is assigned.

Open the exam.



To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o].

Log the SP into the exam component.

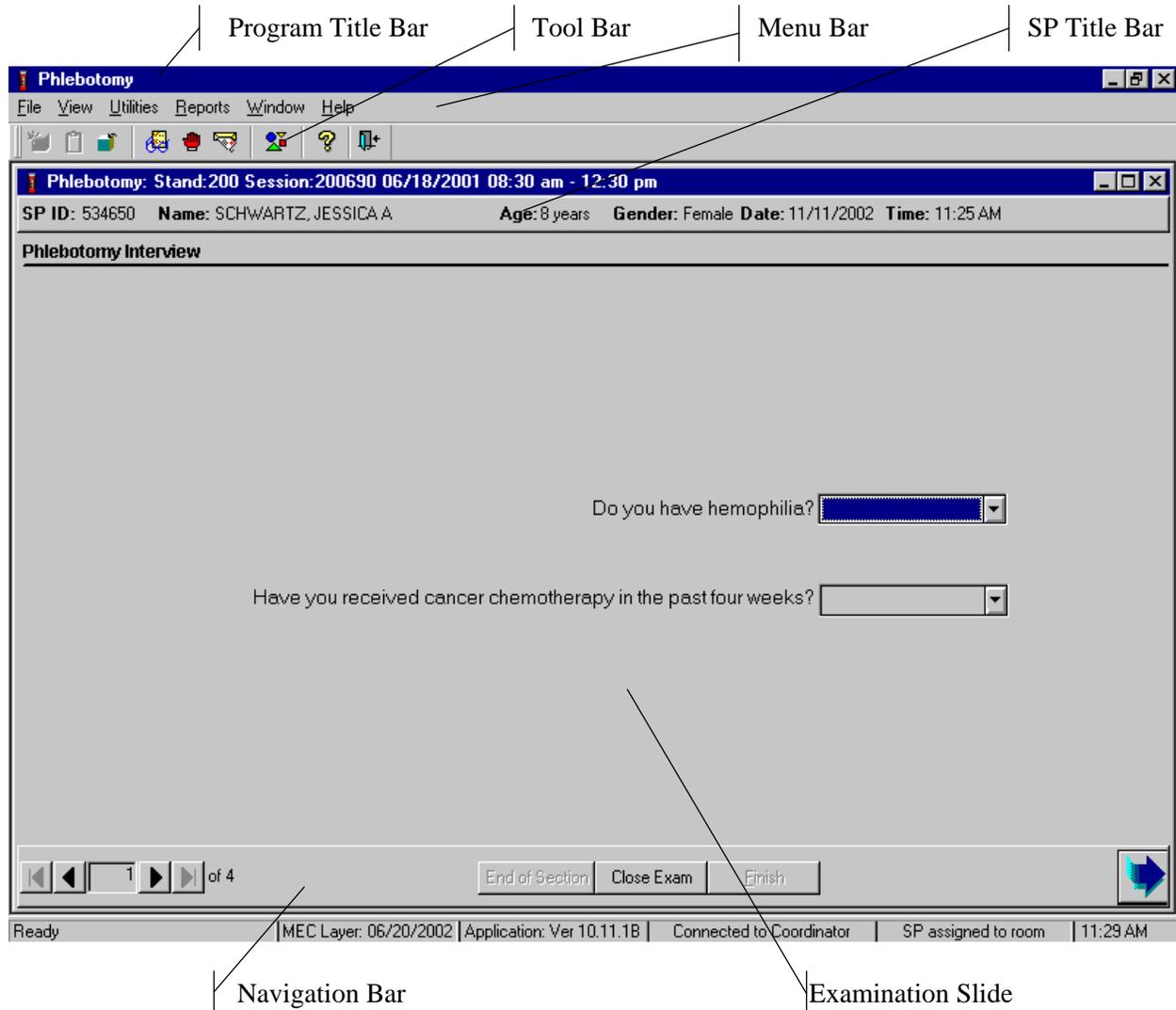


The SP Logon window displays for the SP assigned to the component. To log the SP into the component either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the OK button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the Cancel button and left click.

Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

### 3.5.4 Examination Screen Overview

The first examination screen appears after a SP is logged in or an existing record is opened. This example screen, shown on this page, displays the basic visual appearance and design used throughout all MEC components.



- Program Title Bar shows the component program title, stand, session, and date time information.
- Menu Bar displays the commands, functions, options, and information available during an examination.

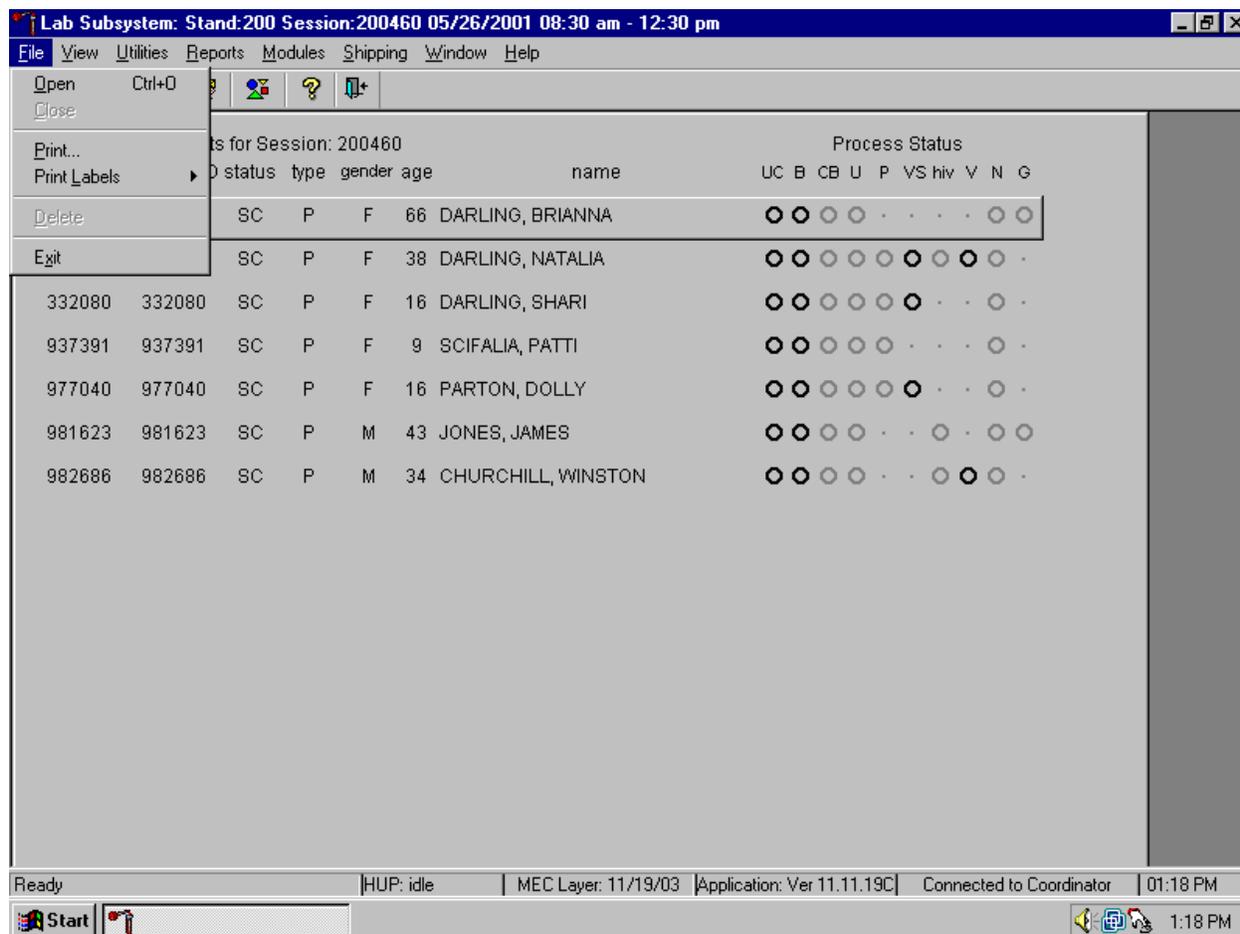
- Tool Bars hold buttons that execute common commands and other actions available in the menu bar. Buttons that are dimmed are not available.
- SP Title Bar displays SP information during the course of the examination.
- Examination Slide captures the measurements and other information.
- Navigation Bar is used to move forward or back in the examination and displays the examination's relative location.
- Microhelp and Status Bar displays the status of the computer, completion percentage message to the coordinator, and other information triggered by events.

#### 3.5.4.1 Menu Bar Options

Each MEC application has tailored menu options to support the specific examination. The menu options below list all available options. The options marked with an asterisk appear on all MEC examination programs. Options are grayed (inverted) or not present when they are not available for a specific subsystem.

Note the underlined letters in both the Menu and Menu Option. These underlined letters, used in conjunction with the **Alt** key, provide keyboard access to the menu selection without using the mouse. For example, pressing **Alt+F+O** will open a file. The **Ctrl+keystroke**, such as **Ctrl+O**, will also open a file.

## File Menu Options



Asterisks (\*) denote menu options common to all MEC examination components.

<b>*File</b>	
* <u>O</u> pen <i>Ctrl+O</i>	Opens a new, partial, or not done SP exam; the SP must be assigned by coordinator if the application is not in standalone mode.
* <u>C</u> lose	Closes the current examination.
* <u>P</u> rint	Prints the current examination screen or report.
Print <u>L</u> abels	Allows the laboratory medical technologist to print laboratory labels for a SP or for all SPs in a session.
* <u>D</u> elete	Deletes current exam and any associated references. Used primarily to delete an examination that clearly is in error, such as the wrong SP. Only enabled if it is a new exam and the status is not done or partial.
* <u>E</u> xit	Exits the application.

## View Menu Options

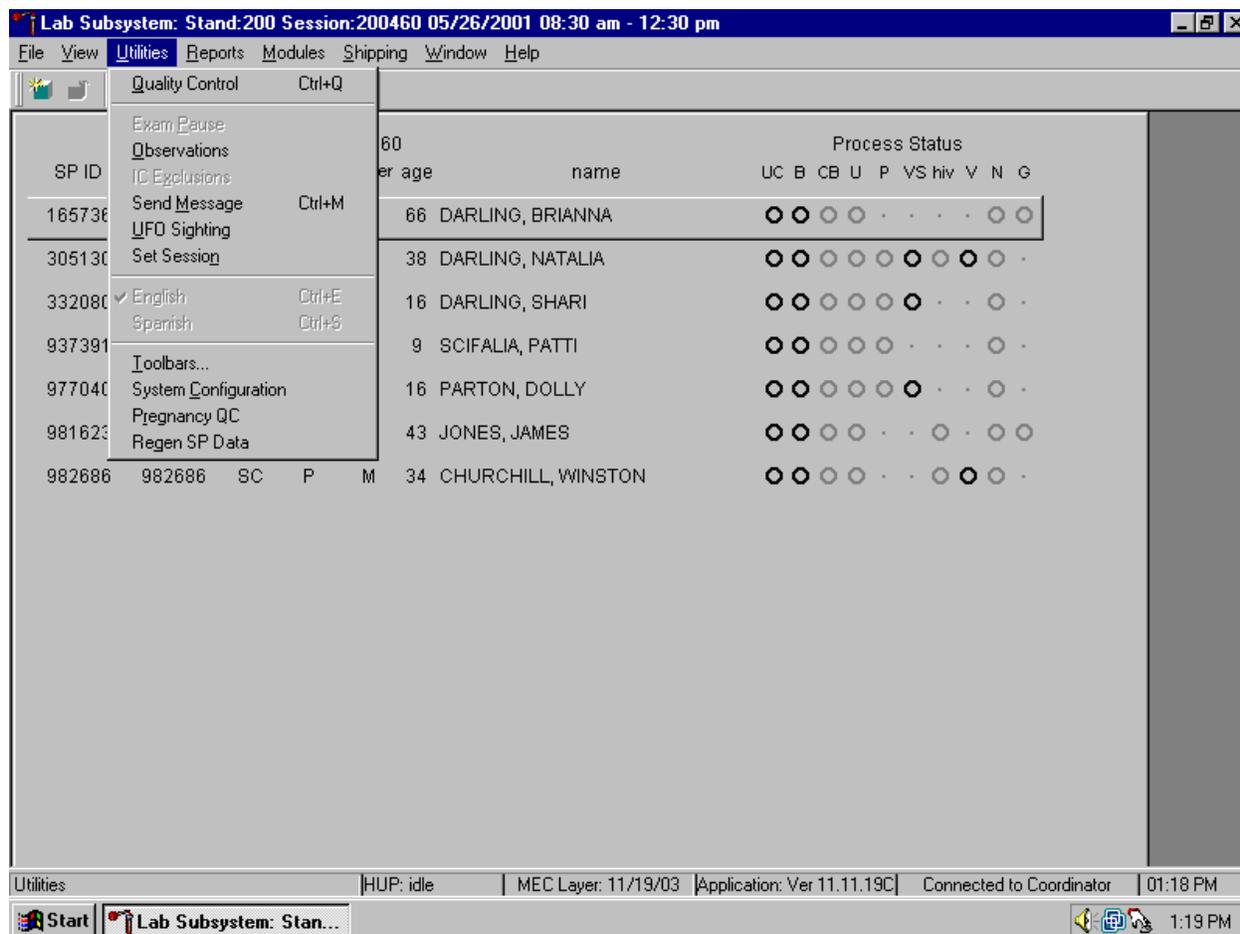
The screenshot shows a software window titled "LAB: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The "View" menu is open, showing options: "First", "Next", "Prior", "Last", and "1 Heads-Up for Session: 200690".

		690				Process Status											
der	age	name				UC	B	CB	U	P	VS	hiv	V	N			
✓ 1		39	EYRAMYA, AUNTIE				○	○	○	○	○	○	○	○			
281396	281396	CI	P	M	1	ERAMIA, STANLEY				-	○	○	-	-	-	-	○
304755	304755	SC	P	F	48	ERAMIA, YVETTE				○	○	○	○	○	○	-	○
356294	356294	CI	P	F	21	SCHWARTZ, DAWN				○	○	○	○	○	○	-	○
373348	373348	SC	P	F	53	ERAMIA, JUDY				○	○	○	○	○	○	-	○
416806	416806	SC	G	M	29	ERAMIA, NEBILLE				-	○	○	-	-	-	-	-
534650	534650	BE	P	F	8	SCHWARTZ, JESSICA A				○	○	○	○	○	-	-	○
562086	562086	SC	P	F	3	LANGBERG, CARMEN				-	○	○	-	-	-	-	○
672812	672812	SC	P	M	54	ERAMIA, BEN				○	○	○	○	-	-	-	○
805106	805106	SC	P	F	13	SCHWARTZ, EMILY A				○	○	○	○	○	-	-	○

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 11:35 AM

<b>*View</b>	
* <u>F</u> irst	Returns examination screen to first slide.
* <u>N</u> ext	Advances to next examination slide.
* <u>P</u> rior	Displays previous slide IN THE SKIP PATTERN.
* <u>L</u> ast	Advances to last slide.
<u>H</u> eads-Up for Session: <u>XXXXXX</u>	Displays the current heads-up display for the current session.

## Utilities Menu Options



*Utilities	
Quality Control <i>Ctrl+Q</i>	Opens the quality control dialog box to initiate quality control procedures.
*Exam Pause	Used in case of an emergency in the MEC, such as an ill SP. Pauses the exam temporarily to stop the exam timer (in NH_Exam); sends “Exam paused” message to coordinator.
*Observation	Submits an observation to the physician for possible referral.
IC Exclusions	Posts an exclusion record for those SPs who do not want HIV, STD, genetic, PSA or vaginal tests performed or samples stored for future research; this utility is available only for coordinator, physician, & phlebotomy.

<b>*Utilities</b>	
*Send <u>M</u> essage <i>Ctrl+M</i>	Opens a dialog box to send messages to the coordinator.
*UFO Sighting	Opens the Unusual Field Occurrence utility to document an unusual equipment, SP, protocol, trailer, or supply issues.
Set <u>S</u> ession	Allows the laboratory medical technologist to change the current session in the laboratory application.
<u>E</u> nglish <i>Ctrl+E</i>	Toggle option to set exam language to English.
<u>S</u> panish <i>Ctrl+S</i>	Toggle option to set exam language to Spanish.
* <u>T</u> oolbars	Configures placement of toolbars.
System <u>C</u> onfiguration	
Pregnancy <u>Q</u> C	Allows the laboratory medical technologist to access the Pregnancy QC module.
Regen <u>S</u> P Data	Allows the laboratory medical technologists to regenerate or recalculate a new profile for an SP.

## Report Menu Options

The screenshot shows the 'Reports' menu in the Lab Subsystem. The menu options are:

- Show Results
- Room Log
- Session Preview
- Container Map
- Subsample Preview
- Supply Use
- Unusual Occurrences
- Rescheduled Appointments
- Informed Consent Status

The background table displays patient information:

SP ID	Sample	name	UC	B	CB	U	P	VS	hiv	V	N	G
165736	165	DARLING, BRIANNA	○	○	○	○	○	○	○	○	○	○
305130	305	DARLING, NATALIA	○	○	○	○	○	○	○	○	○	○
332080	332	DARLING, SHARI	○	○	○	○	○	○	○	○	○	○
937391	937391	SCIFALIA, PATTI	○	○	○	○	○	○	○	○	○	○
977040	977040	SC P F 16 PARTON, DOLLY	○	○	○	○	○	○	○	○	○	○
981623	981623	SC P M 43 JONES, JAMES	○	○	○	○	○	○	○	○	○	○
982686	982686	SC P M 34 CHURCHILL, WINSTON	○	○	○	○	○	○	○	○	○	○

### \*Reports

#### Show Results

\*Room Log Lists the SPs who have completed the component, including appt/exam and component status.

\*Session Preview\* Lists all SPs in current session.

Container Map Displays a list of laboratory containers and a graphic description of the contents.

Subsample Preview List the SPs who are eligible for the various subsamples.

Supply Use Links to and launches the Word Supply Use Control Log document.

Unusual Occurrences Links to and launches the Word Unusual Occurrence document.

Rescheduled Appointments Lists the SPs who have rescheduled from a previous session into the current session.

Informed Consent Status Lists the various modules that require consent and displays the result of the consent – excluded or not excluded.

## Modules

The screenshot shows a software window titled "Lab Subsystem: Stand:200 Session:200460 05/26/2001 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The "Modules" menu is open, showing "Hematology", "Lead Dust Processing", and "Lead Dust QC". Below the menu is a table of appointments with columns for "SP ID", "Sample ID", "stat", "name", and "Process Status". The process status is represented by a grid of circles, some of which are filled.

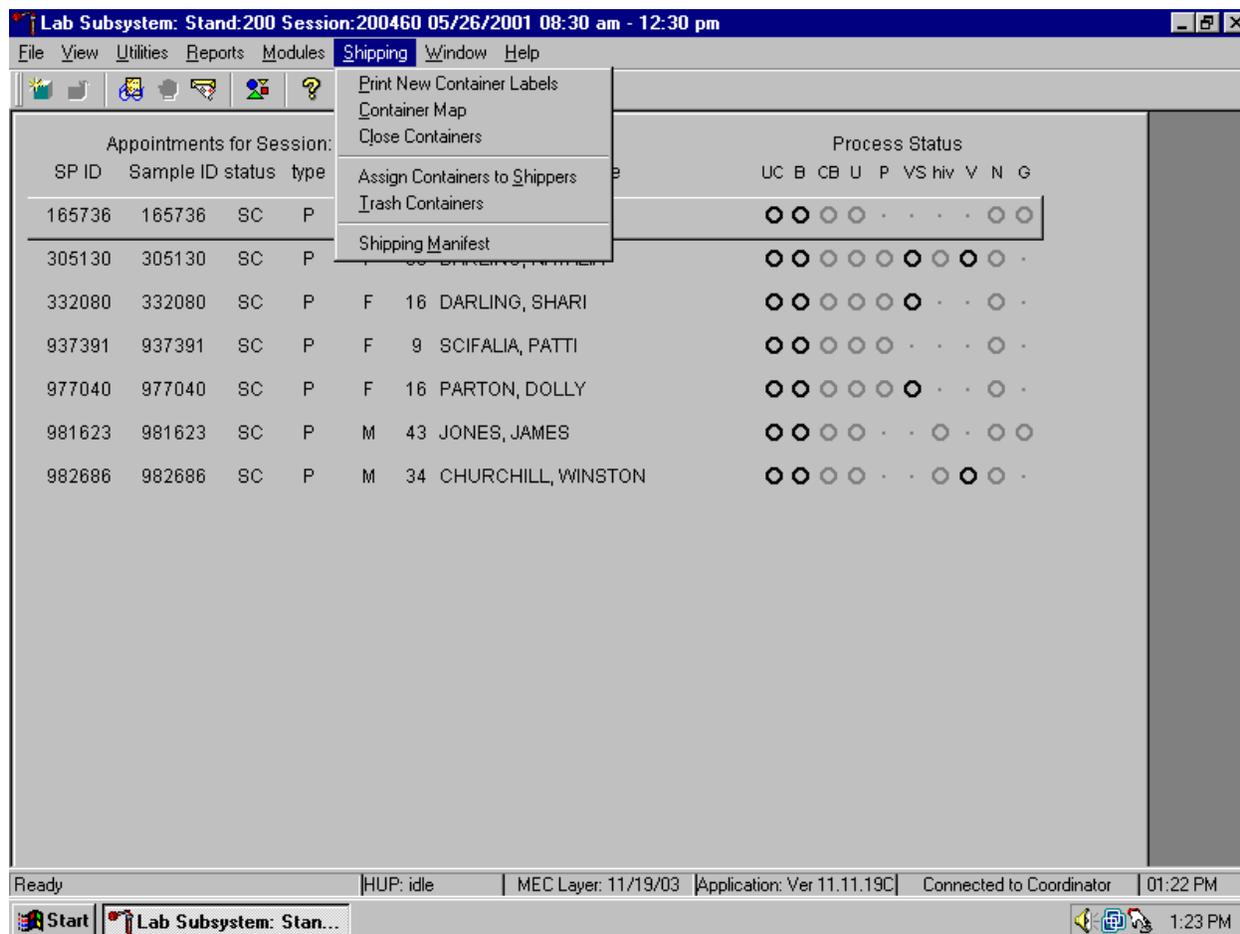
Appointments for		Process Status												
SP ID	Sample ID	stat		name	UC	B	CB	U	P	VS	hiv	V	N	G
165736	165736	SC	P	F 66	DARLING, BRIANNA	○	○	○	○	○	○	○	○	○
305130	305130	SC	P	F 38	DARLING, NATALIA	○	○	○	○	○	○	○	○	○
332080	332080	SC	P	F 16	DARLING, SHARI	○	○	○	○	○	○	○	○	○
937391	937391	SC	P	F 9	SCIFALIA, PATTI	○	○	○	○	○	○	○	○	○
977040	977040	SC	P	F 16	PARTON, DOLLY	○	○	○	○	○	○	○	○	○
981623	981623	SC	P	M 43	JONES, JAMES	○	○	○	○	○	○	○	○	○
982686	982686	SC	P	M 34	CHURCHILL, WINSTON	○	○	○	○	○	○	○	○	○

The status bar at the bottom shows "Ready", "HUP: idle", "MEC Layer: 11/19/03", "Application: Ver 11.11.19C", "Connected to Coordinator", and "01:19 PM". The taskbar includes the Start button and a taskbar icon for "Lab Subsystem: Stan...".

### Modules

<u>H</u> ematology	Opens the laboratory hematology module.
<u>L</u> ead Dust Processing	Opens the laboratory lead dust-processing module.
<u>L</u> ead <u>D</u> ust <u>Q</u> C	Opens the laboratory lead dust QC module.

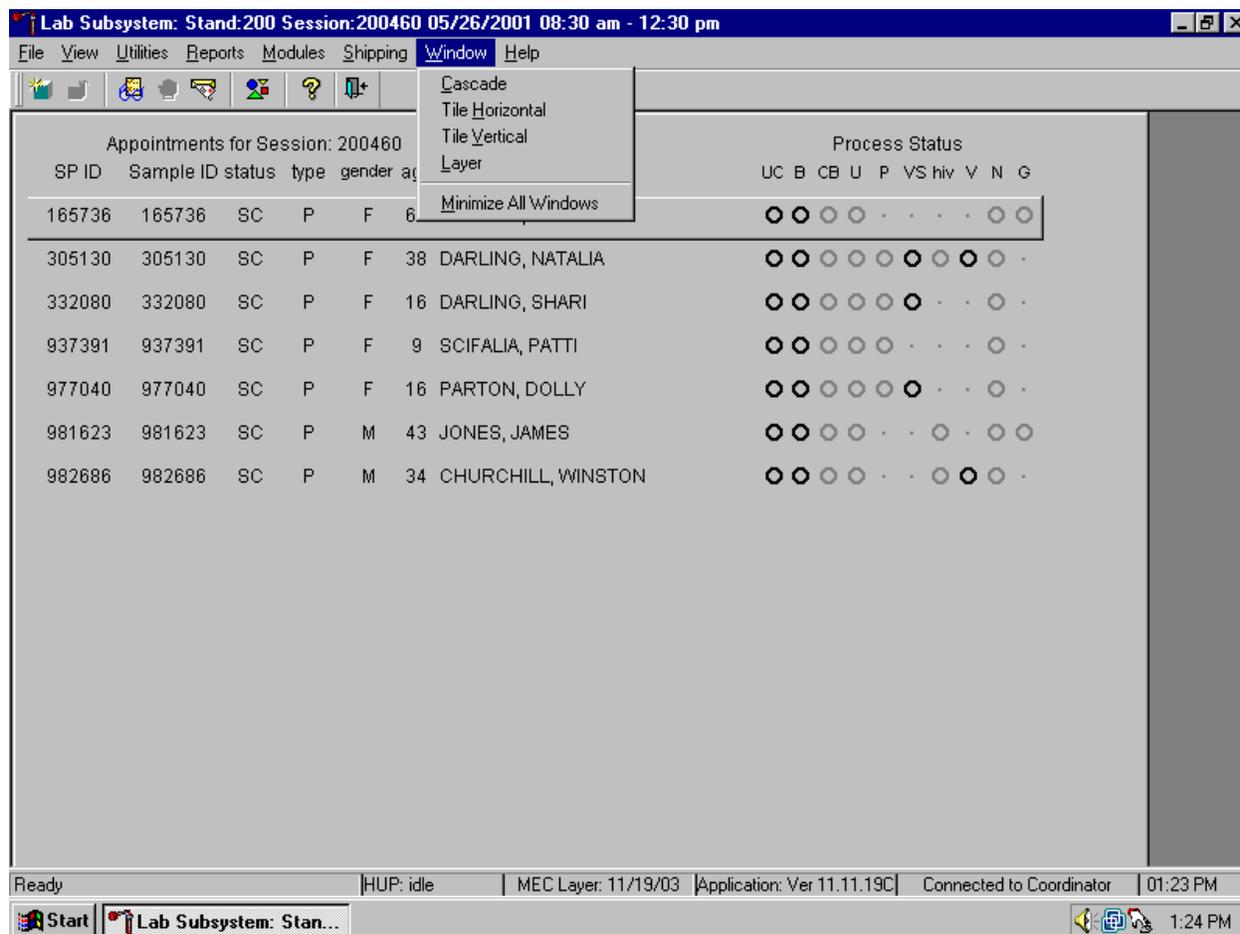
## Shipping



### Shipping

Print <u>N</u> ew Container Labels	Allows the medical technologist to print labels for containers such as a 5-inch box with 9 x 9 grid.
<u>C</u> ontainer Map	Allows the medical technologist to view a list of all containers with a graphic representation of the samples assigned to that container.
C <u>l</u> ose Containers	Allows the medical technologist to “close” active containers that have been previously opened.
Assign Containers to <u>S</u> hipper	Allows the medical technologist to assign or associate a closed container with a FedEx airbill number.
<u>T</u> rash Containers	Allows the medical technologist to delete container label numbers in the database for labels that are damaged.
Shipping Manifest	Allows the medical technologist to print hard copy manifests and electronically send email files to the contract laboratories.

## Window



### \*Window

* <u>C</u> ascade	Displays multiple windows overlapped and slightly offset as to show the title bar of each open window.
*Tile <u>H</u> orizontal;	Displays open windows on top of each other and sized to fit all in the main program window.
*Tile <u>V</u> ertical	Displays open windows next to each and sized to fit in the main program window.
* <u>L</u> ayer	Displays open windows stacked over each other.
* <u>M</u> inimize All Windows	Reduces all windows to a button in the lower portion of the main program window.

## Help Menu Options

The screenshot shows the 'Lab Subsystem' application window. The title bar reads 'Lab Subsystem: Stand:200 Session:200460 05/26/2001 08:30 am - 12:30 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. The 'Help' menu is open, showing three options: 'Help Topics', 'OMB Statement', and 'About'. The main window displays a table of appointments for session 200460. The table has columns for 'SP ID', 'Sample ID', 'status', 'type', 'gender', 'age', 'name', and 'Process Status'. The 'Process Status' column contains a series of circles, some of which are filled, representing the status of various tests for each patient.

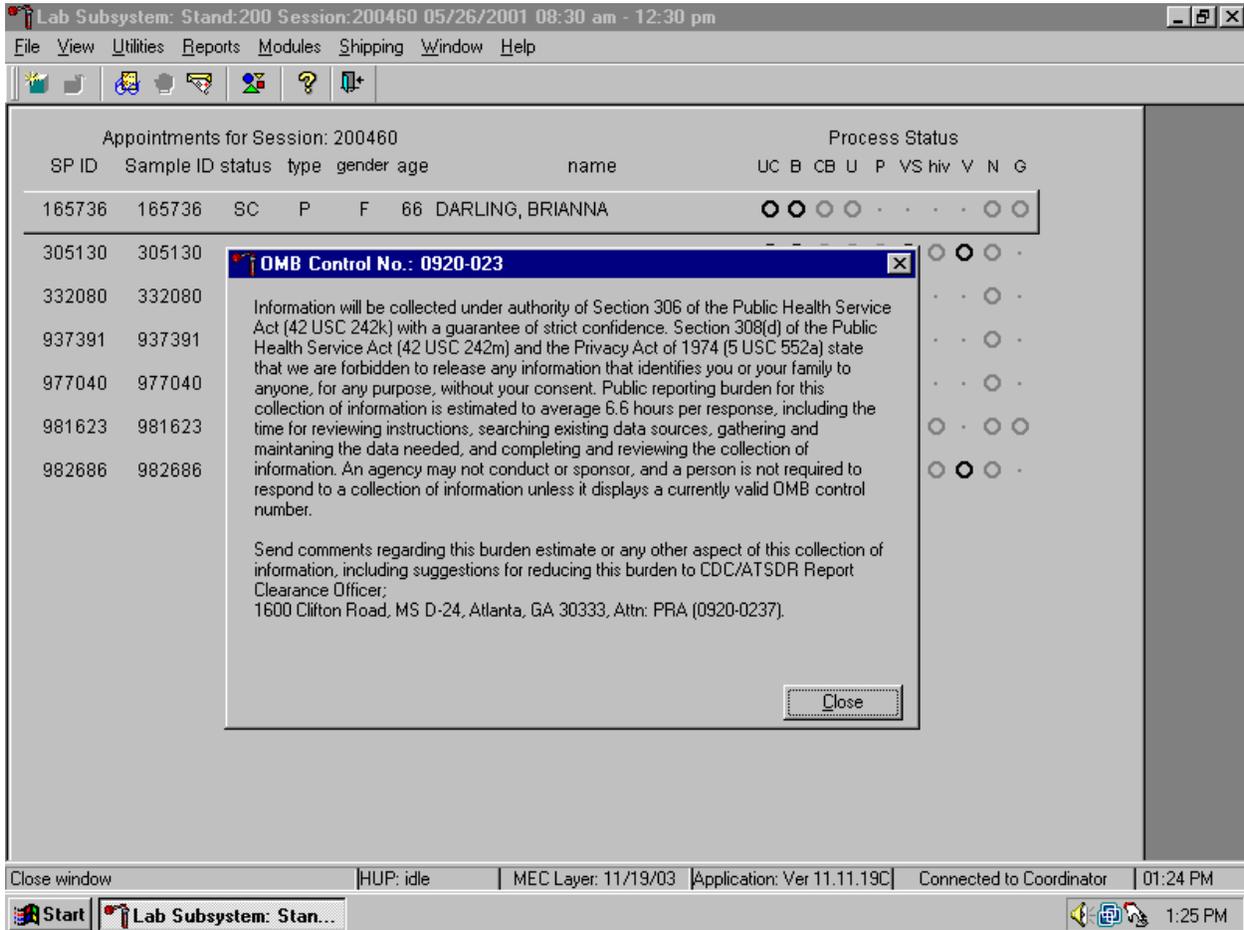
Appointments for Session: 200460							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
165736	165736	SC	P	F	66	DARLING, BRIANNA	○	○	○	○	○	○	○	○	○	○
305130	305130	SC	P	F	38	DARLING, NATALIA	○	○	○	○	○	○	○	○	○	○
332080	332080	SC	P	F	16	DARLING, SHARI	○	○	○	○	○	○	○	○	○	○
937391	937391	SC	P	F	9	SCIFALIA, PATTI	○	○	○	○	○	○	○	○	○	○
977040	977040	SC	P	F	16	PARTON, DOLLY	○	○	○	○	○	○	○	○	○	○
981623	981623	SC	P	M	43	JONES, JAMES	○	○	○	○	○	○	○	○	○	○
982686	982686	SC	P	M	34	CHURCHILL, WINSTON	○	○	○	○	○	○	○	○	○	○

The taskbar at the bottom shows the system is 'Ready', 'HUP: idle', 'MEC Layer: 11/19/03', 'Application: Ver 11.11.19C', 'Connected to Coordinator', and the time is '01:23 PM'. The taskbar also shows the 'Start' button and the 'Lab Subsystem: Stan...' window.

### \*Help

* <u>H</u> elp Topics	Displays ISIS system Help contents.
* <u>O</u> MB Statement	Displays the OMB Confidentiality Statement.
* <u>A</u> bout	Displays the About dialog box.

## OMB Confidentiality Statement



### 3.5.3.2 Tool Bars

Tool Bar buttons display when the program first opens to provide an easy way to access menu commands. Buttons are dimmed to signify that the action is temporarily unavailable, such as a dimmed **Print** button when no examination is open.

The Tool Bar buttons are listed below:



Opens a New Sample Person Examination



Arranges toolbar buttons



Sends message to coordinator



Quits the Exam Application



Performs Quality Control Procedures



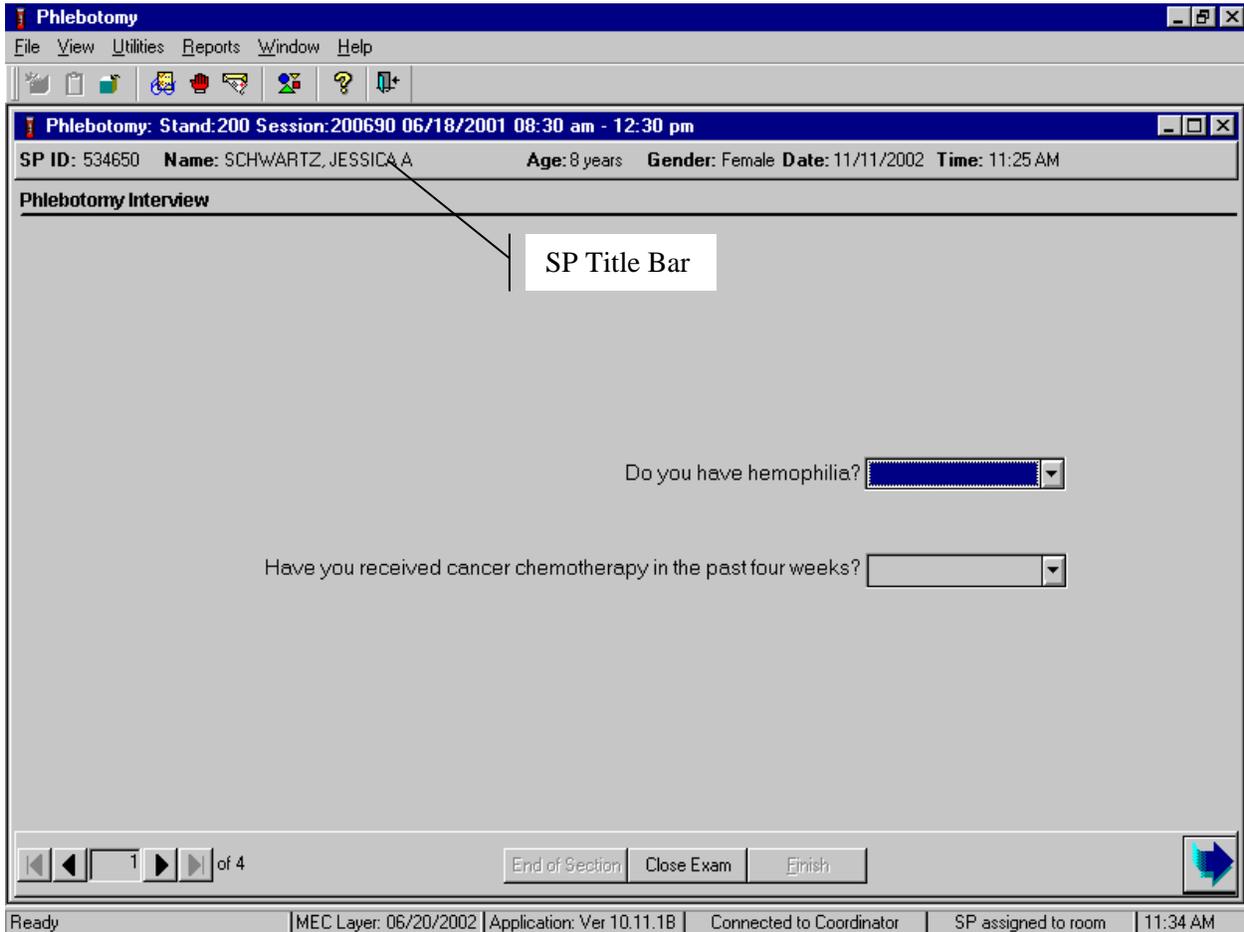
Pauses the current SP examination



Displays program Help

### 3.5.3.3 SP Title Bar

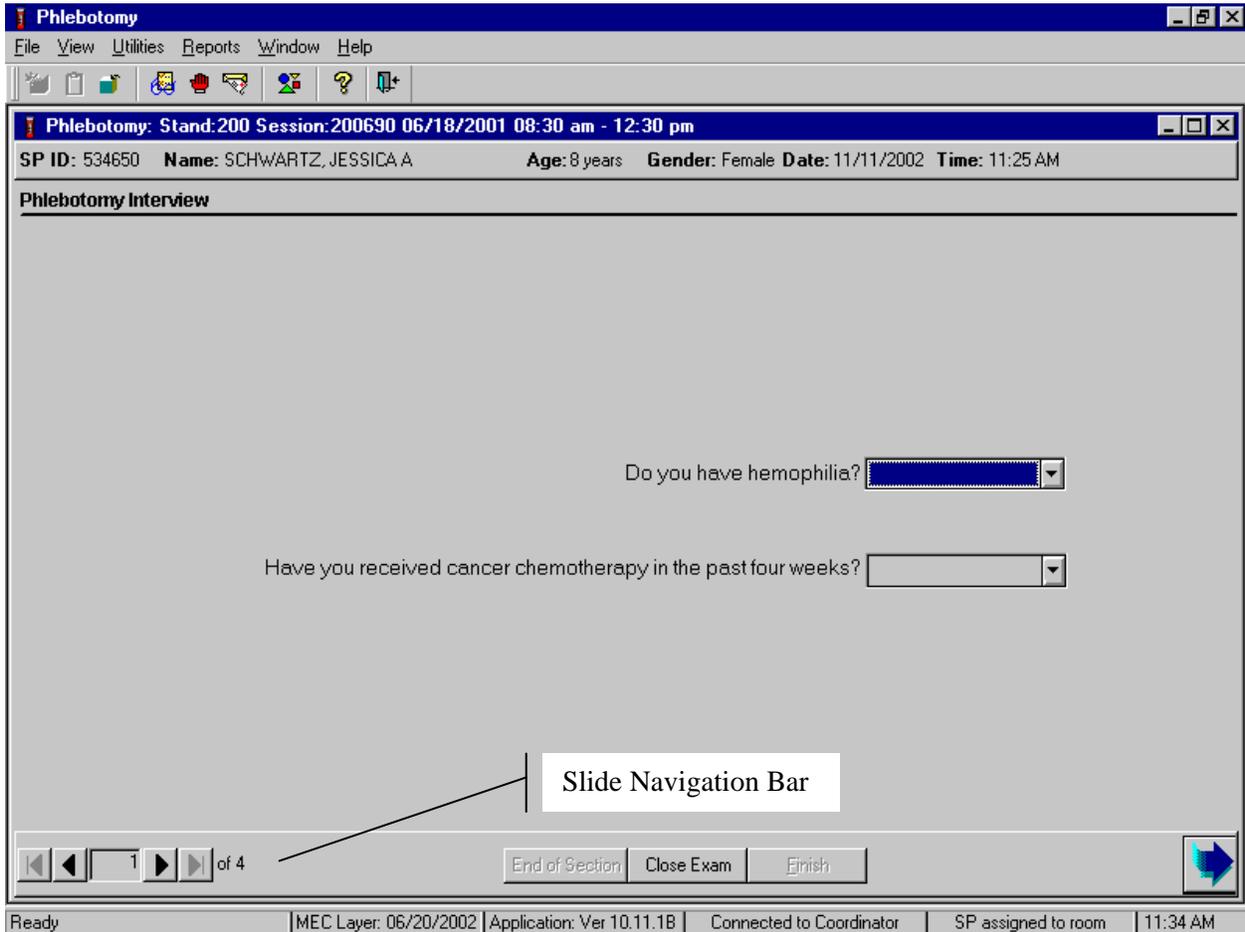
The title bar appears with the first examination slide after the SP is logged onto the exam component.



The title bar remains visible throughout the examination process. The example above illustrates the actual information displayed.

### 3.5.3.4 Exam Slide Navigation

The slide navigation bar provides a means to move forward and back through an examination.



The features of this bar are listed below:



View first slide in examination sequence. Disabled (dimmed) if current slide is first in examination sequence.



View previous slide in examination sequence. Disabled (dimmed) if current slide is first in examination sequence.



View next slide in examination sequence. Disabled (dimmed) if current slide is last slide in examination sequence.



View last slide in examination sequence. Disabled (dimmed) if current slide is last slide in examination sequence.



View next slide in examination sequence. An easy to click button.

Note the slide counter between the previous and next slide buttons. This counter aids in determining the current location in the slideshow sequence.

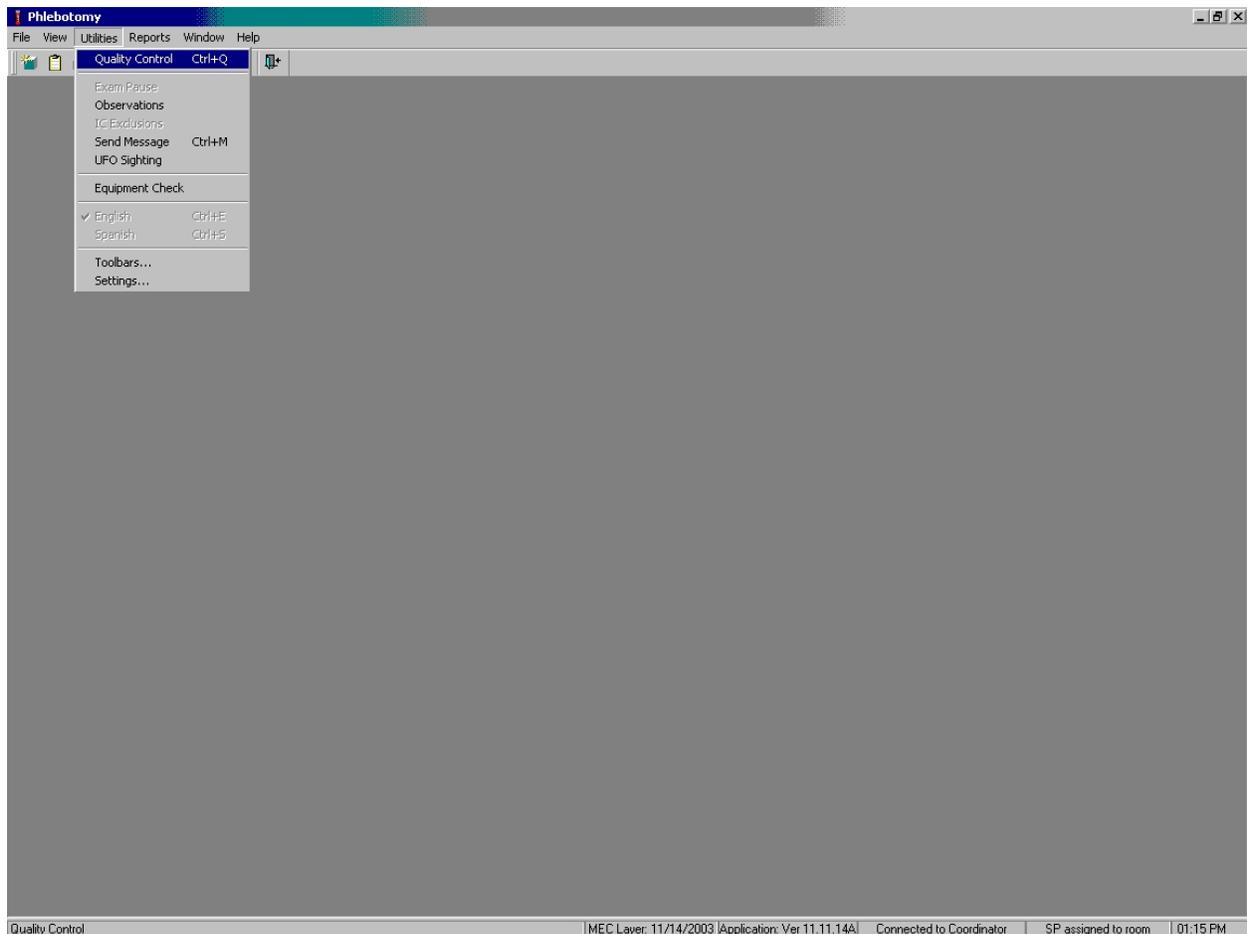
- End of Section button advances the examination slide to the status slide for the current section or the end of the examination for single section examinations.
- Close button interrupts the examination and displays the Status screen for an appropriate status code and comment.
- Finish button is disabled (dimmed) until the examination is complete. Partial and Not Done examinations require a status code and comment to activate the Finish button. The action completes the current examination.

### 3.6 Quality Control

Several examinations incorporate medical equipment that requires periodic maintenance and inspection. These components have detailed procedures on conducting their specific inspection checks. Each subsystem notifies the examiner that QC inspections have not been performed when the examination program is started.

### 3.6.1 Component Quality Control

Perform quality control as indicated in the component protocol.



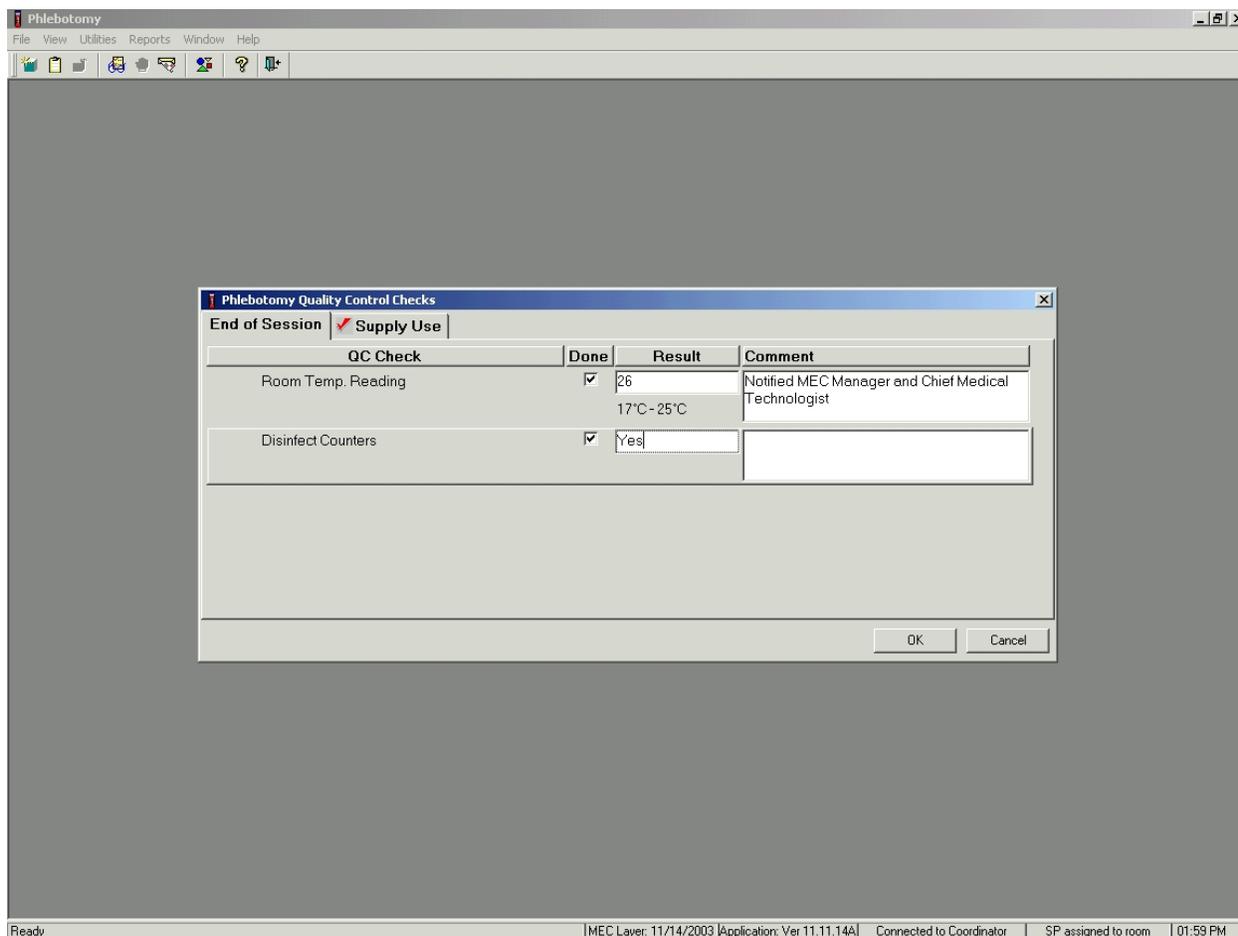
To access the component QC module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Quality Control} and left click, or select [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

Record the quality control activities. Mark each done check box with a check mark.

QC Check	Done	Result	Comment
Room Temp. Reading	<input checked="" type="checkbox"/>	17°C - 25°C	
Disinfect Counters	<input type="checkbox"/>		

To record a check mark in the check box, use the mouse to direct the mouse arrow to the check box and left click, then select [Tab] to move to the Result box. Type “Yes” or “Not Done” in the Comment text box and then [Tab] to add free form text explaining any “Not done” or abnormal response.

Continue entering the QC.

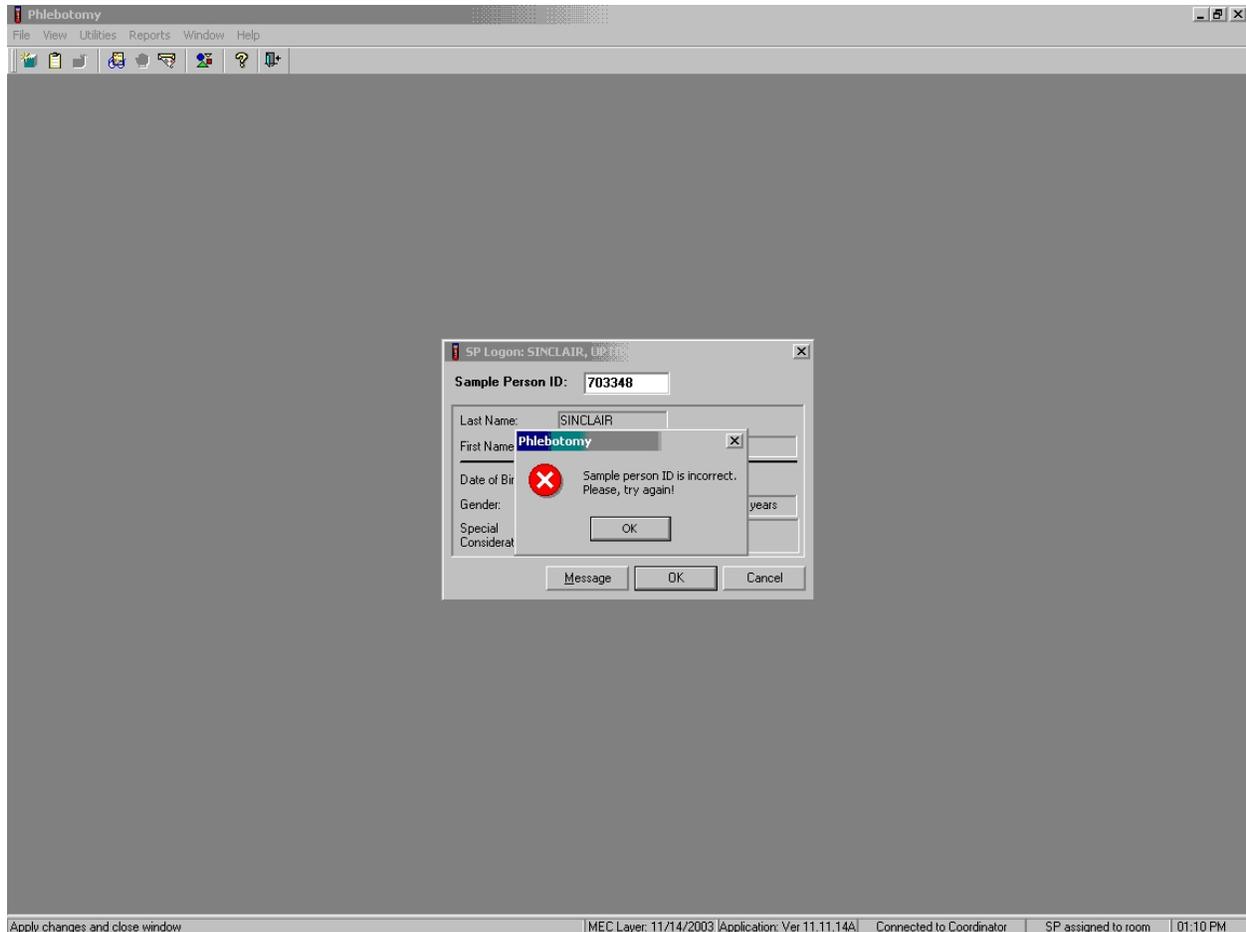


If the result is unexpected, such as “No,” document the actions taken to resolve the situation in the Comment text box. To save these actions in the database, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the QC module without saving these actions in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

### 3.7 Warning and Error Messages

Throughout the course of an examination, warning and error messages may appear when an attempt is made to perform an action the program cannot execute or requires confirmation to continue the action. The message normally appears with statements explaining the error condition. Complying with the

error message statement will normally remedy the error. When required to confirm an action, such as deleting records, be sure the action is necessary because in most cases the action is irreversible.

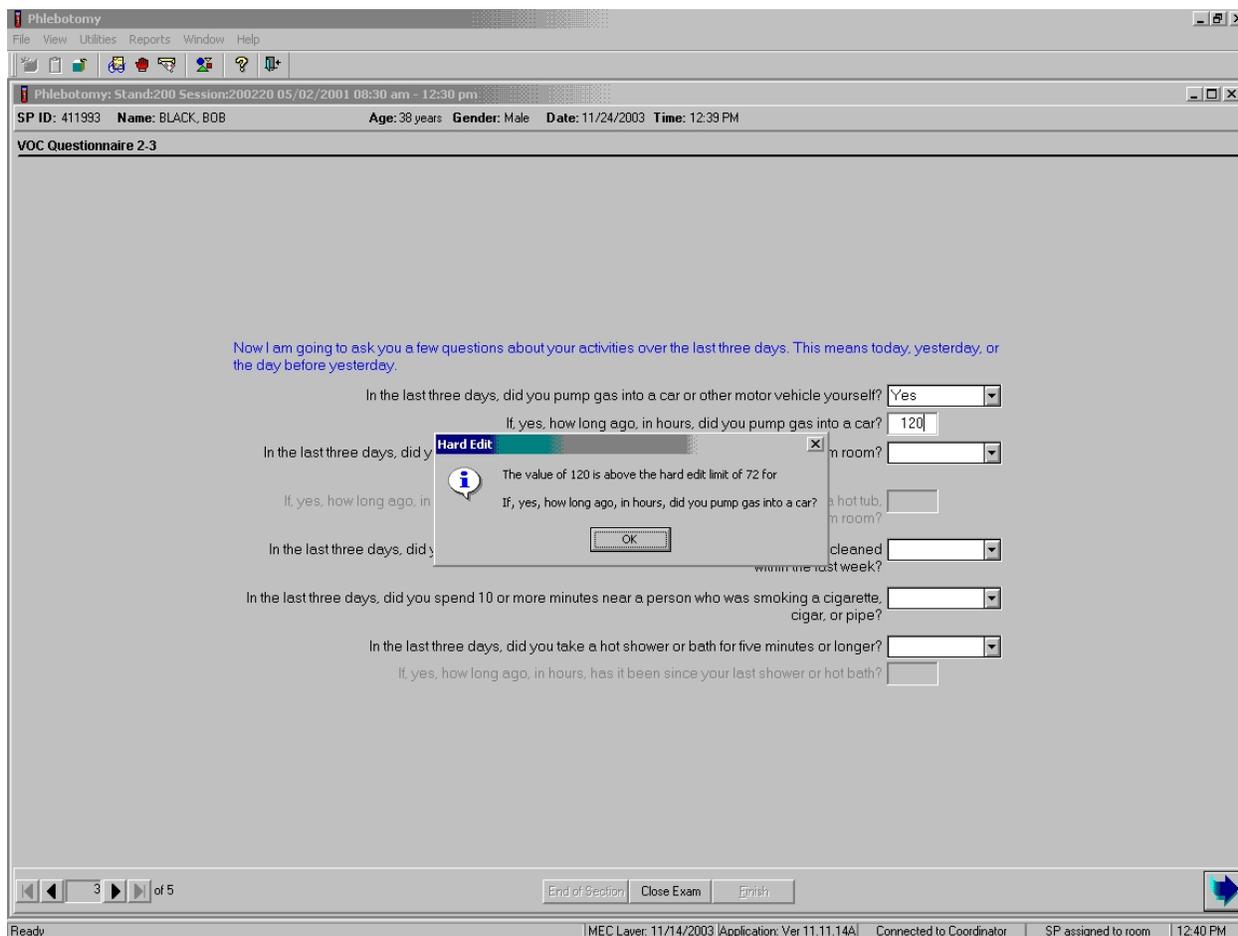


For example, if the Sample Person ID is incorrect in the SP Logon window a warning message box displays indicating the problem and remedial instructions. To remove the warning message box, use the mouse to direct the mouse arrow to the OK button and left click.

### 3.7.1 Hard and Soft Edits

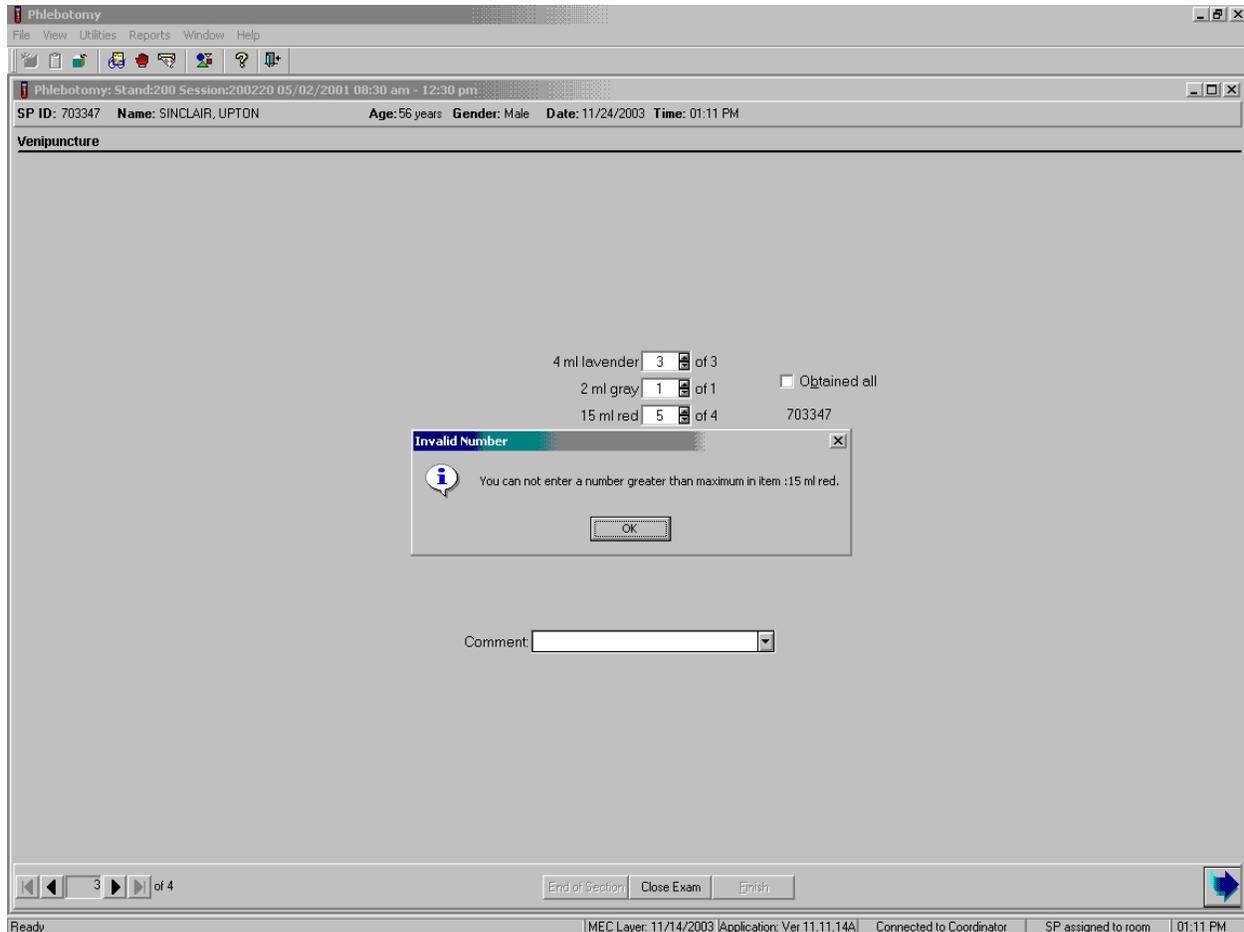
Data entry fields may have limitations on the acceptable range of values. The limitations imposed on these values are called **hard** and **soft edits**.

**Hard edits** impose a strict limitation on values entered in a data field.



A data value entered outside of the hard edit range is not accepted and a program warning displays. For example, if a VOC questionnaire result is restricted to a number between 1 and 76, an entry of “120” will not be accepted. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter.]

**Soft edits** are flexible limitations on values but prompts a confirmation if a value exceeds the limit.



For example, if a phlebotomy soft edit limitation is one 5-mL EDTA tube; an entry of 3 will prompt a confirmation dialog box. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter.]

### 3.8 Buttons, Drop-down Lists, and Boxes

The examination slides use a variety of methods to capture acquired data. The methods include the following data control devices.

## Radio Buttons

The screenshot shows a software window titled "LAB" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. A sub-window titled "NS: 590381" is open, displaying a form with the following fields:

Tech ID: 1126    Sample ID: 590381    Name: COURNOYER, JOANNE    Gender: F    Age: 39  
SP ID: 590381    SubSample: 1    Fasting\_Req: 3

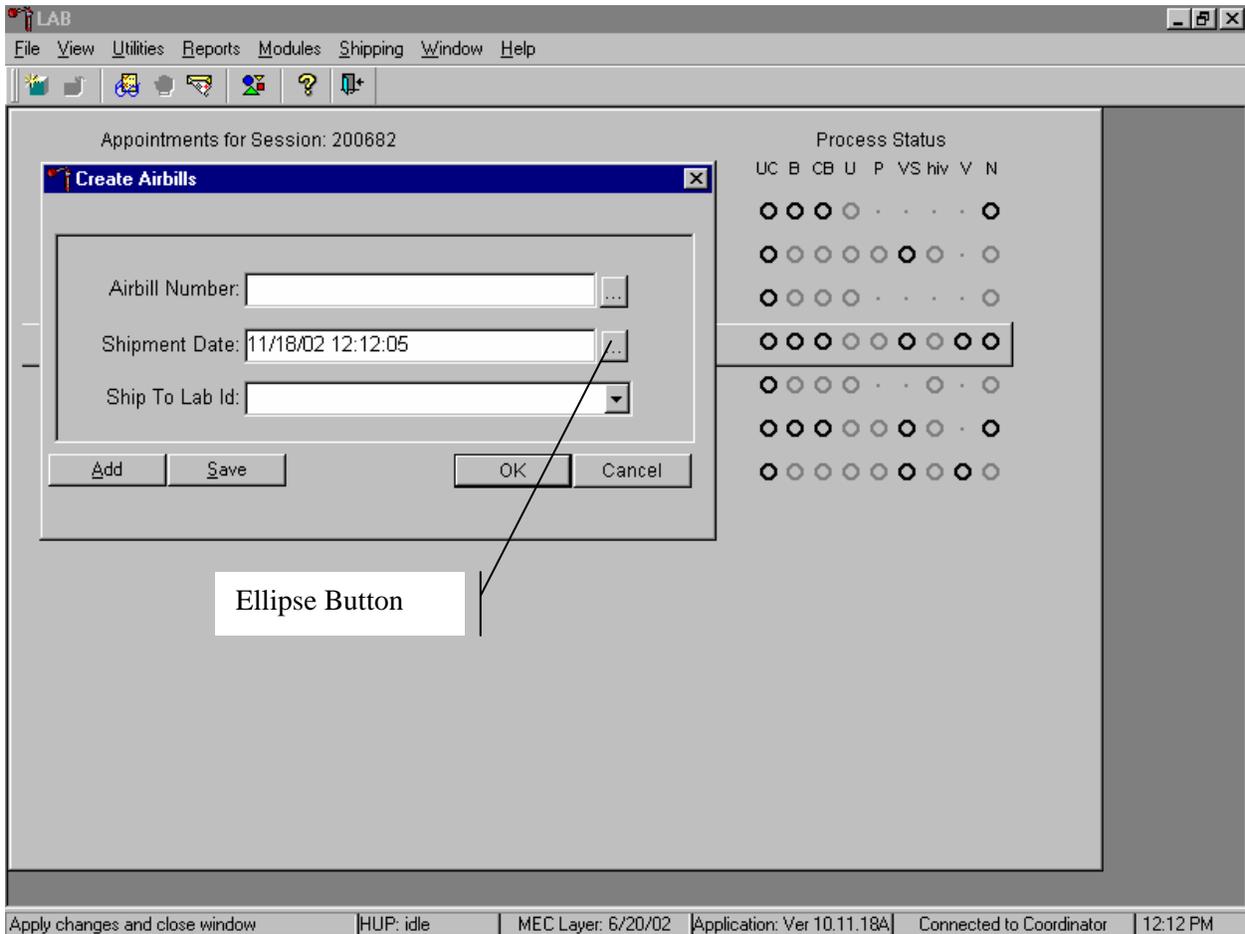
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
76	MRSA	1.0	NS	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)		

A callout box labeled "Radio Button" points to the "Yes" radio button in the "Filled" column. Below the table are buttons for "Save", "OK", and "Cancel".

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.18A | Connected to Coordinator | 12:08 PM

The radio button requires a single response out of the responses displayed. The responses are mutually exclusive, but may have more than two displayed responses. To select a response, simply click on the appropriate button. The selected button will appear with a black dot in the center of the circle.

## Ellipsis Button



The ellipsis button indicates additional action is available, such as browsing for either additional information or the calendar.

## Drop-down List

**Phlebotomy**

File View Utilities Reports Window Help

**Phlebotomy: Stand:200 Session:200502 05/30/2001 05:30 pm - 09:30 pm**

SP ID: 693249 Name: KLING, ANNA Age: 54 years Gender: Female Date: 11/09/2001 Time: 02:51 PM

**VOC Questionnaire 2-3**

Now I am going to ask you a few questions about your activities over the last three days. This means today, yesterday, or the day before yesterday.

In the last three days, did you pump gas into a car or other motor vehicle yourself? Yes

If, yes, how long ago, in hours, did you pump gas into a car? 15

In the last three days, did you spend any time at a swimming pool, in a hot tub, or in a steam room?

If, yes, how long ago, in hours, has it been since you spent time in a swimming pool, in a hot tub, or in a steam room?

In the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

In the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

In the last three days, did you take a hot shower or bath for five minutes or longer?

If, yes, how long ago, in hours, has it been since your last shower or hot bath?

3 of 5

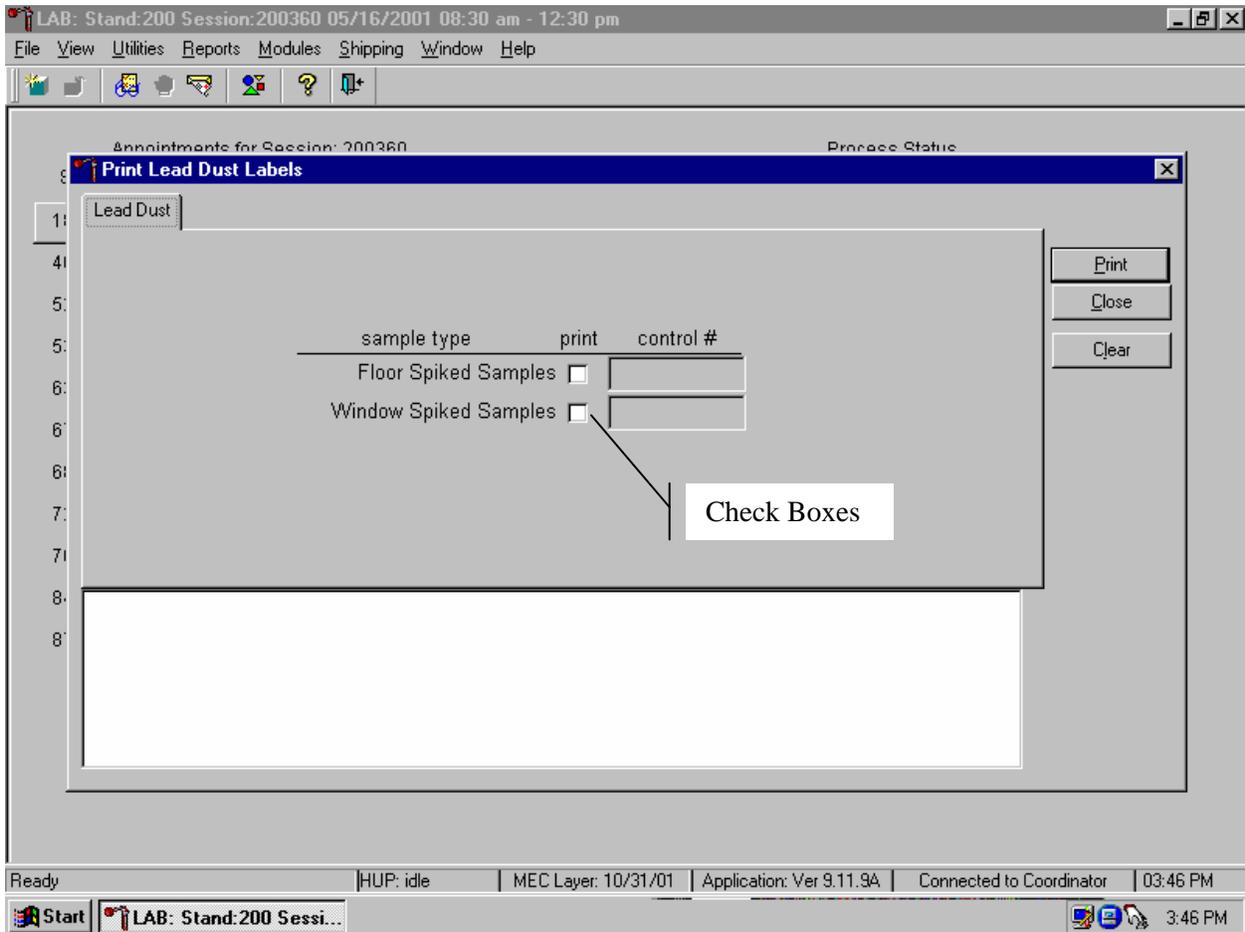
End of Section Close Exam Finish

Ready MEC Layer: 10/31/01 Application: Ver 9.10.24B Connected to Coordinator SP assigned to room 03:12 PM

Start Phlebotomy 3:12 PM

The drop list, or drop-down list, provides a rapid means of selecting a desired response from a fixed set of possible responses. The drop-down list window may initially appear blank, as shown in the top example above. To drop down the list of possible responses, click on the down arrow button. A scrollbar may appear on the window's right side to enable you to scroll down the list. Click to select the desired response. The selection will appear in the upper list window.

## Check Boxes



Marking a check box enables all corresponding applicable responses. The responses are not mutually exclusive. To select a response, simply click on the appropriate box. The selected box will appear with a black check in the center of the box. Click on a selected box to deselect.

## Spin Boxes

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200191 04/29/2001 01:30 pm - 05:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar displays patient information: "SP ID: 428042 Name: LOUGANIS, GREG Age: 33 years Gender: Male Date: 11/16/2001 Time: 03:42 PM". The main area is titled "Venipuncture" and contains three spin boxes for specimen counts: "3 ml lavender" (0 of 2), "5 ml lavender" (0 of 2), and "10 ml red" (0 of 4). To the right of these boxes is a checkbox labeled "Obtained all" and two text fields containing "428042" and "176196". A callout box labeled "Spin Box" points to the "10 ml red" spin box. Below the spin boxes is a "Comment:" label followed by a dropdown menu. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish", along with a blue arrow button. The Windows taskbar at the bottom shows the Start button, a taskbar with "Logon to WESTAT Email ..." and "Phlebotomy: Stand:2...", and the system tray with the time "3:42 PM".

The spin box accepts a limited set of discrete responses. The “spin” name is derived from the up-down arrow buttons that can be used to “spin” the set of responses up or down. To select a response, simply click on the appropriate up or down arrow button to increment the responses or type the response value in the spin window, if known.

### 3.9 Section or Component Status

The Section or Component Status screen displays the relative completion of the examination – **Complete**, **Partial**, or **Not Complete**. This is the last exam slide at the end of a section or a component if there are multiple sections. The status automatically displays and is not editable. Interruptions, emergencies, refusals, and other events that prematurely stop the examination will trigger this screen for appropriate incomplete comment codes. Comments are not recorded for Complete examinations.

Component status codes indicate the degree of component examination completion.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar is a header bar for the current session: "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". Below this is a patient information bar: "SP ID: 281396 Name: ERAMIA, STANLEY Age: 1 year Gender: Male Date: 11/11/2002 Time: 11:59 AM". The main area is titled "Venipuncture Status" and contains a "Status" section with three radio buttons: "Complete", "Partial" (which is selected), and "Not Done". Below the status section are two input fields: "Comments" (a drop-down menu) and "Other text" (a text box). At the bottom of the main area is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, and a blue arrow button on the right. The status bar at the very bottom shows "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "12:02 PM".

Comment codes are used to explain partial or not done status codes. Select the comment from the Comments drop-down list and type [Enter.]

Comment Codes defined below are common to all exams. There are other specific components and section comment codes that are defined in each manual chapter.

<b>Safety Exclusion:</b>	The examinee was excluded from the component for safety reasons as defined by the component protocol.
<b>SP Refusal:</b>	This is a SP initiated response due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator can code the exam. If the SP refuses after starting the exam, the examiner will code the refusal.
<b>No Time:</b>	The SP comes on time and stays for the entire session, there is adequate staff in the MEC, but at the end of the session there is no time to do the examination.
<b>Physical Limitations:</b>	SP is unable to have the test due to physical problems. For example, the SP is unable to lie flat for the total body composition scan.
<b>Communication Problems:</b>	SP is unable to understand and follow the instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
<b>Equipment Failure:</b>	The component equipment malfunctioned and the test could not be performed on the SP.
<b>SP Ill/ Emergency:</b>	The SP became ill or an emergency occurred and the test was not performed on the SP.
<b>Interrupted:</b>	An exam is interrupted, usually for a MEC-wide emergency, and cannot be completed by the SP.
<b>Other, specify:</b>	If the above reason for a Status Code of Partial or Not Done is not explained by one of the above Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

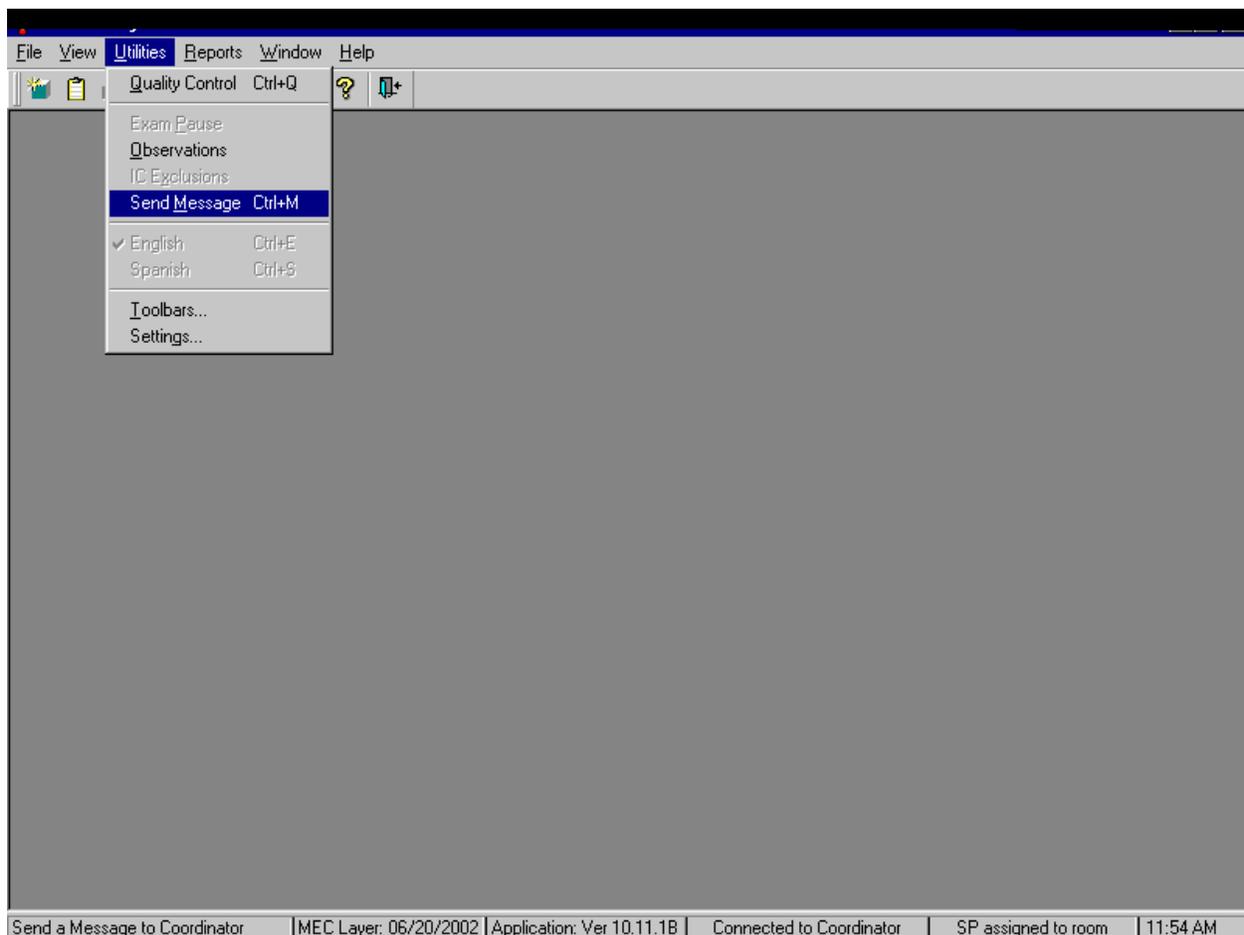
Examinations closed before completion are automatically assigned a Partial status and the examiner is prompted to enter an appropriate comment.

### 3.10 The Messaging Subsystem

The messaging subsystem is the communication nerve center that continually informs the coordinator on the status of each component examination progress, assigned examiner(s), components available for SPs, and other management information.

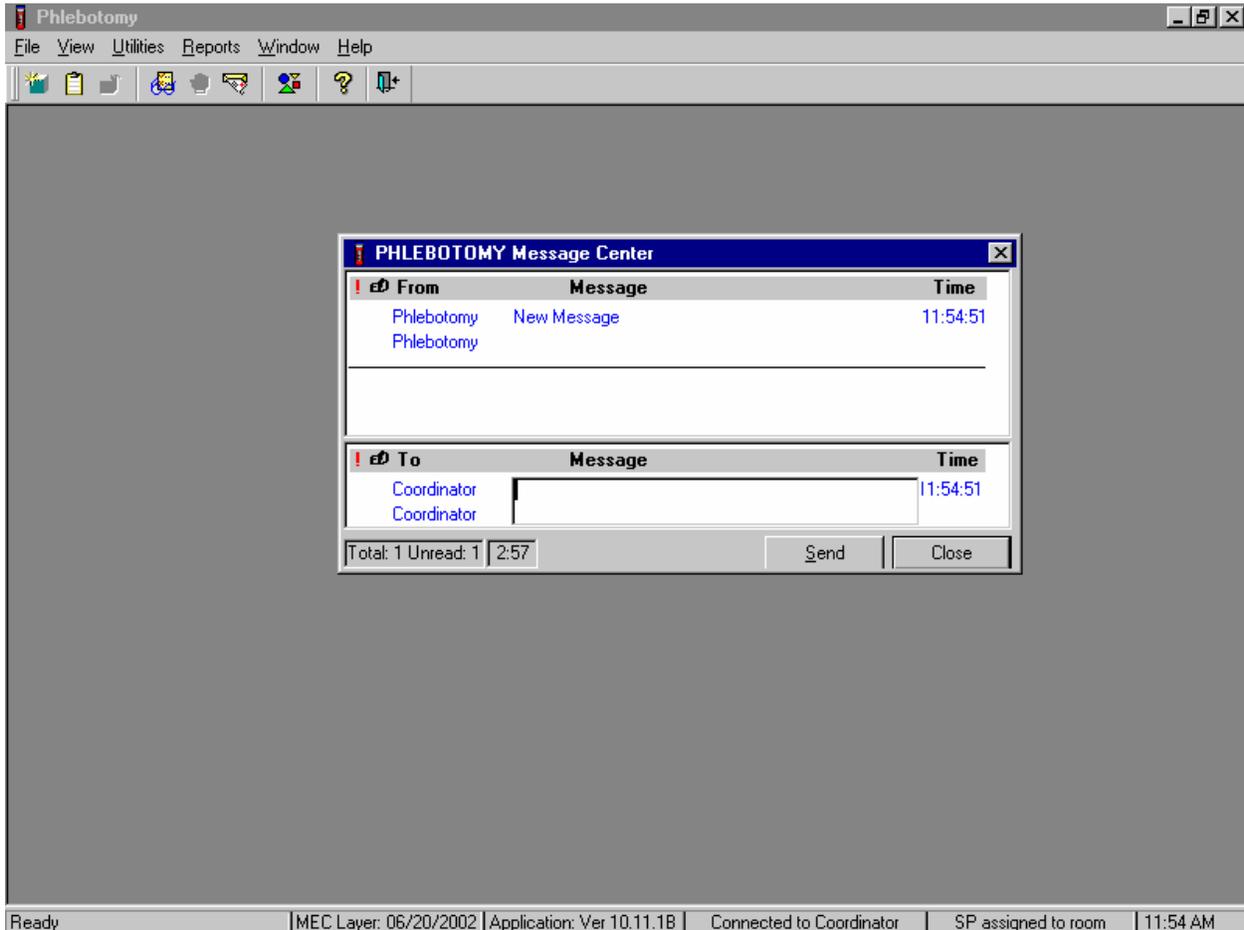
Communication between the coordinator and staff in the examination components is readily available through the Utilities menu or the Send Message button on the toolbar.

Send a message to the coordinator.



To access the Send Message subsystem, use the mouse to direct the mouse arrow to {utilities} in the menu bar, drag the mouse arrow to {Send Message}, and left click or type [Alt] [U/u], [M/m].

The Message Center transmittal box appears.



Messages sent to the coordinator appear in the message center window on the coordinator screen. Messages received from the coordinator will remain visible on the screen for approximately 30 seconds.

Messages that have been flagged as “Read” (click the Read Flag column next to the read message) will be removed from the Messages Received pane during the system update, usually every 30 seconds.

### 3.11 Sample Reports

The Reports menu options include the Session Preview, Room Log, and Results reports. Most reports display on screen and all reports can be printed.

#### To Print a Report:

Default printers are designated for each workstation and cannot be changed with the examination program.

The screenshot shows the Phlebotomy software interface. The main window displays a 'Session Preview Report' for session 200690 on 06/18/2001 from 08:30 AM to 12:30 PM. The report lists patient information in a table format. The status bar at the bottom indicates 'Prints the item', 'MEC Layer: 06/20/2002', 'Application: Ver 10.11.1B', 'Connected to Coordinator', 'SP assigned to room', and '11:57 AM'.

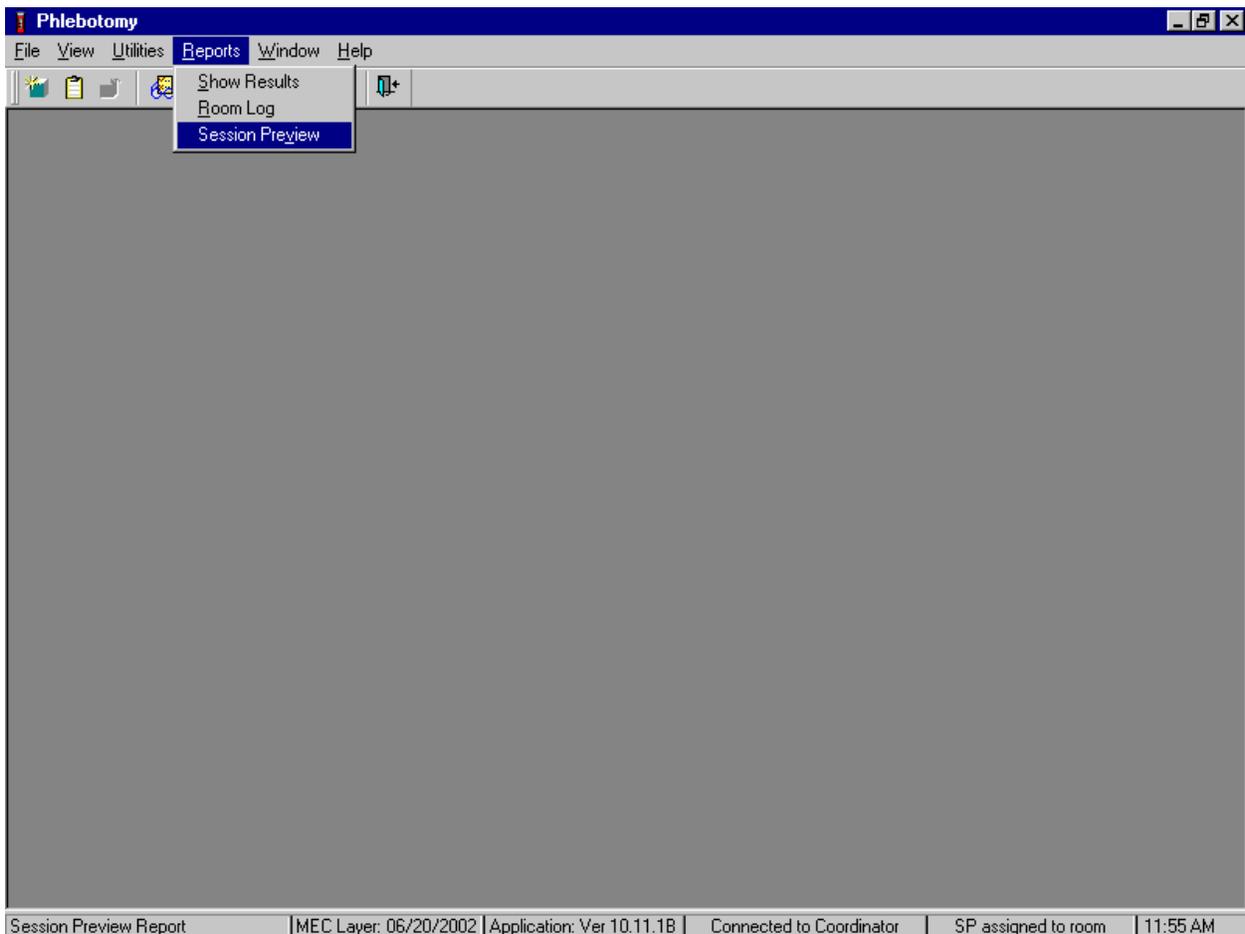
SP	SP Type	SP Name	Age	Gender	Special Considerations
200-00-0000-00-00	416806	Guest	NEBILLE ERAMIA	29 years	Male
200-02-0013-06-09	562086	Primary	CARMEN LANGBERG	3 years	Female
200-02-0013-06-11	534650	Primary	JESSICA A SCHWARTZ	8 years	Female
200-02-0013-06-12	356294	Primary	DAWN SCHWARTZ	21 years	Female
200-02-0013-06-15	304755	Primary	YVETTE ERAMIA	48 years	Female
200-02-0013-06-17	248274	Primary	*AUNTIE EYRAMYA	39 years	Female

Page 1 of 3

Open the report. To print a report, use the mouse to direct the mouse arrow to {File} in the menu bar, drag the mouse arrow to {Print} and left click or type [Alt] [F/f], [P/p]. The report or print capable window is automatically sent to the default printer.

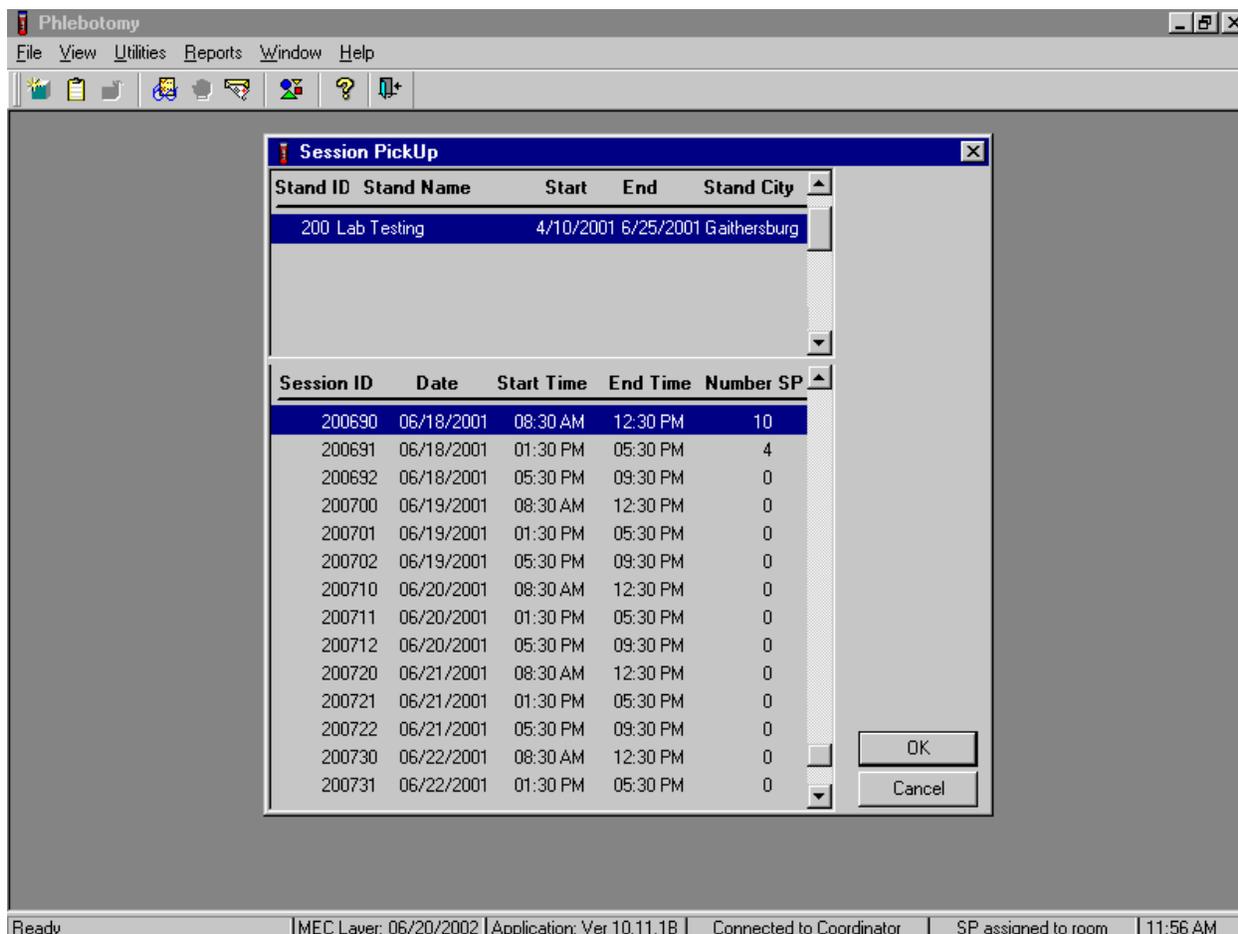
### 3.11.1 Session Preview Report

Access the Session Preview report to view all SPs scheduled into any session including the current session.



To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Session Preview}, and left click or type [Alt] [R/r], [V/v].

Select the session.



The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

The Session Preview Report displays.

**Phlebotomy**

File View Utilities Reports Window Help

**Phlebotomy Subsystem Stand:200 Session:200690**

**Session Preview Report** 11/11/02 11:57  
Stand: 200

---

Session: 200690 06/18/2001 08:30 AM - 12:30 PM

SP	SP Type	SP Name	Age	Gender	Special Considerations
200-00-0000-00-00	416806 Guest	NEBILLE ERAMIA	29 years	Male	
200-02-0013-06-09	562086 Primary	CARMEN LANGBERG	3 years	Female	
200-02-0013-06-11	534850 Primary	JESSICA A SCHWARTZ	8 years	Female	
200-02-0013-06-12	356294 Primary	DAWN SCHWARTZ	21 years	Female	
200-02-0013-06-15	304755 Primary	YVETTE ERAMIA	48 years	Female	
200-02-0013-06-17	248274 Primary	*AUNTIE EYRAMYA	39 years	Female	

Page 1 of 3

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 11:57 AM

The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last), Age, Gender, and any Special Considerations or Consent Comments. A blue asterisk (\*) in front of a name indicates that the SP is eligible for the VOC component. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Session Preview Report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Session Preview Report, use the mouse to direct the mouse arrow to the \_ box in the upper right corner of the Session Preview Report (minimize window button) and left click.

### 3.11.2 Subsample Preview

Access the Subsample Preview to view all SPs in the current session and the selected subsamples for which they are eligible.



To access the Subsample Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Subsample Preview}, and left click.

Review the Subsample Preview.

Appointments for Session: 200682

Process Status

SP ID Sample ID status type gender age name UC B CB U P VS hiv V N

**Subsample Report for Session 200682**

**SPs Selected for Subsamples in Session 200682**

Appt.ID	SP ID	Person Name	Gender	Age	Type	Subsample Description
2004276	422055	NEWELL, BRIAN	M	14	1	Urine Phytoestrogens 1 PAH 1 Phthalates
2004277	447279	JOHNSON, JULIE	F	28	1	CIDI 1 DIMES-In person 1 Urine Phytoestrogens 1 PAH 1 Phthalates
2004278	501571	QUINLAN, TIM	M	86	1	DIMES-In person 1 Urine Phytoestrogens 1 PAH

11/18/02 Page 1 of 3

Close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.18A | Connected to Coordinator | 12:19 PM

The Subsample Preview report includes all SPs assigned to the current session and the subsamples for which they are eligible. This report contains the appointment ID, SP ID, person name, gender, age, person type, and subsample description. Only SPs selected for inclusion in specific subsamples are eligible to have the related vessel filled. To view the entire report, use the mouse to direct the mouse arrow to the right scroll bar, and drag the arrow up or down. To print a copy of the report, use the mouse to direct the mouse arrow to the Print button and left click. To exit and close the report, use the mouse to direct the mouse arrow to the Close button and left click.

### 3.11.3 Room Log

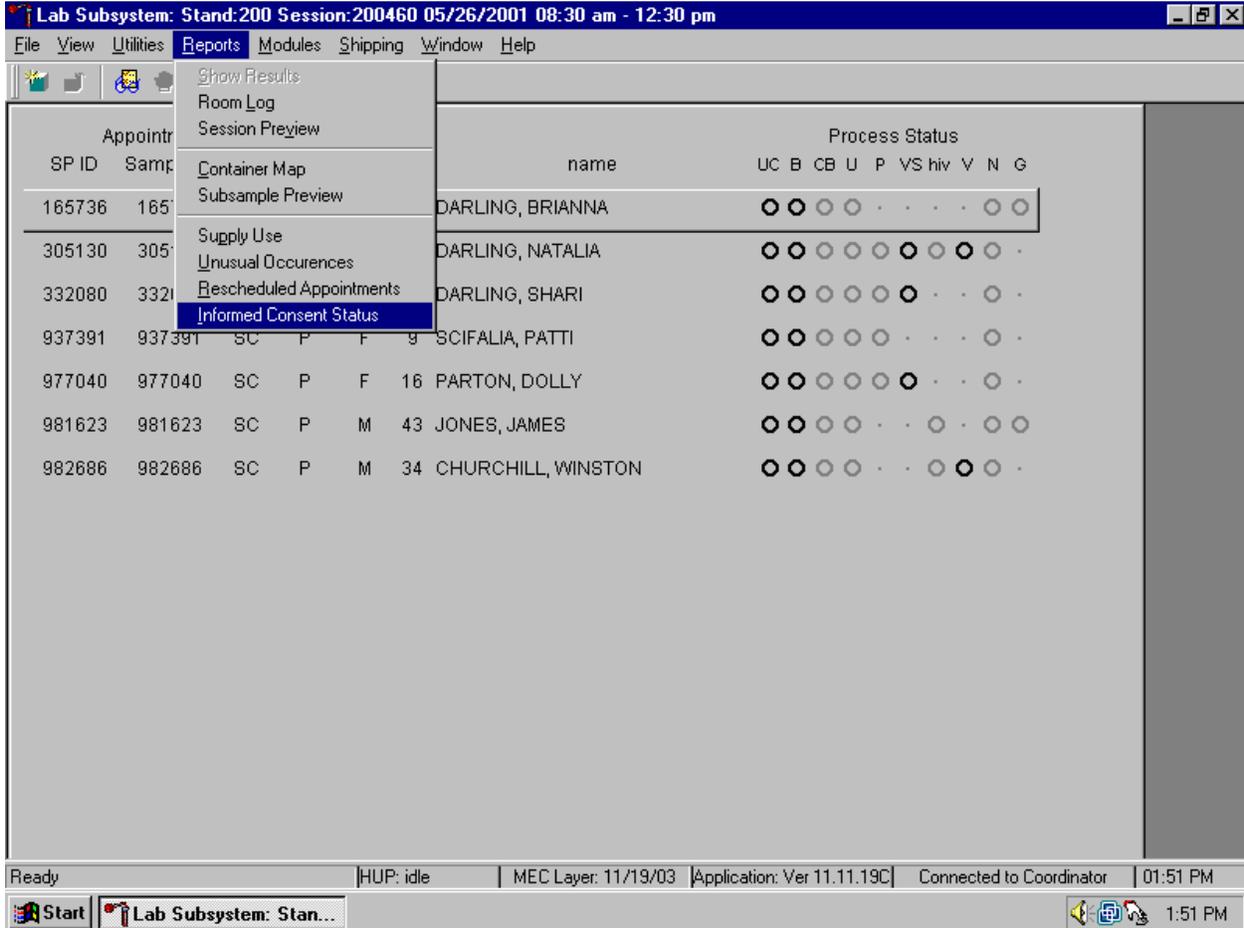
The Room Log displays the SPs in the current session and their component status. The status is listed as Complete, Partial, or Not Done. Use this report to assess the session status.

SP ID	SP Name	Gender	Age	Component Status
281396	Stanley Eramia	Male	1	partial
534650	Jessica A Schwartz	Female	8	complete

The Phlebotomy Room Log lists the stand number, session number, session date and time, current date and time, SP's ID, first and last name, gender, age, SP status, and component status. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Room Log report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Room Log report, use the mouse to direct the mouse arrow to the \_ box in the upper right corner of the Room Log report (minimize window button) and left click.

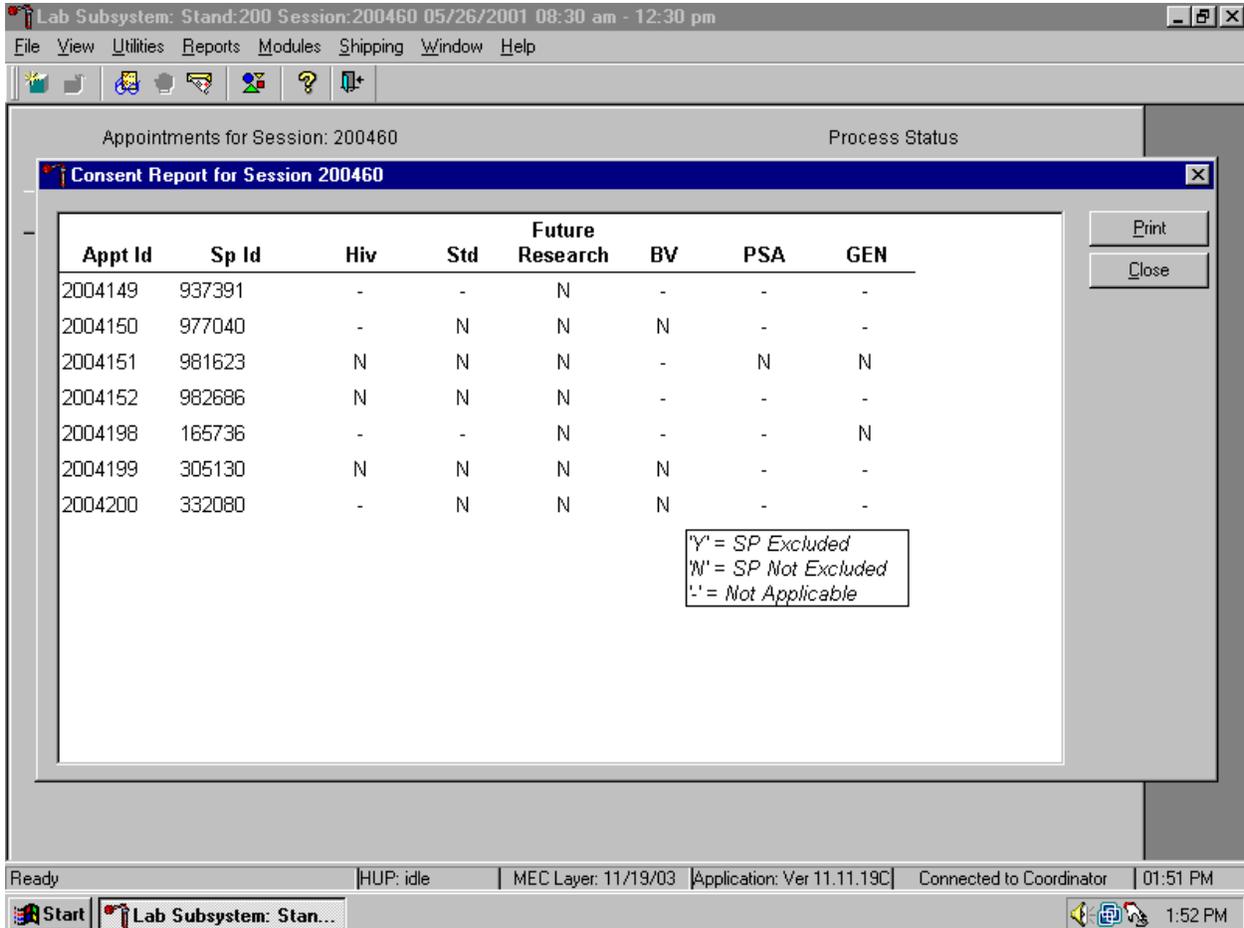
### 3.11.4 Informed Consent Status

Access the Informed Consent Status report to view SPs and the status of the informed consent result for various tests and/or groups of tests.



To access the Informed Consent Status report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Informed Consent Status} and left click or type [Alt] [R/r], [I/i].

Review the SPs scheduled into the current session and the status of their informed consent by using the Informed Consent Status report.



The consent report lists all SPs scheduled into the current session, their appointment and SP IDs, and the exclusion status for the following tests or groups of tests:

- HIV (vessels 22 – serum, 53 - urine)
- STD (vessels 24 – HSV, 46 – Chlam/GC, 74 – Syphilis)
- Future research (vessels 8 – plasma, 32-37 – serum, 51-52 – urine)
- BV (vessel 72 – bacterial vaginosis, 73 – *T. vaginalis*, 78 – HPV swab)
- PSA (vessel 75)
- GEN (vessels 95 – DNA blood, 96 – RNA Blood, 97 – RNA Buccal) *Pilot 2003 only*

The status is “Y” or “yes” if the SP is excluded and “N” if the SP is not excluded.

### 3.12 Convert Screen Text to English or Spanish

Convert exam screen text from English to Spanish or from Spanish to English at any time before, during, or after an exam.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and navigation. The main content area displays patient information: "SP ID: 248274", "Name: EYRAMYA, AUNTIE", "Age: 39 years", "Gender: Female", "Date: 11/11/2002", and "Time: 02:56 PM". Below this is the "VOC Questionnaire 2-3" section. The text is in Spanish and asks about activities in the last three days. The questions and their corresponding input fields are:

- En los últimos tres días, ¿le echó gasolina usted mismo a un carro u otro vehículo de motor?
- Si, sí, ¿cuánto tiempo hace, en horas, que usted le echó gasolina a un carro?
- En los últimos tres días, ¿pasó algún tiempo en una (alberca/piscina), en una bañera caliente, o en un cuarto de vapor?
- Si, sí, ¿cuánto tiempo hace, en horas, desde que usted pasó algún tiempo en una (alberca/piscina), en una bañera caliente, o en un cuarto de vapor?
- En los últimos tres días, ¿visitó una lavandería de lavado en seco o usó ropa que había sido lavada en seco dentro de la última semana?
- En los últimos tres días, ¿pasó 10 minutos o más cerca de una persona que estaba fumando (cigarro/cigarrillo), (puro/cigarro/tabaco) o pipa?
- En los últimos tres días, ¿se dio una ducha o un baño caliente por cinco minutos o más?
- Si, sí, ¿cuánto tiempo hace, en horas, desde la última vez que se dio una ducha o un baño caliente?

At the bottom of the questionnaire, there are navigation controls: "3 of 5" and buttons for "End of Section", "Close Exam", and "Finish". A blue arrow icon is also present.

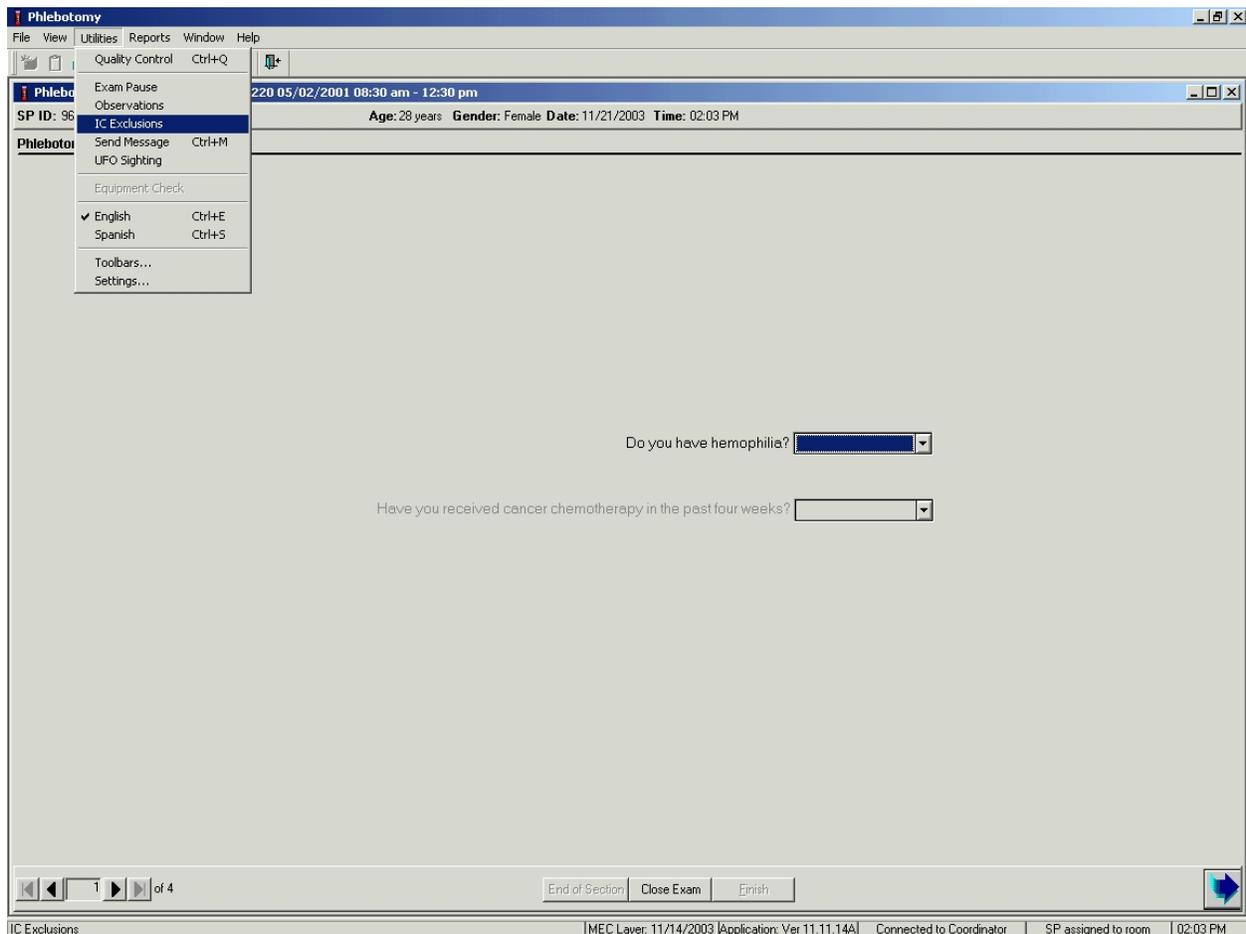
Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 03:01 PM

To view the exam screen text in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S/s]. To return exam screen text to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E/e].

### 3.13 Informed Consent Exclusions

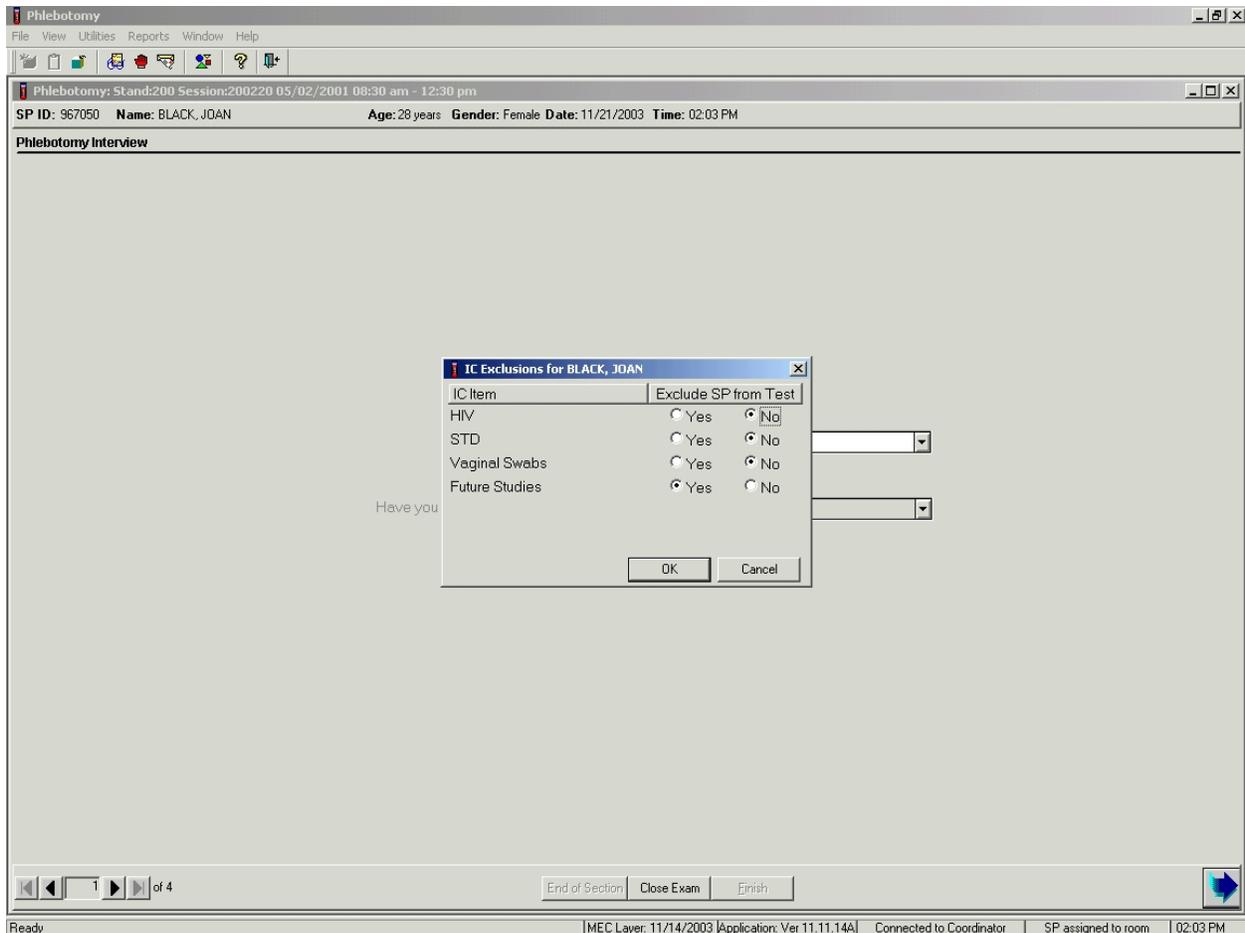
If at any time during the phlebotomy or physician exam the SP indicates they do not want their blood tested for HIV (AIDS), STD (sexually transmitted diseases include chlamydia, gonorrhea, herpes, and syphilis), future studies, or genetic testing (pilot 2003 only), then enter this information using the IC Exclusions module.

Access the IC Exclusions module.



To access the IC (informed consent) Exclusions module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {IC Exclusions}, and left click, or type [Alt] [U/i], [X/x].

The IC Exclusions window displays all the specific exclusion item tests or groups of tests for which the SP is eligible and the status for each exclusion item.

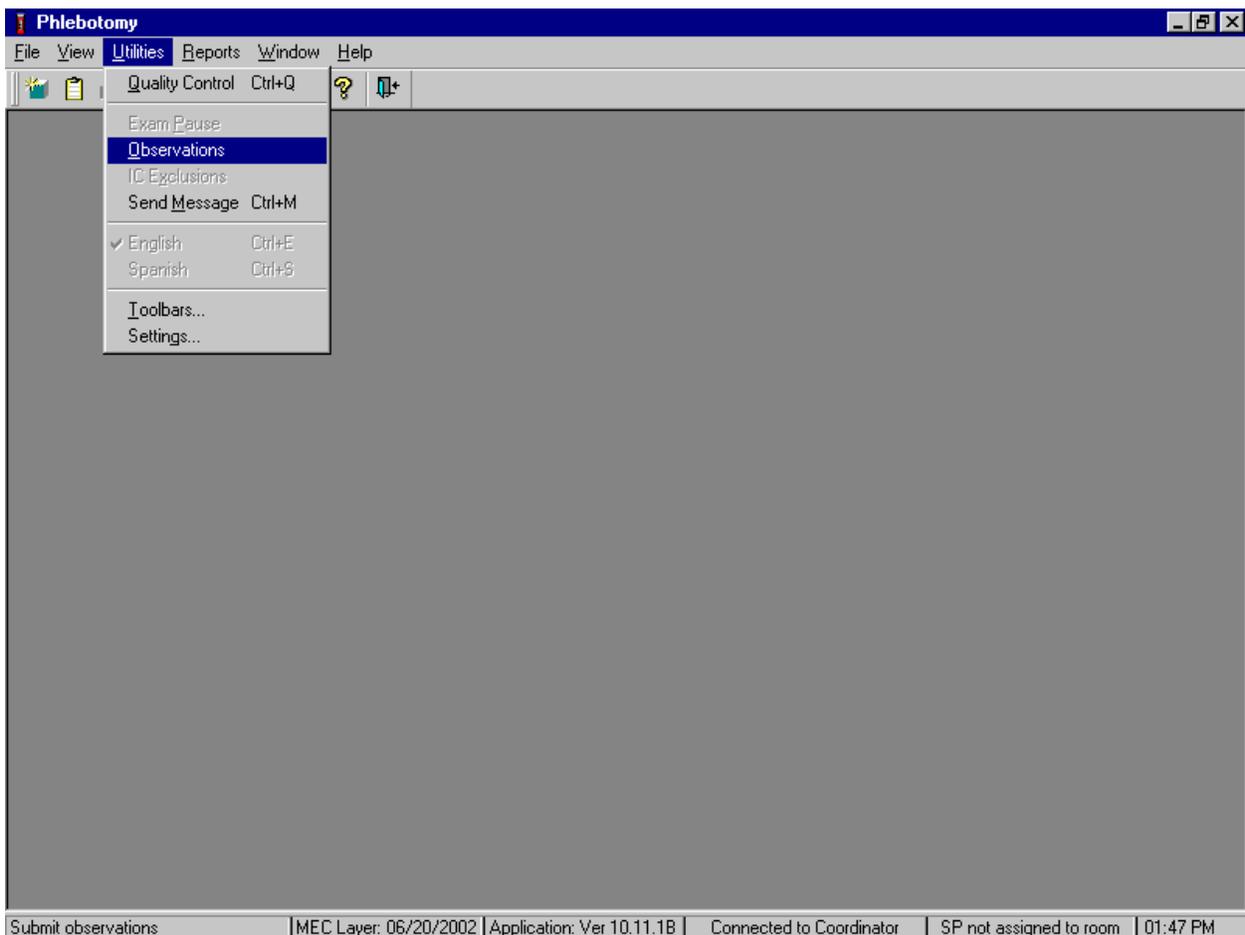


Record each item as directed by the SP. To mark each item, use the mouse to direct the mouse arrow to the “Yes” or “No” radio button and left click. To record these actions and save them to the database, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions without saving the data to the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

### 3.14 Observations

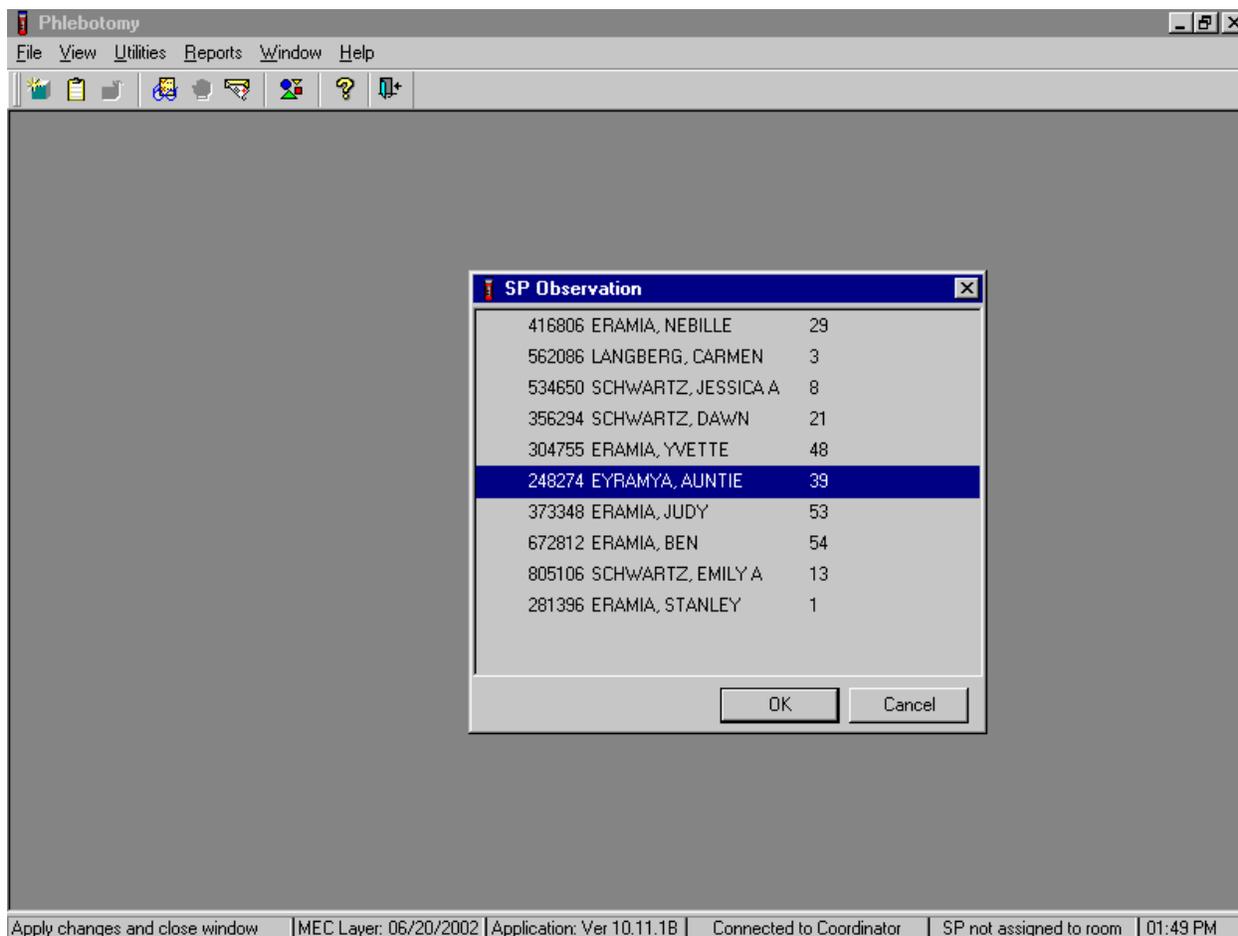
Send confidential observations to the MEC physician. Send an observation on any SP scheduled into the MEC session or the SP currently assigned to the component.

Send an observation on any SP scheduled into the MEC session. Access the observation function.



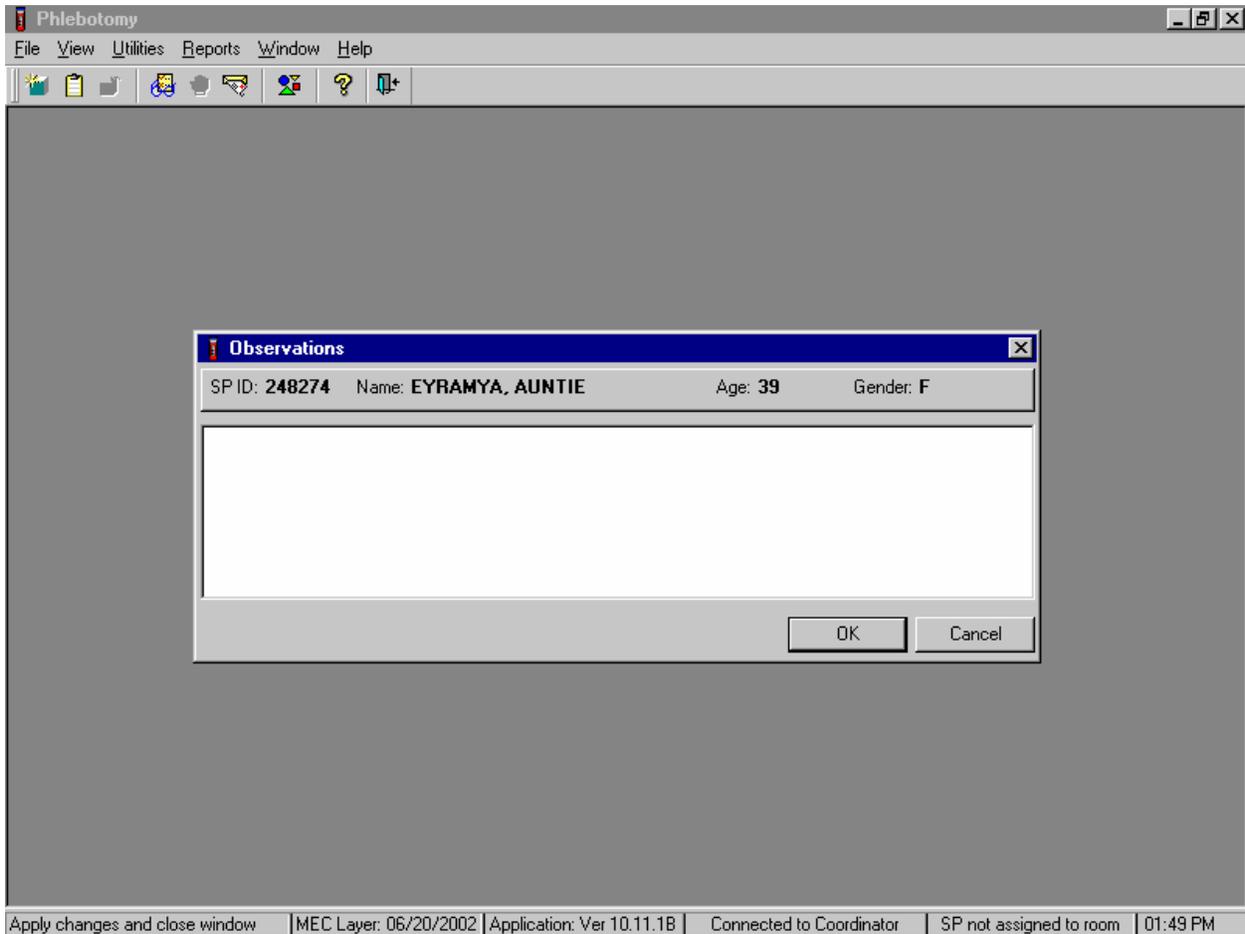
To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations}, and left click, or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



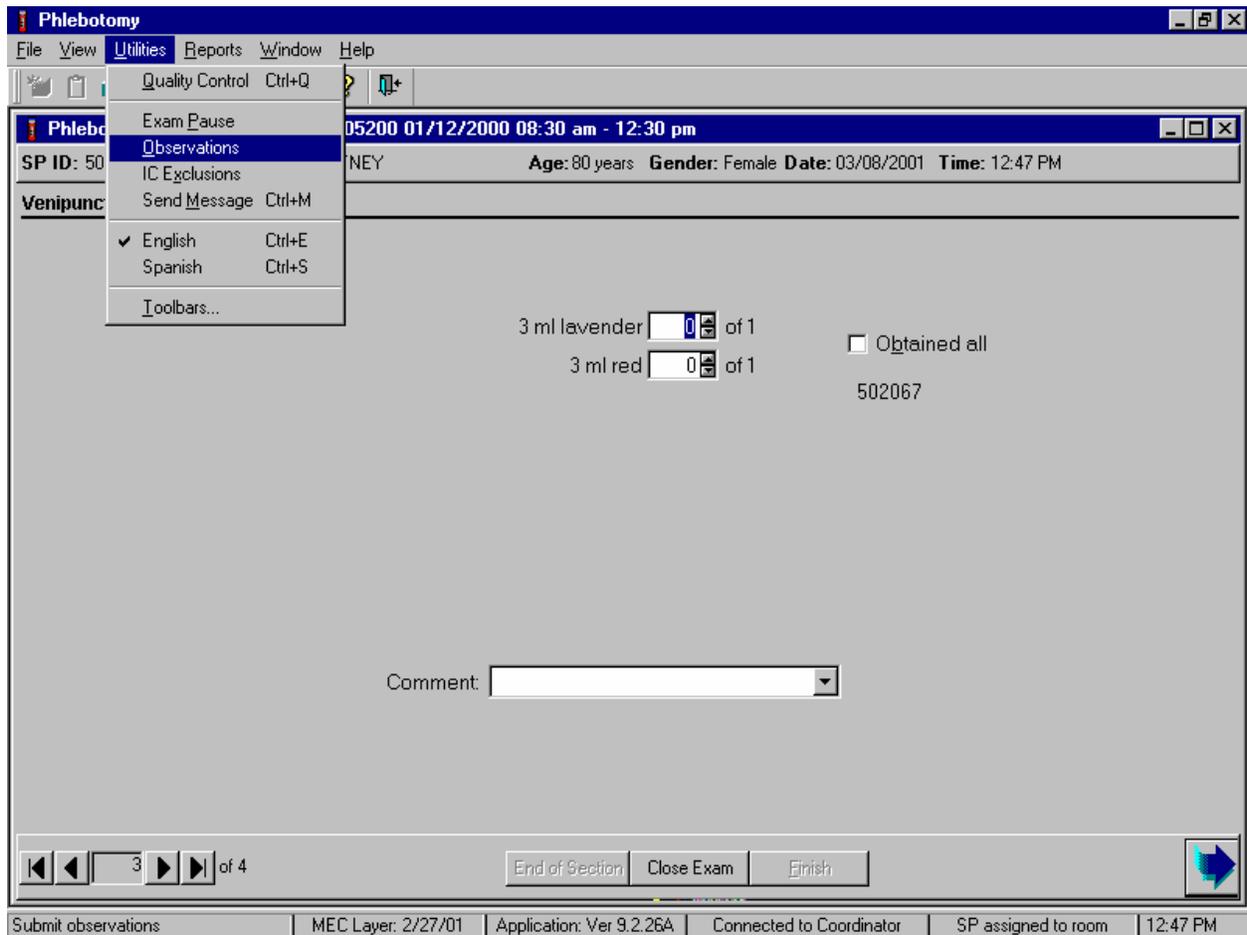
To select or highlight a SP, drag the mouse arrow to the correct SP and left click or use the up and down arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the Cancel button and left click.

The observation window displays.



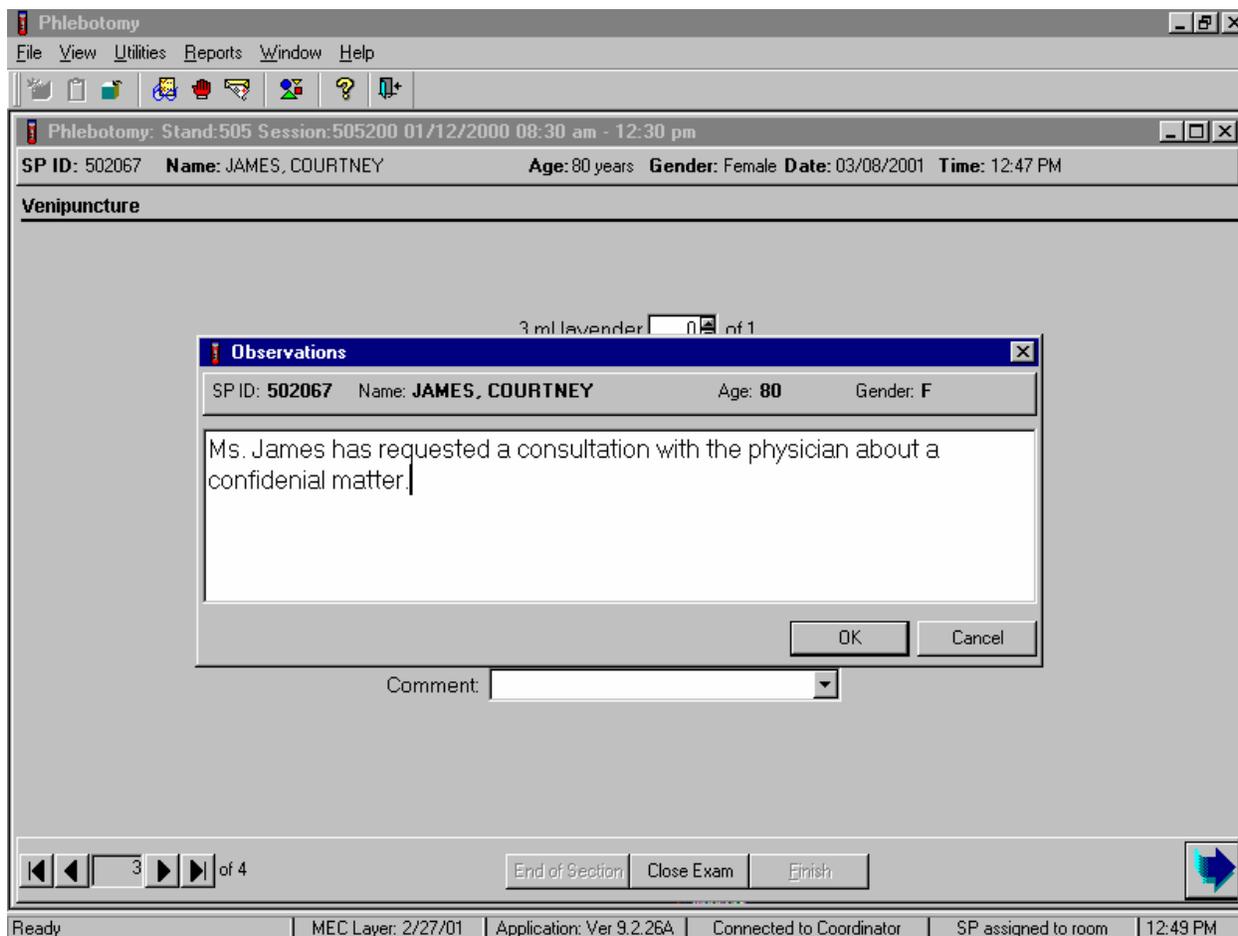
The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Enter an observation on the SP currently assigned to the component.



To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations} and left click, or type [Alt] [U/u], [O/o].

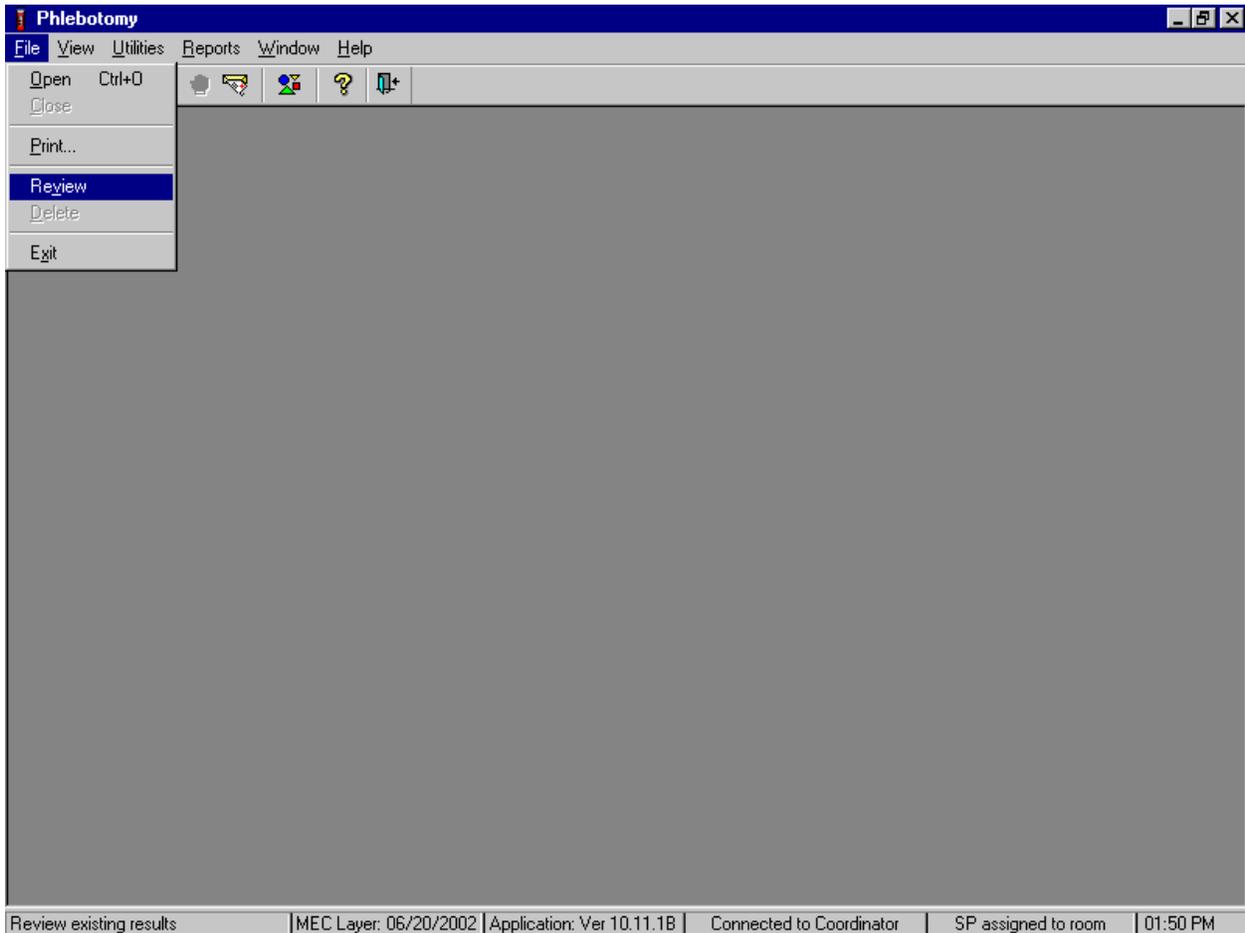
The observation window displays.



The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

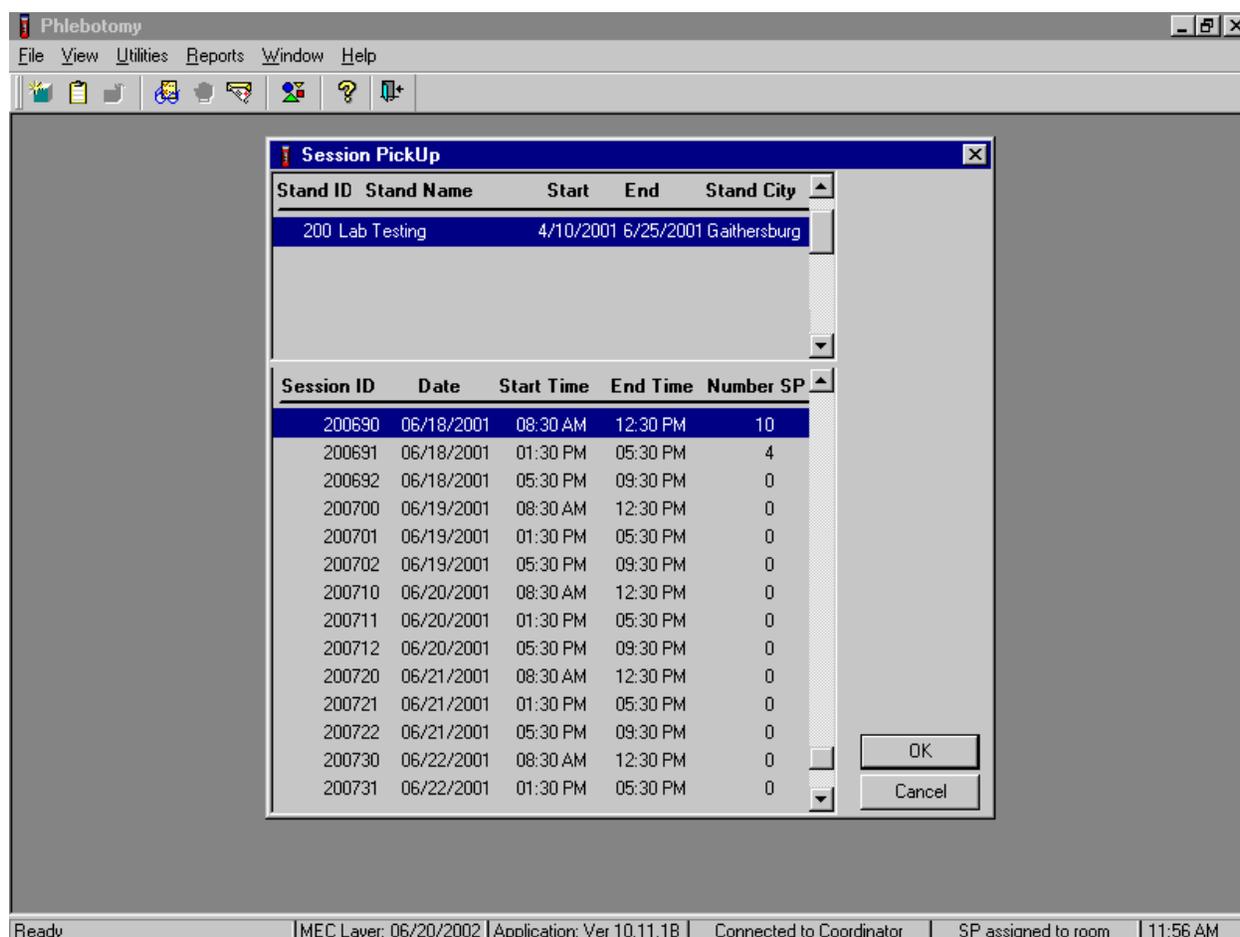
### 3.15 Review an Exam

Review a completed exam. Access the Review module.



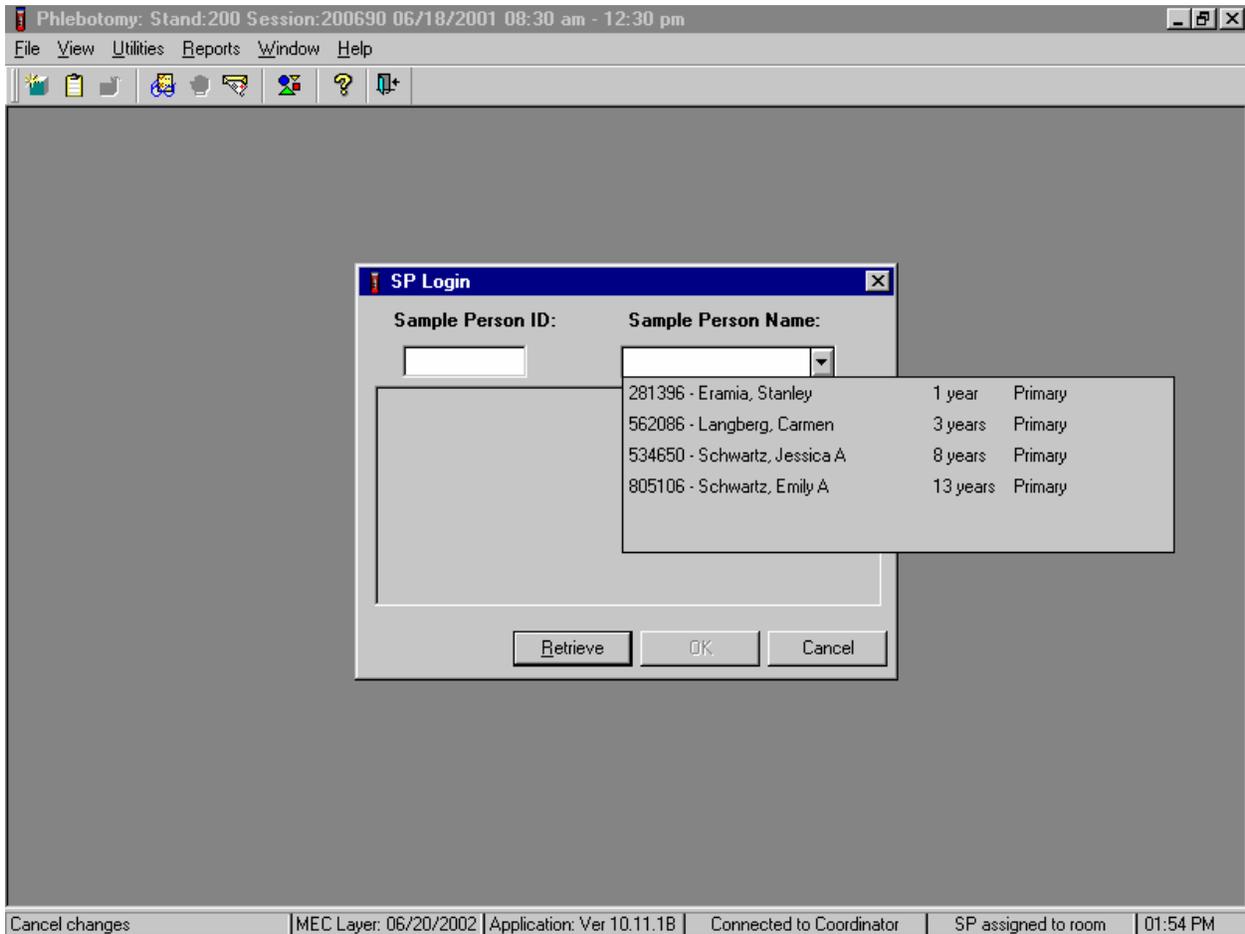
To access the Review module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Review} and left click, or type [Alt] [F/f], [V/v]. The Session Pickup list displays.

Select the session.



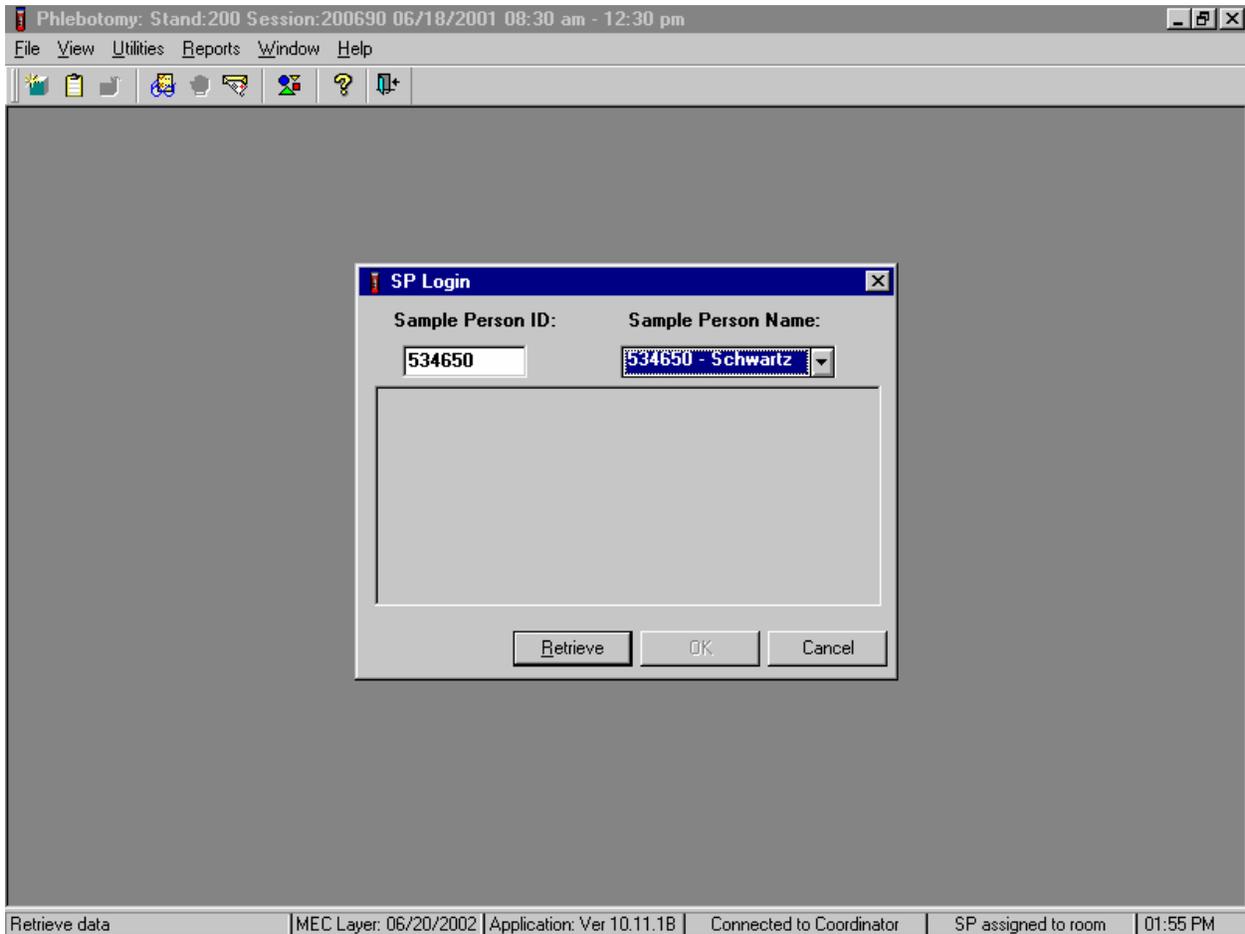
The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection or use the up and down arrows to move up and down the list and press [Enter]. To proceed, use the mouse to direct the mouse arrow to the OK button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the Cancel button and left click.

Select the SP.



The SP Login window displays. To view a list of previously examined SPs, use the mouse to direct the mouse arrow to the drop-down arrow on the Sample Person Name text box and left click. To select or identify a specific SP, drag the mouse arrow to the correct SP and left click.

Continue to select the SP.



The Sample Person ID and Sample Person Name text boxes fill in with the SP ID and the SP ID and last name. To continue, use the mouse to direct the mouse arrow to the Retrieve button and left click, or select [Enter]. To exit, use the mouse to direct the mouse arrow to the Cancel button and left click.

Continue to select the SP.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP Login

Sample Person ID: 534650 Sample Person Name: 534650 - Schwartz

Last Name: SCHWARTZ  
First Name: JESSICA Middle Name: A  
Date of Birth: 04/05/1994  
Gender: Female Age at Interview: 8 years  
Special Considerations:

Retrieve OK Cancel

Retrieve data | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:01 PM

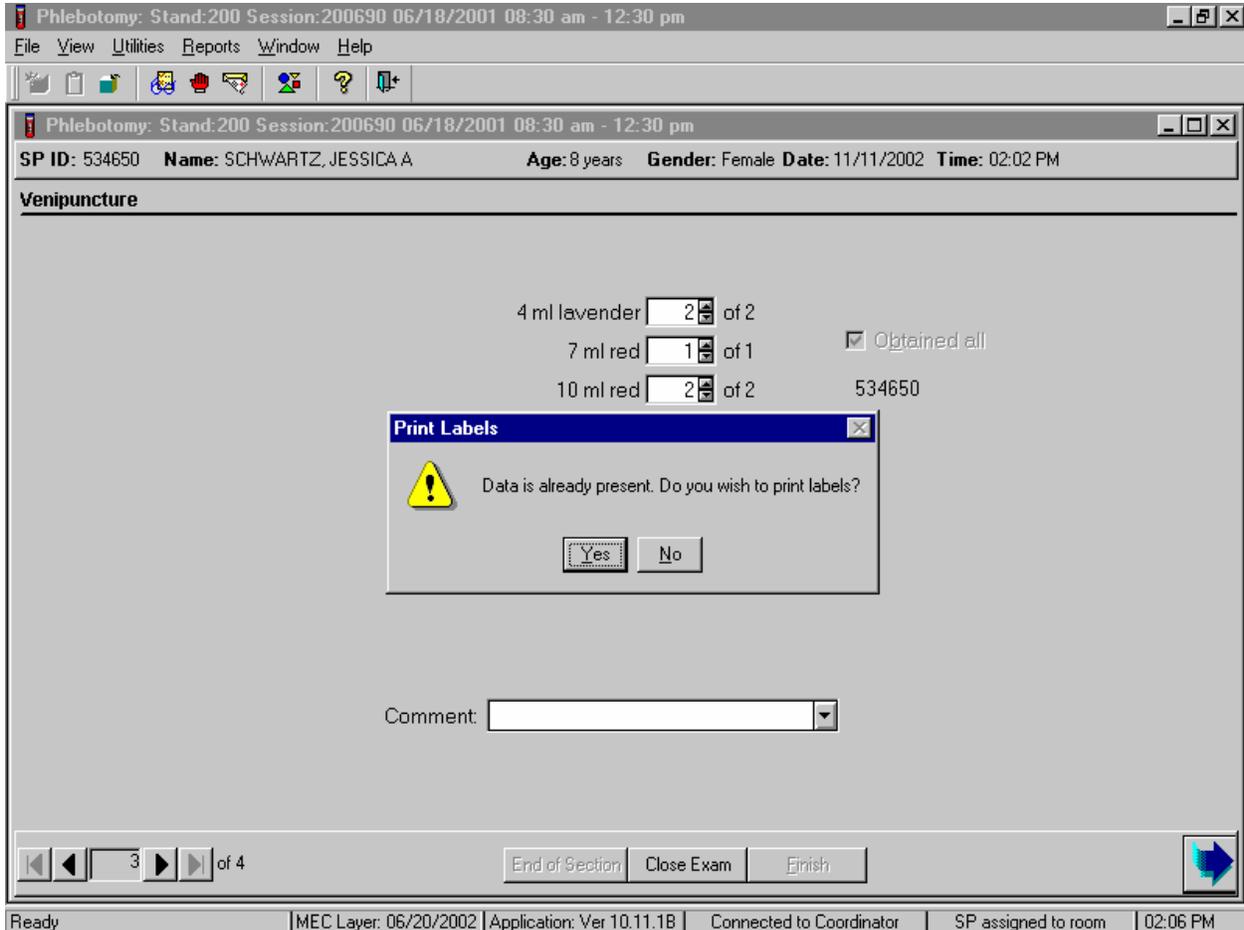
Once the Retrieve button is selected, the remaining data in the SP Login box fills in. To move forward and to review the exam, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

The phlebotomy exam screens with results are displayed.

The screenshot displays a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The window contains a "Fasting Questionnaire" for patient "SCHWARTZ, JESSICA A", aged 8 years, female, dated 11/11/2002 at 02:02 PM. The questionnaire asks about the last time the patient ate or drank (06:00 AM on 11/11/2002) and whether they had coffee, alcohol, gum, antacids, or dietary supplements since 6:00 AM. All these items are marked as "No". The "Fasting Time" is recorded as 8 Hours and 3 Minutes. At the bottom, there are navigation buttons: "End of Section", "Close Exam", "Finish", and a large blue arrow. A status bar at the very bottom shows system information like "MEC Layer: 06/20/2002" and "Application: Ver 10.11.1B".

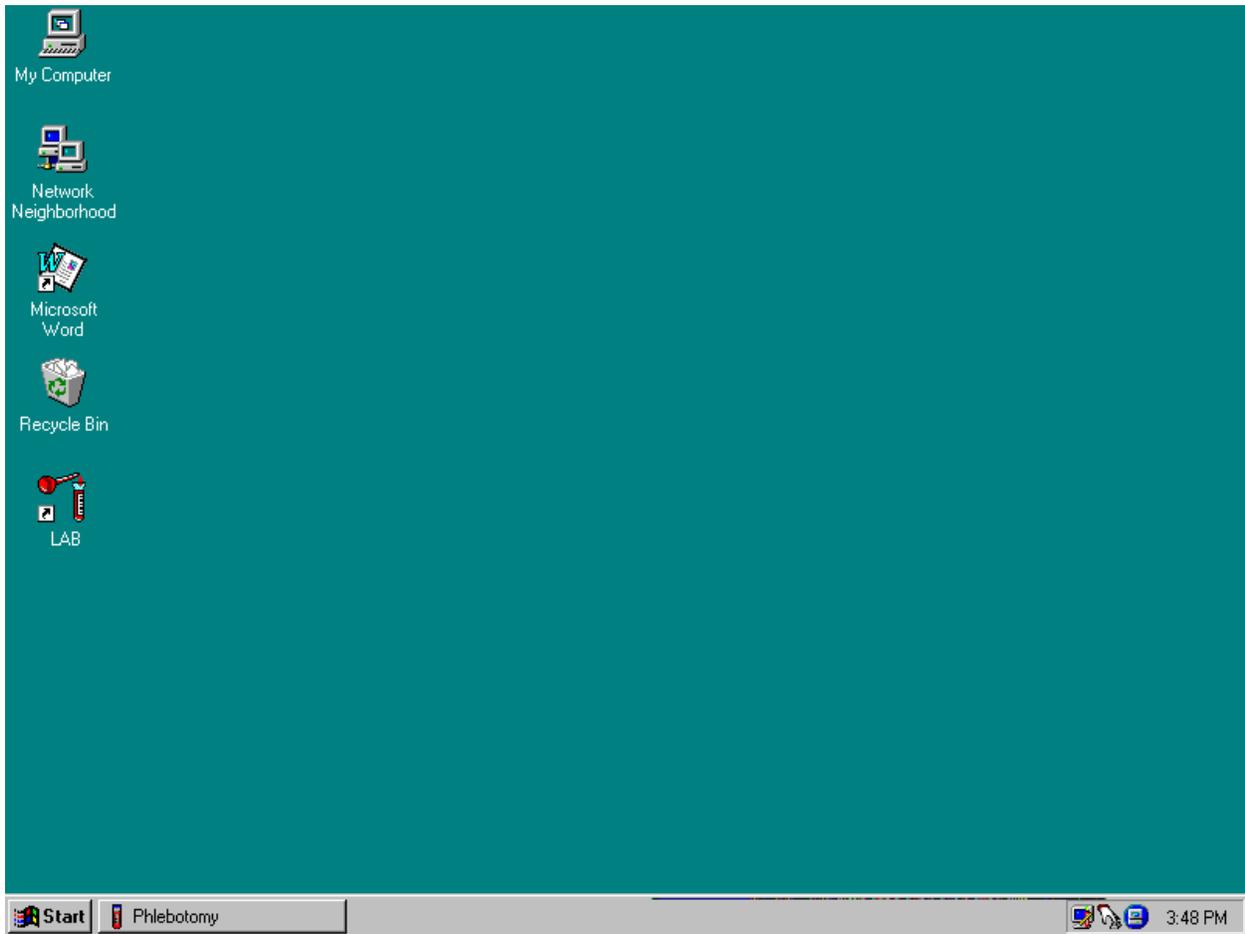
To progress through the screens, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

After the Venipuncture protocol screen is displayed and the bright blue arrow in the bottom right hand corner is selected, a Print Labels message text box displays.



The Print Labels informational message text box displays the following message; “Data is already present. Do you wish to print labels?” To reprint the labels, use the mouse to direct the mouse arrow to the Yes button and left click, or select [Enter]. To decline the opportunity to reprint labels, use the mouse to direct the mouse arrow to the No button and left click. The Venipuncture status window displays. To finish, select [Enter] or use the mouse to direct the mouse arrow to the End of Section button and left click.

### 3.16 Open an Application.



To open an application, use the mouse to direct the mouse arrow to the application icon on the desktop and double click.

### 3.17 Laboratory Application Functionality

#### 3.17.1 Laboratory Heads-up Display

Use the laboratory heads-up display to view the SPs scheduled into the session, the modules for which they are eligible, and their current process status.

Appointments for Session: 200460							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
165736	165736	SC	P	F	66	DARLING, BRIANNA	○	○	○	○	○	○	○	○	○	○
305130	305130	SC	P	F	38	DARLING, NATALIA	○	○	○	○	○	○	○	○	○	○
332080	332080	SC	P	F	16	DARLING, SHARI	○	○	○	○	○	○	○	○	○	○
937391	937391	SC	P	F	9	SCIFALIA, PATTI	○	○	○	○	○	○	○	○	○	○
977040	977040	SC	P	F	16	PARTON, DOLLY	○	○	○	○	○	○	○	○	○	○
981623	981623	SC	P	M	43	JONES, JAMES	○	○	○	○	○	○	○	○	○	○
982686	982686	SC	P	M	34	CHURCHILL, WINSTON	○	○	○	○	○	○	○	○	○	○

Ready | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 01:54 PM

Start | Lab Subsystem: Stan... | 1:55 PM

The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, LI=Logged-in, CI=checked-in, BE=being examined, EX=exited), Person Type (P=primary, G=guest, VIP=VIP guest, S=surplus, D=dry run), Gender (M=male, F=female), Age, and Name (last, first.)

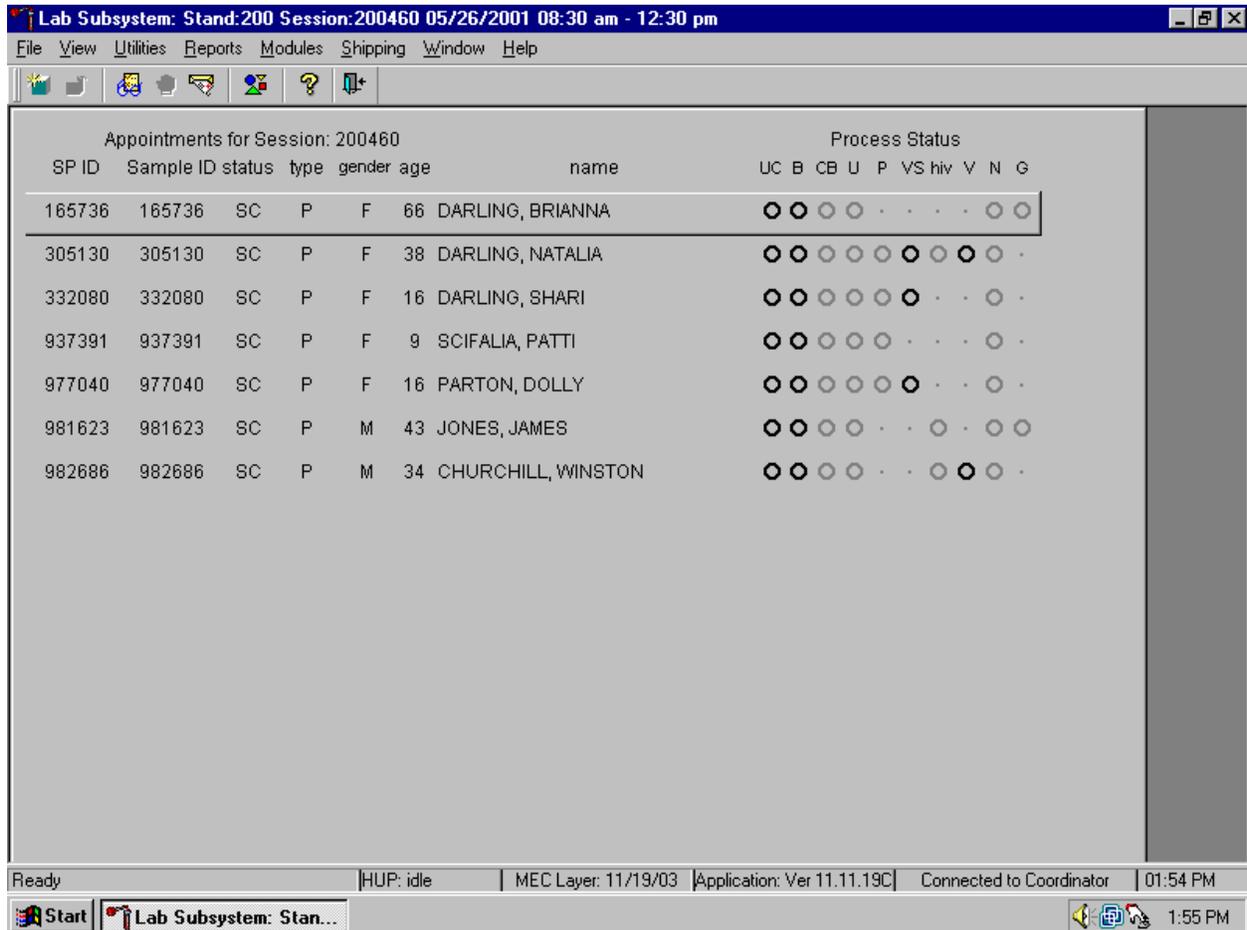
The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), VS (vaginal swab processing), hiv (HIV urine processing), V (VOC processing), N (nasal swab processing) and G (*genetic processing – pilot 2003 only*). The SP is ineligible for a module when the process status is \*. The SP is eligible for a module but no results have been recorded when the process status is O. The SP is eligible for a module and some results have been recorded when the process status is ⊙. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is ●. The SP is eligible for a module but the process status for blood processing (B), the complete blood count (CB), the nasal swab (N), and genetic testing (*G - pilot 2003 only*) is O until the SP's blood tubes, nasal swabs, and buccal swabs (*genetic pilot 2003 only*) are recorded as collected in the phlebotomy component. The process status is O for urine processing (U) and pregnancy testing (P) until the SP's urine is marked as collected in the UC module. Once these samples are collected, the process status changes from O to ⊙. The SP is eligible for the hiv module but the status is O until the SP's blood processing HIV result is recorded. If the HIV serum vessel (#21) is marked as “not filled” because the quantity of HIV serum is insufficient, the status changes from O to ⊙. The process status regularly updates and changes after each result is saved.

The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if active SP is not the SP of choice.

To view all SPs, the modules for which they are eligible, and their process status use the mouse to direct the mouse arrow to the vertical scroll bar, left click, and drag the bar up or down.

### 3.17.2 Laboratory Task Bar

Monitor the activity in the laboratory task bar.

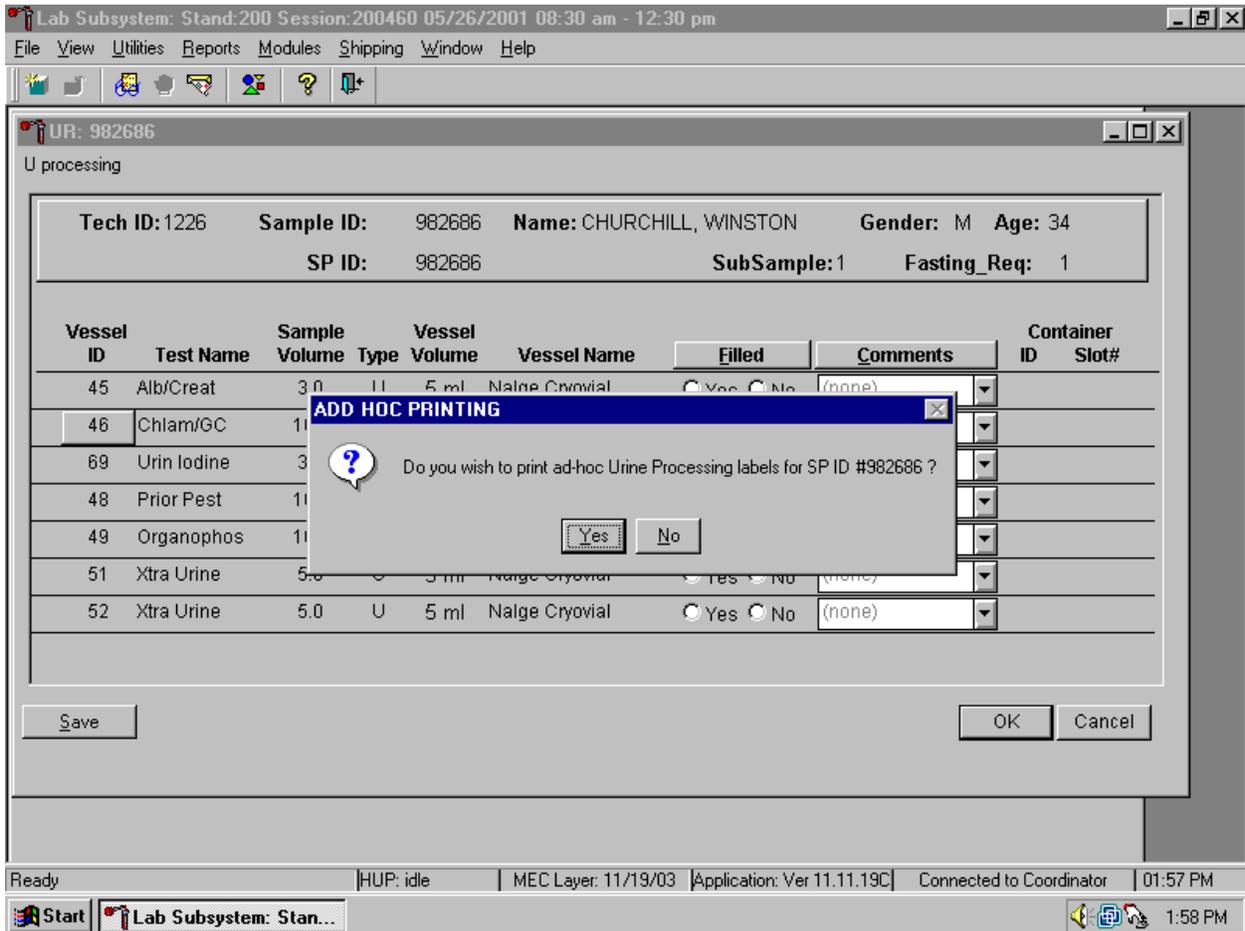


The laboratory task bar displays the following information:

- The status of the refresh routine such as when the labels are printing or the data is updating;
- The status of the heads-up display such as when it is “idle;”
- The current version of the MEC Layer;
- The current version of the application;
- The status of the connection to the coordinator; and
- The current time.

### 3.17.3 Print an Ad Hoc Label

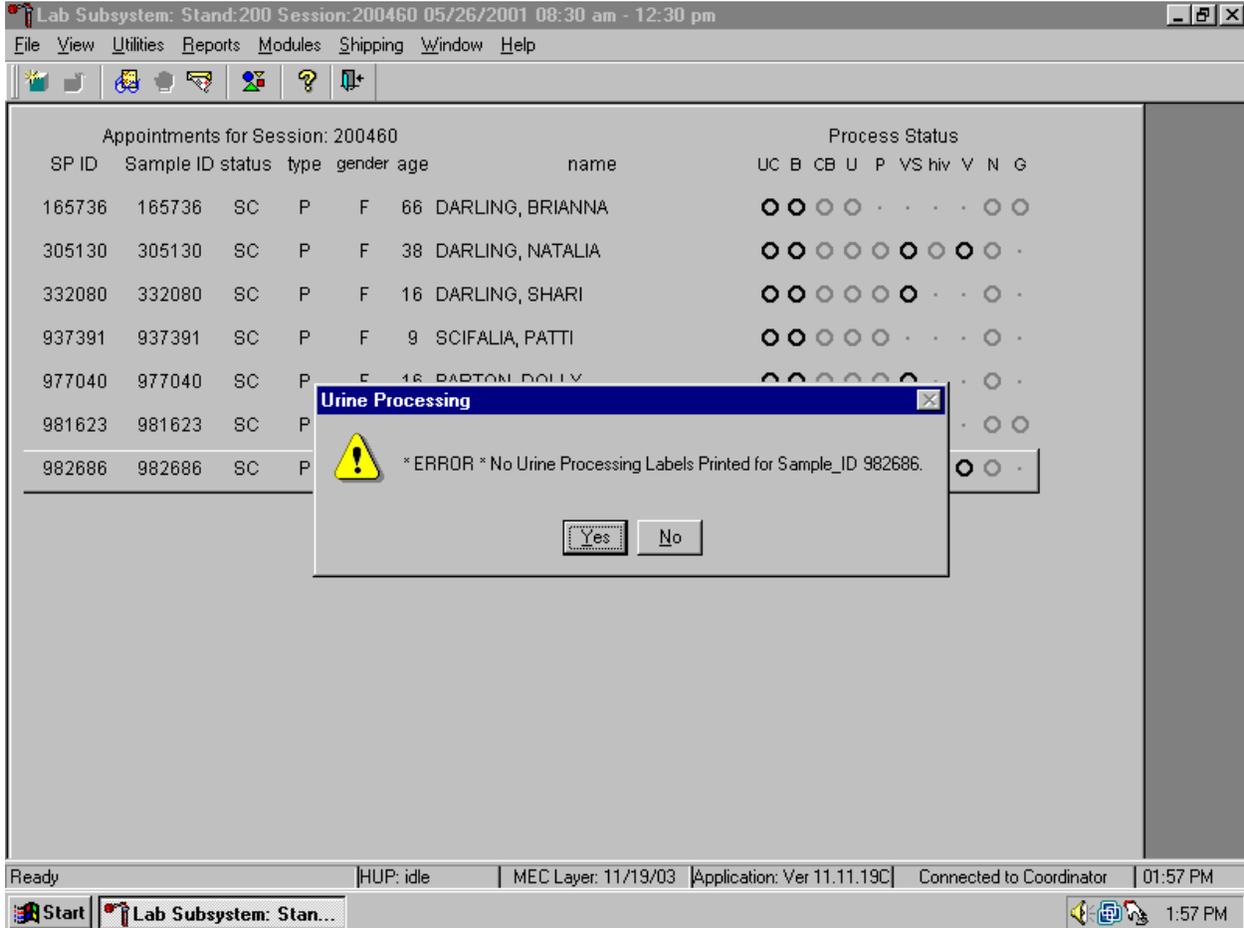
Print an ad hoc label for a single vessel.



To print one ad hoc label for any one vessel in any of the processing modules, use the mouse to direct the mouse arrow to the Vessel ID button and right click. An ADD HOC PRINTING message text box displays. Respond to the message text box request. To print the label and remove the message text box, use the mouse to direct the mouse arrow to the Yes button and left click, or select [Enter]. To remove the message text box without printing a label, use the mouse to direct the mouse arrow to the No button and left click or type [N/n].

### 3.17.4 Labels Must be Printed in Advance

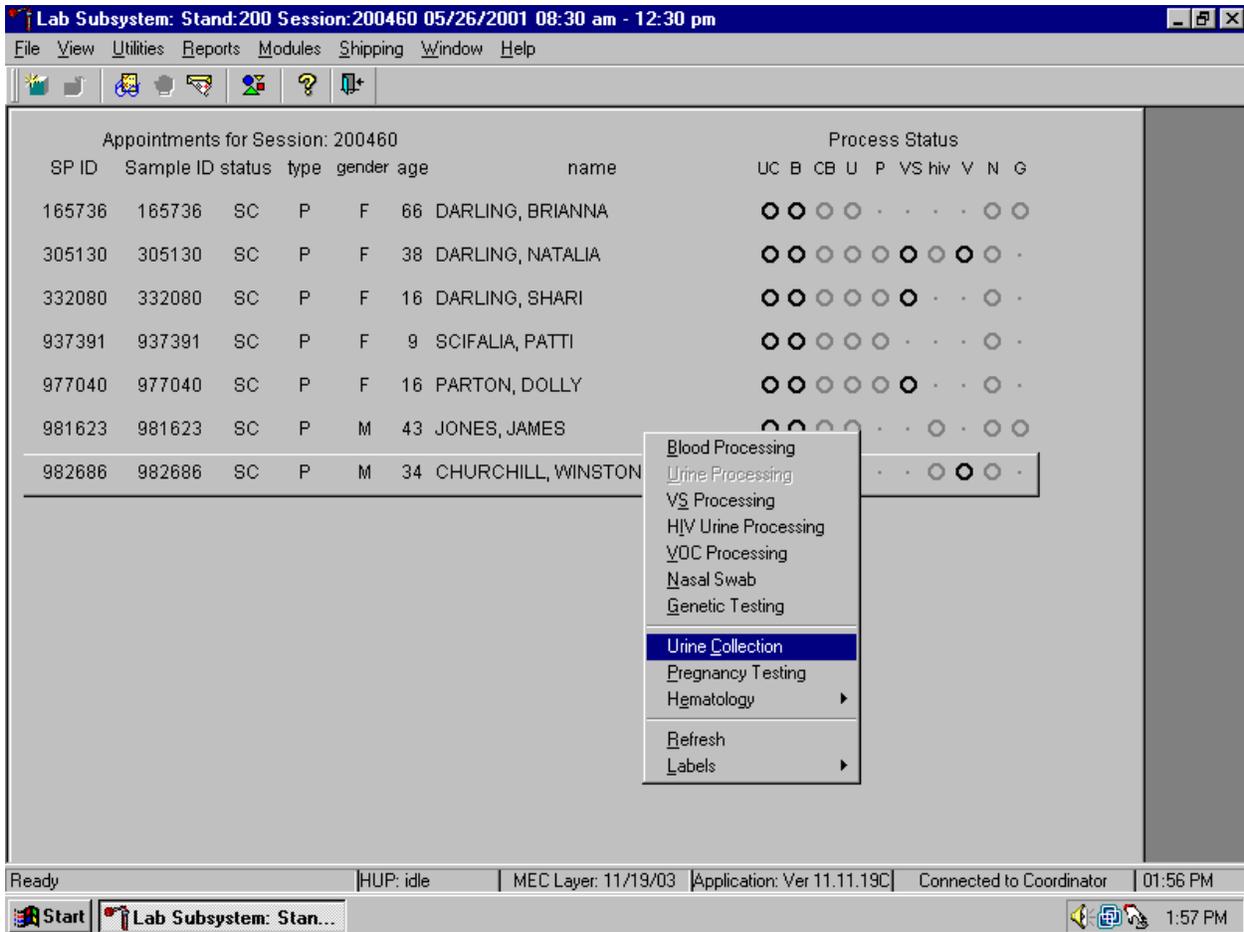
If labels have not been printed in advance, a module-specific processing message box displays.



Specimen processing cannot occur unless labels have been printed in advance. To remove the Sample Processing message box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. Reprint the labels for all SPs or an individual SP in a session.

### 3.17.5 Access a Processing Module

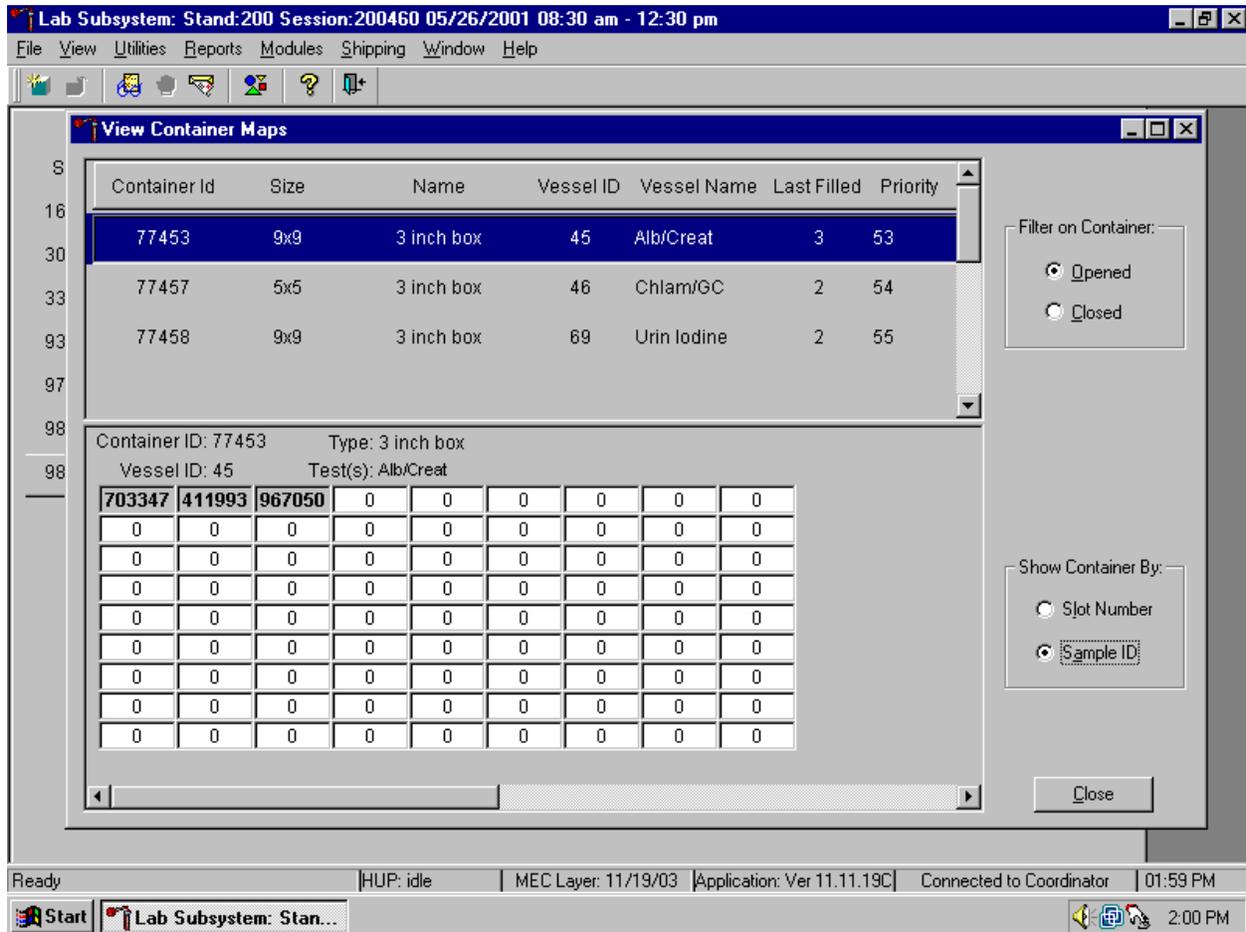
Select the correct SP and access the module of interest. Use the scroll bar to view all SPs scheduled into the session. The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.



To select an SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the a specific processing module, drag the mouse arrow to {Blood Processing}, {Urine Processing}, {VS Processing}, (HIV Urine Processing), {VOC Processing}, {Nasal Swab}, {Genetic Testing}(Pilot 2003 only), {Urine Collection}, {Pregnancy Testing} or {Hematology} and left click or right click and type the first letter for the module of interest ([B/b, U/u, S/s, I/I, V/v, N/n, C/c, P/p, or E/e].) Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to



Verify the contents of each container against the container map.



- Set the Filter on Container to “Opened” by using the mouse to direct the mouse arrow to “Opened” and left click.
- Set the Show Container By to “Sample ID” by using the mouse to direct the mouse arrow to “Sample ID” and left click.
- Highlight or select the first container ID for the first vessel by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find the correct vessel ID.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.
- Segregate (separate out) the specimens that have been checked. When subsequently checking the Container Map Report for this container, begin checking specimens that are not segregated.

- Continue checking each container map report for the remaining vessels.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

### 3.17.7 Set Session Utility

Sign onto the computer terminal. Open the laboratory application. If the laboratory is conducting a MEC session, the heads-up display will default to the current session.

Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm

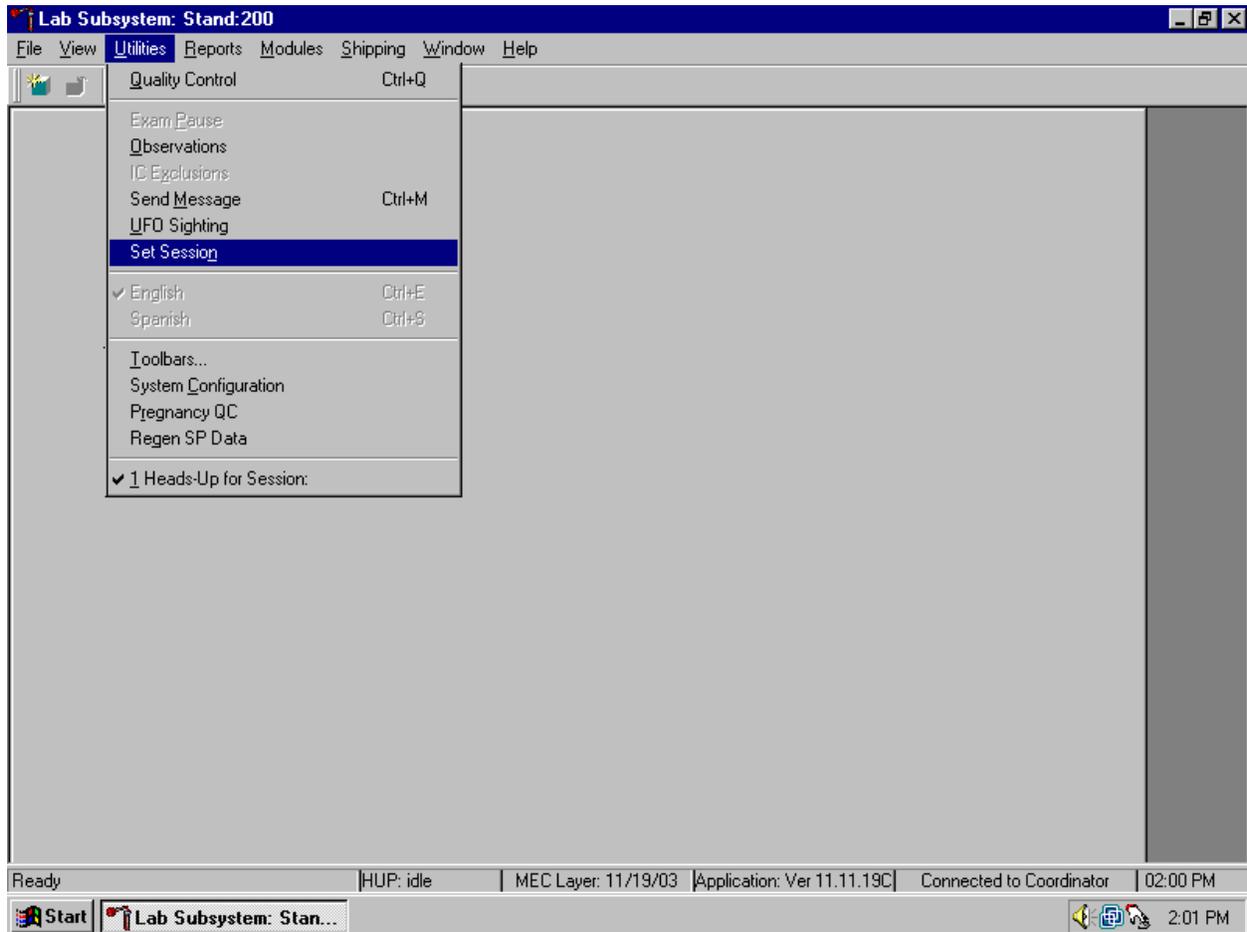
File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 200360							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
181334	181334	SC	P	M	38	SHELLY, PERCY B	●	●	●	●	·	·	·	·	·	·
409795	409795	SC	P	F	2	BRONTE, EMILY	·	●	●	·	·	·	·	·	·	·
525442	525442	SC	P	M	43	DARCY, MISTER	●	●	●	●	·	·	·	·	·	·
530000	530000	BE	P	F	28	BRONTE, CHARLOTTE	●	●	●	●	●	●	●	●	●	·
637775	637775	SC	P	M	20	GODWIN, WILLIAM	●	●	●	●	·	·	·	·	·	·
673397	673397	SC	P	F	16	WOOLF, VIRGINIA	●	●	●	●	●	●	·	·	·	·
686649	686649	SC	P	M	85	WREN, CHRISTOPHER	●	●	●	●	·	·	·	·	·	·
725205	725205	SC	P	F	48	BENNETT, ELIZABETH	●	●	●	●	●	●	●	●	●	●
764397	764397	SC	P	F	34	EYRE, JANE	●	●	●	●	●	●	●	●	●	·
840285	263929	SC	V	F	33	REED, WALTER	·	·	·	·	·	·	·	·	●	·
878167	878167	SC	P	F	55	WOLLSTONECRAFT, MARY	●	●	●	●	●	●	·	·	●	●

Ready | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:33 PM

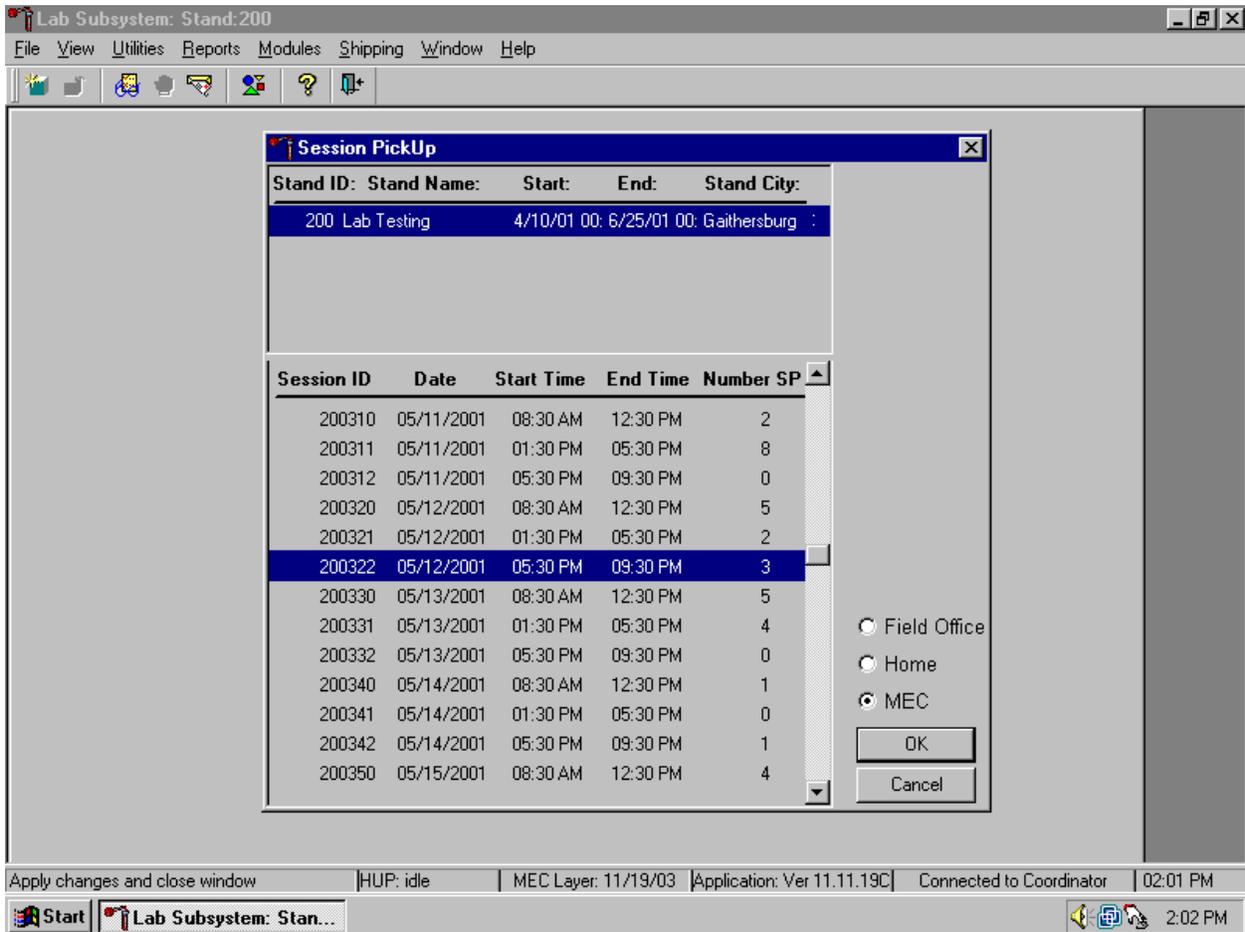
Start | Lab Subsystem: Stan... | 2:33 PM

Use the Set Session utility to access a session.



To access the Set Session utility, use the mouse to direct the mouse arrow to {Utility} in the menu bar, drag the arrow to {Set Session}, and left click or type [Alt] [U/u] [N/n].

The Session PickUp list displays. Select the correct session from the pick list.



The Session PickUp window displays. The current stand is displayed in the top section of the window. To select or highlight the correct MEC session, use the mouse to direct the mouse arrow to the correct session, date, and time and right click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

After selecting a session from the Session PickUp list and selecting OK, the laboratory heads-up screen displays.

The screenshot shows a software window titled "Lab Subsystem: Stand:200 Session:200322 05/12/2001 05:30 pm - 09:30 pm". The window contains a table of appointments and a status bar at the bottom.

Appointments for Session: 200322							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
484296	484296	SC	P	F	27	PAUL, RU	●	●	●	●	●	●	●	●	●	●
899087	899087	SC	P	F	42	EDNA, DAME	●	●	●	●	●	●	●	●	●	●
972952	972952	SC	P	F	26	LEWIS, DONNA	●	●	●	●	●	●	●	●	●	●

The status bar at the bottom of the window displays the following information: Ready | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:08 PM. The taskbar shows the Start button and the application icon "Lab Subsystem: Stan..." with a system clock showing 2:09 PM.

## 4. VENIPUNCTURE

### 4.1 Introduction

The blood collection procedure consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw. The phlebotomist also collects one additional blood tube on and administers a questionnaire to SPs selected for the VOC special study, collects a nasal swab to test for Methicillin-Resistant *Staphylococcus aureus* (MRSA), and recruits SPs to wear a physical activity monitor (PAM) for 7 days.

The phlebotomist conducts an interview to screen SPs for conditions that exclude them from the blood draw. The phlebotomist also administers a fasting questionnaire to determine fasting compliance. The venipuncture protocol is dependent on the SP's age, appointment type, and session time. Exhibits 4-1 through 4-3 illustrate the various venipuncture protocols; tubes are listed in priority order. These protocols indicate the types and numbers of tubes in priority order for each age group and person type. A chart located on the wall in the phlebotomy room also illustrates this information. It is extremely important to perform the venipuncture protocol as described for each SP. Use comments to describe differences between the actual tubes drawn and the established protocol. After the results of the blood draw are entered, labels automatically print for the blood tubes. The phlebotomist immediately labels collected tubes, places them through the pass-through window to the laboratory, and escorts the SP to the coordinator area after offering refreshments.

Exhibit 4-1. Venipuncture protocol – primary

Age in Years	1-2	3-5	6-11	12+
3-mL Lavender	1	2		
4-mL Lavender			2	3
2-mL Gray (Morning sessions only)				1
3-mL Red	2			
7-mL Red		2	1	
15-mL Red				4
10-mL Red			2	2
10-mL Gray (20-59)				*1

\* SPs selected for inclusion in the VOC subsample

Exhibit 4-2. Venipuncture protocol – VIP guest

Age in Years	1-2	3-5	6-11	12+
3-mL Lavender	1	2	2	1
4-mL Lavender				1
2-mL Gray (Morning sessions only)				1
3-mL Red	1	2		
7-mL Red			2	
15-mL Red				
10-mL Red				2

Exhibit 4-3. Venipuncture protocol – guest and surplus

Age in Years	1-11	12+
3-mL Lavender	1	1
3-mL Red		1

If the veins of an SP appear too fragile to accommodate the size of the large red top tubes, substitute smaller red top tubes as an alternative protocol. Exhibit 4-4, alternative venipuncture protocol – primary, illustrates the alternative size and number of tubes in bold with the original tube protocol in parentheses. When the alternative protocol is substituted for the original protocol, a comment must be recorded. This protocol constitutes a deviation from the established standard; it should only be used in rare circumstances.

Exhibit 4-4. Alternative venipuncture protocol – primary

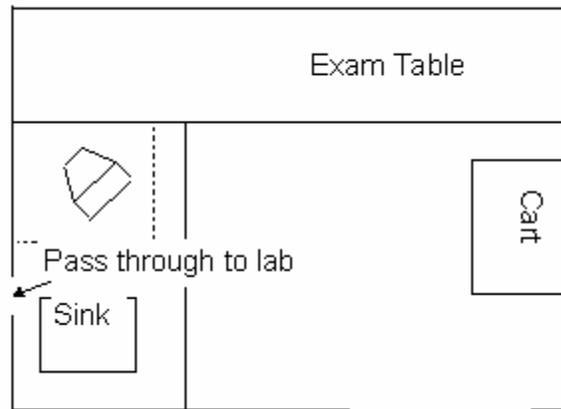
Age in Years	3-5	6-11	12+
3-mL Red	<b>4</b>		
7-mL Red	(2)	<b>4 (1)</b>	<b>8 (1)</b>
15-mL Red			(3)
10-mL Red		(2)	

(#) Represents the standard protocol

## 4.2 Equipment and Supplies

The phlebotomy room contains an exam table, a sink, data terminal, thermal transfer label printer, refrigerator, supply cart, and cabinets. Figure 4-1 illustrates the floor plan for the phlebotomy room.

Figure 4-1. Floor plan for phlebotomy room



At the start and end of each stand, take a complete inventory using procedures described in Chapter 11, Section 11.3.

The equipment and supplies used in venipuncture are listed in Exhibit 4-5.

Exhibit 4-5. Equipment and supplies - phlebotomy

BD Hemogard Vacutainer® 3-mL EDTA	Stretch disposable tourniquet
BD Hemogard Vacutainer® 3-mL Red	Latex tourniquet
BD Hemogard Vacutainer® 4-mL EDTA	Alcohol wipe
BD Hemogard Vacutainer® 2-mL Gray	2 x 2 Gauze square
BD Hemogard Vacutainer® 7-mL Red	Co-Flex NL cohesive bandage
BD Vacutainer® 15-mL Red	Adhesive bandage
BD Vacutainer® 10-mL EDTA	Adhesive bandage – children
BD-Vacutainer® 10-mL Red	Transpore tape
BD Saf-T EZ® set 19 gauge	Surgical paper tape
BD Luer adapter for use with the 19 gauge	Cartoon stickers
BD Safety-Lok® 21 gauge with adapter	Kleenex
BD Safety-Lok® 23 gauge with adapter	Antibacterial hand soap
BD Vacutainer® multiple Eclipse 21 gauge needle	Hand cream
BD Vacutainer® needle holder – single use	Ammonia inhalant packet
Air sickness bag	Sharps container 8 gallon
Heel warmer	Biohazard bags 19 x 23
Labels and ribbons for Intermec printer	Pillow and disposable pillow cover
Nonsterile, powder-free, latex (nonlatex for use by latex allergic staff) gloves -- small, medium, large	Squeeze ball
Juice and crackers	Tube racks
List of reportable tests (handout)	Phlebotomy cart
Bleach bottle	Floor mat
Step stool	Solar wall thermometer
Opsite dressing	Printhead cleaning card
CPR mask	

For each SP, the phlebotomist routinely requires the following materials:

- Alcohol wipes
- 2”x 2” gauze squares
- Vacutainer® tubes of the appropriate size and type
- Disposable tourniquet
- Needle assembly
- Bandage

### 4.3 Overview

The coordinator tracks each SP through the MEC using the coordinator system. This system tracks the SP throughout the exam, including arrival, location during the session, and exit. The coordinator uses this system to direct the SP to the appropriate workstations in the MEC and to determine if all the appropriate examinations are complete. The MEC coordinator monitors exam component status using responses from examination stations.

Each SP receives a bar-coded ID bracelet upon arrival at the MEC. The bracelet remains on the SP throughout the session. This bracelet contains the SP's ID number in bar code and eye-readable format. The phlebotomist "wands" the bracelet bar code with a bar code scanner (wand) to log the SP into the phlebotomy component. If necessary, the ID number can be entered manually by reading it from the bracelet.

The phlebotomist is responsible for completing the following sections of the phlebotomy exam:

- Venipuncture
- VOC special study
- Nasal swab collection
- Physical Activity Monitor

Set up the appropriate blood collection cart in advance, making sure there are sufficient supplies for all SPs in the session. Access the phlebotomy application and open the phlebotomy exam. Log the SP into phlebotomy by scanning the bar code on the SP ID bracelet or manually typing the SP ID when the SP arrives in phlebotomy.

Conduct the phlebotomy interview and administer the fasting questionnaire. The phlebotomy protocol screen displays. Draw the appropriate tubes, and enter the number of tubes collected next to the expected values. Labels generate automatically. Enter the appropriate comment(s) for any tube that was not collected. Label the blood tubes. Verify that the phlebotomy completion status is correct. The phlebotomy section status is "Complete" if all blood tubes are collected, "Partial" if some, but not all blood tubes are collected, and "Not Done" if no blood tubes are collected.

#### 4.4 Gaining Cooperation

The coordinator will introduce the SP to the examination and briefly explain the examination process. The coordinator can answer any general questions the SP has about venipuncture. However, the phlebotomist must be prepared to answer all the questions the SP poses about the venipuncture procedure. In addition, the phlebotomist must convince the SP of the importance of cooperation in the venipuncture component of the examination.

Prepare to answer questions about the rationale for the venipuncture, the discomfort involved, the amount of blood being drawn, and the possibility of contracting an infectious disease from the process. To address SPs' concerns effectively, know the following information about the procedures used for the study:

- **Rationale**

Although the SP has provided much useful information in the household and individual interviews, the successful completion of the venipuncture component of NHANES is critical to the success of the study. Using the various specimens, researchers and laboratories are able to perform over 250 different biochemical tests (SPs 12+), which provide detailed information about the SP's health and nutritional status. NHANES data produce descriptive statistics that measure and monitor the health of the U.S. population. Much of this information would not be available in any other way. The laboratories that conduct the analysis are considered the "gold standard" for their particular analyte(s).

- **Discomfort**

Venipuncture causes only minimal discomfort. A certified, experienced, phlebotomist performs venipunctures. A variety of blood collection needles are available so that the most appropriate size can be selected for each SP.

- **Amount**

Phlebotomists draw the following amount of blood:

1-2 years primary SP, 9-mL (0.3 ounces), 0.6 tablespoons

3-5 years primary SP, 20-mL (0.7 ounces), 1.3 tablespoons

6-11 years primary SP, 35-mL (1.1 ounces), 2.3 tablespoons

12+ years primary SP, 104-mL (3.4 ounces), 6.9 tablespoons

1-2 years VIP guest, 6-mL (0.2 ounces), 0.4 tablespoons

3-5 years VIP guest, 12-mL (0.4 ounces), 0.8 tablespoons

6-11 years VIP guest, 21-mL (0.7 ounces), 1.4 tablespoon

12+ years VIP guest, 29-mL (1.0 ounces), 1.9 tablespoons

1-11 years guest and surplus, 3-mL (0.1 ounces), 0.2 tablespoons

12+ years guest and surplus, 6-mL (0.2 ounces), 0.4 tablespoons

An average adult male has 12 pints of blood and an average female has 9 pints. The Red Cross routinely draws 450-mL (or one pint) during a routine donation. Their requirements limit donation to every 8 weeks. The Red Cross does allow autologous donations where an individual can donate his or her own blood before surgery. This consists of one unit per week for up to 6 consecutive weeks. The maximum volume drawn during a MEC exam amounts to less than 25 percent (102-mL) of the amount drawn from regular donors by the Red Cross. The body manufactures blood daily and replaces this volume of blood within 24 hours.

■ **Infection control**

The supplies used for venipuncture are completely sterile and are used only once. There is absolutely no possibility of the SPs being infected by any blood-borne disease, such as hepatitis or AIDS, because of participation in the venipuncture component of the NHANES exam.

Gaining the cooperation of an SP is easier if the atmosphere in the phlebotomy room is pleasant and makes the SP feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere in the phlebotomy room.

- Maintain a clean and uncluttered work area. This is especially important because of today's concern with blood-borne infectious diseases, such as hepatitis and AIDS.
- Be aware of body image; a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a smile.
- Speak face-to-face with the subject and maintain eye contact. Staring at other areas in the room may cause the SP some uneasiness since it implies that he/she is not important. It also implies disinterest.
- Avoid nervous behaviors, such as squirming and tapping that can be distracting. The SP may begin to feel nervous, hurried, and anxious because of such behaviors.

#### **4.4.1 Refusal Conversion**

The coordinator should notify the phlebotomist of all venipuncture refusals so that the phlebotomist can attempt a refusal conversion.

The phlebotomist should discuss the condition of the SP's refusal with the coordinator before he/she attempts a conversion. If the coordinator indicates that the SP is an adamant refusal, the phlebotomist should not attempt to approach the SP or conduct the phlebotomy interview. If, however, the coordinator and the phlebotomist decide that the SP is a good candidate for a refusal conversion attempt, the phlebotomist may conduct the phlebotomy interview as part of the conversion attempt. If appropriate, the phlebotomist should enlist the help of the coordinator, the health technician, and/or the MEC physician when attempting to convert refusals.

#### **4.5 Performing the Venipuncture on SPs Who Do Not Speak English**

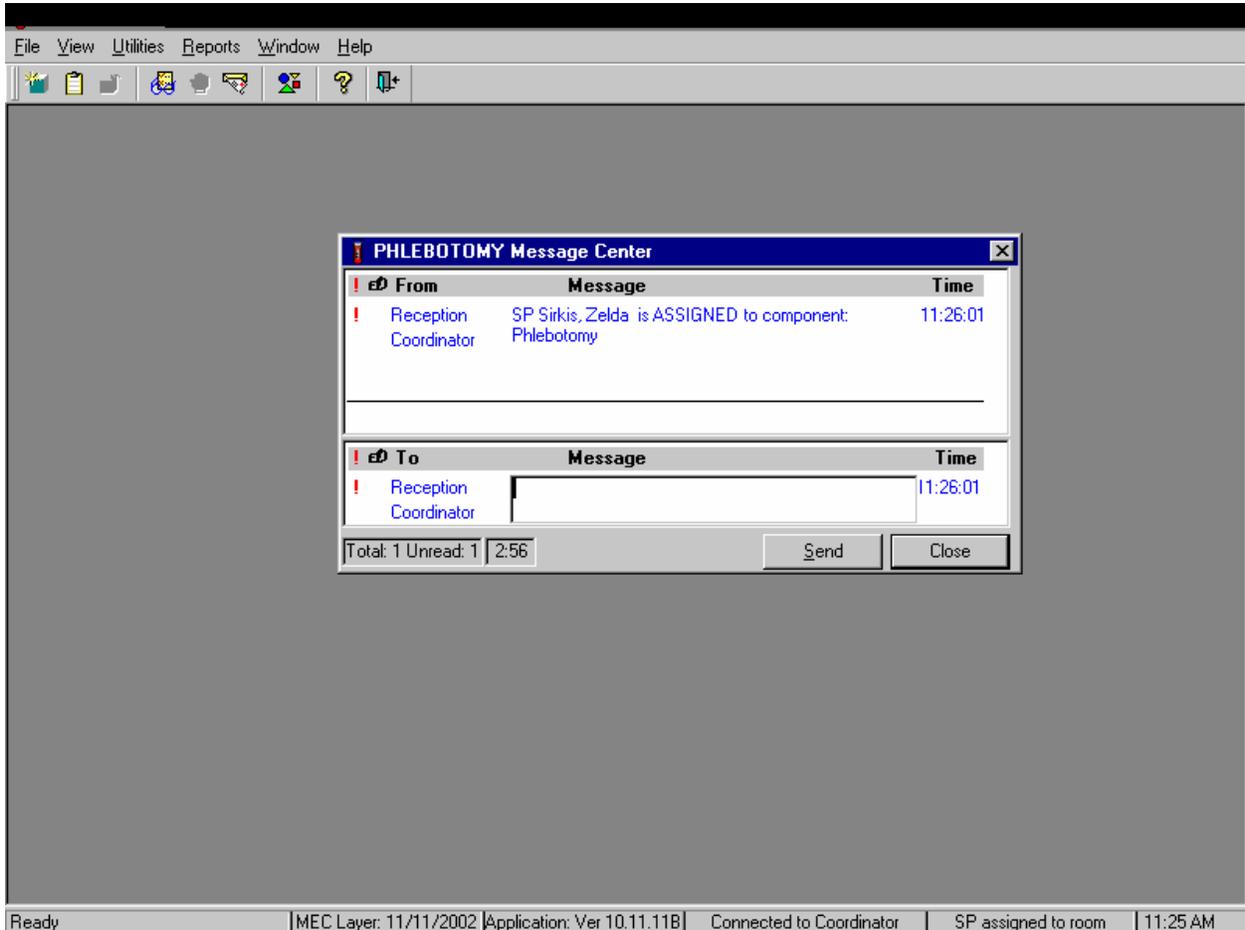
When the phlebotomist must administer the venipuncture procedure to an SP who does not speak English and the phlebotomist does not speak the language of the SP, a translator who does speak the language of the SP assists the phlebotomist.

The translator stays with the phlebotomist and the SP for the entire procedure. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the venipuncture.

#### 4.6 Open the Exam and Log the SP into the Exam

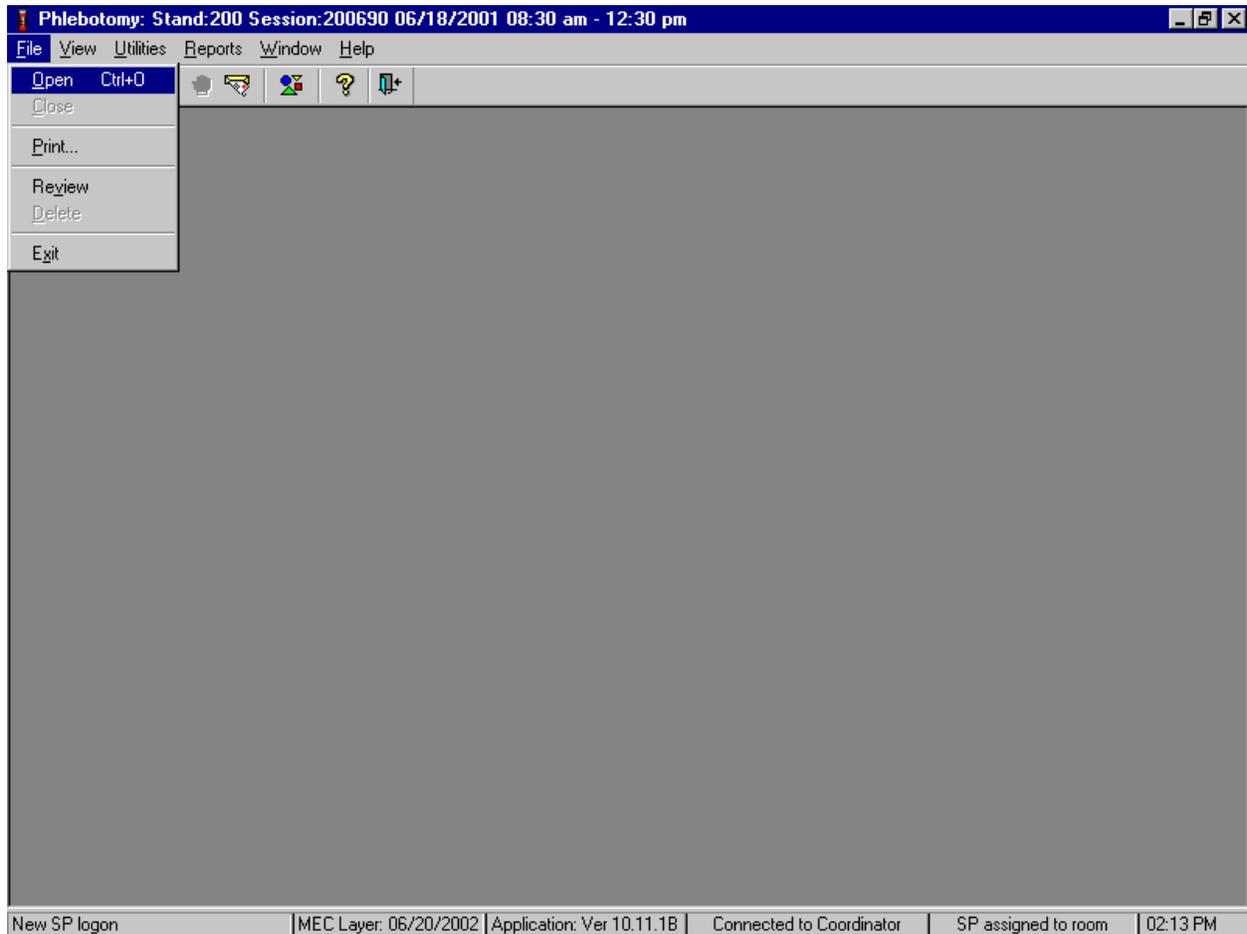
Open and log onto the Phlebotomy application.

The message center window identifies the SP assigned to phlebotomy.



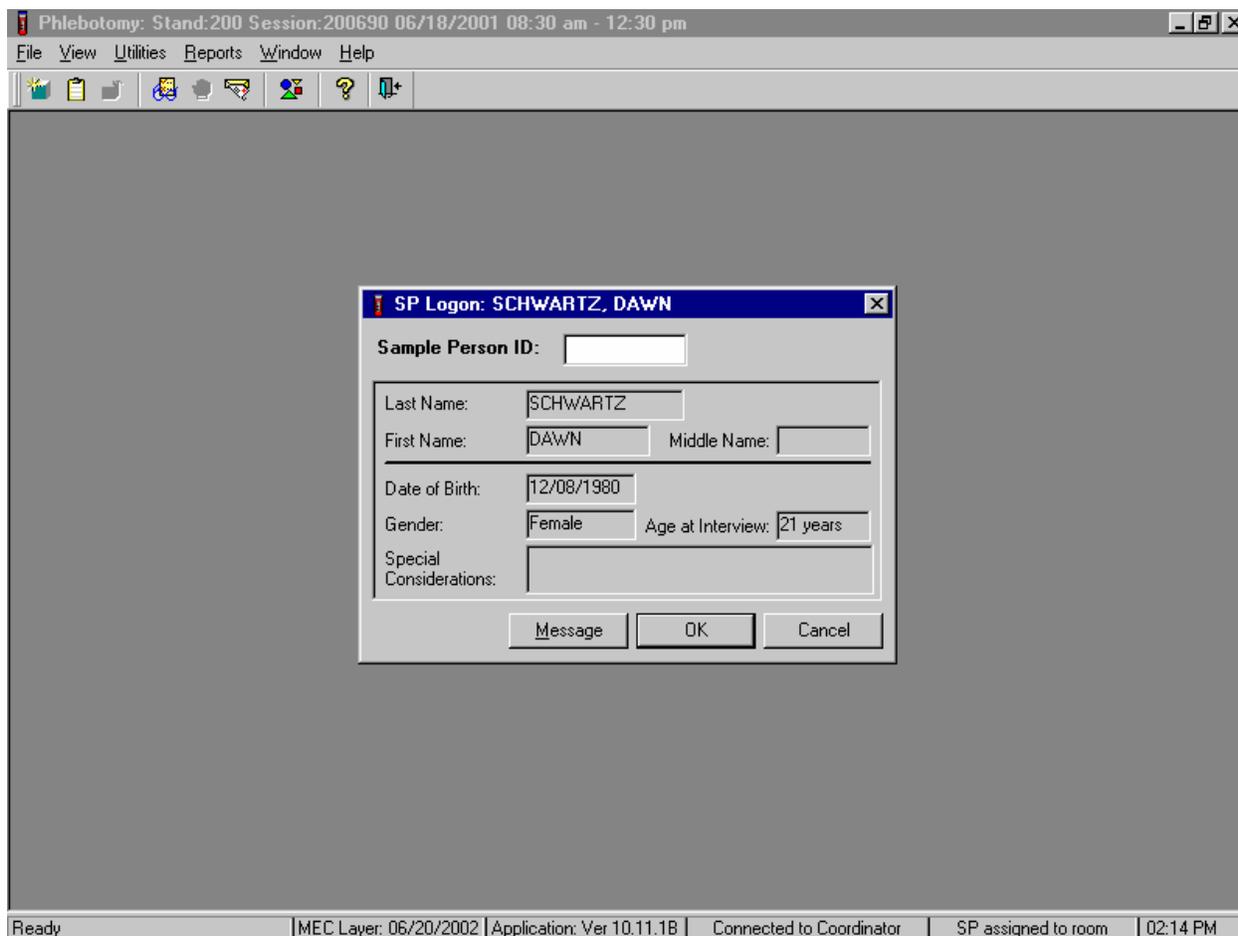
A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the Send button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the Close button and left click, or select [Enter].

Open the phlebotomy exam.



To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o].

The SP Logon window displays.



The SP Logon window displays for the SP assigned to the component. To log the SP into the component, either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the OK button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the Cancel button and left click.

Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

## 4.7 The Phlebotomy Interview

The phlebotomy interview screens the SP for safety exclusions. There are only two reasons to exclude an SP from venipuncture—hemophilia, and having received chemotherapy within the past 4 weeks. Administer the interview (and fasting questionnaire) directly to SPs over the age of 18 or administer the interview questions (and fasting questionnaire) to the SP’s parent or guardian for SPs under age 18.

Administer the phlebotomy interview immediately before performing the venipuncture. Read the text exactly and record the responses.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "Phlebotomy Interview" and displays the following information: "SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM". Below this information are two questions, each with a dropdown menu: "Do you have hemophilia?" and "Have you received cancer chemotherapy in the past four weeks?". At the bottom of the window, there is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, and a status bar with "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "02:16 PM".

Conduct the phlebotomy interview by asking the question displayed on the screen, “Do you have hemophilia?”

**Q1: Do you have hemophilia?**

<p>Q1: This question asks whether the SP has hemophilia, which is an exclusion criterion for this procedure.</p>	<p>Explain that we cannot perform phlebotomy on participants who have hemophilia. Hemophilia is a rare disease where an individual's blood does not clot. If an SP's relative has hemophilia but the SP does not, the SP is not excluded. If the SP is excluded, the Blood Draw Exclusion box displays. Read the text in the box to the SP and escort the SP back to the coordinator station.</p>
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Record the exact response.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM

Phlebotomy Interview

Do you have hemophilia?

Have you received cancer chemotherapy in the past four weeks?

Yes  
No  
Refused  
Don't Know

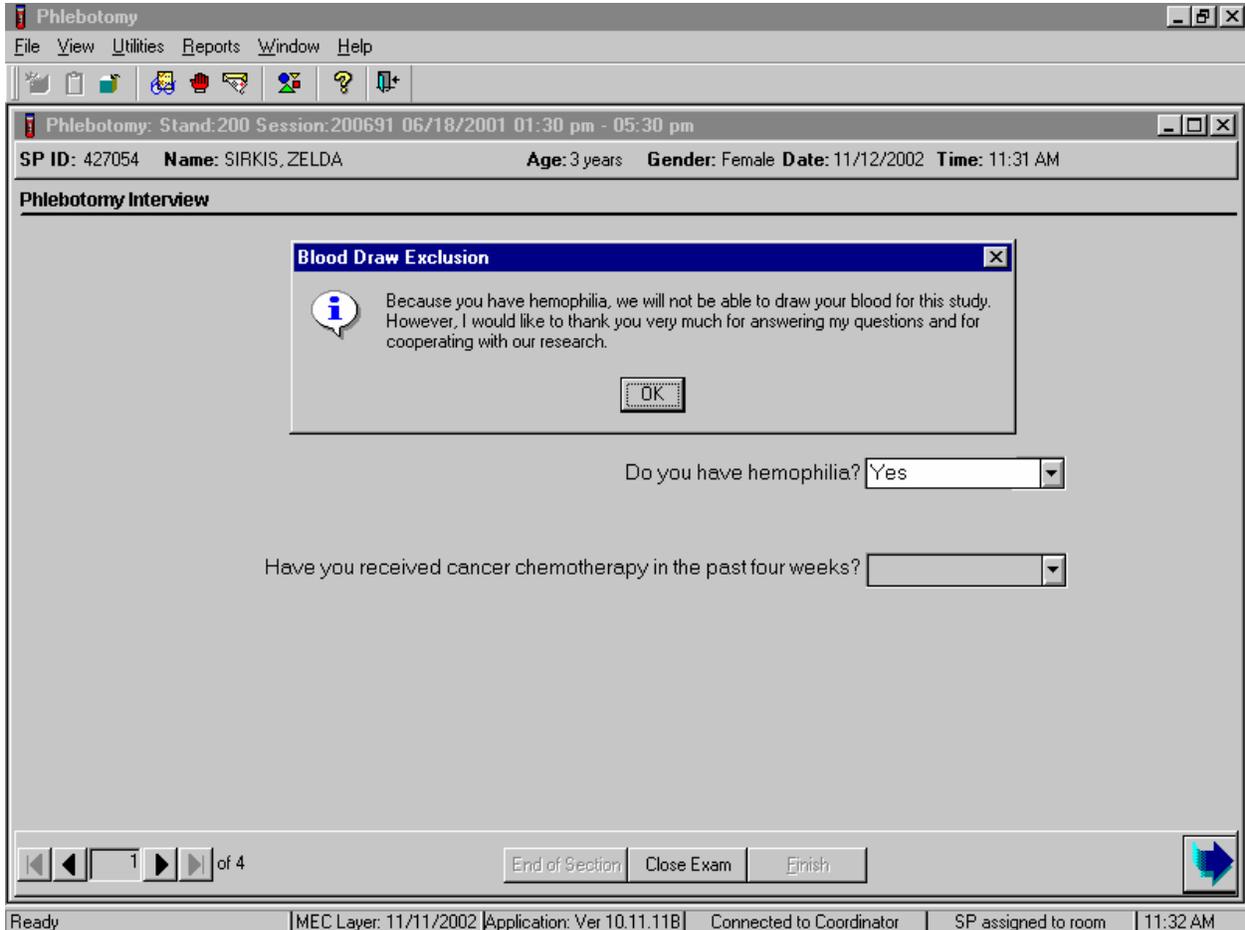
1 of 4

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:18 PM

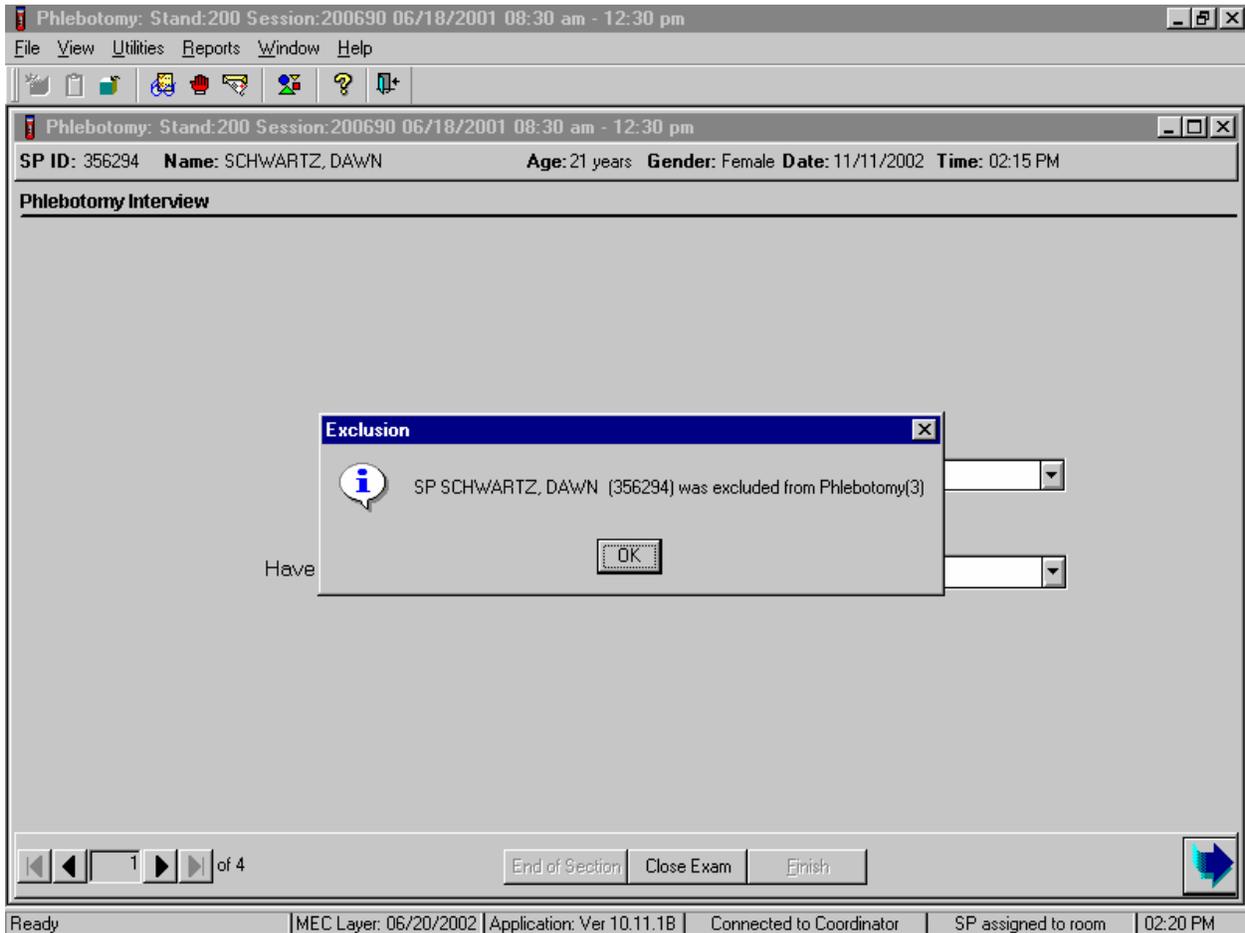
Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” “Refused,” or “Don’t Know,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].

If the SP is excluded from the phlebotomy exam due to hemophilia, the Blood Draw Exclusion informational message text box displays.



Read the script to the SP. To remove the Blood Draw Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

If the SP is excluded from the phlebotomy component due to hemophilia, an Exclusion message text box displays. In some cases more than one Exclusion message box will display, one after the other.



To remove the Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

Verify the status.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM

**Venipuncture Status**

Status

Complete

Partial

Not Done

Comments safety exclusion

Other text

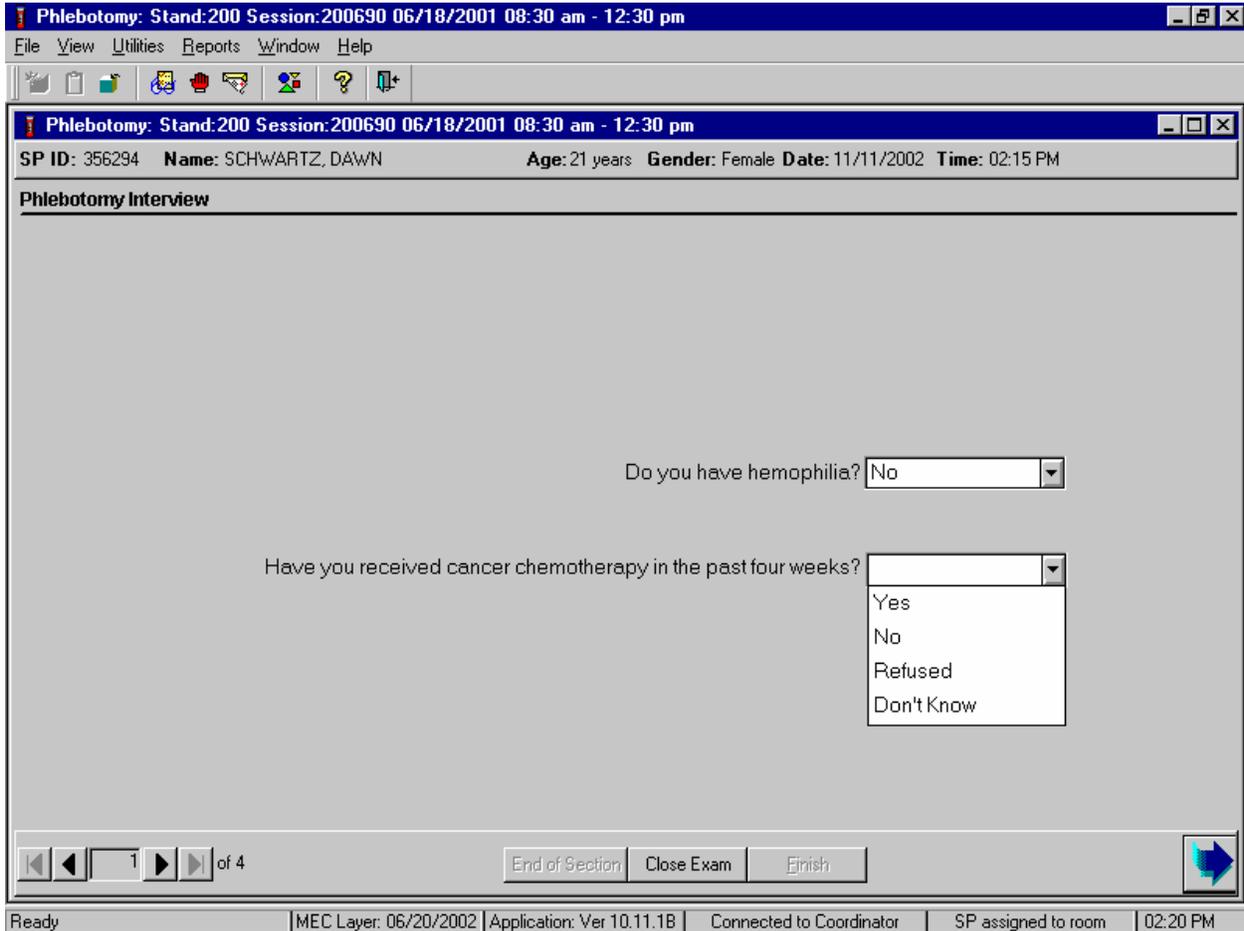
4 of 4

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:20 PM

SPs excluded due to hemophilia are automatically coded by the application as “safety exclusion.” Escort the SP back to the coordinator or to the next component as directed by the Message Center.

If the SP has not been excluded due to hemophilia, continue the phlebotomy interview by asking the second question displayed on the screen, “Have you received cancer chemotherapy in the past four weeks?”

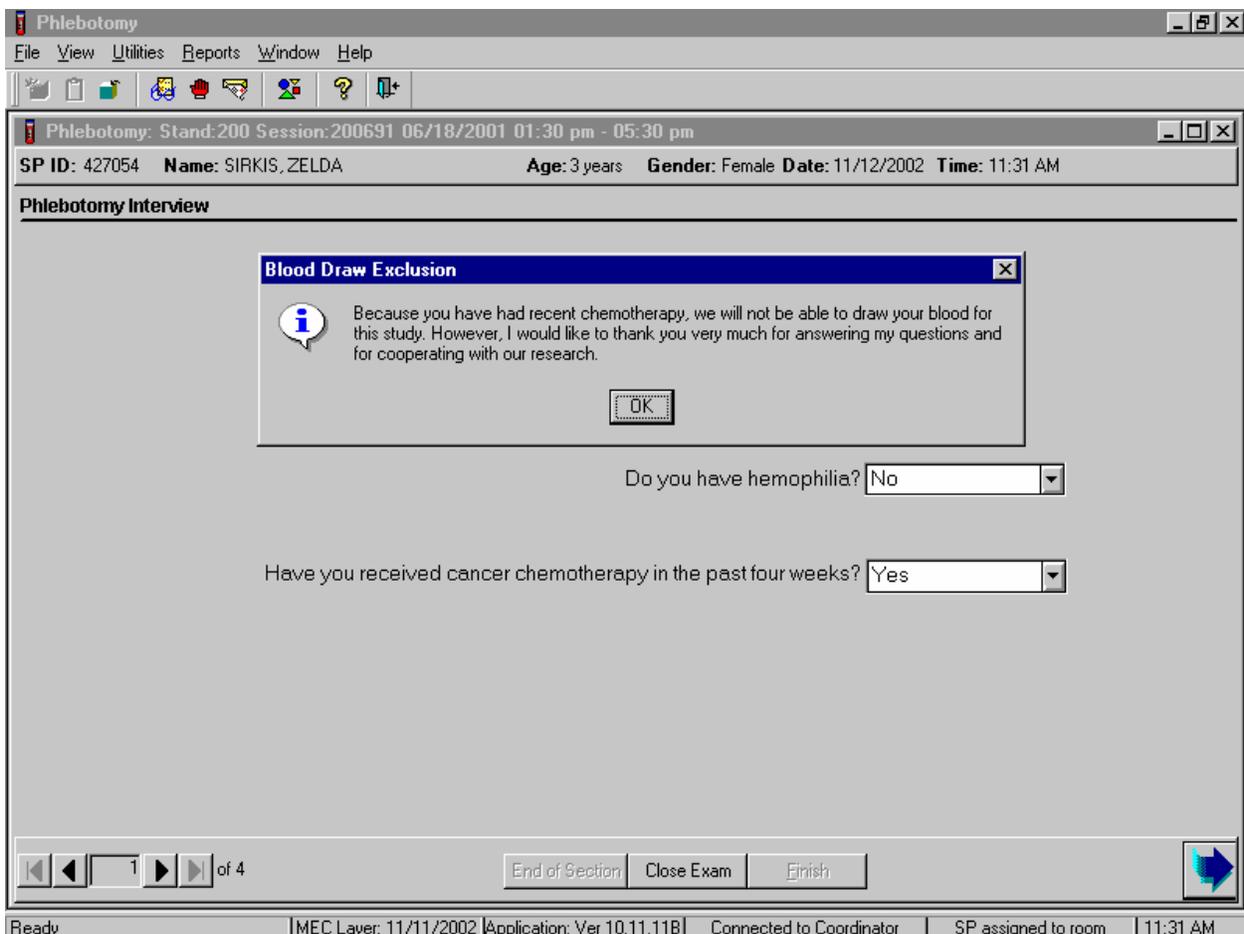


**Q2: Have you received cancer chemotherapy in the past four weeks?**

<p>Q2: This question asks whether the SP has received chemotherapy in the past 4 weeks. This situation excludes the SP from this procedure.</p>	<p>Explain that we cannot perform phlebotomy on participants who have received cancer chemotherapy within the past 4 weeks. If the SP is excluded, the Blood Draw Exclusion box is displayed. Read the text in the box to the SP and escort him or her back to the coordinator station.</p>
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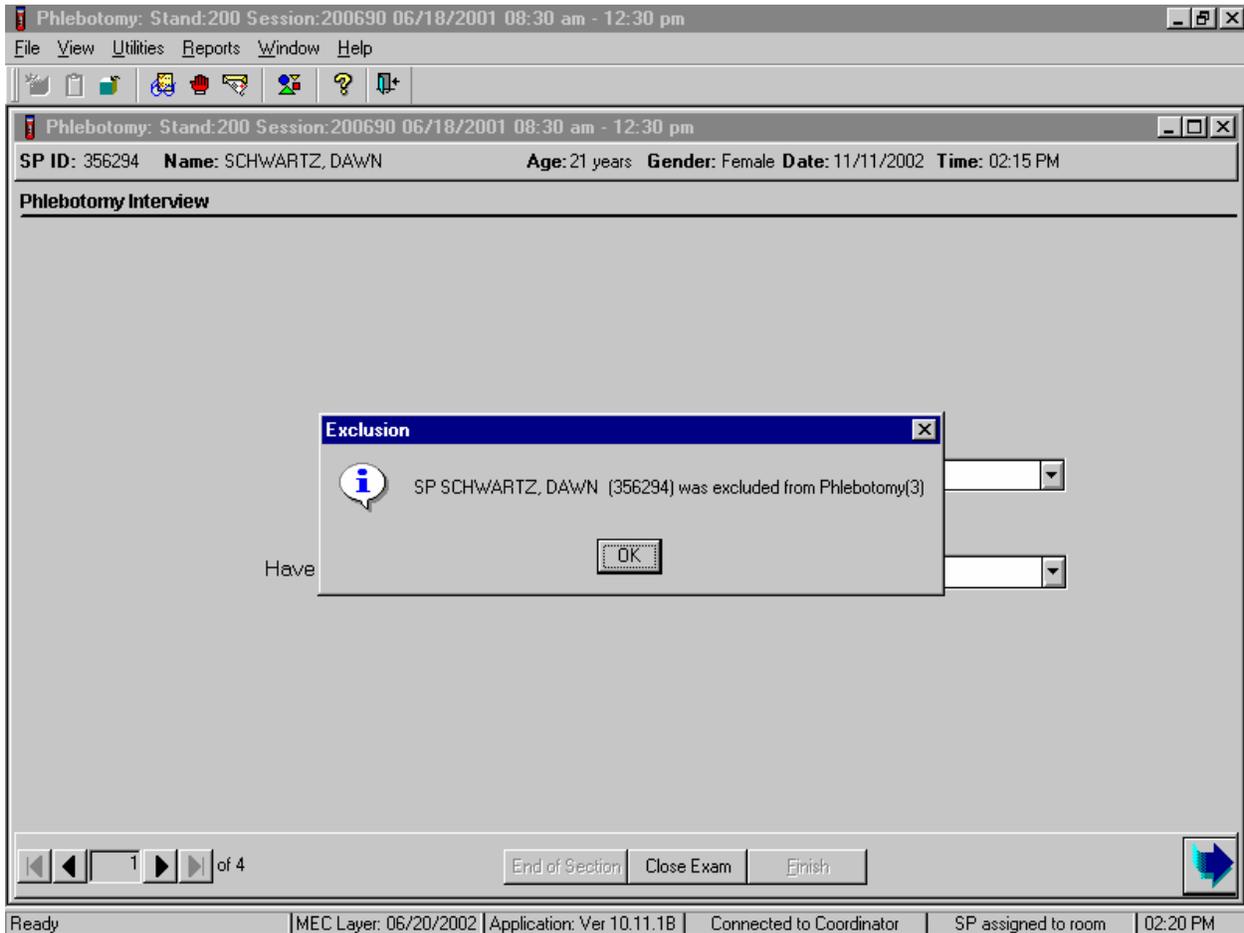
Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” “Refused,” or “Don’t Know,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click.

If the SP is excluded from the phlebotomy exam due to cancer chemotherapy, the Blood Draw Exclusion informational message text box displays.



Read the script to the SP. To remove the Blood Draw Exclusion message box, use the mouse to direct the mouse arrow to the OK button and left click.

If the SP is excluded from the phlebotomy component due to chemotherapy, an Exclusion message text box displays. In some cases more than one Exclusion message box will display, one after the other.



To remove the Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To progress to the component status screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

Review the Status.

The screenshot displays a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and navigation. Below the menu bar, a header bar displays patient information: "SP ID: 356294", "Name: SCHWARTZ, DAWN", "Age: 21 years", "Gender: Female", "Date: 11/11/2002", and "Time: 02:15 PM". The main content area is titled "Venipuncture Status" and contains a form with the following elements:

- A "Status" section with three radio buttons: "Complete", "Partial", and "Not Done". The "Not Done" option is selected.
- A "Comments" section with a dropdown menu showing "safety exclusion".
- An "Other text" section with an empty text input field.

At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "02:20 PM".

SPs excluded due to chemotherapy are automatically coded by the application as “safety exclusion.” Escort the SP back to the coordinator or to the next component as directed by the Message Center.

If the response to both exclusion questions is “No,” continue to the next screen.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "Phlebotomy Interview" and contains two questions, each with a dropdown menu set to "No":

Do you have hemophilia?

Have you received cancer chemotherapy in the past four weeks?

At the bottom of the window, there is a navigation bar with a back button, a forward button, and a page indicator "1 of 4". To the right of the page indicator are three buttons: "End of Section", "Close Exam", and "Finish". In the bottom right corner of the main content area, there is a bright blue arrow icon pointing to the right.

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:24 PM

To progress to the fasting questionnaire screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

## **4.8 Administering the Fasting Questionnaire**

Fasting is critical to many of the laboratory analytes, and fasting data are required for correct interpretation of laboratory results. No primary SPs aged 1-11, or diabetics taking insulin by injection, are required to fast. All other primary SPs aged 12+ have required fasting times based on the examination session to which they are appointed. SPs appointed to a morning session are asked to fast for 9 hours while SPs appointed to an afternoon or evening session are asked to fast for 6 hours. The phlebotomist administers the fasting questionnaire to all SPs, and the application calculates and displays the fasting time in number of hours and minutes. The phlebotomist performs the venipuncture if the SP meets the fasting requirement. If the SP has not met the fasting requirement but will meet the required fast within 30 minutes of the end of the session, the SP is asked to continue with other examination components and return to phlebotomy once the fast has been met. The coordinator reassigns the SP to phlebotomy.

The overall objective is to perform phlebotomy on SPs who have met their fast but SPs can be reassigned to phlebotomy at any time, whether they have met the fasting requirement or not. Base the decision to reassign an SP to phlebotomy on the greater goal of completing as many components as possible within the time constraints of the session, with phlebotomy as the highest priority component. Sometimes an SP insists on leaving the MEC, and it is preferable to get blood from an SP who has not met the fast rather than not to obtain any blood on the SP. The coordinator and MEC manager are able to provide the best overall assessment of the status of a particular SP. The coordinator and/or the MEC manager should make the decision to reassign an SP to phlebotomy before the fasting period ends. The coordinator and/or the MEC manager should include the phlebotomist in their discussion whenever possible so everyone understands the situation.

Guest, dry run, VIP guests, and surplus participants do not have a fasting requirement.

SPs may opt to return to the MEC to complete exams that were missed or complete exams that were begun but not finished. These SPs are designated as “Partial” SPs. When the SP returns to the phlebotomy component, be sure to ask and record the fasting questions a second time so that the data is accurate. If there are data in the text boxes (previous responses from the initial visit) delete it and enter the new responses.

Read the text exactly and record the time.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.]

Q2. Have you had any of the following

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]

Alcohol, such as beer, wine, or liquor?

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies?

Antacids, laxatives, or anti-diarrheals?

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

Fasting Time: Hours Minutes

2 of 4

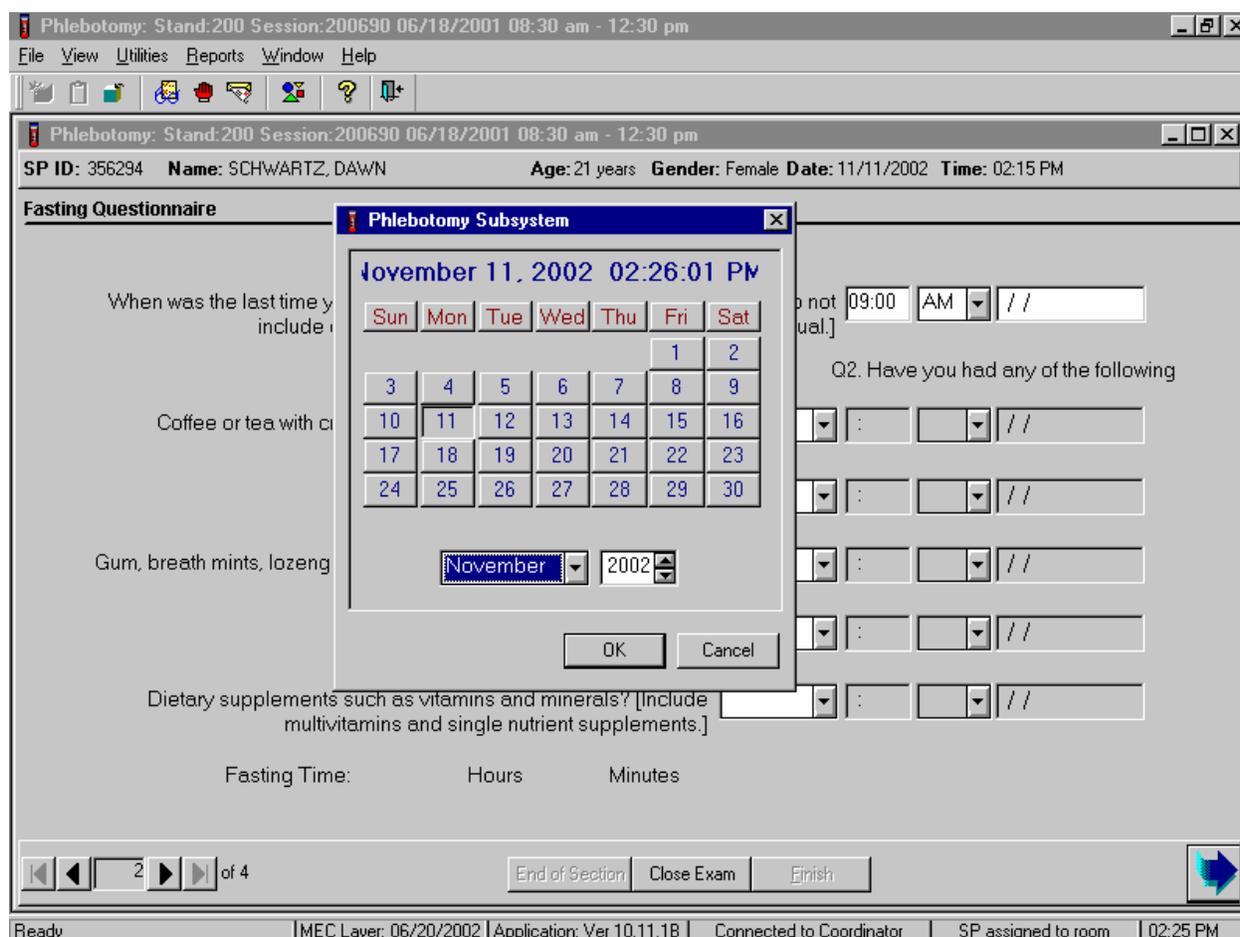
End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:25 PM

**Q1: When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.]**

<p>Q1: This question elicits the last time the SP ate or drank anything and determines fasting time.</p>	<p>SPs are allowed to consume diet soda, black coffee or tea with saccharine or Equal since these have no effect on study analytes. Do not include flavored waters.</p>
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Enter the response.



Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to “AM,” or “PM” and left click.

Type in the date using the keyboard’s numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct

the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Continue administering the questionnaire. Verify the initial time response by asking the remaining questions.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.] 09:00 AM 11/11/2002

Have you had any of the following since today at 9:00 AM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] Yes

Alcohol, such as beer, wine, or liquor? No

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies?

Antacids, laxatives, or anti-diarrheals?

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

Fasting Time: 5 Hours 26 Minutes

2 of 4

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:26 PM

**Q2: Have you had any of the following since (time from question 1 inserted here)?**

<p>Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]</p>	<p>Black coffee is acceptable but coffee with any additives other than saccharine or Equal are unacceptable. Include all milk products such as half and half, light cream, non-fat milk, and all other non-dairy creamers like Creamora or Coffee-Mate.</p>
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Alcohol, such as beer, wine, or liquor?	Alcohol includes all types of spirits including light beer and wine. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed, and the correct time.
Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?	Include sugar-free gum and mints in this category. Give the SP the laminated card that lists common over-the-counter cough drops and cough and cold remedies to refresh his or her memory if he or she appears unsure about these items. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed, and the correct time.
Antacids, laxatives, or anti-diarrheals?	Antacids neutralize stomach acids. Laxatives stimulate evacuation of the bowels. Anti-diarrheals relieve diarrhea and cramping. Include all over-the-counter antacids, laxatives, and anti-diarrheals. Give the SP the laminated card that lists all over-the-counter antacids, laxatives, and anti-diarrheals to refresh his or her memory if he or she appears unsure about these items. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed, and the correct time.
Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]	Vitamins refer to various relatively complex organic substances occurring naturally in plant and animal tissue. They are essential in small amounts for the control of metabolic processes. Many are available over the counter as multivitamin-multimineral or single-nutrient supplements like Vitamin C. Include all of these when clarifying the response to this question. Give the SP the laminated card that lists all over-the-counter vitamins, antioxidants, multivitamins, multivitamins with minerals, and therapeutics to refresh his or her memory if he or she appears unsure about these items. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed and the correct time.

To enter a “Yes” or “No” response, type [Y/y] for “Yes” and [N/n] for “No.” Use the up and down arrow keys to toggle between the two choices. Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the response text box, select “Yes” or “No” and left click. If “No” is

entered, the next response box is highlighted. If “Yes” is entered, the time and date text boxes are highlighted. Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to “AM,” or “PM,” and left click.

Type in the date using the keyboard’s numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary), and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Review the data in the Fasting Questionnaire.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.] 09:00 AM 11/11/2002

Have you had any of the following since today at 9:00 AM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] No

Alcohol, such as beer, wine, or liquor? No

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? No

Antacids, laxatives, or anti-diarrheals? No

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] Yes 09:30 AM 11/11/2002

Fasting Time: 5 Hours 26 Minutes

2 of 4

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:27 PM

To progress to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter].

If the SP does not meet his or her fast, but will meet the fast within 30 minutes before the end of the session, the “Return for blood draw” informational text box displays.

The screenshot shows the Phlebotomy software interface. At the top, the window title is "Phlebotomy". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar with various icons is located below the menu bar. The main window displays the following information:

Phlebotomy: Stand:200 Session:200691 06/18/2001 01:30 pm - 05:30 pm  
SP ID: 445970 Name: SIRKIS, LEANN Age: 25 years Gender: Female Date: 11/12/2002 Time: 11:36 AM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.] 06:00 AM 11/12/2002

Have you had any of the following since today at 6:00 AM?

Coffee or tea with sugar or cream?  Yes  No

Gum, breath mints, or candy?  Yes  No

Antacids, laxatives, or anti-diarrheals? No : //

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] No : //

Fasting Time: 5 Hours 37 Minutes

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows: "Ready | MEC Layer: 11/11/2002 | Application: Ver 10.11.11B | Connected to Coordinator | SP assigned to room | 11:36 AM".

A dialog box titled "Return for blood draw" is overlaid on the questionnaire. It contains the following text: "I will need to have you wait until approximately 12:00 PM before I can collect your blood. I will have the Coordinator bring you back here at the right time." There is an "OK" button at the bottom of the dialog box.

Read the text to the SP. To remove the Return for blood draw text box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

When the SP returns to phlebotomy, open the exam, wand the SP's ID bracelet, and proceed with the interview questions. If the fasting requirement will not be met by the end of the session, proceed with the venipuncture. Continue to administer the questionnaire.

## **4.9 Venipuncture Procedures**

The Vacutainer® system of blood collection consists of glass or plastic tubes with color-coded stoppers containing a premeasured vacuum that provides a controlled draw. Some tubes may contain additives to prohibit coagulation or inhibit glycolysis of blood cells. Draw the tubes in the order designated by the venipuncture protocol.

The exact quantity of blood drawn into each tube varies slightly with altitude, ambient temperature, and venous pressure. Fill tubes with additives completely to ensure proper ratio of blood to additive. Thoroughly mix the lavender and 2-mL and 10-mL gray top tubes immediately after drawing the tubes and place the tubes on the specimen rocker until the tubes are labeled and passed through to the window to the laboratory.

Use Vacutainer® tubes at room temperature. Protect tubes from extreme temperatures and store in a cool place. It is important to note the expiration date printed on Vacutainer® tubes. Do not use expired tubes unless they are the only tubes available. Use expired tubes if they still contain a vacuum. Indicate if using expired tubes by using the “Other, specify” comment option on the venipuncture status screen.

Document the use of each Vacutainer® type in the Supply Use Control Log. Keep a separate line in the log for each type of Vacutainer®. When opening a new box, record the date, the lot number of the box, date in use, the expiration date, and tech ID number.

Allow two venipuncture attempts with the SP’s verbal consent or with the parent’s consent if an SP is a child or an infant.

If an SP faints or becomes ill causing the termination of procedure without collecting all of the blood, repeat the procedure with the SP’s consent after the SP has recovered.

### **4.9.1 Preparation of the Puncture Site**

It is extremely important that the anticipated puncture site is thoroughly cleaned and all necessary equipment, including needles and tubes, are kept sterile and free from contamination.

Follow the steps outlined below to prepare the puncture site.

- Place venipuncture equipment where it is readily available but not in danger of being upset. Keep extra equipment within easy reach.
- Thoroughly wash hands.
- Put on gloves.
- Place appropriate blood collection tubes in a test tube rack in the order dictated by the venipuncture protocol. If an SP exhibits nervousness, keep the tubes covered.
- Instruct the SP to sit on the exam table. **Never** attempt a venipuncture on a standing subject. Having the subject sit helps guard against any injury that might result if the subject faints. Place the SP in a supine position if it is impossible for the SP to sit upright during the procedure. Instruct the SP to extend the arm palm up and straight at the elbow. If the SP is a child or infant, have a medical technologist hold the SP in the proper position.
- Position the arm on the armrest or a pillow so that the veins are readily accessible and the phlebotomist is able to work in a comfortable position. Be sure that the arm is in a downward position with the elbow lower than the heart to prevent backflow. Dispose of the pillow weekly for hygienic purposes. Change the pillowcase daily.
- Inspect the arm. Use the left arm unless unsuitable. The veins of choice are the cephalic, basilic, and median cubital veins located in the antecubital fossa area.
- If the veins in the antecubital space are not suitable, look for suitable veins on the forearm or on the dorsal side of the hand.
- Apply the tourniquet several inches above the selected site.
- Select a vein that is palpable and well fixed to surrounding tissue. Palpate even when the vein is visible. Use the following techniques if the veins do not distend quickly.
  1. Massage the arm from wrist to elbow to force blood into the veins.
  2. Tap the area sharply with the index and second finger two or three times to cause the veins to dilate.
  3. Allow the arm to hang at the SP's side without a tourniquet to allow the veins to fill to their capacity.
  4. Examine the SP's other arm; sometimes the veins in one arm are larger than in the other.
  5. Check carefully for scar tissue or tendons near the vein.

Apply the tourniquet for no more than 1 minute while searching for a vein and then release the tourniquet for 2 to 3 minutes. Avoid prolonged obstruction of blood flow by the tourniquet because it is uncomfortable for the SP and may alter certain results (e.g., cholesterol).

- Reapply the tourniquet when ready to perform the venipuncture.
- Cleanse the area with an alcohol wipe. Do not touch the side of the alcohol wipe that is in contact with the puncture site. Cleanse the area using a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleansed.
- Repeat with a second alcohol wipe. Dry the cleansed area using a 2x2 gauze pad. The area should be completely dry before performing the venipuncture to reduce the burning sensation caused by alcohol penetrating the skin.
- Determine the correct needle size. Use a 19g, 21g, or 23g butterfly or a 21g multisample needle depending on the condition of the SP's veins. The 19g butterfly should be suitable for most SPs. If the SP's veins appear fragile or small, use a 21g or 23g butterfly. If the SP is obese, use a 21g multisample needle.

#### **4.9.2 Venipuncture Technique for the BD Saf-T EZ® Blood Collection Set (19 gauge)**

1. Prepare the blood collection set. Obtain one blood collection set and one luer adapter. Open the blood collection package and inspect the unit. Open the blue adapter cover by twisting the two ends at the seal. Push the male luer adapter firmly and securely into the female end of the needle assembly. Attach a yellow tube holder onto the adapter.
2. Ask the SP to make a fist. Do not have the SP pump his/her fist since this action may alter certain results.
3. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of the phlebotomist's less dominant hand.
4. Approach the vein in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
5. Remove the needle cover. Grasp the wings and push the needle firmly and deliberately into the vein. Do not grasp the translucent needle shield to insert. If the needle is in the vein, a small amount of blood will appear in the butterfly tubing. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the butterfly tubing. If no blood enters the tube and no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for 3 minutes.

Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again if using the same arm for a second try.

6. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.
7. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the dominant hand free to pick up and change the tubes. If left-handed, do the reverse.
8. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
9. Immediately invert the lavender and gray tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender and gray tubes on the rocker. Do not invert or agitate the red top tubes.
10. Insert the next tube and push it down gently onto the adapter.
11. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
12. Fill tubes in the proper order, according to the protocol.
13. When the last tube has filled, remove the needle in a smooth quick motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. To activate the shielding mechanism, either grab the tubing and hold the needle guard at the end closest to the tubing and pull the tubing until the needle guard locks in place or hold the needle guard at the end closest to the tubing, grab the wings and slide the wings back until the needle guard locks in place.
14. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

#### **4.9.3 Venipuncture Technique for the BD Safety-Lok ® Blood Collection Set (21 and 23 gauge)**

1. Prepare the blood collection set. Open the package and inspect the unit. Check to ensure that the female luer adapter is firmly and securely attached on the male luer.
2. Ask the SP to make a fist. Do not have the SP pump his/her fist since this action may alter certain results.

3. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of the phlebotomist's less dominant hand.
4. Approach the vein in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
5. Remove the needle sheath. Grasp the wings and push the needle firmly and deliberately into the vein. Do not grasp the yellow safety shield to insert. If the needle is in the vein, a small amount of blood will appear in the butterfly tubing. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the butterfly tubing. If no blood enters the tube and no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for 3 minutes. Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again if using the same arm for a second try.
6. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.
7. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the dominant hand free to pick up and change the tubes. If left-handed, do the reverse.
8. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
9. Immediately invert the lavender and gray tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender and gray tubes on the rocker. Do not invert or agitate the red top tubes.
10. Insert the next tube and push it down gently onto the adapter.
11. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
12. Fill tubes in the proper order, according to the protocol.
13. When the last tube has filled, remove the needle in a smooth quick motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. Activate the safety shield.
  - a. One-hand technique – Hold tubing in hand and advance the translucent yellow safety shield with thumb and index finger until a click is heard indicating that the needle is completely retracted and the safety shield is locked in place over the needle tip.

- b. Modified one-hand technique – Apply pressure to site by using three middle fingers to hold the gauze over the puncture site. Withdraw the needle by grasping the translucent yellow safety shield grip area with the thumb and index finger. With opposite hand, grasp tubing between the thumb and index finger while pushing the safety shield forward until a click is heard indicating that the needle is completely retracted and the safety shield is locked into place over the needle tip.
  - c. Two-hand technique – Grasp either wing with one hand and grip the area of the yellow safety shield base with the other hand. Slide the wings back into the rear slot of the safety shield, until a click is heard indicating that the needle is completely retracted and the safety shield is locked into place over the needle tip.
14. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

#### **4.9.4 Venipuncture Technique for the Eclipse Multisample Needle**

1. Prepare the needle. Holding both colored shields, twist and remove the white shield. Screw the needle onto the holder. Rotate safety shield back. Twist and pull needle shield straight off.
2. Place the first tube into the holder, securing it slightly, but not penetrating the stopper.
3. Ask the SP to make a fist. Do not have the SP pump his/her fist since this may alter certain results.
4. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of the phlebotomist's less dominant hand.
5. Approach the veins in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
6. Push the needle firmly and deliberately into the vein. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the Vacutainer® tube. If no blood enters the tube but no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for 3 minutes. Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again, if using the same arm for a second try.
7. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.

8. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the right (dominant) hand free to pick up and change the tubes. If left-handed, do the reverse.
9. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
10. Immediately invert the lavender and gray tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender and gray tubes on the rocker. Do not invert or agitate the red top tubes.
11. Insert the next tube and push it down gently onto the adapter.
12. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
13. Fill tubes in the proper order, according to the protocol.
14. When the last tube has filled, remove the needle in a quick, smooth motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. Firmly push forward on the safety shield, lock into place and inspect. After withdrawing the needle, immediately press clean gauze squares over the venipuncture site.
15. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

#### **4.9.5 Concluding the Venipuncture**

1. Have the SP place two fingers on the gauze to hold it in place, then ask the SP to raise the arm straight up, elevating the arm above the level of the heart, without bending the elbow. The SP should remain in this position for 2 to 3 minutes to help prevent hematomas.
2. Corresponding computer-generated bar code labels print automatically for the tubes drawn. Label the 10-mL gray top tube with the label containing the Vessel ID - 54. Label all other tubes with bar-coded labels with the bar code vertical on the tube. The time prints on the label.
3. Place the rack containing the blood collection tubes in the pass-through window located over the sink. Alternatively, deliver the rack to the laboratory, and distribute as described below:
  - Place the lavender and gray tubes on the rocker located next to the centrifuge.

- Place the red top tubes upright in the test tube rack located next to the centrifuges in the laboratory.
4. Place all used needles in a sharps container and dispose of all visibly contaminated waste in a biohazard bag.
  5. Check the venipuncture site for clotting. Apply an adhesive bandage over the gauze pad. Instruct the SP to remove it in no less than 45 minutes if the bleeding has stopped. Also, suggest that the SP sit quietly for a few minutes. If bleeding continues, keep direct pressure on the site for 5 minutes or more.

#### Opsite Dressing

Venipuncture should generally be performed using the median cubital, cephalic, or basilic veins in the left arm unless this arm is unsuitable. If the veins in the left arm are unsuitable, look for suitable veins on the right arm. If the veins in the antecubital space on both arms are not suitable, then look for veins in the forearm or dorsal side of the hand on the left arm/hand and then the right arm/hand.

**All SPs** - If the venipuncture is performed on a vein in the antecubital space of the right arm then apply one transparent film dressing to the venipuncture site in place of the regular Band-Aid or CoFlex dressing. Open the transparent dressing package. Peel off the paper backing and center the transparent dressing over the puncture site with the widest side positioned across the arm from left to right. Apply the dressing by gently pressing the entire dressing in an even manner against the skin, smoothing it to ensure a flat, wrinkle-free surface. Instruct the SP to leave the transparent dressing on for 24 hours or at least until after he or she has exited the MEC. Use judgment when applying this dressing to elderly SPs. The skin of the elderly can be very thin and fragile and the transparent dressing may irritate or cause the skin to tear when the dressing is removed.

6. Report any adverse reaction to the venipuncture to the physician immediately and document it by entering an explanation in the Comments section of the Venipuncture Data Entry Screen and by recording the event in the Unusual Occurrence Log.
7. If the SP has been fasting, offer him or her a snack and juice.
8. Escort the SP back to the coordinator.
9. If blood has spilled on the table or the arm board, wash the area with a 10 percent solution of bleach and water then prepare the workstation for the next SP. Routinely disinfect the table or arm board with 10 percent bleach solution.
10. Wash hands and change gloves before approaching the next SP.

#### **4.10 Pediatric Venipuncture**

Pediatric venipuncture requires special techniques. Because the phlebotomist will be dealing with children of different age ranges and levels of understanding, it is important to be able to recognize at what stage a child is in early in the venipuncture process.

Infants and toddlers, aged 1 to 2 years, experience the world through their senses and do not have much of a language base. Therefore, verbal explanations are virtually meaningless. Expect crying and resistance from the start, even at the first touch. Restrain children of this age by enlisting the assistance of a medical technologist. The best techniques to use with these children are to maintain a reassuring tone, to reinforce that the child is a good boy or girl, and to draw the blood quickly. Be sure to reassure the child after the procedure and to use cartoon adhesive bandages and stickers when finished.

Preschoolers, aged 2 to 6 years, think concretely and in absolute terms; things are good or bad, right or wrong, painful or not painful. For these children, use simple, concrete terms when describing the procedure and its consequences. Always be honest. Try to avoid the word “take” which implies remove, “test” that implies pass or fail, and “fix” which implies broken. With children of this age, it is still important to emphasize that the child is a good boy or girl and to use colorful adhesive bandages and stickers. Try using distractions, such as holding something, counting things in the room, and breathing deeply. These techniques may work with the older children in this age group. The phlebotomist may have a medical technologist assist with most of these children.

School-aged children, 7 to 12 years, have a better grasp of language and view the world more realistically. They understand past and future, that is, “this will be over soon,” and relative terms, such as “this will hurt a little or a lot.” Detailed explanations of the procedure are extremely effective. Again, always be honest. Include demonstrations, that is with a doll, whenever possible. Having the child help during the procedure distracts the child as well as letting him or her have some control. Be sure to reinforce how big a help he or she was after the draw. Give the child realistic choices, such as which arm to choose. The phlebotomist may need to consider having a medical technologist assist with some children even at this stage. Adhesive bandages continue to be important.

Although adolescents aged 12 to 18 years old are beginning to think abstractly, they often regress when placed in stressful situations. It is best to assume that they will act younger than their chronological age. However, it is still very important to address the adolescent as an adult and not as a

child. Provide detailed explanations and inform the adolescent that the best technique is being used. It is very important that the adolescent maintain control of the situation; therefore, give the child some choices as well as allowing him or her to help if offered. Be very clear about rules, such as remaining motionless, but do not restrain the child.

Pediatric venipunctures are most successful when children are immobile, the veins are maximally distended, and all supplies are handy. Many children prefer a cloth or gauze under the tourniquet to prevent pinching of skin.

The usual site for pediatric venipunctures is the antecubital fossa. Most venipunctures in children are successful using a 23-gauge butterfly needle. Follow the general guidelines in Section 4.9 for performing venipunctures.

#### **4.10.1 Age-Specific Techniques in Phlebotomy Competency**

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The Learning Scope:

Understanding and incorporating age-specific competence in evaluating the phlebotomist's performance

By Donna R. Kirven, BA, BPPVE, PBT(ASCP), CLA

##### **Learning Objectives**

At the conclusion of this article the participant will be able to:

State the importance of communicating and incorporating techniques in the performance of phlebotomy procedures based on the physical age and developmental stage of the patient.

Identify at least three major developmental considerations in the performance of phlebotomy procedures for each age-specific group.

Formulate an age-specific competency that can be used as part of the phlebotomy evaluation process.

All health care professions that involve direct patient contact require certain specialized techniques and competencies that are based on characteristics of the patient receiving service. The invasive procedures of phlebotomy are no exception.

Traditionally for some phlebotomists, the majority of their patients could be categorized in one or two age groups, while the experience of others include all age groups. Age-specific concerns are age, growth, development and safety considerations that must be assessed and incorporated into phlebotomy practices for successful outcomes with all patient age groups.

Simply defined, age-specific competence is the knowledge, skills, ability and behaviors essential for providing care to specific populations of patients and their families. These considerations require expanded knowledge and an increased experience level of physical, psychological and interpersonal assessment skills. The newly certified (or trained) phlebotomist should begin using that training on older children, and as confidence and technical skills are attained, progress to performing venipunctures on younger children and, subsequently, infants.<sup>1</sup> Performing a venipuncture on pediatric patients can present a greater technical and emotional challenge to the phlebotomist, and without proper age-specific techniques can result in an unnecessarily unpleasant experience for the child, the parents and the phlebotomist.

To make quality health care services available to communities served by acute care facilities, age-specific phlebotomy techniques are now becoming a standard part of the phlebotomy training curriculum and annual competencies.

### **Factors in Age-Specific Techniques**

Age-specific techniques in phlebotomy involve much more than simply using a smaller tourniquet and collecting a minimum volume of blood. Considerations for motor skills, communication skills development, social needs, and physical and learning disabilities also are a part of the age-specific assessment. The rationale for age-specific techniques is based on the fact that different age groups of patients have special physical and psychosocial needs. Knowledge of the basic nutritional and social needs such as feeding, sucking and physical affection in the infant patient can exemplify professionalism and confidence to anxious parents. Recognition of the increased potential for diminished hearing, vision and mobilization can dispel feelings of embarrassment and frustration in the elderly patient.

Safety is also an age-specific criteria issue. While the phlebotomist should exercise safe practices with all patients, it is important to be aware of the special safety precautions that should be used with pediatric, elderly and disabled patients that are specifically attributable to age. Communication skills on the part of the patient as well as the phlebotomist are also important factors. When performing phlebotomy procedures on an infant, informing the parent or guardian of the details of the procedure in addition to reassurance can alleviate anxiety and build their trust before attempting the procedure. Becoming a highly qualified, experienced phlebotomist skilled in age-specific techniques requires good interpersonal skills such as integrity, effective communication and confidence, as well as demonstrated technical skill.

By incorporating awareness growth and development theories into phlebotomy training, the phlebotomist can provide service and perform procedures in a manner that meets the practical (quality specimen collection) and personal (trust, reassurance, respect) needs of patients and their family members. Table 1 shows six stages of development and the corresponding age divisions.

### **The Neonate/Infant**

Venipunctures should not be performed on children under the age of 6 months unless the test ordered requires the volume and type of specimen that can only be obtained by a needlestick. Nonetheless, heelsticks, the most frequently used method performed for mandatory newborn screens that test for phenylketonuria (PKU), galactosemia, hypothyroidism, primary congenital hypothyroidism and several

other hemoglobinopathies,<sup>2</sup> are performed on a routine basis and require highly specialized skills and age-specific techniques.

The phlebotomist must select the appropriate method of obtaining a blood sample after considering two factors: the patient's age and sample requirements for the test ordered. The novice phlebotomist must study anatomy and physiology, become familiar with special types of equipment specifically designed for the pediatric patient, observe various techniques as performed by experienced phlebotomists or nurses, and practice the techniques themselves to develop the necessary skills. They must make every attempt to collect the minimum amount of blood required for testing because of the small blood volume of infants. Removal of more than 10 percent of an infant's blood volume at one time can lead to cardiac arrest,<sup>1</sup> while removal of large amounts of blood over an extended period of time can lead to anemia, possibly requiring the infant to undergo a blood transfusion. Improperly performing a heel incision, or using a safety lancet that is not of appropriate pediatric size on small children, can lead to puncture of the calcaneus bone, infection and osteomyelitis.

Specific guidelines for performing a heelstick include:

Refrain from puncturing the anteromedial aspect or the posterior curve of the heel to avoid puncturing the underlying calcaneus.

Hold the infant's foot securely but gently so as not to bruise his/her delicate tissue or restrict blood flow.

Avoid milking or squeezing the foot, which can dilute the blood with interstitial (tissue) fluid or cause hemolysis of the specimen.

Refrain from covering the puncture site with adhesive bandages that can macerate the infant's fragile skin underneath.

The emotional challenge of performing phlebotomy procedures on neonates requires that the phlebotomist be prepared to handle not only the infant's reaction to the procedure, but also the parent or guardian who may be present. It is important that the experienced phlebotomist build trust with the parent by communicating in a warm, compassionate manner while displaying a calm and confident approach. These types of interpersonal skills, in addition to requesting the parent's assistance in comforting the infant, can help calm parental anxiety and foster trust in the phlebotomist, allowing her to perform the procedure in a less frenzied environment. Consider the following:

### **Case Study**

Jordan Smith is a 9-month old boy who has been brought to the outpatient laboratory by his parents for some lab work ordered by Jordan's pediatrician. Aside from the newborn screening performed shortly after his birth, Jordan has never had a blood test. His pediatrician has ordered electrolytes and a complete blood count.

Once Jordan's parents have completed the necessary laboratory registration, Monica, a phlebotomist with 15 years experience, having reviewed the requisition and assembled her phlebotomy supplies beforehand, calls Jordan and his parents into the outpatient drawing room. After introducing herself and completing the patient identification procedure with Jordan's mother, Monica greets Jordan and notices that Jordan's father appears to be frozen with fear, hasn't spoken a word and has large beads of perspiration covering his forehead. Jordan's mother, on the other hand, appears significantly less nervous and is engaged in physically and verbally comforting him. Her years of experience have taught Monica that she should address these observations before beginning the procedure. The dialogue proceeds as follows:

**Monica:** Mr. and Mrs. Smith, has Jordan ever had a blood test performed?

**Mother:** No.

**Father:** (*Shakes his head designating “No”*)

**Monica:** I’d like to take a minute or two to explain the procedure to you, but first I’d like to reassure you that I will do my best to perform this procedure with as little discomfort as possible for Jordan and for you.

**Mother:** Thank you.

**Father:** (*Mumbles “Thank you”*)

**Monica:** Mr. Smith, you appear to be a little nervous, and that’s quite understandable. Our phlebotomy staff here have an average of 10 years experience in performing these procedures on patients who are Jordan’s age and younger. I understand your hesitation and respect your concern. If you feel that observing the procedure may be a bit too upsetting for you, you’re welcome to have a seat in our waiting area while your wife remains here with us during the procedure, but if you prefer to stay that’s fine too.

**Father:** Well, it’s just that he’s so small—and do you really have to stick him with a needle to get blood, can’t you just prick his foot or something like they did when he was born?

**Monica:** Children who are Jordan’s age have usually begun to stand or walk, and in preparation for this, the skin of the foot has grown thicker and more resilient. To incise or cut the heel at his age and size, in the same method as that for newborns, would not allow sufficient blood flow required to complete the tests that his physician has ordered. Our standard practice for a patient Jordan’s age is to obtain a blood specimen from a vein in the arm, which is believed to be a more efficient and less traumatic method of performing a blood test.

**Father:** How can you find a vein in a little arm like this?

**Monica:** That’s a question that I’m often asked by parents. My training for collecting blood specimens from children required that I learn to feel the veins in little arms just as proficiently as I did in older arms, and after proper training and practice, I did. Sometimes, it’s easier to find the veins in someone Jordan’s size than it is to find them on an adult.

**Father:** So you’ve been doing this a long time?

**Monica:** I personally have more than 10 years experience drawing infants and children.

**Father:** Well, that’s good to know. I feel a little bit better now so I think I’ll stay in here.

**Monica:** That’s great. Mrs. Smith do you have any questions?

**Mother:** No. I just want this done and over with.

**Monica:** Great! If I can get you to help me by holding Jordan just this way, it will really help us complete this procedure quickly and ensure that we have collected a quality specimen. Dad, you can help too by giving Jordan lots of encouragement and praise during the procedure.

## **The Pre-School Child**

Although the pre-school aged patient has begun to verbally communicate in small statements, it is important that the phlebotomist explain the intended procedure in terminology appropriate for the child. As this patient age group is heavily engaged in security-seeking behavior, the presence of the phlebotomist—a stranger clad in a white lab coat—can often exacerbate their fear and increase their anxiety level even before they see a needle. Approach them slowly and gain their trust before handling equipment or touching their arms to look for a vein.<sup>2</sup>

One of the goals of age-specific techniques for this group is to attempt to keep the child calm and reduce crying which, if prolonged, can actually raise the white blood cell count and the blood pH level.<sup>3</sup> Several methods can be used to accomplish this, some of which may not work for every child; however, the appropriate choices can be more easily made with the phlebotomist's increasing experience level.

Some of these methods are:

Prepare materials and gather equipment before you encounter the child. Doing this in the child's presence will allow more time for the child's anxiety to build.

Approach the child in a friendly, cheerful and empathetic manner. Speak before you touch the child, even if the child cannot or will not respond. Introduce yourself and address the child by name.

Speak in a soothing, non-threatening tone of voice. Even if the child does not completely understand what you are saying, a calming tone communicates a non-threatening intention.

Explain the procedure in terms that are appropriate for the child's age. This, coupled with a soothing tone of voice, can help to lessen the child's fear.

Do *not* say, "It will not hurt." Explain that some pain will be involved in the procedure, and that it is OK to say "ouch" or cry a bit, but that it is important to keep the arm as still as possible.

During the procedure, keep the child informed of how much longer it will be—"Just one more tube"—while using appropriate praise for the child, even if he/she did not cooperate as much as possible. Phrases such as "You are doing such a good job of helping me. Thank you, (patient's name)" can provide reinforcing recognition that may encourage the child to approach his/her next phlebotomy experience with less anxiety.

## **The School-Aged Patient**

Performing phlebotomy procedures on the 8-12 year old patient can be more of a physical challenge than an emotional one. This age group has mastered the meaning and use of the word "No," and is prepared to defend their fear with it. Proper immobilization of the pediatric patient is necessary to ensure the safety of the child as well as the phlebotomist. Instructing the parent/guardian on the correct "hugging" hold method for a child seated on the parent/guardian's lap, or the appropriate restraint for the prone child can allow the phlebotomist to collect the specimen in a manner that will also ensure accurate test results.

The school-aged patient has moved from security-seeking behavior to independence-seeking behavior and as such can exhibit unceasing curiosity. It is important that all phlebotomy equipment be kept out of reach of the child; however, be sure to respond to the child's inquiries as appropriate. Asking questions is an integral part of the learning process, and responding initiates effective communication skills. These

young patients have begun to establish their identities, and the phlebotomist must communicate with them as individuals, in age-appropriate terminology.

Also, most of these children have begun the initial stages of puberty, so the phlebotomist must allow for the privacy of the child in preparation for the phlebotomy procedure. In an outpatient setting, if a urine specimen is ordered, give the child instructions for collection, in age-appropriate terminology, and allow him/her to attempt specimen collection assisted by the parent/ guardian or alone.

### **The Adolescent Patient**

In dealing with the adolescent patient, it is essential for the health care provider to remember the importance of demonstrating an understanding of the significance of peer relationships to the adolescent. Embarrassment can be this age group's mascot. The phlebotomist can implement this understanding by recognizing that some reassuring comments or approaches, if not age-appropriate, can actually instill *more* anxiety for the adolescent patient. Providing age-appropriate praise and positive feedback for this group of patients can lessen their anxiety.

Adolescents in the higher age range are usually engaged in thoughts, goals and behavior that they believe will eliminate the perception of a child, and establish that of an adult. These behaviors can, however, manifest themselves in a sensitivity-heightened and non-interactive manner that can test the communication skills of the phlebotomist, as well as the parent/guardian. It is important to continue to initiate communication with adolescent patients and welcome their limited inquiries.

The older adolescent male, for some unknown cause, possibly hormonal, can demonstrate a greater potential for fainting during a venipuncture procedure. One of the age-specific safety techniques that can be used with this patient age group is to more closely assess the patient before, during and after the procedure. Listen for a previous history of syncope or light-headedness when first encountering the adolescent patient.

During the procedure, periodically check for pre-syncope signs such as profuse perspiration, change in skin pallor, and/or the onset of clammy hands. Another indication of pre-syncope can be the adolescent patient who is suddenly silent in the middle of a conversation or extremely talkative after having been previously silent.

It is important that the phlebotomist be familiar with the department's policy/procedure for dealing with patients who experience syncope, light-headedness or dizziness.

### **The Adult Patient**

Some of the typical conditions that commonly affect the adult patient are stress and depression, which are usually related to pressures of the workplace, marriage, childbearing, parenting and social expectations. Additionally, these roles can induce a stronger identification with their parents or primary caregivers, known as generativity, as well as a closer reflection with their own mortality.

For the average adult, the focus of learning patterns and thinking lies mainly on problem solving. Accordingly, the phlebotomist must use effective communication skills by clearly and honestly informing the adult patient of the procedure while continually maintaining a professional, confident manner. Adult patients are more than willing to cooperate if they are aware of the benefits of their cooperation.

An adult patient can possess the same fear as that of a pediatric patient; however, the adult patient is usually more willing to allow the procedure as long as it is performed in a professional and concise

manner. Conditions that may begin to affect the middle-aged adult patient are the onset of cardiovascular disease and menopause, stroke and cancers. On the other hand, a significant percentage of adult patients who are directed toward maintaining good mental and physical health, optimal energy and social activity exists. These patients are usually less stressed about phlebotomy procedures and view them as an integral part of the preventive health care process.

One of the most effective tools of good communication is eye contact. Eye contact promotes a sense of trust and honesty between the patient and phlebotomist; however, if a patient does not return the eye contact when being spoken to, he/she may prefer less direct eye contact due to cultural or modesty reasons. Experienced phlebotomists will take cues from the patient to monitor and satisfy the patient's comfort level needs.

When interacting with adult patients, the phlebotomist should refrain from engaging in negative body language such as crossed arms, wrinkled forehead or frequently glancing at a clock or watch. These behaviors can detract from the professional image when communicating with adult patients.

### **The Elderly Patient**

With the expanding life expectancy tables, many phlebotomists' patients are likely to be elderly.<sup>3</sup> As with infants and younger patients, this can present both physical and psychological challenges for the health care professional. Likewise, working with the older adult can be extremely rewarding for the phlebotomist who continues to perfect her technical expertise and take the time to treat the patient with respect and compassion.

Elderly patients may feel that they are in less control of their medical situation than other patients, may feel apprehensive about having the procedure performed and embarrassed about feeling this way about it. As with all patients, elderly patients should be treated with consideration for their special needs and with tender, loving care. However, elderly patients are sometimes under the impression that they are a burden and become anxious about the procedure because they don't wish to be a bother. Phlebotomists can help to ease this anxiety by being friendly and cheerful, and taking the time to not only listen to their patients and talk with them, but also to encourage verbalization of their concerns and fears. This can help establish the patient's trust in the phlebotomist and dispel feelings of being a bother.

As people age, they usually undergo a number of physical changes that can have a significant impact on their safety and the effectiveness of normal collection procedures. The elderly patient experiences skin changes, such as the loss of elasticity and moisture, as well as the thinning of skin layers. Loss of supportive connective tissue can lead to "loosened" skin, and loss of muscle tissue and tone may allow for greater movement of veins.<sup>3</sup> The phlebotomist must treat the skin of the elderly patient in a gentle manner. Sometimes the tourniquet that is applied in a tight or rough fashion can easily tear this delicate skin.

In this age group, patients may experience a decrease in peripheral circulation due to narrowed vessels that are the result of atherosclerosis<sup>4</sup> and, combined with loss of vessel elasticity, become more fragile. Gently massaging the intended site rather than slapping or tapping the arm or hand can effectively increase circulation to the site. As skin layers thin, arteries can lay closer to the skin surface in elderly patients, so the phlebotomist must take care to palpate for the "best" vein, and ensure that it does not have a pulse.

Hearing loss is another disorder that is commonly found in the elderly patient. The phlebotomist should approach a patient who communicates that he/she has a hearing impairment by speaking in a slowed,

deliberate and distinct voice to confirm that the patient understands. Some conditions, including Parkinson's disease and stroke, can lead to impaired or unclear speech. This can be a source of frustration for the elderly patient. The phlebotomist must allow the patient to complete his/her statements without being made to feel "rushed," and remember that speech difficulty does not imply difficulty hearing or understanding.

Arthritis also affects a large percentage of the elderly population and may restrict the patient from fully straightening or extending the fingers or arms. The phlebotomist should never force a patient's limb, but should ask the patient whether this action is painful or uncomfortable.

Tremor is also common in advanced aging<sup>3</sup> and may present some difficulty for the patient to hold his/her arm steady during the venipuncture procedure.

A large number of adults over the age of 50 begin to experience loss of visual acuity and, as such, it is vitally important that the phlebotomist ensure that the entrance and floor areas are free of any debris that may not be visible to the elderly patient. Clear plastic needle covers and small pieces of tape can be falling hazards. Inpatient beds that are raised should be lowered before leaving the patient's room.

Poor nutrition and chronic degenerative disease may lead to emaciation, which can make the elderly patient more susceptible to infection due to loss of immune function,<sup>3</sup> so these potential falling hazards should be eliminated to avoid cuts, lacerations and broken limbs.

Forgetfulness, confusion and dementia are more commonly found in the elderly population.<sup>3</sup> Reliability on the inpatient's armband to confirm identification is a must. Some confused patients may not fully understand your intentions and may lash out in defense. If the patient does not demonstrate a clear understanding of the procedure, the phlebotomist should check with the nurse and seek assistance if appropriate.

## **Summary**

Age-specific care techniques are a requirement for all health care professions involving direct patient contact, such as phlebotomy. It is vitally important that these techniques be introduced and incorporated into all phlebotomy training programs, competencies and continuing education. Learning these techniques requires not only a fundamental knowledge of human growth and development, but also the ability to combine technical expertise with age-specific interpersonal skills.

Incorporating the physical, psychological and social needs of patients into the formal phlebotomy training curriculum can provide a vital foundation for all those who aspire to successfully perform phlebotomy procedures. Probationary and annual competencies should specifically address age-specific topics such as tone of voice, eye contact and active listening skills. The implementation of age-specific techniques into the phlebotomy training curriculum and competency format will yield more effective phlebotomy practices and, subsequently, quality patient care.

## References

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**1. Which of the following is considered a personal need of the patient?**

- a) reassurance
- b) respect
- c) trust
- d) all of the above

**2. Which of the following age groups is heavily engaged in security-seeking behavior?**

- a) elderly
- b) pre-school
- c) adolescent
- d) school-aged

**3. Immobilizing the pediatric patient can allow the phlebotomist to:**

- a) collect a specimen in a manner that will ensure accurate results.
- b) build trust.
- c) demonstrate confidence.
- d) facilitate development and growth.

**4. Which of the following age groups includes a population that demonstrates a greater potential for fainting during a venipuncture procedure?**

- a) elderly
- b) pre-school
- c) adolescent
- d) school-aged

**5. To monitor and satisfy the adult patient's comfort level needs, the experienced phlebotomist will take his/her cues from the:**

- a) physician.
- b) nurse.
- c) family.
- d) patient.

**6. To ease anxiety with the elderly patient, the phlebotomist can:**

- a) be friendly and cheerful.
- b) listen and talk with the patient.
- c) encourage verbalization of concerns and fears.
- d) do all of the above.

**7. One of the age-specific goals for the school-aged group is to:**

- a) facilitate bonding.
- b) satisfy practical needs.
- c) encourage commitment to task and contribution.
- d) assess limiting physical conditions.

**8. Infant cardiac arrest can result from removal of:**

- a) 10 percent of infant's blood volume over an extended period of time.
- b) small amounts of blood over an extended period of time.
- c) 10 percent of infant's blood volume at one time.
- d) 2 percent of infant's blood volume at one time.

**9. When performing venipuncture on the pre-school patient, the phlebotomist should:**

- a) say nothing.
- b) say, "it will not hurt."
- c) not say, "it will not hurt."
- d) say none of the above.

**10. The experienced phlebotomist must demonstrate an understanding of the importance of peer relationships when performing phlebotomy procedures with patients in the:**

- a) elderly age group.
- b) adolescent age group.
- c) adult age group.
- d) pre-school age group.

**11. Some of the typical conditions that commonly affect the adult age group are:**

- a) diminished hearing.

- b) loss of skin elasticity.
- c) stress and depression.
- d) embarrassment.

**12. One of the conditions of advanced aging that can make it difficult for the elderly patient to hold his/her arm steady during the venipuncture procedure is:**

- a) skin layer thinning.
- b) loss of visual acuity.
- c) tremor.
- d) poor nutrition.

**13. Which of the following is considered one of the basic characteristics of the pre-school aged patient?**

- a) feeding
- b) privacy
- c) imagination
- d) generativity

**14. Which of the following should be specifically addressed in probationary and annual competencies?**

- a) eye contact
- b) tone of voice
- c) active listening skills
- d) all of the above

**15. Age, growth and development and safety considerations must be assessed and incorporated into phlebotomy practices for:**

- a) increased facility profit.
- b) addressing practical patient needs only.
- c) successful outcomes with all patient age groups.
- d) enhanced interdepartmental communications.

**16. In the case study, which of the following is a method that the phlebotomist used to build trust?**

- a) taking the time to explain the procedure

- b) asking the parents if the patient had a blood test performed before
- c) explaining the venipuncture procedure
- d) all of the above

**17. The phlebotomist in the case study demonstrated professional and timely assessment skills by:**

- a) explaining the procedure to the parents before beginning the procedure.
- b) communicating her years of experience before beginning the procedure.
- c) addressing the father's anxiety before beginning the procedure.
- d) assembling the phlebotomy equipment before beginning the procedure.

**18. By thoroughly answering the parent's questions and communicating her length of experience, the phlebotomist in the case study demonstrated:**

- a) compassion.
- b) proper immobilization technique.
- c) satisfaction of practical needs.
- d) confidence.

**19. By explaining why the child was too old to have the specimen collected by skin puncture, the phlebotomist in the case study illustrated:**

- a) age appropriate terminology.
- b) non-threatening tone of voice.
- c) knowledge of growth and development.
- d) respect for patient privacy.

**20. In the case study, which of the following demonstrates that the phlebotomist addressed the personal needs of the patient and his parents?**

- a) explaining the procedure with compassion
- b) reassuring the parents
- c) addressing the father's anxiety
- d) all of the above

[http://www.advanceformlp.com/common/editorialsearch/viewer.aspx?FN=03mar10\\_mtplsanswers.html&AD=3/10/2003&FP=mt](http://www.advanceformlp.com/common/editorialsearch/viewer.aspx?FN=03mar10_mtplsanswers.html&AD=3/10/2003&FP=mt)

#### **4.11 Hand Venipuncture**

It is acceptable to use dorsal hand veins as the venipuncture site. This site should be used only if the antecubital veins are unsuitable, such as when the antecubital area is edematous, burned or scarred areas, there are casts on both arms, or the veins are thrombosed.

- Select a vein that is palpable, lightly brushing a finger across the back of the hand as it is palpated. This helps select the best vein and determines its direction. Palpate even when the vein is visible.
- Use a 21g or 23g butterfly blood collection set depending on the condition of the SP's veins.
- Follow the venipuncture technique described in Section 4.9.3 to draw the blood.

## 4.12 Recording the Results of the Venipuncture Procedure

The Venipuncture screen displays the tube protocol for the SP.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Window, and Help. The toolbar contains icons for file operations and navigation. The main window displays patient information: SP ID: 356294, Name: SCHWARTZ, DAWN, Age: 21 years, Gender: Female, Date: 11/11/2002, Time: 02:15 PM. The "Venipuncture" section lists the tube protocol: 4 ml lavender (0 of 3), 2 ml gray (0 of 1), 7 ml red (0 of 1), and 15 ml red (0 of 3). A checkbox labeled "Obtained all" is present. A "Comment:" field with a dropdown arrow is located below the tube list. The bottom of the window features navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom shows "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "02:33 PM".

Each SP's profile is dependent on his or her age, appointment type, selection for inclusion into randomly-selected subsamples, and the session time.

Immediately after completing the venipuncture, enter the results of the blood draw, the reasons for a tube not being drawn according to the protocol, and any comments about the venipuncture.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area displays patient information: "SP ID: 356294", "Name: SCHWARTZ, DAWN", "Age: 21 years", "Gender: Female", "Date: 11/11/2002", and "Time: 02:15 PM". Below this is a section titled "Venipuncture". It contains four rows of tube counts: "4 ml lavender" with a spin box set to "3" of 3, "2 ml gray" with a spin box set to "1" of 1, "7 ml red" with a spin box set to "1" of 1, and "15 ml red" with a spin box set to "3" of 3. To the right of these counts is a checked checkbox labeled "Obtained all:" and the ID number "356294". Below the tube counts is a "Comment:" label followed by a text input field. At the bottom of the window is a navigation bar with a left arrow, a right arrow, a spin box set to "3" of 4, and three buttons: "End of Section", "Close Exam", and "Finish". The system tray at the bottom of the screen shows "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "02:33 PM".

To record all tubes as filled or obtained, use the mouse to direct the mouse arrow to the “Obtained all” check box and left click, or type [Alt] [B/b]. This records a check mark in the box and marks all tubes as obtained. To mark individual tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number of each tube up or down or type the correct number using the numeric keys.

Document circumstances where the alternative protocol was used or the SP was in the supine position.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM

**Venipuncture**

4 ml lavender  of 3

2 ml gray  of 1  Obtained all

7 ml red  of 1 356294

15 ml red  of 3

Comment:

3 of 4

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:34 PM

To record either “Alternative Protocol Used” or “SP in Supine Position” comments in the Comment text box, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, type [A/a] for “Alternative Protocol Used” or [S/s] for “SP in Supine Position” and [Enter], or use the up and down arrows to toggle between the two choices and [Tab.]

To progress to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

## 4.13 Venipuncture Status

Verify the venipuncture status.

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 356294 Name: SCHWARTZ, DAWN Age: 21 years Gender: Female Date: 11/11/2002 Time: 02:15 PM

**Venipuncture Status**

Status

Complete  
 Partial  
 Not Done

Comments

Other text

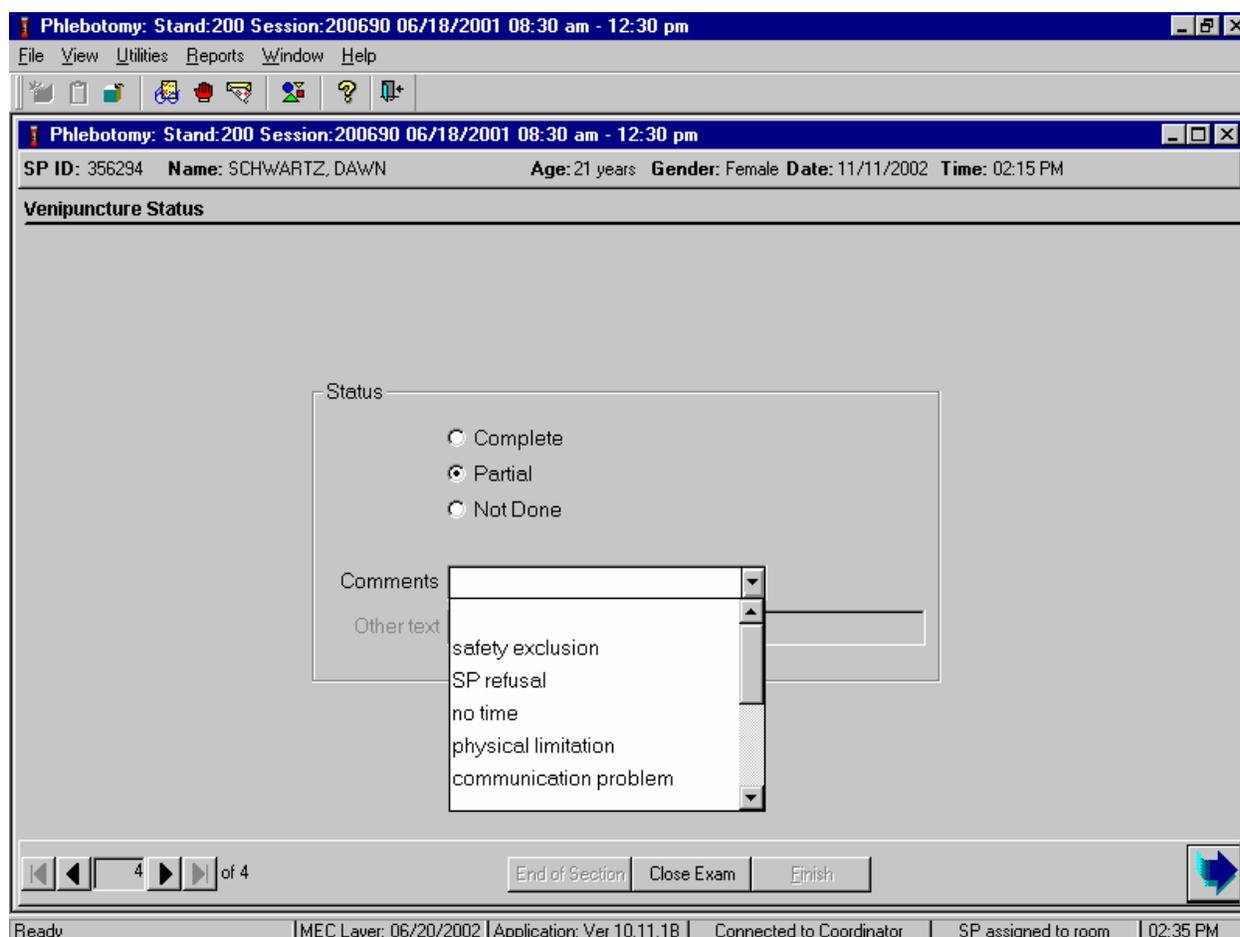
4 of 4

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:34 PM

The venipuncture status is complete if all tubes were collected.

Comment codes are used to explain Partial and Not Done status codes.



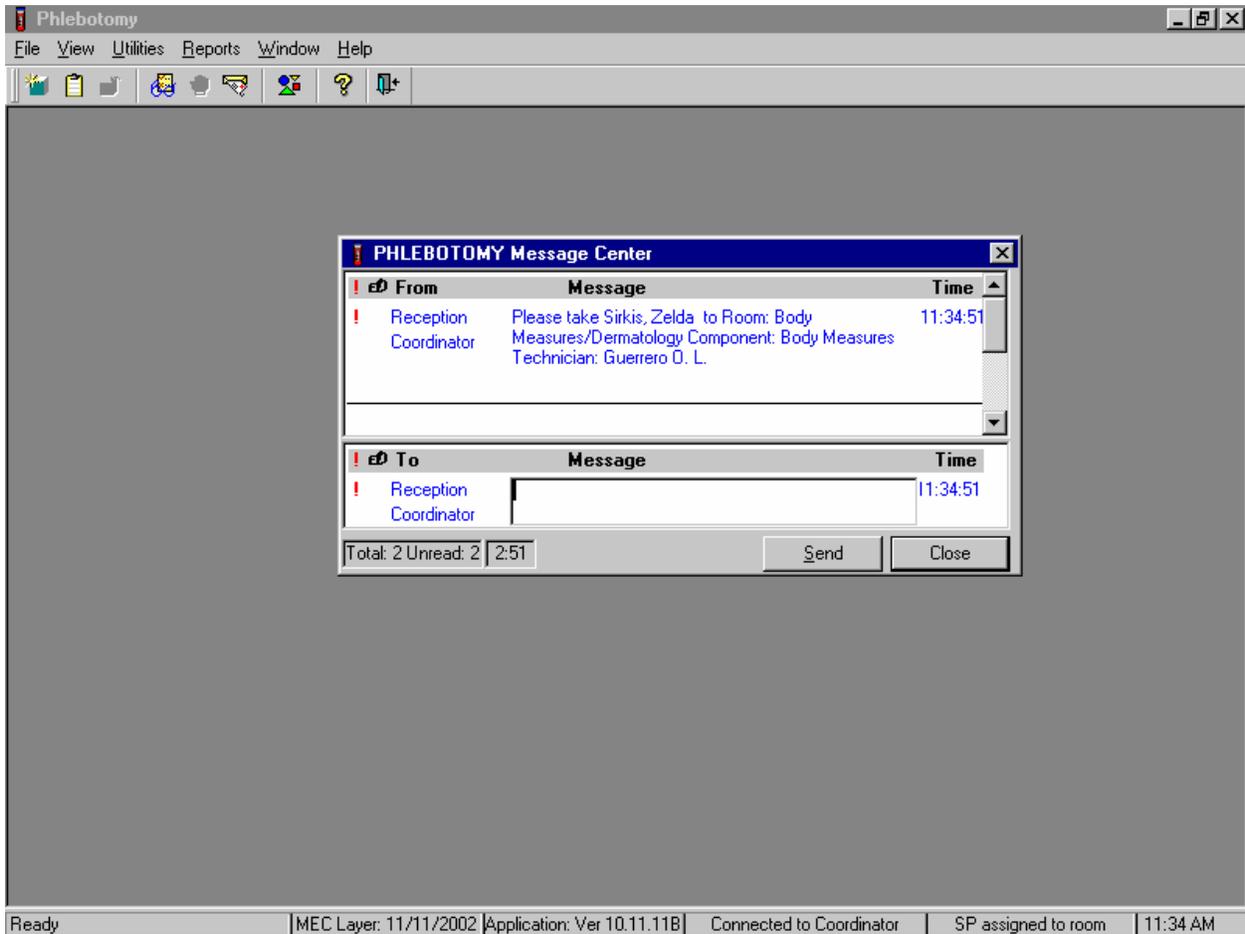
Choose and enter the appropriate comment code when the venipuncture section status is Partial or Not Done. To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

Comment Code	Use when:
safety exclusion	Not applicable This is reserved for positive responses to the hemophilia and chemotherapy exclusion questions and it is automatically coded by the application. The coordinator may code exams using this comment.

Comment Code	Use when:
SP refusal	The SP refuses to have his/her blood collected. This is an SP-initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam. Use this comment to code partial exams when the SP refuses after one tube has been drawn, or the blood flow stops after one tube but before all tubes have been successfully drawn.
no time	Not applicable
physical limitation	Use this comment to code exams as not done (no tubes drawn) when the SP does not have an accessible vein, any arms available, casts on both arms, there is a rash over the entire area, or the blood draw was started but there was no blood in the tubing. Use this comment to code exams as partial when one or more tubes are successfully drawn but blood flow stops before all tubes are drawn or when the veins collapse.
communication problem	Not applicable.
equipment failure	Not applicable.
SP ill/emergency	Use this comment to code not done or partial when the SP faints or is about to faint or the SP became ill or an emergency occurred and the test could not be performed on the SP.
Interrupted	Not applicable.
SP did not meet fast	Not applicable. This is reserved for instances when the SP did not meet the required fasting time but may meet the requirements 30 minutes before the end of the session and it is automatically coded by the application.
error (technician/software/supply)	Use this comment to code partial and not done exams when there are phlebotomist errors, or software or supply issues.
other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click to exit or to progress to the next section, (VOC) or nasal swab, or select [Enter] when this blue arrow is highlighted.

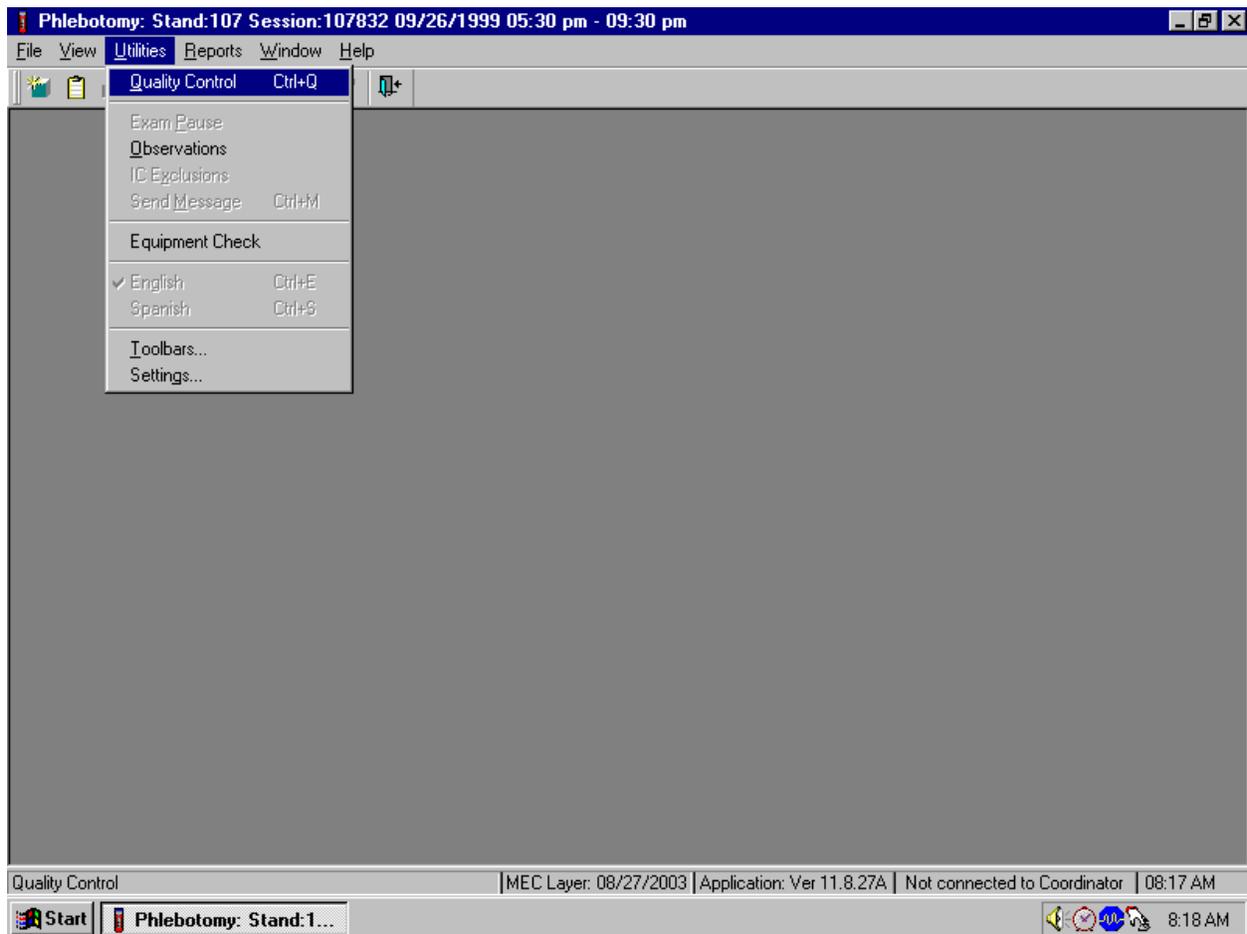
Escort the SP to the location indicated in the Message Center text box.



Review the instructions in the Message Center text box and follow the directions.

#### 4.14 Phlebotomy Quality Control

Perform phlebotomy quality control at the end of each session even if there are no SPs scheduled into the session. Record the room temperature reading and the action that the counters were disinfected using the End of Session tab. Record the supplies in using the Supply Use tab.



To access the phlebotomy QC module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Quality Control} and left click, or select [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

Record the quality control activities. Mark each Done check box with a check mark.

QC Check	Done	Result	Comment
Room Temp. Reading	<input type="checkbox"/>	17°C - 25°C	
Disinfect Counters	<input type="checkbox"/>		

To record a check mark in the Room Temp. Reading check box, use the mouse to direct the mouse arrow to the check box in the Done column and left click, then select [Tab] to move to the Result text box. Enter the temperature in the Result text box and select [Tab] to move to the Comment text box. If the reading is outside the established range (17-25°C), document the actions taken to resolve the situation in the Comment text box. Select [Tab] to move to the next QC item.

Continue entering the QC.

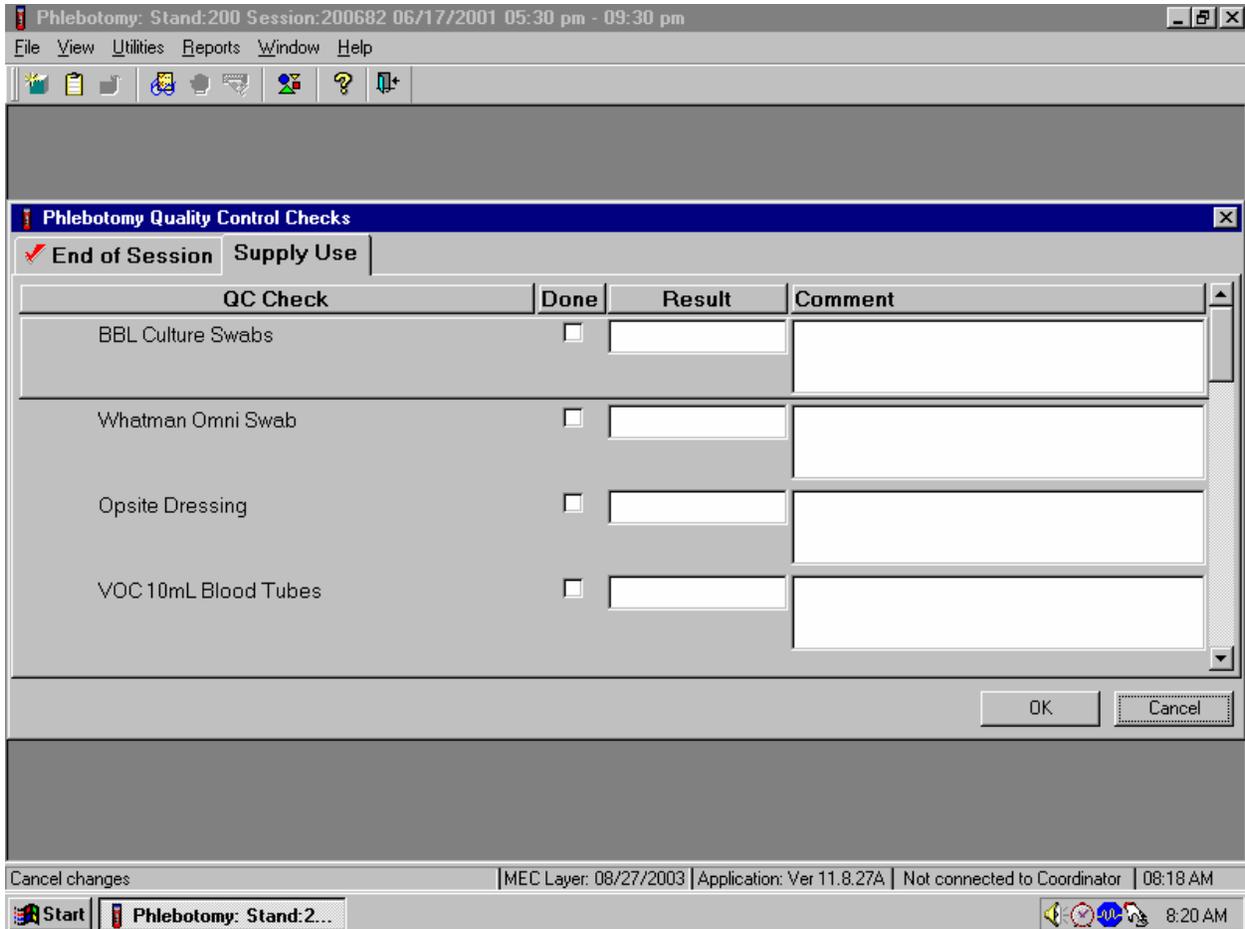
QC Check	Done	Result	Comment
Room Temp. Reading	<input checked="" type="checkbox"/>	26 17°C - 25°C	Notified MEC Manager and Chief Laboratory Technologist
Disinfect Counters	<input checked="" type="checkbox"/>	Yes	

OK Cancel

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 11:50 AM

To record a check mark in the Disinfect Counters check box, use the mouse to direct the mouse arrow to the check box and left click, then select [Tab] to move to the Result box. Type “Yes” or “Not Done” in the Disinfect Counters Comment text box and then [Tab] to add free form text explaining why the counters were not disinfected for any “Not done” response.

Enter the lot numbers and expiration dates in the Supply Use module. This module lists every inventory item associated with the component.



Select the correct activity (Supply Use) by using the mouse to direct the mouse arrow to the correct heading on the top of the file and left click. **Mark each check box and record the lot and expiration date of each item at the start of the stand and whenever a new lot is put into use.**

Mark activities as done and enter the lot number and expiration date in the Comment text box.

QC Check	Done	Result	Comment
BBL Culture Swabs	<input checked="" type="checkbox"/>		55645, 12/03/04 55646, 12/31/05
Whatman Omni Swab	<input checked="" type="checkbox"/>		6898741-M, 06/18/05
Opsite Dressing	<input checked="" type="checkbox"/>		
VOC 10mL Blood Tubes	<input type="checkbox"/>		

To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the Done column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box. Do not enter the response or reading in the Result text box. Select [Tab] or [Enter] to move to the Comment text box.

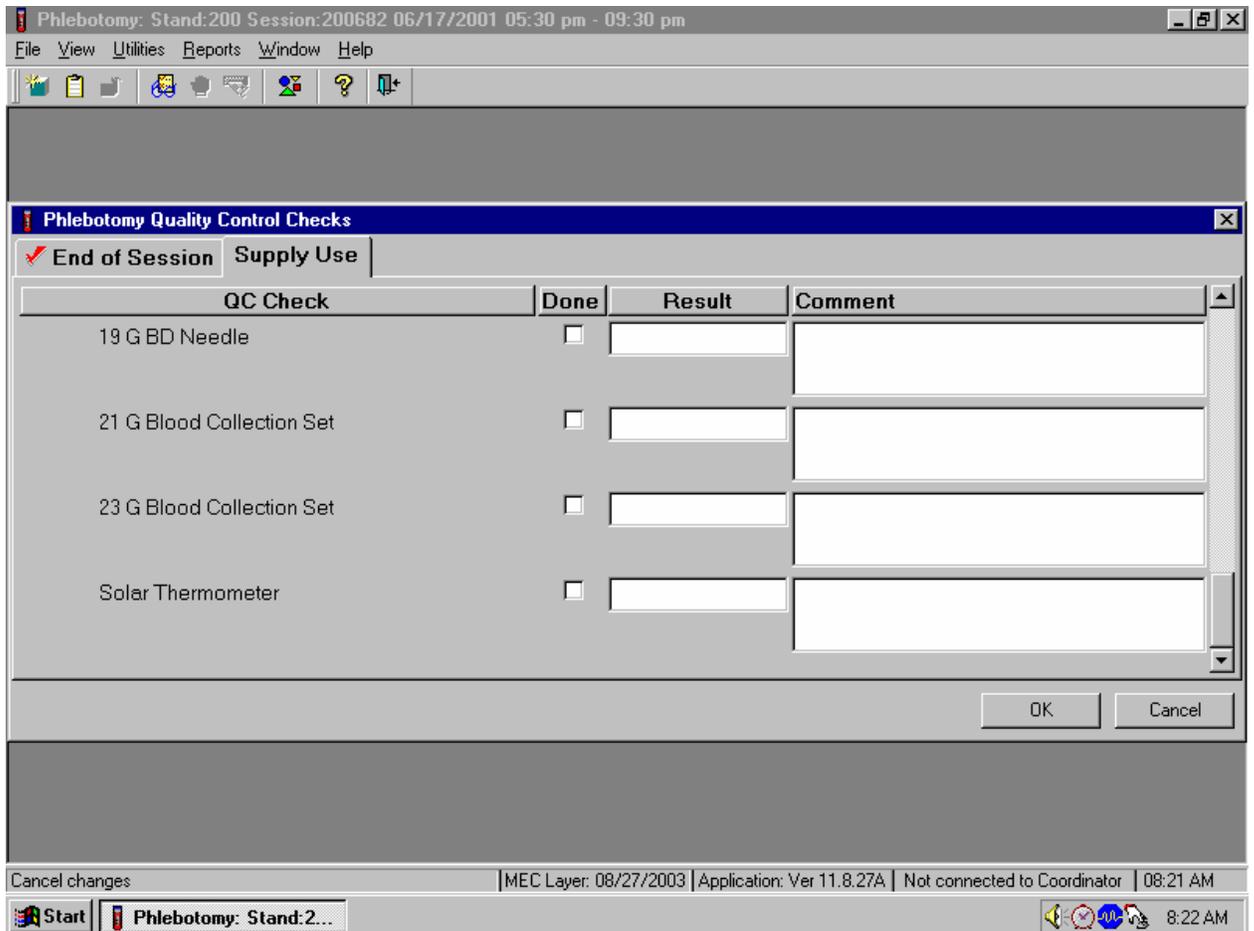
**For each item:**

**Record the lot number;**

**Add a comma; and**

**Record the expiration date using the MM/DD/YY format.**

There is no frequency requirement for this module within the QC application. Update the information each time a new lot is put into use.



To save the results to the database, use the mouse to direct the mouse arrow to the OK button and left click. To exit the QC module without saving the results, use the mouse to direct the mouse arrow to the Cancel button and left click.

To save these actions in the database, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the QC module without saving these actions in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

#### 4.15 Red Cross Procedures for Handling Fainting (Syncope)

“Fainting” is a partial or complete loss of consciousness. This is due to a reduced supply of blood to the brain for a short time. Occasionally, a person collapses without warning. Recovery of consciousness usually occurs when the victim falls. Injury may occur from the fall. To prevent a fainting attack, a person who feels weak and dizzy should lie down or bend over with his or her head at the level of the knees.

- Signs and symptoms include:
  1. Extreme paleness
  2. Sweating
  3. Coldness of the skin
  4. Dizziness
  5. Numbness and tingling of the hands and feet
  6. Nausea
  7. Possible disturbance of vision

If at any time during the venipuncture procedure the SP exhibits any of the manifestations listed above, conclude the venipuncture immediately and perform the first aid procedures listed below.

- Place the SP in a supine position.
- Loosen any tight clothing and keep crowds away.

Provide a disposable airsickness bag if the SP vomits and roll him/her onto his/her side or turn his/her head to the side.

- Maintain an open airway.
- **Do not** pour water over the SP’s face because of the danger of aspiration; instead, provide a cool wet cloth to the forehead.
- **Do not** give any liquid unless the SP has revived.
- Examine the SP to determine if he/she has suffered injury from falling.

- Seek medical assistance. Do not leave the SP. Call for assistance or use the intercom to speak to the coordinator. Observe the SP carefully afterward because fainting might be a brief episode in the development of a serious underlying illness.<sup>1</sup>

#### **4.16 How to Deal With System Failure**

If the computer system fails, record results on a preprinted Phlebotomy Worksheet (Exhibits 4-6 and 4-7). Complete a Phlebotomy worksheet for each SP while conducting the exam. Enter the results after the system is operational.

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<sup>1</sup> From *Standard First Aid and Personal Safety*, Second Edition, the American Red Cross, New York: Doubleday and Company, Inc., 1981, pp. 173-174.

Exhibit 4-6. Phlebotomy worksheet – English Primary

**PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL**

**PRIMARY SP**

SP ID \_\_\_\_\_

<b>Phlebotomy Interview</b>	<b>Responses</b> <b>Yes, No, Refused, Don't Know</b>	
Do you have hemophilia?		
Have you received cancer chemotherapy in the past four weeks?		
<b>Fasting Questionnaire</b>	<b>Record time and date</b>	
Q1. When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal]		
Confirmation Question: Q2. Have you had any of the following since {insert time from Q1 here}?	<b>Responses</b> <u>Yes, No</u>	<b>If Yes, record time and date</b>
Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]		
Alcohol, such as beer, wine, or liquor?		
Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?		
Antacids, laxatives, or anti-diarrheals?		
Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]		
<b>Primary SP Protocol</b>	<b># Filled</b>	<b>Not Filled <input type="checkbox"/></b>
3 mL lavender (1 age 1-2, 2 age 3-5)		
4 mL lavender (2 age 6-11, 3 age 12+)		
2 mL gray (morning only 1 age 12+)		
3 mL red (2 age 1-2)		
7 mL red (2 age 3-5, 1 age 6-11, 1 age 12+)		
15 mL red (3 age 12+)		
10 mL red (2 age 6-11, 2 age 12+ if eligible for Persis Pest)		
10 ml gray (1 age 20-59 if eligible for VOC subsample)		
Comments:		

Exhibit 4-7. Phlebotomy worksheet – Spanish Primary

**PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL**

**PRIMARY SP**

SP ID \_\_\_\_\_

<b>Phlebotomy Interview</b>	Responses <b>Yes, No, Refused, Don't Know</b>	
¿Tiene hemofilia?		
¿Ha recibido algún tratamiento para el cáncer en las cuatro semanas pasadas??		
<b>Fasting Questionnaire</b>	Record time and date	
Q1. ¿Cuándo fue la última vez que comió o bebió algo que no haya sido agua sola? [No incluya soda de dieta, café sin azúcar ni leche o té con sacarina o “Equal”.]		
Confirmation Question: Q2. ¿Ha tomado o comido algo de lo siguiente desde ayer a las {insert time from Q1 here}?	Responses <u>Yes</u> , <u>No</u>	If Yes, record time and date
¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.]		
¿Alcohol, tal como cerveza, vino o licor?		
¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado?		
¿Antiácidos, laxantes, o antidiarréicos?		
¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.]		
<b>Primary SP Protocol</b>	# Filled	Not Filled <input type="checkbox"/>
3 mL lavender (1 age 1-2, 2 age 3-5)		
4 mL lavender (2 age 6-11, 3 age 12+)		
2 mL gray (morning only 1 age 12+)		
3 mL red (2 age 1-2)		
7 mL red (2 age 3-5, 1 age 6-11, 1 age 12+)		
15 mL red (3 age 12+)		
10 mL red (2 age 6-11, 2 age 12+ if eligible for Persis Pest)		
10 ml gray (1 age 20-59 if eligible for VOC subsample)		
Comments:		

## 5. URINE SPECIMEN COLLECTION AND PROCESSING

### 5.1 Introduction

The purposes of urine collection and processing are to collect sufficient urine from primary SPs aged 6 years and older to be able to (1) perform a pregnancy test for selected females aged 8-11 years and all females aged 12 to 59 years, (2) allocate urine into (processing/storage) vessels for transport to various laboratories for analysis, and (3) process urine on SPs aged 18-49 years for HIV if the phlebotomist is not performing the blood draw or the quantity of serum is insufficient for serum HIV. Collect sufficient urine on VIP guest, guest, and surplus appointment types to be able to (1) perform a pregnancy test on all females aged 12 to 59 years and (2) allocate urine into (processing/storage) vessels for transport to various laboratories for analysis.

Collect a urine specimen from all SPs who are 6 years of age and older. The volume of urine required to complete each SP's protocol is displayed in the urine collection module. Document urine collection, perform pregnancy test if indicated, process urine, and store the vessels. At least 5-mL of urine is required on VIP guest, guest, and surplus appointment types. Document urine collection, perform pregnancy test if indicated, process urine, and store the vessels.

The MEC coordinator instructs each SP aged 6 years and older to provide a urine sample at the same time the SP changes clothes. If the SP cannot provide a urine sample at that time, the coordinator asks the SP to provide the sample as soon as possible. After collection, the coordinator or assistant coordinator transports the urine specimen to the laboratory.

The coordinator explains the following instructions to the subject before urine collection:

- Wash hands with soap and water;
- It is important that the cup and cap not touch or come into contact with any parts of the body, clothing, or external surfaces; and
- Close container to minimize exposure to air.

## 5.2 Supplies

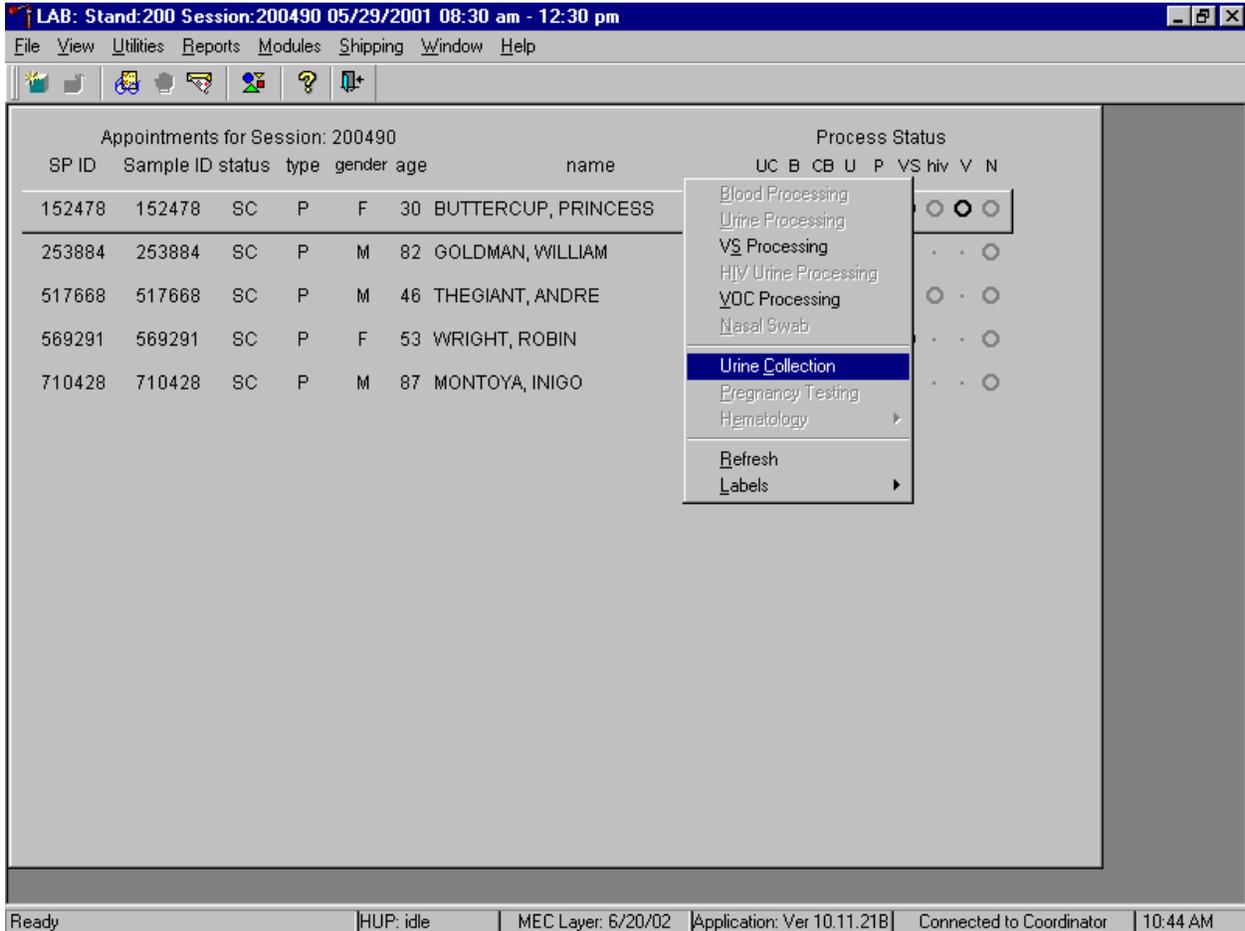
The supplies needed for urine collection and urine processing and storage are listed in Exhibit 5.1.

Exhibit 5-1. Equipment and supplies - urine processing and storage

5-mL cryovial sterile	14-mL snap cap test tube
14-mL snap cap vial with colored dot (Urn Merc)	Transfer pipette
Bench Kote paper	Kimwipes
Cube rack – 4 way flipper rack	Nonsterile, powder-free, latex (nonlatex for use by latex allergic staff) gloves—small, medium, large
5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid	5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid
5.25 x 5.25 x 3.0 inch cardboard box without grid	Three inch 5 x 5 cardboard grid

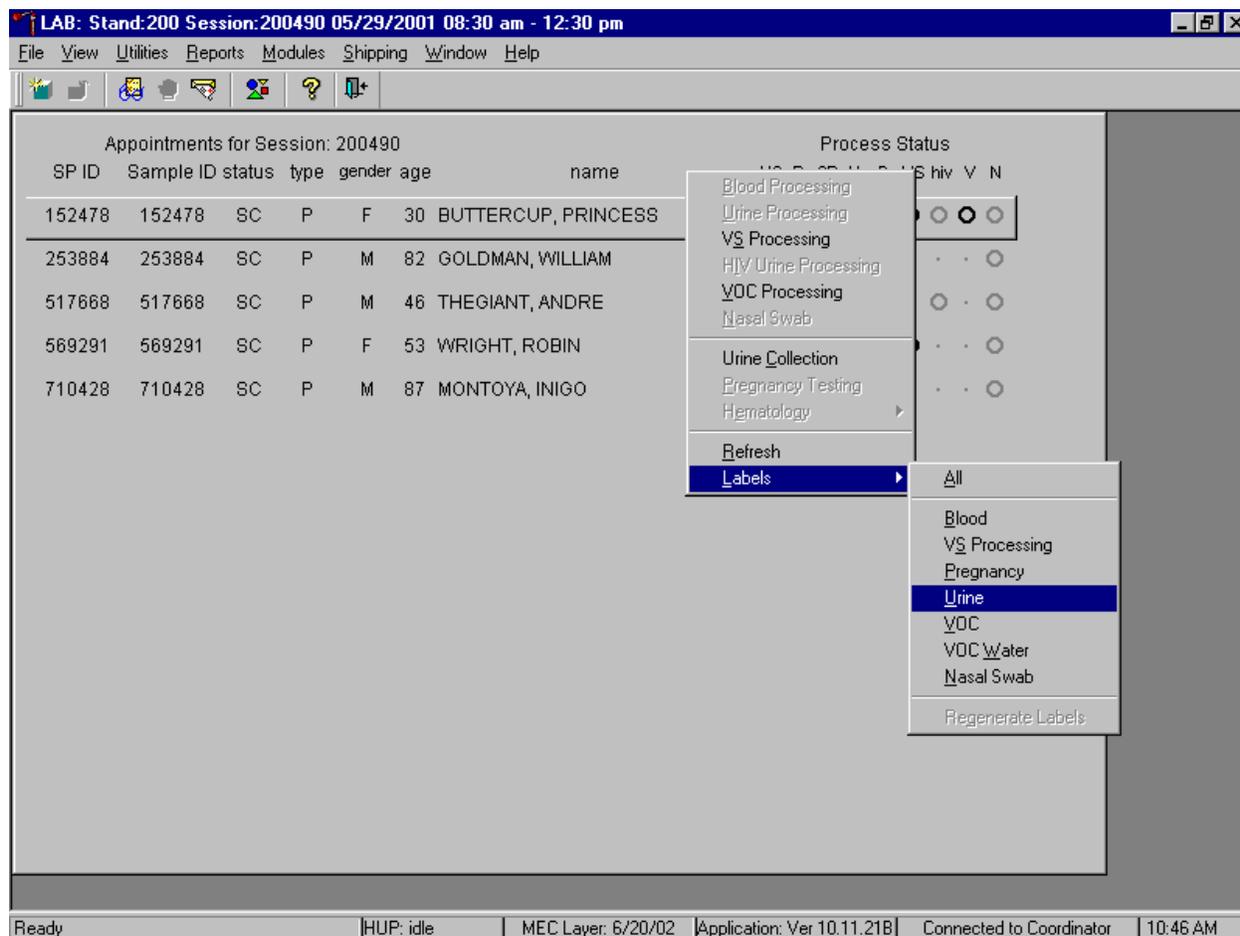
### 5.3 Document Urine Collection

Select the correct SP and access the Urine Collection module.



To select a SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the Urine Collection module, drag the mouse arrow to {Urine Collection} and left click or left click and type [C/c].

Print additional labels for a particular SP using the heads-up display.



To print additional labels for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then drag the arrow to {Urine} and right click or right click on the correct SP, and type [L/1][U/u]. Urine processing labels print for the SP in the Label/Ship area.

The urine collection window displays.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UC: 200490

none

SP ID	Person Name	Ttl. Vol.	Gender	Age	Urine Collected
152478	BUTTERCUP, PRINCESS	48	F	30	(none)
253884	GOLDMAN, WILLIAM	22	M	82	(none)
517668	THEGIANT, ANDRE	25	M	46	(none)
569291	WRIGHT, ROBIN	26	F	53	(none)
710428	MONTOYA, INIGO	36	M	87	(none)

Save OK Cancel

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.21B | Connected to Coordinator | 10:50 AM

The urine collection window contains columns for the SP ID, Person Name (last, first), Ttl Vol (total volume required to complete the protocol), Gender, Age, and Urine Collection and Comment result fields. The total volume includes 1-mL for pregnancy testing.

Only SPs who have checked into the MEC session are available for processing.

The screenshot shows a software window titled "LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". Below the menu bar is a toolbar with several icons. The main area contains a table titled "Appointments for Session: 200490". The table has columns for "SP ID", "Sample ID", "status", "type", "gender", "age", "name", and "Process Status". The "Process Status" column has sub-columns: "UC", "B", "CB", "U", "P", "VS", "hiv", "V", "N". There are five rows of data. The first row, for "BUTTERCUP, PRINCESS", has a yellow warning icon in the "UC" column. A dialog box titled "Urine Collection" is overlaid on the table, containing a yellow warning icon and the text: "\* WARNING \* Sample\_ID 152478 has not checked-in with the Coordinator." Below the text is an "OK" button. At the bottom of the window, there is a status bar with the following information: "Ready", "HUP: idle", "MEC Layer: 6/20/02", "Application: Ver 10.11.21B", "Connected to Coordinator", and "10:46 AM".

Appointments for Session: 200490							Process Status								
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N
152478	152478	SC	P	F	30	BUTTERCUP, PRINCESS									
253884	253884	SC	P	M	82	GOLDMAN, WILLIAM									
517668	517668	SC	P	M	46	THEGIANT, ANDRE									
569291	569291	SC	P	F	53	WRIGHT, ROBIN									
710428	710428	SC	P	M	87	MONTOYA, INIGO									

**Urine Collection**

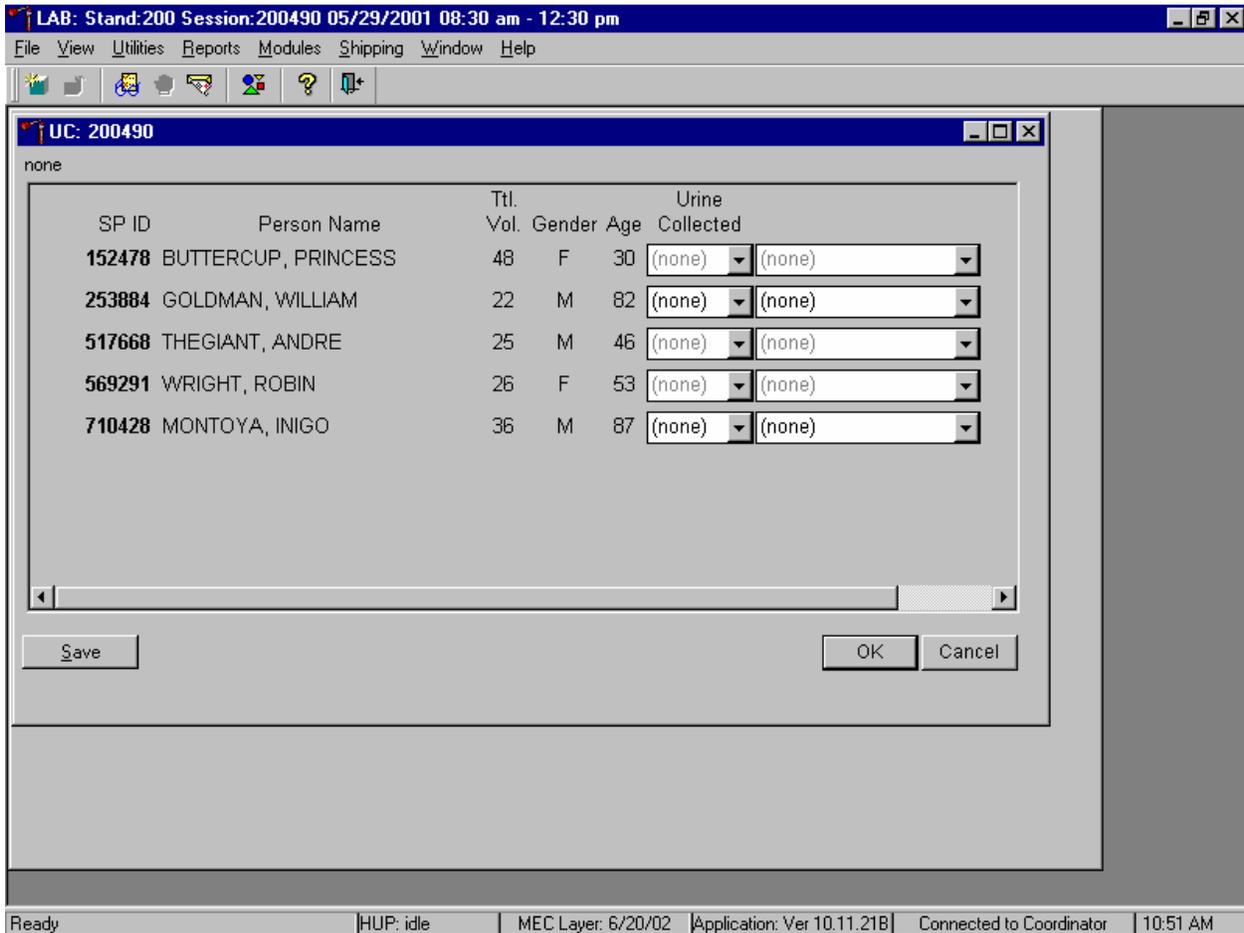
\* WARNING \* Sample\_ID 152478 has not checked-in with the Coordinator.

OK

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.21B | Connected to Coordinator | 10:46 AM

To remove the Urine Collection message box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

This result field for checked-in SPs is indicated in black while the result field for SPs who have not checked into the MEC session is gray. Use the scroll bar to view all SPs scheduled into the session.



Evaluate the sufficiency of the quantity of urine received in the laboratory. Compare the number displayed in the Ttl Vol column and the actual volume of urine (using the gradations on the urine collection cup).

Record the urine collection result for each SP.

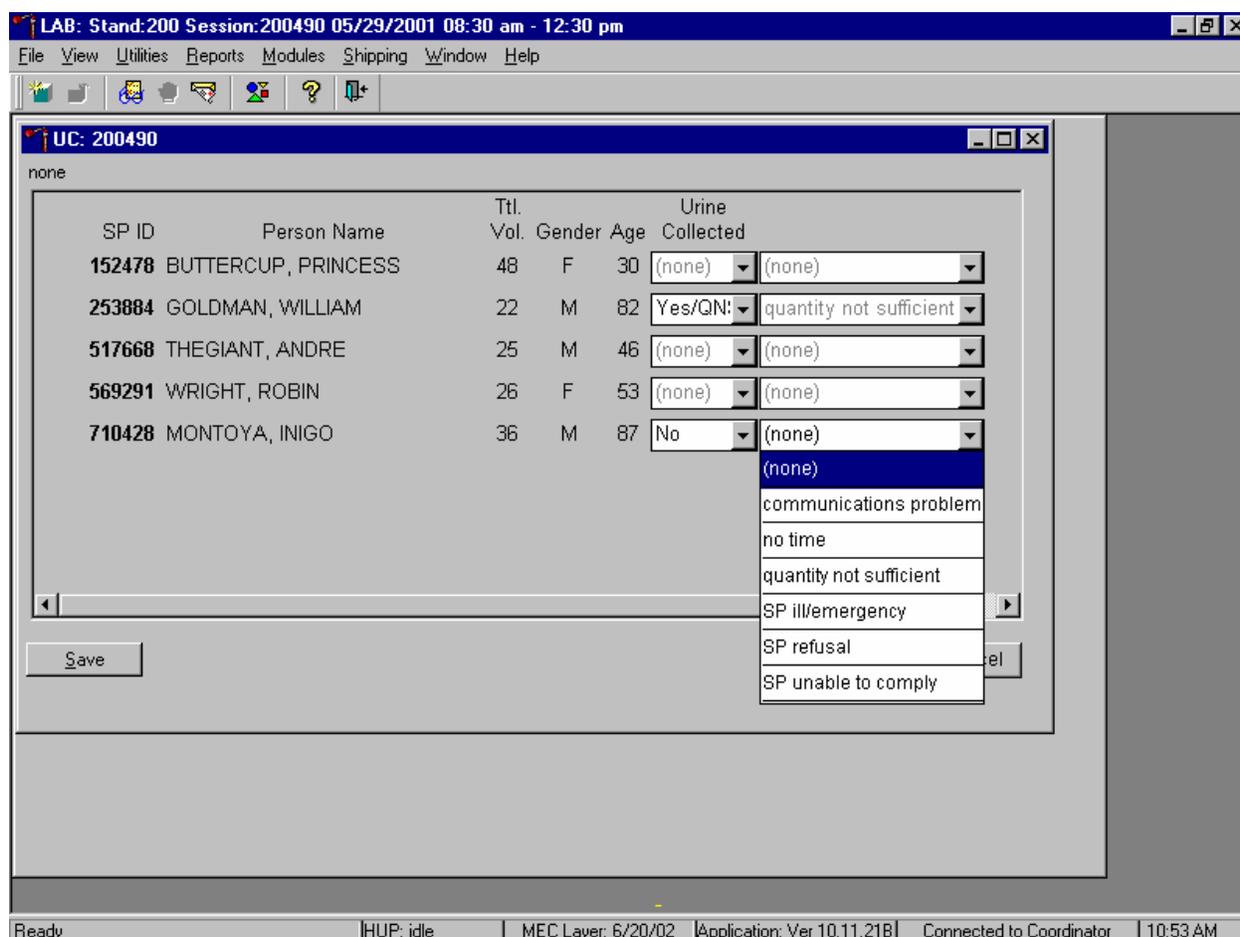
SP ID	Person Name	Ttl. Vol.	Gender	Age	Urine Collected
152478	BUTTERCUP, PRINCESS	48	F	30	(none)
253884	GOLDMAN, WILLIAM	22	M	82	(none)
517668	THEGIANT, ANDRE	25	M	46	(none)
569291	WRIGHT, ROBIN	26	F	53	(none)
710428	MONTOYA, INIGO	36	M	87	(none)

Record the urine collection result for each SP by typing [Y/y] for “Yes,” [N/n] for “No,” or [Y/y] a second time for “Yes/QNS.” Alternatively, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to “Yes,” “No,” or “Yes/QNS” and left click. A “Yes/QNS” result automatically notifies the coordinator, who then asks the SP to provide an additional urine specimen.

**Refrigerate all insufficient urine samples. When additional urine is obtained, pool the urine, mix, and process.**

**Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each SP. Enter “No” in the result field for all SPs who have not produced a urine sample. Record a result other than “(none)” for all SPs.**

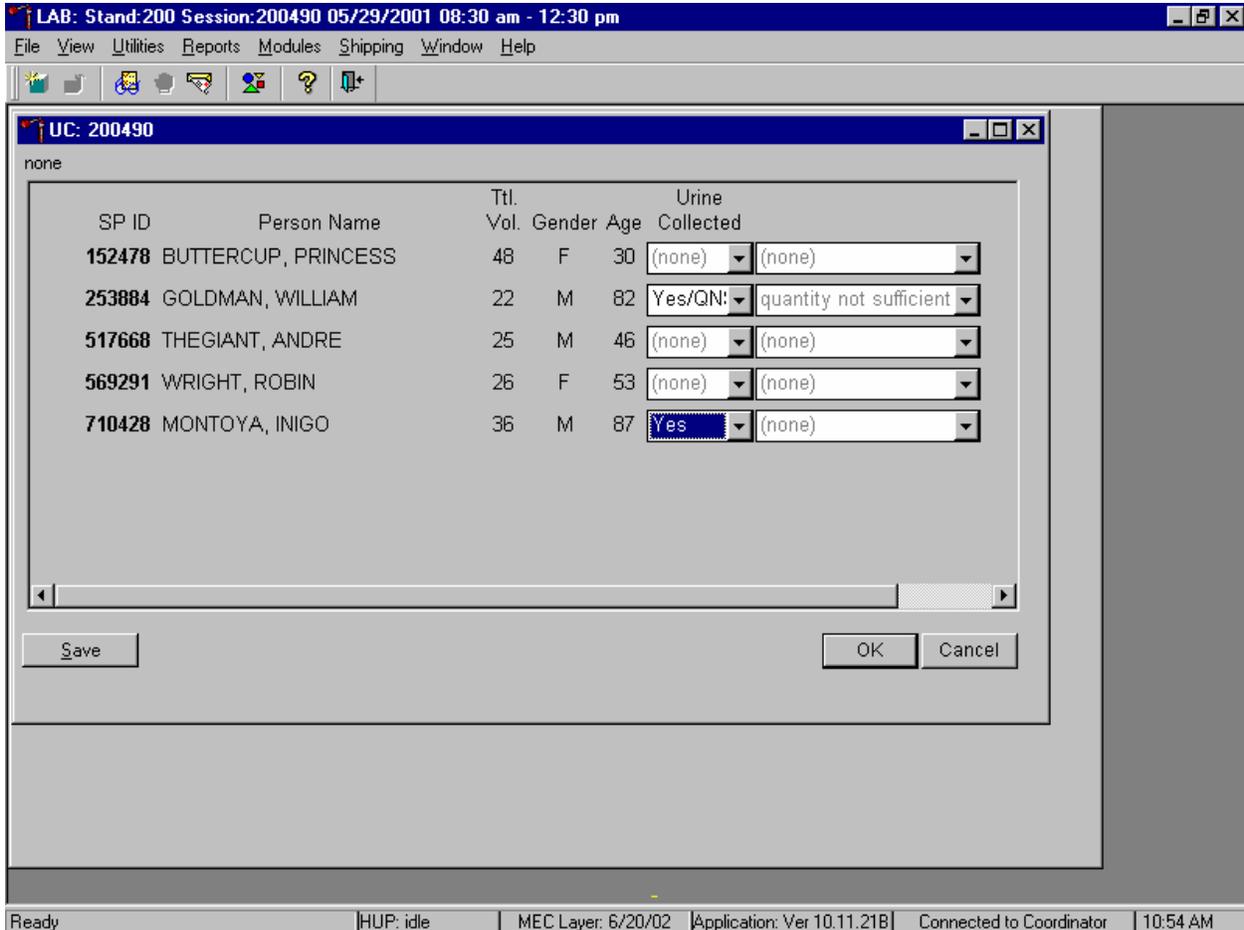
Record a comment for all insufficient urine collections.



To record a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, and select the most appropriate choice. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click.

Comment Code	Use when:
Communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test
no time	Not applicable
quantity not sufficient	The quantity of urine is insufficient to process any or all urine vessel(s)
SP ill/emergency	Not applicable
SP refusal	SP refuses to provide urine during the session
SP unable to comply	SP has a physical limitation that prohibits them from producing a urine specimen or the SP is unable to produce urine during the session

Continue recording and updating urine collection results as specimens are delivered to the laboratory.



Make sure to use the scroll bar to view all SPs. Save each result after entering it in the Urine Collected result field. To save a result to the database without exiting the module or removing the window, use the mouse to direct the arrow to the Save button and left click or press [Enter] when it is highlighted. To save a result to the database and exit the module and to remove the window, use the mouse to direct the mouse arrow to the OK button and left click. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to Cancel button and left click. To exit the module or close the window after saving results to the database and without recording any further actions, use the mouse to direct the mouse arrow to the  Close Window button and left click.

## **5.4 Urine Specimen Assays**

Process urine specimens for the following tests:

- Pregnancy test for selected females aged 8-11 and all females aged 12 to 59 years
- Albumin/Creatinine (Alb/Creat) on primary SPs and VIP Guests aged 6+ years old
- Chlamydia/Gonorrhea (Chlam/GC) on primary SPs 14-39 years old
- Urinary Iodine (Urn Iodine) on selected SPs 6+ years old
- Speciated Arsenic (Spc Arsenic) on selected SPs 6+ years old
- Priority Pesticides (Prior Pest) on selected SPs 6+ years old
- Organophosphates (Organophos) on selected SPs 6+ years old
- Urine Mercury (Urn Merc) on selected SPs 6+ years old
- Heavy Metal on selected SPs aged 6+ years old
- Phytoestrogens (Urn Phytoes) on selected SPs aged 6+ years old
- Polyaromatic Hydrocarbons (PAH) on selected SPs aged 6+ years old
- Phthalates on selected SPs aged 6+ years old
- Extra urine (Xtra Urine) on SPs aged 6+ years old
- HIV Urine for SPs 18-49 years old if no blood is collected or the quantity of serum is insufficient for serum HIV and the SP has not refused HIV

## **5.5 Urine Specimen Protocols**

Table 5-1 summarizes the urine processing protocol for primary SPs. Process urine in priority order with vessel 45 filled first, 46 second, etc.

Table 5-1. NHANES urine processing protocol – primary

Vessel No	Assay	Age in years	Sample size mL	Vessel
45	Alb/Creat	6+	3	5-mL Cryovial
46	Chlam/GC	14-39	10	14 mL snap cap tube
69	Urn Iodine	6+	3	5-mL Cryovial
86	Spc Arsenic	6+	3	5-mL Cryovial
48	Prior Pest	6+	10	14 mL snap cap tube
49	Organophos	6+	10	14-mL snap cap tube
62	Urn Merc	6+	5	14-mL snap cap tube with colored dot
50	Heavy Metal	6+	10	14-mL snap cap tube
65	Urn Phytoes	6+	3	5-mL Cryovial
66	PAH	6+	3	5-mL Cryovial
67	Phthalates	6+	3	5-mL Cryovial
51	Xtra Urine	6+	5	5 mL Cryovial
52	Xtra Urine	6+	5	5 mL Cryovial
53	HIV	18-49	3	5 mL Cryovial

Table 5-2 summarizes the urine processing protocol for the VIP guest appointment type.

Table 5-2. NHANES urine processing protocol – VIP guest

Vessel No	Assay	Age in years	Sample size mL	Vessel
45	Alb/Creat	6+	3	5-mL Cryovial

## 5.6 Labeling Urine Processing Vessels

The appropriate bar code labels automatically print for each SP based on the SP's age, sex, appointment type, and subsample selection. The label/ship technologist at workstation 3 prints the labels at least one session in advance. The printing procedure is described in Chapter 9. Place labels at workstation 2.

Process urine on one SP at a time. Set up each urine processing rack using the preprinted labels. Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally making sure the label wraps onto itself. Place the label so the first digit of the vessel number is at the top of the vessel. Set the vessels in the cube racks in priority order.

## 5.7 Urine Specimen Processing

- Perform pregnancy test and record results before aliquoting the urine specimen.
- Label all urine aliquot vessels for the SP and place in priority order in the rack.

Allocate the urine sample for each of these tests using the following procedure:

45. Pour 3-mL of the specimen for Alb/Creat into a 5-mL vessel.
46. Pour 10-mL of the specimen for Chlam/GC into 14-mL vessel.
69. Pour 3-mL of the specimen for Urn Iodine into a 5-mL vessel.
86. Pour 3-mL of the specimen for Spc Arsenic into a 5-mL vessel.
48. Pour 10-mL of specimen for Prior Pest into 14-mL vessel.
49. Pour 10-mL of specimen for Organophos into 14-mL vessel.
62. Keep vessel 62 upright at all times; do not invert the tube because the preservative could drain into the caps and spill when opened. If the vessel does become inverted, stand it upright for at least several hours or overnight, then open the cap, and pipette the urine into the 14-mL vessel. Tap the bottom of the capped vessel against a hard surface before opening. Use a plastic transfer pipette to transfer exactly 5-mL of urine into the 14-mL snap cap vessel, snap the cap closed, and mix gently. Do not discard

the prepared tubes even if the preservative crystallizes. If the preservative crystallizes, add 5-ml of urine with the transfer pipette and mix extremely well. Do not use these tubes for any other purpose since they contain a preservative.

50. Pour 10-mL of the specimen for Heavy Metal into a 14-mL vessel.
65. Pour 3-mL of the specimen for Urn Phytoes into a 5-mL vessel.
66. Pour 3-mL of the specimen for PAH into a 5-mL vessel.
67. Pour 3-mL of the specimen for Phthalates into a 5-mL vessel.
51. Pour 5-mL of the specimen for Xtra Urine into a 5-mL vessel.
52. Pour 5-mL of the specimen for second Xtra Urine into second 5-mL vessel.
53. Pour 3-mL of specimen for HIV Urine into 5-mL vessel (give this tube to the blood processing technologist).

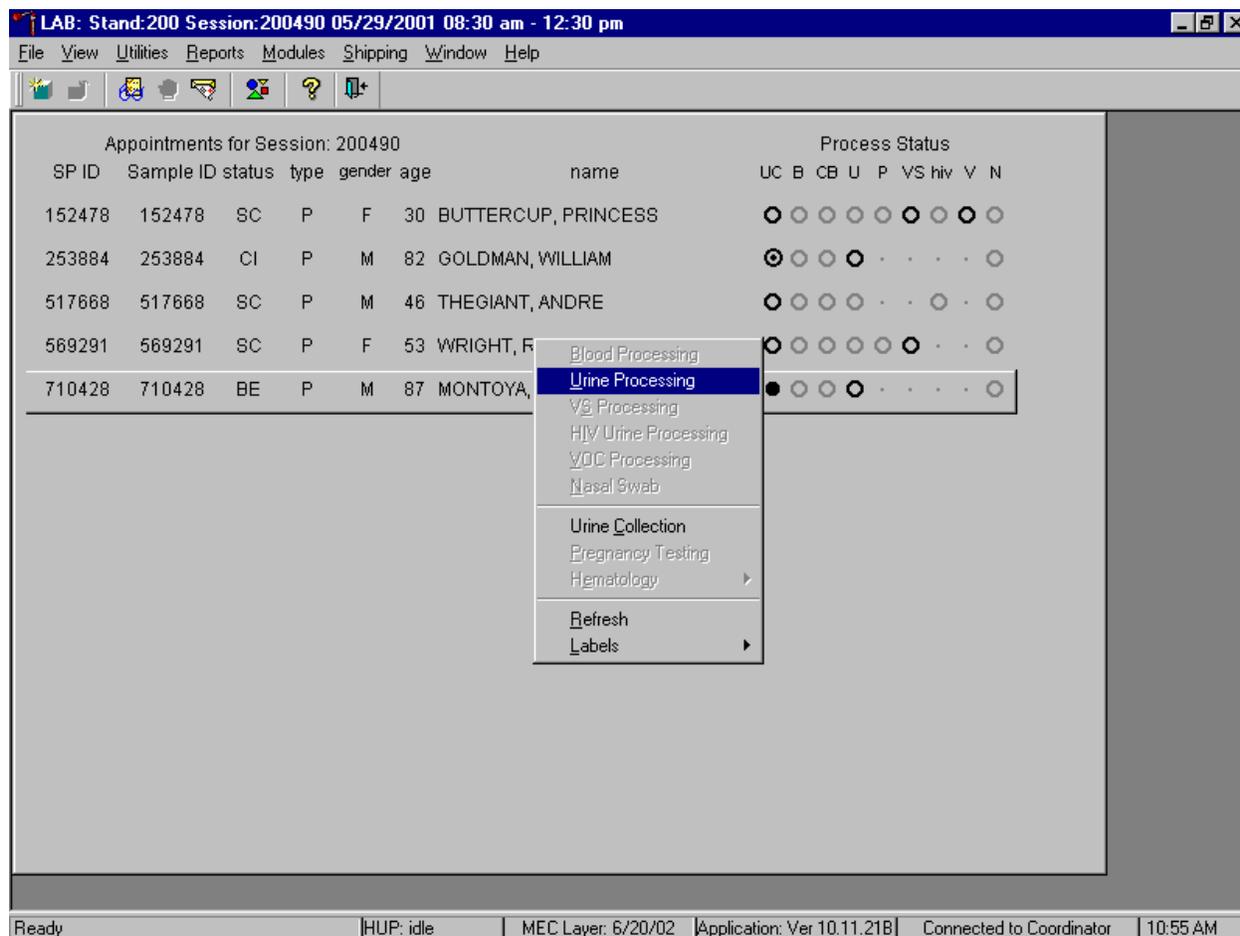
Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink that is connected to the sewer. Flush the sink with water. Discard urine cup in the biohazard trash.

**Do not process urine on more than one SP at a time.**

## **5.8 Record the Results of Urine Specimen Processing**

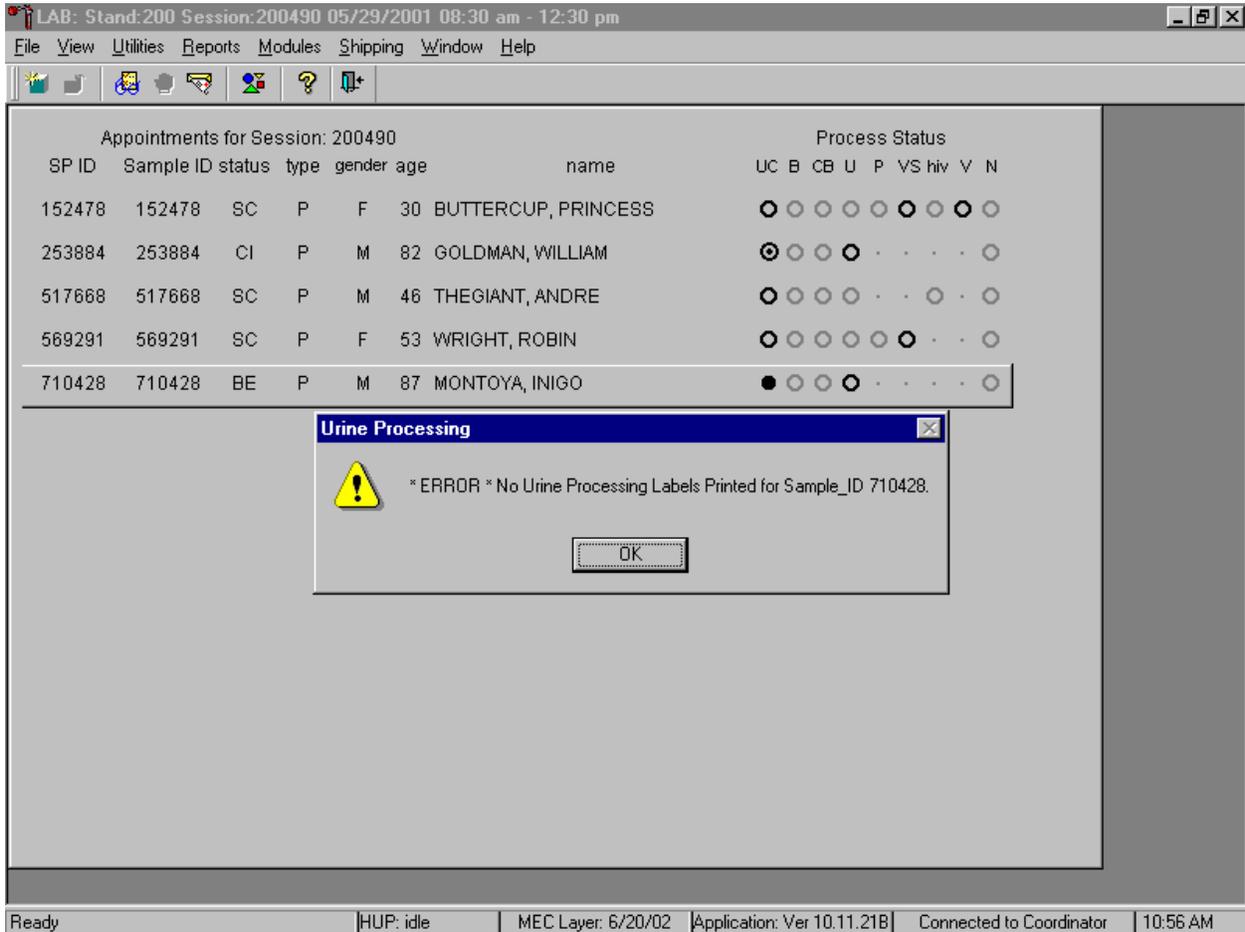
After filling the urine specimen vessels for each SP, use the Urine Processing module to enter the results of urine processing.

Access the Urine Processing module.



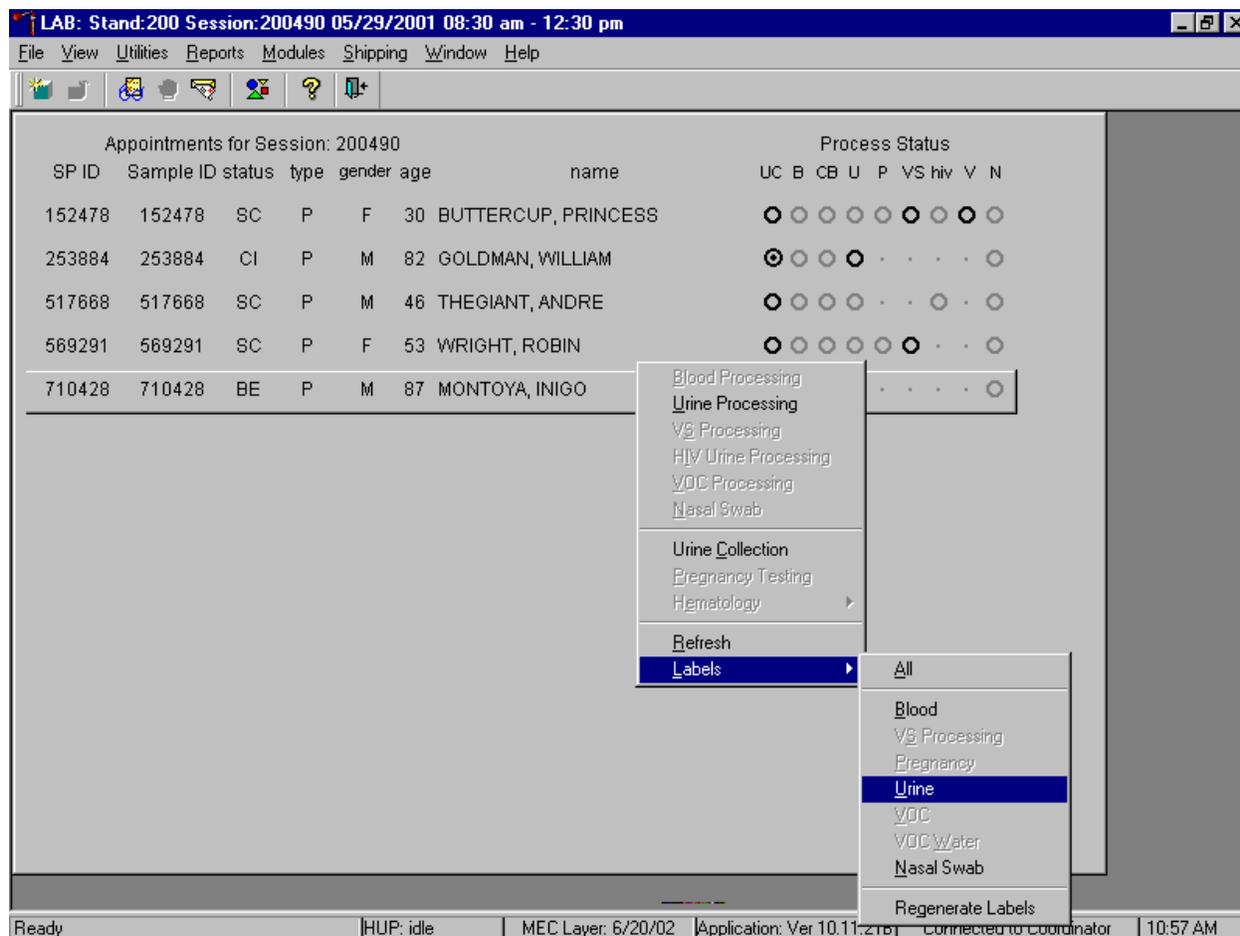
To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Urine Processing} and right click or right click and type [U/u]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Urine Processing} and right click or right click and type [U/u].

If labels have not been printed in advance, a Urine Processing message box displays.



Urine processing cannot occur unless labels have been printed in advance. To remove the Urine Processing message box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. Print the labels for each SP.

Print labels for an individual SP using the heads-up display.



To print labels for an SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then {Urine}, and left click or left click and type [L/l] [U/u]. Labels print in the label/ship area. Continue processing urine on this SP.

The SP's urine processing window displays.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UR: 710428

none

Tech ID: 1126    Sample ID: 710428    Name: MONTOYA, INIGO    Gender: M    Age: 87  
 SP ID: 710428    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
69	Urin Iodine	3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
48	Prior Pest	10.0	U	14 ml	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	(none)		
49	Organophos	10.0	U	14 ml	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	(none)		
51	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
52	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    10:58 AM

The urine processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting\_Req, columns for Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Container ID/Slot #, and Filled and Comments buttons.

Individually mark each vessel as Filled--“Yes.”

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UR: 710428

none

Tech ID: 1126    Sample ID: 710428    Name: MONTOYA, INIGO    Gender: M    Age: 87  
 SP ID: 710428    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077087	6
69	Urin Iodine	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077093	2
48	Prior Pest	10.0	U	14 ml	17 x 100	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077094	2
49	Organophos	10.0	U	14 ml	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	(none)		
51	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
52	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    11:00 AM

To mark an individual urine vessel as collected or Filled--“Yes” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As each vessel is marked as Filled--“Yes,” it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled–“No.”

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UR: 710428

none

Tech ID: 1126    Sample ID: 710428    Name: MONTOYA, INIGO    Gender: M    Age: 87  
 SP ID: 710428    SubSample: 1    Fasting\_Req: 1

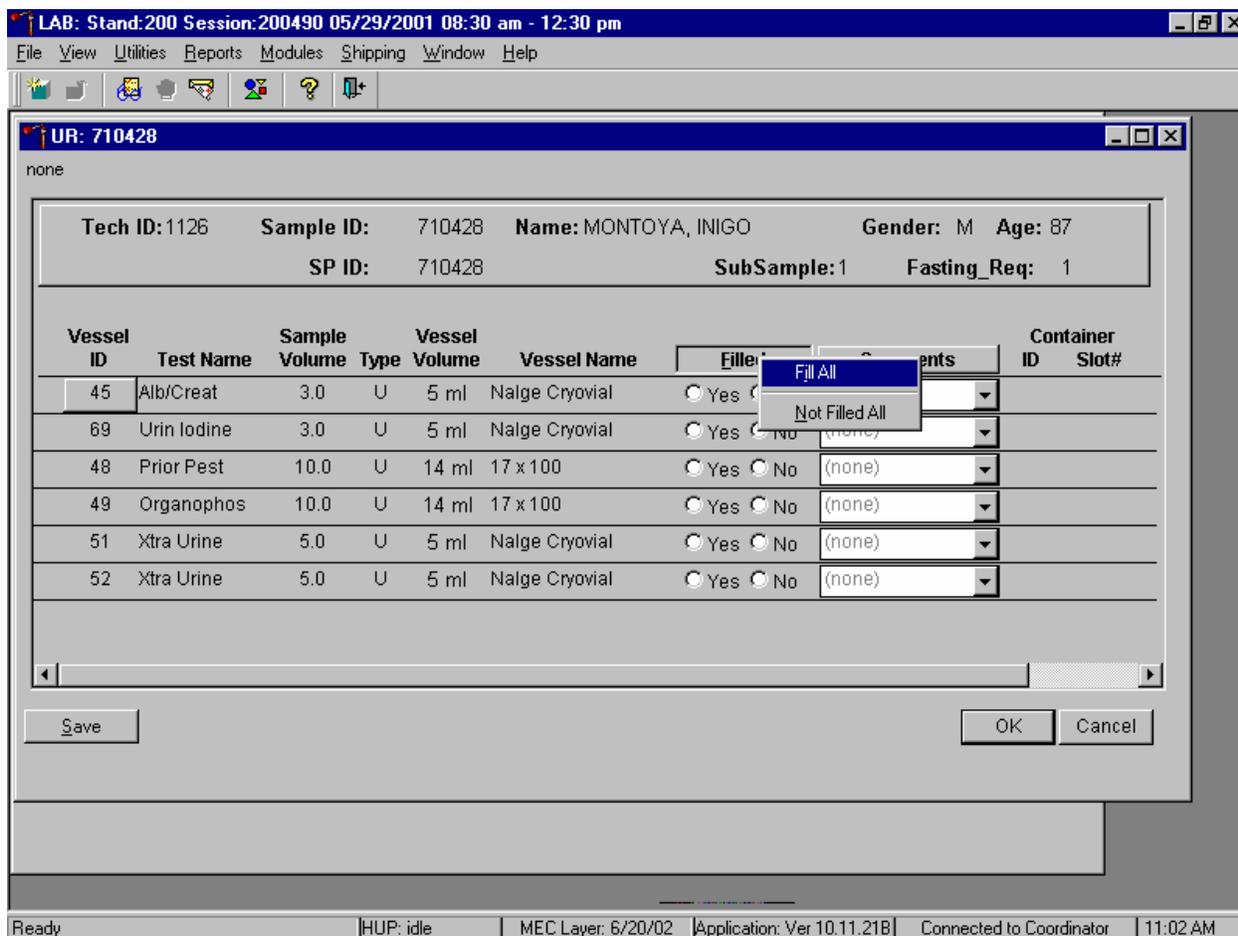
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077087	6
69	Urin Iodine	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077093	2
48	Prior Pest	10.0	U	14 ml	17 x 100	<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not suffic		
49	Organophos	10.0	U	14 ml	17 x 100	<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not suffic		
51	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
52	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    11:01 AM

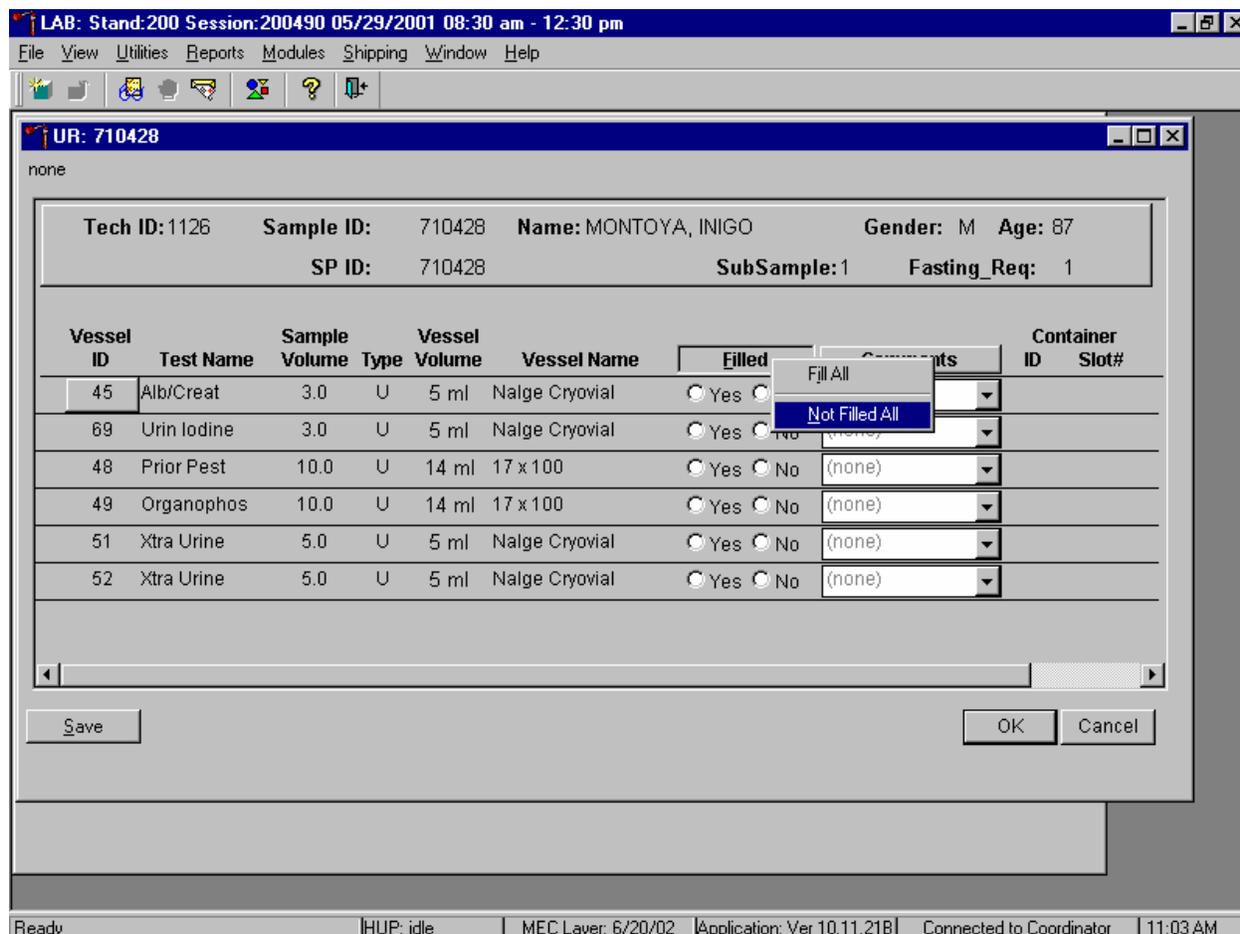
To mark an individual urine vessel as not collected or Filled–“No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. As each vessel is marked as Filled “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column.

Collectively mark all vessels as Filled--“Yes.”



To collectively mark all vessels as Filled--“Yes,” use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, and drag the arrow to {Fill All} and left click or type [Shift] [F/f], [I/i.]

Collectively mark all vessels as Filled–“No.”



To mark all vessels as Filled–“No,” use the mouse to direct the mouse arrow to the Filled box, left click, drag the mouse arrow to {Not Filled All}, and left click or type [Shift] [F/f], [N/n.]

Use the quality comment code to indicate if blood is present.

Comment Code	Use when:
Blood present	Blood is visible in the specimen.

Attach the quality comment code to indicate if blood is present.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UR: 710428

none

Tech ID: 1126    Sample ID: 710428    Name: MONTOYA, INIGO    Gender: M    Age: 87  
 SP ID: 710428    SubSample: 1    Fasting\_Req: 1

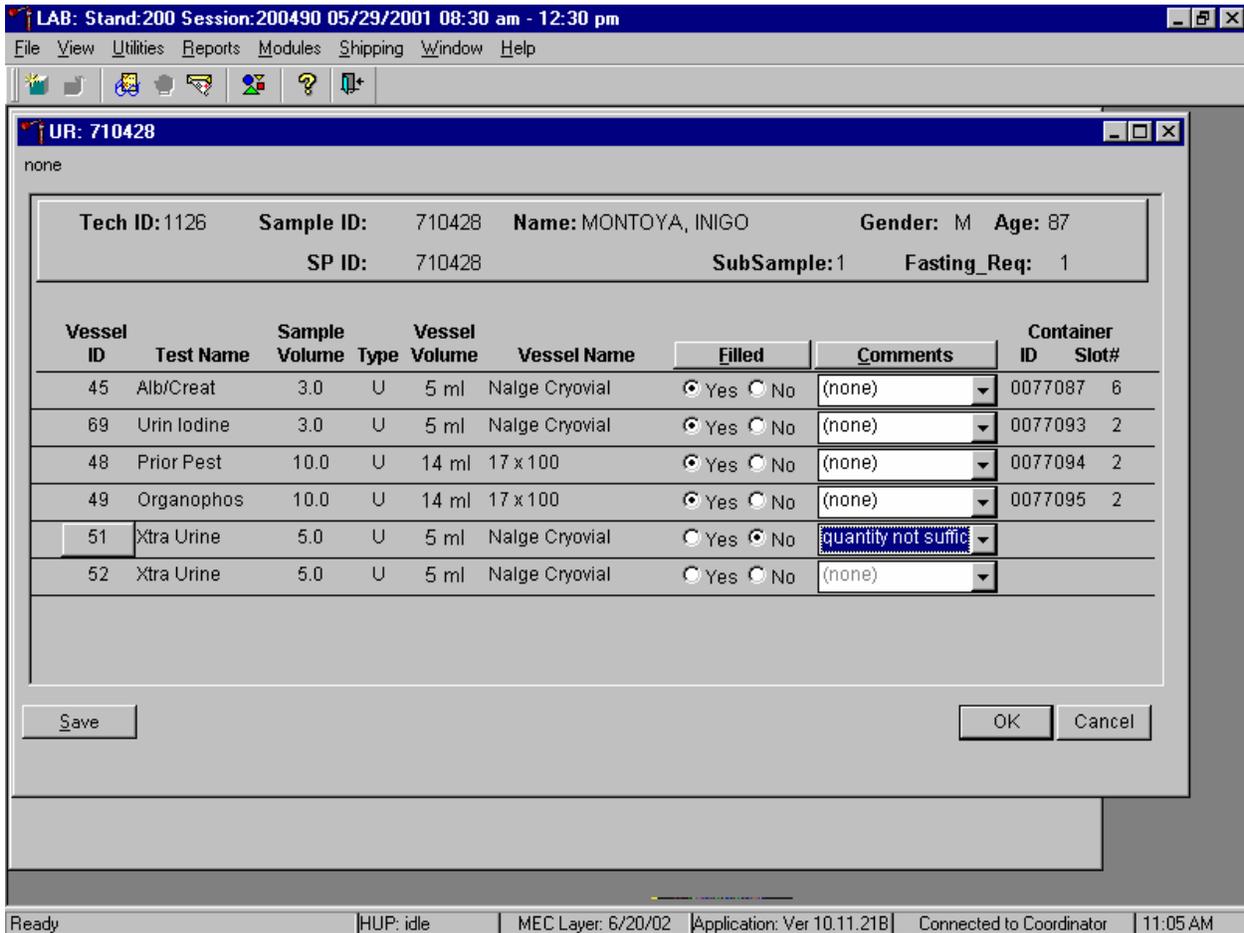
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077087	6
69	Urin Iodine	3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
48	Prior Pest	10.0	U	14 ml	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	blood present		
49	Organophos	10.0	U	14 ml	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	(none)		
51	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
52	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    11:04 AM

To enter the quality control comment “blood present” for a filled vessel, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {blood present}, and left click.

If a vessel is marked as Filled--“No,” the comment “quantity not sufficient” is automatically entered. Review the comment for all insufficient urine collections.



Comment Code	Use when:
container discarded	Not applicable
laboratory error	A technologist makes an inadvertent error when processing
quantity not sufficient	The amount of urine received in the lab is insufficient to fill this vessel

Continue recording and updating urine collection results as specimens are delivered to the laboratory.

Review the information in the urine-processing window and save the data to the database.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UR: 710428

none

Tech ID: 1126    Sample ID: 710428    Name: MONTOYA, INIGO    Gender: M    Age: 87  
 SP ID: 710428    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077087	6
69	Urin Iodine	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077093	2
48	Prior Pest	10.0	U	14 ml	17 x 100	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077094	2
49	Organophos	10.0	U	14 ml	17 x 100	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077095	2
51	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077104	3
52	Xtra Urine	5.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077104	4

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    11:06 AM

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

All vessels marked as Filled–“No” require a comment.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UR: 710428

none

Tech ID: 1126    Sample ID: 710428    Name: MONTOYA, INIGO    Gender: M    Age: 87  
 SP ID: 710428    SubSample: 1    Fasting\_Req: 1

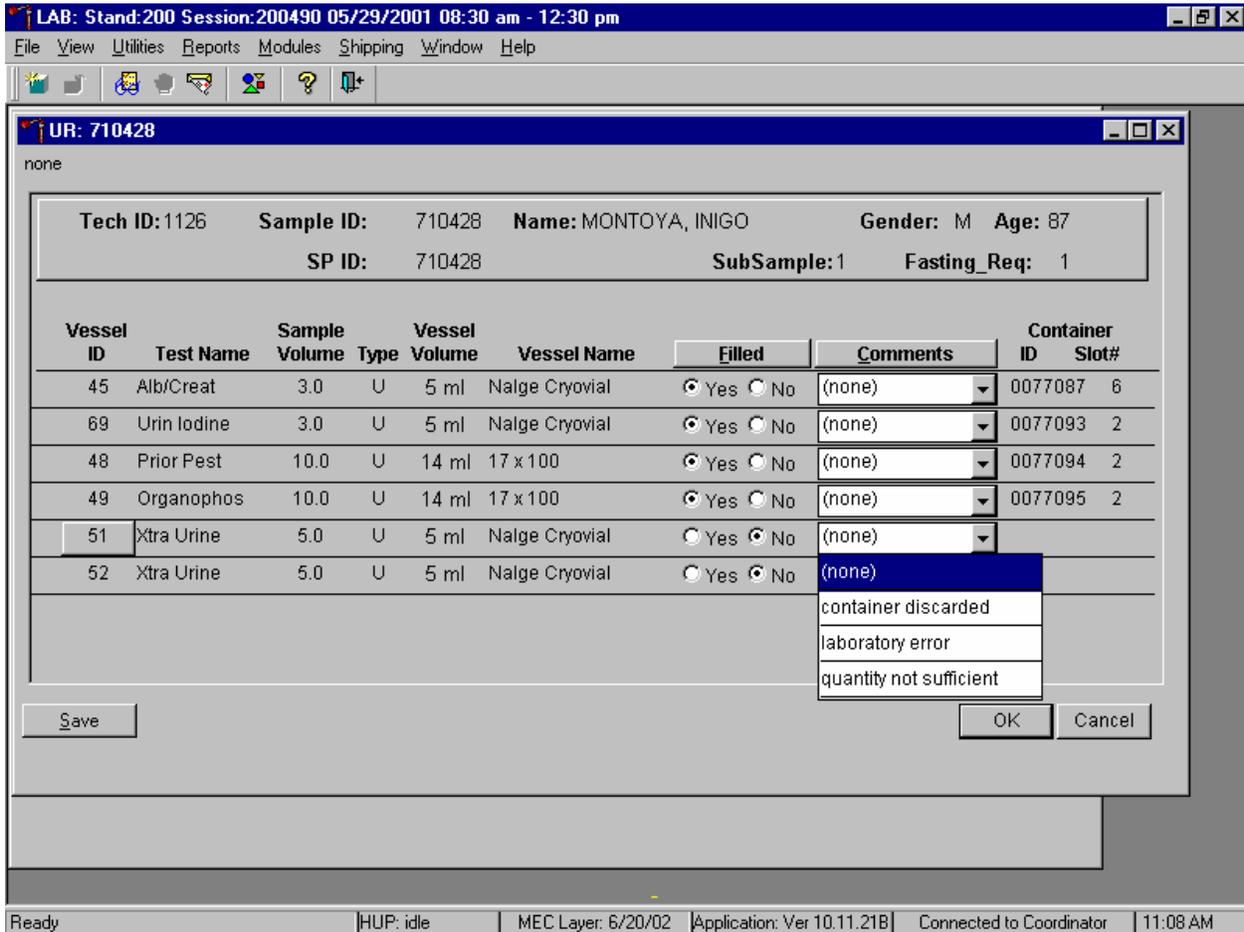
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077087	6
69	Urin Iodine	3.0					w_sheet_process::data verification	0077093	2
48	Prior Pest	10.0						0077094	2
49	Organophos	10.0						0077095	2
51	Xtra Urine	5.0							
52	Xtra Urine	5.0							

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    11:06 AM

If the Save or the OK button is selected and all vessels are not marked as either Filled–“Yes” or Filled–“No,” a warning message box displays requesting a comment for each unfilled vessel. To remove the warning message box, use the mouse to direct the mouse arrow to the OK button and left click. Enter a comment for all unfilled vessels and save the result.

Do not use the comment, “container discarded” for Filled–“No” vessels.



The drop-down comment list for Filled–“No” contains {container discarded}. Do not use this comment.

## 5.9 Second Urine Samples

If the initial urine sample does not meet the minimum volume requirement, refrigerate the initial urine until enough additional urine is received to meet the minimum requirements to complete the protocol or the session ends. If a subsequent second sample fulfills this requirement, pool the initial and subsequent urine samples, update the Urine Collection module, access the Urine Processing module, fill the vessels, and record the results. If the session ends and no additional urine has been collected, access the Urine Processing module, fill as many vessels as possible (in priority order), mark the remaining vessels as filled “No,” and save the results.

## 5.10 Specimen Storage

Fill the urine vessels, enter the urine processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Table 5-3. Check the slot assignment of the lead dust container at the end of each processing session by accessing the Container Map Report. Verify the contents of each container against the container map.

At the beginning of each stand, generate and print a series of bar-coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process “opens” a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in containers are assigned according to a standard left to right, top to bottom procedure. Store each vessel in the appropriate slot in the correct container immediately after processing.

Table 5-3. Storage protocol for urine

Shipping Location	Vessels	Conditions	Vessel Storage
University of Minnesota	45 Alb/Creat	Frozen	9 x 9 three-inch box
CDC, NCID NCHSTD	46 Chlam/GC	Frozen	5 x 5 three-inch box
CASPIR	69 Urn Iodine	Frozen	9 x 9 three-inch box
CASPIR	86 Spc Arsenic	Frozen	9 x 9 three-inch box
CDC/Dr. Dana Barr	48 Prior Pest	Frozen	5 x 5 three-inch box
CDC/Dr. Dana Barr	49 Organophos	Frozen	5 x 5 three-inch box
CASPIR	62 Urn Merc	Frozen	5 x 5 three-inch box
CASPIR	50 Heavy Metal	Frozen	5 x 5 three-inch box
CASPIR	65 Urn Phytoes	Frozen	9 x 9 three-inch box
CASPIR/Dr. Courtney D. Sandau	66 PAH	Frozen	9 x 9 three-inch box
CDC/Dr. Antonia Calafat	67 Phthalates	Frozen	9 x 9 three-inch box
CASPIR	51 & 52 Xtra Urine	Frozen	9 x 9 three-inch box

## 5.11 How to Deal With System Failure

If the computer system fails, record results on a preprinted Workstation 2 processing worksheet (Exhibit 5-2). Complete a workstation 2 worksheet for each SP after performing the pregnancy test, and while processing the urine specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 5-2. Workstation 2 processing worksheet

**URINE COLLECTION, PREGNANCY TEST, URINE PROCESSING**

SP ID \_\_\_\_\_

	Urine Collected Age 6+	Yes ✓	Yes/QNS ✓	No ✓	Comments: Communication problem No time Quantity not sufficient SP ill/emergency SP refusal SP unable to comply		
Result							
	Pregnancy Test Age 8-17	Negative ✓	Invalid ✓	Positive ✓	Serum Confirmation Result (Send observation to physician)		
Result							
	Pregnancy Test Age 18-59	Negative ✓	Invalid ✓	Positive ✓			
Result							
ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Comments <i>ONS</i> <i>Blood Present</i>	Slot #
45	Alb/Creat	6+	3	Urine			
46	Chlam/GC	14-39	10	Urine			
69	Urn Iodine	6+	3	Urine			
86	Spc Arsenic	6+	3	Urine			
48	Prior Pest	6+	10	Urine			
49	Organophos	6+	10	Urine			
62	Urn Merc	6+	5	Urine			
50	Heavy Metal	6+	10	Urine			
65	Urn Phytoes	6+	3	Urine			
66	PAH	6+	3	Urine			
67	Phthalates	6+	3	Urine			
51	Xtra Urine	6+	5	Urine			
52	Xtra Urine	6+	5	Urine			
53	HIV	18-49	3	Urine			



**National Health and Nutrition Examination Survey  
National Center for Health Statistics  
United States Public Health Service  
Procedure: Pregnancy Testing  
January, 2004**

Prepared by \_\_\_\_\_

Date Adopted \_\_\_\_\_

Approved by \_\_\_\_\_

Director

Signed \_\_\_\_\_

Director

Dated \_\_\_\_\_

Director

Reviewed by \_\_\_\_\_

Date Reviewed \_\_\_\_\_

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## 6. URINE PREGNANCY TEST

### I. Purpose and Principle of the Test

Perform a pregnancy test on females of all appointment types who are aged 12-59 years, and girls 8-11 who report that they are menstruating when asked during the home interview. A positive test result excludes pregnant women aged 8-59 from participating in the dual-energy x-ray absorptiometry (DXA) and bioelectrical impedance analysis (BIA) sections of the Body Composition component of the MEC exam. Report test results immediately since these components are not assigned until the results of the pregnancy test are documented. If a urine pregnancy test is positive on any female SP aged 8-17 years, the result is confirmed using a serum test. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.

Tests for confirming pregnancy are based on detecting elevated levels of human chorionic gonadotropin (hCG), a hormone that the placenta begins to produce in increasing amounts shortly after fertilization. The Icon® 25 hCG (Urine/Serum) test kit is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy.

In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period, and peaking in the 100,000 to 200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid raise in concentration during early gestational growth, make an excellent marker for the detection of pregnancy.

The Icon® 25 hCG test is a rapid test that qualitatively detects the presence of hCG in urine or serum sample at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum. At the level of claimed sensitivity, the ICON ® 25 hCG test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH, and hTSH at high physiological levels.

The assay is conducted by adding urine or serum sample to the sample well of the test device. The sample migrates via capillary action along the membrane to react with colored conjugate. Positive samples react with the specific antibody-hCG-colored conjugate to form a colored line at the test region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

## **II. Special Safety Precautions**

### ICON® 25 hCG Test (Urine or Serum)

- For professional *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- The test device should remain in the sealed pouch until use.
- Observe standard guidelines for handling biological hazards.
- Wear gloves while handling specimens. After use, dispose of gloves and other contaminated materials appropriately in a proper biohazard container and wash hands.

### Sure-Vue™ hCG Urine and Serum Control Sets

- Sure-Vue™ hCG urine and serum controls are intended to be used to monitor the performance and accuracy of pregnancy test kits. These controls are for professional use only.
- The use of known controls in the laboratory is invaluable. It is important to verify testing procedures to confirm the validity of the results reported. Testing Sure-Vue™ hCG Urine and Serum Controls will provide assurance that the pregnancy test kit is performing properly.
- Reagents in these kits contain 0.2% of sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build up. This reagent is harmful if swallowed. Contact with acids liberates very toxic gas. After contact with skin, wash immediately with plenty of water.
- Do not use the controls beyond the expiration date.

### **III. Computerization: Integrated Survey and Information System (ISIS)**

The MEC-automated ISIS system captures all data and stores it electronically at Westat's home office in Rockville, Maryland. Access the Pregnancy QC module to enter the quality control results. The session number, technologist ID, and run number are automatically captured; enter the kit lot number and expiration date, and the urine and serum control lot and expiration dates. Record control results and save them to the database. All pregnancy quality control results are immediately available electronically at the home office. All data are backed up and stored at Westat's home office.

### **IV. Specimen Collection and Preparation**

Collect a urine specimen on all SPs 6 years and older into a clean and dry plastic container and document the collection in the urine collection module as described in Chapter 5. Perform a urine pregnancy test on females of all person types who are aged 12-59 years and girls aged 8-11 who report that they are menstruating when asked during the home interview. If a urine pregnancy test is positive on any female SP aged 8-17, confirm the result using serum. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function. Assay all specimens immediately and record results in the Laboratory Pregnancy Testing module.

### **V. Procedure for Microscopic Examination**

Not applicable.

## **VI. Reagents and Supplies**

### **A. Reagents**

ICON® 25 hCG Urine/Serum test kit

Product Number 43025 (25)

Beckman Coulter

4300 N. Harbor Blvd

Fullerton, CA 92834-3100

1-800-877-6242 or 650-845-3526

#### ■ Components

- One test device. (25) – Contains anti-hCG particles and anti-hCG coating on the membrane.
- Disposable sample droppers - Plastic pipettes for measuring and dispensing patient samples. (Packaged together with the test device in a white foil pouch.)
- Zip closable bag with two extra sample droppers
- Product instructions

#### ■ Storage and Stability

- Store the ICON 25 hCG test kit at 2 - 30°C, (59 - 83°F). The test device is stable up to the expiration date printed on the sealed pouch. Keep the test device in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond expiration date. Date and initial the kit when putting it into use.

Sure-Vue™ hCG Control Sets – Urine and Serum

Sure-Vue™ hCG Control Sets – Urine

Product Number SA087413-F

Fisher Scientific Company

1-888-727-3315 (Technical assistance)

#### ■ Components - Sure-Vue™ hCG Control Set

- Urine is a stable human urine-based material for use as a quality control material. Use controls in the same manner as SP specimens in accordance with the protocol provided in the Sure-Vue™ hCG Control Sets directional insert.

- Low Positive Control: Human urine containing approximately 25 mIU hCG/mL and 0.2% sodium azide as a preservative. ( 1 x 5 mL)
- High Positive Control: Human urine containing approximately 250 mIU hCG/mL and 0.2% sodium azide as a preservative. ( 1 x 5 mL)
- Negative Control: Contains 0.2% sodium azide as a preservative. ( 1 x 5 mL)
- Storage and Stability - Sure-Vue™ hCG Control Set
  - Store the urine control set between 2 to 8°C (35 to 46°F) at which temperatures these controls are stable until the expiration date printed on the label.

Sure-Vue™ hCG Serum Control Set  
 Product Number 087712-F  
 Fisher Scientific Company  
 1-888-727-3315 (Technical assistance)

- Components - Sure-Vue™ hCG Serum Control
  - The Sure-Vue™ hCG Serum Control is a stable human serum-based material for use as a quality control material. Use controls in the same manner as SP specimens in accordance with the protocol provided in the Sure-Vue™ hCG Control Set directional insert.
  - Low Positive Control: Human serum containing approximately 25 mIU hCG/mL and 0.2% sodium azide as a preservative. ( 1 x 5 mL)
  - High Positive Control: Human serum containing approximately 250 mIU hCG/mL and 0.2% sodium azide as a preservative. ( 1 x 5 mL)
  - Negative Control: Contains 0.2% sodium azide as a preservative. ( 1 x 5 mL)
- Storage and Stability - Sure-Vue™ hCG Serum Control
  - Store the Sure-Vue™ hCG Serum Control Set between 2 to 8°C (35 to 46°F) at which temperatures these controls are stable until the expiration date printed on the label.

## **B. Supplies**

- Timer

**VII. Calibration**

Not applicable

**VIII. Assay Procedure**

ICON® 25 hCG Test kit

- Label each test device with the preprinted label or write the SP ID on a clear section of the test device using a felt tip pen.
- Use a new transfer dropper for each specimen.

Sure-Vue™ hCG Urine and Serum Control Sets

- The Sure-Vue™ urine and serum controls have their own droppers. The use of the control droppers to add three drops of sample has been validated; do not use the ICON 25 hCG plastic pipette to add controls.
- Allow controls to reach room temperature before testing. The controls are ready to use. No dilution is required.
- The controls are used in place of the specimen and should be tested according to the ICON® 25 hCG test procedure.
- Discard the high positive urine and serum vials. (250 mIU/mL).

**Urine or Serum Testing Procedure**

Perform the test procedure for ICON® 25 hCG Urine/Serum test at room temperature (15 - 30°C, 59 - 86°F). Before proceeding, carefully read Section XII. entitled “Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions.”

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer three full drops of urine or serum (approximately 100 µL) to the sample well (S)

of the test device, and then start the timer. Avoid trapping air bubbles in the sample well.

3. Wait for the red line(S) to appear. Read the results at 3 minutes when testing a urine sample or 5 minutes when testing a serum sample. It is important that the background is clear before the result is read.

Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period; therefore, do not interpret the result after 3 minutes when testing a urine sample or after 5 minutes when testing a serum sample.

## **IX. Reportable Range of Results**

Report test results as Positive, Negative, or Invalid.

## **X. Quality Control**

Run negative and low positive urine controls containing hCG at concentrations of 0 and 25 mIU/mL, respectively, just prior to or concurrently with the first examinee pregnancy test each exam day and when putting a new lot into use. Run negative and low positive serum controls with each serum pregnancy test. The pregnancy QC module contains the following information:

- The session ID number links to the stand number, stand location, date, including day, month, and year. The technologist ID is automatically captured.
- Kit lot number and expiration date fill in automatically from the prior QC report. Update or manually enter this information if necessary.
- The control lot number and expiration date for both the urine and serum control fills in automatically from the prior QC report. Update or manually enter this information if necessary.
- The Control QC Type is either urine or serum. The default type is set as urine.
- Negative Control result
- Positive Control result

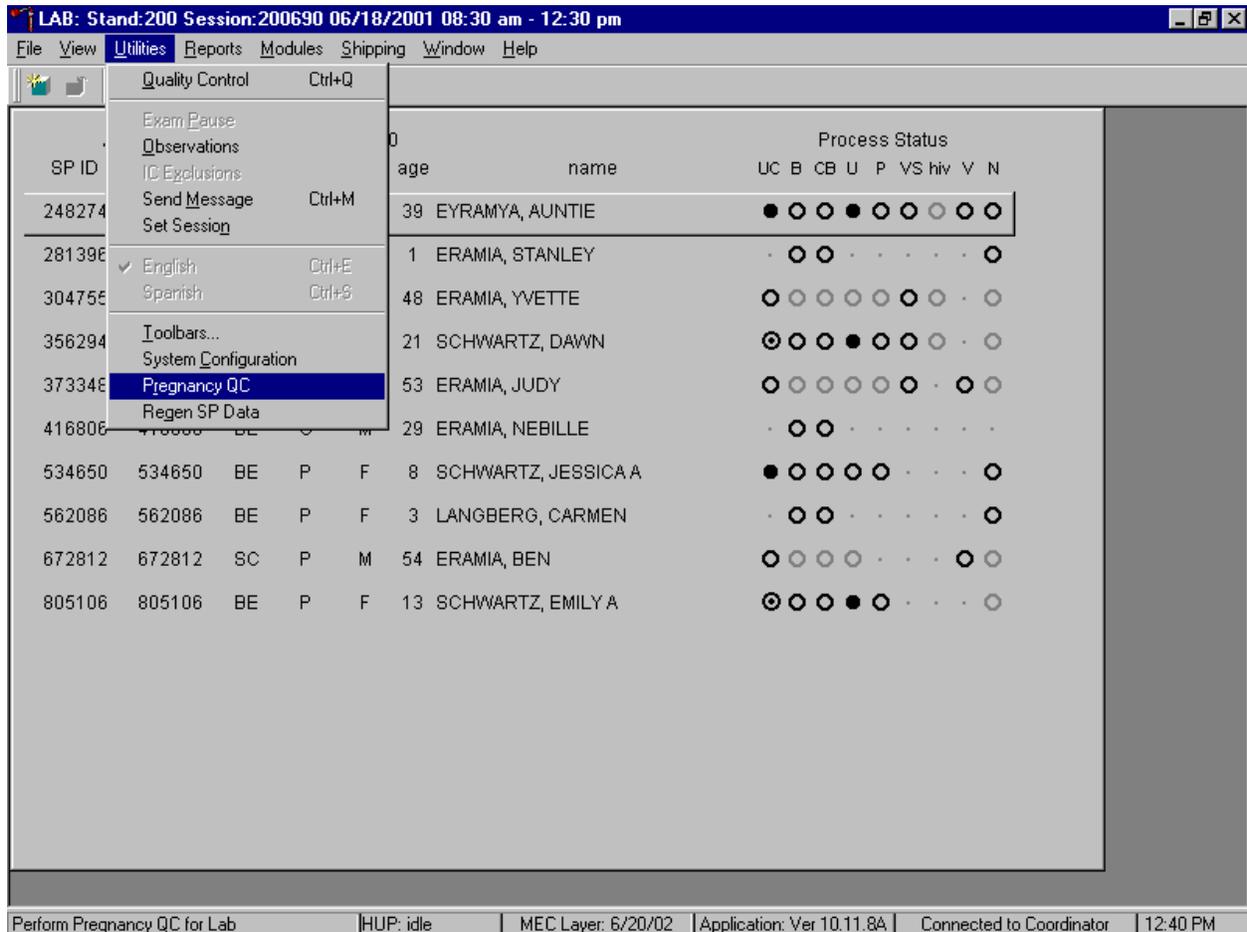
## **CAP Proficiency Testing**

For purposes of this document, proficiency testing is one method of external quality control in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 3 months).

Participation in the College of American Pathologist (CAP) EXCEL proficiency-testing program is part of the comprehensive quality control program. Each MEC submits results for CAP specimens for evaluation. CAP compares the results to established values and issues a report.

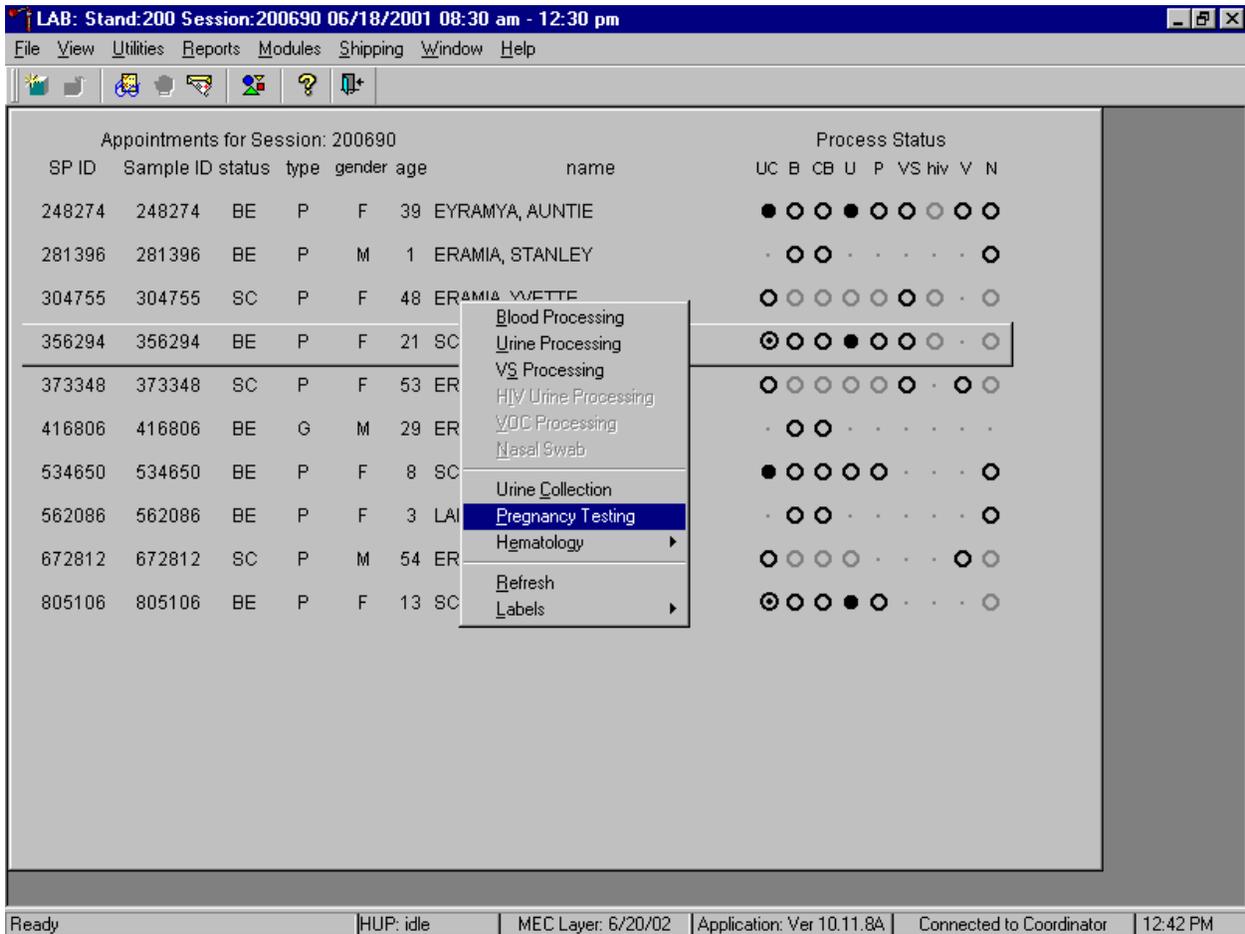
CAP sends samples three times a year for qualitative serum hCG and urine hCG. Each serum survey includes five lyophilized sera specimens and each urine survey includes 5 liquid specimens. Handle and analyze these samples in a manner identical to SP samples. Record results on the CAP forms and send to the address specified by CAP Surveys Program Support. Send a copy of the CAP form to the home office at the end of the stand.

Open the Pregnancy QC module.



To open the pregnancy QC module, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the arrow to {Pregnancy QC}, and left click or type [Alt] [U/u], [R/r].

Alternatively, open the Pregnancy QC module from the heads-up screen.



To access the Pregnancy QC module from the heads-up screen, use the up and down keys to move up and down the list until the correct SP is highlighted or use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing}, and left click or left click and type [P/p].

The pregnancy QC window displays.

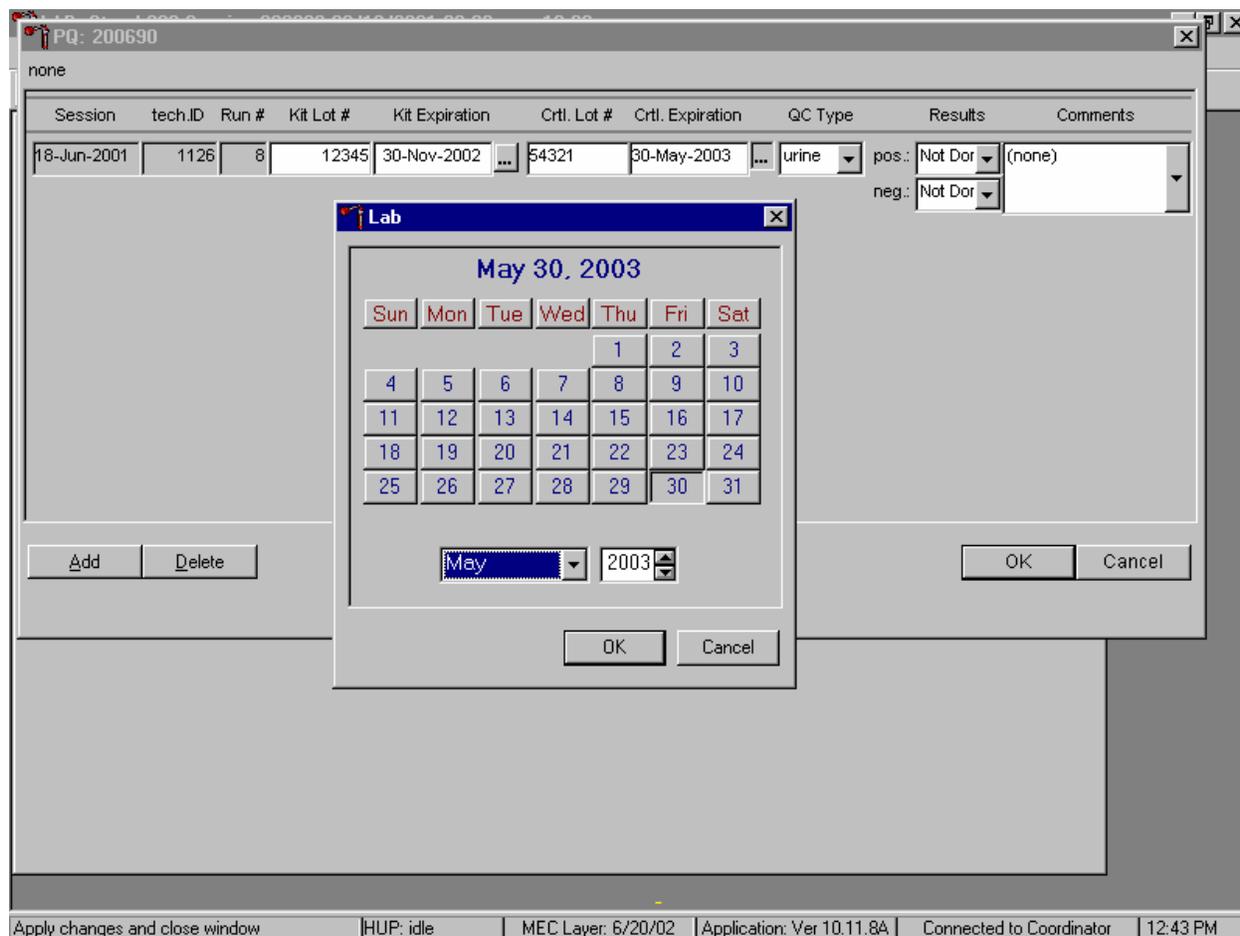
The screenshot shows a software window titled "PQ: 200690". Inside the window, there is a data entry form with the following fields and values:

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Not Done neg.: Not Done	(none)

At the bottom of the window, there are buttons for "Add", "Delete", "OK", and "Cancel". The status bar at the very bottom of the application shows: "Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:43 PM".

The pregnancy QC module automatically captures the session date and technologist ID and assigns the run number. The module defaults to the last kit lot number, kit expiration date, Ctrl (control) lot number, Ctrl expiration date, and the QC type - urine. Verify the existing kit lot number and expiration date. If the lot number is incorrect, type in the new kit lot number using the keyboard's numeric keys and select [Tab] to progress to the Kit Expiration blank. Use the calendar to correct the Kit Expiration date. If the screen defaults to the current Ctrl lot number, verify the existing lot number and expiration date. If the lot number is incorrect, type in the new control lot number using the keyboard numeric keys and select [Tab] to progress to the Ctrl Expiration blank. Use the calendar to correct either the Kit or the Ctrl Expiration date.

Update the Kit or Ctrl Expiration date using the calendar function.



Type in the date using the keyboard's numeric keys and the dd/mm/yyyy format and select [Tab] or use the calendar to enter the date. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis and left click. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to up down controls on the spin box and toggle the year up and down. To transfer this date into the text box, use the mouse to direct the mouse arrow to the OK button and left click; to exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Select the control QC type.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Not Dor	(none)
							serum	neg.: Not Dor	
							urine		

Buttons: Add, Delete, OK, Cancel

Footer: Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:44 PM

The QC control type default is “Urine.” To change the QC type to serum or to select urine, use the mouse to direct the mouse arrow to the drop-down list, drag the mouse arrow to either serum or urine and left click. Alternatively, highlight the QC type text box and type [S/s] for serum or [U/u] for urine and [Tab] to move to the result test boxes.

Record the positive and negative control results.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Not Done neg.: Positive Negative Invalid	(none)

Buttons: Add, Delete, OK, Cancel

Footer: Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:45 PM

To enter a result in the positive result text box, type [P/p] for “Positive,” [N/n] for “Negative,” or [I/i] for “Invalid” or use the up and down arrow keys to toggle between the three choices: Positive, Negative, and Invalid and select [Tab]. Alternatively, use the mouse to direct the mouse arrow to the drop-down list, drag the mouse arrow to “Positive,” “Negative,” or “Invalid” and left click. If “Positive” is entered, the Negative response box is highlighted. Type [Tab] to move to the negative result text box.

Enter a result in the negative result text box.

The screenshot shows a software window titled "PQ: 200690" with a table of data. The table has columns for Session, tech.ID, Run #, Kit Lot #, Kit Expiration, Crtl. Lot #, Crtl. Expiration, QC Type, Results, and Comments. The first row contains the following data: 18-Jun-2001, 1126, 8, 12345, 30-Nov-2002, 54321, 30-May-2003, urine, and pos.: Positive (none). A dropdown menu is open for the "neg." column, showing options: Not Done, Positive, Negative, and Invalid. The "Not Done" option is currently selected. Below the table are buttons for "Add", "Delete", "OK", and "Cancel". At the bottom of the window, a status bar displays: "Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:45 PM".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Positive (none) neg.: Not Done	

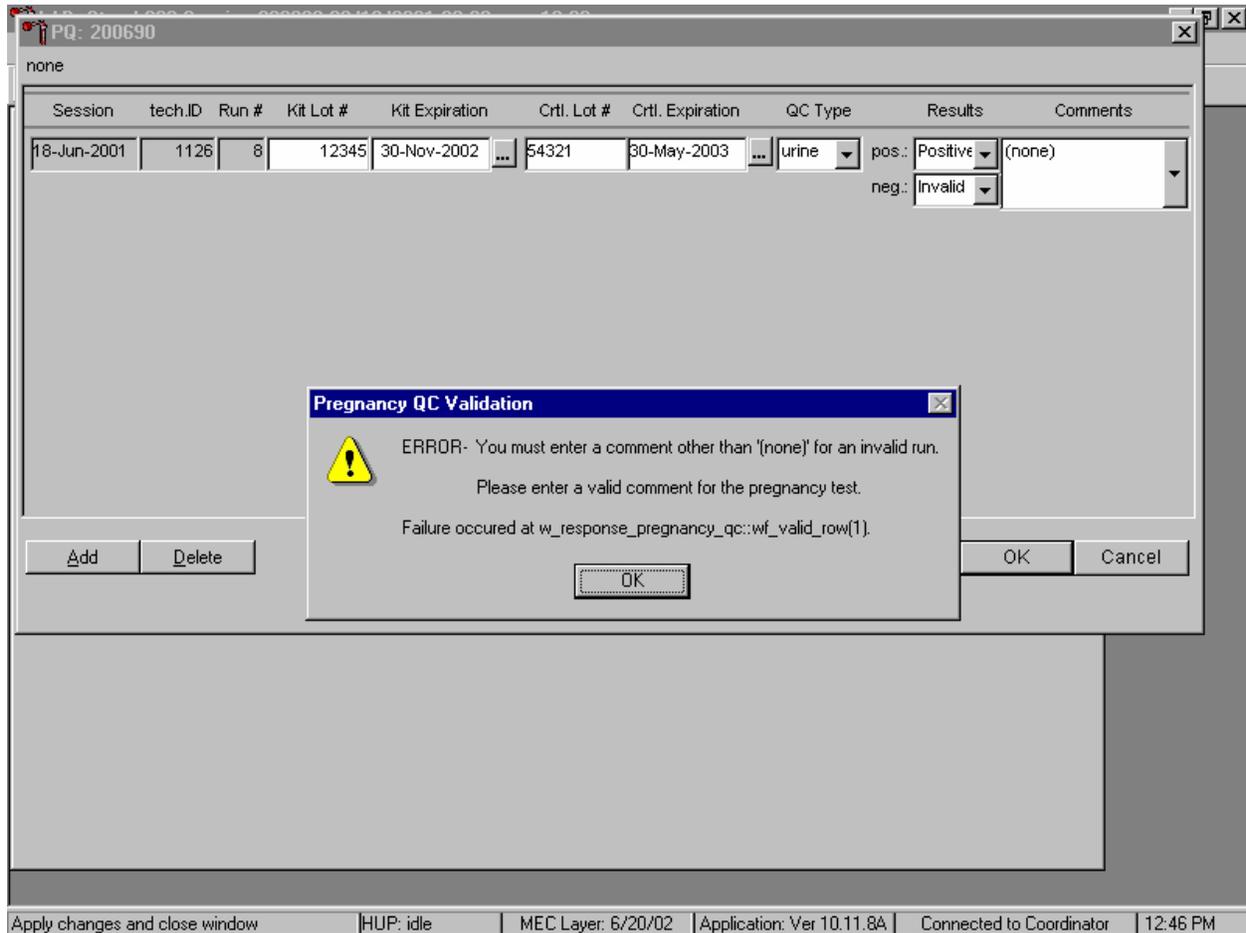
To enter a result in the negative result text box, type [P/p] for “Positive,” [N/n] for “Negative,” or [I/i] for “Invalid” or use the up and down arrow keys to toggle between the three choices: Positive, Negative, and Invalid and [Tab]. Alternatively, use the mouse to direct the mouse arrow to drop-down list, drag the mouse arrow to “Positive,” “Negative,” or “Invalid,” and left click.

Save results when positive and negative controls demonstrate the expected result.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Positive neg.: Negative	(none)

If the positive and negative controls demonstrate the expected result, use the mouse to direct the mouse arrow to the OK button and left click to save these results and to proceed with pregnancy testing. To cancel and exit the module without recording or saving any QC results to the database, use the mouse to direct the mouse arrow to the Cancel button and left click. To delete the information in the window and exit the module without recording or saving any QC results to the database, use the mouse to direct the mouse arrow to the Delete button and left click or type [Shift] [D/d].

Enter a comment for any result that is inconsistent with expected results. If the OK button is selected before a comment is entered, the ERROR informational message box displays. Review the text in this box.



To close the box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

Enter a comment for any result that is inconsistent with expected results.

The screenshot shows a software window titled "PQ: 200690" with a table of data. The table has the following columns: Session, tech.ID, Run #, Kit Lot #, Kit Expiration, Ctrl. Lot #, Ctrl. Expiration, QC Type, Results, and Comments. The first row of data is: 18-Jun-2001, 1126, 8, 12345, 30-Nov-2002, 54321, 30-May-2003, urine, pos.: Positive, neg.: Invalid, and (none). A dropdown menu is open over the "Results" column, showing a list of options: (none), no additional test kit, opened new test kit s, repeat negative contro, and repeat positive contro. The "Comments" column is currently empty. At the bottom of the window, there are buttons for "Add", "Delete", "OK", and "Cancel". The status bar at the bottom of the window displays: "Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:46 PM".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Positive neg.: Invalid	(none)

Enter the appropriate comment in the "Comments" column by using the mouse to direct the mouse arrow to the drop-down list, left click to display the choices, drag the mouse arrow to the most appropriate choice, and left click when the correct choice is highlighted. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

Review the comment.

none

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Positive neg.: Invalid	repeat negative cont

Add Delete OK Cancel

Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:47 PM

Review all the information in the QC window to verify its accuracy.

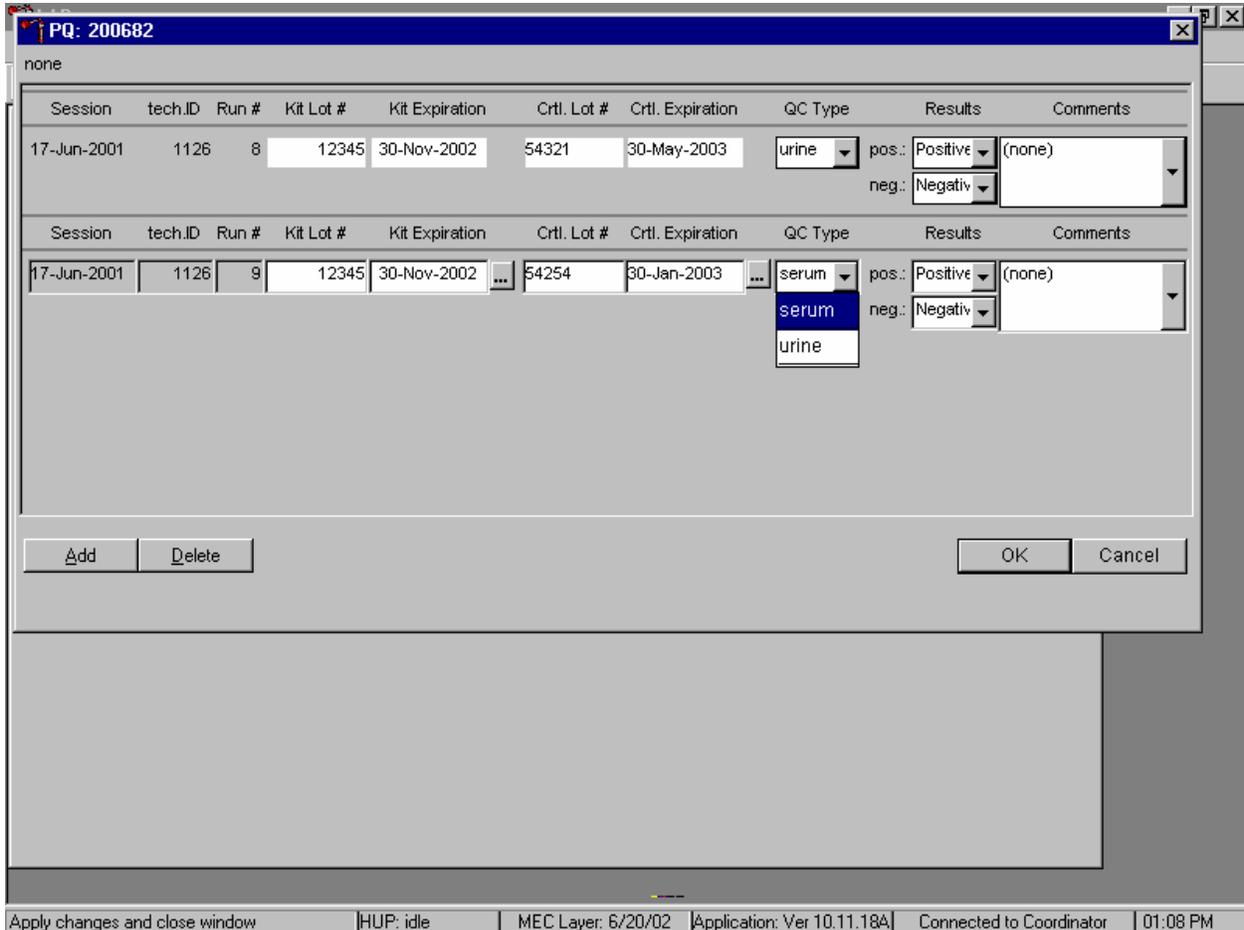
Add a new QC record and repeat the control for invalid or unexpected results.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Positive neg.: Invalid	repeat negative conti
18-Jun-2001	1126	9	12345	30-Nov-2002	54321	30-May-2003	urine	pos.: Positive neg.: Negative	(none)

Rerun or repeat the control that demonstrated the unexpected result. Add a new test line to record the new control results. To add a new QC test line, use the mouse to direct the mouse arrow to the Add button and left click or type [Shift] [A/a]. Record the new results. If this resolves the inconsistency, use the mouse to direct the mouse arrow to the OK button and left click to save these results and to proceed with pregnancy testing.

If this does not resolve the situation, repeat the procedure with a different lot of controls. If this fails to resolve the problem, discard the entire lot of pregnancy test kits and test a new lot.

Add a new test line each time a control is run and remember to record the serum QC each time it is performed.



To add a new QC test line, use the mouse to direct the mouse arrow to the Add button and left click or type [Shift] [A/a]. The QC Type defaults to “Urine.” Correct the control lot number and expiration date. To change the QC type to serum, use the mouse to direct the mouse arrow to the drop-down list, drag the mouse arrow to serum and left click.

Record the serum control results.

The screenshot shows a software window titled "PQ: 200690" with a table of QC records. The table has columns for Session, tech.ID, Run #, Kit Lot #, Kit Expiration, Ctrl. Lot #, Ctrl. Expiration, QC Type, Results, and Comments. Two records are visible. The second record is selected, and the "serum" option is chosen for the QC Type. The result for the positive control is "Positive" and for the negative control is "Negative".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
18-Jun-2001	1126	8	12345	21-Jul-2001	54321	21-Jul-2001	urine	pos.: Positive neg.: Negative	(none)
18-Jun-2001	1126	9	12345	21-Jul-2001	54254	21-Jul-2001	serum	pos.: Positive neg.: Negative	(none)

Buttons: Add, Delete, OK, Cancel

Footer: Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:49 PM

If the positive and negative serum controls demonstrate the expected result, use the mouse to direct the mouse arrow to the OK button and left click to save these results and to proceed with pregnancy testing. If the positive and/or the negative serum controls fail to demonstrate the expected result(s), add a new QC record, and repeat the control.

**XI. Interpretation of Results and Remedial Action**

**ICON® 25 hCG Test**

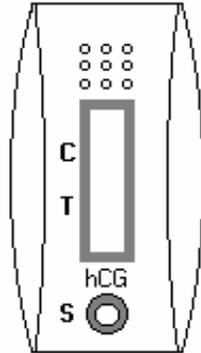


Figure 1  
ICON 25 test device

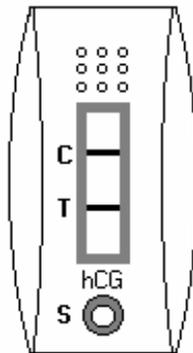


Figure 2  
Positive Result  
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

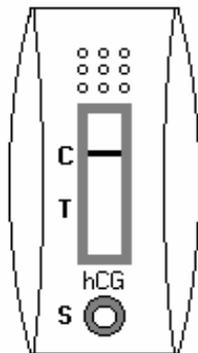


Figure 3  
Negative Result  
One red line appears in the control region (C). No apparent red or pink line appears in the test region.

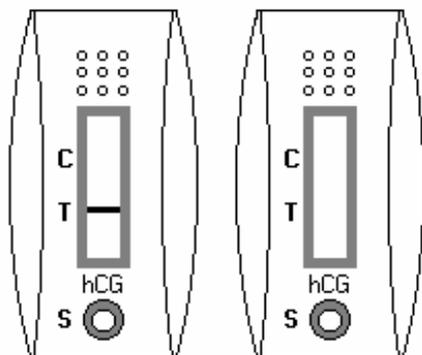


Figure 4  
Invalid Result  
Control line fails to appear.

**Positive Result:**

A specimen that produces two distinct red lines is positive for the presence of hCG. One line should be in the control region (C) and another line should be in the test region (T).

**Negative Result:**

A specimen that does produce a red line appears in the control region (C) or no apparent red or pink line in the test region is negative for the presence of hCG.

**Invalid Result (any of the following):**

For the test to be valid, a red line must appear in the control region (C). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit and immediately contact the technical supervisor.

If an invalid test result occurs repeatedly, or for technical assistance, contact the Technical Support Department, 1-800-877-6242.

**Sure-Vue™ hCG Urine and Serum Control Sets**

**Positive Result:**

The 25 mIU/mL hCG positive urine and serum controls should produce positive results.

**Negative Result:**

The negative urine and serum control should produce a negative result.

## XI. Record Results

Use the heads-up display and the Pregnancy Testing module to enter the results of the ICON® 25 hCG test kit pregnancy test result for each SP.

Use the heads-up display to access the Pregnancy Testing module.

The screenshot shows a software window titled "LAB: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The interface includes a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar with various icons. The main area displays a table of appointments for session 200690. The table has columns for SP ID, Sample ID, status, type, gender, age, name, and Process Status. The Process Status column contains a series of circles representing different test results. A context menu is open over the row for SP 356294, with "Pregnancy Testing" highlighted. The status bar at the bottom shows "Ready", "HUP: idle", "MEC Layer: 6/20/02", "Application: Ver 10.11.8A", "Connected to Coordinator", and "12:51 PM".

Appointments for Session: 200690							Process Status								
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N
248274	248274	BE	P	F	39	EYRAMYA, AUNTIE	●	○	○	○	○	○	○	○	○
281396	281396	BE	P	M	1	ERAMIA, STANLEY	-	○	○	-	-	-	-	-	○
304755	304755	SC	P	F	48	ERAMIA, YVETTE	-	-	-	-	-	-	-	-	-
356294	356294	BE	P	F	21	SCHWARTZ, DAWN	●	○	○	○	○	○	○	○	○
373348	373348	SC	P	F	53	ERAMIA, JUDY	-	-	-	-	-	-	-	-	-
416806	416806	BE	G	M	29	ERAMIA, NEBILLE	-	-	-	-	-	-	-	-	-
534650	534650	BE	P	F	8	SCHWARTZ, JESSI	○	○	-	-	-	-	-	-	○
562086	562086	BE	P	F	3	LANGBERG, CARM	-	-	-	-	-	-	-	-	○
672812	672812	SC	P	M	54	ERAMIA, BEN	○	-	-	-	-	-	○	○	-
805106	805106	BE	P	F	13	SCHWARTZ, EMILY	●	○	-	-	-	-	-	-	○

To access the Pregnancy Testing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing}, and left click, or left click and type [P/p]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Pregnancy Testing}, and left click or left click and type [P/p].

The Pregnancy Testing window displays.

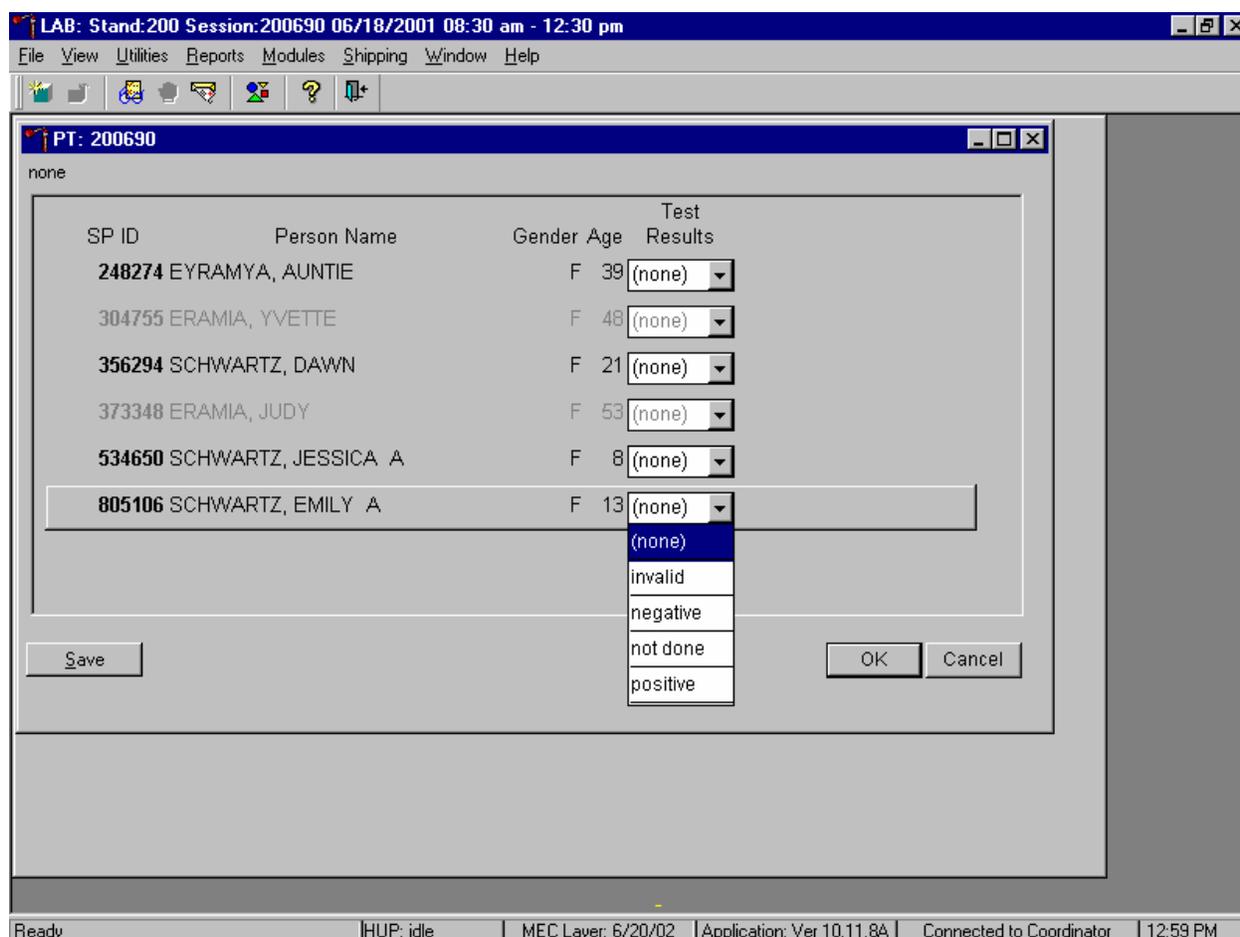
The screenshot shows a software window titled "LAB: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". Inside, there is a sub-window titled "PT: 200690" with a "none" label. The main area contains a table with the following data:

SP ID	Person Name	Gender	Age	Test Results
248274	EYRAMYA, AUNTIE	F	39	(none)
304755	ERAMIA, YVETTE	F	48	(none)
356294	SCHWARTZ, DAWN	F	21	(none)
373348	ERAMIA, JUDY	F	53	(none)
534650	SCHWARTZ, JESSICA A	F	8	(none)
805106	SCHWARTZ, EMILY A	F	13	(none)

Below the table are three buttons: "Save", "OK", and "Cancel". The status bar at the bottom shows: "Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.8A | Connected to Coordinator | 12:58 PM".

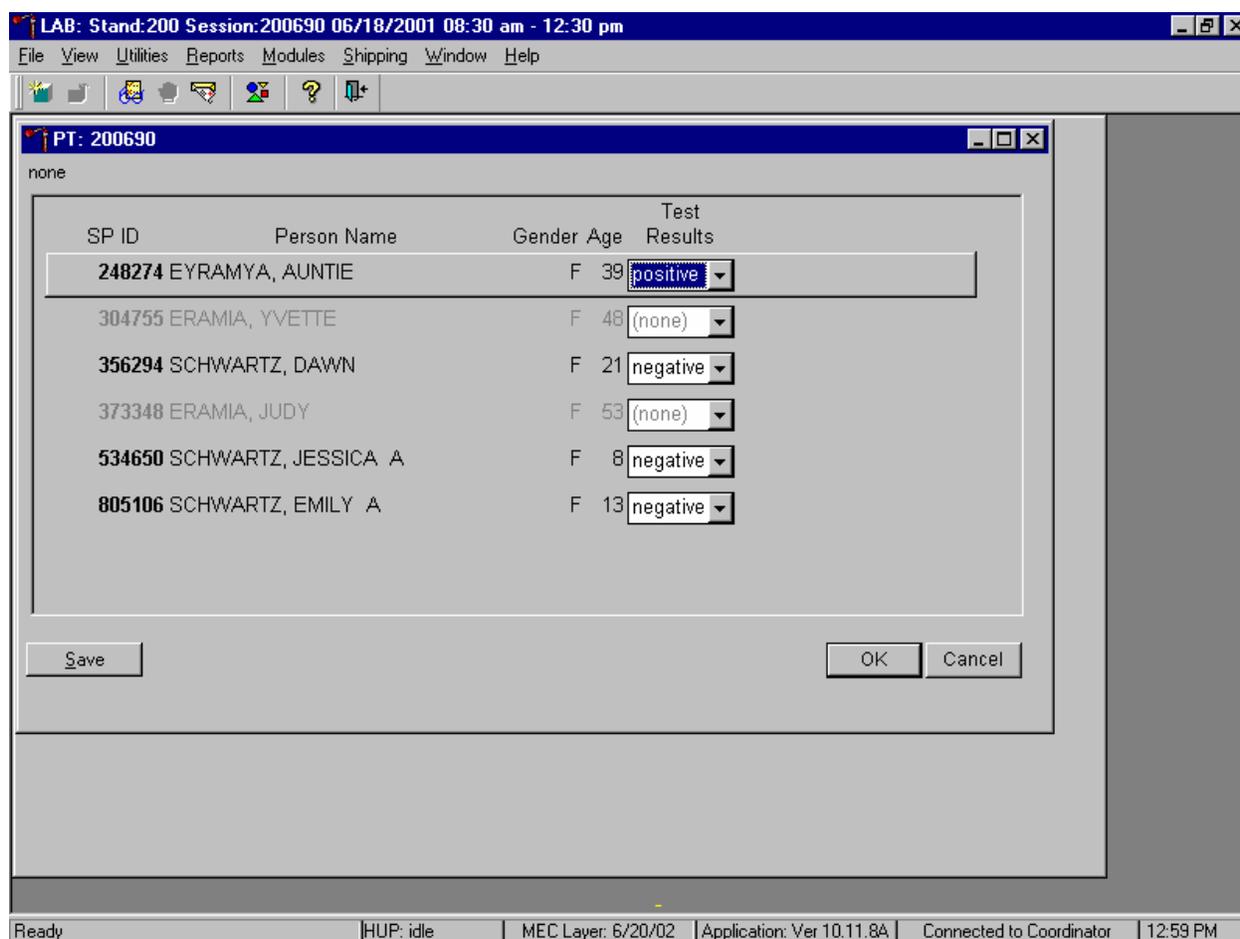
The text is black for SPs who have urine collection results recorded as “yes” or “yes/QNS.” The text is gray for SPs who do not have urine collection results recorded. The window lists the SP ID, Person Name, Gender, Age, and includes a Test Results column (text box).

Report the results for each SP as Positive, Negative, or Invalid.



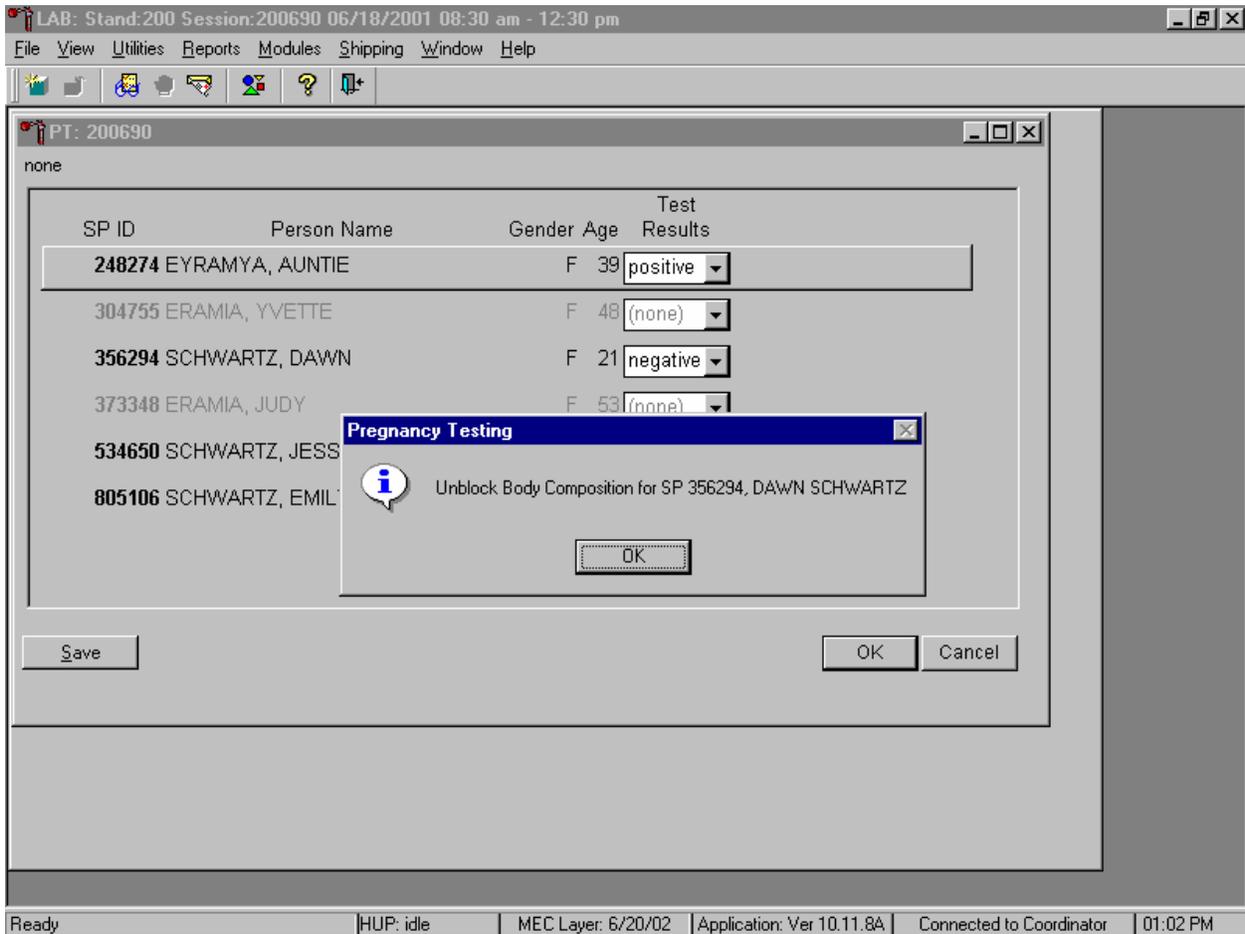
If the Test Result field is black or highlighted, record the result by typing [P/p] for Positive, [N/n] for Negative, or [I/i] for an invalid result. Alternatively, to record a result, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct choice and left click. To update the results without exiting the window, use the mouse to direct the mouse arrow to the Save button and left click or type [ALT] [S/s]. To update the results and exit the window, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit the module without saving any result, use the mouse to direct the mouse arrow to the Cancel button and left click.

Continue performing pregnancy tests and recording the results.



Save the test results after entering each positive, negative, or invalid result. To update the results without exiting the window, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To update the results and exit the window, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit the module without saving any result, use the mouse to direct the mouse arrow to the Cancel button and left click.

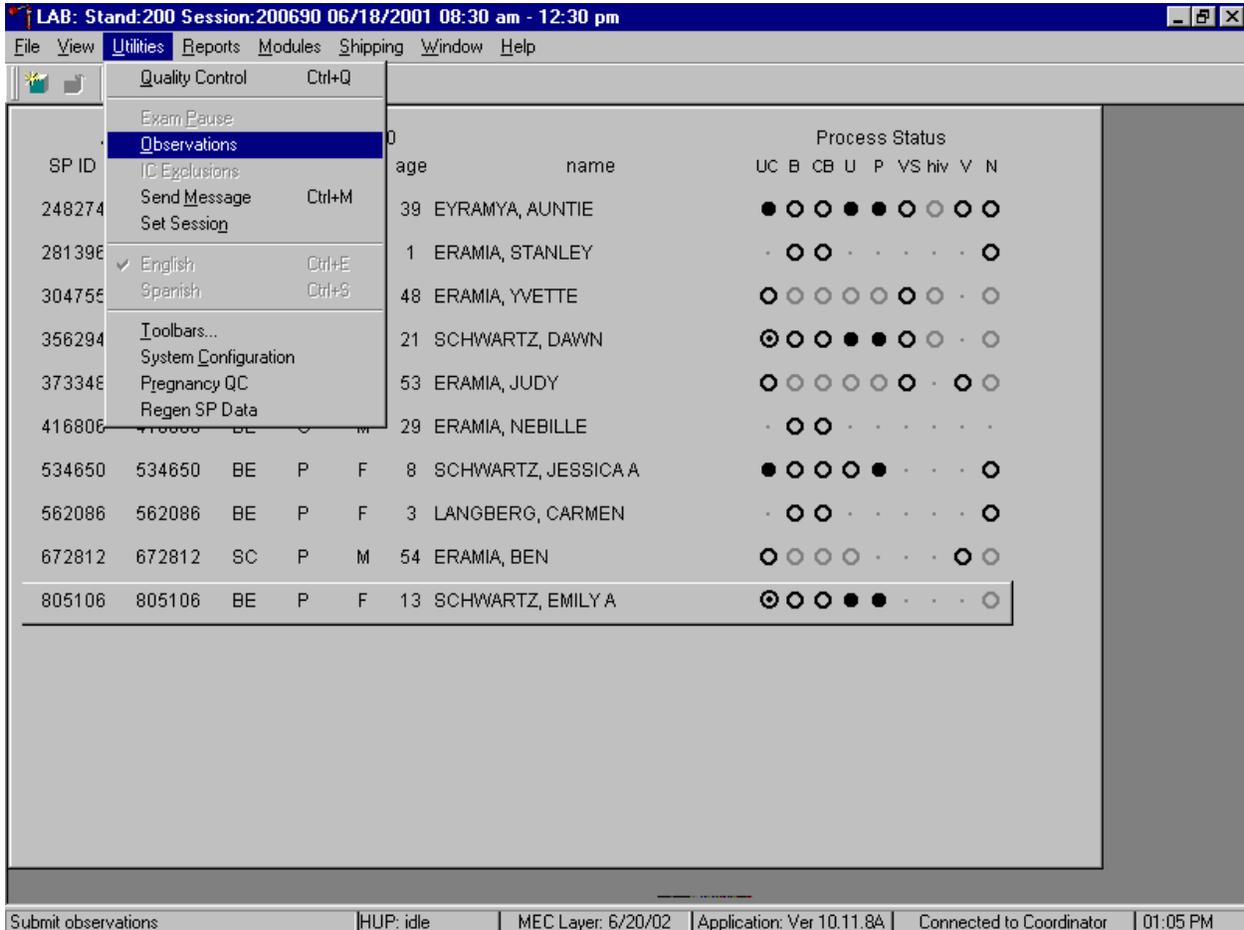
After each negative result is saved to the database, an unblocking message box displays.



To remove the informational message box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

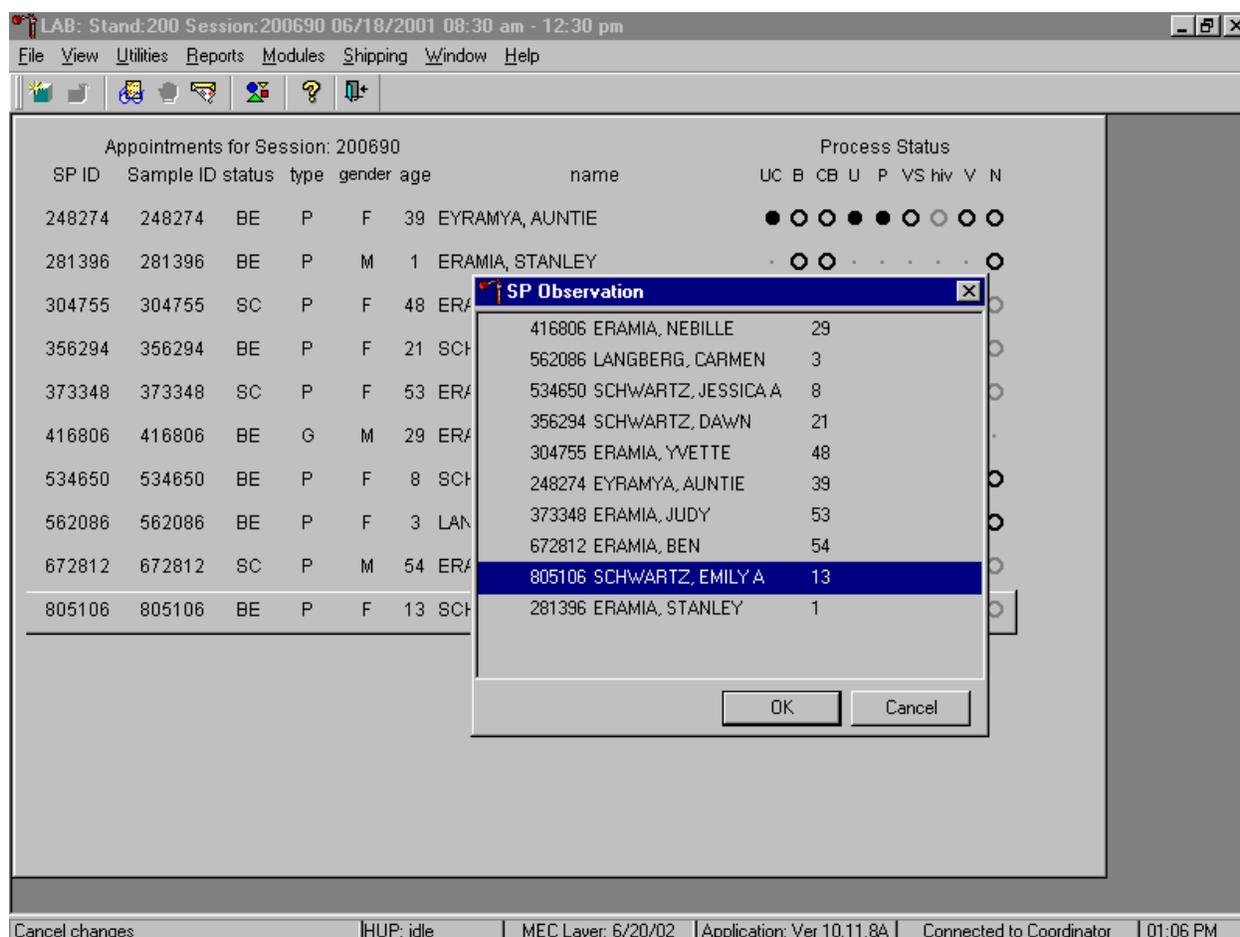
If a urine pregnancy test is positive on any female SPs aged 8-17 years, confirm the result using serum. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.

Access the observation function to send an observation to the physician.



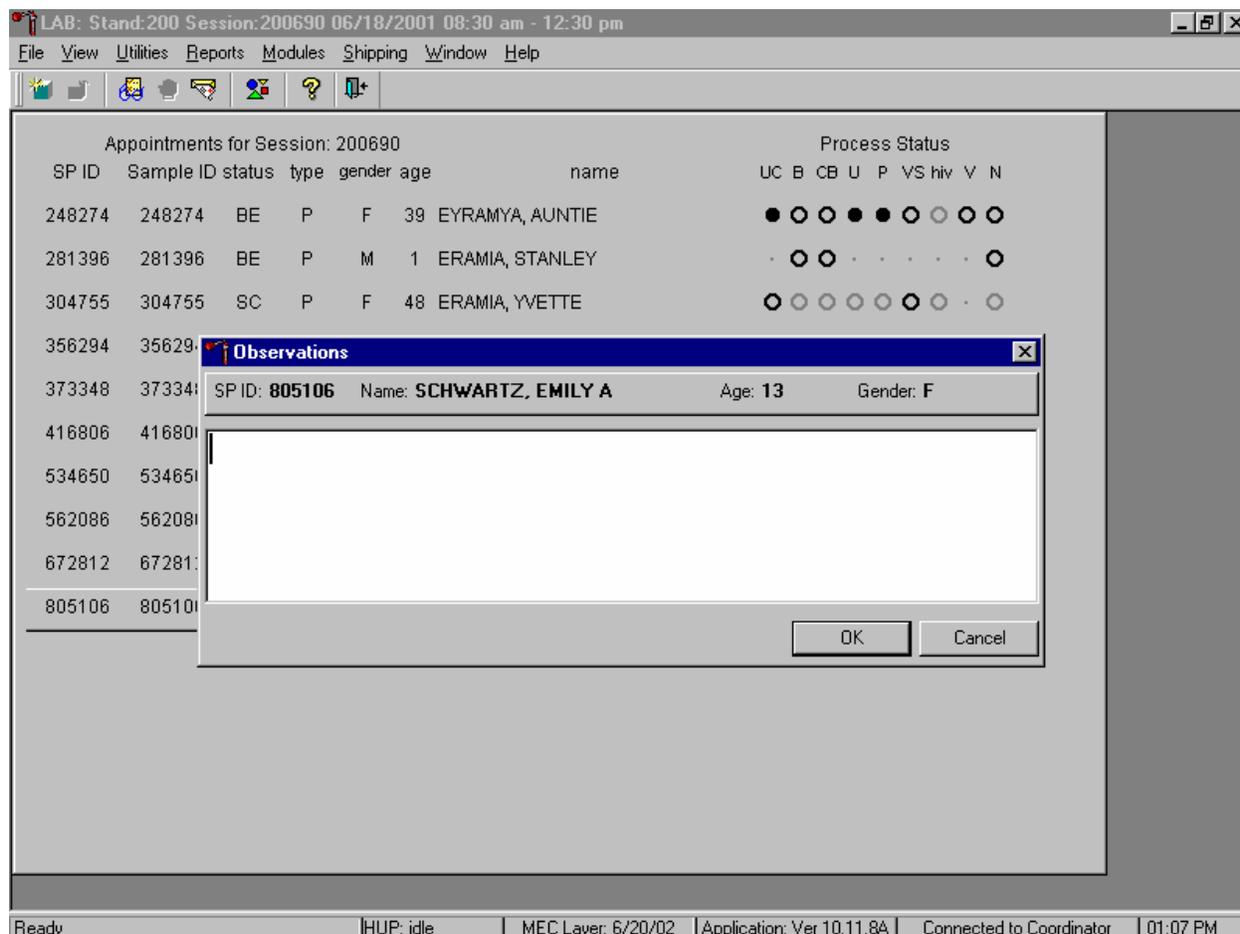
To send an observation to the physician, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the mouse arrow to {Observations} and left click or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



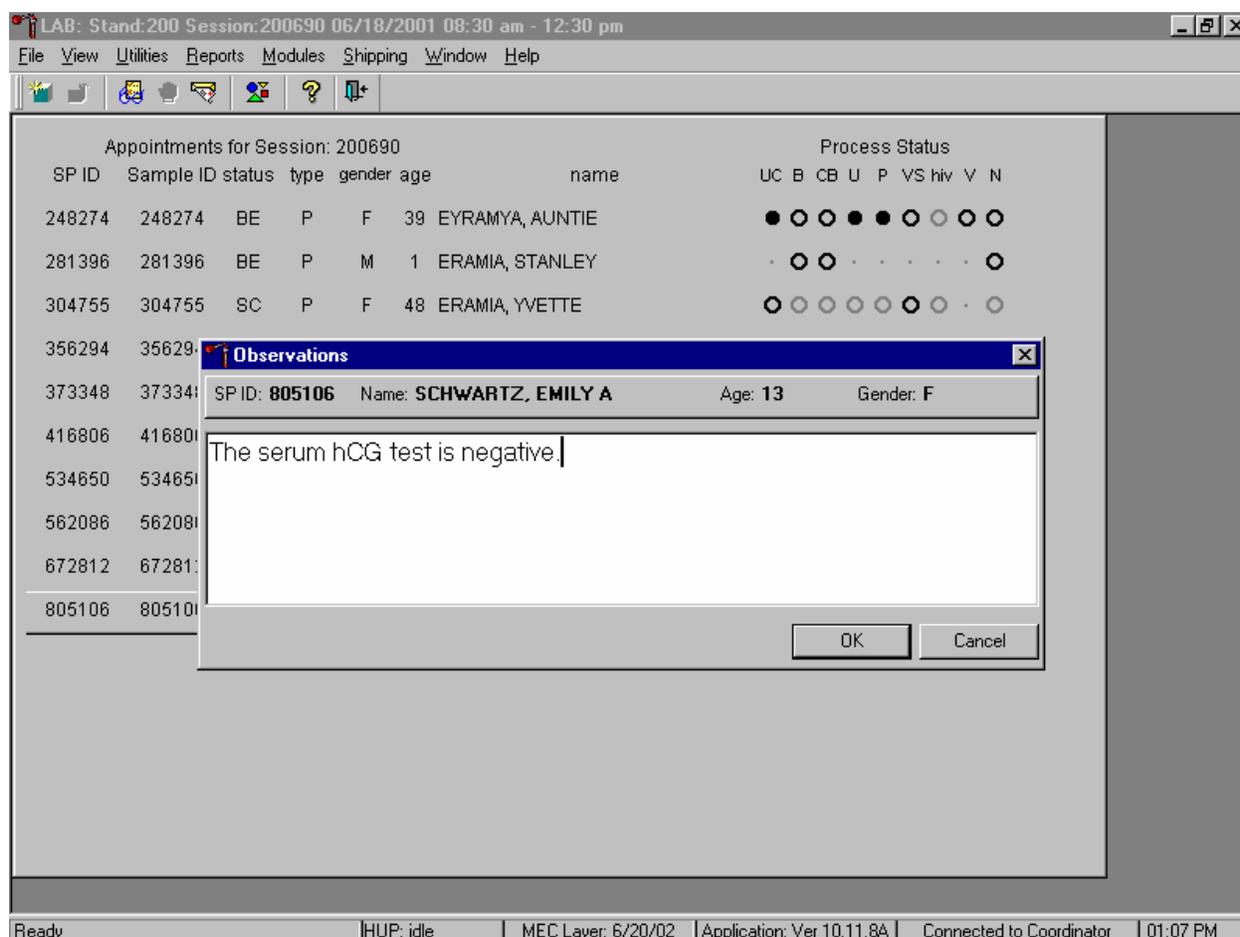
To select or highlight an SP, drag the mouse arrow to the correct SP and left click. Verify that the SP ID, name, and age are correct. Use the vertical scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the Cancel button and left click.

The observation text window displays.



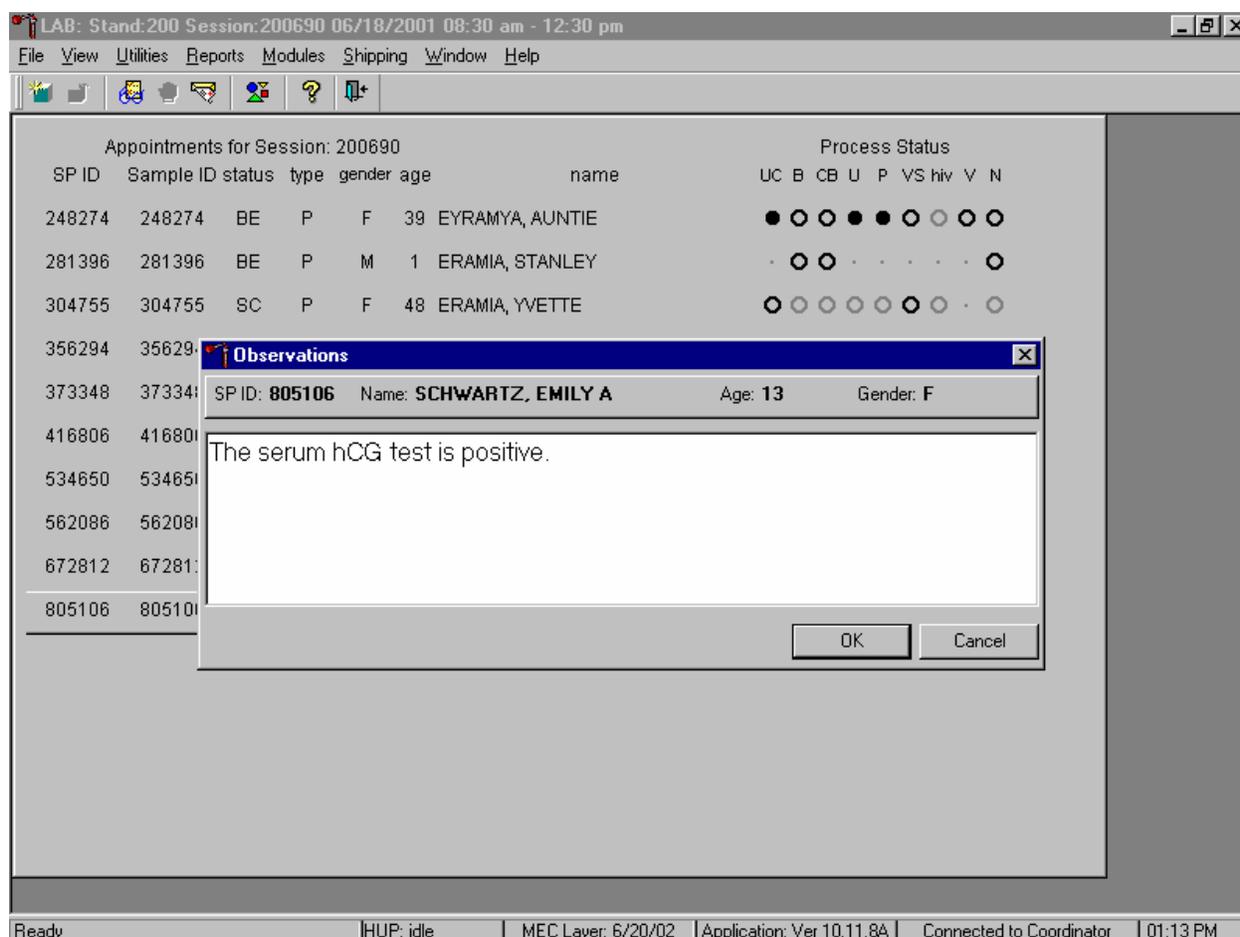
The observation text window contains the SP ID, name, age, and gender. Type the observation using the keyboard's keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report a negative serum test result on SPs aged 8-17 years.



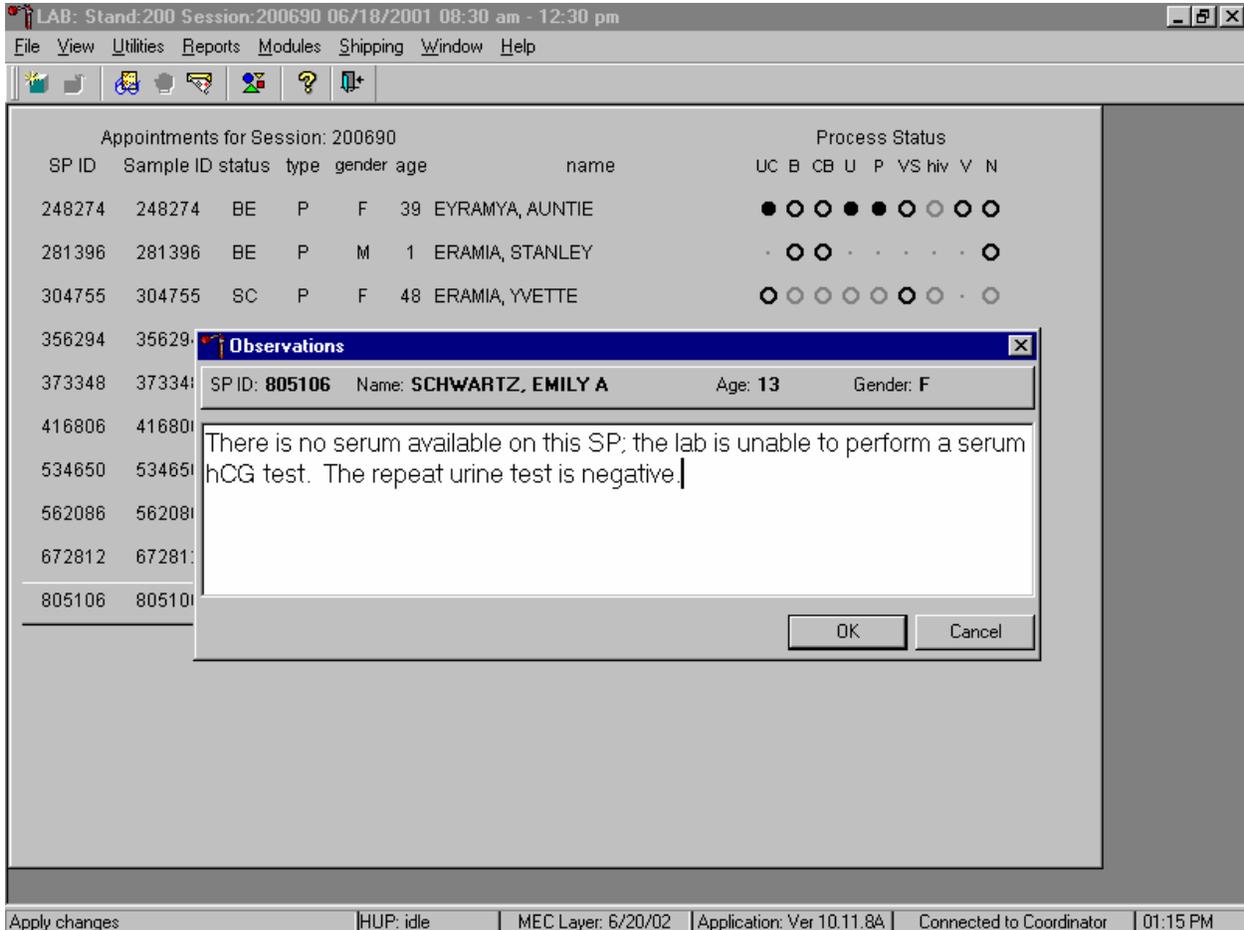
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum hCG test is negative” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report a positive serum test result on SPs aged 8-17 years.



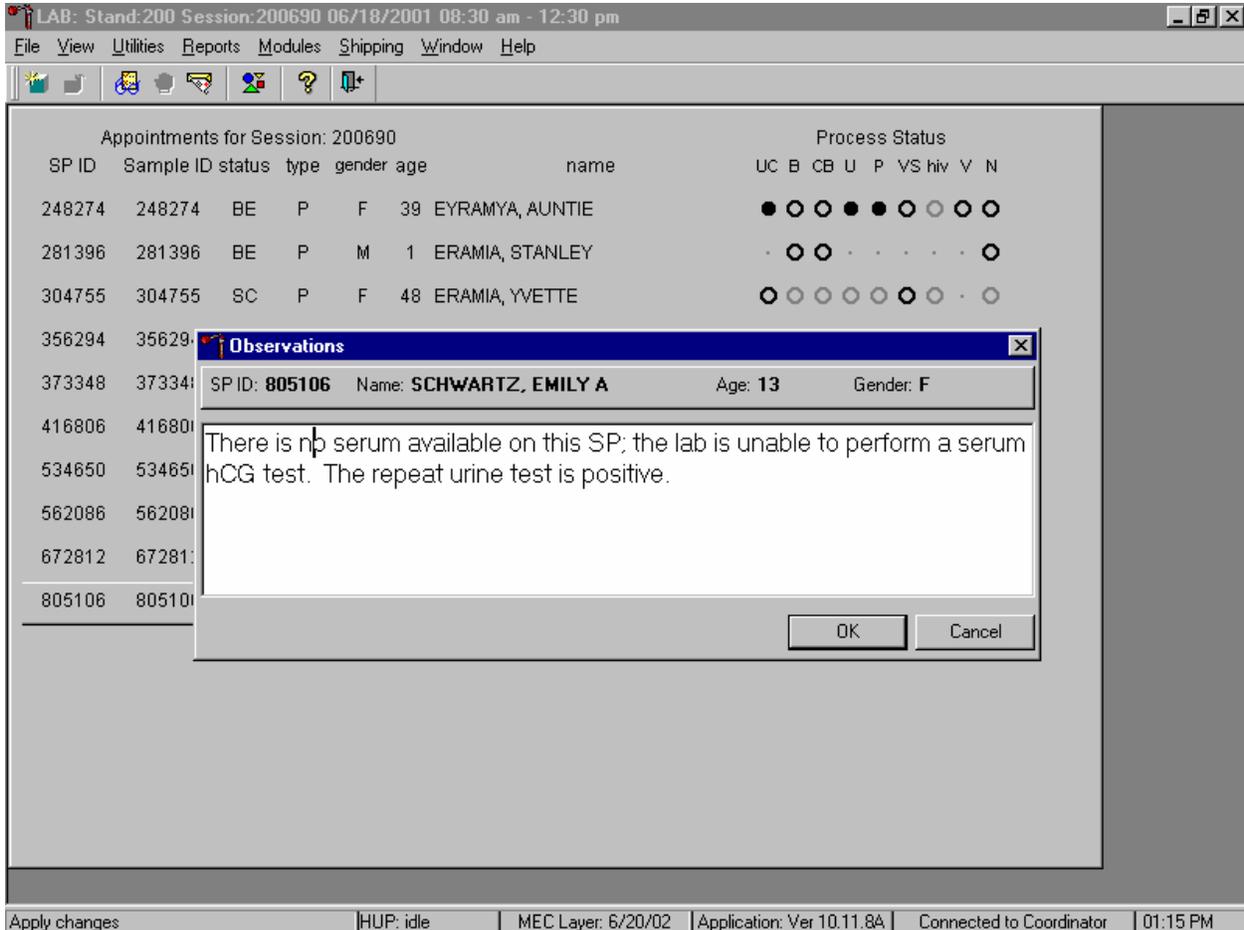
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum hCG test is positive” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report the inability to perform the serum confirmation test and to report the results of a repeat negative urine test on female SPs aged 8-17 years.



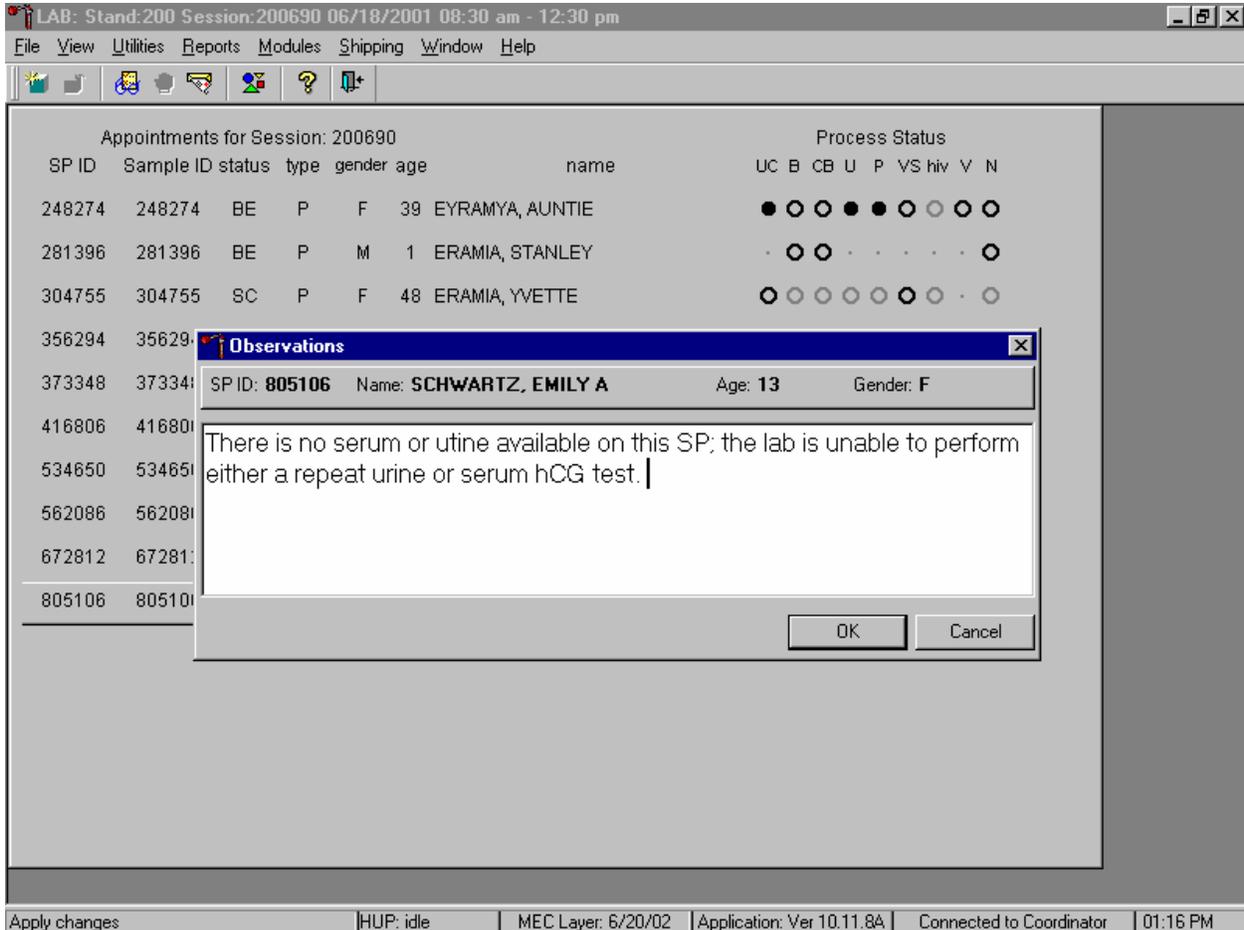
The observation window contains the SP ID, name, age, and gender. Type the observation, "There is no serum available on this SP; the lab is unable to perform a serum hCG test. The repeat urine hCG test is negative." using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report the inability to perform the serum confirmation test and to report the results of a repeat positive urine test on female SPs aged 8-17 years.



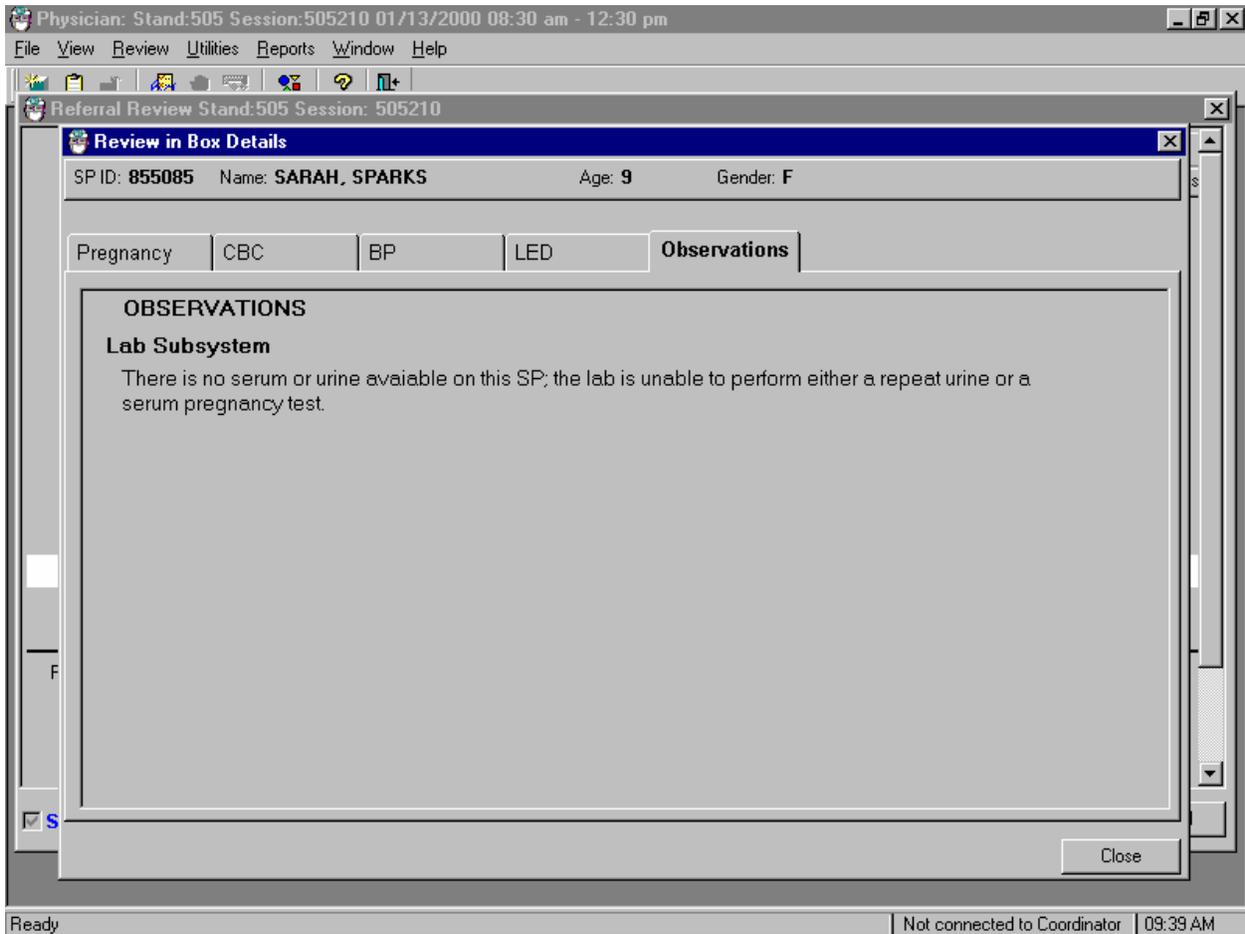
The observation window contains the SP ID, name, age, and gender. Type the observation, "There is no serum available on this SP; the lab is unable to perform a serum hCG test. The repeat urine hCG test is positive." using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report the inability either to perform the serum confirmation test or to repeat the urine test on female SPs aged 8-17 years.



The observation window contains the SP ID, name, age, and gender. Type the observation, "There is no serum or urine on this SP; the lab is unable to perform either a repeat urine or serum hCG test." using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

The physician reviews all observations.



The physician accesses the observations using the Review in Box Details.

## **XII. Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions**

Read the following procedural notes to ensure the best results with the ICON 25 hCG test kit.

## ICON® 25 hCG Test

- Dispensing Specimen

Do not reuse a test device or use a test device for multiple patient samples or controls, as this will produce inaccurate results.

- Incubation Times

The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the sample. However, neither the qualitative value nor the rate of increase in hCG can be determined by this qualitative test.

- Batch Processing

If several specimens are to be tested during one run, perform each test step for all specimens and controls at timed intervals before proceeding to the next test step. It is recommended that no more than ten (10) test devices be run in one batch.

- Specimens Containing Particulate Matter

Urine samples exhibiting visible precipitates should be centrifuged or allowed to settle to obtain a clear sample for testing.

- Very dilute urine samples, as indicated by a low specific gravity, may not contain representative levels of hCG.

- False negative results may occur when the levels of hCG are below the sensitivity level of the test.

- Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum samples shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed.

- A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine or serum should not be used to diagnose pregnancy unless these conditions have been ruled out.
- This test provides a presumptive diagnosis for pregnancy. A physician should only make a confirmed pregnancy diagnosis after all clinical and laboratory findings have been evaluated.
- Negative results are expected in healthy nonpregnant women and healthy men. Healthy pregnant women have hCG in their urine and serum samples. The amount of hCG will vary greatly with gestational age and between individuals. Concentrations of hCG in pregnant women are generally between 10 and 30 mIU hCG/mL in the 7-10 days following implantation or 3 weeks after the last menstrual period (LMP). During the latter part of the first trimester of pregnancy, the hCG concentration reaches a maximum level of greater than 100,000 mIU/mL.
- The ICON 25 hCG test has a stated sensitivity of 25 mIU/mL and is capable of detecting pregnancy as early as 1 day after the first missed menses.
- Do not use urine samples containing grossly hemolyzed blood since they may give inaccurate or erratic results.

#### Sure-View™ hCG Urine and Serum Control Sets

- These controls are formulated for use as quality control specimens in the reagent verification of pregnancy test kits.

## Sensitivity and Specificity

### ICON® 25 hCG Test

#### Accuracy

A multicenter clinical evaluation was conducted comparing the results obtained using the ICON® 25 hCG test and another commercially available urine/serum membrane hCG test. The urine study included 159 samples and both tests identified 88 negative and 71 positive results. The serum study included 73 samples and both assays identified 51 negative and 21 positive and 1 inconclusive results. The results demonstrated a 100 percent overall agreement (for an accuracy of >99%) of the ICON® 25 hCG test when compared to the other urine/serum membrane hCG test.

		Commercially Available Test	
		+	-
ICON® 25 hCG Urine	+	71	0
	-	0	88

		Commercially Available Test	
		+	-
ICON® 25 hCG Serum	+	21	0
	-	0	51

#### Sensitivity

- The ICON® 25 hCG test detects hCG at concentrations of 25 mIU hCG/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of 300 mIU/mL of luteinizing hormone, (LH), 1000 mIU/mL of follicle stimulating hormone (FSH), and 1000 mIU/mL of thyroid stimulating hormone (TSH) to negative (0 mIU/mL hCG) urine/serum specimens and to positive (25mIU/mL hCG) urine/serum specimens did not exhibit cross-reactivity in the assay.

### Specificity

- The following potentially interfering substances were added to hCG negative and positive samples.
- None of the substances at the concentrations tested interfered in the test.

### Interfering Substances

<b>Substance Added</b>	<b>Concentration</b>
Acetaminophen	20 mg/dL
Ascorbic Acid	20 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Atropine	20 mg/dL
Bilirubin (serum)	40 mg/dL
Glucose	2 g/dL
Hemoglobin	1 mg/dL
Bilirubin (Urine)	2 mg/dL
Triglycerides	1200 mg/dL

### Sure-Vue™ hCG urine and Serum Controls

These controls have been designed to produce correct results in pregnancy test kits. These controls have been tested with the ICON® 25 hCG test and were found to produce satisfactory results.

#### **XIV. Reference Ranges**

Not applicable.

#### **XV. Action Limits**

Not applicable.

**XVI. Specimen Storage and Handling During Testing**

Serum

Serum is required; do not use plasma. Specimens may be stored for 48 hours at 2°C - 8°C (36°F - 46°F) before testing. Specimens held for longer times should be frozen at -20°C (-4°F) before testing. Bring all specimens to room temperature before beginning the assay procedure and mix before testing. Use clear non-hemolyzed samples when possible.

Urine

A urine sample must be collected in a clean and dry container. Centrifuge very turbid urine specimens at 2500 RPM for 5 minutes before use. Do not shake or disturb specimens containing particulate matter, such as salts that have settled out of solution; pipette samples from the clear supernatant of such specimens.

**XVII. Alternative Method for Performing Test or Storing Specimens if Test System Fails**

There is no alternative method for testing.

**XVIII. Test Results Reporting System Protocol for Reporting Action Limits**

Not applicable.

**XIX. Specimen Accountability and Tracking**

All records, including QA/QC data are maintained for 6 years. Use only numerical identifiers for SP results.

**XX. Quality Control Summary Statistics and Graphs**

Quality control reports are monitored by stand and maintained for 6 years.

## XXI. References

Batzer, F.R. (1980). Hormonal evaluation of early pregnancy, *Fertility & Sterility*, 34(1), 1-13.

Catt, K.J., Dafau, M.L., and Vaitukaitis, J.L. (1975). Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte, *J. Clin. Endocrinol. Metab.*, 40(3), 537-540.

Braunstein, G.D., Rasor, J., Adler, J., and Danzer, H. (1976). ME Wade Serum human chorionic gonadotropin levels throughout normal pregnancy, *AM. J. Obstet. Gynecol.*, 126(6), 678-681.

Lenton, E.A., Neal, L.M., and Sulaiman, R. (1982). Plasma concentrations of human chorionic gonadotropin from the time of implantation until the second week of pregnancy, *Fertil. Steril.*, 37(6), 773-778.

Steier, J.A., Bergsjö, P., and Myking, O.L. (1984). Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy, *Obstet. Gynecol.*, 64(3), 391-394.

Dawood, M.Y., Saxeba, B.B., and Landersman, R. (1977). Human chorionic gonadotropin and its subunits in hydatiform mole and choriocarcinoma, *Obstet. Gynecol.*, 5(2), 172-181.

Braunstein, G.D., Vaitukaitis, J.L., Carbone, P.P., and Ross, G.T. (1973). Ectopic production of human chorionic gonadotropin by neoplasms, *Ann. Intern. Med.*, 78(1), 39-45.



**National Health and Nutrition Examination Survey  
National Center for Health Statistics  
United States Public Health Service  
Procedure: Complete Blood Count (CBC)  
January, 2004**

Prepared by \_\_\_\_\_

Date Adopted \_\_\_\_\_

Approved by \_\_\_\_\_

Director

Signed \_\_\_\_\_

Director

Dated \_\_\_\_\_

Director

Reviewed by \_\_\_\_\_

Date Reviewed \_\_\_\_\_

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## 7. COMPLETE BLOOD COUNT

### Introduction

Perform a complete blood count (CBC) in duplicate on all Sample Persons (SPs) age 1 and older. Perform the CBC on the Beckman Coulter® MAXM. Run a CBC on the SP's EDTA blood tubes.

The three Coulter MAXMs serial numbers and system IDs are:

MAXM #1	Serial # AA06042	System ID # 13017
MAXM #2	Serial # AA31227	System ID # 29894
MAXM #3	Serial # AB08075	System ID # 31831

### I. Purpose and Principle of Test

The Beckman Coulter® method of sizing and counting particles uses measurable changes in electrical resistance produced by nonconductive particles suspended in an electrolyte.

A suspension of blood cells passes through a small orifice simultaneously with an electric current. A small opening (aperture) between electrodes is the sensing zone through which suspended particles pass. In the sensing zone, each particle displaces its volume of electrolyte. Beckman Coulter® measures the displaced volume as a voltage pulse, the height of each pulse being proportional to the volume of the particle.

The quantity of suspension drawn through the aperture is for an exact reproducible volume. Beckman Coulter® counts and sizes individual particles at a rate of several thousand per second. This method is independent of particle shape, color, and density.

The MAXM is a quantitative, automated, differential cell counter for *in vitro* diagnostic use.

The MAXM measures these parameters in whole blood:

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
WBC	White Blood Cell Count	WBC bath	≥35 fL	$n \times 10^3$ cells/ $\mu$ L
RBC	Red Blood Cell Count	RBC bath	36 to 360 fL	$n \times 10^6$ cells/ $\mu$ L

Hgb	Hemoglobin Concentration	WBC bath	525 nm	g/dL
Hct	Hematocrit	Computed	RBC x MCV/10	% Percent
MCV	Mean Cell Volume	Derived from RBC histogram	# x size of RBC/Total RBC	fL
MCH	Mean Cell Hemoglobin	Computer	Hgb/RBC x 10	pg
MCHC	Mean Cell Hemoglobin Concentration	Computed	Hgb/Hct x 100	g/dL
RDW	Red Cell Distribution Width	Derived from RBC histogram	CV expressed in % of the RBC size distribution	% Percent
Plt	Platelet Count	RBC bath	2 to 20 fL	n x 10 <sup>3</sup> cells/ $\mu$ L
MPV	Mean Platelet Volume	Derived from Plt histogram	Mean volume of Plt population under the fitted curve x constant	fL
NE%	Neutrophil Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	% Percent
NE #	Neutrophil Number	Absolute number	NE%/100 x WBC Count	10 <sup>3</sup> cells/ $\mu$ L
LY%	Lymphocyte Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	% Percent
LY#	Lymphocyte Number	Absolute number	Ly%/100 x WBC Count	10 <sup>3</sup> cells/ $\mu$ L
MO%	Monocyte Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	% Percent
MO#	Monocyte Number	Absolute number	MO%/100 x WBC Count	10 <sup>3</sup> cells/ $\mu$ L

EO%	Eosinophil Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	EO % Percent
EO#	Eosinophil Number	Absolute number	EO%/100 x WBC Count	10 <sup>3</sup> cells/μL
BA%	Basophil Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	BA % Percent
BA#	Basophil Number	Absolute number	BA%/100 x WBC Count	10 <sup>3</sup> cells/μL

**\*PDW -- Platelet Distribution Width and Pct -- Platelet Crit are NOT for diagnostic use and do not print. Coulter uses the value for PDW as an internal check on the reported platelet parameters, Pct and MPV.**

Methodology: The methods used to derive CBC parameters are based on the Beckman Coulter® method of counting and sizing, in combination with an automatic diluting and mixing device for sample processing, and a single beam photometer for hemoglobinometry. The WBC differential uses VCS technology. Analysis and classification of WBCs use three simultaneous measurements of individual cell volume (V), high frequency conductivity (C), and laser light scatter (S). The scattergram plots the cells based upon the measurements of these three parameters.

## II. Special Safety Precautions

All specimens may be potentially positive for infectious agents including HIV and the hepatitis B and C virus. Observe universal precautions. It is mandatory to wear gloves and lab coat when handling all human blood products and Beckman Coulter® controls. Wear safety glasses whenever operating the instrument in SECONDARY mode. Dispose of all biological samples in a biohazard container and wipe down all work surfaces with 10% bleach solution at the end of each session.

The Mobile Examination Center (MEC) Hazardous Chemicals Manual contains all Coulter material safety data sheets (MSDS).

### III. Computerization: Integrated Survey and Information System (ISIS)

The MAXM Data Management System (DMS) transmits individual SP results to the MEC automated ISIS system. Review all SP results at the Coulter DMS monitor. The hematology module in the laboratory application automatically receives the results or transmits them manually to the hematology module. The laboratory application evaluates the data for completeness and accuracy. The final decision to accept or reject a result is the responsibility of the medical technologist.

All data are backed up and stored at Westat's home office.

### IV. Specimen Collection and Preparation

#### A. Specimen collection

1. The phlebotomist collects a 3 or 4-mL K<sub>3</sub> EDTA tube on all SP's age 1+ following established venipuncture protocol and procedures. (A 1-2% dilution effect occurs in this liquid EDTA tube.)

#### B. Specimen preparation

1. The blood specimen-processing technologist initially processes the tube by taking off whole blood for various tests. The blood specimen-processing technologist places the specimen on a rocker until the hematology technologist can perform the CBC. Run the CBC as soon as possible; there is no requirement to wait any length of time between drawing the blood and running the CBC.

### V. Procedure for Microscopic Examination

Not Applicable - Do not prepare differential microscopic slides.

## VI. Reagents and Supplies

The MAXM DMS stores and maintains the lot numbers and expiration dates.

### A. Reagents, controls and calibrators

1. Isoton III® -- PN 8546733 (20 L) -- an isotonic electrolyte
  - Expires on expiration date printed on container.
2. Beckman Coulter® Clenz -- PN 8546930 (5L) -- a cleaning agent that cleans and rinses diluter parts
  - Expires 90 days after being opened and installed on the instrument.
3. Lyse-S III® diff lytic reagent- PN 8546983 (1L) -- a lytic reagent used for the CBC mode
  - Expires 60 days after being opened and installed on the instrument.
4. Scatter Pak® -- PN 8546917
  - Diff Lytic Reagent -- Erythrolyse II® erythrocyte lytic reagent
  - Diff Leukocyte Preservative -- StabiLyse® leukocyte preservative
  - Expires 60 days after being opened and installed on the instrument.
5. Latron® Controls - PN 7546914 (5 x 16-mL)
  - Expires 30 days after being opened.
6. Latron® Primer - PN 7546915 (5 x 16-mL)
  - Expires 30 days after being opened.

7. 5C® Cell Controls Tri Pack contains Normal, Abnormal I, Abnormal II - PN 7547001 (9 x 3.3-mL)
  - Expires 13 days or 13 events after being opened.
8. Calibration S-CAL® - PN 7546808 (2 x 6-mL) (With Lin-C PN 6605374)
  - Use at the start of each stand. Expires 1 hour after being opened.
9. 5C® Cell Control Normal - PN 7546923 (9 x 3.3-mL)
  - Use when calibrating with S-CAL for reproducibility study.

B. Supplies

1. 3-mL K<sub>3</sub> EDTA Becton Dickinson Hemogard Vacutainer® tube
2. Tube rocker
3. Bleach, 5.25% Sodium Hypochlorite 1-800-292-2200
4. Bottled distilled water
5. Three 30 mL plastic containers with lid
6. Two one-liter containers with lid
7. Plastic squirt bottle
8. Cotton gauze pads
9. Three hole paper punch
10. Notebook
11. Fujitsu printer ribbon
12. Flashlight

13. 10-mL syringe with plastic tubing
14. Precision screwdriver set
15. Distilled water bottle
16. Disposable lab jacket – 48 inches long

#### C. Notes

1. If reagents become frozen in transit, mix thoroughly by inversion and let bubbles settle before use.
2. Do not place reagents on or near electric cords or lines to avoid electrical interference.

#### VII. Calibration

S-CAL® (PN 7546808 - 2 x 6-mL) The S-CAL® calibrator kit determines the adjustment factors for the calibration of the Beckman Coulter® MAXM. Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. Perform calibration in the close-vial mode, at ambient room temperature range (16-32°C, 60-90°F), using S-CAL® as an alternative to whole blood.

##### A. Perform calibration:

- At the beginning of each stand;
- After replacing any component dealing with dilution preparation, such as BSV or primary measurement, such as an aperture;
- If the Beckman Coulter® representative suggests calibration;
- If controls show unusual trends or are outside limits; and
- When room temperature varies more than 10°F (5.5°C) from the room temperature during the last calibration.

1. Principle - The MAXM uses the S-CAL® kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. S-CAL® calibrates the **WBC, RBC, Hgb, MCV, Plt, and MPV** parameters. It is a stabilized human-blood preparation. S-CAL® is an acceptable alternative to whole blood calibration.

The calibration procedure uses replicate measurements of S-CAL® calibrator. The S-CAL® divides the average result into the calibrator Assigned Value to give the Adjustment Factor. Then, it obtains and adjusts an instrument reading according to the Adjustment Factor.

Hct, MCH, MCHC, RDW, and the DIFF parameters do not require calibration.

2. Reagents - S-CAL® consists of treated, stabilized, human erythrocytes and platelet sized components in an isotonic bacteriostatic medium. Fixed erythrocytes simulate leukocytes.

Materials required -- Before calibrating, assemble the following materials: S-CAL® kit containing two 6-mL vials of S-CAL® calibrator, one plastic pipette, and two empty glass-mixing tubes with pierceable caps.

3. Storage, handling and stability -- Sealed vials are stable through the expiration date when stored at 2-8°C (35-46°F). Open and/or pooled vials are stable for 1 hour.

Potential biohazard – Each human donor used in preparation of this material was tested by an FDA-approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV), as well as for hepatitis B surface antigen, and found to be negative (were not repeatedly reactive). Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- The supernatant should show no gross turbidity and be light red in color. Significant darkening of the supernatant might indicate hemolysis and a reduction of the red cell count.

B. Pre-calibration, reproducibility, and carryover check

Perform a calibration after the instrument has been "Shut Down" (Section VIII D.) for at least 30 minutes. Select **DILUTOR FUNCTIONS, START-UP**.

1. Pre-calibration procedure

Bleach the aspiration system using the Clean Needle procedure.

- a) Prepare a fresh bleach solution. Put one-mL bleach and one-mL distilled water into 5-mL lavender top Vacutainer® tube.
- b) Stop the system before it performs the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE, [F3], Run. Press [F9] Stop.**
- c) Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, FLUIDIC TESTS, and CLEAN NEEDLE**. Press [Enter] and follow the screen instructions. Wait for green light before placing tube into the carousel.

To rinse the system, perform daily Start Up. Select **DILUTOR FUNCTIONS; START UP [Enter]**.

Run 5C® cell controls.

2. Reproducibility check

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Select [F5] to access options. Change [F5] Print: to none and [F6] Host to Off.
- b) Use an unopened, normal-level, 5C®-cell control for reproducibility studies. Label the control vial with date and initial. Use of expired controls for this procedure is acceptable.
- c) Select **SPECIAL FUNCTIONS, CALIBRATION, REPRODUCIBILITY** [Enter].
- d) Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop.
- e) Press [F6]. Press space bar to turn the DIFF ON. Press [Enter]. Press [F2] *START PRIMARY*.
- f) Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "yes." Press [Enter]. This deletes the old data.

If there are runs present in the table and the message does not appear, press [F8] Delete. Press the space bar to answer "YES." Press [Enter]. This deletes the old data.

- (1) Follow the directions listed in Section X for preparation and mixing the 5C®-cell control.
- (2) Cycle the sample 11 times. Do not use the bar code reader. Mix gently before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.

(3) Check the results. Verify the average %CV does not exceed these limits:

- WBC 2.5%
- RBC 2.0%
- Hgb 1.5%
- MCV 2.0%
- Plt 5.0%
- MPV 3.0%

Check the low to high difference (bottom line, right hand side) for the diff parameters with these limits:

- LY%  $\leq 4.8$
- MO%  $\leq 3.2$
- NE%  $\leq 4.8$
- EO%  $\leq 1.6$
- BA%  $\leq 1.6$

If the results are outside the limits, call the Beckman Coulter® representative.

(4) Press [F4] to print the screen for the logbook. Press [F3] Run [F9] STOP. Press [Esc]. Proceed with a Carryover Check.

g) Notes

(1) Be sure the PR↓ is on the status line before starting the reproducibility study.

(2) Be sure to delete any data on the reproducibility screen before starting a new study.

(3) On the reproducibility screen, use the %CV line for CBC parameters only and the Diff line for the DIFF parameters only.

3. Carryover check (Draw two 4-mL EDTA tubes of normal blood)
- a) Select **SPECIAL FUNCTIONS, CALIBRATION, and CARRYOVER**. Press [F2] *START PRIMARY*. Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "yes." Press [Enter]. This deletes the old data.
- (1) Use a routine 4-mL Vacutainer® EDTA for the carryover check clean vials. Fill three separate vials with diluent, then cap.
  - (2) Follow the screen directions. Cycle two vials of normal blood and three vials of diluent. Do not use the bar code reader. Insert the tube into the carousel when the green light appears.
  - (3) Check the lower right corner of the screen for CARRYOVER ACCEPTABLE. If the result is not acceptable and the H flags appear next to the carryover value results, repeat the procedure. If results are still OUT, call the Beckman Coulter® representative.
  - (4) Press [F4] to print the carryover screen for the logbook. Press [F9] to return to the main menu.
- b) Notes
- (1) Choose a sample with a WBC count of  $10,000 \pm 1,000$  if possible. All other parameters should be within normal ranges.
  - (2) Ignore count period (CP) voteouts on diluent runs.
  - (3) Percent carryover is calculated by the formula.

(4) 
$$\frac{\text{1st diluent sample} - \text{3rd diluent sample}}{\text{2nd sample}} \times 100 = \% \text{ carryover}$$

C. CBC calibration with S-CAL® calibrator

Take the S-CAL® calibrator from the refrigerator. Let it warm to ambient temperature for 20 minutes. Meanwhile, continue with the following steps:

1. Select **SPECIAL FUNCTIONS, CALIBRATION, and CBC CALIBRATION**. Press [F2] START PRIMARY. Delete any data in the table. Press [F8]. Press the space bar to answer "yes." Press [Enter].
2. Prepare the CBC calibration screen.
  - a) Enter the S-CAL® calibrator assigned values from the Table of Assigned Values on the package insert on the REF: VALUES line at the cursor. The Hct is not calibrated although the value is listed on the package insert.
  - b) Enter the expiration date and the lot number.

3. Prepare and cycle the calibrator

- a) Mix by hand as follows: Roll the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.
- b) Determine that all cells are uniformly distributed by inspecting the vial contents. If the cells are not totally distributed, repeat the mixing procedure. Use cotton gauze pads to remove the rubber stopper from the vial. Absorb any spray produced by pressure within the vial by using the gauze pads, avoiding accidental contact with the product.
- c) With the pipette, fill each of two mixing tubes to within 1/4 inch of the top. Dispose of extra S-Cal. Set one of these tubes aside in a test tube rack. Do not refrigerate or place on rocker. Use Tube #1 for calibration and tube #2 for verification if needed.
- d) Cycle the first cap-pierceable calibrator 11 times. Do not use the bar code reader. Invert the vial and mix the S-CAL® calibrator before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.
- e) After the cycles are complete, press [F4] Print to print the screen for the logbook. Press [F3] Run, [F9] STOP. Press [Esc.]

4. Assess the run

- a) Check for trending. If trending is present, stop and contact a Beckman Coulter® representative.

- b) Check the %CV values against these precision %CV limits. If any parameter exceeds the limit, STOP and contact a Beckman Coulter® representative.

Parameter	Precision (CV%)
WBC	≤2.5
RBC	≤2.0
Hgb	≤1.5
MCV	≤2.0
Plt	≤5.0
MPV	≤3.0

- c) FAC %DIFF values against these limits (disregard minus signs. The values are absolute numbers). If any parameter exceeds its limit, STOP and call a Beckman Coulter® representative.

Parameter	Acceptable FAC %DIFF
WBC	≤5.0
RBC	≤2.0
Hgb	≤3.0
MCV	≤2.5
Plt	≤9.0
MPV	≤20.0

- d) Determine the need for calibration. Check the FAC %DIFF and DELTA DIFF values against these limits (disregard minus signs. The values are absolute numbers).

Parameter	Do not calibrate if FAC %DIFF is:	Do not calibrate if DELTA DIFF is:
WBC	≤1.25	≤0.10
RBC	≤0.70	≤0.03
Hgb	≤0.78	≤0.10
MCV	≤1.18	≤1.00
Plt	≤2.70	≤6.0
MPV	≤5.00	≤0.50

- e) If both the FAC %DIFF and DELTA DIFF values for all parameters are less than or equal to these limits, DO NOT calibrate: Press [F4] to print the screen for the logbook.
- f) If the FAC %DIFF or DELTA DIFF value of any of these parameters is greater than these limits continue with the next steps to verify the calibration.

5. To verify calibration:

- a) Determine which calibration factors to change. Check the FAC % DIFF and DELTA DIFF values against these ranges.

Parameter	Calibrate if FAC %DIFF is:	Calibrate if DELTA DIFF is:
WBC	>1.25 but ≤5.00	>0.10 but ≤0.40
RBC	>0.70 but ≤2.00	>0.03 but ≤0.09
Hgb	>0.78 but ≤3.00	>0.10 but ≤0.40
MCV	>1.18 but ≤2.50	>1.00 but ≤2.00
Plt	>2.70 but ≤9.00	>6.0 but ≤20.0
MPV	>5.00 but ≤20.00	>0.50 but ≤2.00

- b) If any value is outside these ranges, then, is *Select Function* displayed? If NO, press [F3] Run [F9] STOP [Esc]. If YES, Press [F5]. Choose SELECT PARAMETERS. Press [Enter]. Use the space bar to select YES for parameters that need adjusting, NO for others. Press [Esc]. Select TRANSMIT FACTORS. Press [Enter]. The following message appears: "WARNING -- DATA WILL BE CLEARED AFTER TRANSMISSION. DO YOU WANT TO PRINT DATA? Y/N" Select N since the values have already been printed.
- c) Press [F3] Run [F2] START PRIMARY. Gently invert the second cap-pierceable vial of S-CAL® calibrator 8-10 times. Cycle the S-CAL® calibrator 11 times. Before each cycle, invert the vial and mix the S-CAL® calibrator. Check the FAC %DIFF and DELTA DIFF values

results for all parameters against these limits (disregard minus signs) to be sure that they are below the lower limit.

Parameter	FAC %DIFF	DELTA DIFF
WBC	≤1.25	≤0.10
RBC	≤0.70	≤0.03
Hgb	≤0.78	≤0.10
MCV	≤1.18	≤1.00
Plt	≤2.70	≤6.0
MPV	≤5.00	≤0.50

- d) If any value is above these limits, call a Beckman Coulter® representative. Turn the printer back on using Options. Press [F4] to print the screen for the logbook. Rerun controls.

## 6. Calibration terms and formulas

### a) MEAN

- The average of the 10 S-CAL calibrator runs

### b) NEW CAL FAC

- The calibration factor needed to obtain the S-CAL Calibrator Reference value. The instrument calculates and displays it whether or not it needs to be changed.
- Reference Value x Old Cal Factor = NEW CAL FAC  
S-CAL mean value (n=10)

### c) OLD CAL FAC

- The current calibration factor

d) %CV

- Indicates the reproducibility of the S-CAL calibrator run. Check to ensure that the data being used is valid when making decisions to recalibrate or not.

e) FAC % DIFF

- The difference between the OLD CAL FAC and the NEW CAL FAC expressed as a percentage.
- $$\frac{\text{NEW CAL FAC} - \text{OLD CAL FAC}}{\text{OLD CAL FAC}} \times 100 = \text{FAC \% DIFF}$$

f) DELTA DIFF

- The absolute difference between the reference value and the S-CAL calibrator MEAN.

g) REF VALUES.

- The assigned value for each parameter.

## VIII. Assay Procedure

### A. Run Start Up at the beginning of the first session each operational day.

1. Leave the instrument on and operate the MAXM with all panels closed. Check to make sure the date and time displayed are correct. To set date and time select **SPECIAL FUNCTIONS, SET UP, SYSTEM SET UP, SET DATE/TIME**. Move the cursor and enter the correct date or time and press [Enter] or the arrow keys. Press [F10] to save and exit.
2. To begin Start Up, select **DILUTER FUNCTIONS, and START UP**. Press [Enter]. Follow the instructions on the screen.
3. After Start Up is complete, evaluate the display. Expired reagents and failed checks appear in red. Press [F2] to view detailed results. Make sure the Background and other Start Up results are within limits. Results outside limits turn red. Results automatically print. File in the logbook.
4. Review and verify sample analysis set up.
  - a) Select **SAMPLE ANALYSIS, RUN SAMPLE** [F3]. Sample mode? Press [F5] for options. Press the corresponding function key to enter specific options. Use [F6] to turn the Diff ON. Use [F5] to change XB and DB to ON, Print to NONE, Host to ON, and Display Only to OFF. Press [Esc] to exit.

### B. Run controls

Run Beckman Coulter® LATRON primer and latex control, and all three levels, normal (blue), abnormal I (yellow), and abnormal II (pink), of Beckman Coulter® 5C® cell control daily at the beginning of the first session. Run all three levels (normal, abnormal I, and abnormal II) of Beckman Coulter® 5C® cell control at the beginning of the second session.

### C. Run Sample Persons

1. Review the placement of the bar code on the sample tube to make sure it is parallel to the stopper and does not cover the bottom of the tube.
2. Run all samples in duplicate.
3. Run samples in the primary mode.

Check to verify connection and working order of the printer.

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].
  - b) Is Sample Mode? Displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.
  - c) Press [F2] START PRIMARY.
  - d) Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep -- Place the tube in the carousel. If the red light appears, wait and try reading the bar code label again.
4. Alternatively, cycle samples in the SECONDARY mode.

Blood detectors are inactive in the SECONDARY mode. This mode does not check sample and aspiration integrity. Run samples in the SECONDARY mode only if the primary mode is unavailable.

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].

- b) Is Sample Mode? displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.
  - c) Press [F3] SECONDARY.
  - d) Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep. If the red light appears, wait and try reading the bar code label again.
  - e) Cycle the sample in the SECONDARY mode:
    - (1) Mix the sample gently.
    - (2) Open the tube and immerse the aspirator tip in the sample.
    - (3) Press and release the sample bar.
    - (4) Remove the sample when the instrument beeps.
    - (5) Monitor the aperture-viewing screens for debris during the COUNT period.
5. Review data and transmit
- a) Review the data using the criteria described in Section X.
  - b) Set host computer to  $\uparrow$ . Data from the Coulter DMS is automatically transmitted to the ISIS system.

#### D. Daily Shut Down

- 1. Shut down the instrument at the end of each day. Shut down the instrument for at least 30 minutes but less than 48 hours.

2. To begin shut down make sure the status line displays *Select Function*. Select **DILUTER FUNCTIONS** and **SHUT DOWN**. Press [Enter].
3. When it is time to use the instrument, perform Start Up. Results must be within tolerance.
4. Perform daily QC and operate as usual.

#### E. Prolonged Shut Down

1. If the instrument is going to be shut down for 48-72 hours, perform the following steps:
  - a) Perform daily Shut Down. Let cleaning agent remain in the instrument for at least 30 minutes.
  - b) Perform Start Up to put diluent in the system.
  - c) Turn off the power.
  - d) When it is time to use the instrument, turn power on, and perform a Start Up. Results must be within tolerance.
  - e) Perform daily QC and operate as usual.
2. If the instrument is going to be shut down for more than 72 hours, perform the following steps:
  - a) Place all reagent pickup tubes into distilled water.
  - b) Repeatedly perform Shut Down and Start Up procedures throughout the day.
  - c) Let distilled water remain in the reagent lines.

- d) Turn off the power.
- e) Place reagent caps on all open containers.
- f) When it is time to use the instrument, turn on the power and place the reagent pickup tubes into the reagent containers, prime all reagents, perform a shut down and then perform a Start Up. Results must be within tolerance.
- g) Perform daily QC and operate as usual.

#### F. Beginning and end of stand operations

##### 1. Beginning of stand

- a) Obtain one urine collection container or a 50-mL conical tube, seven 3 or 4-mL EDTA tubes (1 clean aspiration system, 3 reproducibility, 3 carryover), enough supplies to draw two 4-mL EDTA blood tubes, and a few plastic transfer pipettes.
- b) Using all new containers of reagents, carefully unwrap and place all reagent pickup tubes in their appropriate container after pouring 30-mL Isoton® III into 30-mL plastic container. Use the Isoton® when performing the calibration carryover check. Handle reagent tubes by the collar only to avoid contamination. Turn the power ON. Prime reagents through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS**, and choose **ALL**.
- c) Perform the Start Up procedure. This should take approximately 5-6 minutes. Results should be within tolerance.
- d) Contact the local Beckman Coulter® representative to perform an instrument verification procedure on set-up day or as soon as possible.

- e) Calibrate, perform, and verify QC checks according to procedure.
- f) Review and verify system set up. Select **SPECIAL FUNCTIONS, SET UP, SYSTEM SET UP:**
  - (1) Select **SHIFT**
    - (a) Move the cursor and set up the starting times for each shift and press [Enter] or the arrow keys. The system automatically calculates the end of the shift to prevent overlap.
    - (b) Set shift 1 "Time" at 0800.  
Set shift 2 "Time" at 1230.  
Set shift 3 "Time" at 2230.
    - (c) Press [F10] to save and return to the previous screen.
  - (2) Select **REAGENTS** - Update reagent logs
    - (a) To record new reagent information: Key in the new reagent information: lot number, date reagent opened (pressing [Enter] automatically gives today's date), and the expiration date. Do not forget to enter revised expiration dates where appropriate. Press [Enter] after each item. Press [F10] to save the data and leave the reagent screen.
  - (3) Select **INSTITUTION.**
    - (a) Enter the "SUPER" password. Type in:  
Name, NHANES  
Lab Director, Brenda Lewis  
Address, NCHS  
Maryland  
Telephone, 301-436-7080  
(Default) Instrument, AA06042  
AA31227  
AB08075

Use space bar to choose YES for Name Printed on Graphic Printer and NO for all other information. Press [F10] to save.

(4) Select **COMMUNICATION DEF.** Enter the **SUPERVISOR PASSWORD, "super."** Select, **HOST COMPUTER DEFINITION.**

- (a) Use [Enter] or arrow keys to move to the appropriate field.
- (b) Type in the following information where necessary and use the space bar to choose between the responses.

STKS 2A Host Mode	No	Enable Spooler	Yes
		Replace Null by SP	No
Timeout (secs)	8		
Baud rate	9600		
Parity	none		
Stop bits	1		
Handshake	Yes		
Block size	256		
Graphic transmission			
DF1	No		
DF2	No		
CVS histograms	No		
RBC histograms	No		
PLT histograms	No		

- (c) Press [F10] to save and [Esc] to return to previous screen.

(5) Select **Language.**  
Ensure the default is "ENG." Press [F10] to save and exit.

(6) Select **IQAP ID#.**  
Type in the IQAP number.  
Enter 32979 1 T1 for instrument AA06042  
32979 1 T2 for instrument AA31227  
32979 1 T3 for instrument AB08075  
Press [F10] to save and exit.

(7) Select **SET DATE/TIME**.  
Move the cursor and enter the correct date or time and press [Enter] or use the arrow keys. Press [F10] to save and exit.

(8) Select **LYSE VOLUME**.  
Press space bar to choose 1 L. Press [F10] to save and exit.

(9) Select **OPTIMIZE HARD DISK**.  
Type in the password "super" at the prompt and then press [Enter]. Use the spacebar to select YES. Press [F10] to save. Press [F9] to return to the main menu.

g) Review sample analysis set up. Select **SPECIAL FUNCTIONS, SET UP, and SAMPLE ANALYSIS SET UP**. Type in the password "super."

(1) Select **DISPLAY FORMATS, REPORTING UNITS**.  
Use the space bar to toggle to US 1. Press [F10] to save and [F9] to return to main menu.

(2) Select **PRINT OPTIONS**.  
**Auto Print Format**  
Select [**GRAPHIC FORMAT**]

**Ticket Options**

Verify the following settings.

PRINT UNITS:	Y
PRINT NORMAL RANGES:	Y
PRINT PARAMETER LABELS:	Y
TICKET PRINTER CONNECTED:	N
S/D FLAGS:	Y
DIFF ORDER:	Standard
AUTO-TICKET PRINT:	N

TICKET FORMAT START OF  
NEXT FORM            Continuous

### Spooler Priority

Leave [AUTO PRINT] as the default.

### Graphic Options

Verify the following settings.

	Width/Font
Page Format	Wide/Large

DF 1. RBC, PLT	:	Yes
DF2, DF3	:	No
VCS Histograms	:	No
Demographics	:	No
S/D flags	:	Yes
Print Units	:	No
Print Diff Box	:	No
Print Normal Ranges	:	No

### Optional Printer

Select "N."

- (3) Select **ACTION LIMITS** [Enter], **DEFINITIVE FLAG LIMITS** [Enter].

Disable definitive flag limits. Set low limit for all parameter values to zero except for PCT. Set lower limit for PCT to 0.000. Set high limit to 99.9 for all parameters except RBC, PLT, and PCT. Set RBC upper limit to 9.9, PLT to 999 (with no decimal) and PCT to 0.990. Press [F10] and [Enter] to save and exit.

- (4) Select **ACTION LIMITS** [Enter], **HIGH/LOW FLAG LIMITS** [Enter].

Disable High/Low flag limits. Set low limit for all parameter values to zero except for PCT. Set lower limit for PCT to 0.000. Set high limit to 99.9 for all parameters except RBC, PLT, and PCT. Set RBC upper limit to 9.9, PLT to 999 (with no decimal) and PCT to 0.990. Press [F10] and [Enter] to save and exit.

(5) Select **XB LIMITS**.

Enter target and limit percent values.

XB Limits

	Target	Limit %
MCV	88.5	3
MCH	29.5	3
MCHC	33.5	3

Press [F10] to save and exit.

2. End of stand

a) Obtain three urine collection cups and three 4-mL EDTA blood tubes.

b) Review, print, and clear error file.

(1) Select **SPECIAL FUNCTIONS, ERROR FILE** [Enter]. Review data and print [F4]. Document any relevant information on the print out and file in the logbook. Delete file [F8] -- "Do you want to delete error file; NO" message will appear. Use the space bar to change NO to YES [Enter]. Return to main menu [F9].

c) Download IQAP files to diskette following procedure in Section X.D.1.

d) Perform daily Shut Down. Let cleaning agent remain in the instrument for at least 30 minutes.

e) Perform Start-up.

- f) Disable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTIONS, FLUIDIC TESTS,** and **DISABLE REAGENT SENSORS.** Toggle through each reagent line using the space bar to change "ON" to "OFF."
- g) Bleach the reagent lines.
- (1) Remove all reagent pickup tubes from the reagent containers. Dispose of all open containers. Wash and save the reagent collars.
  - (2) Prepare a 25% solution of bleach (250-mL) and distilled water (750-mL) in one liter bottle. Place all reagent pickup tubes into the 25% bleach/distilled water solution. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL.** Press [Enter]. Repeat this procedure two more times.
- h) Place all reagent pickup tubes into containers of distilled water.
- i) Bleach the apertures and flow cell.
- (1) Mix 15-mL bleach and 15-mL distilled water in a plastic container.
  - (2) Put 30-mL of distilled water in a second plastic container.
  - (3) Open the front panel.
  - (4) Select **DILUTER FUNCTIONS,** and **DISINFECT.** Press [Enter].
  - (5) The instrument defaults to 15 minutes; stop the procedure after 3 minutes. Press [Enter].

- (6) Immerse the bleach probe in the bleach solution when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE BLEACH." Press any key. Aspirate all the bleach solution.
  - (7) Immerse the bleach probe in the distilled water when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE WATER." Press any key. Aspirate all the distilled water. Stop the cycle after 3 minutes by pressing [F4].
  - (8) Wait until the screen displays *Select Function* before touching any keys. When *Select Function* is displayed, continue with the following procedure.
- j) Disinfect the needle. Bleach the aspiration system using the Clean Needle procedure.
- (1) Prepare a fresh bleach solution. Put 1-mL bleach and 1-mL distilled water into 4-mL lavender top Vacutainer® tube.
  - (2) Stop the system before beginning the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE**, [F3], Run. Press [F9] Stop.
  - (3) Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, FLUIDIC TESTS, and CLEAN NEEDLE**. Press [Enter] and follow the screen instructions. Wait for green light before placing tube into the carousel.
- k) Perform reproducibility in Primary and Secondary mode using this 1% bleach solution. Prepare a 1% bleach solution and fill one 4-mL EDTA blood tube with this solution. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START*

*PRIMARY.* Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY.** Select Primary and aspirate three samples of 1% bleach. Enter [F3]; sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of 1% bleach solution.

- l) Rinse the reagent lines. Make sure all reagent lines are immersed in containers of distilled water. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL.** Press [Enter]. Repeat this procedure two more times.
- m) Perform a Start Up. Make sure containers are full.
- n) Perform reproducibility in Primary and Secondary mode by using distilled water. Fill one 4-mL EDTA blood tube with this distilled water. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START PRIMARY.* Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY.** Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY.** Select Primary and aspirate three samples of distilled water. Enter [F3], sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of distilled water. Press [Enter].
- o) Select **DILUTER FUNCTIONS, START-UP.** Press [Enter]. Perform one additional Start-Up procedure with the lines in the distilled water containers.
- p) Cycle the instrument dry.
  - (1) Remove all reagent pickup tubes from the distilled water containers.

- (2) Continue to cycle the instrument dry by priming air through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS** and choose **ALL**. Repeat these actions at least three times.
  - (3) Open front cover. Using hemostats, seal tubing with check valve coming out of the bottom of the sheath tank. Loosen the four large screws that hold the panel containing the sheath tank. Gently pull panel away from instrument. Trace two red wires from top of sheath tank to plastic electrical connection. Disconnect the junction. Insert paper clip into junction so that a circuit is formed on the instrument side of the connector. Do this by bending paper clip into a U and placing one end of paper clip into each of the open sockets on the instrument side of the junction. This will allow the instrument to Drain, Vent, and Shut Down without reagent. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTION, and DRAIN AND VENT**. Press [Enter.]
  - (4) Select **DILUTER FUNCTIONS, and SHUT DOWN**. Press [Enter].
  - (5) After cycles are complete, remove paper clip, reconnect junction, put panel back into instrument and tighten screws, then remove hemostats.
- q) Enable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, FLUIDIC TESTS, and DISABLE REAGENT SENSORS**. Toggle through each reagent line using the space bar to change "No" to "Yes."
- r) To protect the reagent pickup tubes from contamination, wrap them securely in paper towels. Allow air to continue to dry the tubes.

- s) Turn off the power.
- t) Rinse exterior of BSV with distilled water to remove built up Isoton and blue Clenz agent. Blot the BSV dry with lint free tissue. Do not use gauze.
- u) Wash exterior of instrument with distilled water.
- v) Empty waste and rinse container.
- w) Blow air through the flow cell at the end of each stand. This is referred to as the Triple Transducer Module (TTM). Address questions to the service representative at 1-800-526-7694. Remove the 6-inch sample line to the flow cell at the mixing chamber. Connect a 10-mL syringe with tubing to the 6-inch line and force air into the line to remove ALL remaining liquid from the flow cell and the 6-inch sample line. Reconnect the sample line.

IX. Beckman Coulter® Reportable Range of Results

Parameter	Linearity	Limits: The greater of
WBC x 10 <sup>3</sup> cells/μL	0 to 99.9	0.2 or 3.0%
RBC x 10 <sup>6</sup> cells/μL	0 to 7.00	0.05 or 2.0%
Hgb g/dL	0 to 25.0	0.2 or 3.0%
MCV fL	50.0 to 150.0	2.0 or 3.0%
Plt x 10 <sup>3</sup> cells/μL	0 to 999	10.0 or 7.0%
MPV fL	5.0 to 20.0	5.0%

## X. Quality Control

A. Latron® latex controls (PN 7546914 - 5 x 16-mL) The Latron® control is for use in monitoring the volume, conductivity, and light scatter (VCS) parameters on the MAXM. Use the Latron® control immediately following the Latron® primer. Run this control at the beginning of each day. Date and initial the vials when opened.

1. Principle -- The Latron® control is a ready-to-use suspension of latex particles. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter.
2. Reagents -- Latex particles suspended in a buffered bacteriostatic and fungistatic medium containing a surfactant.
3. Storage, handling, and stability -- Sealed vials are stable until their expiration date when stored and used at 2-30°C (35-86°F). Once open, date, and initial vials. Opened vials are stable for 30 days when stored at recommended temperatures. Keep vials tightly capped when not in use.
4. Indications of instability or deterioration -- Inability to recover expected results might indicate product instability or deterioration due to improper storage, handling, or contamination. Discard vial if debris is visible and put new vial into use.
5. Instructions for use -- Before running control, verify that a Start Up has been performed.
  - a) Run Latron® primer in the secondary mode. Select **CONTROLS**, then **CONTROL RUN** and press [Enter]. If the **LATEX FILE** does not appear, press [F2] File. Select the **LATEX FILE**. Press [Enter]. Press [F3] Run [F4] Primer. Cycle the primer by immersing the aspirator tip completely in the primer. Press and release the sample bar. The aspirate

probe for open vials will begin to aspirate the primer. Remove vial when the audible "beep" occurs. Evaluate primer results. Results should be less than 500. Press [Esc] to remove the primer run.

- b) Run the latex control. Mix a room-temperature control vial gently by inverting five (5) to eight (8) times. Be careful to avoid foaming. When *Select Function* appears on the status line, press [F3] Run, [F3] Control (SECONDARY). Cycle the control by immersing the aspirator tip completely in the vial. Press and release the sample bar. The aspirate probe for open vials will begin to aspirate the control. Remove vial when the audible "beep" occurs.
- c) Examine the Mean Channel and Coefficient of Variation for volume, conductivity, and light scatter for the Diff Mode only. Compare the results to the Assigned Mean Values and Expected Coefficient of Variation. Check for **H** (high) or **L** (low) beside the results. If there are no H's or L's, results are within range. Press [F4] to print results for the logbook. If a H or L displays, do the following:
- (1) Bubbles in the flow cell or improper vial handling -- Rerun the primer and control.
  - (2) Contaminated control, improperly mixed, or past open vial expiration date -- Wipe the aspirator tip. Try a new vial of Latron® control. Mix gently according to directions.
  - (3) ":::::" System detects a clog in the flow cell -- Press [F3]. Press [F7] to PURGE the flow cell. Press [F4]. Cycle the Latron® primer again. Press [Esc] [F3] [F3]. Cycle the Latron® latex control again. If the control is still "out" of range, repeat the actions 2 or 3 more times. If the problem remains, perform a ShutDown and Start Up procedure. If problem continues, call a Beckman Coulter® representative for assistance.

- (4) Assigned value or range is incorrect -- Be sure the assigned values and ranges match the ones on the Latron® package insert. If in error, correct them by selecting **SPECIAL FUNCTIONS, SET-UP, CONTROL SET UP.**

6. Setting up a Latex control file

Set up a file each time a new lot number is received. Assigned channel, expected range, and %CV are automatically entered; change them to assigned values on assay sheet, if necessary.

Choose **SPECIAL FUNCTIONS, SET UP, CONTROL SET-UP, LATEX FILE.** Select a NOT SET-UP or an inactive file. Enter the name of the file, (Latex), Lot #, expiration date, and technician initials. Check entries. Press [F10] to save and exit.

B. 5C® Cell Controls Tri Pack contains Normal (blue), Abnormal I (yellow), Abnormal II (pink) (PN 7547001 - 9 x 3.3 mL.) The 5C®-cell control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. Run this control at the beginning of each session. Date and initial the open vials.

1. Principle -- The 5C® cell control consists of human blood so repeated measurements to monitor daily performance of the instrument system is possible.
2. Reagents -- 5C®-cell control consists of treated, stabilized human erythrocytes in an isotonic bacteriostatic medium. 5C®-cell control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes.
3. Storage, handling, and stability -- Store 5C®-cell control at 2-8°C. When stored at 2-8°C, sealed vials are stable at least until the expiration date shown on the Table of Expected Results. Note: The MCV and/or RDW parameters may show trending through the shelf life of the product. This is inherent to the product and

is not an indicator of product stability. Date and initial open vials. Opened vials are stable for 13 days or 13 events when stored at 2-8°C.

Potential biohazard -- Each human donor used in preparation of this material was tested by an FDA-approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) as well as for hepatitis B surface antigen and found to be negative (were not repeatedly reactive). Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (darkly colored supernatant) indicate product deterioration. However, a slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.
5. Instructions for use -- Remove 5C® cell control tubes from refrigerator and warm to ambient temperature for 10-15 minutes. After warming, mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.

- a) Run the 5C®-cell control in the Primary Mode of the instrument. Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Is **SAMPLE MODE** displayed? If no, press [F9] **STOP**. Make sure the **DIFF** is on. If it is off, press [F6]. Press [F2] **START PRIMARY**. Complete the entire procedure and return the controls to the refrigerator within 30 minutes.
- b) Identify the sample by holding the bar code label in front of the reader. Place the control in the carousel. Repeat for other levels of controls.

c) Check the results of each control. Select **CONTROLS, REVIEW, OR REPORT** and [F2] to select a file for review. Choose one control file and [Enter]. Check for **H** (high) or **L** (low) beside the results. If there are no H's or L's, results are within range. To print results for the logbook for the last control run, press [F4] Print. Use [F2] to select another file and repeat actions. Review and print reports for all three controls and file in the logbook. If a **H** or **L** displays, consider the following reasons and perform and document the following actions:

- (1) Improper mixing -- Follow instructions and rerun control.
- (2) Control files set-up incorrectly -- Make sure the assigned values and ranges match those on the control package insert. If in error, correct them by selecting, **SPECIAL FUNCTIONS, SET UP, CONTROL SET UP.**
- (3) Chance (statistical outlier) -- Rerun the control. If it is still out, continue with the following actions.
- (4) Change in the control -- Try another vial or level of control.
- (5) Instrument change -- Watch for normal sample flow. Call Beckman Coulter® representative to help troubleshoot abnormal operation.

#### 6. Setting up a CBC/Diff control file

Set up a file whenever receiving a new lot number of control. Enter control package insert information for control with differential. Enter information using the bar code wand. Enter information manually if necessary.

Choose **SPECIAL FUNCTIONS, SET UP, and CONTROL SET-UP.** Select **CBC DIFF/FILE.** Select a NOT SET-UP or an inactive file.

a) Using bar code scanner

Scanning bar code units -- Choose the correct section of the package insert to scan making sure to select the part with the correct Unit Format (US), for the correct instrument (MAXM).

- (1) Hold the wand like a pencil.
- (2) Place the wand in section 1, Lot No. Read this section first.
- (3) Gently slide the wand back and forth over the bar code until the instrument beeps. The lot number is now entered. Start and end each scan in the white space.
- (4) Beckman Coulter®'s expected ranges appear automatically when the control lot number is entered in an empty file.
- (5) Follow the same procedure for the expiration date and assigned values. (Values 2-10)
- (6) Manually select and enter Shift and Operator ID.  
Check all entries to make sure they are correct. Press [F10] to save and exit.

b) Manual entry

Enter lot number. This enters the IQAP number automatically. Enter the expiration date, shift, and operator code. Continue to enter the package insert data. Press [Enter] after each entry. Press [↓] at the end of each row. The system automatically enters the level and default ranges based on the first two digits of the lot number. Check to make sure all entries are correct. Press [F10] to save and return to the previous screen.

## C. Control statistics and graphs

### 1. Use to review and print:

Control results, cumulative statistics and graphs for CBC/DIFF files or  
Control results, cumulative statistics and histograms for LATEX Files or  
Check cumulative results for trends or shifts as necessary for troubleshooting.

Print, review, and delete cumulative statistics and graphs for all CBC/DIFF and LATEX files at the end of each stand after transferring information to the IQAP disk and file in the logbook.

### 2. CBC/DIFF control review and report

- a) Use this report to review and print control results and cumulative statistics for CBC files. Select **CONTROLS, REVIEW OR REPORT**, and [Enter]. Press [F2] to select one of the following files, Normal, Abnormal I, Abnormal II, and Latex [Enter]. Press [F4] to print. Review and file in logbook. Continue to select each file in turn, print, and file.

Screen-specific function keys:

[F2] File      Displays all available files. Use ↓ and ↑ to select the correct file. Press [Enter].

[F4] Print      Prints the entire control file in a line list format on 8.5 x 11 in paper.

[F6] Remove/Restore

Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] restores the run and original statistics.

[F8] Delete File

Deletes the current control file. Displays a message "*You have asked to delete ENTIRE control file. Are you sure you want to delete?*" No. Press the space bar to select Yes or No.

[←] [→] Press [←] or [→] to see parameters not currently displayed on the screen.

[F9] Menu Displays the main menu.

3. Latex control review and report

a) Use this report to review and print control results and cumulative statistics and histograms for LATEX files. Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.

b) Screen-specific function keys:

Press [←] To go back to DIFF Latex Control Review

[F2] File Displays all available files. Use ↓ and ↑ to select the correct file. Press [Enter].

[F4] Print Prints the entire control on a graphic printer.

[F6] Remove/Restore

Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] again restores the run and original statistics.

[F8] Delete File

Deletes the current control file. Displays a message "*You have asked to delete ENTIRE control file. Are you sure you want to delete?*" No. Press the space bar to select Yes or No

[←] [→] Press [←] or [→] to see parameters not currently display on the screen.

[F9] Menu Displays the main menu.

#### D. Interlaboratory Quality Assurance Program (IQAP)

All instruments participate in Beckman Coulter®'s IQAP program. The IQAP program includes saving results of 5C® Cell controls, transferring them to a disk, and sending them to Beckman Coulter® who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. Perform this procedure at the end of each stand, or when a lot expires.

Follow procedure for CBC/DIFF and Latex control review and report. After downloading and printing results, delete control files [F8].

1. Procedure to download IQAP files to diskette.
  - a) Slide the diskette into the drive with the arrow side up and pointed toward the drive in the Beckman Coulter® Data Management System. Gently push the diskette until it clicks into place.
  - b) Turn the computer OFF. Wait 15 seconds, and then turn the computer back ON. A screen will appear showing the Beckman Coulter® Corporation logo. To exit this screen, follow the instructions on the bottom left portion of the screen, and press [Esc].
  - c) The screen will indicate the process the system is performing. Read the instructions on the screen. When the process is complete, the DMS displays the list of possible files on the screen for review and selection. If some of the values are incorrect, edit or delete the fields on this screen. Any alteration to this screen will affect only data on the IQAP diskette, not in the MAXM computer.

- d) FILE\_NAME indicates the files by file number for downloading to the diskette.
- LOT\_# indicates the type of control. Prefixes 86, 87, and 88 refer to 5C® Cell Controls.
  - SHIFT refers to the shift designation selected for running the controls. Edit this field if necessary. Use arrow keys to position.
  - START and END indicate beginning and end dates for each file. These fields are not editable.
  - REPORT indicates whether IQAP will issue a report on the lot number.
  - N\_REC indicates the number of records found in the file.
- e) Press [Esc] to leave this screen. If the IQAP# and Serial# are present and valid, the following screen message will appear, "Updating the IQAP Disk." After writing the control files to the diskette, a screen message will give instructions to follow. Follow these instructions and the computer will reboot to the routine program. To remove the diskette, press the eject button on the lower right of the diskette drive opening. Do not remove the diskette until the drive indicator light is off.
- f) Label the diskette with the supplied IQAP ID label. Place the diskette in the pre-addressed mailer provided and mail. Do not place the label over the drive spindle or high-density hole.

#### E. $X_B$ analysis

1.  $X_B$  analysis is a QC method monitoring instrument performance by tracking the MCV, MCH, and MCHC parameters of SP samples. These indices are very stable and show little variance between SP samples. This method displays the moving average of SP samples and compares it to established target values. Target values are MCV = 88.5, MCH = 29.5, and MCHC = 33.5. Review and print the  $X_B$  current batch at the beginning on each session when printing the 5C

Cell control results. Review, print, and file the Coulter  $X_B$  current batch at the beginning of each session when printing the 5C Cell control results.

2.  $X_B$  batch means

Use to view the calculated means for the last batch of 20 SP results. The MAXM calculates MCV, MCH, and MCHC means. Review, print, file, and delete the Batch Means at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Evaluate the percentage difference from the target limit to determine whether the batch is in or out of control. Select **SAMPLE ANALYSIS,  $X_B$ , and CURRENT  $X_B$  BATCH.** Press [F2] [F4]. Print and file in logbook.

To change the status of  $X_B$ , select [F5] Optns on the **RUN SAMPLES** screen.

Screen-specific function keys:

[F4] Print      Prints the table.

[F6] Delete Last Batch

Deletes the last batch. Delete only if the batch is badly skewed because of non-random sampling or an instrument problem that will adversely effect many later batches.

[F8] Delete Table

Deletes the entire table.

[←] [→]      Press [←] or [→] to see parameters not currently displays on the screen.

[F9] Menu      Displays the main menu.

3.  $X_B$  Graphs

Review, print, file, and delete the Batch Means and graphs at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Select **SAMPLE ANALYSIS,  $X_B$ ,  $X_B$  GRAPHS,** and [F4] to print. File in the logbook.

F. Proficiency testing

Evaluation and participation in the College of American Pathologist (CAP) proficiency-testing program is part of the comprehensive quality control program. These survey materials are shipped three times per year and consist of 5 3-mL whole blood specimens. Follow all CAP instruction in preparing the materials before performing the test. Run specimens in a manner identical to routine specimens. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

G. Linearity for WBC, RBC, Hgb and Plt parameters

Lin-C™ (PN 7547065 - 5 x 3.3-mL) The Lin-C™ linearity controls verifies the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent.

OR

CAP Hematology Calibration Verification/Linearity Survey (LN9) - These materials are shipped twice per year and consist of 18 3-mL liquid specimens. Follow all CAP instruction in preparing and running the materials before performing the test. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

Run either the Lin-C™ or CAP LN9 survey material:

- At installation
  - At least yearly
  - Whenever experiencing an altitude change of 1 mile or more between stands
1. Principle - Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems. Controls contain one each of Ultra Low Range, Low Range, Mid Range, High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt.

To ensure the accuracy of linearity control ranges, Beckman Coulter® system calibrates with S-CAL® calibrator.

2. Reagents -- Lin-C™ controls consist of treated, stabilized, human erythrocytes in an isotonic bacteriostatic medium. Linearity controls also contain a stabilized platelet-sized component, and fixed erythrocytes to simulate leukocytes.
3. Storage, handling, and stability -- Ship Lin-C™ controls in thermally insulated containers designed to keep kits cool. Store Lin-C™ linearity controls between 2-8°C (35-46°F). Store vials in an upright position to achieve maximum product yield. Storage of the control product in a cap down position might require additional mixing or complete resuspension of cellular components.

Potential biohazard -- Each human donor used in preparation of this material was tested by an FDA approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) as well as for hepatitis B surface antigen and found to be negative (were not repeatedly reactive.) Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (dark colored supernatant) indicates product deterioration. A slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.
5. Instructions for use -- Remove Lin-C™ controls from refrigerator and warm to ambient temperature for 10-15 minutes. After warming mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again. Controls expire 7 days after opening.

- a) Turn the blood detectors off to analyze the Ultra Low Range. Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, BSV TESTS, and BLOOD DETECTOR ON/OFF**. Press [Enter]. Use space bar to select On or OFF. Press [Enter].
- b) Disable the differential before analyzing Lin-C™ linearity controls. Is SAMPLE MODE displayed? If no, press [F9] STOP. Make sure the DIFF is off. If it is on, press [F6].
- c) When analyzing Lin-C™ linearity controls, flags such as L, LL, H, HH, R, RR, \*, \*R, and \*V will occur. Ignore these flags if a numerical result is obtained. When ---- (voteout), ..... (incomplete computation) or ++++ (over range) flags occur, the sample should be repeated. Ignore Beckman Coulter® histogram differential flags and results.
- d) Run the Lin-C™ controls in the Primary Mode of the instrument. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Press [Enter]. Press [F2] START PRIMARY. Analyze controls six times and record the results for WBC, RBC, Hgb, and Plt parameters for each sample on the worksheet. Repeat flagged samples with non-numeric results.
- e) Beckman Coulter® recommends that five sample results should be used to calculate the mean value. Use a minimum of three samples to calculate the mean when repetitive results with non-numeric values occur. Delete the first sample result. Plot mean recovered values on the Lin-C™ linearity control graphs.
- f) Compare the mean value to the linearity control ranges listed on the Table of Expected Results on the package insert. Mean values should recover within the ranges. Use the ranges established by Beckman Coulter® Corporation as a guideline.

- g) Plot the instrument background count as a zero value to extend the reportable range. Beckman Coulter® will prepare tabular summaries and graphic presentations of the data. Submit the top copy of the worksheet to IQAP at the following address:

Beckman Coulter Corporation  
IQAP (M/C 31 B04)  
PO BOX 169015  
Miami, FL 33116-9015

## XI. Interpretation of Results and Remedial Action

### A. Sample Person hemoglobin and hematocrit review and remedial actions.

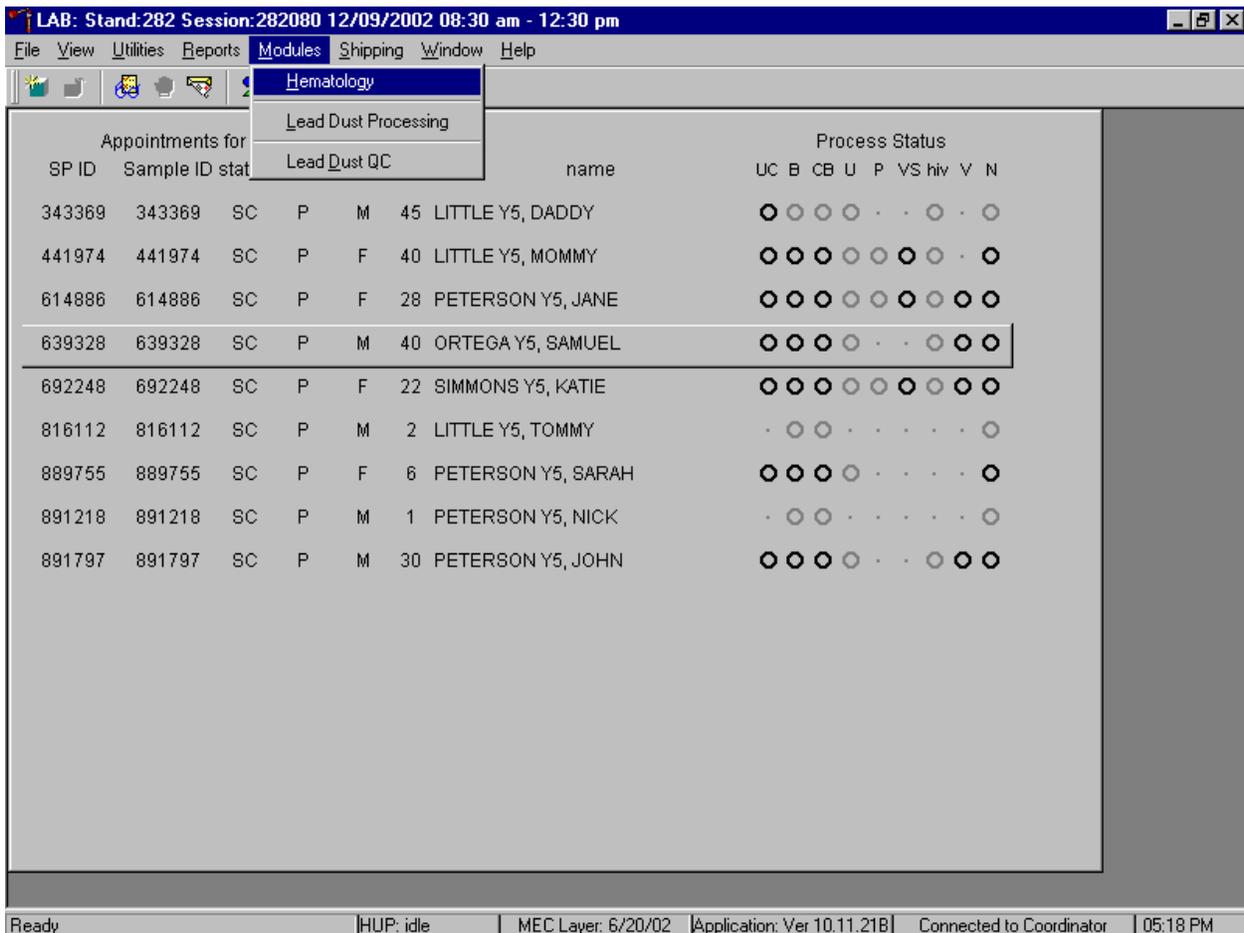
1. Review all results to make sure the hemoglobin and hematocrit are acceptable. The hematocrit should be approximately three times the hemoglobin.

B. Sample person parameter value review and remedial actions.

1. Access the Hematology module or reject a clotted blood tube.

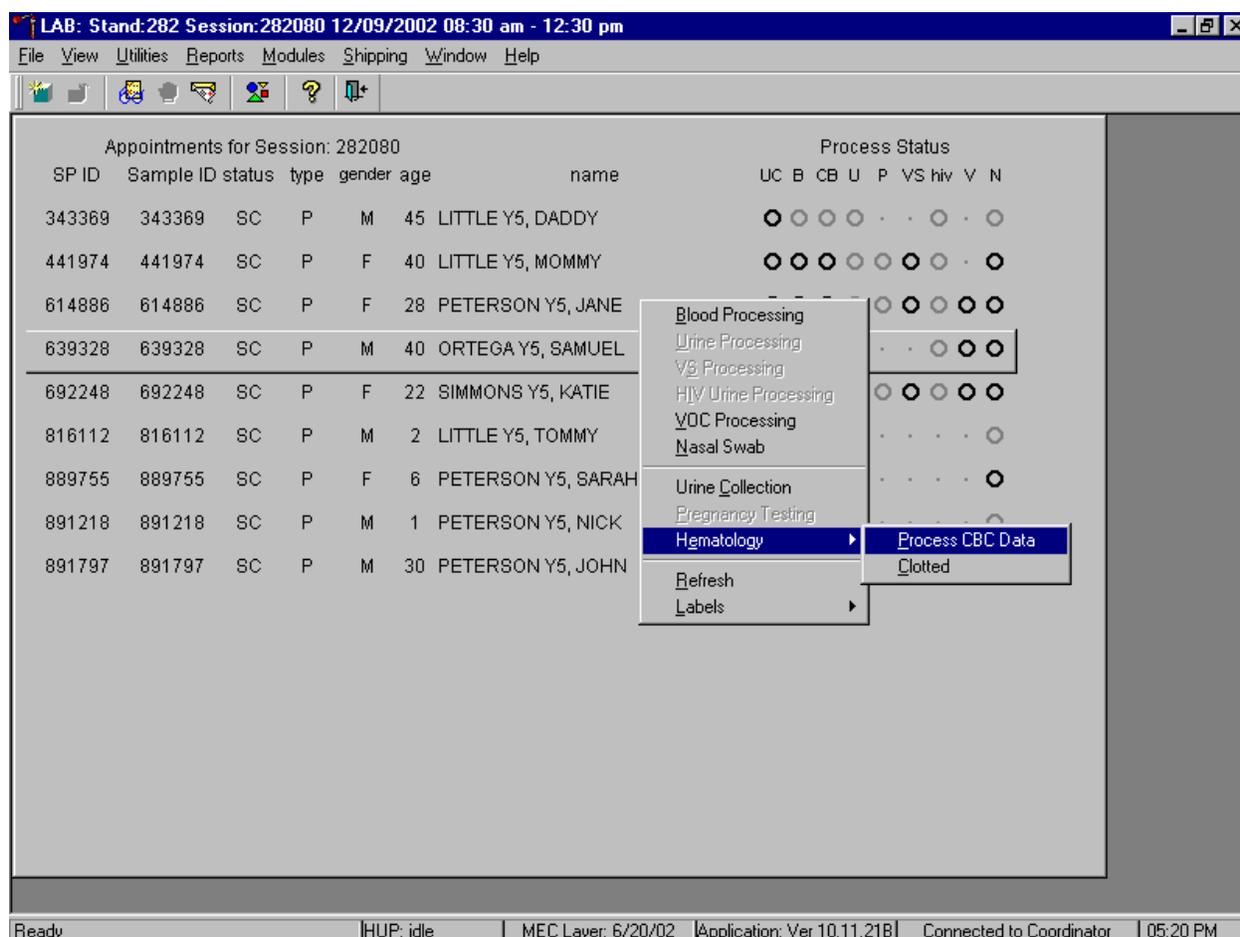
Make sure the Hematology module is open before running SP samples on the MAXM.

Open the Hematology module.



To open the Hematology module, use the mouse to direct the mouse arrow to {Modules}, in the top menu bar, left click, drag the mouse arrow to {Hematology}, and right click, or type [Alt][M/m], [H/h].

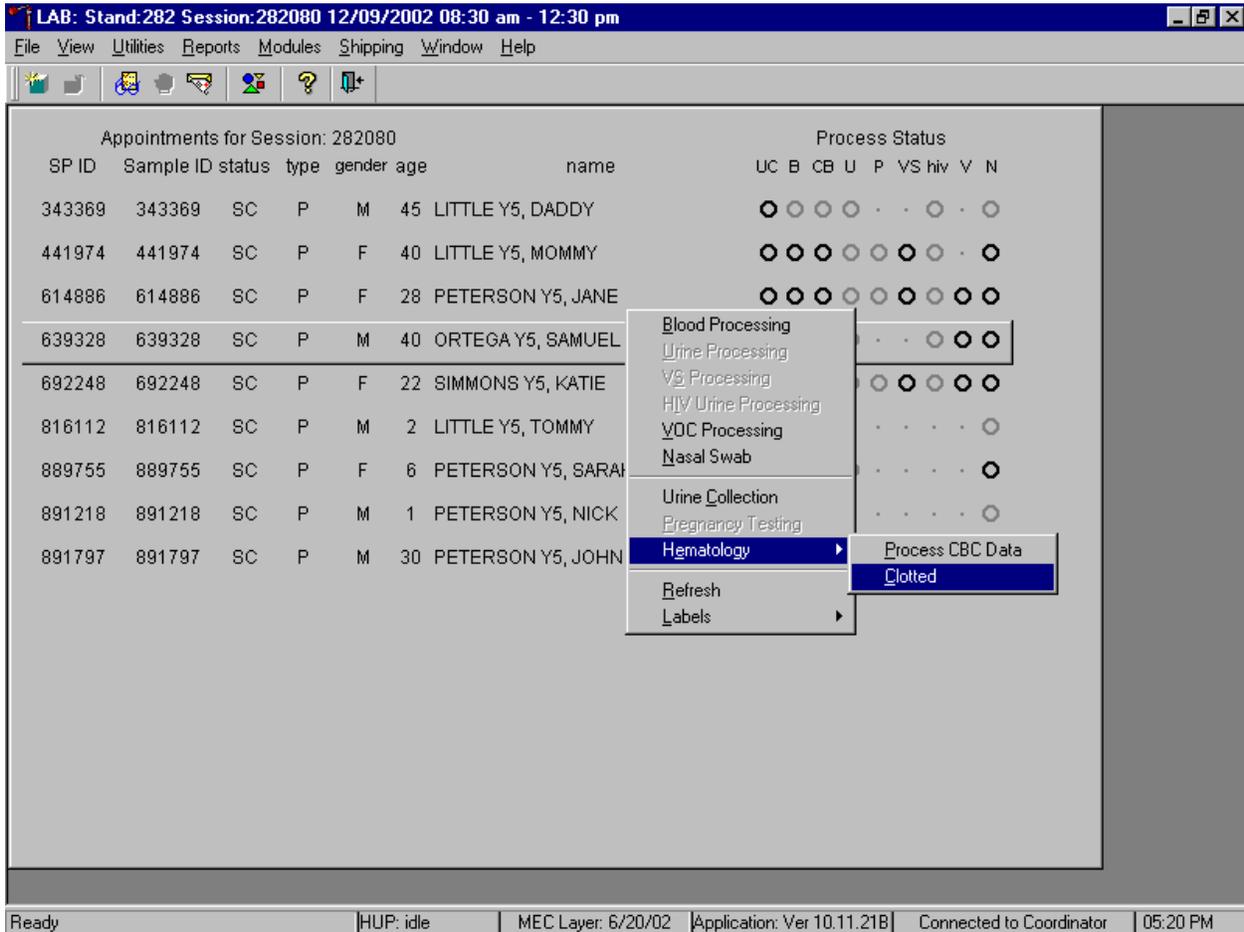
Alternatively, open the Hematology module from the heads-up display.



To access the Hematology module, use the mouse to direct the mouse arrow to any SP, right click, drag the mouse arrow to {Hematology}, and right click or right click and type [Shift] [E/e]. Alternatively, use the up and down keys to move up and down the list until a particular SP is highlighted, right click, drag the mouse arrow to {Hematology}, and right click or right click and type [Shift] [E/e].

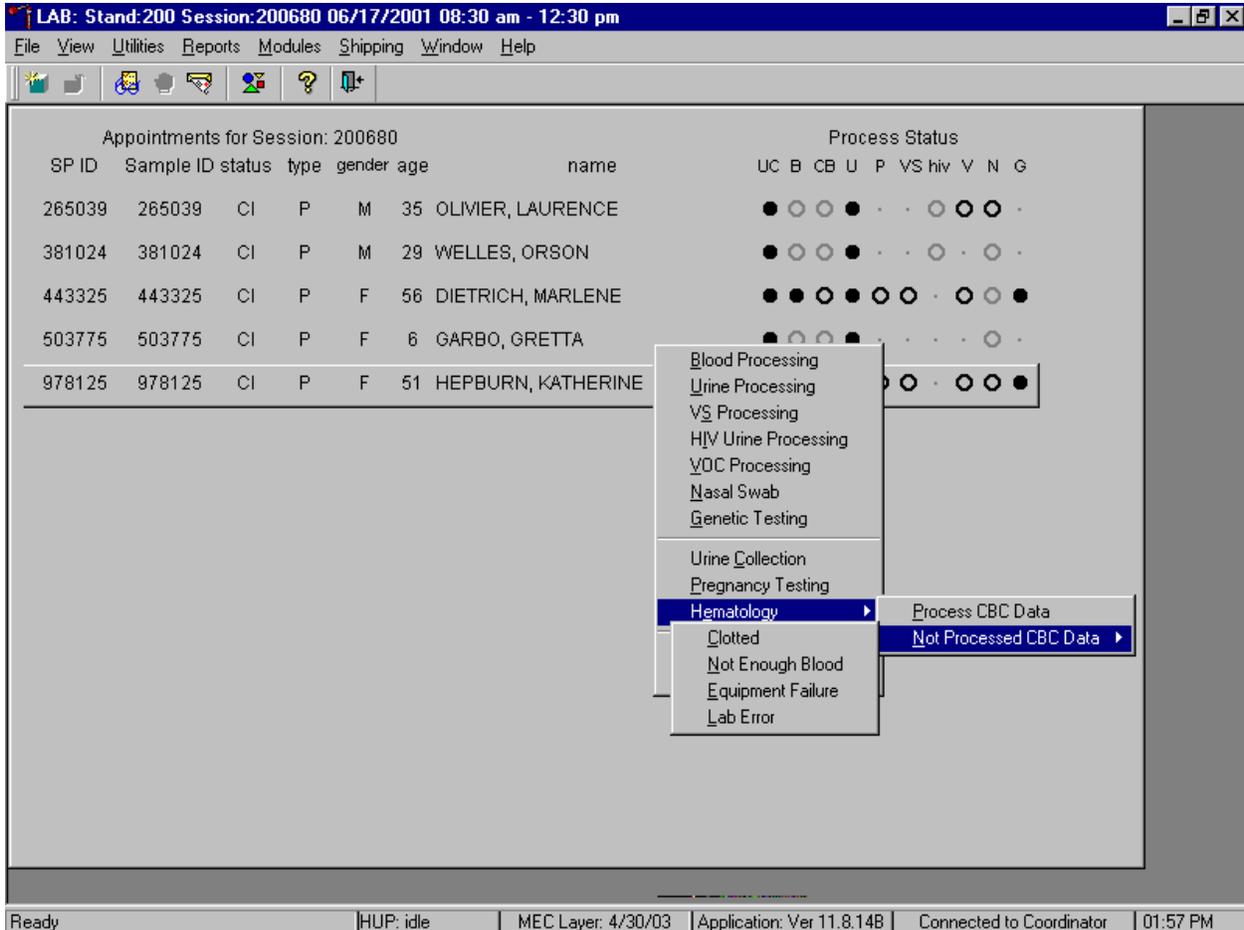
Either open the module or reject the specimen and add a reason or comment for every CB record where blood was drawn in phlebotomy AND there are no CBC results.

Complete opening or accessing the Hematology module.



To complete opening or accessing the Hematology module, use the mouse to direct the mouse arrow to {Process CBC Data} and right click or type [P/p.]

Add a reason or comment for every CB record where blood was drawn in phlebotomy AND there are no CBC results.



Open the module {Process CBC Data} or record a reason why the CBC is not being run {Not Processed CBC Data}. Select or record a comment for every CBC that is not run. To complete opening or accessing the Hematology module, use the mouse to direct the mouse arrow to {Process CBC Data} and right click or type [P/p.] To record a reason why a CBC is not being run, use the mouse to direct the mouse arrow to the exact SP's line on the heads-up display, right click, drag the mouse arrow to {Not Processed CBC Data}, and drag the mouse arrow to the correct reason and right click. Alternatively, type [Shift] [E/e] [N/n] and [C/c] for Clotted, [N/n] for Not Enough Blood, [E/e] for Equipment Failure, or [L/l] for Lab Error.

A popup window will display. Confirm the selection.

The screenshot shows a software window titled 'LAB: Stand:200 Session:200680 06/17/2001 08:30 am - 12:30 pm'. The window contains a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. Below the toolbar is a table titled 'Appointments for Session: 200680'. The table has columns for SP ID, Sample ID, status, type, gender, age, name, and Process Status. The Process Status column includes sub-columns: UC, B, CB, U, P, VS, hiv, V, N, G. A dialog box titled 'CBC Data Not Processed' is overlaid on the table, asking 'Would you like to mark sample id 443325 as clotted?' with 'Yes' and 'No' buttons.

Appointments for Session: 200680							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
265039	265039	CI	P	M	35	OLIVIER, LAURENCE	●	○	○	●	.	.	○	○	○	.
381024	381024	CI	P	M	29	WELLES, ORSON	●	○	○	●	.	.	○	.	○	.
443325	443325	CI	P	F	56	DIETRICH, MARLENE	●	●	○	●	○	○	.	○	○	●
503775	503775	CI	P	F	6	GARBO, GRETTA	●	○	○	●	.	.	.	.	○	.
978125	978125	CI	P	F	51	HEPBURN, KATHERINE	●	○	○	●	○	○	.	○	○	●

**CBC Data Not Processed**

Would you like to mark sample id 443325 as clotted ?

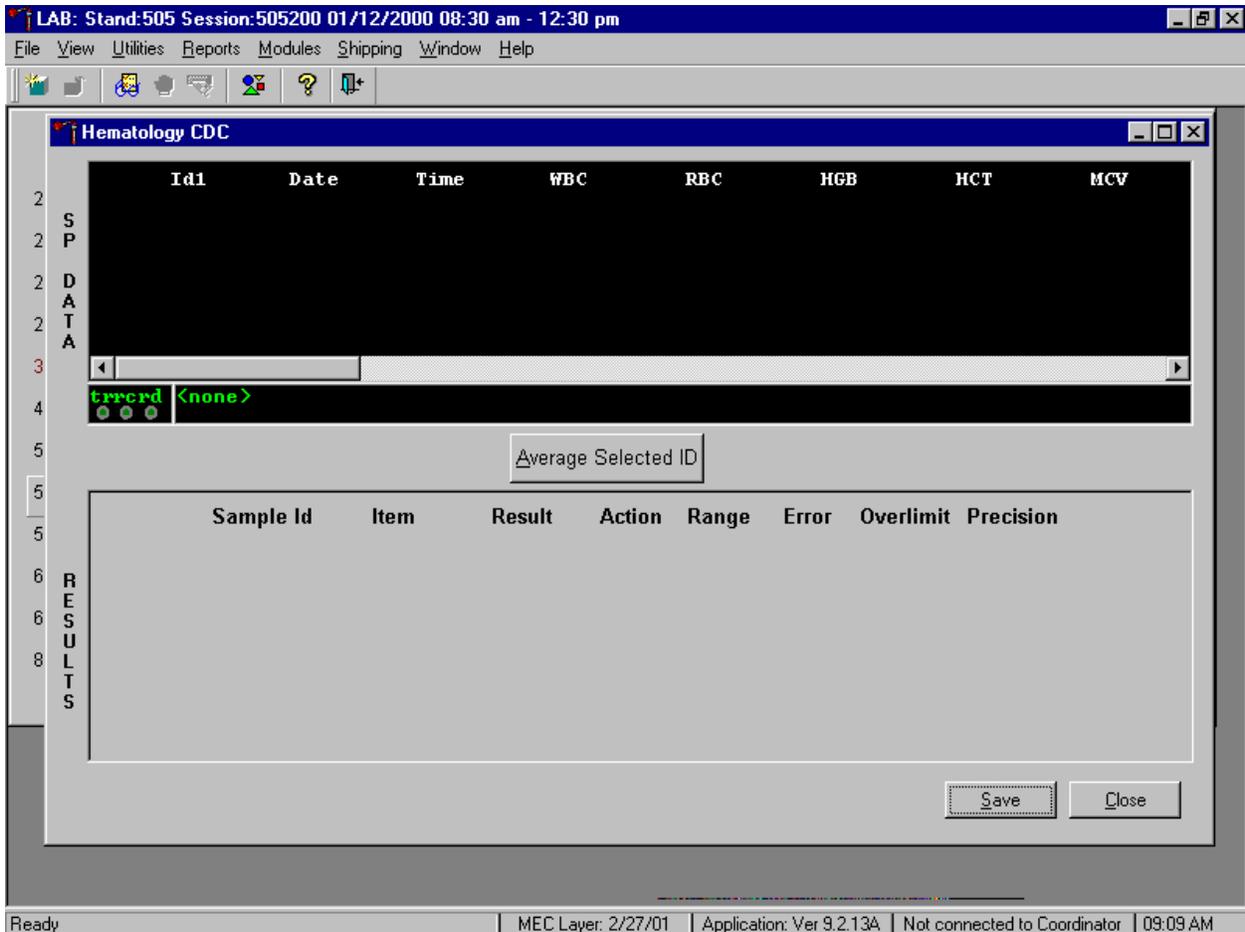
Yes No

Ready | HUP: idle | MEC Layer: 4/30/03 | Application: Ver 11.8.14B | Connected to Coordinator | 02:04 PM

A CBC Data Not Processed message text box displays that asks, "Would you like to mark sample id XXXXXX as Clotted/Not Enough Blood/Equipment Failure/Lab Error?" To record a "Yes" response, use the mouse to direct the mouse arrow to the Yes button and left click, type [Y/y], or press [Enter]. To record a "No" response, use the mouse to direct the mouse arrow to the No button and left click, or type [N/n]. If a Yes response is recorded, the comment is saved to the database. If a No response is recorded, no comment is saved to the database. If the record is marked with the selection in the database, then the heads-up display updates to complete (the CB circle fills in).

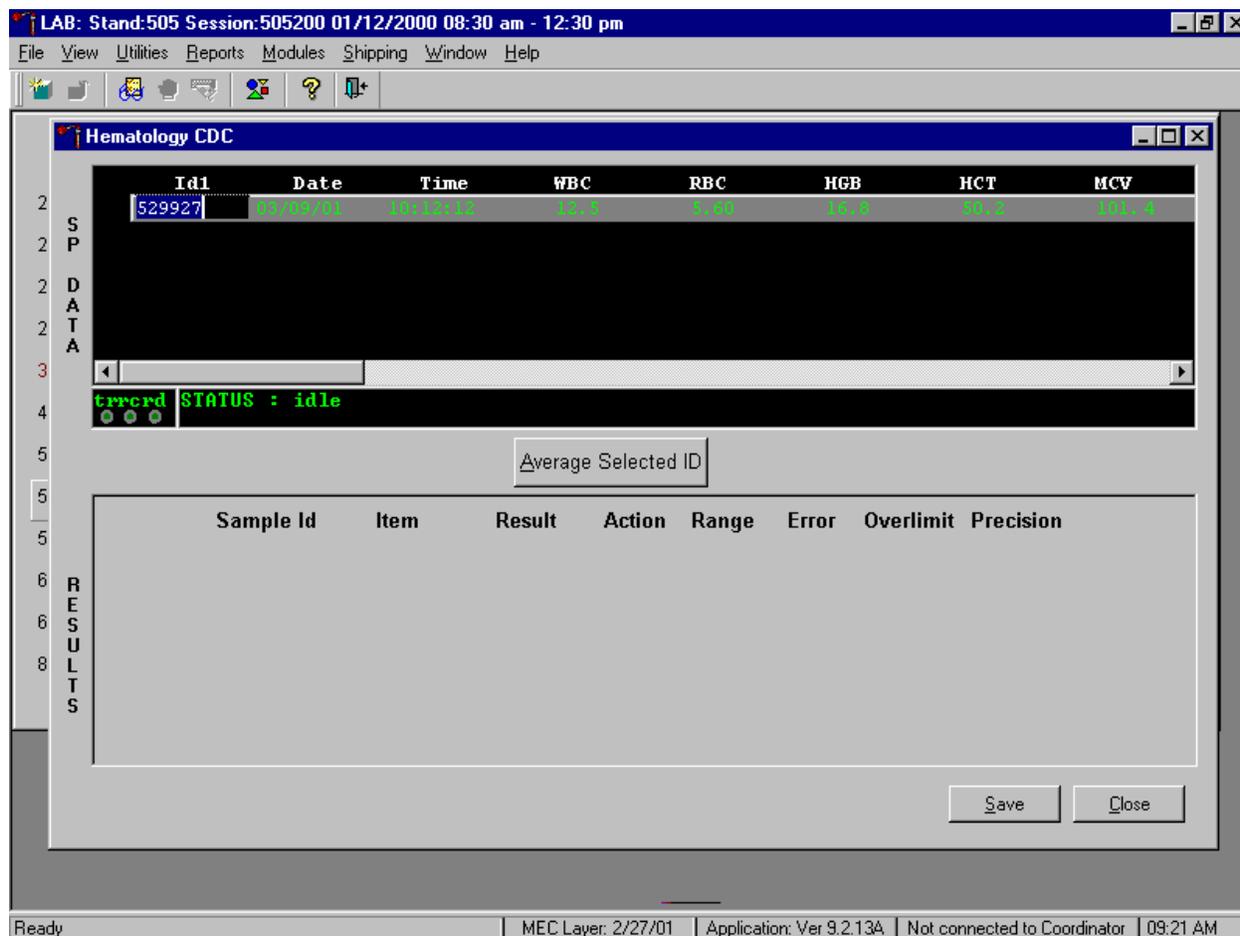
2. Hematology module overview.

Coulter automatically transmits results to the Laboratory application. Make sure the Beckman Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



SP data transmits to the Hematology module and displays it in the top portion of the window, the SP Data section. This section includes the SP ID, the date and time the CBC was run, and columns for each individual parameter. The bottom portion of the window is the Results section. Results display after the Average Selected ID button is selected.

Review all Coulter data in the SP Data section after transmission.



To view SP data for all parameters, use the mouse to direct the mouse arrow to the horizontal scroll bar at the bottom of the SP Data section and drag the scroll bar to the left or right. Alternatively, to view the SP data for all parameters, use the mouse to direct the mouse arrow to the small scroll arrows on the left and right edges of the horizontal scroll bar, and left click.

## The Hematology Results section overview.

The screenshot shows the Hematology CDC software interface. At the top, the title bar reads "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The main window is titled "Hematology CDC" and contains a summary table and a detailed results table.

**Summary Table:**

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
529927	05/05/01	10:12:12	12.5	5.60	16.8	50.2	101.4

Below the summary table, there is a status bar showing "ERROR STATUS : idle".

**Results Table:**

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
529927	CBC_WBC	12.5	<input type="checkbox"/>				
529927	CBC_RBC	5.6	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
529927	CBC_HGB	16.8	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
529927	CBC_HCT	50.2	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

At the bottom of the results table, there is a comment field for "Sample Id# 529927" with the text "result based on single run". There are "Save" and "Close" buttons to the right.

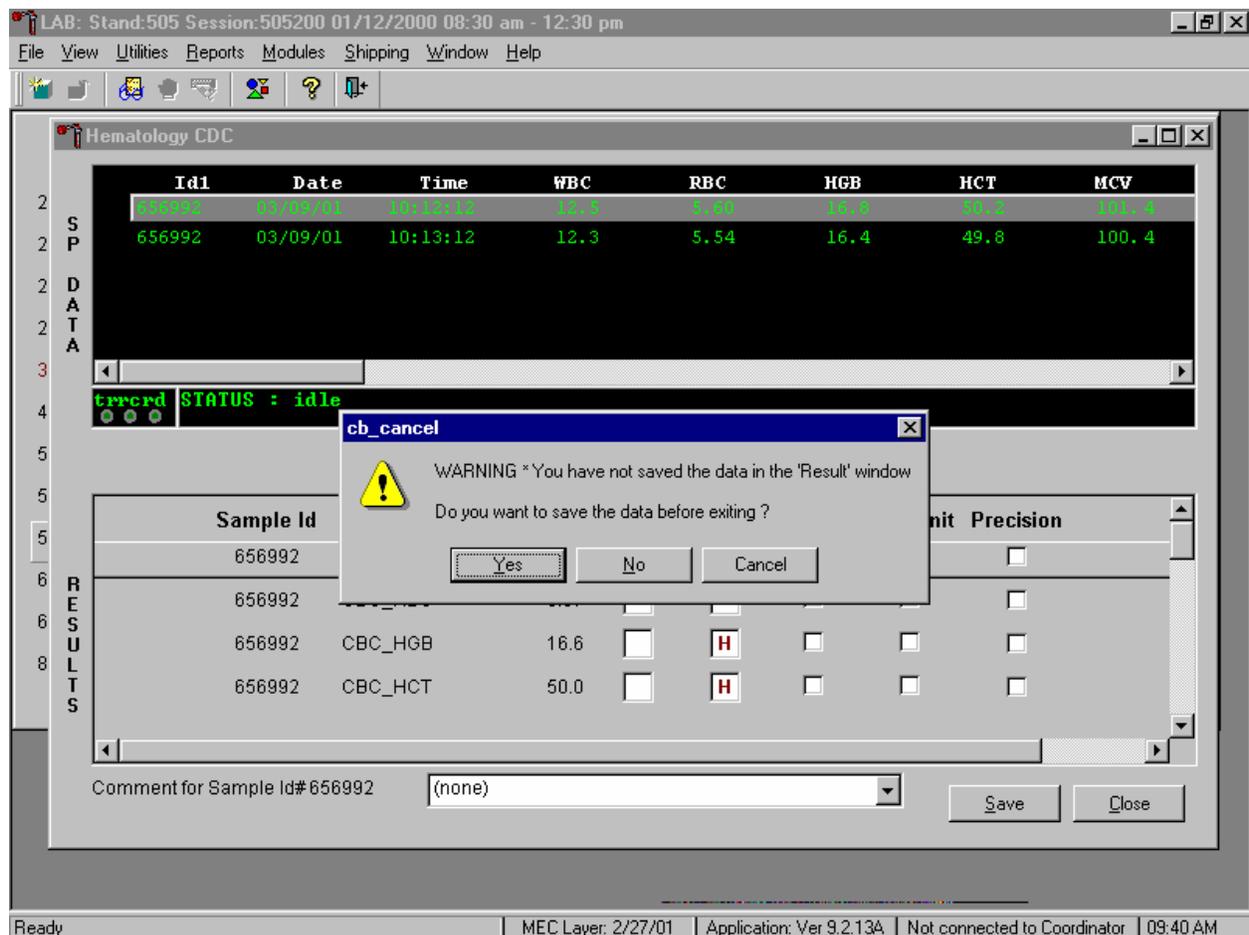
The status bar at the bottom of the window shows: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:23 AM".

The Result columns include: Sample ID, Item (CBC parameter), Result (Coulter data for a single run or the ISIS averaged result for multiple runs), Action (CDC established critical limits), Range (CDC established reference ranges for both genders and four age groups), Error (Coulter transmitted instrument errors), Overlimit (Coulter transmitted result that exceeds the instrument's linearity limit), and Precision (CDC established values for the difference between any two runs.) Checkmarks display in boxes for parameters that have errors, are overlimit, or for those that exceed precision limits. An "H" for "high" and "L" for "low" display for parameters that exceed action limits or reference ranges.

Average, evaluate, and save results for all parameters. The SP's results display in the bottom portion of the window after the Average Selected ID button is selected. To view results for all parameters, use the mouse to direct the mouse arrow to the vertical scroll bar at the right side of the

Results section and drag the bar up or down. Alternatively, to view all the results, use the mouse to direct the mouse arrow to the small scroll arrows on the top and bottom edges of the vertical scroll bar, and left click. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. To save the result to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Cancel button and left click or type [Shift] [C/c].

A warning text box displays if the Close button is selected before the results have been saved.

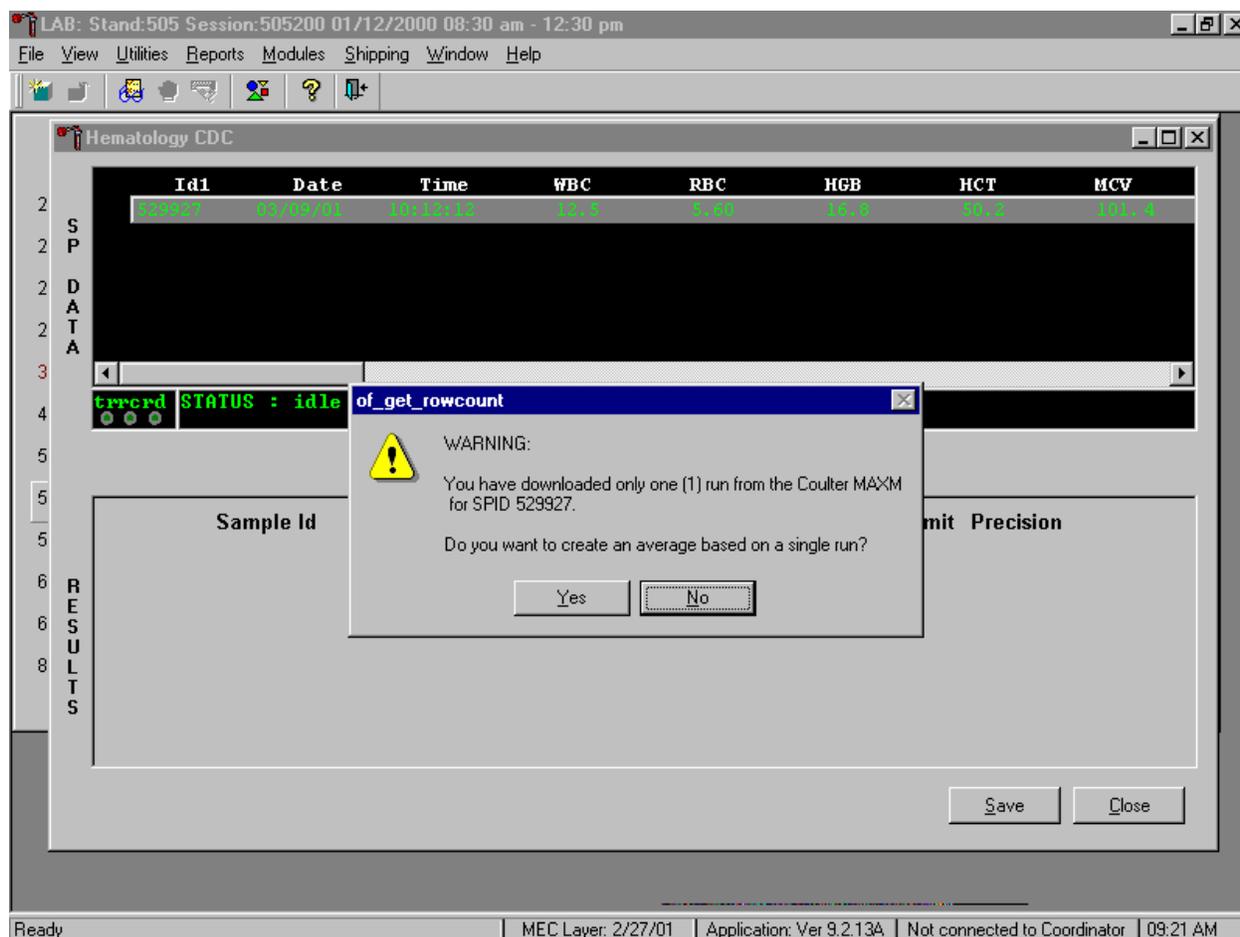


If the Close button is selected before the results are saved to the database, a warning message text box displays that states, "WARNING \*You have not saved the data in the 'Result' window" and asks,

"Do you want to save the data before exiting?" To record a "Yes" response, use the mouse to direct the mouse arrow to the Yes button and left click, type [Y/y], or press [Enter]. To record a "No" response, use the mouse to direct the mouse arrow to the No button and left click, or type [N/n]. To cancel the action, use the mouse to direct the mouse arrow to the Cancel button and left click. If a Yes response is recorded, the CBC results are saved to the database and erased. If a No response is recorded, no results are saved to the database and the data in the Results section is erased. A Cancel response returns the screen to its previous state.

3. Running samples when only one run is possible.

Save results where only one run was possible.

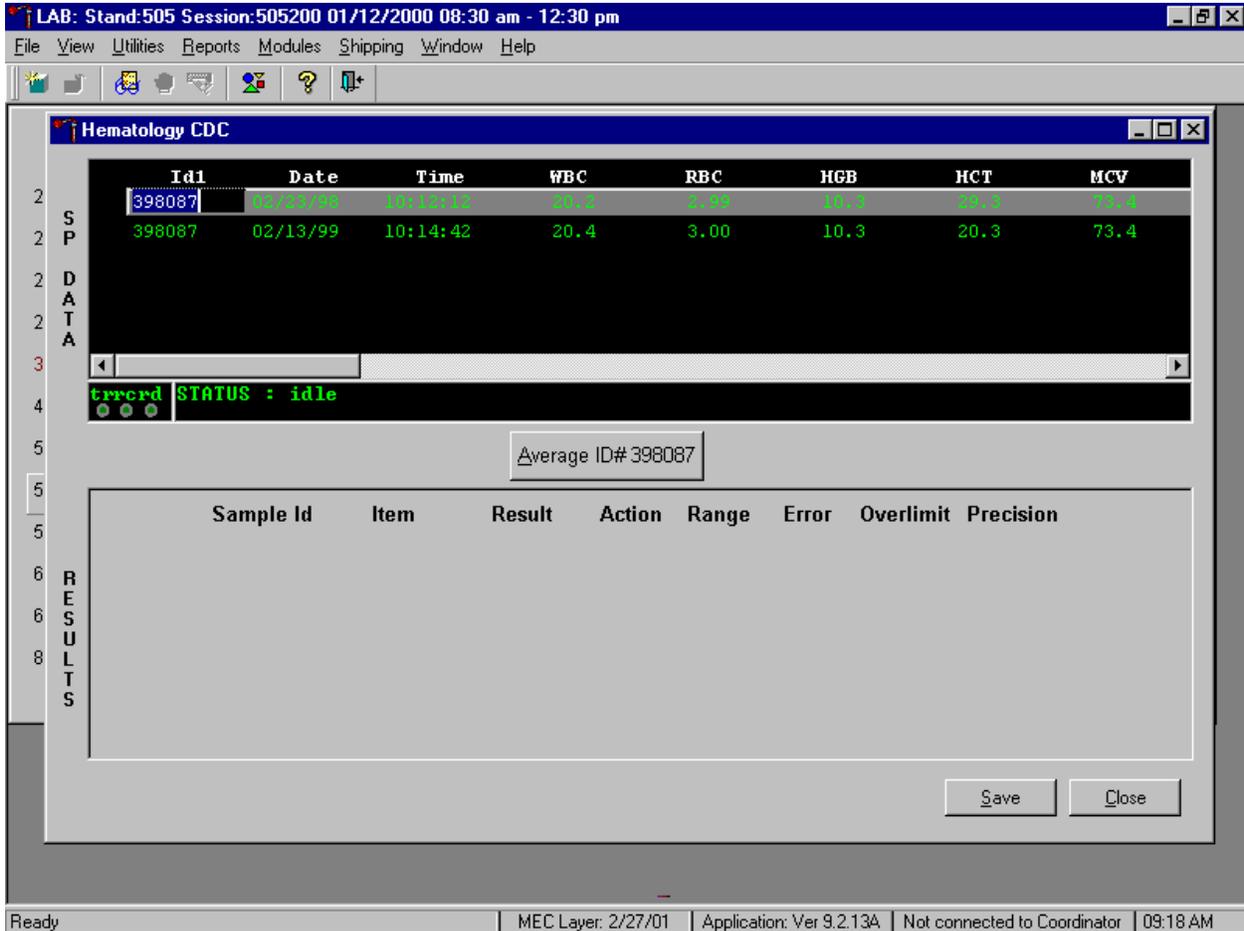


Run samples in duplicate whenever possible. If the whole blood is insufficient, it is acceptable to average and save only one run. To save results where only one run is possible, use the mouse to direct the mouse arrow to the Average Selected ID box and left click. A warning message text box displays that states, "You have downloaded only one (1) run from the Coulter MAXM for SPID XXXXXX" and asks, "Do you want to create an average based on a single run?" To record a "Yes" response, use the mouse to direct the mouse arrow to the Yes button and left click or type [Y/y]. To record a "No" response, use the mouse to direct the mouse arrow to the No button and left click, or type [N/n], or press [Enter]. If a Yes response is recorded, the CBC results display in the bottom Results section of the window. A "No" response cancels the action and returns the window to its previous state.

For results where only one run was possible, the Comment box at the bottom of the window defaults to "result based on single run."

4. Running samples in duplicate.

Run all samples in duplicate and average the data.



Whenever a sample is run in duplicate, both results display in the SP Data section. To average these two results, use the mouse to direct the mouse arrow to Average ID#XXXXXX button and left click.

Results display in the lower section of the window.

The screenshot shows a software window titled "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Inside, there is a "Hematology CDC" window and a "RESULTS" window.

**Hematology CDC Data Table:**

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
656992	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
656992	03/09/01	10:13:12	12.3	5.54	16.4	49.8	100.4

Below the CDC window, the status is "Average ID# 656992" and "errord STATUS : idle".

**RESULTS Data Table:**

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
656992	CBC_WBC	12.4	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_RBC	5.57	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_HGB	16.6	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

At the bottom of the RESULTS window, there is a "Comment for Sample Id# 656992" field with the value "(none)", and "Save" and "Close" buttons.

The status bar at the bottom of the application shows: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:40 AM".

The difference between duplicate values for WBC, RBC, Hgb, MCV, Plt, NE#, LY#, MO#, EO# and BA# are calculated and evaluated to determine if the differences are within the following CDC established precision limits.

CDC established precision limits:

Test	Precision Limits
WBC	$0.4 \times 10^3$
RBC	$0.1 \times 10^6$
Hgb	0.4 g/dL
MCV	2.2 fL
Plt	$23 \times 10^3$
NE#	$0.4 \times 10^3$
LY#	$0.2 \times 10^3$
MO#	$0.2 \times 10^3$
EO#	$0.2 \times 10^3$
BA#	$0.2 \times 10^3$

If RBC parameters are out of range, evaluate XB for a drift. If drift is evident, evaluate the possibility of an instrument malfunction. If any WBC differential absolute number is out of range, check the WBC scattergram for abnormal cell population(s).

Evaluate and save results when precision limits are not exceeded.

The screenshot displays the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The main window is titled "Hematology CDC".

The "DATA" section contains a table with the following data:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
656992	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
656992	03/09/01	10:13:12	12.3	5.54	16.4	49.8	100.4

Below the data table, the status is "errord STATUS : idle".

The "RESULTS" section shows a table with the following data:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
656992	CBC_WBC	12.4	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_RBC	5.57	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_HGB	16.6	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

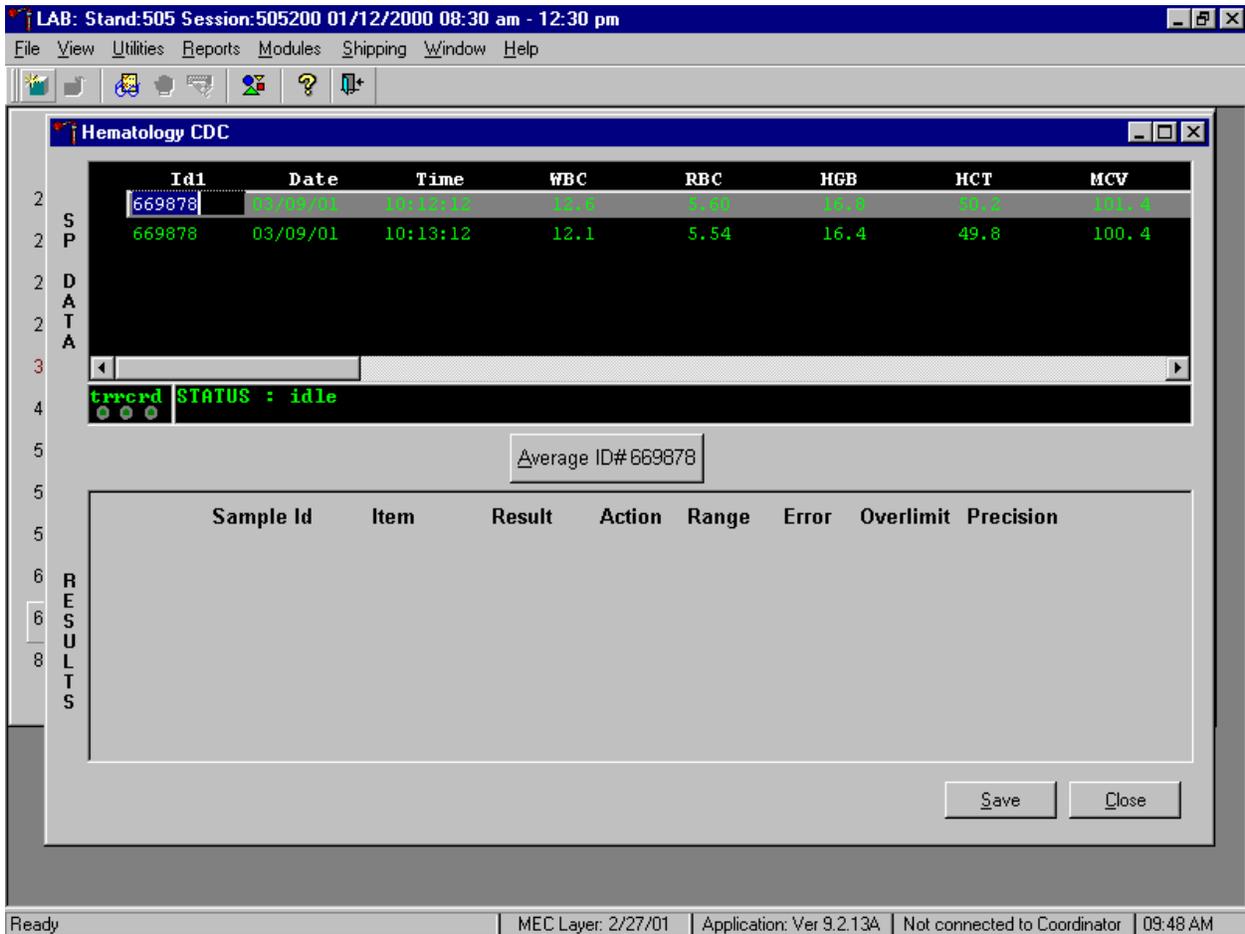
At the bottom of the results table, there is a "Comment for Sample Id# 656992" field with the value "(none)".

The interface includes "Save" and "Close" buttons at the bottom right.

The status bar at the bottom shows: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:40 AM".

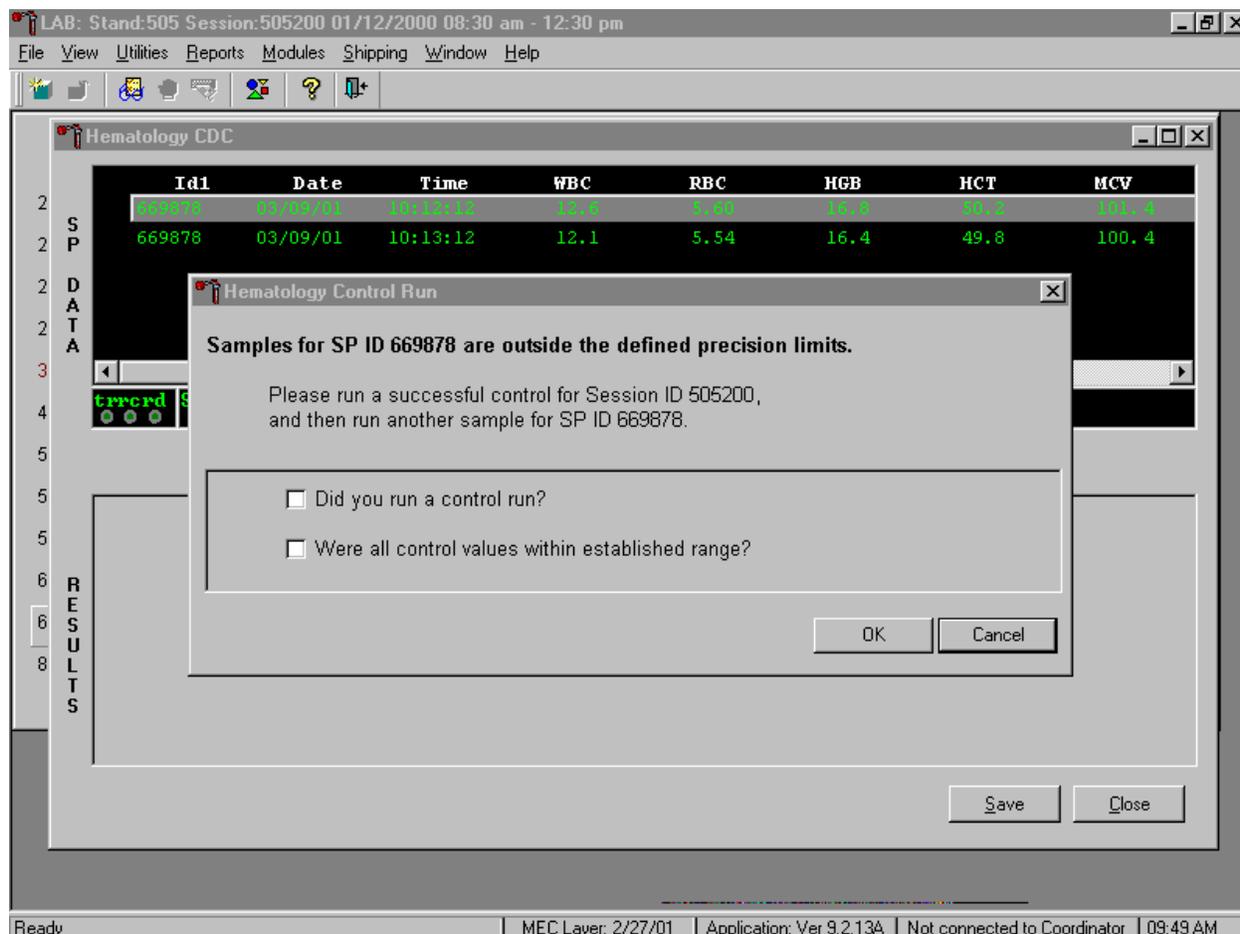
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

Average, evaluate, and rerun specimens that exceed precision limits.



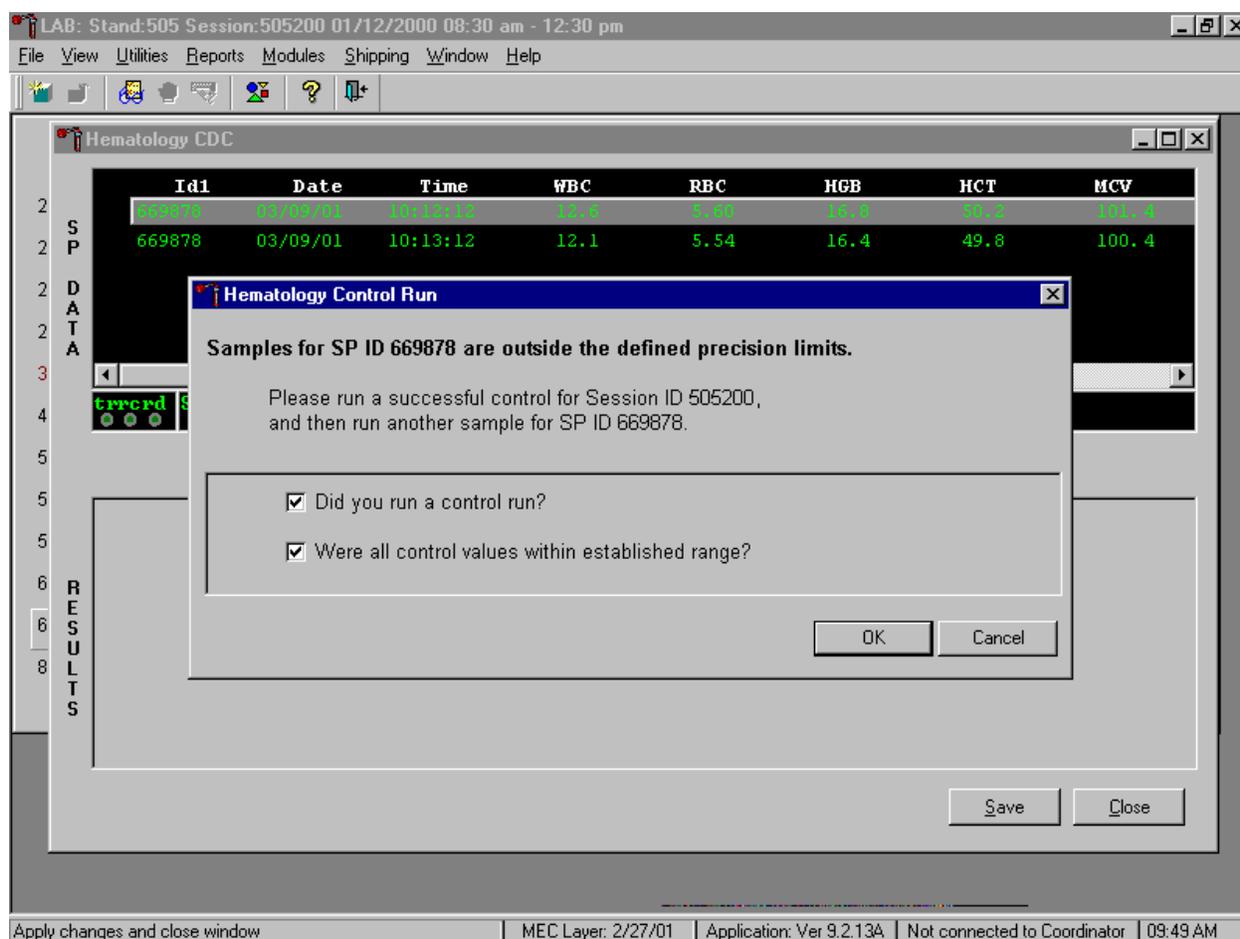
Average the two results by using the mouse to direct the mouse arrow to the Average ID#XXXXXX button and left click. If at this point, precision limits are exceeded for any individual parameter, the technologist is prompted to run a control and evaluate the control to determine if all control values fall within the control's established range.

If any parameter exceeds its precision limit, the Hematology Control Run window displays.



The Hematology Control Run window indicates that the "Samples for SP ID XXXXXX are outside the defined precision limits." It instructs the technologist to "Please run a successful control for Session ID XXXXXX, and then run another sample for SP ID XXXXXX." Run any one level of 5C Cell control and evaluate the results. Respond to the two questions, "Did you run a control run?" and "Were all control values within established range"? To confirm these actions, use the mouse to direct the mouse arrow to each of the two check boxes and left click to record the check marks.

Save the responses to the check box questions.



To save these responses to the database, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter], or to exit the Hematology Control Run window without saving the responses, use the mouse to direct the mouse arrow to the Cancel button and left click. As soon as the OK button is selected, the averages display in the Results section of the window.

Evaluate the results displayed in the Results section of the window.

The screenshot shows the Hematology CDC software interface. The main window displays a table of sample data and a detailed results section.

**SP DATA**

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.6	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.1	5.54	16.4	49.8	100.4

errord STATUS : idle

Average ID# 669878

**RESULTS**

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 669878 (none)

Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:50 AM

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. Use the scroll bar to view all results. When there are checkmarks in any of the Precision columns, meaning that the precision limit was exceeded, rerun the blood sample a third time. If there is insufficient blood to run the CBC a third time, save the result to the database. To save the results to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

Run the specimen a third time when any precision limit is exceeded.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Hematology CDC

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.0	5.54	16.4	49.8	100.4
669878	03/09/01	10:16:45	12.3	5.57	16.8	50.0	100.4

errord STATUS : idle

Average ID#669878

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>				
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id#669878 (none)

Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:58 AM

Run the blood sample a third time. Whenever a sample is run more than once, all results in the SP Data section are displayed. To re-average these results, use the mouse to direct the mouse arrow to Average ID#XXXXXX button and left click. The initial averaged result for parameters that do not exceed precision limits are fixed and are not recalculated.

Override the current averaged results for parameters that exceeded the precision limit with a new average.

The screenshot shows the Hematology CDC software interface. At the top, a status bar reads "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below this is a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The main window displays a table of sample data:

SP	DATA	Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
2		669878	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
2		669878	03/09/01	10:13:12	12.0	5.54	16.4	49.8	100.4
2		669878	03/09/01	10:16:45	12.3	5.57	16.8	50.0	100.4

A warning dialog box titled "wf\_average" is overlaid on the screen. It contains a yellow warning icon and the following text:

WARNING:  
 Averages for SP ID 669878 have already been calculated (but not saved) for Session ID 505200.  
 Please click YES to override these results with a new average.

The dialog box has "Yes" and "No" buttons. Below the dialog box, a table shows the current results for sample 669878:

Sample Id	Parameter	Value	Limit	Unit
669878	CBC_HGB	16.6	H	
669878	CBC_HCT	50.0	H	

At the bottom of the main window, there is a "Comment for Sample Id# 669878" field with the value "(none)" and "Save" and "Close" buttons. The status bar at the very bottom reads "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:59 AM".

Whenever a sample has previously been averaged, and a new average is calculated, a Warning message text box displays stating, "Averages for SP ID XXXXXX have already been calculated (but not saved) for session ID XXXXXX." The text box instructs, "Please click YES to override these results with a new average." To override the current average with a new average (but for only those parameters that exceeded precision limits), use the mouse to direct the mouse arrow to the Yes button and left click or type [Shift] [Y/y], or press [Enter]. To exit or return to the previous screen containing the previous averages, use the mouse to direct the mouse arrow to the No button and left click, or type [Shift] [N/n].

Evaluate the new results.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

**Hematology CDC**

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.0	5.54	16.4	49.8	100.4
669878	03/09/01	10:16:45	12.3	5.57	16.8	50.0	100.4

errord STATUS : idle

Average ID# 669878

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>				
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 669878 (none)

Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:59 AM

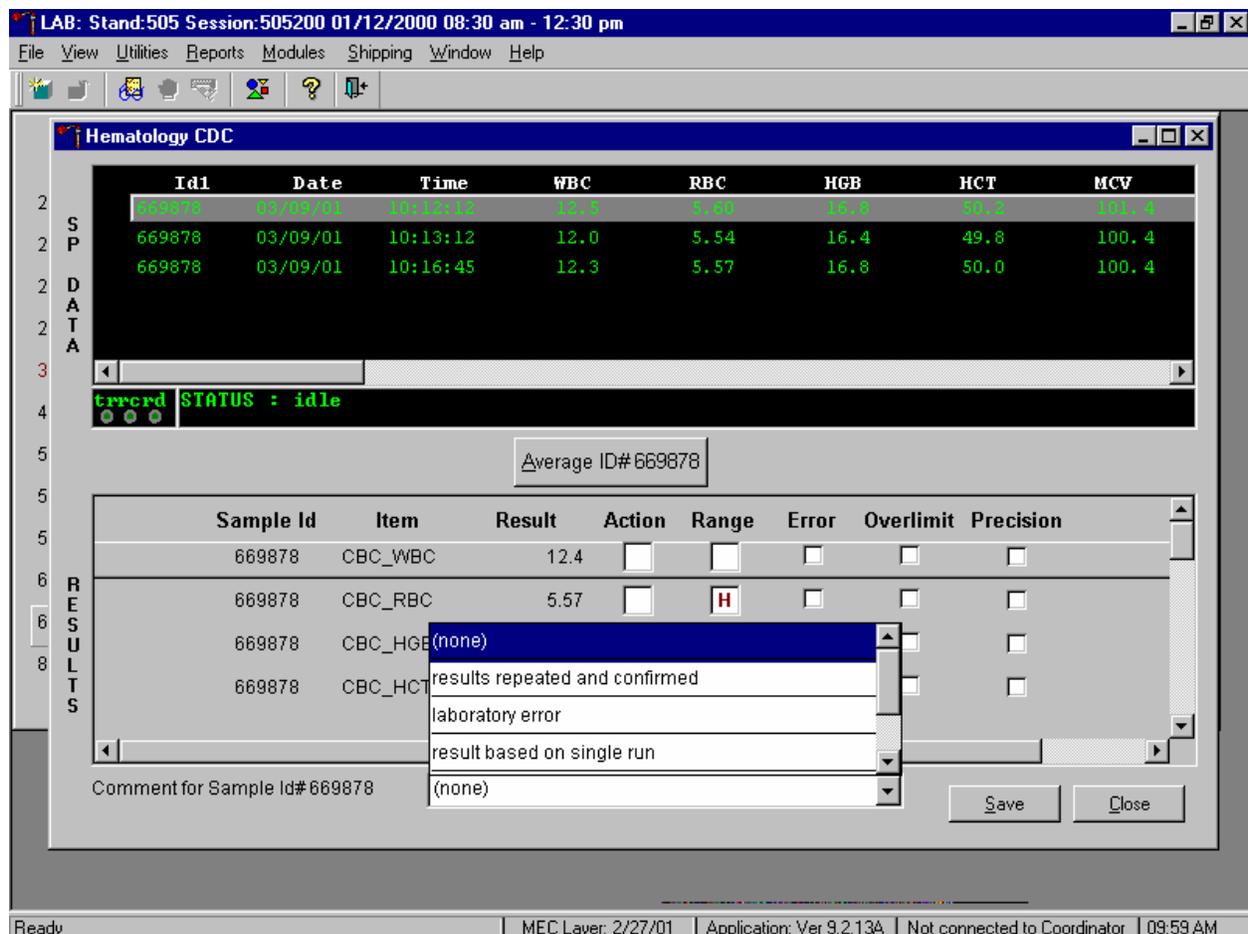
The first three runs are recalculated to find the closest two results for parameters where the difference between any two results exceeded its precision limits. If all parameters now meet precision limits (there are no checkmarks in the Precision column), save the results to the database. To save the result to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

If necessary, run the specimen a fourth time and evaluate.

If precision limits are still not met for any parameter, run the blood tube a fourth time. Re-average, evaluate, and save the results. If after four runs precision limits are still not met for any parameter, a comment is automatically attached to the results. Do not run a specimen more than four times.

5. Attaching comments to the results.

Enter a comment for any run where results were repeated and confirmed, the equipment failed, or there was a laboratory error.



To attach a comment to the results in the database, use the mouse to direct the mouse arrow to the drop-down list on the Comment box, left click to display the codes, drag the mouse arrow to the most appropriate choice, and left click. Alternatively, to record a comment, use the mouse to direct the

mouse arrow to the drop-down list on the Comment box, click to display the codes, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code, and when the correct choice is highlighted, left click.

Comment	Use when:
results repeated and confirmed	Any parameter exceeded an action, range or precision limit and the specimen (blood tube) was run more than once.
equipment failure	The Coulter malfunctioned.
laboratory error	There was a technologist error.
results based on single run	The quantity of specimen is insufficient to run it more than once.
no diff results/diff voteout	The Coulter does not report parameter results for any part of the differential or the instrument reported a voteout for any of the differential parameters.

Save the result after attaching a comment.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The main window is titled "Hematology CDC".

The "S P D A T A" section contains a table with the following data:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.0	5.54	16.4	49.8	100.4
669878	03/09/01	10:16:45	12.3	5.57	16.8	50.0	100.4

Below the data table, there is a status bar showing "errord STATUS : idle".

The "R E S U L T S" section shows the "Average ID# 669878" and a table with the following data:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>				
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

At the bottom, there is a comment field for "Sample Id# 669878" with the text "results repeated and confirmed". There are "Save" and "Close" buttons next to the comment field.

The status bar at the bottom of the window shows: "Save changes | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:59 AM".

Save the averaged result and update the comment, by using the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To exit without saving any data to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

6. Using alternative data manipulation choices.

Retain data for multiple SPs in the SP Data section of the window.



In general, run one SP in duplicate through the Coulter, average the result, and save the data to the database. The Hematology module will display data for multiple SPs in the SP Data section. Each individual SP's results or pairs of results are displayed in a different color. To select or highlight any one SP, use the mouse to direct the mouse arrow to the row containing the correct SP ID and left click.

Average the results for one SP at a time.

The screenshot shows a software window titled "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Inside, there is a "Hematology CDC" window with a table of data and a "RESULTS" section.

SP	Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
2	529927	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
2	565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	73.4
2	565368	03/09/01	10:13:13	16.2	3.29	10.3	29.3	63.4
2	656992	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
2	656992	03/09/01	10:13:12	12.3	5.54	16.4	49.8	100.4

STATUS : idle

Average ID# 565368

RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
5	565368	CBC_WBC	16.2	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	565368	CBC_RBC	3.64		L	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6	565368	CBC_HGB	10.3		L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	565368	CBC_HCT	29.3		L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 565368 (none)

Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:12 AM

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the result to the database. To save the result to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c]. If there are any Precision checkmarks, run a 5C Cell control, evaluate the control results, rerun the blood tube a third time, re-average, evaluate, and save the results.

Use alternative data manipulation choices as desired.

Use the "Clear All Downloads" function to delete all data for all SPs in the SP Data section.

The screenshot shows the Hematology CDC software interface. At the top, the title bar reads "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". A toolbar with various icons is located below the menu bar. The main window is titled "Hematology CDC" and contains several sections:

- SP DATA:** A table with columns: Id#, Date, Time, WBC, RBC, HGB, HCT, and MCV. The data is as follows:

SP DATA	Id#	Date	Time	WBC	RBC	HGB	HCT	MCV
2	529927	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
2	565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	73.4
2	565368	03/09/01	10:13:11			10.3	29.3	63.4
2	656992	03/09/01	10:12:11			16.8	50.2	101.4
2	656992	03/09/01	10:13:11			16.4	49.8	100.4
- STATUS:** A section showing "STATUS : idle".
- RESULTS:** A table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The data is as follows:

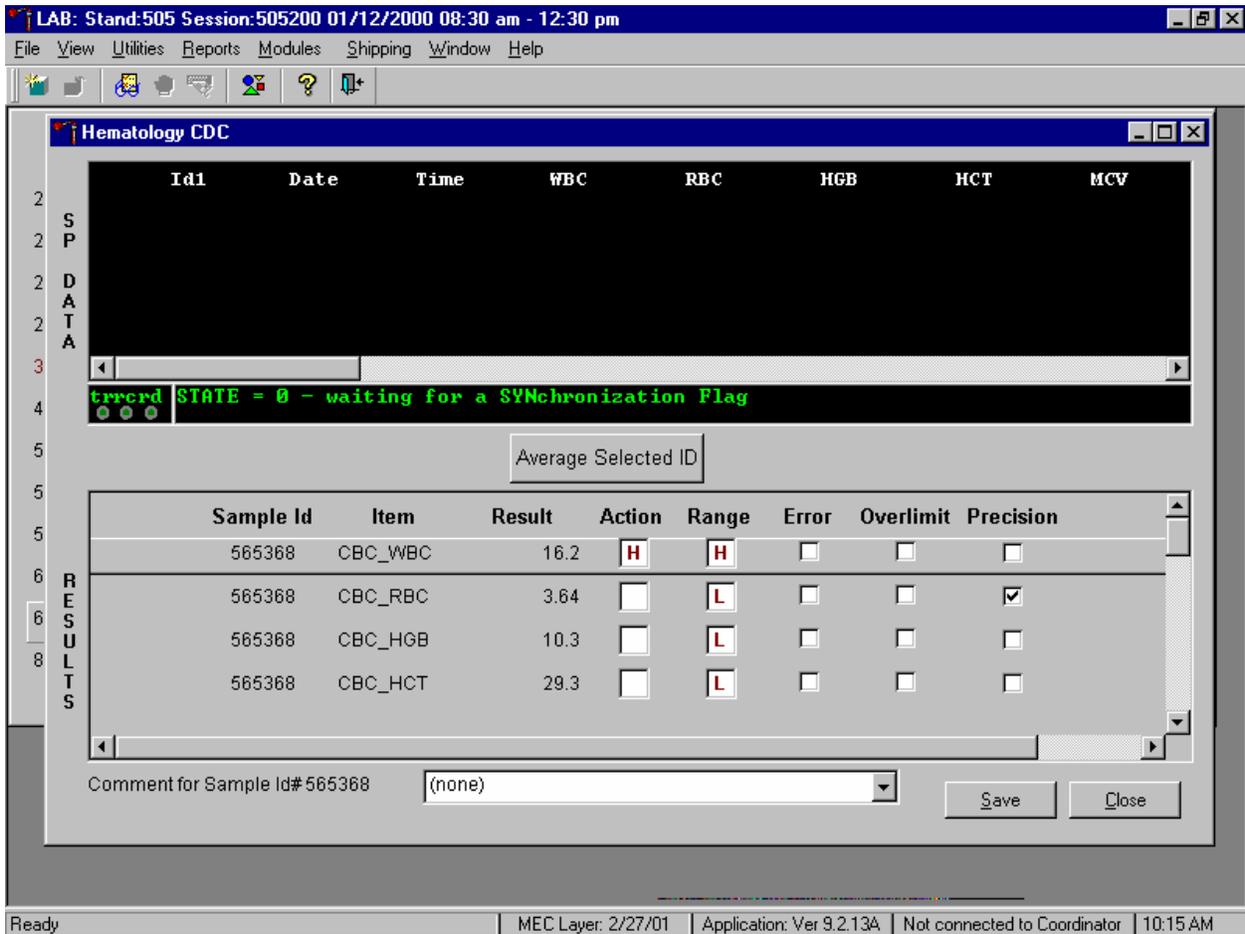
RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
5	565368	CBC_WBC	16.2	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	565368	CBC_RBC	3.64		L	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6	565368	CBC_HGB	10.3		L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	565368	CBC_HCT	29.3		L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Comment for Sample Id#565368:** A dropdown menu showing "(none)".
- Buttons:** "Save" and "Close" buttons.

A context menu is open over the row with Id# 565368, showing options: "Clear ID# 565368", "Clear All Downloads", "View Log For ID# 565368", "Save Averages", "Clear Averages", "Save & Exit", and "Clear & Exit". The "Clear All Downloads" option is highlighted.

At the bottom of the window, the status bar shows: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:14 AM".

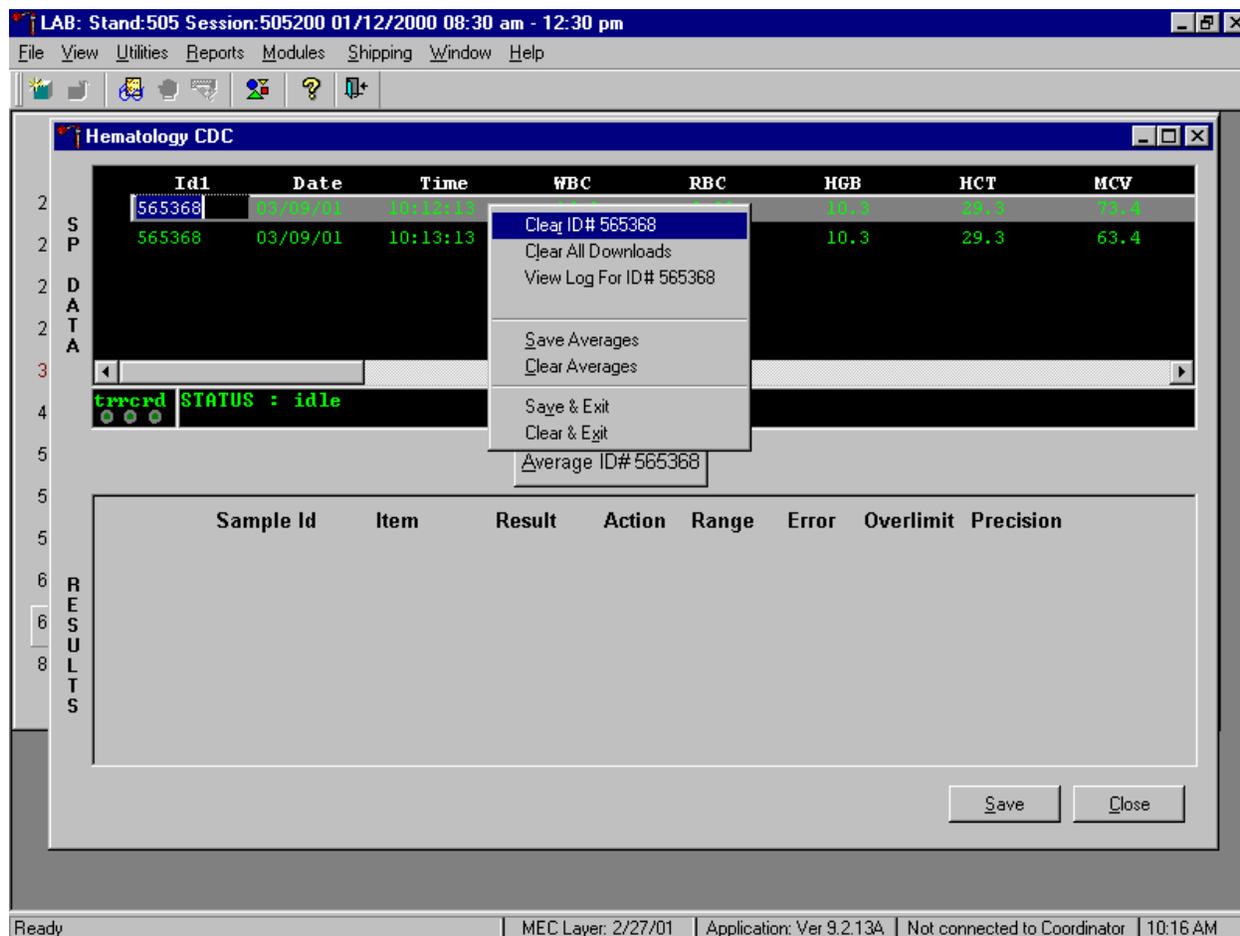
To clear all downloads from the SP Data section, use the mouse to direct the mouse arrow to any individual row in the SP Data section and right click to display the alternative data manipulation choices. To select "Clear All Downloads," drag the mouse arrow to {Clear All Downloads} and left click or type [Shift] [L/I].

Release the mouse button to clear all downloads.



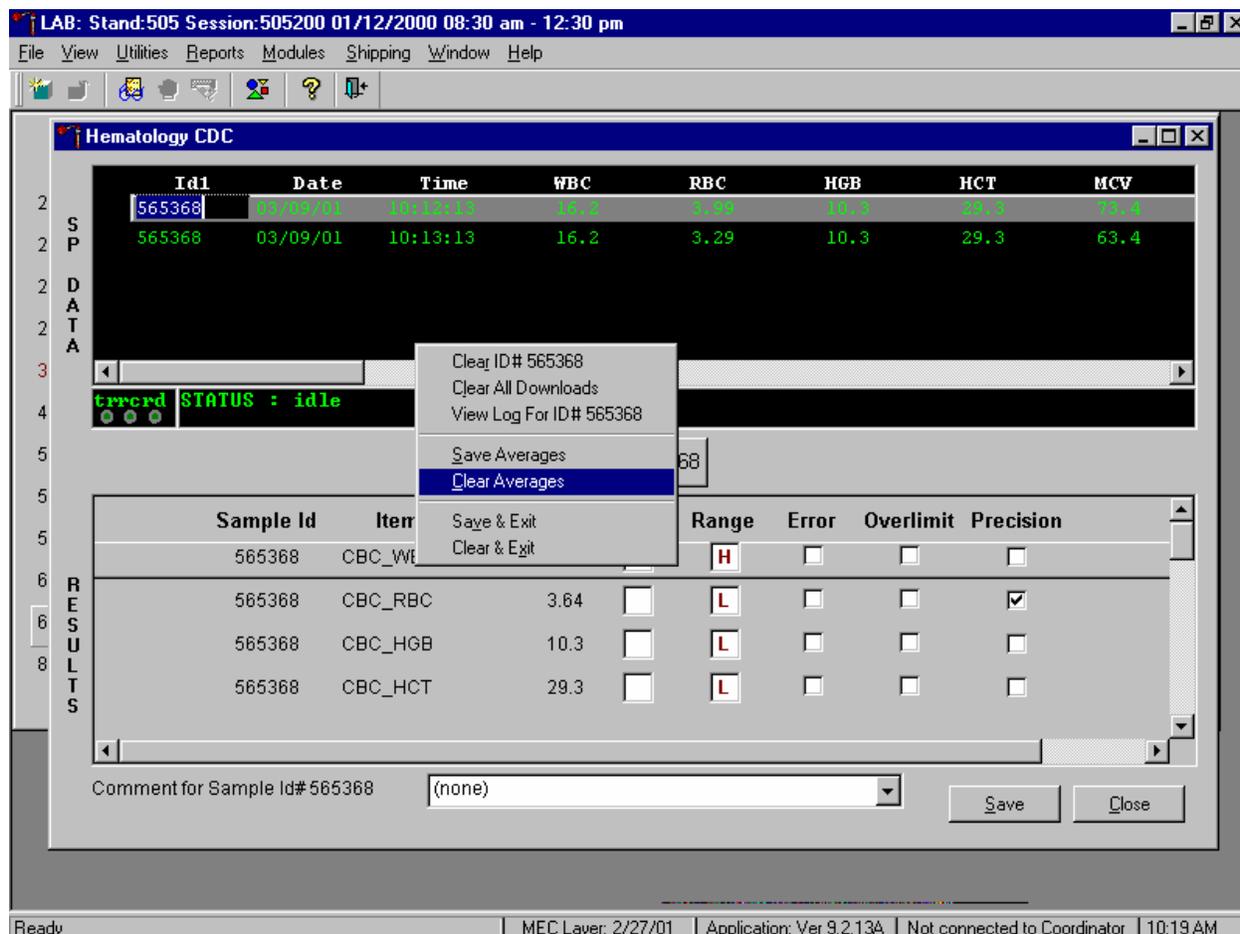
All data in the SP Data section is erased but the last averaged result remains in the Results section of the window. To clear the result section, close the Hematology module. To close the hematology module, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

Use the data manipulation functions to erase or delete one SP's data in the SP Data section.



To clear the Coulter downloads for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to {Clear ID#XXXXXX }, and right or left click or type [Shift] [R/r]. Release the mouse button to clear this download. Retransmit, average, and save the data.

Clear only the averaged results for any SP using data manipulation choices.



To clear the averaged results for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to {Clear Averages}, and right or left click or type [Shift] [C/c].

Release the mouse button to clear the results.

The screenshot shows the Hematology CDC software interface. The main window has a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The central area is titled "Hematology CDC" and contains a table with the following data:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	75.4
565368	03/09/01	10:13:13	16.2	3.29	10.3	29.3	63.4

Below the table, there is a status bar showing "errord STATUS : idle". A button labeled "Average Selected ID" is positioned above a large empty box labeled "RESULTS". At the bottom right of the window are "Save" and "Close" buttons. The status bar at the very bottom of the application reads: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:19 AM".

All results in the Results section of the window are erased. Re-average and save the data.

Use the "View Log for ID# XXXXXX" choice to view all Coulter data, averages, and precision limit values for any SP.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The main window is titled "Hematology CDC".

The "SP DATA" section contains a table with the following data:

SP	Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
2	565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	73.4
2	565368	03/09/01	10:13:13	16.2	3.29	10.3	29.3	63.4

A context menu is open over the first row, with the following options:

- Clear ID# 565368
- Clear All Downloads
- View Log For ID# 565368
- Save Averages
- Clear Averages
- Save & Exit
- Clear & Exit

The "RESULTS" section contains a table with the following data:

Sample Id	Item	Result	Acti	Limit	Precision
565368	CBC_WBC	16.2	H		
565368	CBC_RBC	3.64		L	<input checked="" type="checkbox"/>
565368	CBC_HGB	10.3		L	
565368	CBC_HCT	29.3		L	

At the bottom, there is a "Comment for Sample Id#565368" field with the value "(none)", and "Save" and "Close" buttons.

The status bar at the bottom shows: Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:20 AM

To view the detailed log for any one SP's result, use the mouse to direct the mouse arrow to the individual row in the SP Data section and right click to display the alternative data manipulation choices. Drag the mouse arrow to {View Log for IDXXXXXX} and release the mouse button to view the detailed log for this SP's results.

Review the SP's log.

The screenshot shows a 'Lab' window titled 'MAXM Download For ID#565368'. The log content is as follows:

```

[PROCESSING OF AVERAGES FOR ID#565368]
sample_id:565368 age:65 gender:2
LBXWBCSI
  cmnt[1]: cmnt[2]:
  val[1]:16.20      val[2]:16.20
  dif[1]:.00      dif[2]:      dif[3]:      dif[4]:      dif[5]:      dif[6]:
  difcol[1]:1 difcol[2]:2
  average:16.20      diff:.00      limit:.40
  err.flag:FALSE      over.flag:FALSE      prec.flag:FALSE
  act.flag:H act l,h:3.00,16.00
  ref.flag:H rng l,h:3.90,12.50
LBXRBCSI
  cmnt[1]: cmnt[2]:
  val[1]:3.99      val[2]:3.29
  dif[1]:.70      dif[2]:      dif[3]:      dif[4]:      dif[5]:      dif[6]:
  difcol[1]:1 difcol[2]:2
  average:3.64      diff:.70      limit:.10
  
```

Below the log is a table of results:

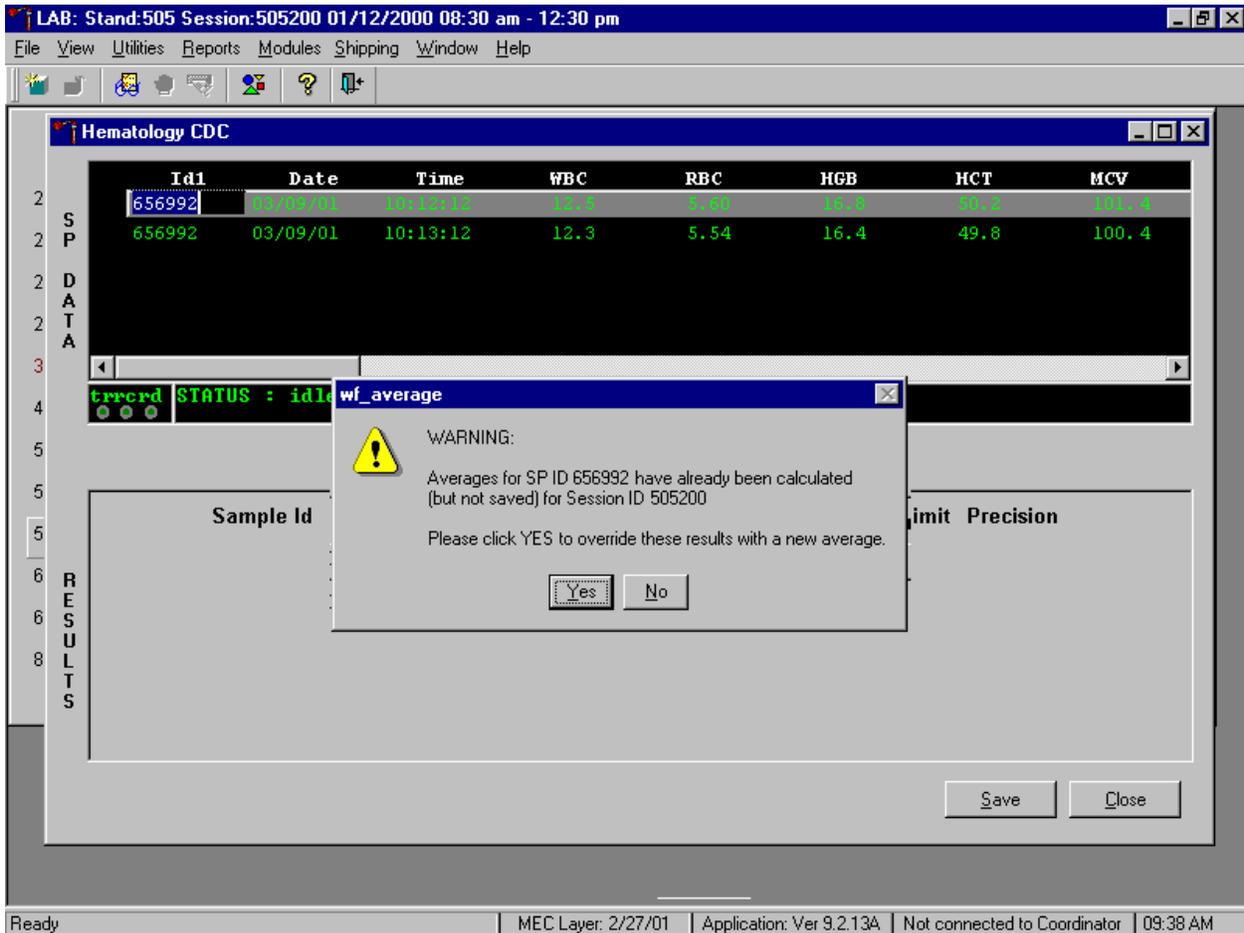
565368	CBC_WBC	16.2	H	H			
565368	CBC_RBC	3.64		L			✓
565368	CBC_HGB	10.3		L			
565368	CBC_HCT	29.3		L			

At the bottom of the window, there is a 'Comment for Sample Id#565368' field with '(none)' selected, and 'Save' and 'Close' buttons.

The SP's log contains detailed information for each parameter and each run. When finished reviewing the information, use the mouse to direct the mouse arrow to the OK button to close the window. To print the log, drag the mouse arrow to the Print button and left click or type [Shift] [P/p]. To clear the log and close the screen, use the mouse to direct the mouse arrow to the Reset button and left click, or type [Shift] [R/r], or select [Enter].

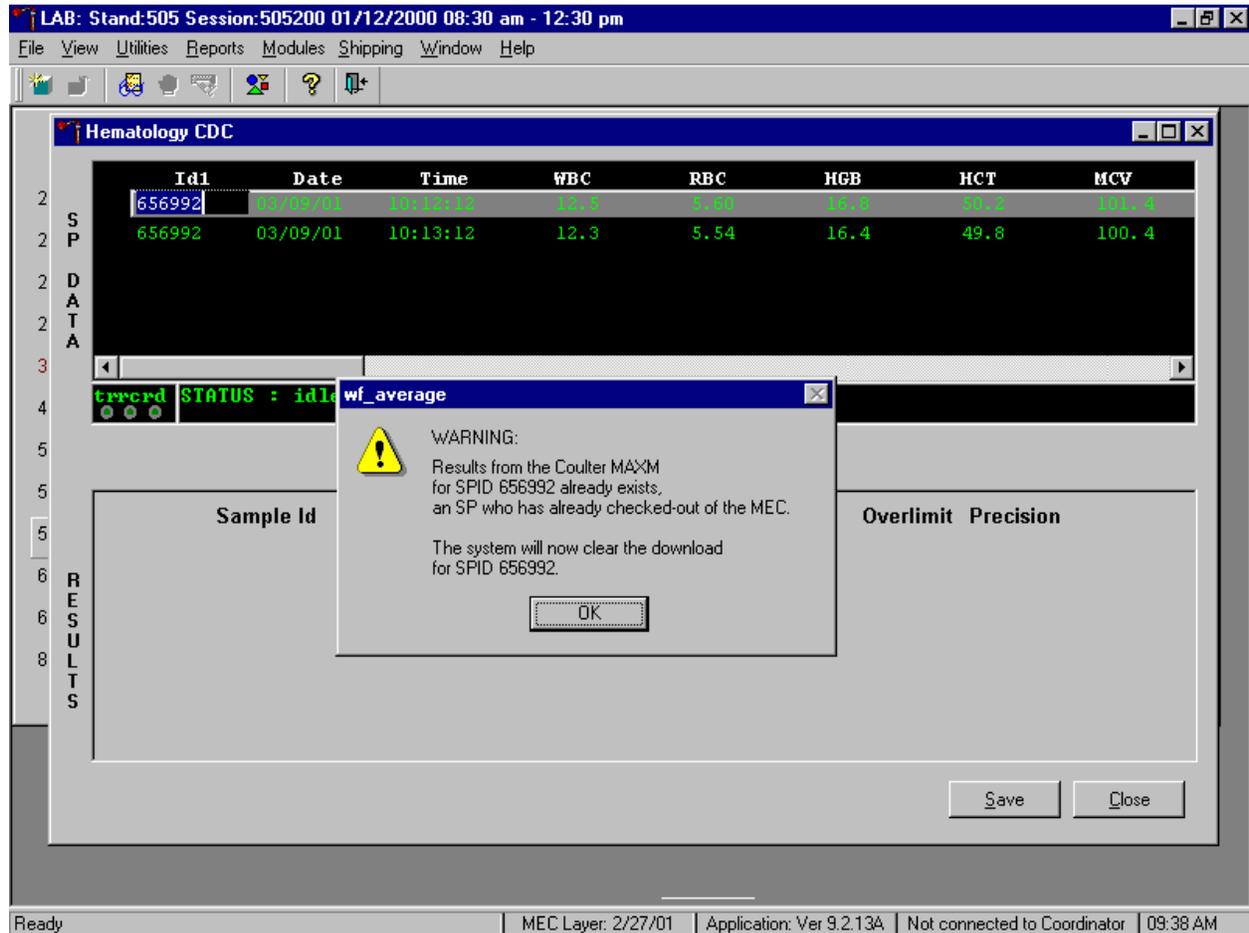
7. Re-averaging results.

Re-average a result that has or has not previously been saved to the database.



If a SP has not exited the MEC and the Report of Findings has not been printed, it is possible to retransmit and re-average the results for a SP and overwrite (save) the results in the database. A warning message text box displays when an attempt is made to save the data on a SP who has not exited the MEC or for whom a Report of Findings has not been printed. This text states, "Averages for SP ID XXXXXX have already been calculated (but not saved) for session XXXXX. Please click yes to override these results with a new average." To override the previous results, use the mouse to direct the mouse arrow to the Yes button and left click or select [Enter] or type [Shift] [Y.] To remove the text box without overriding the previous results, use the mouse to direct the mouse arrow to the No button and left click, or type [Shift] [N].

If the SP has exited the MEC or the Report of Findings has been printed, it is impossible to overwrite (save) the results in the database.



A warning message text box displays when an attempt is made to save the data on a SP either who has exited the MEC or for whom a Report of Findings has been printed. This text states, "Results from the Coulter MAXM for SPID XXXXXX already exist for an SP who has already checked out of the MEC. The system will now clear the download for SP ID XXXXXX." To remove the text box, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter]. The downloaded data, including the results, are automatically erased.

C. MAXM parameter codes

1. Review the message

The Beckman Coulter® MAXM uses triplicate counting with strict voting criteria. It has proprietary flagging algorithms to confirm parameter results before reporting. The instrument may not detect a transient or partial aperture blockage by any of these processes. A partial aperture blockage may cause erroneous results, such as WBC count lower than what is present. Monitor the aperture-viewing screen when cycling specimens that are likely to contain fibrin or debris.

The MAXM displays abnormal parameter results for all cell populations and values. The following table describes the display and cause for the parameter codes.

Display	Cause
<b>All Parameters</b>	
"●●●●" for a single parameter result	Incomplete or abnormal computation
"●●●●" for <b>all</b> parameter results and PART.ASP message displayed	Sample integrity check failed, short sample or clot
"-----" for CBC parameter results, and no average histogram for the affected parameter  If WBC is "-----", then LY#, MO#, NE#, EO# and BA# are "●●●●"  If RBC is "-----", then MCH, MCHC, Hct are "-----"	Total voteout (none of the three counts agreed); Diff parameters do not vote out
"*V"	Single-count period voteout; May indicate an erroneous result due to aperture blockage or lack of mixing bubble

"V"	Appears next to parameter derived from the parameter with the single count period voteout
<p>"+++++" for parameter results</p> <p style="text-align: center;"><b>IMPORTANT</b></p> <p><b>If the WBC, RBC, Hgb, or Plt result is +++++, run a blank cycle to prevent carryover to the next sample.</b></p>	<p>Result exceeds:</p> <p style="padding-left: 20px;">WBC <math>\geq 100.0 \times 10^3</math> cells/<math>\mu</math>L</p> <p style="padding-left: 20px;">RBC <math>\geq 10.00 \times 10^6</math> cells/<math>\mu</math>L</p> <p style="padding-left: 20px;">Plt <math>\geq 1000 \times 10^3</math> cells/<math>\mu</math>L</p> <p style="padding-left: 20px;">MCV <math>\geq 1000</math></p> <p>If WBC is over range an R appears next to the RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, MPV, Plt and Diff % results. Results for Diff% are dots (.....).</p> <p>If RBC is over range an R appears next to Hct, MCH, and MCHC results.</p> <p>If Hgb is over range an R appears next to MCH, and MCHC results.</p> <p>If MCV is over range an R appears next to Hct, MCHC, and RDW results.</p> <p>If Plt is over range an R appears next to WBC, Hgb, MCH, MCHC, diff# and Pct results.</p> <p>Data Base Query displays average values for over range WBC, RBC, or Plt. [F3] Results or [F3] Edit, beneath the definitive flag section. These values are for review only; do not report them.</p>

	<p style="text-align: center;"><b>IMPORTANT</b></p> <p><b>Sample dilution may result in erroneous differential results.</b></p> <p>Set DIFF to OFF before cycling the diluted sample when WBC is over range.</p>
"???" for Diff results	Questionable data
<b>Plt Parameter</b>	
"R" next to Plt and MPV result	<p>PDW &gt;20% mode not between 3 and 15 fL, or non-positive curve detected, or</p> <p>Plt &lt;20,000, or</p> <p>Total voteout of fitted curve, or WBC is over range.</p>
<b>RBC Parameters</b>	
"R" next to RDW result	Excessive asymmetry in RBC histogram, or WBC or MCV over range.
"*R" next to MCV; also "R" next to RBC, Hct, MCH, MCH, RDW, Plt, and MPV	MCV below lower limit of <50 fL.
<b>WBC Parameters</b>	
"*R" next to WBC; also "R" next to Diff numbers	<p>Check of WBC lower threshold failed.</p> <p>Particles are present at the 35 fL threshold (Plt clump, giant Plt, nrbc, lyse resistant RBC, malarial parasites).</p>
"R" next to Diff percentages and numbers	<p>Low differential count statistics. These messages occur also:</p> <p style="padding-left: 40px;">Population message: ABNORMAL WBC POP</p> <p style="padding-left: 40px;">Suspect message: REVIEW SLIDE</p>
":::": for Diff results	<p>System detects a clog in the flow cell. There are three types of clogs:</p> <p style="padding-left: 40px;">FC = Full Clog</p> <p style="padding-left: 40px;">PC1 = Partial Clog 1 (partial clog in the flow cell or sample line)</p> <p style="padding-left: 40px;">PC2 = Partial Clog 2 (partial clog in the sheath system)</p>

2. Remedial action

Review the result for the affected parameter. Rerun the specimen if any of the parameter flags occurs.

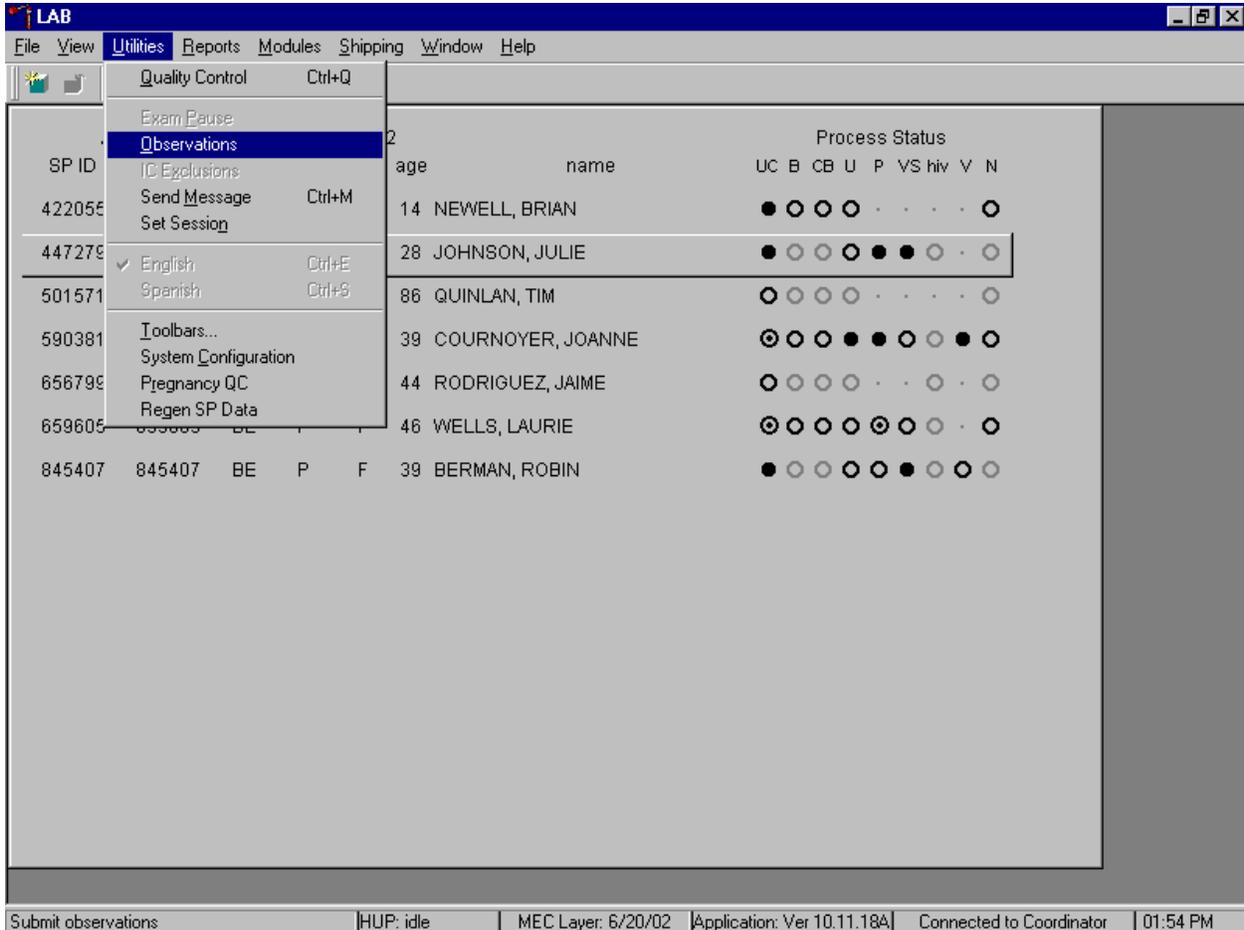
D. MAXM suspect messages

1. Suspect messages flag an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. Specific suspect messages indicate some abnormalities that exhibit characteristic cluster patterns. Suspect messages indicate the possibility of a particular abnormality. Not every atypical scatterplot has a corresponding suspect message.
2. Remedial action -- Rerun the specimen.

E. Physician review

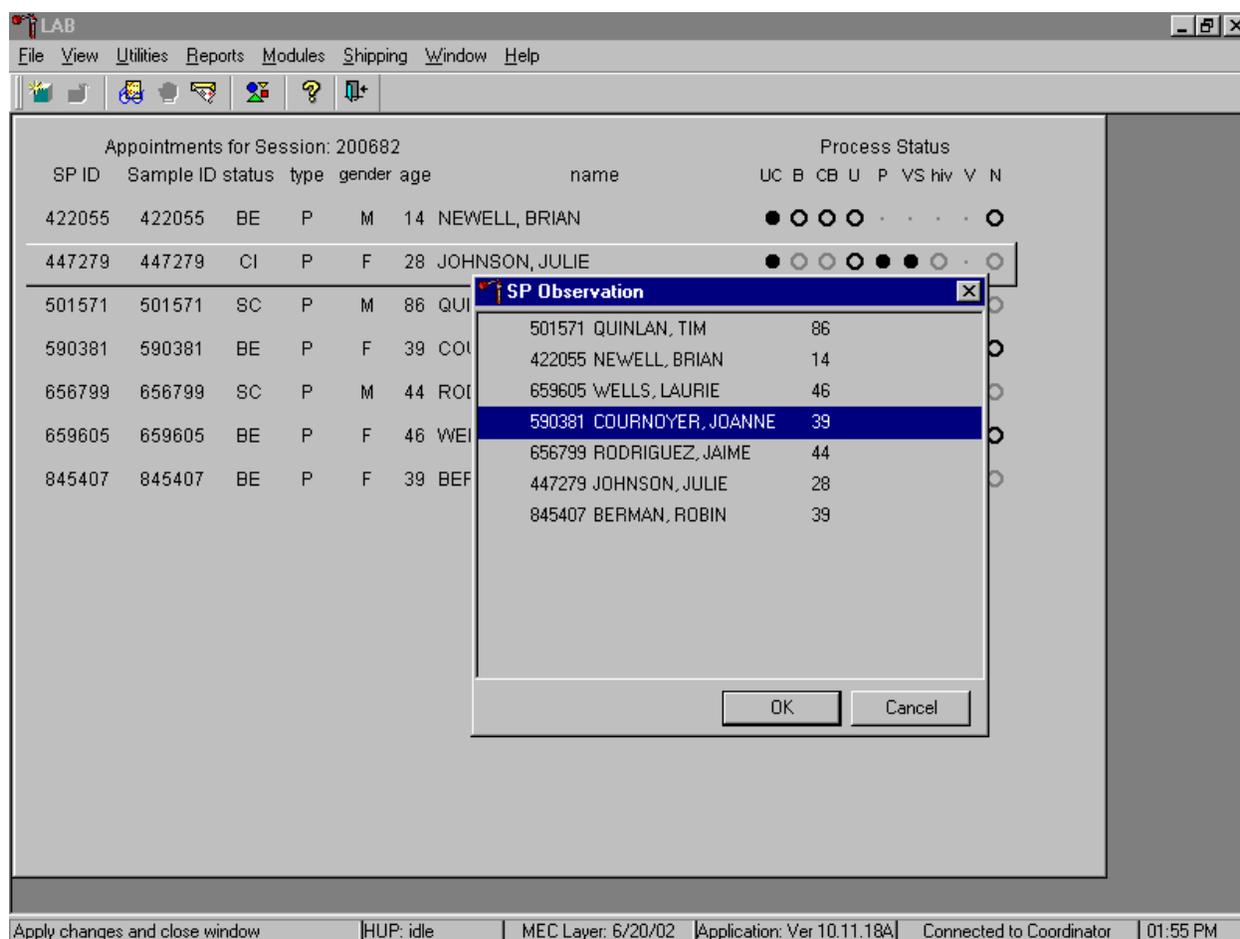
1. The MEC physician reviews and interprets all CBC results. Results outside action limits flash and transmit to the physician immediately. The physician determines if referral for the SP for treatment is necessary.
2. The medical technologist sends an observation to the physician whenever a critical or action limit is detected for any CBC parameter. This observation includes the date, time, responsible laboratory individual, person notified, and test results.

Send an observation on any SP scheduled into the MEC session. Access the observation function.



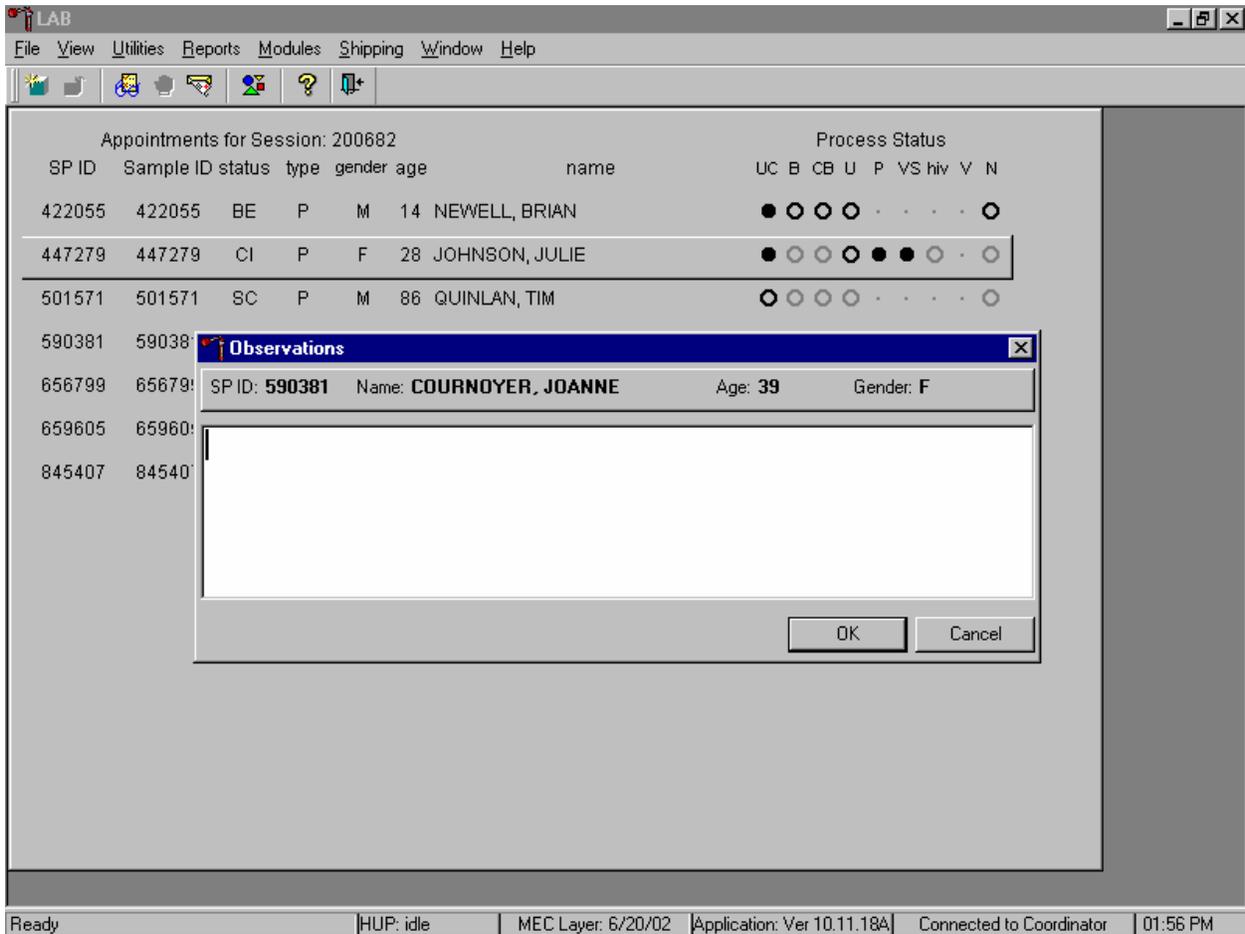
To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations}, and left click, or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



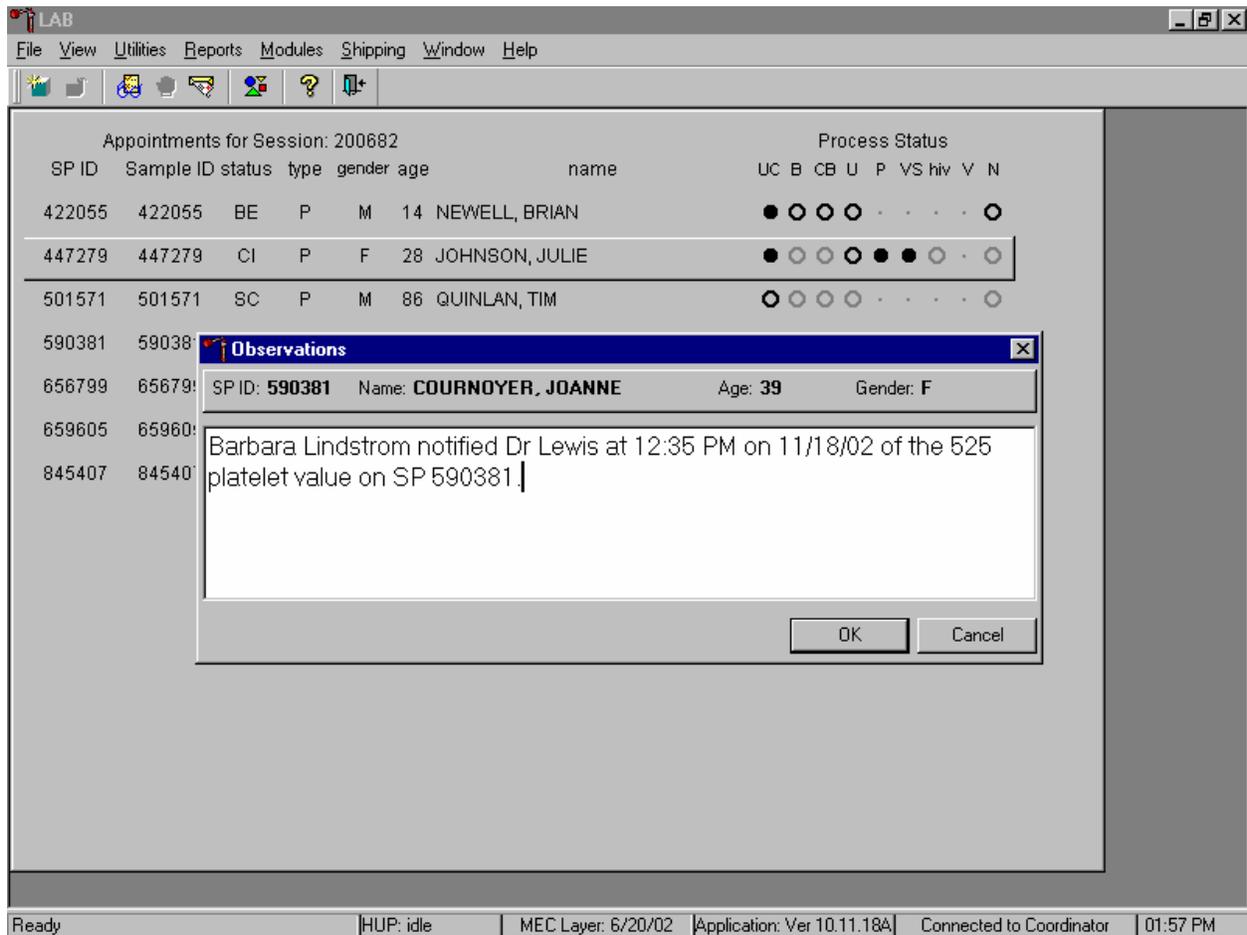
To select or highlight an SP, drag the mouse arrow to the correct SP and left click or use the up and down arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the Cancel button and left click.

The observation window displays.



The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Enter the observation on a SP.



Document the date, time, responsible laboratory individual, person notified, and test results, including the parameter.

## XII. Limitations of Method: Specimen Rejection, Interfering Substances and Conditions

This method limits samples to human whole blood.

### A. Specimen rejection

1. Reject clotted specimens and recollect.

## B. Interfering Substances and Conditions

Because the Coulter directly measures RBC, WBC, Hgb, and Diff %, it is most important to concentrate on analytes and substances that interfere with these parameters. The Coulter calculates HCT, MCH, MCHC, and DIFF # parameters. The Coulter derives MCV, RDW, PLT, and MPV from RBC or platelet histograms. The following are possible interfering substances or conditions:

- Abnormal BUN, glucose, or sodium levels could affect the MCV.
- Abnormal WBCs could affect lymphocytes, monocytes, and granulocytes.
- Abnormally small WBCs could affect white count, lymphocytes, monocytes, and granulocytes.
- Clumped platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Cryofibrinogen and cryoglobulin crystals could affect white count, lymphocytes, monocytes, granulocytes, RBC, hemoglobin, platelet count, and MPV.
- An elevated WBC count could affect RBC, hemoglobin, MCV, RDW, platelet count, and MPV parameters.
- Fragile WBCs could affect white count, lymphocytes, monocytes, granulocytes, platelet count, and MPV.
- Giant platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Hemolyzed specimens could affect RBC, hemoglobin, platelet count, and MPV.
- Lipemic specimens could affect MCV.
- Severely icteric plasma causes increased hemoglobin. Evaluate CBC result carefully and report all parameters except the hemoglobin result
- Nucleated RBCs could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.

### XIII. Reference Ranges

#### 1. Males

Age in Years	1-5	6-18	19-65	66+
WBC (x 10 <sup>3</sup> μL)	4.3-14.1	3.7-11.9	3.9-12.1	3.9-12.3
RBC (x 10 <sup>6</sup> μL)	4.00 - 5.30	4.10-5.60	4.10-5.80	4.00-5.60
Hgb (g/dL)	10.5-13.7	11.5-16.3	12.7-17.1	11.0-16.8
HCT (%)	31.8-40.8	34.4-48.3	38.0-50.3	33.1-50.2
MCV (fL)	67.6-88.2	74.3-93.0	78.1-99.2	78.9-101.4
MCH (pg)	21.7-29.8	24.3-31.7	25.7-33.8	25.6-34.4
MCHC (g/dL)	31.5-35.0	31.9-35.1	32.0-35.3	31.8-35.1
RDW (%)	11.7-16.5	11.7-14.3	11.8-15.3	12.1-16.6
Plt (x 10 <sup>3</sup> μL)	224-568	194-477	157-414	138-407
MPV (fL)	6.3-9.3	6.6-9.9	6.8-10.4	6.7-10.6
LY (%)	24.5-70.0	20.0-56.6	17.8-51.8	13.0-48.3
MONO (%)	0-12	0-12	0-12	0-13
NE (%)	21.4-70.5	33.2-74.7	39.7-77.3	44.7-81.9
EO (%)	0-10	0-11	0-8	0-8
BA (%)	0-2	0-2	0-2	0-2

2. Females

Age in Years	1-5	6-18	19-65	66+
WBC (x 10 <sup>3</sup> μL)	4.2-13.6	4.0-12.4	3.9-12.5	4.0-12.3
RBC (x 10 <sup>6</sup> μL)	3.90 - 5.20	3.90-5.20	3.70-5.20	3.50-5.20
Hgb (g/dL)	10.5-13.7	11.1-14.7	10.4-15.2	10.5-15.5
HCT (%)	32.0-40.6	33.4-43.4	32.0-45.0	32.0-46.0
MCV (fL)	69.0-88.6	74.5-93.9	73.4-98.3	79.7-100.2
MCH (pg)	22.3-30.1	24.2-31.8	23.2-33.3	25.9-33.8
MCHC (g/dL)	31.8-35.1	31.7-35.0	31.4-35.1	31.6-35.0
RDW (%)	11.4-15.4	11.6-14.8	11.8-16.6	12.0-16.1
Plt (x 10 <sup>3</sup> μL)	229-581	202-476	172-453	147-440
MPV (fL)	6.3-9.2	6.7-10.0	6.9-10.7	6.8-10.8
LY (%)	24.9-70.5	18.7-58.5	17.8-52.8	15.7-51.1
MONO (%)	0-12	0-12	0-12	0-13
NE (%)	21.3-69.3	32.9-77.2	39.6-77.8	42.0-79.8
EO (%)	0-10	0-11	0-8	0-8
BA (%)	0-2	0-2	0-2	0-2

3. Reference ranges for normal values were calculated from the NHANES III data set using 95% reference interval(s) determined nonparametrically, through ranking the observations and determining the lower (2.5th percentile) and the upper (97.5th percentile) reference limits. The nonparametric (ranking) method was used because most measured hematology parameters have a skewed, non-Gaussian distribution.

XIV. Action Limits

Action limits are a guide to inform the physician that a CBC result(s) is/are abnormal. Since all specimens are run in duplicate, there is no reason to retest the sample.

- WBC male and female (all ages) < or = to 3 x 10<sup>3</sup> μL or > or = to 16.0 x 10<sup>3</sup> μL
- Hgb male and female (<6 years) <6.5 g/dL or >14.5 g/dL
- Hgb female (>6 years) <6.5 g/dL or >16.0 g/dL

- Hgb male (>6 years) <6.5 g/dL or >18.0 g/dL
- PLT male and female (all ages) <50 x 10<sup>3</sup>  $\mu$ L or >800 x 10<sup>3</sup>  $\mu$ L

Possible causes of abnormal parameters:

- High RBC, Hgb, or HCT -- dehydration, polycythemia, shock, chronic hypoxia
- Low RBC, Hgb or HCT -- anemia, thalassemia and other hemoglobinopathies
- Low MCV -- microcytic anemia
- High MCV -- macrocytic anemia, liver disease
- Low WBC -- sepsis, marrow hypoplasia
- High WBC -- acute stress, infection, malignancies
- Low platelets -- risk of bleeding
- High platelets -- risk of thrombosis

#### XV. Specimen Storage and Handling during Testing

##### A. Specimen storage

1. Store specimens capped and place on a rocker at room temperature until processed.
2. Run within 24 hours of drawing.

#### XVI. Alternative Method for Performing Test or Storing Specimens if Test System Fails

There is no alternative method for this test. Store EDTA tube at room temperature for no more than 24 hours. Restore the instrument to functionality and then run the specimen.

#### XVII. Test Results Reporting System: Protocol for Reporting Action Limits

Results outside the action limits are automatically brought to the physician's attention for a decision as to "course-to-follow."

## XVIII. Specimen Accountability and Tracking

All records, including QA/QC data will be maintained for 6 years. Use only numerical identifiers for SP results.

## XIX. Quality Control Summary Statistics and Graphs

Chapter 10 includes a separate detailed description of the comprehensive quality control plan. Monitor 5C® Cell control results for bias and maintain results for the entire study period. Compare all three instruments CAP proficiency results.

## XX. References

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## 8. BLOOD AND HIV URINE PROCESSING

### 8.1 Introduction

The purpose of blood processing is to (1) perform a complete blood count, (2) allocate blood into 42 vessels for storage and transport to 17 laboratories across the United States for analysis, and (3) allocate plasma and serum into vessels for future studies. Processing includes centrifuging and storing blood collection tubes, aliquoting whole blood into storage vessels, centrifuging, separating, and aliquoting plasma and serum into storage vessels, performing two dilutions, and storing the specimens.

Process urine for HIV if no blood was collected or the quantity of serum was insufficient for serum HIV (for primary SPs aged 18-49) and the SP has not refused the HIV test.

### 8.2 Equipment and Supplies

The blood processing area includes two under-counter refrigerators, four under-counter freezers, two refrigerated centrifuges, two data terminals, a laminar flow hood, and two specimen rockers. This area also includes counter space for processing blood. Store extra supplies for processing in cabinets and the trailer compartments.

Exhibit 8-1. Nonconsumable supplies for blood processing

Blood processing template (12+)	Blood processing template (1-2/3-5/6-11)
One Eppendorf pipette 100-5000 $\mu$ L	Two Eppendorf pipette 50-1000 $\mu$ L
One Eppendorf pipette 5-100 $\mu$	Pipette charging stand
One pipette battery	50-mL graduated cylinder
13mm half rack	Cube rack – 4-way flipper rack
16mm full rack	Floor mat
16mm half rack	Protective eyewear
Distilled water bottle	Beach bottle

Exhibit 8-2. Consumable supplies for blood processing

Cotton swabs	Eight gallon biohazard sharps container
Biohazard bags 25 x 35	Biohazard bags 19 x 23
Kimwipes	Bench Kote paper
Pipette tips 1000 $\mu$ L	Pipette tips 200 $\mu$ L
Pipette tips 5-mL	Wooden applicator sticks
Quart size zip closable bags	3.5-mL transfer pipette nonsterile
5-mL cryovial sterile	14-mL snap cap test tube
Conical tube 50-mL	2-mL cryovial sterile
2-mL cryovial non-sterile	Caps for 2-mL cryovial
Serum filters 13mm x 4 inches	Serum filters 16mm x 6 inches
5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid	5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid
5.25 x 5.25 x 3.0 inch cardboard box without grid	Three inch 5 x 5 cardboard grid
5.25 x 5.25 x 5.0 inch cardboard box with 5 x 5 foam insert	Nonsterile, powder-free, latex (nonlatex for use by latex allergic staff) gloves—small, medium, large
Ascorbic acid 0.5 gm per vessel	Metaphosphoric acid 6%
Sharpie pens	Lab marker – fine

### 8.3 Protocols

Exhibits 8-3 through 8-5 illustrate the primary SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-3. Primary SP's whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad/HG	1-5 6+	0.3 0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	3-5 12-49	0.4 0.4	Whole blood	EDTA	2-mL	12-49 Females only
3	RBC Folate	1+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12+	0.4	Whole blood	EDTA	2-mL	
5	Mercury	1+	0.3	Whole blood	EDTA	2-mL	
6	CD4	18-49	0.5	Whole blood	EDTA	2-mL	
88	Acrylamide	3-5 6+	0.4 1.0	Whole blood	EDTA	2-mL	

Exhibit 8-4. Primary SP's plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
81	Vitamin B6	1-11 12+	0.2 0.5	Plasma	EDTA	2-mL	
7	Homocys/MMA	3+	1.0	Plasma	EDTA	2-mL	Plasma must be off the cells within 30 minutes.
8	Xtra Plasma	6+	0.5	Plasma	EDTA	2-mL	
9	Glucose	12+	0.5	Plasma	Gray	2-mL	Morning SPs only.

Exhibit 8-5. Primary SP's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
70	Vitamin D	1-2 3+	0.3 0.5	Serum	Red	2-mL	
12	Fol/B12	1-5 6+	0.7 1.0	Serum	Red	2-mL	Do not allow protracted exposure to sunlight; sunlight degrades Folate.
13	CRP	1+	0.5	Serum	Red	2-mL	
14	Hep Profile	6+	1.5	Serum	Red	2-mL	
87	Hepatitis ab	2-5	0.4	Serum	Red	2-mL	
99	Fer/TfR	1-2 3-5 12-49	0.3 0.5 0.5	Serum	Red	2-mL	12-49 females only
11	Iron/TIBC	3-5 12-59	1.0 1.0	Serum	Red	2-mL	12-59 females only
17	Cotinine	3-11 12+	1.3 1.8	Serum	Red	2-mL	
21	Lipids	3-5 6+	0.2 1.0	Serum	Red	2-mL	
94	PTH2	6+	1.0	Serum	Red	2-mL	
77	HPV Serum	14-59	0.5	Serum	Red	2-mL	
79	Vitamin C	6+	0.1	Serum	Red	2-mL	Dilute with 400-µL MPA
16	Rub/Mea/Var	6-49	0.1	Serum	Red	2-mL	
19	Bn Alk Phos	8-49	0.5	Serum	Red	2-mL	
20	Toxo	6-11 12-49	0.2 0.5	Serum	Red	2-mL	
18	Biochem	12+	0.8	Serum	Red	2-mL	
23	Insul/Cpep	12+	1.0	Serum	Red	2-mL	Morning SPs only.
22	HIV	18-49	0.5	Serum	Red	2-mL	
24	HSV	14-49	0.2	Serum	Red	2-mL	
74	Syphilis	18-49	0.5	Serum	Red	2-mL	
75	PSA	40+	1.0	Serum	Red	2-mL	Males only
15	Vit A/E/Car	6-11 12+	0.4 0.5	Serum	Red	2-mL	
26	Selenium	40+	0.5	Serum	Red	2-mL	
29	Persis Pest	12+	4.0	Serum	10-mL Red	5-mL	Process separately. Decant this aliquot.
89	Persis Pest2	12+	4.0	Serum	10-mL Red	5-mL	Process separately. Decant this aliquot.
90	Future Res1	12+	4.0	Serum	10-mL Red	5-mL	
91	Future Res2	12+	4.0	Serum	10-mL Red	5-mL	
92	Future Res3	12+	4.0	Serum	10-mL Red	5-mL	

Exhibit 8-5. Primary SP's serum processing protocol (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
93	Future Res4	12+	4.0	Serum	10-mL Red	5-mL	
32	Xtra Serum	3+	0.5	Serum	Red	2-mL	
33	Xtra Serum	6+	0.5	Serum	Red	2-mL	
34	Xtra Serum	6+	0.5	Serum	Red	2-mL	
35	Xtra Serum	12+	0.5	Serum	Red	2-mL	
36	Xtra Serum	12+	0.5	Serum	Red	2-mL	
37	Xtra Serum	12+	0.5	Serum	Red	2-mL	
38	Xtra Serum	12+	1.0	Serum	Red	2-mL	
39	Xtra Serum	12+	1.0	Serum	Red	2-mL	
40	Xtra Serum	12+	1.0	Serum	Red	2-mL	

Exhibits 8-6 through 8-8 illustrate the VIP guest's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-6. VIP Guest's blood whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad/HG	1-5 6+	0.3 0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	3-5 12-49	0.4 0.4	Whole blood	EDTA	2-mL	12-49 females only
3	RBC Folate	1+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12+	0.4	Whole blood	EDTA	2-mL	
5	Mercury	1+	0.3	Whole blood	EDTA	2-mL	

Exhibit 8-7. VIP Guest's plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
81	Vitamin B6	1-11 12+	0.2 0.5	Plasma	EDTA	2-mL	

Exhibit 8-8. VIP Guest's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
12	Fol/B12	1-5 6+	0.7 1.0	Serum	Red	2-mL	Do not allow protracted exposure to sunlight; sunlight degrades Folate.
99	Fer/TfR	1-2 3-5 12-49	0.3 0.5 0.5	Serum	Red	2-mL	12-49 females only
11	Iron/TIBC	3-5 12-59	1.0 1.0	Serum	Red	2-mL	12-59 females only
21	Lipids	3-5 6+	0.2 1.0	Serum	Red	2-mL	
94	PTH2	6+	1.0	Serum	Red	2-mL	
79	Vitamin C	6+	0.1	Serum	Red	2-mL	Dilute with 400-µL MPA
23	Biochem	12+	1.0	Serum	Red	2-mL	Morning SPs only.
15	Vit A/E/Car	6-11 12+	0.4 0.5	Serum	Red	2-mL	

Exhibit 8-9 illustrates the guest and surplus protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-9. Guest and surplus serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
18	Biochem	12+	0.8	Serum	Red	2-mL	

#### 8.4 Blood Processing Age Specific Protocols

Exhibits 8-10 through 8-13 illustrate the blood processing vessels for each primary SP by age group.

Exhibit 8-10. Blood processing protocol for primary SPs aged 1-2 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	1-2	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	1-2	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	1-2	0.3	Whole blood	3-mL EDTA	2-mL
81	Vitamin B6	1-2	0.2	Plasma	3-mL EDTA	2-mL
70	Vitamin D	1-2	0.3	Serum	3-mL Red	2-mL
12	Fol/B12	1-2	0.7	Serum	3-mL Red	2-mL
13	CRP	1-2	0.5	Serum	3-mL Red	2-mL
87	Hepatitis ab	2	0.4	Serum	3-mL Red	2-mL
99	Fer/TfR	1-2	0.3	Serum	3-mL Red	2-mL

Exhibit 8-11. Blood processing protocol for primary SPs aged 3-5 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	3-5	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	3-5	0.4	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	3-5	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	3-5	0.3	Whole blood	3-mL EDTA	2-mL
88	Acrylamide	3-5	0.4	Whole blood	3-mL EDTA	2-mL
81	Vitamin B6	3-5	0.2	Plasma	3-mL EDTA	2-mL
7	Homocys/MMA	3-5	1.0	Plasma	3-mL EDTA	2-mL
70	Vitamin D	3-5	0.5	Serum	7-mL Red	2-mL
12	Fol/B12	3-5	0.7	Serum	7-mL Red	2-mL
13	CRP	3-5	0.5	Serum	7-mL Red	2-mL
87	Hepatitis ab	3-5	0.4	Serum	7-mL Red	2-mL
99	Fer/TfR	3-5	0.5	Serum	7-mL Red	2-mL
11	Iron/TIBC	3-5	1.0	Serum	7-mL Red	2-mL
17	Cotinine	3-5	1.3	Serum	7-mL Red	2-mL
21	Lipids	3-5	0.2	Serum	7-mL Red	2-mL
32	Extra Serum	3-5	0.5	Serum	7-mL Red	2-mL

Exhibit 8-12. Blood processing protocol for primary SPs aged 6-11 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	6-11	0.5	Whole blood	4-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	4-mL EDTA	2-mL
5	Mercury	6-11	0.3	Whole blood	4-mL EDTA	2-mL
88	Acrylamide	6-11	1.0	Whole blood	4-mL EDTA	2-mL
81	Vitamin B6	6-11	0.2	Plasma	4-mL EDTA	2-mL
7	Homocys/MMA	6-11	1.0	Plasma	4-mL EDTA	2-mL
8	Xtra Plasma	6-11	0.5	Plasma	4-mL EDTA	2-mL
70	Vitamin D	6-11	0.5	Serum	10-mL Red	2-mL
12	Fol/B12	6-11	1.0	Serum	10-mL Red	2-mL
13	CRP	6-11	0.5	Serum	10-mL Red	2-mL
14	Hep Profile	6-11	1.5	Serum	10-mL Red	2-mL
17	Cotinine	6-11	1.3	Serum	10-mL Red	2-mL
21	Lipids	6-11	1.0	Serum	10-mL Red	2-mL
94	PTH2	6-11	1.0	Serum	10-mL Red	2-mL
79	Vitamin C	6-11	0.1	Serum	10-mL Red	2-mL
16	Rub/Mea/Var	6-11	0.1	Serum	10-mL Red	2-mL
19	Bn Alk Phos	6-11	0.5	Serum	10-mL Red	2-mL
20	Toxo	6-11	0.2	Serum	10-mL Red	2-mL
16	Vit A/E/Car	6-11	0.4	Serum	10-mL Red	2-mL
32	Xtra Sera	6-11	0.5	Serum	10-mL Red	2-mL
33	Xtra Sera	6-11	0.5	Serum	10-mL Red	2-mL

Exhibit 8-13. Blood processing protocol for primary SPs aged 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	12+	0.5	Whole blood	4-mL EDTA	2-mL
2	Ery Proto	12-49	0.4	Whole blood	4-mL EDTA	2-mL
3	RBC Folate	12+	0.1	Whole blood	4-mL EDTA	2-mL
4	Glycohem	12+	0.4	Whole blood	4-mL EDTA	2-mL
5	Mercury	12+	0.3	Whole blood	4-mL EDTA	2-mL
6	CD4	18-49	0.5	Whole blood	4-mL EDTA	2-mL
88	Acrylamide	12+	1.0	Whole blood	4-mL EDTA	2-mL
81	Vitamin B6	12+	0.5	Plasma	4-mL EDTA	2-mL
7	Homocys/MMA	12+	1.0	Plasma	4-mL EDTA	2-mL
8	Xtra Plasma	12+	0.5	Plasma	4-mL EDTA	2-mL
9	Glucose	12+	0.5	Plasma	2-mL Gray	2-mL
70	Vitamin D	12+	0.5	Serum	15-mL Red	2-mL
12	Fol/B12	12+	1.0	Serum	15-mL Red	2-mL
13	CRP	12+	0.5	Serum	15-mL Red	2-mL
14	Hep Profile	12+	1.5	Serum	15-mL Red	2-mL
99	Fer/TfR	12-49	0.5	Serum	15-mL Red	2-mL
11	Iron/TIBC	12-59	1.0	Serum	15-mL Red	2-mL
17	Cotinine	12+	1.8	Serum	15-mL Red	2-mL
21	Lipids	12+	1.0	Serum	15-mL Red	2-mL
94	PTH2	12+	1.0	Serum	15-mL Red	2-mL
77	HPV Serum	14-59	0.5	Serum	15-mL Red	2-mL
79	Vitamin C	12+	0.1	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	12-49	0.1	Serum	15-mL Red	2-mL
19	Bn Alk Phos	8-49	0.5	Serum	15-mL Red	2-mL
20	Toxo	12-49	0.5	Serum	15-mL Red	2-mL
18	Biochem	12+	0.8	Serum	15-mL Red	2-mL
23	Insul/Cpep	12+	1.0	Serum	15-mL Red	2-mL
22	HIV	18-49	0.5	Serum	15-mL Red	2-mL
24	HSV	14-49	0.2	Serum	15-mL Red	2-mL
74	Syphilis	18-49	0.5	Serum	15-mL Red	2-mL
75	PSA	40+	1.0	Serum	15-mL Red	2-mL
16	Vit A/E/CAR	12+	0.5	Serum	15-mL Red	2-mL
26	Selenium	40+	0.5	Serum	15-mL Red	2-mL
32	Xtra Serum	12+	0.5	Serum	15-mL Red	2-mL
33	Xtra Serum	12+	0.5	Serum	15-mL Red	2-mL
34	Xtra Serum	12+	0.5	Serum	15-mL Red	2-mL
35	Xtra Serum	12+	0.5	Serum	15-mL Red	2-mL
36	Xtra Serum	12+	0.5	Serum	15-mL Red	2-mL
37	Xtra Serum	12+	0.5	Serum	15-mL Red	2-mL
38	Xtra Serum	12+	1.0	Serum	15-mL Red	2-mL
39	Xtra Serum	12+	1.0	Serum	15-mL Red	2-mL
40	Xtra Serum	12+	1.0	Serum	15-mL Red	2-mL

Exhibit 8-13. Blood processing protocol for primary SPs aged 12+ years (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
29	Persis Pest	12+	4.0	Serum	10-mL Red	5-mL
89	Persis Pest2	12+	4.0	Serum	10-mL Red	5-mL
90	Future Res1	12+	4.0	Serum	10-mL Red	5-mL
91	Future Res2	12+	4.0	Serum	10-mL Red	5-mL
92	Future Res3	12+	4.0	Serum	10-mL Red	5-mL
93	Future Res4	12+	4.0	Serum	10-mL Red	5-mL

Exhibits 8-14 through 8-17 illustrate the blood processing vessels for each VIP guest.

Exhibit 8-14. Blood processing protocol for VIP guest aged 1-2 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	1-2	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	1-2	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	1-2	0.3	Whole blood	3-mL EDTA	2-mL
81	Vitamin B6	1-2	0.2	Plasma	3-mL EDTA	2-mL
12	Fol/B12	1-2	0.7	Serum	3-mL Red	2-mL
99	Fer/TfR	1-2	0.3	Serum	3-mL Red	2-mL

Exhibit 8-15. Blood processing protocol for VIP guest aged 3-5 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	3-5	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	3-5	0.4	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	3-5	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	3-5	0.3	Whole blood	3-mL EDTA	2-mL
81	Vitamin B6	3-5	0.2	Plasma	3-mL EDTA	2-mL
12	Fol/B12	3-5	0.7	Serum	3-mL Red	2-mL
99	Fer/TfR	3-5	0.5	Serum	3-mL Red	2-mL
11	Iron/TIBC	3-5	1.0	Serum	3-mL Red	2-mL
21	Lipids	3-5	0.2	Serum	3-mL Red	2-mL

Exhibit 8-16. Blood processing protocol for VIP guest aged 6-11 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	6-11	0.5	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	6-11	0.3	Whole blood	3-mL EDTA	2-mL
81	Vitamin B6	6-11	0.2	Plasma	3-mL EDTA	2-mL
12	Fol/B12	6-11	1.0	Serum	7-mL Red	2-mL
21	Lipids	6-11	1.0	Serum	7-mL Red	2-mL
94	PTH2	6-11	1.0	Serum	7-mL Red	2-mL
79	Vitamin C	6-11	0.1	Serum	7-mL Red	2-mL
16	Vit A/E/Car	6-11	0.4	Serum	7-mL Red	2-mL

Exhibit 8-17. Blood processing protocol for VIP guest aged 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	12+	0.5	Whole blood	4-mL EDTA	2-mL
2	Ery Proto	12-49	0.4	Whole blood	4-mL EDTA	2-mL
3	RBC Folate	12+	0.1	Whole blood	4-mL EDTA	2-mL
4	Glycohem	12+	0.4	Whole blood	4-mL EDTA	2-mL
5	Mercury	12+	0.3	Whole blood	4-mL EDTA	2-mL
81	Vitamin B6	12+	0.5	Plasma	4-mL EDTA	2-mL
9	Glucose	12+	0.5	Plasma	2-mL Gray	2-mL
12	Fol/B12	12+	1.0	Serum	10-mL Red	2-mL
99	Fer/TfR	12-49	0.5	Serum	10-mL Red	2-mL
11	Iron/TIBC	12-59	1.0	Serum	10-mL Red	2-mL
21	Lipids	12+	1.0	Serum	10-mL Red	2-mL
94	PTH	12+	1.0	Serum	10-mL Red	2-mL
79	Vitamin C	12+	0.1	Serum	10-mL Red	2-mL
18	Biochem	12+	0.8	Serum	10-mL Red	2-mL
16	Vit A/E/Car	1+2	0.5	Serum	10-mL Red	2-mL

Exhibit 8-18 illustrates the blood-processing vessel for each guest and surplus.

Exhibit 8-18. Blood processing protocol for guest and surplus aged 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
18	Biochem	12+	0.8	Serum	3-mL Red	2-mL

## 8.5 Labeling Vessels

The phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting up the blood processing racks and in labeling the vessels with the appropriate bar code label.

Use the following materials to set up and label blood racks:

- Styrofoam rack
- Age-appropriate processing template
- Storage vessels of the following sizes
  - 2.0-mL vessel
  - 5.0-mL vessel
  - 14.0-mL tube
  - 50-mL conical tube
- Bar-coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

Prepare one blood processing rack for each SP. The tubes for which each SP is eligible are determined by their sex, appointment type, and inclusion into certain subsamples so each SP's blood processing rack will be unique. When possible, prepare the racks at least 1 day before the SP arrives for the MEC examination.

Before each session, the technologist at workstation 3 prints all labels for all SPs, distributes the labels, and labels the blood processing racks. The correct bar code labels automatically print for each SP based on the SP's unique profile.

While the technologist assigned to shipping is responsible for labeling the vessels and setting up the blood processing racks, it is the blood-processing technologist's responsibility to verify that each vessel has the correct label before filling. Do not rely only upon memory or the positioning of the vessels in a rack to indicate which vessels to fill.

Always double check:

- The SP's ID number on the bar code label;
- The vessel number on the label;
- The adhesion quality of the labels; and
- To ensure that specimens are not missing labels or incorrectly labeled.

Save and recycle unused vessels:

- If the SP does not show up for their MEC exam at the appointed date and time, then it is possible they will reschedule;
- Store the SPs labels in a zip closable bag until the end of the stand; and
- If the SP has not shown up by the end of the stand, discard the unused vessels.

## **8.6 Equipment**

### **8.6.1 Benchtop Centrifuges**

Each laboratory contains two benchtop refrigerated Beckman GS-6R centrifuges.

The centrifuge has the following safety features:

- An imbalance detector triggers an automatic shutdown if rotor loads are severely out of balance.
- A safety-lock mechanism and secondary manual latch prohibit opening the centrifuge door during a run until the rotor is virtually stopped.
- A lockout system requires the door to be closed and latched before the centrifuge will start.
- An anchoring system secures the centrifuge in place. Anchoring systems reduce the possibility of injury or damage that could result from centrifuge movement in case of a major rotor mishap.

The control panel is mounted at an angle on the centrifuge front for easy visibility and access. The control panel has the following features:

- Power - This rocker switch, labeled I (ON), and O (OFF), controls electrical power to the centrifuge. The chamber door cannot be opened unless the power is turned ON.
- Door - When pressed to the OPEN position, this switch releases the latch mechanism and allows the door to be opened when the secondary manual latch lever is switched to UNLOCK (the rotor must be stopped and the power switched on).
- Brake - Use this switch to select the brake mode used during deceleration. Set the position to HIGH or LOW. The HIGH break position activates the dynamic and the electromechanical disk breaking. Dynamic breaking starts immediately after the timer turns the rotor off. At 1600 rpm the disk break engages and remains on until the speed reaches 400 rpm, followed by dynamic breaking alone to 50 RPM. At 50 rpm, all breaking stops and the rotor coasts to a stop.
- Time - This knob may be set for any run time between 2 and 30 minutes in 1-minute increments. During a run, the timer rotates back to zero, at which point the centrifuge begins deceleration. A HOLD setting enables longer-duration runs – the centrifuge will run until turned off. Stop runs at any time by turning the knob to OFF. Set appropriate time and temperature for each tube as follows:

-	3 or 4-mL EDTA	10 minutes	4-8°C
-	2-mL gray	10 minutes	17-25°C or 4-8°C
-	3-mL, 7-mL, 10-mL or 15-mL red	15 minutes	17-25°C
- Speed and ACCU-SET - Use this knob to set the drive speed, in 200-rpm increments, up to 8000 rpm. For precise adjustments, the ACCU-SET button can be pressed as the speed knob is turned until the desired speed appears on the RPM display. ACCU-SET can be adjusted at any time during a run. Set the speed at 2,900 rpm.
- RPM - During the run, the display indicates the actual rotor speed to the nearest increment of 10 rpm.
- Temperature - Use this knob to set operating temperature. The dial is marked from -10 to +40°C in 1°C increments. Set the refrigerated centrifuge at 4°C and the room temperature centrifuge at 22°C. The display indicates the temperature (+/-2°C) within the bowl in increments of 1°C.

**Run Procedure:**

1. Press the POWER to switch to ON.
2. Move the door latch lever to UNLOCK. Press the DOOR switch to OPEN and lift the centrifuge door up; it will remain in the open positions.
3. Load the Aerosolve canisters symmetrically. If only two canisters are being run, place the canisters in opposite buckets; place two empty buckets for balance in the other two buckets. If only three canisters are required, balance tubes in empty canister across from third canister.
4. Close the centrifuge door and push firmly down on it until hearing a clicking or latching sound. Move the secondary latch lock to LOCK position.
5. Set the TEMPERATURE knob to the required run temperature.
6. Set the run speed using the following procedure:
  - Press the small ACCU-SET button in; rotate the SPEED dial until the required speed shows on the display.
  - While holding the ACCU-SET button in, rotate the SPEED dial until the required speed shows on the display.
  - When the selected speed is displayed, release the ACCU-SET button.
7. Select the HIGH brake position for the EDTA, gray, and blue top tubes and select the LOW brake for the red top tubes.
8. Turn the timer to the required time. The centrifuge will start. As the run begins, acceleration control protects delicate gradients; when the rotor speed reaches about 200 rpm, full acceleration to set speed occurs.
9. To end a run in progress for any reason: Turn the timer knob to OFF. The door interlock system keeps the door latched until the rotor has virtually stopped.
10. After the rotor stops spinning move the secondary latch lever to UNLOCK and press OPEN switch on the control panel to open the door.
11. After completing a run, unload the canisters.

Leave the door open in order to prevent chamber icing.

## 8.6.2 Laminar Flow Biological Safety Cabinet Operating Sequence

- Turn on the cabinet blower and lights, and check the air intake and exhaust portals of the cabinet to make sure they are unobstructed.
- Check the pressure on the manometric gauge. If the pressure has increased more than 0.1 w.g. since the previous reading, notify the biomedical engineer. Record the pressure reading and any comments in the Laboratory QC module.
- Allow the blowers to operate for a minimum of 15 minutes before beginning work in the cabinet.
- Disinfect the interior of the workspace by wiping it down with a 10% solution of bleach and water (1:10).
- Place a disposable paper blotter on the work surface. Set up the equipment for processing. Do not place any equipment or supplies over the front intake grills.
- Arrange and separate clean and contaminated materials.
- Wait 2 to 3 minutes after placing the materials and supplies in the cabinet before beginning work. This will rid the area of all “loose” contamination.
- Wear a long-sleeved laboratory coat and gloves. This will minimize the shedding of skin flora into the work area and concurrently protect hands and arms from viable agent contamination. Wash hands with soap and water before and after working in the cabinet.
- After completing work, leave the blower on for 2 to 3 minutes to purge the unit.
- Decontaminate interior surfaces after removal of all specimens and biohazard waste by wiping them with a 10% solution of bleach and water (1:10).
- Check the grills and diffuser vents for spills or splashes and clean using appropriate techniques and materials.

## 8.7 Blood Processing Procedures

Centrifuge all blood specimens unopened, then transport to, and uncap and process in the laminar flow hood. The laminar flow hood provides a HEPA filtered, recirculated mass airflow within the workspace, and protects from any spattering that may occur when opening the Vacutainer® tubes or when pouring or pipetting the specimens. It also prevents drawing contaminated air or dust over the specimens. It is mandatory to use the blower.

Always wear gloves when handling specimens. Check gloves for small holes or tears. Change gloves if they become visibly contaminated with blood. Immediately soak visibly contaminated racks in 1:100 bleach solution.

Decontaminate racks and templates by soaking them in 10% bleach solution at the end of each session. Place on blotter to air dry.

### **8.7.1 Eppendorf Research Pro Pipettes**

Pipette whole blood and pooled serum and make dilutions using the Eppendorf Research pro pipettes. Pipette plasma using plastic transfer pipettes.

The MEC laboratory has four Eppendorf Research pro electronic pipettes: one 5-100 $\mu$ L, two 50-1000 $\mu$ L, and one 100-5000 $\mu$ L. The lab also uses 100  $\mu$ L and 1000  $\mu$ L Biopur pipette tips and 5-mL bulk pipette tips. Charge the pipettes in the 4-stand charger.

- Use the one 5-100  $\mu$ L pipette in the standard (PIP) mode and set the volume to 100  $\mu$ L. Use this dedicated pipette to aliquot the whole blood for the RBC folate, vessel 3, and Vitamin C, vessel 79.
- Use one of the two 50-1000  $\mu$ L pipettes in the standard (PIP) mode and set the volume to 1000 $\mu$ L. Use this dedicated pipette to aliquot the ascorbic acid for RBC folate, vessel 3.
- Use the second 50-1000  $\mu$ L pipette in the FIX mode. Set the five fixed volumes to 300  $\mu$ L, 400  $\mu$ L, 500 $\mu$ L, 600  $\mu$ L, and 1000  $\mu$ L. Use this pipette to aliquot all whole blood tests, except the RBC folate, and pooled serum volumes that match the five volume settings. Use this pipette to dilute 100- $\mu$ L serum with 400- $\mu$ L MPA for the Vitamin C assay, vessel 79.
- Use the second 50-1000  $\mu$ L pipette and the 100-5000  $\mu$ L pipette in the DIS mode. Set the DIS volume on the 50-1000  $\mu$ L to 100  $\mu$ L. Set the DIS volume on the 100-5000  $\mu$ L to 500  $\mu$ L. Use these pipettes to aliquot pooled serum.
- Use the 100-5000  $\mu$ L pipette in the FIX mode. Set the five fixed volumes to 1000  $\mu$ L, 2000  $\mu$ L, 3000 $\mu$ L, 4000  $\mu$ L, and 5000  $\mu$ L. Use this pipette to aliquot pooled serum volumes that match the five volume settings.

- Use the 100-5000 µL pipette in the ADS mode. Program this mode in slot 2. Set the volume to 500 µL and the interval to 1 second. Use this pipette to aliquot pooled serum.
- Use the 100-5000 µL pipette in the SD mode. Set the volumes to match the age-specific processing protocols. Set program 1 to match the adult profile for vessels 11-70. Set program 3 to match the child's profile age 1-2. Set program 4 to match the child's profile age 3-5. Set program 5 to match the child's profile age 6-11. Use this pipette to aliquot pooled serum.

Pipette	Tip	Mode	Volume	Matrix
<i>*5-100 µL</i>	<i>200 µL</i>	<i>PIP</i>	<i>100 µL</i>	<i>Whole blood</i>
<i>*50-1000 µL</i>	<i>1000 µL</i>	<i>PIP</i>	<i>1000 µL</i>	<i>Ascorbic acid</i>
<i>50-1000 µL</i>	<i>1000 µL</i>	<i>FIX</i>	<i>300 µL 400 µL 500 µL 600 µL 1000 µL</i>	<i>Whole blood Pooled serum MPA</i>
<i>50-1000 µL</i>	<i>1000 µL</i>	<i>DIS</i>	<i>100 µL</i>	<i>Whole blood Pooled serum</i>
<i>100-5000 µL</i>	<i>5000 µL</i>	<i>FIX</i>	<i>1000 µL 2000 µL 3000 µL 4000 µL 5000 µL</i>	<i>Pooled serum</i>
<i>100-5000 µL</i>	<i>5000 µL</i>	<i>DIS</i>	<i>500 µL</i>	<i>Pooled serum</i>
<i>100-5000 µL</i>	<i>5000 µL</i>	<i>ADS</i>	<i>500 µL 1 second</i>	<i>Pooled serum</i>
<i>100-5000 µL</i>	<i>5000 µL</i>	<i>SD</i>	<i>Program 1 – Adult Program 3 – Child 1-2 Program 4 – Child 3-5 Program 5 – Child 6-11</i>	<i>Pooled serum</i>

*Italic = Pipette's primary program*

\* Dedicated pipette for RBC Folate, vessel 3 and Vitamin C, vessel 79 dilutions

### 8.7.1.1 Safety Precautions, Handling, Care, Maintenance, and Battery for the Research Pro

Before using the Research pro for the first time, please read the entire *Eppendorf Research pro Instruction Manual*. Observe the following points:

#### Handling

- Use the Research pro only when a pipette tip is attached.
- Do not lay down the Research pro when a filled pipette tip is attached.
- After liquid has been aspirated, press the Actuate key only when you are sure the liquid shall be dispensed correctly.
- When the pipette is switched on and when the Reset key is pressed, the piston may move. Please ensure beforehand that the liquid in the pipette tip shall be dispensed correctly.
- Emergency stop: pressing the Reset key can stop a moving piston.
- Operate the Research pro at temperatures between 15°C and 40°C. Operate at a maximum humidity of 80% at a temperature up to 31°C.

#### Care and Maintenance

- Do not clean the display or any of the labeling using acetone or aggressive solutions.
- Do not allow any liquid to enter the device.
- Authorized service personnel may carry out repairs only.
- Use original spare parts and accessories (battery, pipette tips) only.

#### Battery

- Charge the battery before operating the device for the first time.
- Charge the battery in the pipette only, using the charging stand and the original power unit.
- If a flashing battery symbol appears in the display, stop dispensing and charge the battery.

- When charging the battery, do not allow the battery to be exposed to any metallic surfaces.
- Dispose of used batteries as special waste.
- Never charge the Research pro without a battery.
- Before storing the Research pro for a long period, remove the battery.

### 8.7.1.2 Technical Data for the Research Pro

#### Single Channel Pipette

Volume Range $\mu\text{L}$	Step size $\mu\text{L}$	Color code	Pipette tip	Test volume	Inaccuracy %	Imprecision %
5-100	0.1	Yellow	200 $\mu\text{L}$	100 $\mu\text{L}$	$\pm 0.8$	$\leq 0.2$
50-1000	1	Blue	1000 $\mu\text{L}$	1000 $\mu\text{L}$	$\pm 0.6$	$\leq 0.2$
100-5000	10	Violet	5-mL	500 $\mu\text{L}$ 5000 $\mu\text{L}$	$\pm 3.0$ $\pm 0.6$	$\leq 0.6$ $\leq 0.15$

The technical data are valid only when the Research pro is used with Eppendorf pipette tips.

- Test conditions in accordance with DIN 12650 for piston-stroke pipettes with an air cushion by means of a standardized fine balance with a moisture trap
- Number of determination: 10
- Degassed distilled water,  $20^{\circ}\text{C} - 25^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$
- Maximum speed
- Standard operation
- Prewetted pipette tip, dispensing onto inside of tube due to possible evaporation
- Check volumes  $\leq 10 \mu\text{L}$  immediately after aspiration

#### Battery

- Nickel-metal hydride battery pack, 1,200 mAh/2.4 V with reversible overcurrent and overtemperature protection

- Charging time: approximately 9.5 hours for a fully discharged battery; overcharging protection with the pipette

### **Power Unit**

- Input voltage, country-specific: 230 V  $\pm$  10%, 50/60 Hz; 115 V  $\pm$  10%, 60 Hz; 100 V  $\pm$  10%, 50/60 Hz.
- Output voltage: 9 V DC; 200 mA (1.8 VA)

### **Delivery Package**

The Research pro is supplied as a single-channel pipette for different volume ranges. The pipette is delivered without a charging adapter, but each lab is supplied with a charging stand. Each package contains:

- Charging stand with separate power unit
- Special tool(s) according to pipette type
- Operating manual with measuring protocol and CE conformity assurance document
- Ni-MH battery pack

### **Inserting the Battery**

Charge the battery in the pipette. Charging may only be carried out using the charging stand with the original power unit. Do not try to recharge a pipette if the battery is not installed. A new battery does not attain its full capacity until two or three complete charging/discharging cycles have been completed.

For charging purposes, place the pipette in the charging stand.

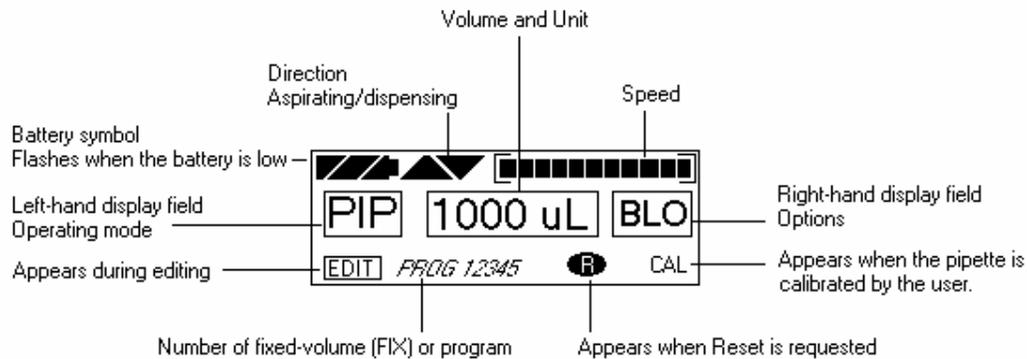
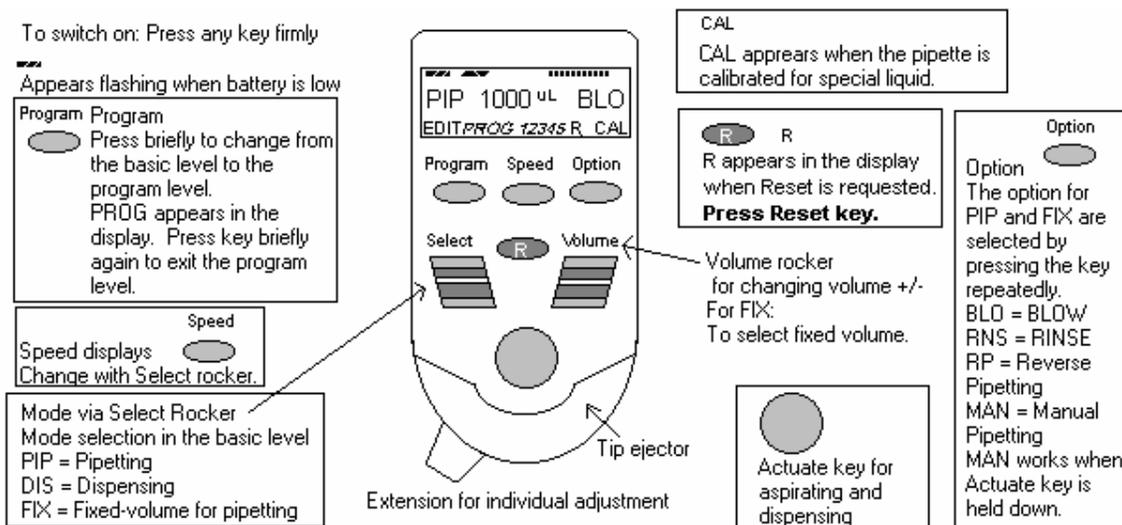
During the start and termination of the charging process, “CON” appears briefly on the left-hand side of the display. The display is switched on during the charging process. The battery symbol appears in a rolling form. During charging, the dispensing function is frozen. When the charging process

has finished, the battery symbol appears in the display without moving. When the pipette has been fully charged, it may remain in the charging stand. To increase the charging capacity, the battery should be discharged until the flashing battery symbol appears. To avoid accidental discharge, remove the battery from the Research pro during extended periods of nonuse. In this case, all data remains stored.

### 8.7.1.3 Operating Principle

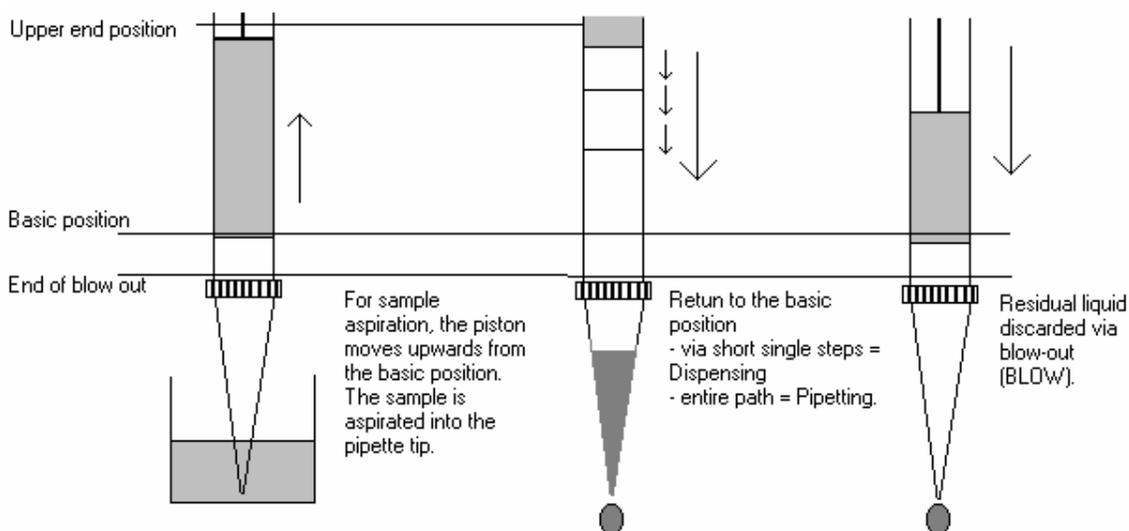
#### Display and Keypad

- To switch on: Press any key firmly.
- To switch off: Unit does this automatically after 10 minutes of nonuse.



#### 8.7.1.4 Functions of the Unit

The Research pro is a microprocessor-controlled pipette, which executes the piston movement with the aid of a stepper motor. The power supply is a rechargeable nickel-metal hydride battery.



Dispensing and reverse pipetting require a different basic position than that for pipetting. *The request to change the basic position is accomplished by selecting the Reset button.*

#### Ejector with Extension

The force translation of the ejector for pipette tips ensures that the tips are ejected very easily. The extension can be individually adjusted to accommodate left- and right-handed users as well as different hand sizes. *Select the desired setting by simply sliding the extension into the position as required.*

#### Hook on the Hand Rest

Loosening the screw enables the hook on the rear of the pipette to be adjusted to suit all hand sizes. This can be done easily with a small Phillips screwdriver.

### **Contact Surface on the Read of the Pipette**

Both upper surfaces are required for charging the nickel-metal hydride battery.

The lower surfaces are the data interfaces for the service department.

The contact to the charging adapter or the charging stand cannot be confused with any other contacts.

### **Acoustic Signals**

Certain signals assist the user for different operations:

- Short signal to acknowledge that the keypad has been pressed;
- Slightly higher tone to indicate that the function for which the key has been pressed cannot be executed;
- Louder tone to indicate that the piston movement has ended;
- Louder tone to indicate that a specific sequence of steps (e.g. Dispensing) has ended; and
- Louder tone to indicate an error message.

The acoustic signals are a great help when you are familiarizing yourself with the operating procedure of the Research pro. They can be switched off if required.

### 8.7.1.5 Mode of Operation

If the display of the Research pro is dark, activate the pipette by pressing any key firmly. If the pipette has not been used for a long period, a motor reset is executed after it has been activated.

- Attach an Eppendorf pipette tip to the Research pro. The color-coding of the Actuate key corresponds to the color code of the racks for the pipette tips. The dispensing liquid is aspirated into the tip.
- When aspirating liquid, immerse the pipette tip vertically – and as little as possible into the liquid. Following aspiration, remove the pipette tip from the liquid after the acoustic signal has been emitted. If the air bubbles have been aspirated, repeat this process.
- Never lay the pipette down when the tip is filled.
- To dispense the liquid, position the pipette tip against the side of the aspirating vessel.
- Discard the pipette tip by pressing the Eject key, attach a new tip, and reaspirate liquid.

## Essential Operating Information

The following sections contain systematic explanations of the operating procedure. It is essential to work through these sections with the pipette in your hand.

Reset



If a Reset is requested in the display, a piston movement always accompanies this Reset request. For this reason, please ensure that any residual liquid in the pipette tip is dispensed beforehand. A Reset can also be used to empty the pipette tip and to end an operating process. If you quit an input field during programming (e.g., changing the speed) using Reset, the changes that have been made are not stored. The Reset button can also act as an emergency stop function.

Motor  
reset

If the Reset key (**R**) is held down until the piston movement begins and R appears in the display, a motor reset is carried out. This motor reset guarantees that the piston movement is correct. This reset lasts for approximately 10 seconds.

Please refer to the following illustrations when going through each operation.

Program



The Research pro has two operating levels. The basic modes for pipetting (PIP and FIX) and (DIS) are accessed in the first level by pressing the Select rocker. **PROG** appears in the display by pressing the “Program” key. You are now in the second level. Using the Select rocker, select from the five available program slots. To quit this level, press the “Program” key briefly and PROG will disappear from the display.



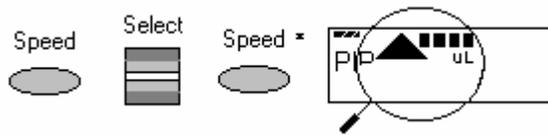
If the piston movements appear in the display without any volumes, this indicates a process that is not connected to liquid aspiration or dispensing.

## Aspirating and Dispensing Speeds

The selected speed can be viewed by pressing the Speed key several times. The speed is changed as follows:



Display and selection of aspirating speed.



Display and selection of dispensing speed.

- This procedure does not have to be completed using the Speed key. Any key, with the exception of Reset, may be used. At the same time, pressing the key executes the respective key function.
- The direction of the arrow for speed flashes in this input field.
- The speed can be altered before every dispensing or aspiration.
- Important - High speeds have a much lower current consumption than low speeds.

**8.7.1.6 Pipetting in the Standard Mode (PIP)** [*use this mode for whole blood RBC folate and Vitamin C (5-100  $\mu$ L pipette) and ascorbic acid (50-1000  $\mu$ L pipette)*]

In the Standard mode, blowout is executed automatically when liquid is dispensed. The standard mode is recommended for rapid series pipetting with aqueous solutions.

Programming - PIP	
Step 1	Select the Pipetting mode “PIP.” Use the Select rocker switch to move up and down through the three modes (PIP, DIS, and FIX) until the “PIP” choice appears in the left-hand side of the display. <i>(If <b>PROG</b> appears in the display: Press the Program key briefly until <b>PROG</b> disappears.)</i>
Step 2	Select the volume. Use the Volume rocker to move the number up or down until the number (volume) 100 for the 5-100- $\mu$ L pipette and 1000 $\mu$ L for the 50-1000- $\mu$ L pipette is reached. If necessary, press the Option key several times until the right-hand side of the display is blank. <b>(Do not use the BLO, RNS, RP, or MAN options.)</b>
Pipetting Procedure	
Step 1	Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip.
Step 2	Place the pipette tip against the side of the receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the liquid with a blowout, press the Aspirate button.
Step 3	The pipette is ready to aspirate again if the Aspirating arrow in the display points up.

**8.7.1.7 Pipetting with a Preselected Fixed (FIX) Volume** (*Use this mode for aliquoting whole blood volumes 300, 400, 500, 600, and 1000  $\mu\text{L}$  and for 400  $\mu\text{L}$  MPA - 50-1000  $\mu\text{L}$  pipette, and for pipetting pooled serum volumes 1000, 2000, 3000, 4000, and 5,000  $\mu\text{L}$  - 100-5000  $\mu\text{L}$ .)*)

FIX is used to rapidly set and recall five frequently used pipette volumes. Five FIX volumes are predefined in the pipette. FIX volumes can be changed via programming.

Programming FIX fixed volumes	
Step 1	Select the Pipetting mode "FIX." Use the Select rocker switch to move up and down through the three modes (PIP, DIS, FIX) until the "FIX" choice appears in the display. <i>(If <b>PROG</b> appears in the display: Press the Program key briefly until <b>PROG</b> disappears.)</i>
Step 2	Hold down the Program key until <b>EDIT</b> appears in the lower left hand corner of the display. The volume flashes.
Step 3	Select the first memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #1 is displayed.
Step 4	Select the volume for memory slot #1. Use the Volume rocker to move the number (volume) up and down until the number (volume) 300 $\mu\text{L}$ for the 5-1000- $\mu\text{L}$ pipette or 1000 $\mu\text{L}$ for the 100-5000 $\mu\text{L}$ pipette is reached.
Step 5	Select the next (second) memory slot for purposes of changing the volume. Select the second memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #2 is displayed.
Step 6	Select the volume for memory slot #2. Use the Volume rocker to move the number (volume) up and down until the number (volume) 400 $\mu\text{L}$ for the 5-1000- $\mu\text{L}$ pipette or 2000 $\mu\text{L}$ for the 100-5000 $\mu\text{L}$ pipette is reached.

Step 7	Select the next (third) memory slot for purposes of changing the volume. Select the third memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #3 is displayed.
Step 8	Select the volume for memory slot #3. Use the Volume rocker to move the number (volume) up and down until the number (volume) 500 $\mu\text{L}$ for the 5-1000- $\mu\text{L}$ pipette or 3000 $\mu\text{L}$ for the 100-5000 $\mu\text{L}$ pipette is reached.
Step 9	Select the next (fourth) memory slot for purposes of changing the volume. Select the fourth memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #4 is displayed.
Step 10	Select the volume for memory slot #4. Use the Volume rocker to move the number (volume) up and down until the number (volume) 600 $\mu\text{L}$ for the 5-1000- $\mu\text{L}$ pipette or 4000 $\mu\text{L}$ for the 100-5000 $\mu\text{L}$ pipette is reached.
Step 11	Select the next (fifth) memory slot for purposes of changing the volume. Select the fifth memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #5 is displayed.
Step 12	Select the volume for memory slot #5. Use the Volume rocker to move the number (volume) up and down until the number (volume) 1000 $\mu\text{L}$ for the 5-1000- $\mu\text{L}$ pipette or 5000 $\mu\text{L}$ for the 100-5000 $\mu\text{L}$ pipette is reached.
Step 13	End the programming. Press the Program key to stop programming. Alternatively, to stop programming and aspirate the volume of liquid in the display, press the Aspirate button. <b>EDIT</b> and the flashing volume disappear from the display.
Pipetting Procedure	
Step 1	Select the correct mode. Use the Select rocker to move up and down through the three mode choices (PIP, DIS, FIX) until FIX displays.

Step 2	Select one of the five programmed fixed volumes. Select the correct memory slot. Use the Volume rocker to move the volume number up and down until the correct choice displays.
Step 3	Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip.
Step 4	Place the pipette tip against the side of the receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the liquid with a blowout, press the Aspirate button.
Step 5	The pipette is ready to aspirate again if the Aspirating arrow in the display points up.

**8.7.1.8 Dispensing (DIS)** (*use this mode to pipette 100  $\mu$ L whole blood and/or pooled serum - 50-1000  $\mu$ L pipette and 500  $\mu$ L pooled serum 100-5000  $\mu$ L pipette*)

During this procedure, the aspirating liquid is dispensed in partial steps. As with “Reverse Pipetting,” slightly more liquid is aspirated than is necessary for the sum of the dispensing steps. The maximum number of dispensing steps per filling of the pipette tip is displayed in the right hand side of the display. The maximum number of dispensing steps is calculated by the pipette and is based on the dispensing volume and the pipette tip. For example, if the dispensing volume is set at 100  $\mu$ L and the pipette tip is 1000  $\mu$ L then there are 10 dispensing steps. If the dispensing volume is set at 500  $\mu$ L and the pipette tip is 5000  $\mu$ L, then there are also 10 dispensing steps.

Programming DIS	
Step 1	Select the Pipetting mode “DIS.” Use the Select rocker switch to move up and down through the three modes (PIP, DIS, FIX) until the “DIS” choice appears in the display. <i>(If <b>PROG</b> appears in the display: Press the Program key briefly until <b>PROG</b> disappears.)</i>

Step 2	Select the volume per dispensing step. Use the Volume rocker to move the number up or down until the number (volume) 100 for the 50-1000- $\mu$ L pipette or 500 $\mu$ L for the 100-5000 $\mu$ L pipette is reached.
Step 3	Select the aspirating speed using the Speed key and the Select rocker. Press the Speed key then use the Select rocker to move the speed indicator all the way to the right. When finished, press the Speed key. The pipette is ready for entry of the dispensing speed.
Step 4	Select the dispensing speed. Use the Select rocker to move the speed indicator all the way to the right. Press the Speed key to exit.
Pipetting Procedure	
Step 1	Select the correct mode. Use the Select rocker to move up and down through the three mode choices (PIP, DIS, FIX) until DIS displays.
Step 2	Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip. (If $\mathbb{R}$ appears in the display: Press the R key briefly.)
Step 3	Place the pipette tip against the side of the first receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the first aliquot, press the Aspirate button. The dispensing step counter (number) on the right-hand side of the display counts down one number.
Step 4	Place the pipette tip against the side of the second receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the second aliquot, press the Aspirate button. The dispensing step counter (number) on the right-hand side of the display counts down one more number.
Step 5	Continue dispensing until the dispensing step number reaches 0. A special acoustic signal is emitted.
Step 6	Complete the “blank” step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted.

Step 7	Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released.
Step 8	The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display.

### 8.7.1.9 Notes on the Programs

- To reach the programming level, press the Program key briefly.
- PROG appears in the display together with a memory slot number from 1 to 5.
- With the aid of the Select rocker, five programs can be shown in the left-hand side of the display.
- To program the five memory slots, it is possible to select from seven different program sequences:
  1. PIP = Pipetting
 

As per PIP outside program level. The complete sequence with volume, option, and speeds is programmed in one memory slot.
  2. SP = Sequential Pipetting
 

Up to five different pipette steps can be linked to each other. Volume, option, and speeds are defined for each pipetting sequence.
  3. DIS = Dispensing
 

As per DIS outside the program level. The complete procedure is programmed in one memory slot with dispensing volume, dispensing steps, and speeds.
  4. SD = Sequential Dispensing
 

Up to 20 dispensing steps can be defined. Each dispensing step may have a different partial volume. The total volume may exceed the filling level of a pipette tip. This means that new liquid for the pipette tip must be aspirated during the dispensing procedure. Only one aspirating and dispensing speed is defined for all dispensing steps.

5. ADS = Automatic Dispensing

With the Actuate key held down, all dispensing strokes are executed automatically with the same volume and in a user-defined rhythm (.01-10.0 seconds). Automatic dispensing may be interrupted by releasing the Actuate key. Apart from this, the procedure is identical to the DIS function.

6. DIL = Diluting

During the diluting process, a diluent, then an air bubble, and finally a sample are aspirated into the pipette tip. The user defines the diluent volume and the sample volume. The air bubble is dependent on the sample volume and is always specified by the program. Selecting a pipetting option can dispense the entire contents of the pipette tip. Depending on the pipette used, the dilution ratio is between approximately 1:2 and approximately 1:20.

7. SDI = Serial Diluting

For serial diluting, a defined volume of liquid is aspirated into the pipette tip. This liquid is dispensed and then mixed with a specific liquid volume by means of a programmable mixing process (volume, mixing cycles). Pressing the Actuate key separately starts the mixing process (MIX).

## **EDIT**

1. If PROG is in the display, holding down the Program key can open the programming level. The Program key must be held down until the word EDIT appears in the display in front of PROG 1-5. Systematically programming is explained in the following subsection.
2. If the programming of a program sequence is quit by pressing Reset, the entries for the program sequence are not stored.
3. The same program sequence – with, for example, different volumes or options – can be stored in several memory slots. It would, therefore, be possible for different pipetting sequences to be stored permanently in the program level.
4. Programming sequences can be overwritten at any time under EDIT (Hold down the Program key). During the programming process, the entry that is to be defined flashes in the display. Selections are made using the Select rocker. Volumes are selected using the Volume rocker.
5. Data is stored by pressing the Actuate key (ENTER function).
6. Options and speeds can be selected in the programming level by using the Select rocker or by using the Option and Speed key. We recommend that you read these sections before you start programming. The following sections on programming

for pipetting contain only a description of operations using the rockers. Programming and execution of the other programs are contained in Part B of the Research pro manual.

#### 8.7.1.10 Introduction – Additional Program Sequences

During programming (EDIT and PROG in display), the Speed and Option keys and the Volume rocker can also be used. This enables users to skip backwards and forwards during the program sequence.

When the programs are executed (only PROG is in the display), the Speed and Option keys and the Volume rocker are blocked.

If only parts of the program have been changed, programming can be ended prematurely by pressing the Program key briefly.

If a memory slot is quit using Reset before programming has been completed, the changes that have not been carried out for this memory slot are not saved. EDIT disappears from the display.

#### 8.7.1.11 SD = Sequential Dispensing *(use this mode to pipette the 4 age-specific (1-2, 3-5, 6-11 and 12+) serum protocols - 100-5000 $\mu$ L pipette)*

The sequential dispensing program can be used when different volumes of a solution have to be dispensed consecutively. Up to 20 steps can be defined. If the sum of the dispensing steps is larger than the volume of the pipette tip, the procedure for normal dispensing is applicable when a liquid is aspirated repeatedly.

Programming SD	
Step 1	Select the programming mode. Press the Program key. PROG appears in the display.
Step 2	Select the memory slot number 1. Use the Select rocker to move up and down through the 5 program numbers until “1” is selected.
Step 3	Hold down the Program key until EDIT appears in the display.

Step 4	Select the SD program. Use the Select rocker to move through the programming choices until “SD” appears in the display. Press the Actuate key.
Step 5	Determine the dispensing steps 1-20. Use the Select rocker to move the number up or down until the number 19 is displayed. Press the Actuate key to store the number of steps in the program.
Step 6	Select and store the volume for the first dispensing step. Use the Select or Volume rocker to move the number up or down until the number 1000 is displayed. Press the Actuate key to store the volume for step 1.
Step 7	Continuing programming the remaining 18 steps and volumes for the 12+ protocol.
Step 8	Select the aspirating and dispensing speed using the Speed key and the Select rocker. Press the Speed key then use the Select rocker to move the speed indicator all the way to the right. Press the Actuate key to store the speed in the program.
Step 9	Programming is complete. The display should show: “SD 500 $\mu$ L 19”
<b>Pipetting Procedure</b>	
Step 1	The necessary or largest possible amount of serum is aspirated. Aspirate the serum. Make sure the direction of the aspirating arrow is pointed up. Press the Actuate key once. The pipette will aspirate 1000 $\mu$ L.
Step 2	Dispense the serum. Make sure the direction of the aspirating arrow is pointed downward.
Step 3	Place the pipette tip against the side of the first receiving vessel. To dispense the first aliquot, press the Actuate key once to dispense one 1000 $\mu$ L aliquot. The dispensing step counter (number) on the right-hand side of the display counts down one number.
Step 4	Place the pipette tip against the side of the second receiving vessel.
Step 5	Continue dispensing the remaining aliquots until the (number) on the right-hand side of the display reaches 0. If a slot in the processing rack is empty, dispense the aliquot back into the pooled serum vessel.

Step 6	Complete the “blank” step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted.
Step 7	Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released.
Step 8	The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display.

Continue programming the remaining program slots, age-specific protocols, and volumes.

**8.7.1.12 ADS = Automatic Dispensing** (*use this mode to repetitively pipette 500 $\mu$ L pooled serum - 100-5000 $\mu$ L pipette*)

The automatic dispensing function allows a single volume to be dispensed repetitively with a predetermined time interval of between 0 and 10 seconds.

Programming ADS	
Step 1	Select the programming mode. Press the Program key. PROG appears in the display.
Step 2	Select the memory slot number 2. Use the Select rocker to move up and down through the 5 program numbers until “2” is selected.
Step 3	Hold down the Program key until EDIT appears in the display.
Step 4	Select the ADS program. Use the Select rocker to move through the programming choices until “ADS” appears in the display. Press the Actuate key.
Step 5	Select and store the dispensing volume. Use the Select or Volume rocker to move the number until 500 is displayed. Press the Actuate key to store the volume in the program.

Step 6	Select the aspirating and dispensing speed using the Speed key and the Select rocker. Press the Speed key, then use the Select rocker to move the speed indicator all the way to the right. Press the Actuate key to store the speed in the program.
Step 7	Reduction of the dispensing steps. The total number of dispensing steps displays in the right-hand side of the display. Do not use the Select rocker to change this number. The pipette has calculated the number of dispensing steps based on the aspirating volume and the size of the pipette tip. Press the Actuate key to store the number of calculated dispensing steps and to move to the final programming step, setting the dispensing frequency.
Step 8	Set the dispensing frequency. Use the Select rocker to move the number of seconds (SEC) up or down until 1 is displayed before SEC in the display. Press the Actuate key to store this frequency in the program.
Step 9	Programming is complete. The display should show: “ADS 500 $\mu$ L 10”
<b>Pipetting Procedure</b>	
Step 1	Aspirate the serum. Make sure the direction of the aspirating arrow is pointed upward. Press the Actuate key once. The pipette will aspirate 5000 $\mu$ L.
Step 2	Dispense the serum. Make sure the direction of the aspirating arrow is pointed downward. Press the Actuate key once. Dispensing is carried out while the Actuate key is held down. An acoustic signal is emitted after the dispensing step. To interrupt the action, release the Actuate key.
Step 3	Place the pipette tip against the side of the first receiving vessel. To dispense the first aliquot, press the Actuate key once to dispense one 500 $\mu$ L aliquot or to automatically pipette sequential 500 $\mu$ L aliquots, <u>hold the actuate key down</u> . The dispensing step counter (number) on the right-hand side of the display counts down one number. As soon as you hear the acoustic signal move the pipette tip to the next vessel.

Step 4	Place the pipette tip against the side of the second receiving vessel.
Step 5	Continue dispensing 500 $\mu\text{L}$ aliquots until the (number) on the right-hand side of the display reaches 0.
Step 6	Complete the “blank” step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted.
Step 7	Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released.
Step 8	The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display.

### 8.7.1.13 Device Parameters

Trained personnel may change device parameters only after a thorough inspection.

Device parameters are made up of the following:

- BE1 To switch on/off the acoustic signal for the keypad (short beep).
- BE2 To switch on/off the second acoustic signal for the end position of the dispensing piston, for warning and for confirmation (different beeps).
- CAL To alter the calibration data  $\mu\text{L}$ , axle section (b) and gradient (m).
- OPT Option for volume restriction.  
When the 200  $\mu\text{L}$  tips are used with the 300- $\mu\text{L}$  pipettes (limit: 200  $\mu\text{L}$ ).  
With “RP” and “DIS” when filtertips are used.
- INI To initialize the original pipette data upon delivery.

The device parameters can all be found on one list. The Actuate key functions as an Enter key. After Enter has been pressed, the next line appears in the display.

To access the device parameters	With the pipette switched on, press both the Speed and Option keys briefly at the same time.
To switch off/on acoustic signal for the keypad	Use the Select rocker to move through the selections until “BE 1” is displayed in the left side of the display window. Press the Actuate key.
To switch on/off (on), second acoustic signal	Use the Select rocker to move through the selections until “BE 2” is displayed in the left side of the display window. Press the Actuate key.
To exit the device parameters	Press the Actuate key when “INI” is displayed in the left side of the display window.
To initialize the pipette and to erase all settings	Using “ENTER,” access “INI” in device parameters. Hold down the Program key. Initialization is completed when the device parameter “INI” disappears from the display.

#### 8.7.1.14 Care, Sterilization, Maintenance, and Ordering Information

The outside of the pipette can be wiped with a moist cloth. The use of water with wetting agent is also permitted.

**DO NOT ALLOW ANY LIQUID TO ENTER THE PIPETTE.**

Only the lower part of the pipette should be rinsed with distilled water and dried. The pipette may be wiped clean with 60% Isopropanol.

If the pipette is very contaminated or if very aggressive chemicals are dispensed, the lower half of the Research pro should be disassembled. The individual parts are rinsed in distilled water and then dried. The piston is then lightly lubricated using silicone grease.

After opening the pipette, please check that the piston is correctly positioned. A motor reset must also be executed. The motor reset is triggered by holding down the Reset key until **R** appears in the display.

### **Sterilization**

Only the lower half of the pipette can be disassembled. The individual parts of the lower part must be disassembled as separate pieces. Please review the diagrams on page 27 of the *Eppendorf Research pro Instruction Manual* before attempting to disassemble any pipette.

To loosen the lower part of the pipette for all pipettes except the 5,000  $\mu$ L:

1. Hold down the ejector and pull off the ejector sleeve. Force may be required.
2. Unscrew the lower part using the key. During disassembly, do not damage the piston!
3. Unscrew the piston. If necessary, first loosen the piston at the upper end using flat nose pliers. The piston is moved to the lowest position.

To loosen the lower part of the 5,000  $\mu$ L pipette:

1. Hold down the ejector and pull off the ejector sleeve. Force may be required.
2. Unscrew the cylinder. The piston is held in place magnetically. During reassembly, do not damage the piston!
3. Pull the piston out of the upper part.

Assemble in reverse order. Engage the magnetic coupling of the 5,000  $\mu$ L piston as shown in the diagram on page 27 of the instruction manual. Check that the dispensing function of the pipette is working correctly.

## Maintenance

Apart from general care and occasional discharging (when the battery symbol starts flashing) and recharging of the pipette, no special maintenance is necessary if the pipette is used correctly. The lower part of the pipette may be replaced completely. The process for replacing the seals in the lower part is described in Part B of the Research pro manual: “Ordering information/service parts.” The Service Department may carry out maintenance on the Research pro. Contact Brinkmann Instruments at 800-645-3050 Ext 404.

A complete list of troubleshooting information is included on pages 28 and 29 of the Research pro Instruction Manual.

## Ordering information

Item	Size	Part number
Eppendorf Research pro	5-100 $\mu$ L	2246-136-2
Eppendorf Research pro	50-1000 $\mu$ L	2246-138-9
Eppendorf Research pro	100-5000 $\mu$ L	2246-139-7
Charging stand	Four pipettes	2246-155-9
<b>Pipette Tips</b>		
Bulk-packaged, in bags	5-mL	2235-081-1
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips	200 $\mu$ L	2249-002-8
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips	1000 $\mu$ L	2249-006-1
<b>Additional accessories</b>		
Spare Ni-MH battery, 1,200 mAh		2246-701-8

Page 102 in the Instruction Manual contains a complete list of additional parts and accessories.

- Use the dedicated 5-100  $\mu\text{L}$  and the dedicated 50-1000  $\mu\text{L}$  Eppendorf Research pro pipettes and trace metal free pipette tips to aliquot whole blood and perform the dilution for RBC Folate using 1.0-uL ascorbic acid.

#### Pipetting Procedure

1. Using the pipette tip dispenser tray, press the pipette nozzle firmly into a fresh tip.
2. Aspirate and dispense the whole blood, serum, and ascorbic acid using procedures described in Section 8.7.
3. Place the tip against the inner wall of the cryovial as close to the bottom as possible.
4. Discard the tip in the sharps container.
5. Cover the pipette tips at the end of each session to prevent contamination.

### **8.7.2 Process the 3-mL and 4-mL EDTA Tubes**

Use the well-mixed lavender 3-mL and 4-mL EDTA tubes for the hematology profile (CBC) and certain blood tests. The EDTA (tripotassium salts of ethylene diamine-tetracetic acid) acts as a chelating agent to combine with calcium in the blood to prevent coagulation.

#### **8.7.2.1 Process the 3-mL or 4-mL EDTA Tube for Lead/Cad/HG, Ery Proto, RBC Folate, Glycohem, Mercury, CD4, and Acrylamide**

The hematology technologist runs the CBC on the room temperature 3-mL or 4-mL EDTA tube after the blood-processing technologist verifies proper identification and labeling, and processes the tube for the Lead/Cad/HG, Ery Proto, RBC Folate, Glycohem, Mercury, CD4, and Acrylamide vessels. If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad/HG), vessel 3 (RBC Folate), vessel 4 (Glycohem), vessel 5 (Mercury), or vessel 6 (CD4); process vessel 2 (Ery Proto) and vessel 88 (Acrylamide) and attach the comment, "Clotted." If the CBC was accidentally run before the whole blood

for vessels 1 (Lead/Cad/HG) and 5 (Mercury) was pipetted, do not process these two vessels and add the comment “empty vial” to vessel 1 and “laboratory error” to vessel 5. Continue to pipette the whole blood for vessels 2, 3, 4, 6, and 88 even if the CBC was run before the whole blood was pipetted.

Complete the following process for all SPs. Use the following tubes for the whole blood protocol:

- ✓ Process the single 3-mL EDTA tube for primary SPs aged 1-5
  - ✓ Process the one (first) 4-mL EDTA tube for primary SPs aged 6-11
  - ✓ Process the two (first and second) 4-mL EDTA tubes for primary SPs aged 12+
  - ✓ Process the single 3-mL EDTA tube for VIP Guests aged 1-2
  - ✓ Process the one (first) 3-mL EDTA tube for VIP Guests aged 3-11
  - ✓ Process the single 4-mL EDTA tube for VIP Guests aged 12+
- The blood-processing technologist initially processes the 3-mL or 4-mL EDTA tube.
- Invert the appropriate EDTA tube several times to remix contents thoroughly.

#### **Vessel 1**

- Use trace metal free pipette tips and the 50-1000  $\mu$ L Eppendorf pipette to aliquot 0.3-mL whole blood for vessel 1 (Lead/Cad/HG) on primary SPs and VIP guests ages 1-5 into a 2-mL vessel.
- Use trace metal free pipette tips and the 50-1000 $\mu$ L Eppendorf pipette to aliquot 0.5-mL whole blood for vessel 1 (Lead/Cad/HG) on primary SPs and VIP guests ages 6+ into a 2-mL vessel.

#### **Vessel 2**

- Use trace metal free pipette tips and the 50-1000 $\mu$ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 2 (Ery Proto) on primary SPs and VIP guests ages 3-5 and females ages 12-49 into a 2-mL vessel.

#### **Vessel 3**

- Use trace metal free pipette tips and the dedicated 5-100 $\mu$ L Eppendorf pipette to pipette 0.1-mL whole blood for vessel 3 (RBC Folate) on primary, and VIP guests age 1+ into a 2-mL vessel. Do not prewet the pipette tips. Dilute the whole blood with ascorbic acid. Use trace metal free pipette tips and the

dedicated 50-1000 $\mu$ L Eppendorf pipette to immediately pipette 1.0-mL ascorbic acid into the 2-mL vessel. Mix well. Refrigerate L-ascorbic acid diluent when not in use. Discard unused diluent at end of each stand.

#### **Vessel 4**

- Use trace metal free pipette tips and the 50-1000 $\mu$ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 4 (Glycohem) on primary and VIP guests ages 12+ into a 2-mL vessel.

#### **Vessel 5**

- Use trace metal free pipette tips and the 50-1000 $\mu$ L Eppendorf pipette to aliquot 0.3-mL whole blood for vessel 5 (Mercury) on primary SPs and VIP guests ages 1+ into a 2-mL vessel.

#### **Vessel 6**

- Use trace metal free pipette tips and the 50-1000 $\mu$ L Eppendorf pipette to aliquot 0.5-mL whole blood for vessel 6 (CD4) on primary SPs ages 18-49 into a 2-mL vessel.

#### **Vessel 88**

- Use trace metal free pipette tips and the 50-1000 $\mu$ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 88 (Acrylamide) on primary SPs ages 3-5 into a 2-mL vessel.
  - Use trace metal free pipette tips and the 50-1000 $\mu$ L Eppendorf pipette to aliquot 1.0-mL whole blood for vessel 88 (Acrylamide) on primary SPs ages 6+ into a 2-mL vessel.
- Securely close all vessels to prevent leakage and evaporation.
  - Record results using the blood-processing module as described in Section 8.8.
  - Store all specimens immediately as outlined in Section 8.10.
  - Place the EDTA tube on a hematology rocker until the hematology technologist performs the CBC.

Run the CBC within 2 hours. If unable to run the CBC within 2 hours, store the 2-mL EDTA blood tube at room temperature for no more than 24 hours. After 24 hours, the blood will undergo changes that will render the WBC, RBC, HgB, and HCT results inaccurate.

### 8.7.2.2 Process the 3 or 4-mL EDTA Tube for Plasma for Vitamin B6, Homocys/MMA, and Xtra Plasma

Process the EDTA tube for Vitamin B6, Homocys/MMA, and Xtra Plasma immediately and centrifuge at 4-8°C or refrigerate the tube until it can be centrifuged. Remove the plasma from the cells within 30 minutes. Red blood cells synthesize homocysteine, which results in a 10 percent increase after 30 minutes. After 1 hour, the increase in homocysteine is 2-16 percent, after 2 hours 11-30 percent, after 4 hours 23-35 percent, and after 6 hours 22-42 percent.

Use the following tubes for the plasma protocol:

- ✓ Process the remaining blood in the single 3-mL EDTA blood tube on SPs aged 1-2
- ✓ Process the second 3-mL EDTA tube for primary SPs aged 1-5
- ✓ Process the second 4-mL EDTA tube for primary SPs aged 6-11
- ✓ Process the third 4-mL EDTA tubes for primary SPs aged 12+
- ✓ Process the second 3-mL EDTA tube for VIP Guests aged 1+

Complete the following process for all SPs.

- Place the tube in the centrifuge carrier of the refrigerated tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Immediately centrifuge the remaining whole blood from the first 3-mL EDTA tube for primary SPs aged 1-2 and the whole blood in the second or third 3 or 4-mL EDTA tube in the at 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 81 (Vitamin B6), vessel 7 (Homocys/MMA) and vessel 8 (Xtra Plasma.)

#### Vessel 81

-  a calibrated plastic transfer pipette to aliquot at least 0.2-mL plasma for vessel 81 (Vitamin B6) on primary SPs and VIP Guests aged 1-11 into a 2-mL vessel.
- Use a calibrated plastic transfer pipette to aliquot at least 0.5-mL plasma for vessel 81 (Vitamin B6) on primary SPs and VIP Guests aged 12+ into a 2-mL vessel.

### **Vessel 7**



Use a calibrated plastic transfer pipette to aliquot at least 1.0-mL plasma for vessel 7 (Homocys/MMA) on primary SPs aged 3+ into a 2-mL vessel.

### **Vessel 8**

-- Use a calibrated plastic transfer pipette to aliquot at least 0.5-mL plasma for vessel 8 (Xtra Plasma) on primary SPs aged 6+ into a 2-mL vessel.

- If there is any excess plasma remaining after pipetting the protocol then add 1.0-mL to vessel 7 and any remainder to vessel 8.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

## **8.7.3 Process the 2-mL Gray Tube for Glucose**

Centrifuge and separate the plasma from the 2-mL gray top tube as soon as possible. Process the specimen even if the contents of the gray tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 2-mL gray tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 9 (Glucose.)

### **Vessel 9**

-- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 9 (Glucose) on primary and VIP guests aged 12+ into a 2-mL vessel.

- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Close all vessels secured to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

#### 8.7.4 Process the 3-mL, 7-mL, 10-mL, and 15-mL Red Top Tubes for Pooled Sera

- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in each 3-mL, 7-mL, 10-mL, and 15-mL red top tube to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.
- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.
  - Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.

If the serum in any one red top tube from a SP is grossly hemolyzed, do not pool it with serum from the remaining tubes. Reserve it for the storage vessels 32-37.

If the serum in all red top tubes for a SP is turbid, lipemic, or icteric, pool it and allocate as usual.

- **Vessels 70, 12, 13, 14, 87, 99, 11, 17, 21, 94, 77, 79, 16, 19, 20, 18, 23, 22, 24, 74, 75, 16, 26, 32-40**
  - Use a serum separator to remove serum from all the red top tubes by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard. Do not touch the serum separator to the clot barrier.
  - Label the 50-mL conical tube with SP ID # label. Pool all clear sera. For each SP pool the serum from all red top tubes by decanting the separated serum into the 50-mL polypropylene tube. Hold the tube and the separator level while decanting the serum. Be careful to avoid introducing any cellular debris. Discard all tubes and separators in a sharps container.
  - Securely close the 50-mL polypropylene tube and mix its contents by gentle inversion.
  - Confirm that all vessels have the correct information with the appropriate SP's bar code ID label before filling them.
  - Use a trace metal free pipette tip and the dedicated 5-100µL Eppendorf pipette to aliquot 0.1-mL serum for vessel 79 (Vitamin C) on primary SPs aged 6+ into a 2-mL vessel. Do not prewet the pipette tips. Invert the container with the 6%MPA for 30 seconds every 10 minutes or before each use. Use the Eppendorf pipette to immediately pipette 400-µL 6%MPA into the 2-mL

vessel. Cap and vigorously shake the vial for 15-20 seconds. Refrigerate MPA diluent when not in use. Discard unused diluent at end of each stand.

- Use the 100-5000 Eppendorf® pipette and 5-mL pipette tips to aliquot the serum for all vessels except vessel 79.
  - Using clear serum only, fill as many vessels as possible in the priority order shown in Section 8.3. Exhibits 8.10 – 8.18 describe the order of allocation and specific procedures to follow for each person type and vessel.
  - If excess serum remains after completing the entire protocol, add an additional 1.5-mL serum beginning with vessel 32 and continuing through vessel 37 until the serum is exhausted. If extra serum remains, continue to top off the other serum vessels beginning with vessel 11 until the serum is exhausted.
- Securely close all vessels to prevent leakage and evaporation.
  - Record results using the blood-processing module as described in Section 8.8.
  - Store all specimens immediately as outlined in Section 8.10.
  - If the serum cannot be aliquoted immediately, refrigerate it at 4°C for no more than 4 hours.

#### **8.7.5 Process the 10-mL Red Top Tubes for Environmental Subsamples**

The Environmental subsample is a 1/3 non-overlapping sample of SPs age 12+. An SP is eligible for vessels 29 and 89 or vessels 90 and 91 or vessels 92 and 93.

- Do not substitute any other red top tube for these vessels; the 10-ml red top tube is prescreened by the CDC for these tests.
- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in the 10-mL red top tubes to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.
- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.

### **Vessel 29/Vessel 90/Vessel 92**

- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.
- Use a serum separator to carefully remove serum from the first 10-mL red top tube by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard or some flow through may occur. Do not touch the serum separator to the clot barrier.
- Aliquot the serum immediately by pouring the serum for vessel 29 (Persis Pest), vessel 90 (Future Res1) or vessel 92 (Future Res3) on primary SPs age 12+ into a 5.0-mL vessel.

### **Vessel 89/Vessel 91/Vessel 93**

- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.
  - Use a serum separator to carefully remove serum from the second 10-mL red top tube by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard or some flow through may occur. Do not touch the serum separator to the clot barrier.
  - Aliquot the serum immediately by pouring the serum for vessel 89 (Persis Pest2), vessel 91 (Future Res2), or vessel 93 (Future Res4) on primary SPs age 12+ into a 5.0-mL vessel.
- Securely close all vessels to prevent leakage and evaporation.
  - Record results using the blood-processing module described in Section 8.8.
  - Store all specimens immediately as outlined in Section 8.10.

## **8.7.6 Reagent Processing and Preparation**

The Centers for Disease Control and Prevention supplies premeasured 1% ascorbic acid (AA) for the RBC Folate assay. Prepare this reagent before processing the blood samples. Allow the reagent to equilibrate to room temperature before pipetting and performing the dilution. Use the Eppendorf Research pro pipettes to make the dilution. Add 1.0-mL ascorbic acid to 0.1-mL whole blood for the RBC Folate assay. Mix by gentle inversion.

- The ascorbic acid powder is in a 50-mL Falcon tube. Dissolve the powder in 50-mL of distilled water using a graduated cylinder to measure the water and mix gently.

Prepare this reagent weekly. Date and label the Falcon tube. If the powder appears discolored or the solution appears cloudy, discard and prepare fresh reagent. If no bottled distilled water is available, use tap water. Record the reagent in the Supply Use Control Log each time it is prepared.

- Refrigerate the prepared reagent at the end of each day to maintain its stability and bring the reagent back to room temperature the next day.

The Centers for Disease Control and Prevention supplies premeasured 6% metaphosphoric acid (MPA) for the Vitamin C assay. Prepare this reagent before processing the blood samples. Allow the reagent to equilibrate to room temperature before pipetting and performing the dilution. Use calibrated Eppendorf Research Pro pipettes to make the dilution. Add 400- $\mu$ L MPA to 0.1-mL or 100- $\mu$ L serum for the Vitamin C assay. Do not add the serum to the MPA; the MPA should be added to the serum. Mix vigorously for 15-20 seconds. Invert every 10 minutes until dissolved. It is normal for the MPA crystals to take about 15 to 30 minutes to dissolve while gently mixing the 50 cc tube of water. It is acceptable to warm it by placing it between the hands while mixing it gently back and forth.

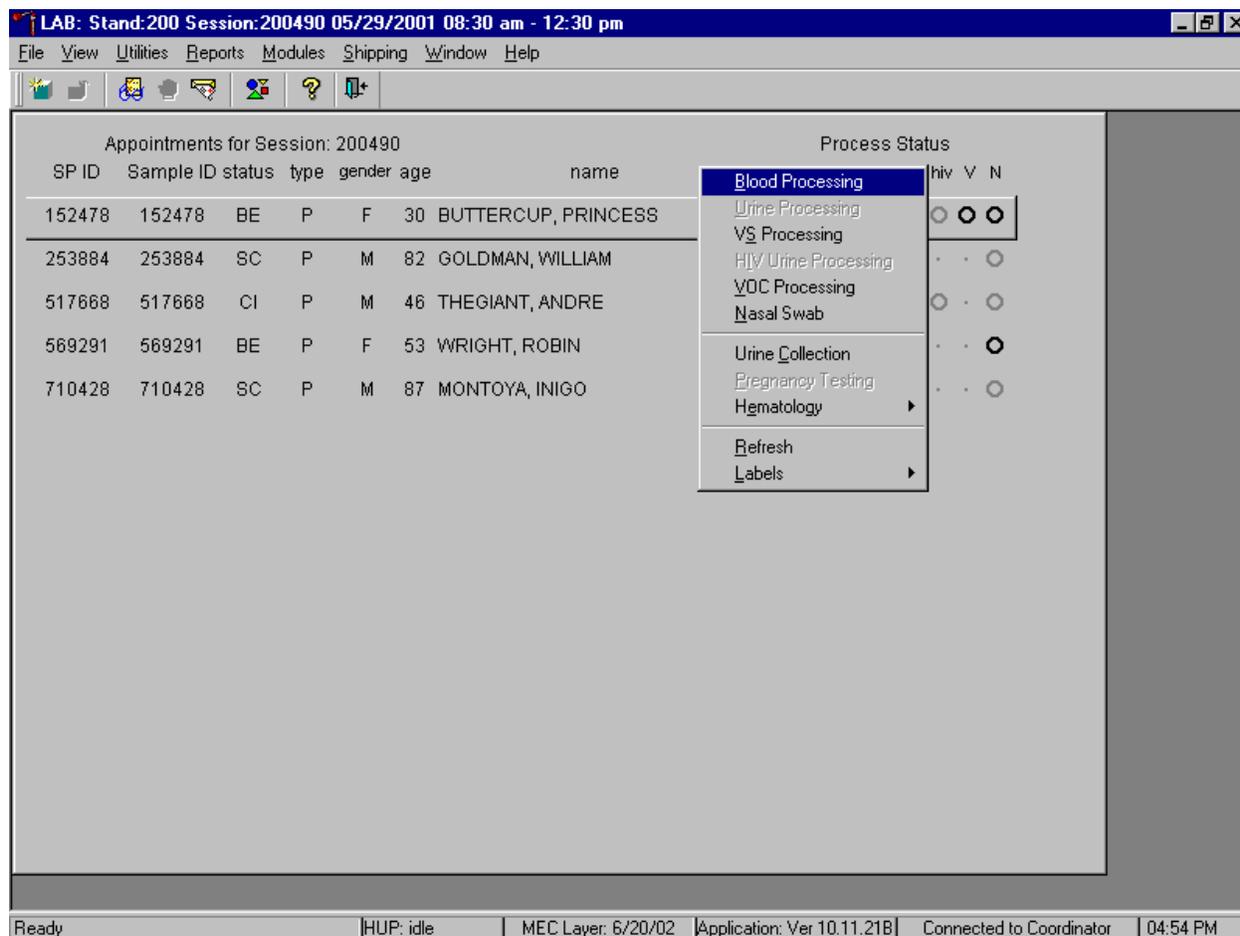
- The premeasured MPA crystals are supplied in glass vials. Dump the crystals into a clean 50-mL Falcon tube. Add exactly 50-mL of distilled water to the MPA crystals. It is acceptable to rinse the glass vial with a portion of the 50-mL distilled water and pour this into the 50-mL conical tube. It takes about 30 minutes for the crystals to go into the solution. Mix gently every 10 minutes. Prepare this reagent weekly. Date and label the Falcon tube. If no bottled distilled water is available, use tap water. Record the reagent in the Supply Use Control Log each time it is prepared.
- Transfer 8-mL from the 50-mL Falcon tube to a 14-mL Falcon snap cap tube at the start of each exam day. Discard any MPA remaining in the 14-mL Falcon snap cap tube at the end of each exam day. Keep the remainder of the solution in the 50-mL Falcon tube refrigerated. Always allow the reagent to warm up to room temperature before dispensing.
- This is a very strong acid; be very careful not to get it on the skin or in the eyes.

## **8.8 Record the Results of Specimen Processing**

After filling or processing the whole blood, plasma, serum, clots, and/or the EDTA tubes for each SP, use the Blood Processing module to enter the blood processing results.

Open and log onto the Laboratory application. Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status.

Select the correct SP and access the Blood Processing module.



If labels have not been printed in advance, a Blood Processing message text box displays. To access the blood processing module, highlight the SP, right click, drag the mouse arrow to {Blood Processing}, and left click or type [Alt] [B/b].

The SP's blood processing screen displays.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

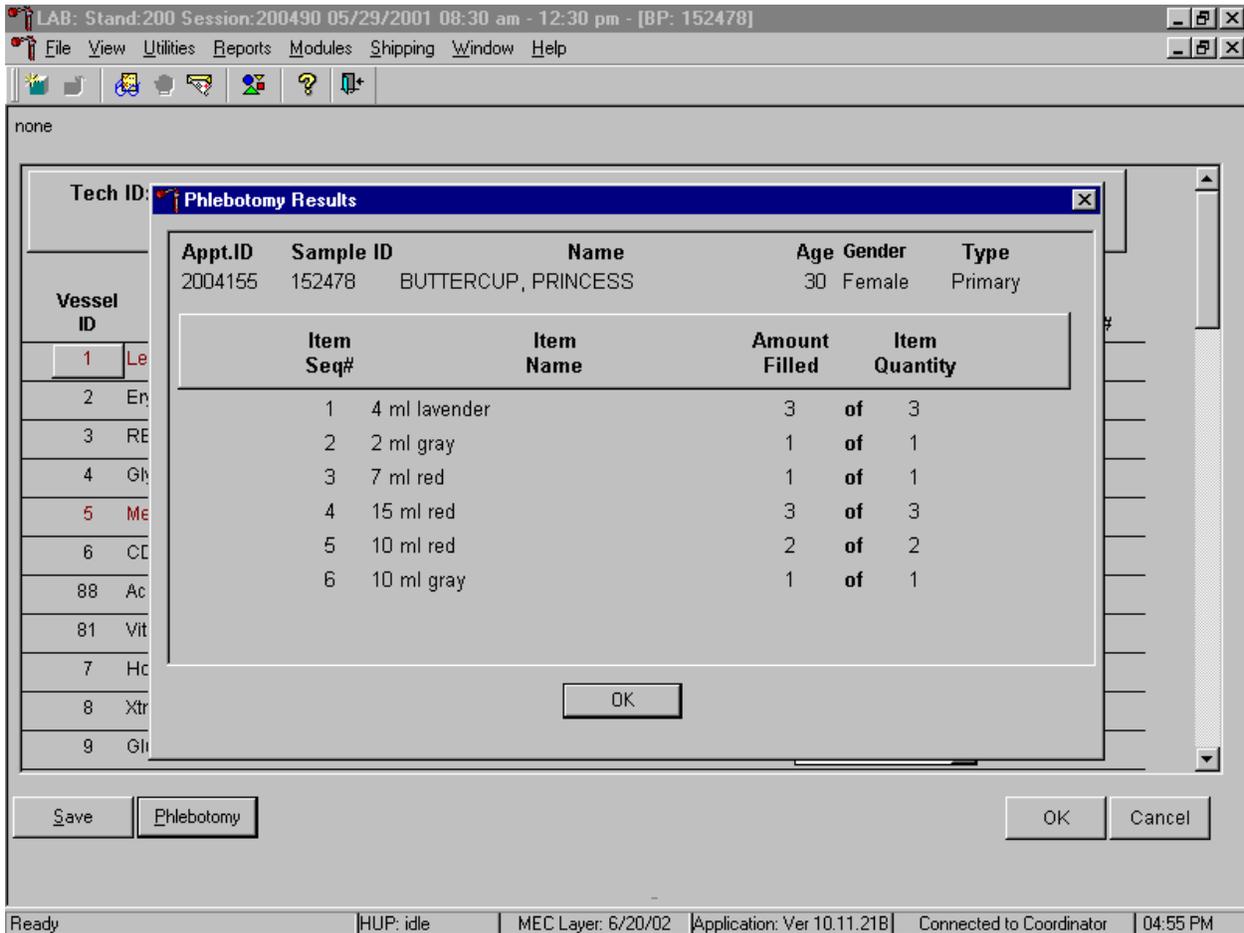
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
5	Mercury	0.3	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
88	Acrylomide	1.0	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
7	Homocys/MMA	1.0	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
8	Xtra Plasma	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    Phlebotomy    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:55 PM

The blood processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting\_Req, columns for Vessel ID, Test Name, Sample Volume, Type (blood tube, whole blood, plasma, serum, clots, packed cells), Vessel Volume, Vessel Name, Container ID/Slot #, and Filled and Comments buttons. Vessels that require sterile 2-mL cryovials are displayed in red.

Inspect the SPs Vacutainer® tubes. Compare the Sample ID on the tubes to the bar code label on the vessels. Verify that the number of tubes and the recorded amount of blood collected are correct.



To review the phlebotomy results, use the mouse to direct the mouse arrow to the Phlebotomy button on the blood processing screen and left click or type [Shift] [P/p.] The phlebotomy protocol and number of tubes successfully collected displays. To close this screen, use the mouse to direct the mouse arrow to the OK button and left click.

Record blood processing results for each SP. Individually mark each vessel as Filled--“Yes.”

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077106	1
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077107	1
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077145	1
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077146	1
5	Mercury	0.3	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077147	1
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077148	1
88	Acrylamide	1.0	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077149	1
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
7	Homocys/MMA	1.0	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
8	Xtra Plasma	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    Phlebotomy    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:56 PM

To mark an individual blood vessel as collected or Filled--“Yes” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As each vessel is marked as Filled--“Yes,” it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled–“No.”

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

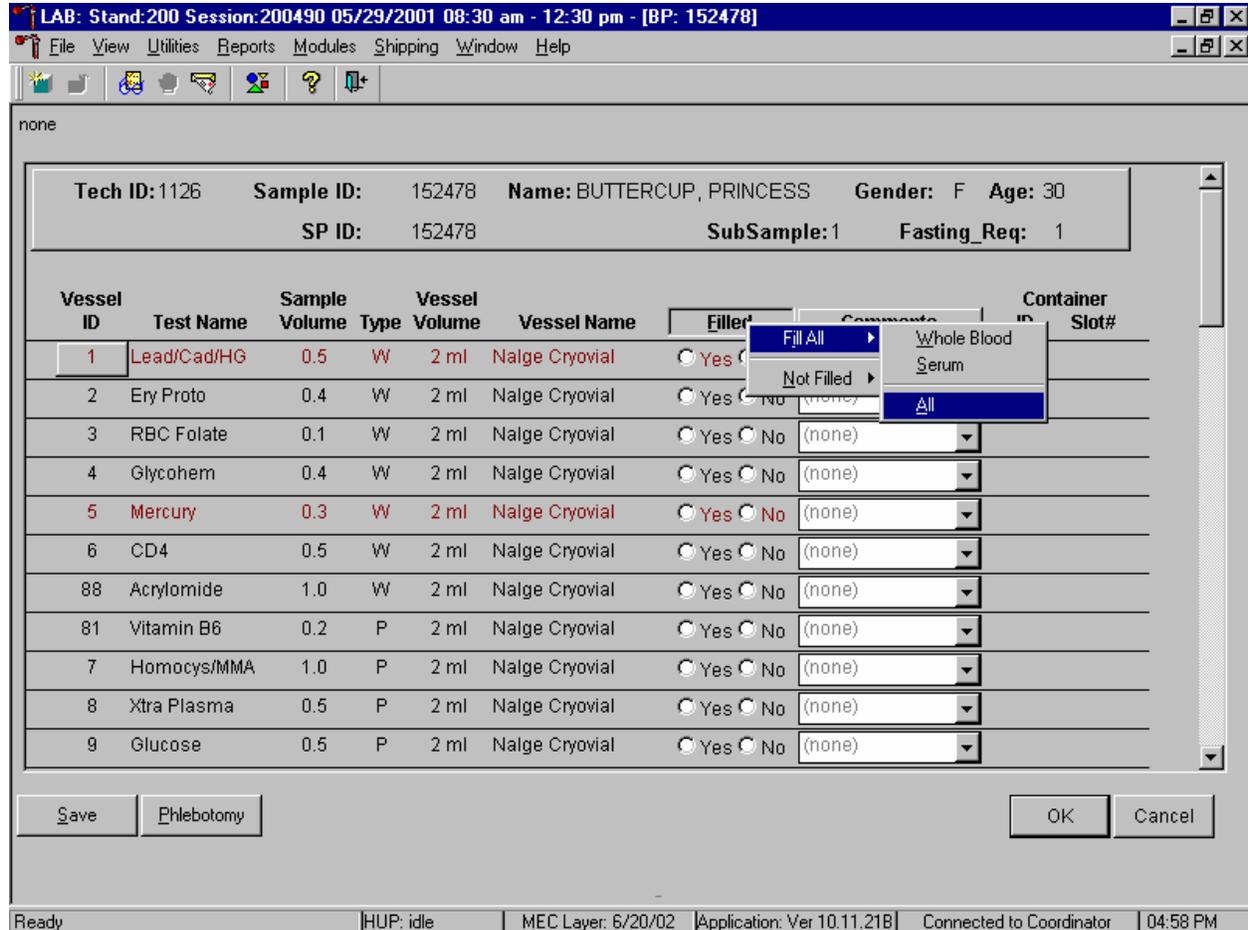
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077106	1
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077107	1
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077145	1
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077146	1
5	Mercury	0.3	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077147	1
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077148	1
88	Acrylomide	1.0	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077149	1
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
7	Homocys/MMA	1.0	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
8	Xtra Plasma	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    Phlebotomy    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:57 PM

To mark an individual blood vessel as not collected or Filled–“No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. Vessels marked as “No” require a comment.

Collectively mark all vessels as Filled–“Yes” or selectively mark whole blood or serum vessels as Filled–“Yes.”



To collectively mark all vessels as Filled–“Yes,” use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {All}, and left click. To collectively mark all whole blood vessels as Filled–“Yes,” use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {Whole Blood}, and left click. To collectively mark all serum vessels as Filled–“Yes,” use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {Serum}, and left click. As each vessel is marked as “Filled,” it is automatically assigned to a slot in an existing (open) container.

Alternatively, to collectively mark all vessels as Filled–“Yes,” type [Shift] [F/f], [I/i], and [A/a.] To collectively mark all whole blood vessels as Filled–“Yes,” type [Shift] [F/f], [I/i] and [W/w.] To collectively mark all serum vessels as Filled–“Yes,” type [Shift] [F/f], [I/i], and [S/s.]

Quality comment codes are available to describe the quality of the specimen.

Comment for filled vessels	Use when:
icteric	There is visible orange color to the serum or plasma. Icteric refers to orange color imparted to a sample because of the presence of bilirubin. Bilirubin present in serum results in visible “jaundice” color when the concentration of bilirubin is above 430 $\mu\text{mol/L}$ .
lipemic	There is turbid appearance to the serum or plasma. Lipemia refers to the presence of lipid particles (usually very low-density lipoprotein) in a sample, which gives the sample a turbid appearance. Plasma appears visibly lactescent or lipemic when the concentration of triglycerides exceeds 4.6 $\text{mmol/L}$ .
equipment failure	Pipettes are malfunctioning.
clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
hemolyzed	There is red appearance to the serum or plasma. Hemolysis refers to the abnormal lysis of erythrocytes. Hemolysis can occur before venipuncture ( <i>in vivo</i> hemolysis) or during the analytic procedure ( <i>in vitro</i> hemolysis). If <i>in vivo</i> , hemolysis will give plasma a red color. Use when describing visible hemolysis, which occurs when the concentration of hemoglobin exceeds 200 $\text{mg/L}$ .

Attach a comment to an individual filled vessel.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

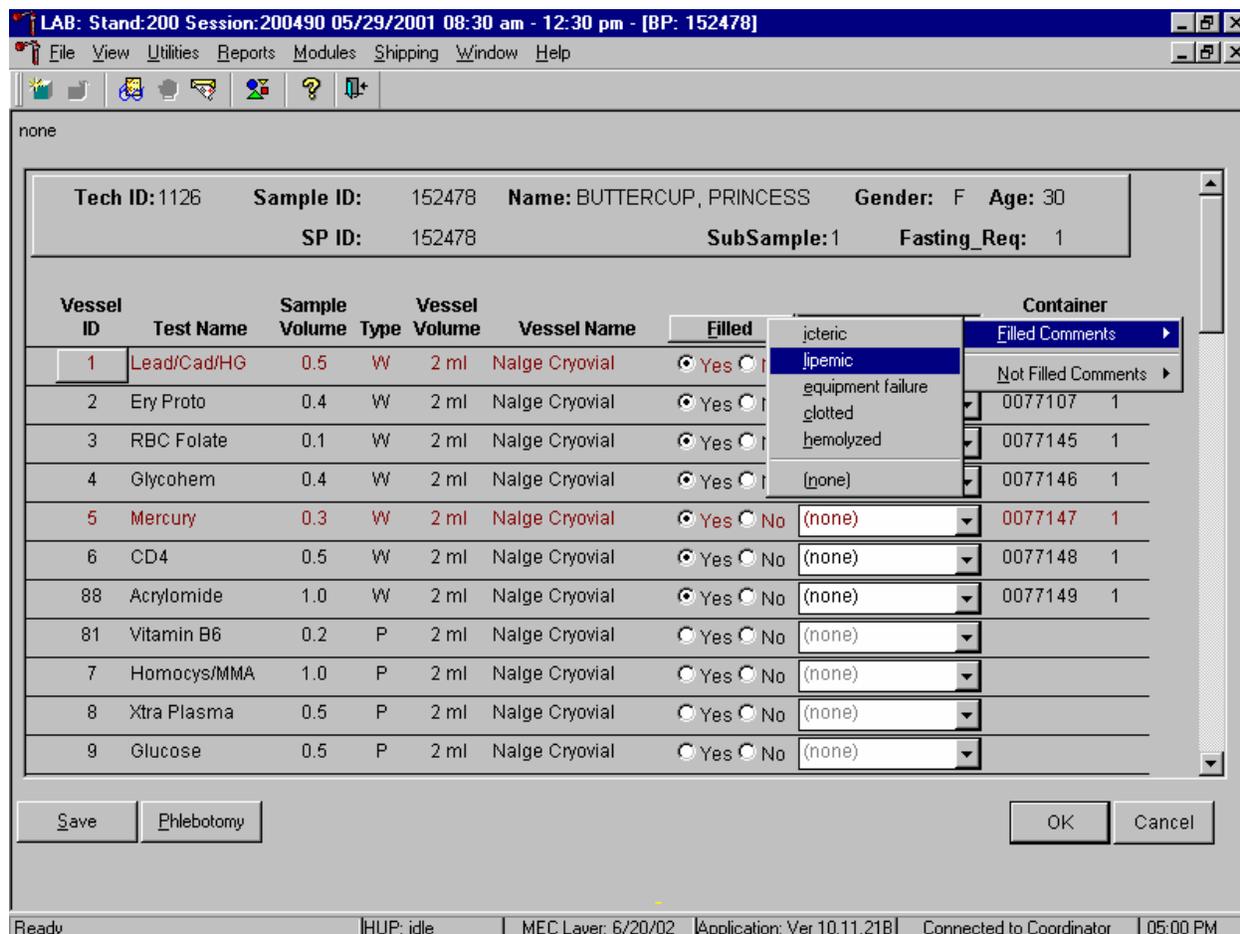
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077106	1
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077107	1
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	77145	1
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	clotted	77146	1
5	Mercury	0.3	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	equipment failure	77147	1
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	hemolyzed	77148	1
88	Acrylomide	1.0	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	icteric	77149	1
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	lipemic		
7	Homocys/MMA	1.0	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
8	Xtra Plasma	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    Phlebotomy    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:59 PM

To attach a quality control comment to an individual filled vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (i, l, e, c, h.)

Use the following procedure when all filled vessels require the same comment.



To collectively assign the same comment to all vessels, use the mouse to direct the mouse arrow to the Comments button on the top of the radio buttons, left click, drag the arrow to {Filled Comments}, drag the mouse arrow to the correct choice, and left click. Alternatively, to assign the same comment to all filled vessels type [Shift] [C/c], and the first letter of the correct choice (i, l, e, c, h.)

All plasma vessels must be marked individually. All vessels marked as Filled–“No” require a comment or explanation.

Enter comment codes to describe the reasons why a vessel is marked as Filled–“No,” or why the protocol is incomplete.

Comment for not filled vessels	Use when:
container discarded	Do not use this comment.
laboratory error	A tube breaks in the centrifuge, contents spill, or other technologist error.
quantity not sufficient	Quantity of blood is not sufficient to complete the protocol.
SP refusal	The SP does not provide consent and consequently, excluded from HIV.

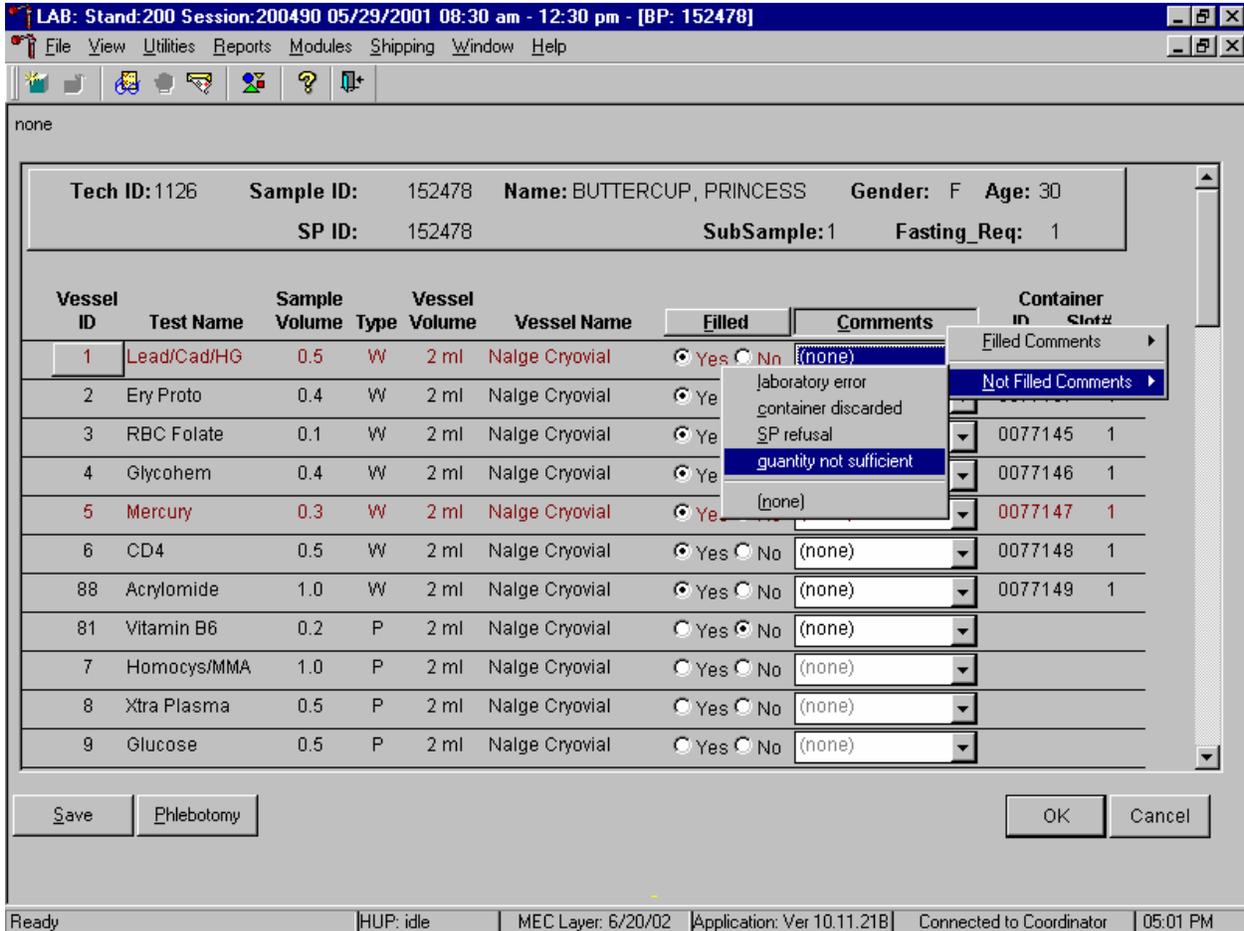
Attach a comment to an individual Filled–“No” vessel.

The screenshot shows a software window titled "LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]". The interface includes a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main area displays patient information: Tech ID: 1126, Sample ID: 152478, Name: BUTTERCUP, PRINCESS, Gender: F, Age: 30, SP ID: 152478, SubSample: 1, Fasting\_Req: 1. Below this is a table of vessels with columns for Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Filled status, Comments, Container ID, and Slot#. The table lists 10 vessels, with Vessel 81 (Vitamin B6) selected. A dropdown menu is open for the Comments field of Vessel 81, showing options: (none), container discarded, laboratory error, quantity not sufficient, and SP refusal. At the bottom, there are buttons for Save, Phlebotomy, OK, and Cancel. The status bar at the very bottom shows "Ready", "HUP: idle", "MEC Layer: 6/20/02", "Application: Ver 10.11.21B", "Connected to Coordinator", and "05:00 PM".

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077106	1
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077107	1
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077145	1
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077146	1
5	Mercury	0.3	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077147	1
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077148	1
88	Acrylomide	1.0	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077149	1
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
7	Homocys/MMA	1.0	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
8	Xtra Plasma	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

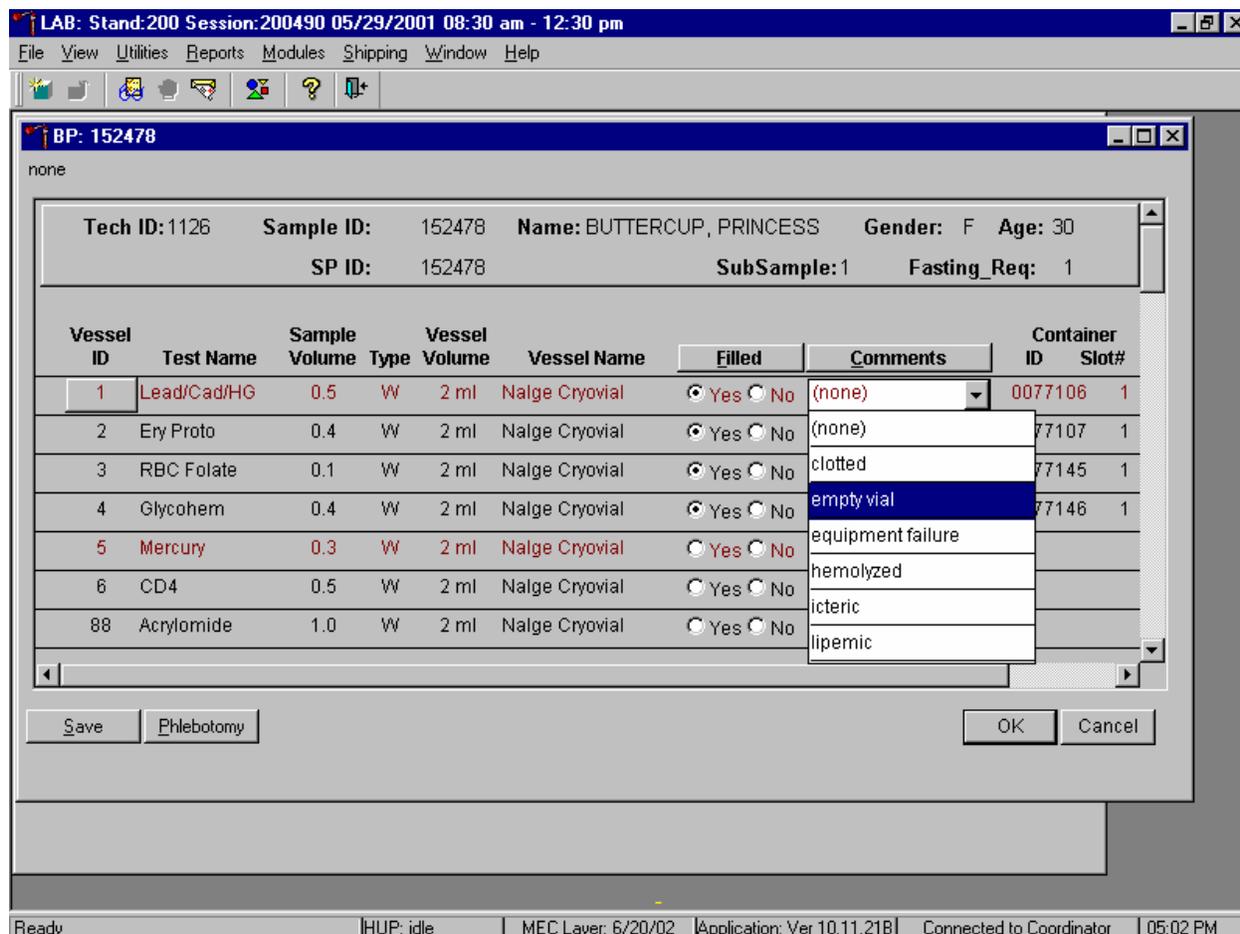
To attach a Filled–“No” comment to an individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

Use the following procedure when all Filled – “No” vessels require the same comment.



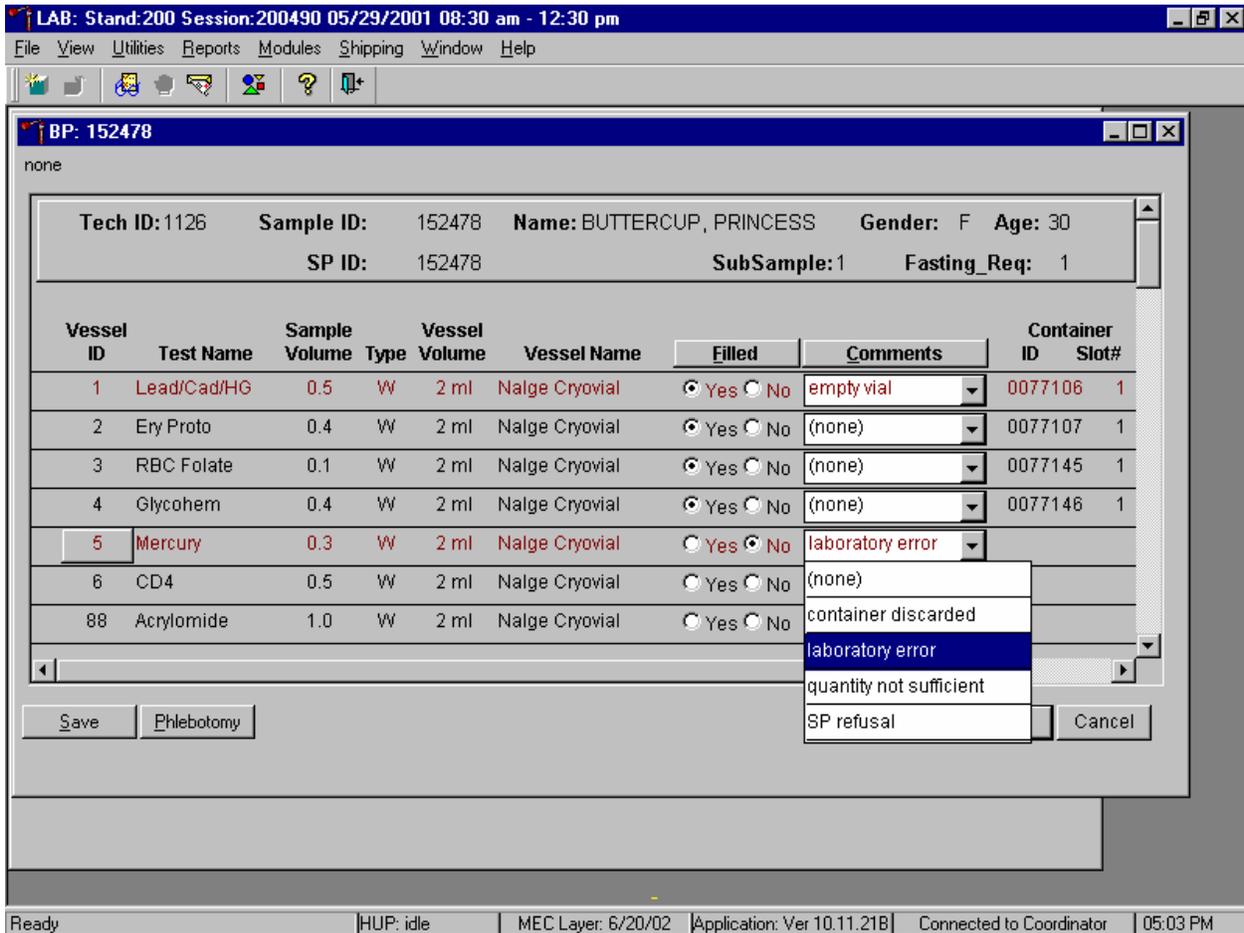
To collectively attach the same comment to all Filled–“No” vessels, use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Not Filled All}, drag the mouse arrow to the desired choice, and left click. Alternatively, to collectively attach the same comment to all vessels marked as Filled – “No” type [Shift] [C/c], [N/n], and the first letter of the desired choice (l=laboratory error, s= SP refusal, q=quantity not sufficient.).

Every SP who has any vessel filled must have vessel 1 marked as filled.



Mark vessel 1 as Filled—"Yes," even if the blood is clotted, but do not fill the vessel. Attach the comment, "empty vial" to this vessel. To attach the comment "empty vial" to this individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to {empty vial}, and left click.

If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad), vessel 3 (RBC Folate), vessel 4 (Glycohem), vessel 5 (Mercury) or vessel 6 (CD4). Process vessel 2 (Ery Proto) and but attach the comment, “Clotted.”



If the CBC was accidentally run before the whole blood for vessels 1 (Lead/Cad) and 5 (Mercury) was pipetted, then do not process these two vessels. Mark vessel 1 as Filled–“Yes” and attach the comment “empty vial.” Mark vessel 5 as Filled–“No” and attach the comment “laboratory error.” Continue to pipette the whole blood for vessels 2, 3, 4 and 6 even if the CBC was run before the whole blood was pipetted.

Continue to enter results as vessels are processed. Review the information in the blood-processing window and save the data to the database.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077106	1
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077107	1
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077145	1
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077146	1
5	Mercury	0.3	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077147	1
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077148	1
88	Acrylomide	1.0	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077149	1
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077150	1
7	Homocys/MMA	1.0	P	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077151	1
8	Xtra Plasma	0.5	P	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077152	1
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077153	1

Save    Phlebotomy    OK    Cancel

Apply changes and close window    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    05:04 PM

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

Data cannot be saved until all vessels marked as Filled–“No” are assigned a comment.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
19	Bn Alk Phos	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077165	1
20	Toxo	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077166	1
18	Biochem	0.8						0077167	1
23	Insul/Cpep	1.0						0077168	1
22	HIV	0.5							
24	HSV	0.2						0077170	1
74	Syphilis	0.5						0077171	1
15	Vit A/E/Car	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077172	1
29	Persis Pest	4.0	S	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077173	1
89	PerPest2NP	4.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077173	2
32	Xtra Sera	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077174	1

Save    Phlebotomy    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    05:06 PM

If the Save or the OK button is selected and all vessels are not marked as either Filled–“Yes” or Filled–“No,” a warning message box displays requesting a comment for each unfilled vessel. To remove the warning message box, use the mouse to direct the mouse arrow to the OK button and left click

## 8.9 Process HIV Urine

At the end of each session, process urine for HIV if no blood was collected or the quantity of serum was insufficient for serum HIV (for SPs 18-49) and the primary SP has not refused the HIV test. Record the HIV vessel 22 result to the database.

If the quantity of serum is insufficient and the SP has not refused the test, mark vessel 22 as Filled–“No.”

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
19	Bn Alk Phos	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077165	1
20	Toxo	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077166	1
18	Biochem	0.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077167	1
23	Insul/Cpep	1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077168	1
22	HIV	0.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not suffici		
24	HSV	0.2	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077170	1
74	Syphilis	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077171	1
15	Vit A/E/Car	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077172	1
29	Persis Pest	4.0	S	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077173	1
89	PerPest2NP	4.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077173	2
32	Xtra Sera	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077174	1

Save    Phlebotomy    OK    Cancel

Checking Inclusions for SampleID# 152478    |HUP: phase 3    | MEC Layer: 6/20/02    |Application: Ver 10.11.21B    | Connected to Coordinator    | 05:07 PM

Once the blood processing result for vessel #22 (HIV) is Filled–“No” and the result is saved to the database, the HIV Urine Processing module becomes enabled.

Select the correct SP from the heads-up display. The process status HIV circle changes from gray to black when an SP is eligible for the HIV urine vessel. Access the HIV Urine Processing module.

The HIV Urine Processing screen displays.

none

Tech ID: 1126	Sample ID: 152478	Name: BUTTERCUP, PRINCESS	Gender: F	Age: 30
	SP ID: 152478	SubSample: 1	Fasting_Req: 1	

Vessel ID	Test Name	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
53	HIV Urine	U	3.0	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save OK Cancel

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.21B | Connected to Coordinator | 05:07 PM

The HIV Urine Processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting\_Req, columns for Vessel ID, Test Name, Type (U=urine), Vessel Volume, Vessel Name, Container ID/Slot #, and Filled and Comments buttons.

Mark the vessel as Filled--“Yes” or Filled--“No.”

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

HIV: 152478

none

Tech ID: 1126	Sample ID: 152478	Name: BUTTERCUP, PRINCESS	Gender: F	Age: 30
SP ID: 152478	SubSample: 1	Fasting_Req: 1		

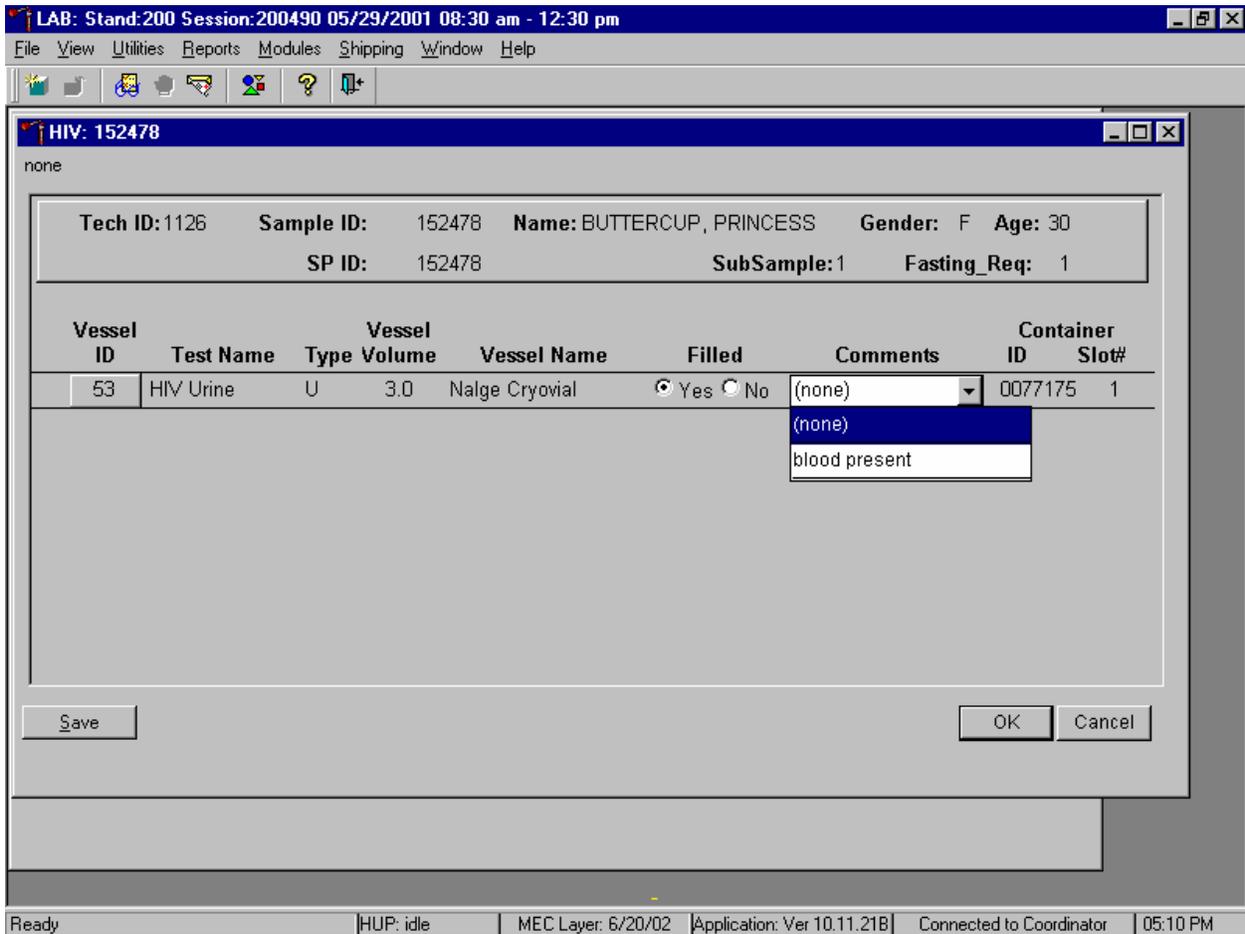
Vessel ID	Test Name	Vessel Type	Volume	Vessel Name	Filled	Comments	Container ID	Slot#
53	HIV Urine	U	3.0	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077175	1

Save OK Cancel

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.21B | Connected to Coordinator | 05:09 PM

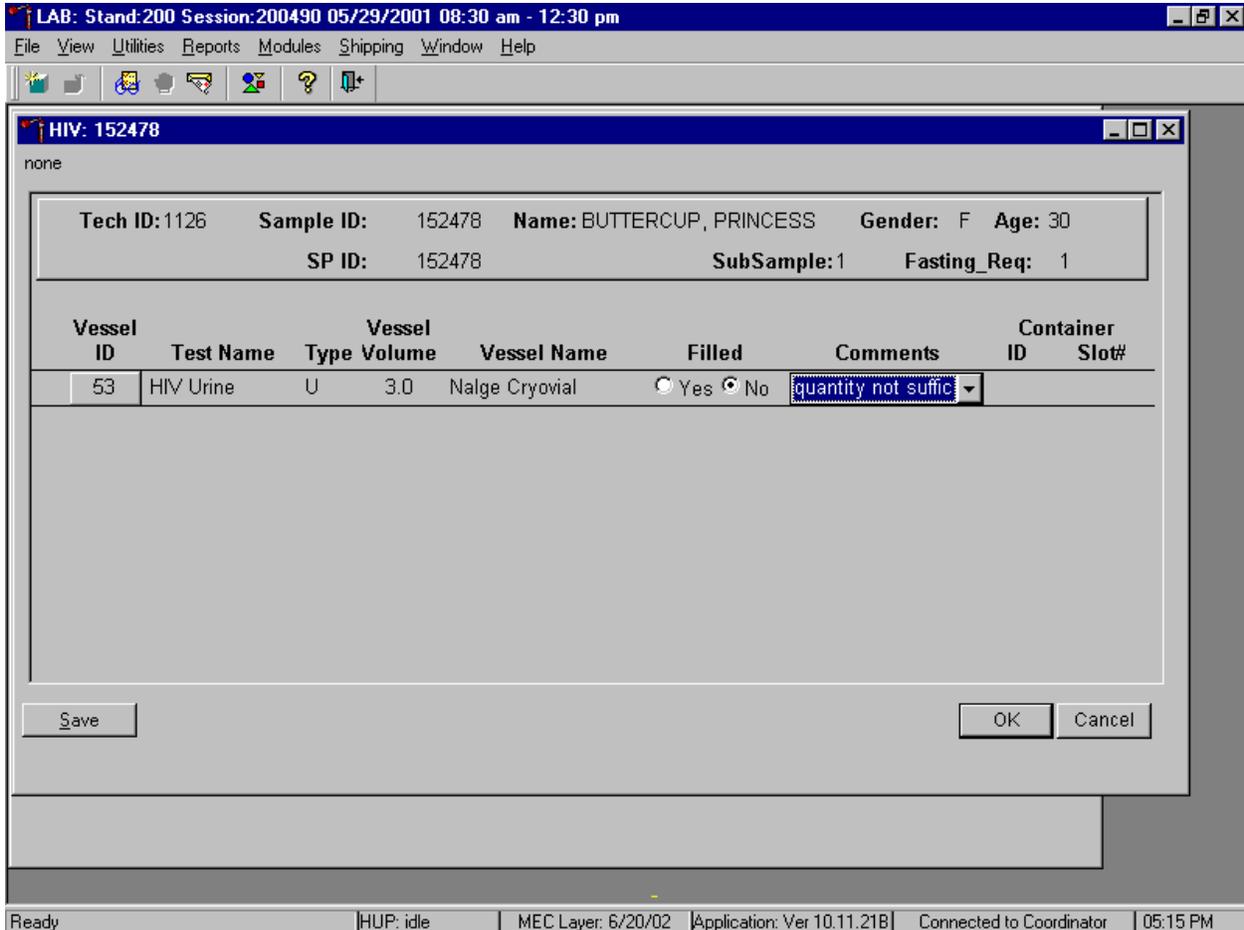
To mark the HIV urine vessel as collected or Filled--“Yes,” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As this vessel is marked as Filled--“Yes,” it is automatically assigned to a slot in an existing (open) container. To mark the HIV urine vessel as not collected or Filled--“No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click.

Use the quality comment code to indicate if blood is present.



To enter the quality control comment “blood present” for a filled vessel, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {blood present}, and left click.

If this vessel is marked as Filled–“No,” the comment, “quantity not sufficient” is automatically entered in the Comments column.



Review the information in the urine-processing window and save the data to the database. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

## **8.10 Blood Specimen Storage**

### **8.10.1 Blood Specimen Storage Protocol**

Fill the blood vessels, enter the blood and HIV urine processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Table 8-1.

At the beginning of each stand, generate and print a series of bar-coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process “opens” a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in containers are assigned according to a standard left to right, top to bottom procedure. Store each vessel in the appropriate slot in the correct container immediately after processing.

Table 8-1. Storage protocol for blood and HIV urine

Shipping Location	Vessels	Conditions	Vessel Storage
CASPIR	1 Lead/Cad/HG	Frozen	9 x 9 two inch box
NYS DOH/Wadsworth CTR L & R	2 Ery Proto	Frozen	9 x 9 two inch box
CASPIR	3 RBC Folate	Frozen	9 x 9 two inch box
Univ of Missouri	4 Glycohem	Refrigerated	9 x 9 two inch box
CASPIR	5 Mercury	Frozen	9 x 9 two inch box
CASPIR	6 CD4	Frozen	9 x 9 two inch box
CASPIR	88 Acrylamide	Frozen	9 x 9 two inch box
AC Diagnostics	81 Vitamin B6	Frozen	9 x 9 two inch box
CASPIR	7 Homocys/MMA	Frozen	9 x 9 two inch box
CASPIR	8 Xtra Plasma	Frozen	9 x 9 two inch box
Univ of Missouri	9 Glucose	Frozen	9 x 9 two inch box
Univ of Washington	10 Fibrin	Frozen	9 x 9 two inch box
CASPIR	70 Vitamin D	Frozen	9 x 9 two inch box
CASPIR	12 Fol/B12	Frozen	9 x 9 two inch box
Univ of Washington	13 CRP	Frozen	9 x 9 two inch box
CDC NCID Hepatitis Ref Lab	14 Hep Profile	Frozen	9 x 9 two inch box
CDC NCID Hepatitis Ref Lab	87 Hepatitis ab	Frozen	9 x 9 two inch box
CASPIR	99 Fer/TfR	Frozen	9 x 9 two inch box
Collaborative Laboratory Services	11 Iron/TIBC	Frozen	9 x 9 two inch box
CASPIR	17 Cotinine	Frozen	9 x 9 two inch box
Lipoprotein Analytical Lab/JHU	21 Lipids	Frozen	9 x 9 two inch box
Univ of Washington	94 PTH2	Frozen	9 x 9 two inch box
CDC Ruth Ann Tucker	77 HPV Serum	Frozen	9 x 9 two inch box
CASPIR	79 Vitamin C	Frozen	9 x 9 two inch box
Calif Dept of Health Services	16 Rub/Mea/Var	Frozen	9 x 9 two inch box
Univ of Washington	19 Bn Alk Phos	Frozen	9 x 9 two inch box
CDC/DPD	20 Toxo	Frozen	9 x 9 two inch box
Collaborative Laboratory Services	18 Biochem	Refrigerated	9 x 9 two inch box
Univ of Missouri	23 Insul/Cpep	Frozen	9 x 9 two inch box
CDC NCID AIDS Division	22 HIV	Frozen	9 x 9 two inch box
Emory University	24 HSV	Frozen	9 x 9 two inch box
CDC DASTLR/NCID	74 Syphilis	Frozen	9 x 9 two inch box
Univ of Washington	75 PSA	Frozen	9 x 9 two inch box
Craft Technologies	15 Vit A/E/Car	Frozen	9 x 9 two inch box
NYS DOH/Wadsworth CTR L & R	26 Selenium	Frozen	9 x 9 two inch box
CDC Wayman Turner	29/89 Persis Pest(2)	Frozen	9 x 9 three inch box
CASPIR	32-40 Xtra Serum	Frozen	9 x 9 two inch box
CDC NCID AIDS Division	53 HIV Urine	Frozen	9 x 9 three inch box
CASPIR	90/91 Future Res1/2	Frozen	9 x 9 three inch box
CASPIR	92/93 Future Res3/4	Frozen	9 x 9 three inch box

## **8.11 How to Deal With System Failure**

If the computer system fails, record results on a preprinted Workstation 1 processing worksheet (Exhibit 8-19). Complete a Blood Processing and HIV Urine Processing worksheet for each SP while processing the blood and HIV urine specimens. Enter the results after the system is operational.

Exhibit 8-19. Workstation 1 processing worksheet

**BLOOD PROCESSING AND HIV URINE PROCESSING**

SP ID \_\_\_\_\_

ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i>	Not Filled Comments <i>ONS</i> <i>SP Refusal</i> <i>Lab Error</i>	Slot #
1	Lead/Cad/HG	1-5 6+	0.3 0.5	WB				
2	Ery Proto	3-5 12-49	0.4 0.4	WB				
3	RBC Folate	1+	0.1	WB				
4	Glycohem	12+	0.4	WB				
5	Mercury	1+	0.3	WB				
6	CD4	18-49	0.5	WB				
88	Acrylamide	3-5 6+	0.4 1.0	WB				
81	Vitamin B6	1-11 12+	0.2 0.5	P				
7	Homocys/MMA	3+	1.0	P				
8	Xtra Plasma	6+	0.5	P				
9	Glucose	12+	0.5	P				
70	Vitamin D	1-2 3+	0.3 0.5	S				
12	Fol/B12	1-5 6+	0.7 1.0	S				
13	CRP	1+	0.5	S				
14	Hep Profile	6+	1.5	S				
87	Hepatitis ab	2-5	0.4					
99	Fer/TfR	1-2 3-5 12-49	0.3 0.5 0.5	S				
11	Iron/TIBC	3-5 12-59	1.0 1.0	S				
17	Cotinine	3-11 12+	1.3 1.8	S				
21	Lipids	3-5 6+	0.2 1.0	S				
94	PTH2	6+	1.0	S				
77	HPV Serum	14-59	0.5	S				
79	Vitamin C	6+	0.1	S				
16	Rub/Mea/Var	6-49	0.1	S				
19	Bn Alk Phos	8-49	0.5	S				
20	Toxo	6-11 12-49	0.2 0.5	S				
18	Biochem	12+	0.8	S				

Exhibit 8-19. Workstation 1 processing worksheet (continued)

ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i>	Not Filled Comments <i>ONS</i> <i>SP Refusal</i> <i>Lab Error</i>	Slot #
23	Insul/Cpep	12+	1.0	S				
22	HIV	18-49	0.5	S				
24	HSV	49-49	0.2	S				
74	Syphilis	18-49	0.5	S				
75	PSA	40+	1.0	S				
16	Vit A/E/CAR	3-11 12+	0.4 0.5	S				
26	Selenium	40+	0.5	S				
32	Xtra Serum	3+	0.5	S				
33	Xtra Serum	6+	0.5	S				
34	Xtra Serum	6+	0.5	S				
35	Xtra Serum	12+	0.5	S				
36	Xtra Serum	12+	0.5	S				
37	Xtra Serum	12+	0.5	S				
38	Xtra Serum	12+	1.0	S				
39	Xtra Serum	12+	1.0	S				
40	Xtra Serum	12+	1.0	S				
53	HIV Urine	18-49	5.0	U				
29	Persis Pest	12+	4.0	S				
89	Persis Pest 2	12+	4.0	S				
90	Future Res1	12+	4.0	S				
91	Future Res2	12+	4.0	S				
92	Future Res3	12+	4.0	S				
93	Future Res4	12+	4.0	S				

P = Plasma

WB = Whole Blood

S = Serum

U = Urine

**Bold = Females only**

## **9. PRINTING LABELS AND SPECIMEN SHIPMENT**

### **9.1 Introduction**

Labels are essential to the laboratory component. Labels support each sample person's (SP's) unique processing protocol. The laboratory record is created when the medical technologist accesses a session for the first time. This record forms the basis for each SP's data in the database. Container labels are generated and assigned to vessel storage containers and allow a processed sample to be tracked from mobile examination center (MEC) processing through contract laboratory receipt.

Ship biological specimens to a variety of contract laboratories in double-sided Styrofoam and corrugated cardboard shippers or hard-sided shippers with Styrofoam inserts using dry ice or wet ice (refrigerant packs). Include a copy of a shipping manifest with each shipment that contains a list of the items contained in the shipment and certain demographic information. Exhibit 9.1, the Blood and urine shipping protocol, illustrates the specifications for the shipment of blood and urine specimens to each contract laboratory.

Ship packages using FedEx. The chief medical technologist is responsible for contacting FedEx at the start of each stand to determine availability. The MEC manager contacts the dry ice company at the start of each stand to establish a contact but the chief medical technologist arranges for the delivery of dry ice on shipping days. It is the chief medical technologist's responsibility to confirm the arrangements for shipping and dry ice delivery with the MEC manager at the beginning of each stand.

The chief medical technologist works with the MEC manager and the home office to determine exactly which days to ship specimens to the contract laboratories. As a rule, pack and ship most specimens once a week during MEC split examination sessions. The exceptions are vessels 6, 8, 90/91, 92/93, 32-40, 51/52, 66, 29/89, 48, 49, 65, and 67. Hold these containers and ship once they are full or hold and ship at the end of the stand. All specimens should arrive at the destination the day after shipping. The next-day limitation may conflict with off days, holidays, and vacations. If a conflict with the shipping schedule, working schedule, or the contract laboratory schedule occurs, consult the MEC manager and the home office technical supervisor.

Exhibit 9-1. Blood and urine shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
<b>Blood</b>				
CASPIR NCEH Vessel 1	Lead/Cad/HG	Frozen	9 x 9 two inch box	Weekly
NYS DOH/Wadsworth CTR Vessel 2	Ery Proto	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 3	RBC Folate	Frozen	9 x 9 two inch box	Weekly
Univ of Missouri Vessel 4	Glycohem	Refrigerated	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 5	Mercury	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 6	CD4	Frozen	9 x 9 two inch box	Full or end of stand
CASPIR NCEH Vessel 88	Acrylamide	Frozen	9 x 9 two inch box	Weekly
AC Diagnostics Vessel 81	Vitamin B6	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 7	Homocys/MMA	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 8	Xtra Plasma	Frozen	9 x 9 two inch box	Full or end of stand
Univ of Missouri Vessel 9	Glucose	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 70	Vitamin D	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 12	Fol/B12	Frozen	9 x 9 two inch box	Weekly
Univ of Washington Vessel 13	CRP	Frozen	9 x 9 two inch box	Weekly
CDC NCID Hepatitis Ref Lab Vessel 14	Hep Profile	Frozen	9 x 9 two inch box	Weekly
CDC NCID Hepatitis Ref Lab Vessel 87	Hepatitis ab	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 99	Fer/TfR	Frozen	9 x 9 two inch box	Weekly
Collaborative Laboratory Service Vessel 11	Iron/TIBC	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 17	Cotinine	Frozen	9 x 9 two inch box	Weekly

Exhibit 9-1. Blood and urine shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Lipoprotein Analytical Lab/JHU Vessel 21	Lipids	Frozen	9 x 9 two inch box	Weekly
Univ of Washington Vessel 94	PTH2	Frozen	9 x 9 two inch box	Weekly
CDC Ruth Ann Tucker Vessel 77	HPV Serum	Frozen	9 x 9 two inch box	Weekly
CASPIR NCEH Vessel 79	Vitamin C	Frozen	9 x 9 two inch box	Weekly
Calif Dept of Health Services Vessel 16	Rub/Mea/Var	Frozen	9 x 9 two inch box	Weekly
Univ of Washington Vessel 19	Bn Alk Phos	Frozen	9 x 9 two inch box	Weekly
CDC/DPD Vessel 20	Toxo	Frozen	9 x 9 two inch box	Weekly
Collaborative Laboratory Service Vessel 18	Biochem	Refrigerated	9 x 9 two inch box	Weekly
Univ of Missouri Vessel 23	Insul/Cpep	Frozen	9 x 9 two inch box	Weekly
CDC NCID AIDS Division Vessel 22	HIV	Frozen	9 x 9 two inch box	Weekly
Emory University Vessel 24	HSV	Frozen	9 x 9 two inch box	Weekly
CDC DASTLR/NCID Vessel 74	Syphilis	Frozen	9 x 9 two inch box	Weekly
Univ of Washington Vessel 75	PSA	Frozen	9 x 9 two inch box	Weekly
Craft Technologies Vessel 15	Vit A/E/Car	Frozen	9 x 9 two inch box	Weekly
NYS DOH/Wadsworth CTR Vessel 26	Selenium	Frozen	9 x 9 two inch box	Weekly
CASPIR/Dr. Wayman Turner Vessels 29 and 89	Persis Pest Persis Pest2	Frozen	9 x 9 three inch box	Full or end of stand
CASPIR Vessels 90 and 91	Future Res1 Future Res2	Frozen	9 x 9 three inch box	Full or end of stand
CASPIR Vessels 92 and 93	Future Res3 Future Res4	Frozen	9 x 9 three inch box	Full or end of stand
CASPIR Vessels 32-40	Xtra Sera	Frozen	9 x 9 two inch box	Full or end of stand

Exhibit 9-1. Blood and urine shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
<b>Urine</b>				
Univ of Minnesota Vessel 45	Alb/Creat	Frozen	9 x 9 three inch box	Weekly
CDC NCID NCHSTP Vessel 46	Chlam/GC	Frozen	5 x 5 three inch box	Weekly
CASPIR NCEH Vessel 69	Urn Iodine	Frozen	9 x 9 three inch box	Weekly
CASPIR NCEH Vessel 86	Spc Arsenic	Frozen	9 x 9 three inch box	Weekly
CDC/Dr. Dana Barr Vessel 48	Prior Pest	Frozen	5 x 5 three inch box	Full or end of stand
CDC/Dr. Dana Barr Vessel 49	Organophos	Frozen	5 x 5 three inch box	Full or end of stand
CASPIR Vessel 62	Urn Merc	Frozen	9 x 9 three inch box	Weekly
CASPIR Vessel 50	Heavy Metal	Frozen	5 x 5 three inch box	Weekly
CASPIR NCEH Vessel 65	Urn Phytoes	Frozen	5 x 5 three inch box	Full or end of stand
CASPIR/Dr. Courtney Sandau Vessel 66	PAH	Frozen	9 x 9 three inch box	Full or end of stand
CDC/Dr. Antonia Calafat Vessel 67	Phthalates	Frozen	9 x 9 three inch box	Full or end of stand
CASPIR Vessels 51 and 52	Xtra Urine	Frozen	9 x 9 three inch box	Full or end of stand
CDC NCID AIDS Division Vessel 53	HIV	Refrigerated	9 x 9 three inch box	Weekly

## 9.2 Equipment and Supplies

Exhibit 9-2 contains a list of label/shipping supplies.

Exhibit 9-2. Supplies for labels/shipping

Small Styrofoam shipper (14 x 14 x 12)	Medium Styrofoam shippers (16 x16 x 15.5)
5-mL cryovial sterile	2-mL cryovial sterile
14-mL snap cap test tube	2-mL cryovial non-sterile
Conical tube 50-mL	Caps for 2-mL cryovial
5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid	5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid
5.25 x 5.25 x 5.0 inch cardboard box with 5 x 5 foam insert	Three inch 5 x 5 cardboard grid
5.25 x 5.25 x 3.0 inch cardboard box without grid	Scale
STP-710 Pressure vessel	STP-310 Pressure vessel
STP-740 Pressure vessel	U-TEK Reusable Refrigerant Packs Large
Plastic bag 9 x 12	Zip closable bags – quart size
Absorbent sheets (2 x 2)	Rubber bands
Large padded envelope	Newsprint paper
Cryo gloves	Full face shield
Hammer	Dry ice scoop
Tape gun	Packaging tape 2”
Air eligible label	DIAGNOSTIC SPECIMENS label
Biohazard label	Refrigerate Do Not Freeze label
Keep Frozen label	Avery 5160 labels
Label Datamax (1.125”)	Printer ribbon, Datamax (thermal transfer)
Sheet-fed laser labels	Wipes, Terri 13” x 18”
FedEx large boxes	FedEx Class 9 label
Clear FedEx label pouches	FedEx preprinted return airbill - warehouse
FedEx form 0215	FedEx preprinted return airbill - stand
Toner cartridge (HP Laser Jet 4000)	Lab jackets (Petite, Lg., X-Lg.)

## 9.3 Print Vessel Labels and Label Blood Processing Racks

Before each session, the technologist at workstation 3 prints all labels for all SPs assigned to a session. The correct bar-coded labels automatically print for each SP based on the SP’s age, sex, appointment type, and selection into one or more subsamples. Print pooled blood tube, pregnancy testing, urine processing, VS processing, and blood processing labels for all SPs in the MEC session. The

phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks.

#### **Distribute labels**

- Place pregnancy testing, VS processing, and urine processing labels at workstation 2 in the laboratory.
- Save and recycle unused vessels.
- If the SP does not show up for the appointment, it is possible he or she will reschedule.
- Store the SP's vessels and labels in a zip-closable bag until the end of the stand.
- If the SP has not shown up by the end of the stand, recycle the unused vessels.

#### **Assemble blood-processing racks**

The phlebotomist and the medical technologist assigned to the shipping workstation are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting up the blood vessel racks and in labeling the vessels with the appropriate bar code label.

Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally and making sure the label wraps onto itself. Place the label so the first digit of the vessel number is at the top of the vessel. Set the vessels in the cube racks in priority order.

Use the following materials to set up and label blood racks:

- Styrofoam rack
- Age-appropriate processing template

- Storage vessels of the following sizes:
  - 2.0-mL vessel
  - 5.0-mL vessel
  - 14.0-mL tube
  - 50-mL conical tube
- Bar-coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

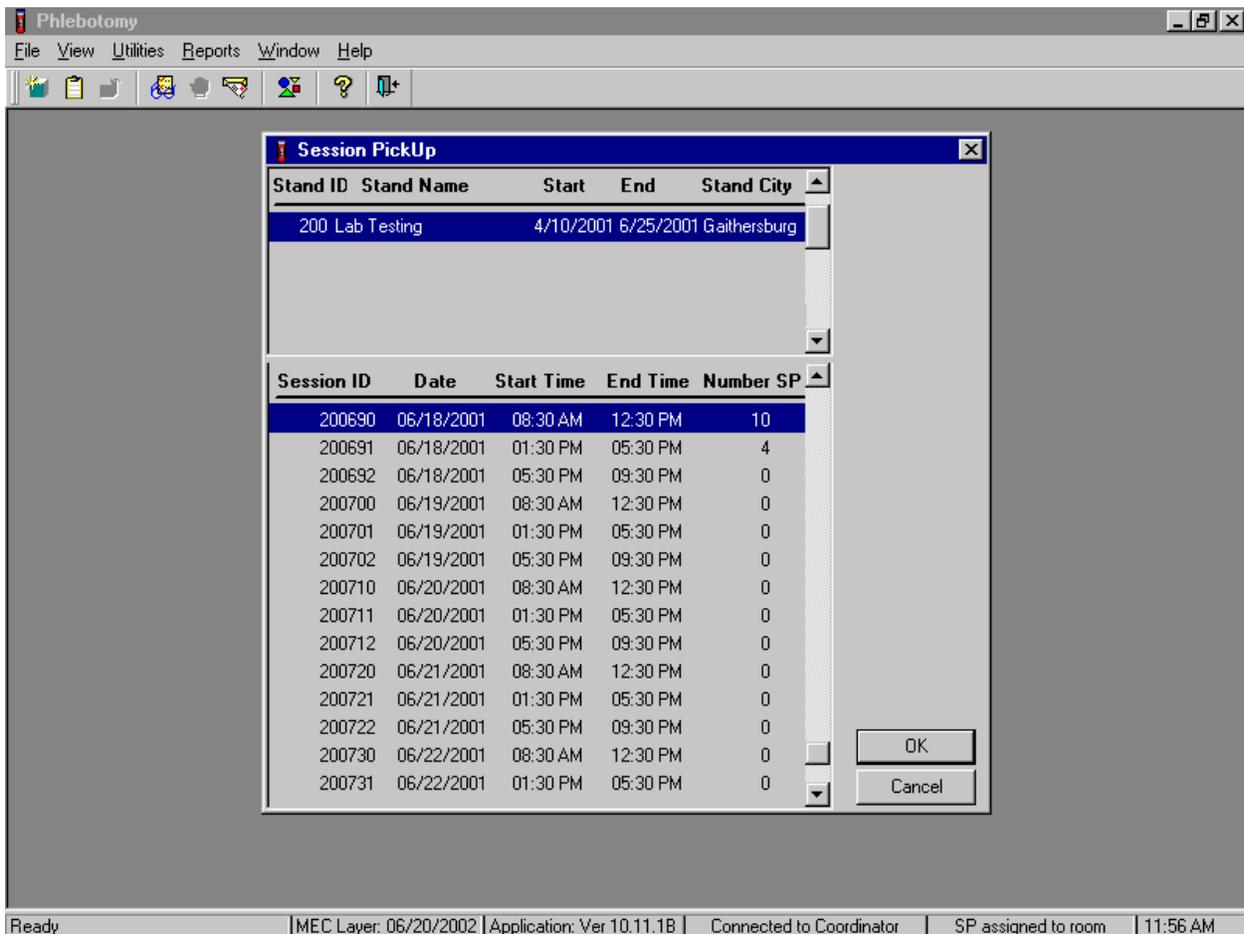
Prepare one blood processing rack for each SP. The set-up of the rack depends on the subject's age, sex, appointment type, and inclusion in selected subsamples. When possible, prepare the racks at least 1 day before the SP arrives for the MEC examination.

- Place the prelabeled blood processing racks in the laboratory at the start of each session.

### 9.3.1 Print Vessel Labels Using the Print Labels Module

Open the Laboratory application. Log onto the computer terminal. If the laboratory is conducting a MEC session, the heads-up display will default to the current session. If the MEC is not conducting a session, then use the Set Session utility to access a different session.

If the MEC is not conducting a session, then the Session PickUp list displays. Select the correct session from the pick list.



The Session PickUp window displays if the MEC is not conducting a session. The current stand is displayed in the top section of the window. To select or highlight the correct MEC session, use the mouse to direct the mouse arrow to the correct session, date, and time and right click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct

session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

After selecting a session from the Session PickUp list and selecting OK, the laboratory heads-up screen displays.

If the staff is conducting a MEC session, the laboratory application defaults to the current MEC session.

Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm

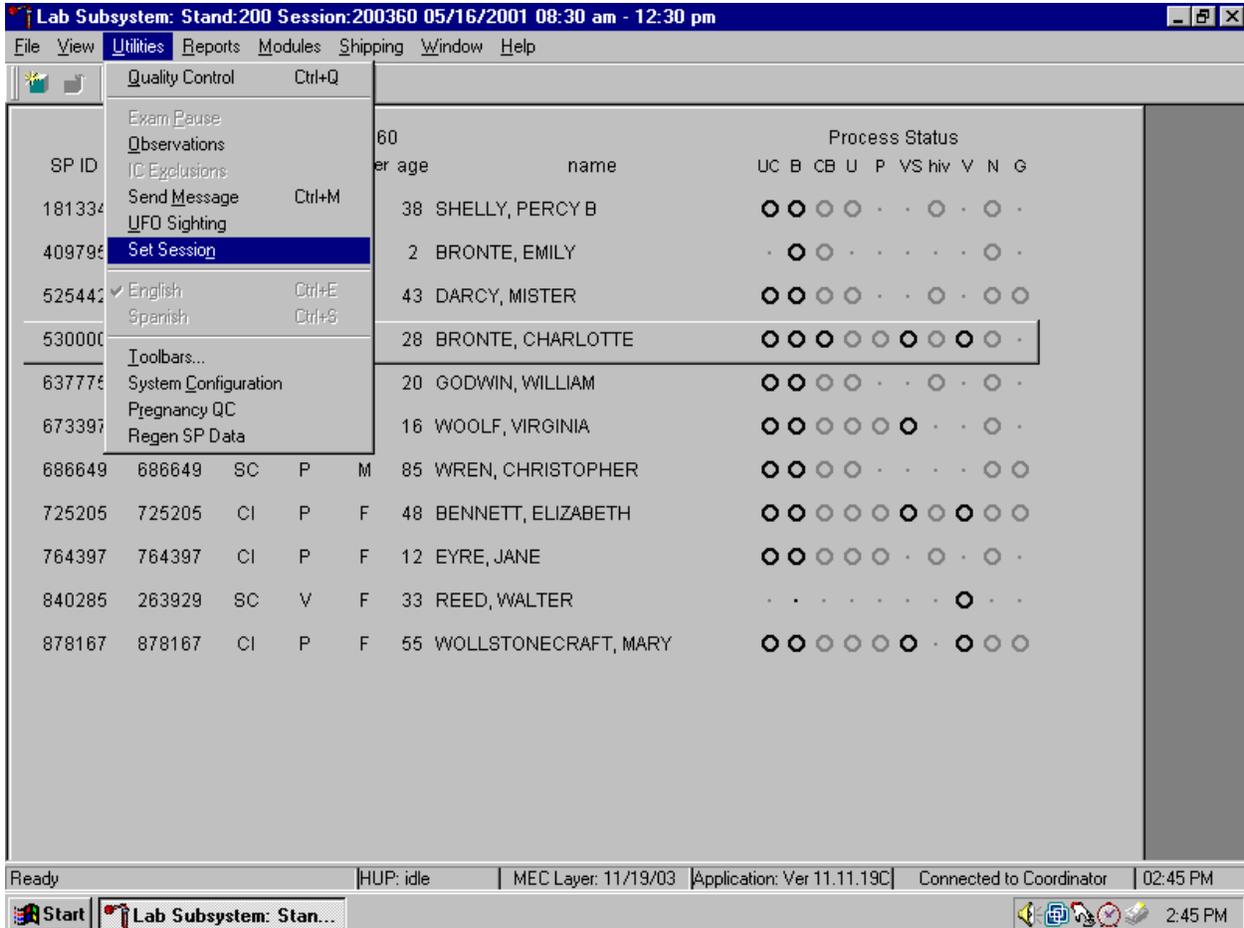
File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 200360							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
181334	181334	SC	P	M	38	SHELLY, PERCY B	●	●	●	●	·	·	·	·	·	·
409795	409795	SC	P	F	2	BRONTE, EMILY	·	●	●	·	·	·	·	·	·	·
525442	525442	SC	P	M	43	DARCY, MISTER	●	●	●	●	·	·	·	·	·	·
530000	530000	BE	P	F	28	BRONTE, CHARLOTTE	●	●	●	●	●	●	●	●	●	·
637775	637775	CI	P	M	20	GODWIN, WILLIAM	●	●	●	●	·	·	·	·	·	·
673397	673397	SC	P	F	16	WOOLF, VIRGINIA	●	●	●	●	●	●	·	·	·	·
686649	686649	SC	P	M	85	WREN, CHRISTOPHER	●	●	●	●	·	·	·	·	·	·
725205	725205	CI	P	F	48	BENNETT, ELIZABETH	●	●	●	●	●	●	●	●	●	●
764397	764397	CI	P	F	12	EYRE, JANE	●	●	●	●	●	·	·	·	·	·
840285	263929	SC	V	F	33	REED, WALTER	·	·	·	·	·	·	·	·	●	·
878167	878167	CI	P	F	55	WOLLSTONECRAFT, MARY	●	●	●	●	●	●	·	●	●	●

Ready | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:44 PM

Start | Lab Subsystem: Stan... | 2:45 PM

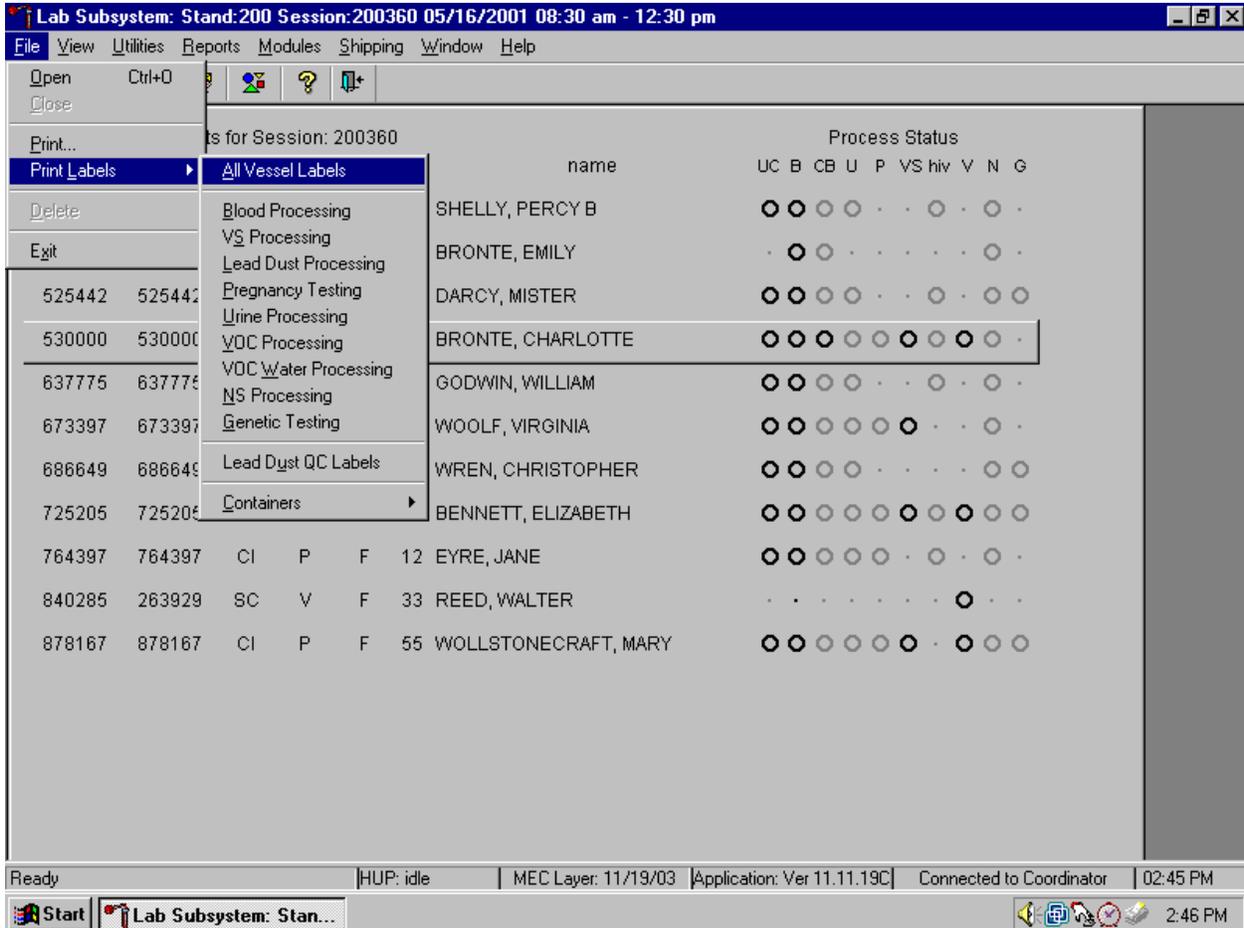
Use the Set Session utility to access a different MEC session when the staff is conducting a MEC session.



To access a different MEC session when the staff is conducting a MEC session, use the mouse to direct the mouse arrow to the {Utilities} module in the top menu bar, drag the mouse arrow to {Set Session}, and left click or type [ALT] [U/u], [N/n].

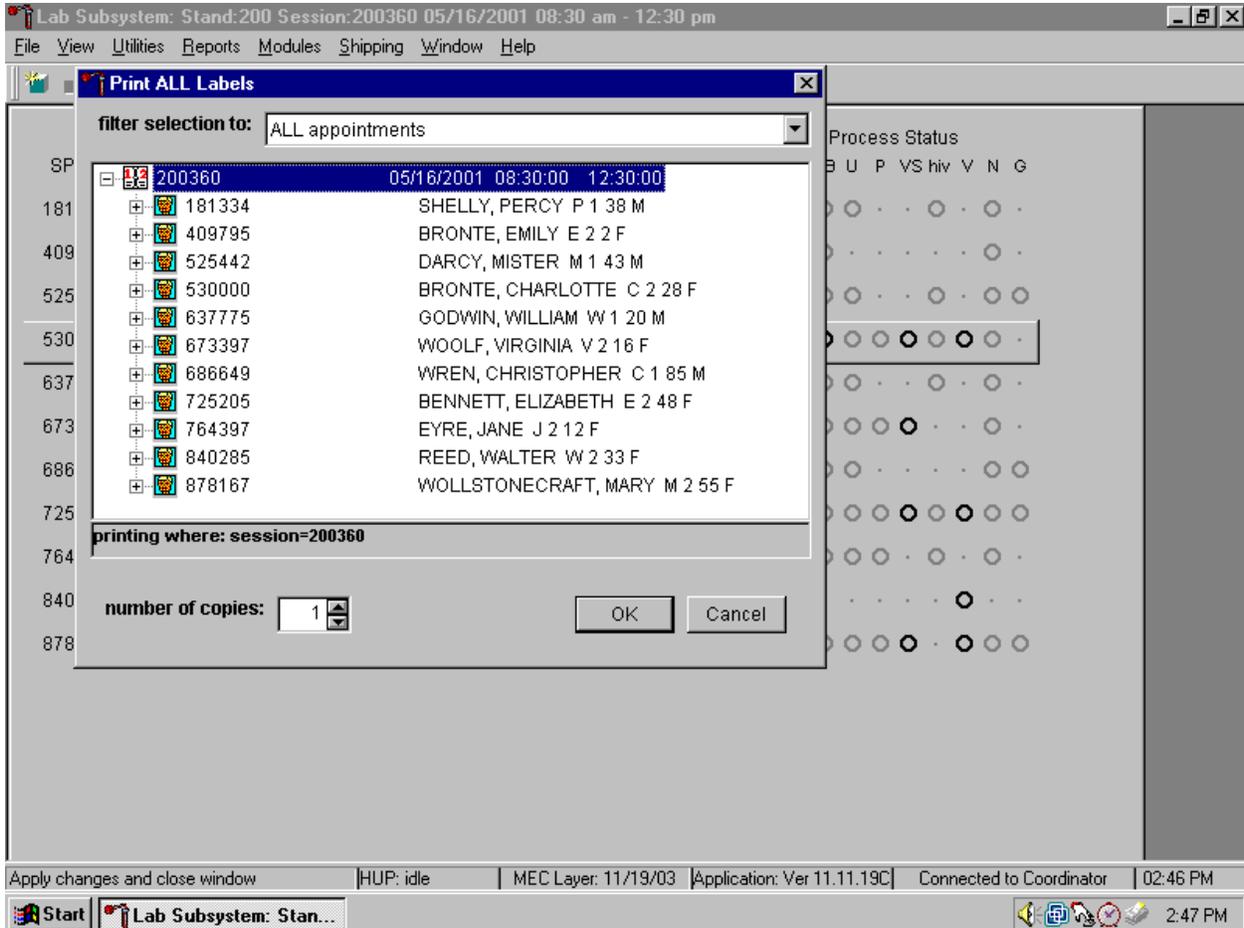
Print vessel labels. It is possible to print labels for all modules (blood, VS, lead dust, urine, pregnancy, VOC, VOC water, nasal swabs and genetic testing – (2003 pilot), or individual modules. It is also possible to print labels for all SPs in a session, an individual SP, or print labels for ALL appointments, appointments NOT previously printed, or appointments previously printed.

Print vessel labels for all modules.



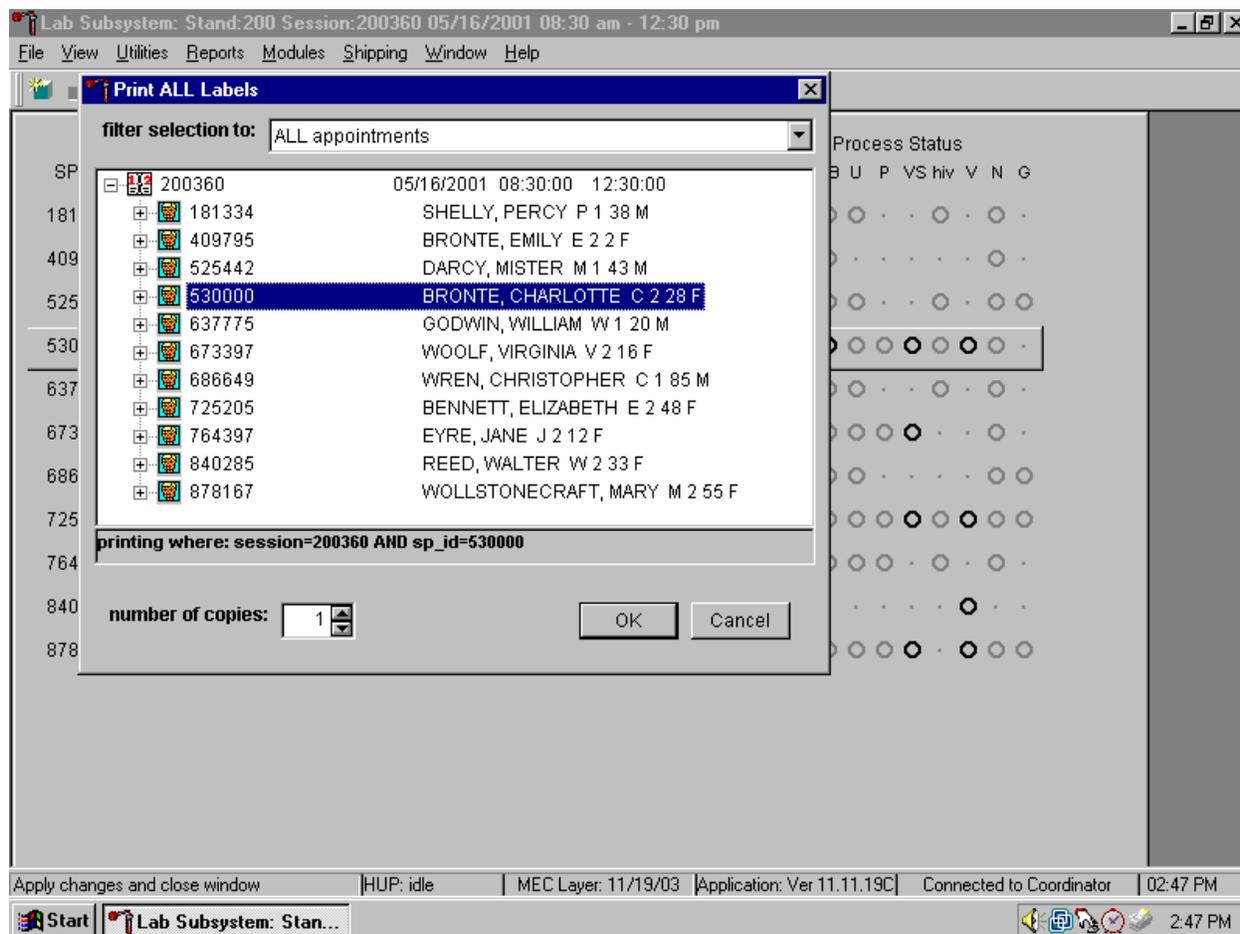
To print vessel labels for all modules, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Print Labels}, then to {All Vessel Labels} and left click, or type [Alt] [F/f], [L/l], [A/a]. Selecting {All Vessel Labels} prints a complete set of blood processing, urine processing, pregnancy testing, VS processing, nasal swab processing and genetic testing – (2003 pilot) labels.

The Print All Labels window displays. Use the Print All Labels window to print vessel labels for all modules for all SPs in a MEC session.



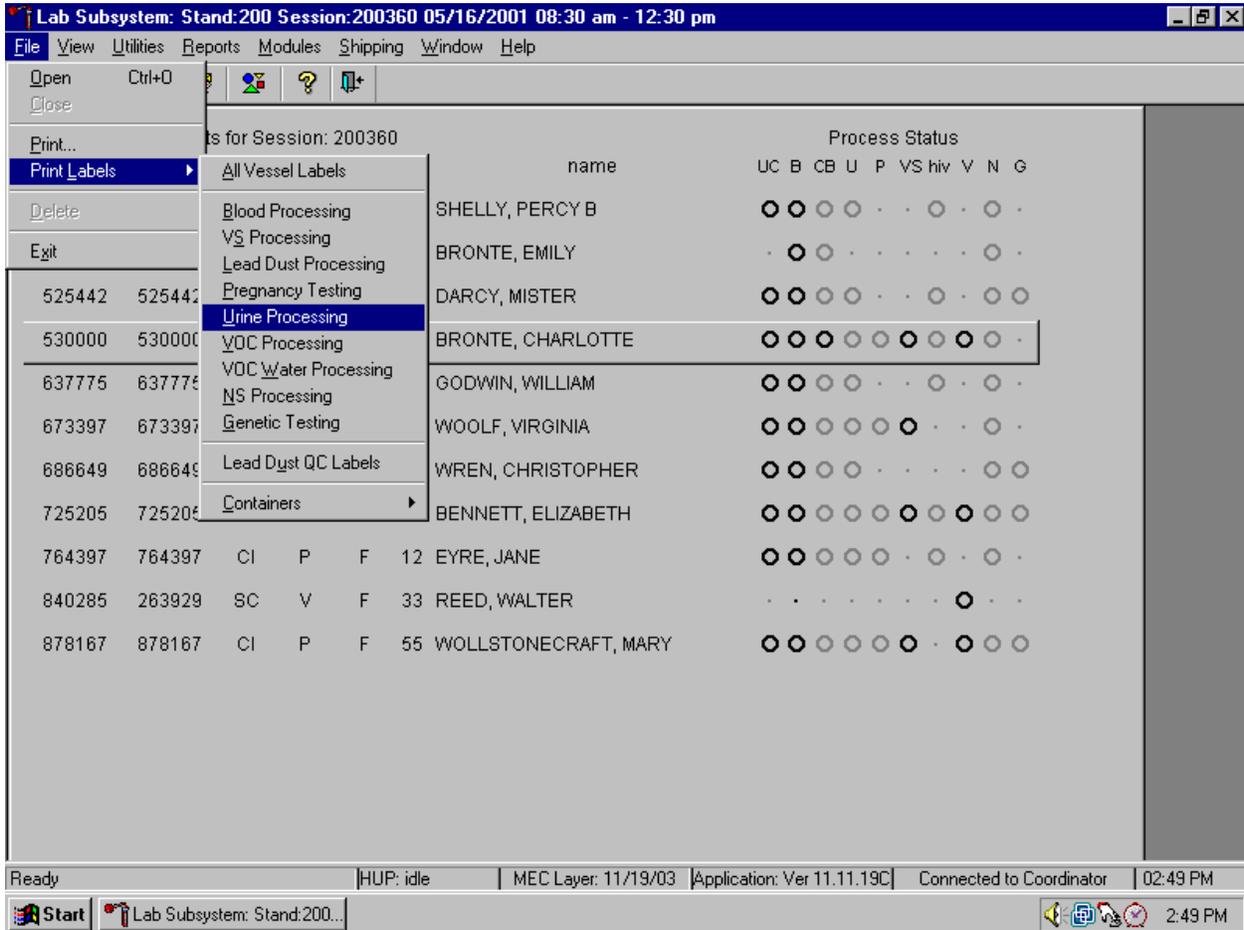
To print vessel labels for all modules for all SPs in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print vessel labels for all modules for one SP in a MEC session.



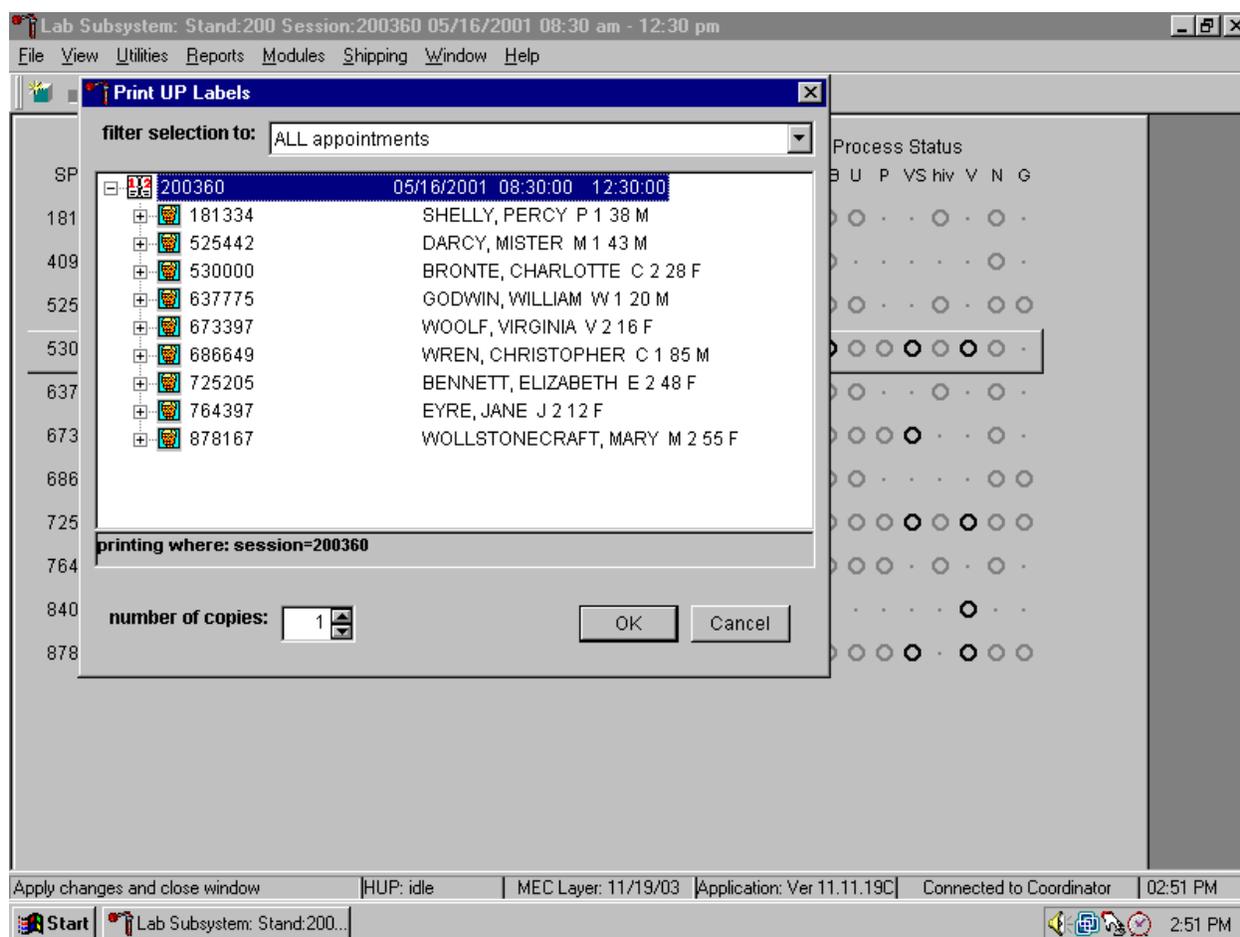
To print vessel labels for all modules for one SP in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print vessel labels for one specific module for all SPs in a MEC session.



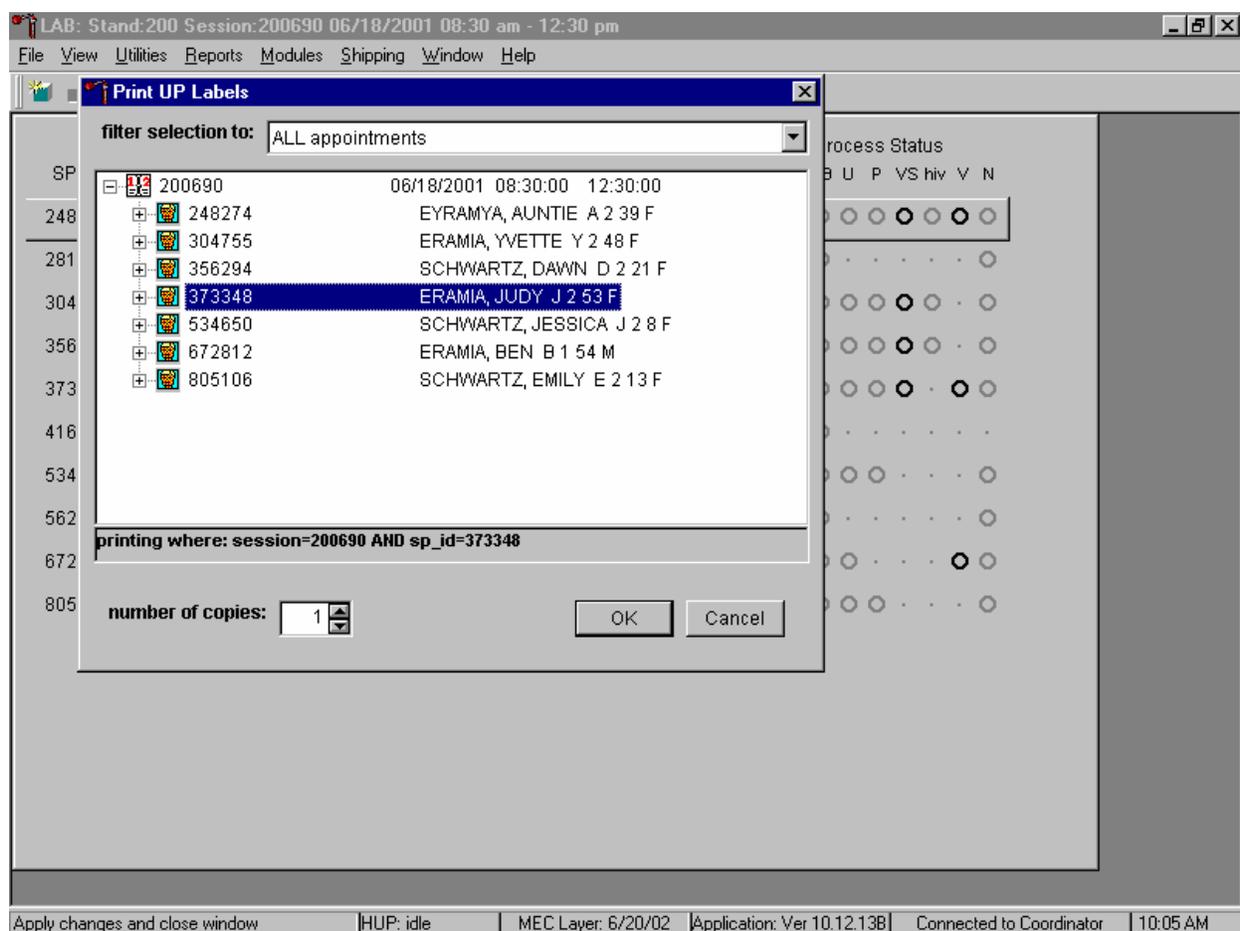
To print vessel labels for one specific module for all SPs in a MEC session, use the mouse to direct the mouse arrow {File} in the top menu bar, drag the mouse arrow to {Print Labels}, then to the specific module and left click or type [Alt] [F/f], [L/l], and the first letter of the specific module.

The Print {Module} Labels window displays.



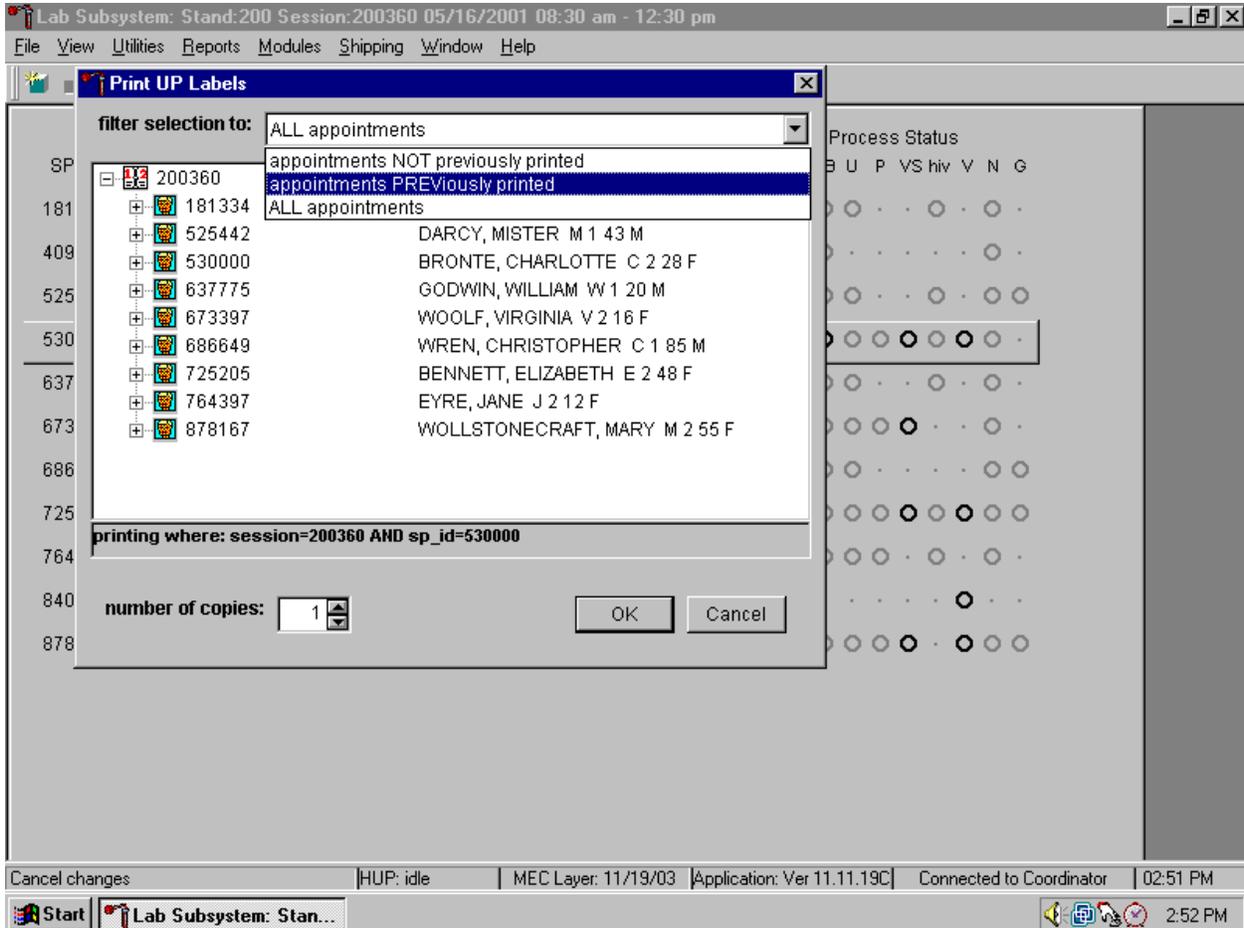
To print vessel labels for one module for all SPs in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print vessel labels for one specific module for one SP in a MEC session.



To print vessel labels for one specific module for one SP in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

It is also possible to print labels for specific SPs using criteria such as “appointments NOT previously printed,” or “appointments PREVIOUSly printed” by using a filter.

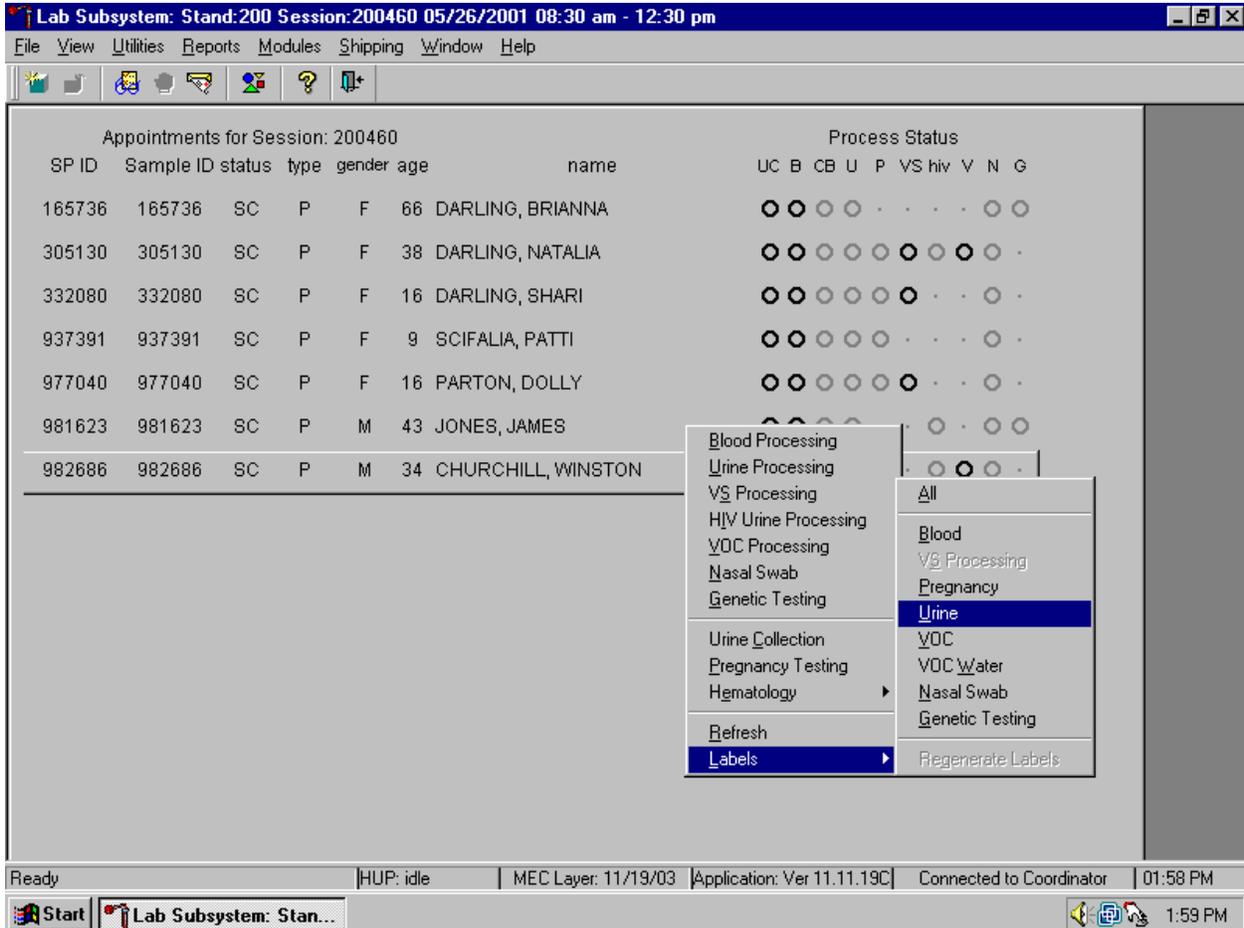


The default filter selection is “ALL appointments.” To select or change a filter, use the mouse to direct the mouse arrow to the drop-down list on the “Filter Selection to:” box and drag the mouse arrow to “Appointments NOT previously printed,” “Appointments PREVIOUSly printed,” or “All appointments” and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

### 9.3.2 Print Vessel Labels Using the Heads-up Display

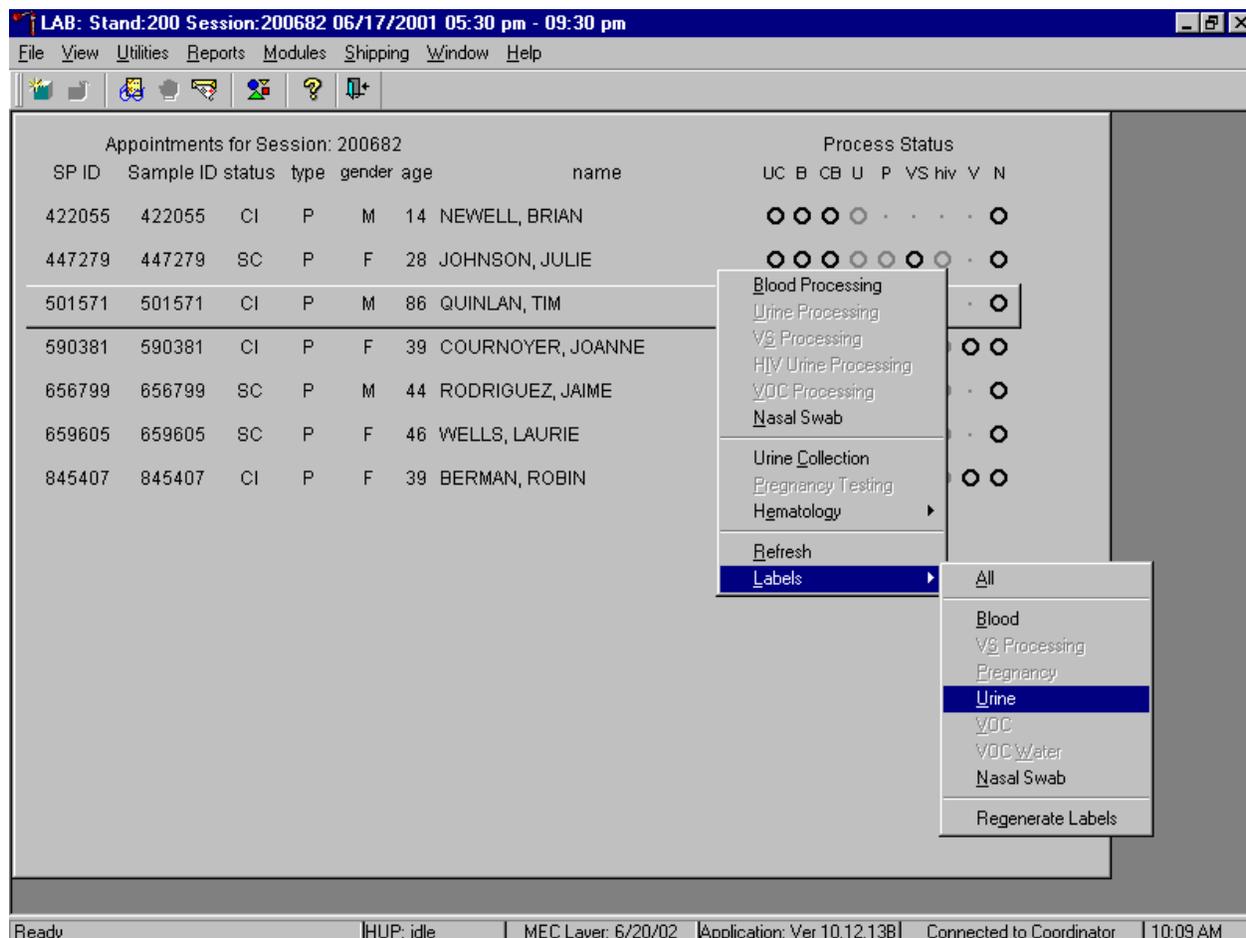
Print labels for a particular SP using the heads-up display. Print labels for all modules or for a specific module.

Print vessel labels for all modules for one SP.



To print labels for all modules for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then to {All} and left click or use the mouse to direct the mouse arrow to the correct SP, right click and type [L/I], [A/a]. Labels print in the label/ship area.

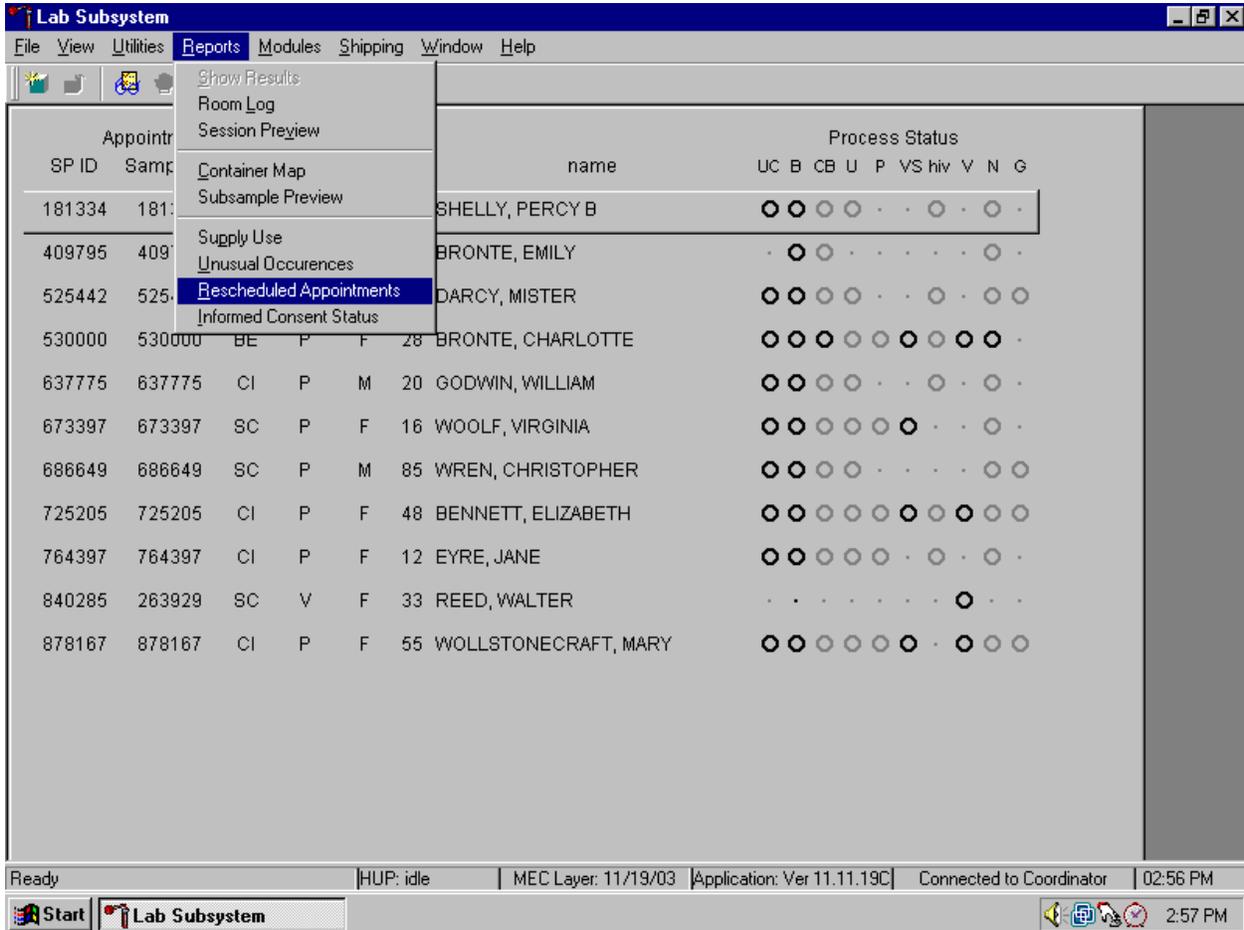
Print labels for one specific module for one SP in a MEC session using the heads-up display.



To print additional vessel labels for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then drag the arrow to {All}, {Blood}, {VS Processing}, {Pregnancy}, {Urine}, {VOC}, {VOC Water}, {Nasal Swab}, or {Genetic Testing} – (*pilot 2003 only*) and right click. Alternatively, to print additional labels, use the mouse to direct the mouse arrow to the correct SP, right click, and type [L/I] and the appropriate letter of the module of interest. The labels print in the Label/Ship area.

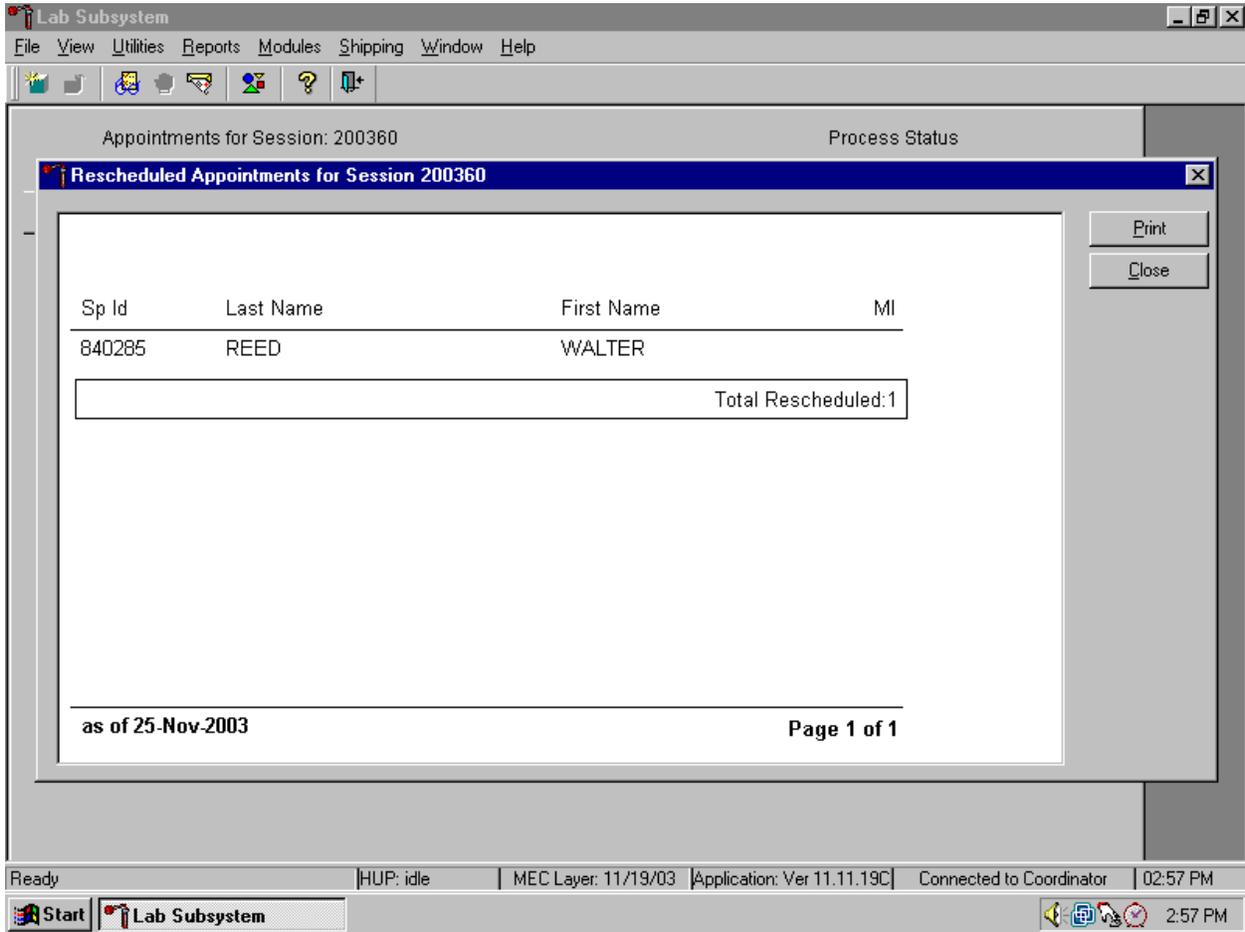
### 9.3.3 Rescheduled Appointments Report

If the SP does not show up for a MEC exam, it is possible they will reschedule. Previously generated labels and vessels may be stored in individual zip closable bags. At the beginning of each session, use the Rescheduled Appointments report to view a list of rescheduled SPs.



To access the Rescheduled Appointments report, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, left click, drag the mouse arrow to {Rescheduled Appointments}, and left click or type [Alt] [R/r], [[R/r].

The Rescheduled Appointments report lists the rescheduled SPs.



To close the report, use the mouse to direct the mouse arrow to the Close button and left click. To print the report, use the mouse to direct the mouse arrow to the Print button and left click.

The report may display a message text box indicating that no appointments have been rescheduled for the current session.

LAB: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 200690							Process Status								
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N
248274	248274	SC	P	F	39	EYRAMYA, AUNTIE	○	○	○	○	○	○	○	○	○
281396	281396	SC	P	M	1	ERAMIA, STANLEY	.	○	○	.	.	.	.	.	○
304755	304755	SC	P	F	48	ERAMIA, YVETTE	○	○	○	○	○	○	○	.	○
356294	356294	SC	P	F	21	SCHWARTZ, DAWN	○	○	○	○	○	○	.	○	○
373348	373348	SC	P	F	53	ERAMIA, JUDY	○	○	○	○	○	○	.	○	○
416806	416806	SC	G	M	29	ERAMIA, JUDY	○	.	.	.	.	.	.	.	.
534650	534650	SC	P	F	8	SC	○	○	○	○	○	○	.	.	○
562086	562086	SC	P	F	3	LA	○	.	.	.	.	.	.	.	○
672812	672812	SC	P	M	54	ER	○	○	○	○	○	○	.	.	○
805106	805106	SC	P	F	13	SCHWARTZ, EMILIA	○	○	○	○	○	○	.	.	○

**Rescheduled Appointments**

None of the appointments for Session ID#200690 have been identified as Rescheduled.

OK

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.12.13B | Connected to Coordinator | 10:12 AM

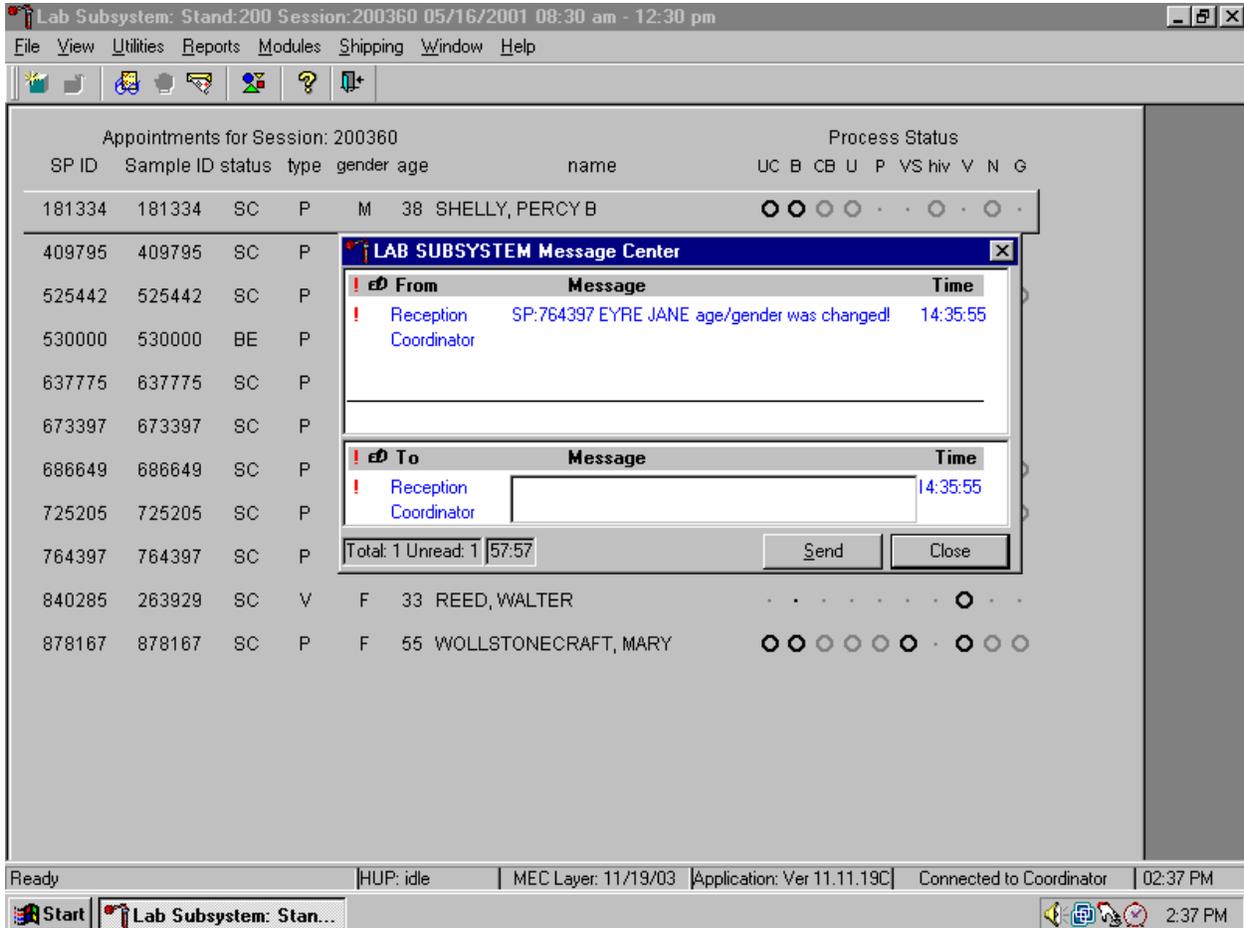
If no appointments have been rescheduled for the current session, the Rescheduled Appointments message text box displays the following message, “None of the appointments for Session IDXXXXXX have been identified as Rescheduled.” To remove the message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

## **9.4           Regeneration of Data**

Processing protocols are SP specific and are based on the age and gender information obtained during the home interview. Protocols are also dependent on session times and appointment type. Labels are based on the SP's unique protocol. When a session is accessed for the first time, the laboratory record is generated. The application compares the profile for each SP when a session is subsequently opened by the coordinator.

If the age or gender information obtained during the home interview is incorrect, or the session time or person type changes, the processing protocol may be affected. If the incorrect information is corrected before labels are generated, no action is necessary. If the incorrect information is corrected after the labels have been printed and the SP's profile changes, the color of the SP's row on the heads-up display turns red. The SP's data must be regenerated to correct the protocol and the record in the database.

If the coordinator changes a SP's age and/or the gender, a message center text box displays on all three laboratory terminals.



Review the information. To send a response to the coordinator, type the text of the response into the lower Message text box, use the mouse to direct the mouse arrow to the Send button, and left click, or type [S/s]. To close the Message Center text box without responding to the message, use the mouse to direct the mouse arrow to the Close button and left click, type [C/c], or select [Enter].

Regenerate the data for each MEC SP indicated in red on the heads-up display.

Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 200360

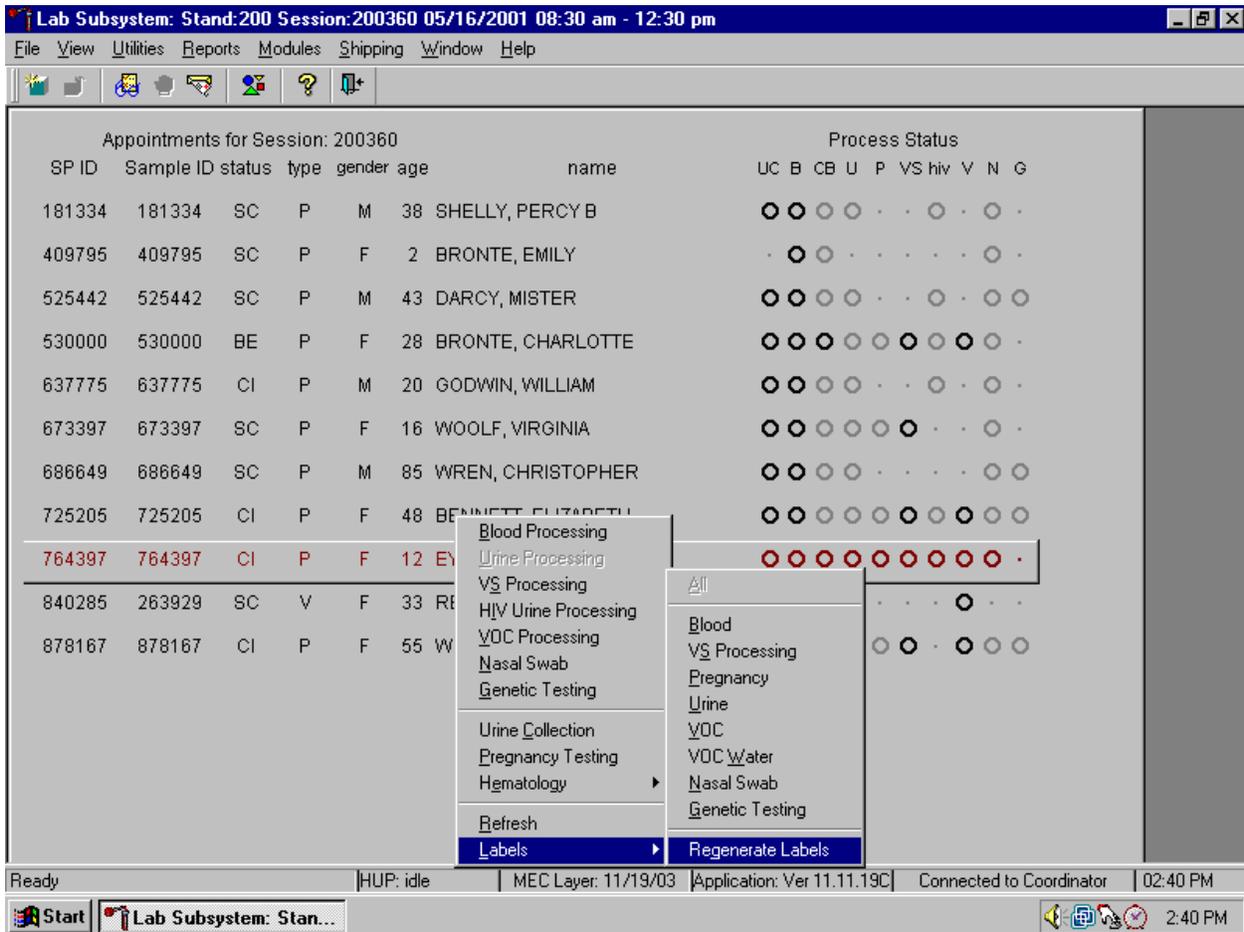
SP ID	Sample ID	status	type	gender	age	name	Process Status														
							UC	B	CB	U	P	VS	hiv	V	N	G					
181334	181334	SC	P	M	38	SHELLY, PERCY B	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
409795	409795	SC	P	F	2	BRONTE, EMILY	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
525442	525442	SC	P	M	43	DARCY, MISTER	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
530000	530000	BE	P	F	28	BRONTE, CHARLOTTE	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
637775	637775	CI	P	M	20	GODWIN, WILLIAM	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
673397	673397	SC	P	F	16	WOOLF, VIRGINIA	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
686649	686649	SC	P	M	85	WREN, CHRISTOPHER	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
725205	725205	CI	P	F	48	BENNETT, ELIZABETH	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
764397	764397	CI	P	F	12	EYRE, JANE	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
840285	263929	SC	V	F	33	REED, WALTER	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
878167	878167	CI	P	F	55	WOLLSTONECRAFT, MARY	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

Ready | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:40 PM

Start | Lab Subsystem: Stan... | 2:40 PM

Do not process the SP's specimens if the line on the heads-up display is red.

Select the correct SP and regenerate the data.



To regenerate the data for the SP, drag the mouse arrow to the SP's row, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and left click. Alternatively, use the up and down keys to move up and down the list until the correct SP is selected or highlighted, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and right click.

Respond to the question in the window.

The screenshot shows a software window titled "Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm". The window contains a table of appointments and a modal dialog box.

Appointments for Session: 200360							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
181334	181334	SC	P	M	38	SHELLY, PERCY B	●	●	●	●	●	●	●	●	●	●
409795	409795	SC	P	F	2	BRONTE, EMILY	●	●	●	●	●	●	●	●	●	●
525442	525442	E														
530000	530000	E														
637775	637775	C														
673397	673397	E														
686649	686649	E														
725205	725205	C														
764397	764397	C														
840285	263929	E														
878167	878167	C														

The dialog box, titled "Data Regen for Sample\_ID 764397", contains the following text:

Are you ready to print the following additional labels for their associated modules:

- PG=>URXPREG
- UP=>45, 48, 49, 51, 52, 69
- BP=>1, 2, 3, 4, 5, 7, 8, 9, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 29, 32, 33, 34, 35, 36, 37, 38, 39, 40, 68, 70, 79, 81, 82, 85, 88, 89, 94
- UC=>URXCOLL
- CB=>
- NS=>76

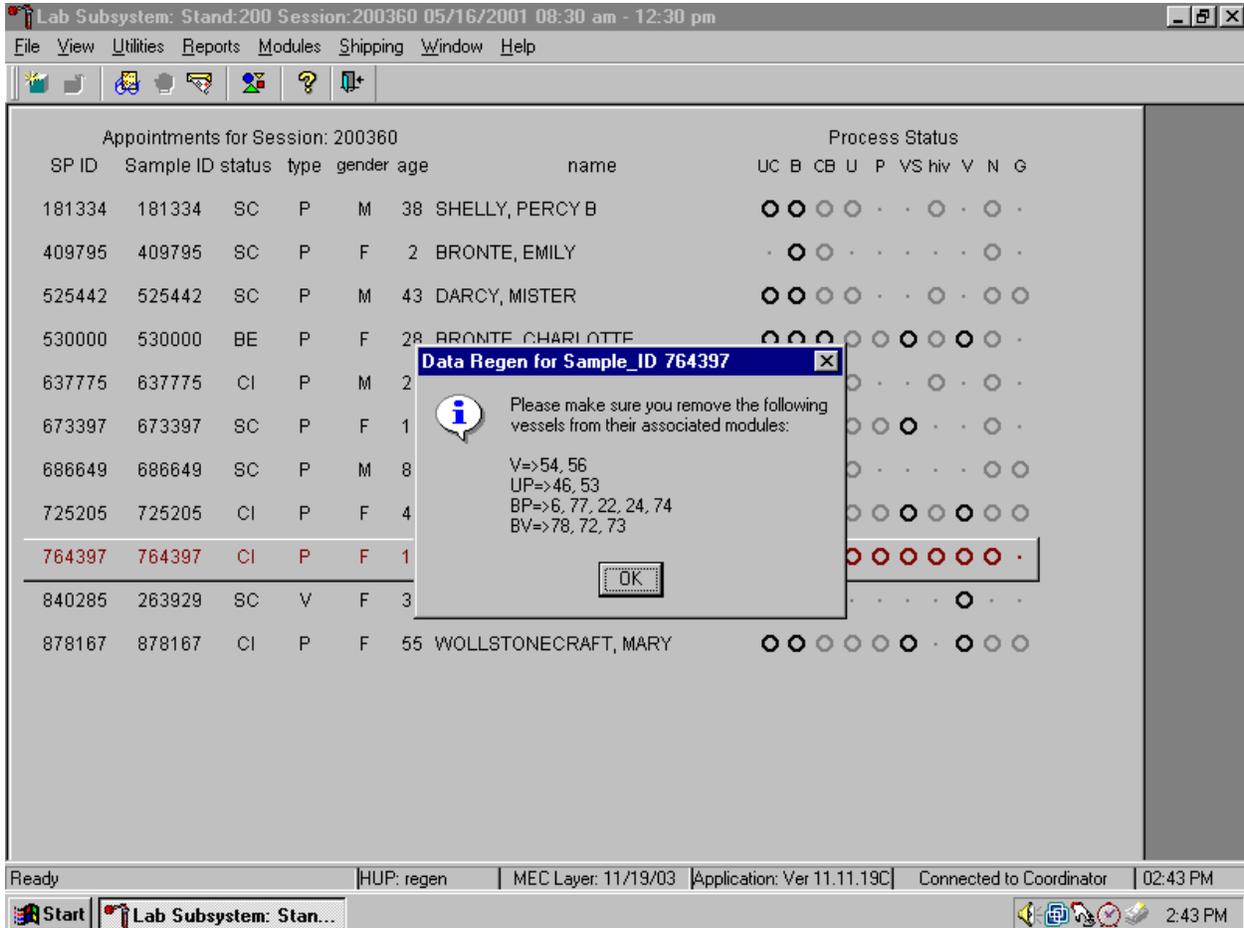
\* PLEASE NOTE \* You are about to regenerate labels for an SP who did not have a complete set of labels printed originally. The new set of labels contains all labels in the new profile.

Buttons: OK, Cancel

Taskbar: Insert mec\_exam\_section 3 for module#8(CB) | HUP: regen | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:42 PM

Review the question and respond. To respond affirmatively to the message, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel the action, use the mouse to direct the mouse arrow to the Cancel button and left click.

New labels print for vessels that are in addition to the existing vessels. If an incomplete set of labels has been printed, then a complete set of all labels print.



The informational message text box displays and states, "Please make sure you remove the following vessels from their associated modules:" Discard (destroy) the vessels and labels indicated in the message. To respond affirmatively to the message, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter].

Allow the heads-up screen to update.

Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 200360

SP ID	Sample ID	status	type	gender	age	name	Process Status													
							UC	B	CB	U	P	VS	hiv	V	N	G				
181334	181334	SC	P	M	38	SHELLY, PERCY B	●	●	●	●	·	·	●	·	·	·	·			
409795	409795	SC	P	F	2	BRONTE, EMILY	·	●	●	·	·	·	·	·	·	·	●	·		
525442	525442	SC	P	M	43	DARCY, MISTER	●	●	●	●	·	·	●	·	●	·	●	·		
530000	530000	BE	P	F	28	BRONTE, CHARLOTTE	●	●	●	●	●	●	●	●	●	●	●	·		
637775	637775	CI	P	M	20	GODWIN, WILLIAM	●	●	●	●	·	·	●	·	·	·	·	·		
673397	673397	SC	P	F	16	WOOLF, VIRGINIA	●	●	●	●	●	●	●	·	·	·	·	·		
686649	686649	SC	P	M	85	WREN, CHRISTOPHER	●	●	●	●	·	·	·	·	·	·	·	●	●	
725205	725205	CI	P	F	48	BENNETT, ELIZABETH	●	●	●	●	●	●	●	●	●	●	●	●	●	
764397	764397	CI	P	F	12	EYRE, JANE	●	●	●	●	●	·	·	·	·	·	·	·	·	
840285	263929	SC	V	F	33	REED, WALTER	·	·	·	·	·	·	·	·	·	·	·	●	·	·
878167	878167	CI	P	F	55	WOLLSTONECRAFT, MARY	●	●	●	●	●	●	●	·	·	·	·	●	●	●

Ready | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:43 PM

Start | Lab Subsystem: Stan... | 2:44 PM

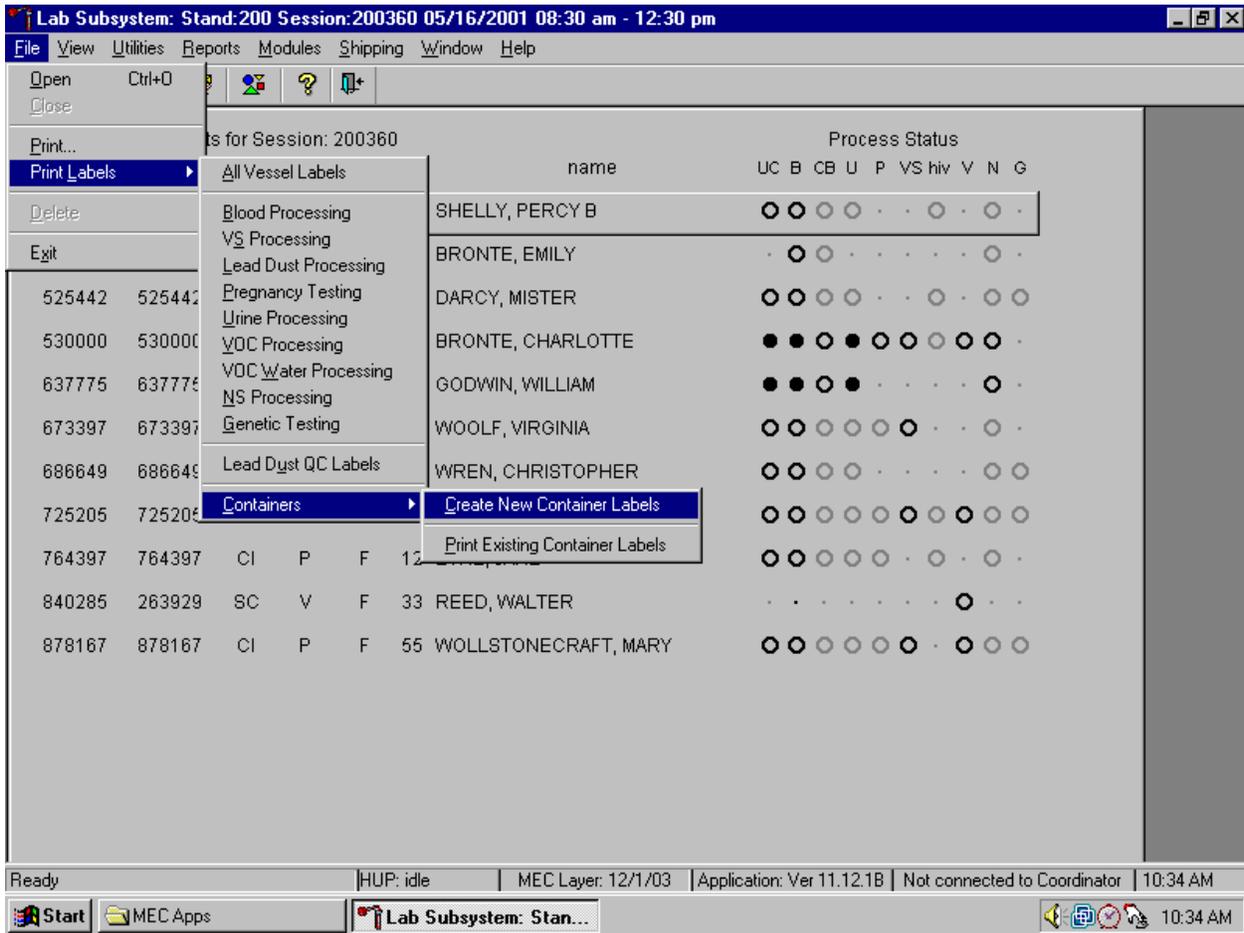
Allow the heads-up display to update before proceeding. After the screen updates, the color of the SP's row changes from red to black.

## **9.5 Create New Container Labels**

Store processed vessels and biological samples in boxes, bags, and slide boxes (containers). Print and assign container labels using the {Create New Container Labels} module. Once a label has been created, the container is designated as “open” in the database; it is available for slot assignments as vessels are marked as filled.

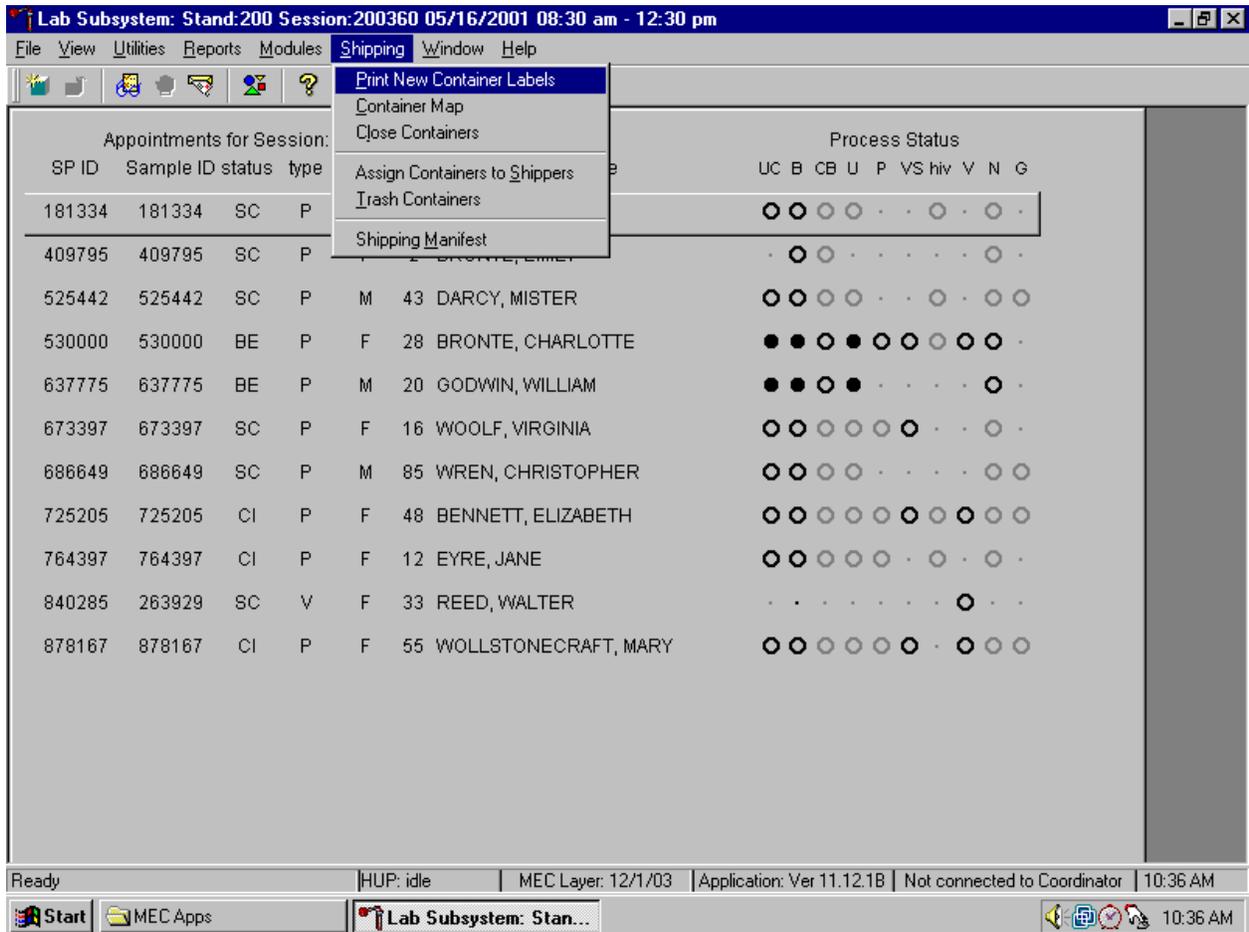
At the beginning of each stand print and assign one new container ID for each vessel using either the {Print} module or the {Shipping} module. Print additional labels as needed. Each stand is allocated a maximum of 750 labels. The actual container label will include the vessel id, the size of the container (9 x 9 two inch box, 4 x 4 bag, etc.), and the vessel name.

Use one of the two locations within the laboratory application to print and assign new container ID numbers or labels. Print and assign new container ID numbers using the {Print Labels} module.



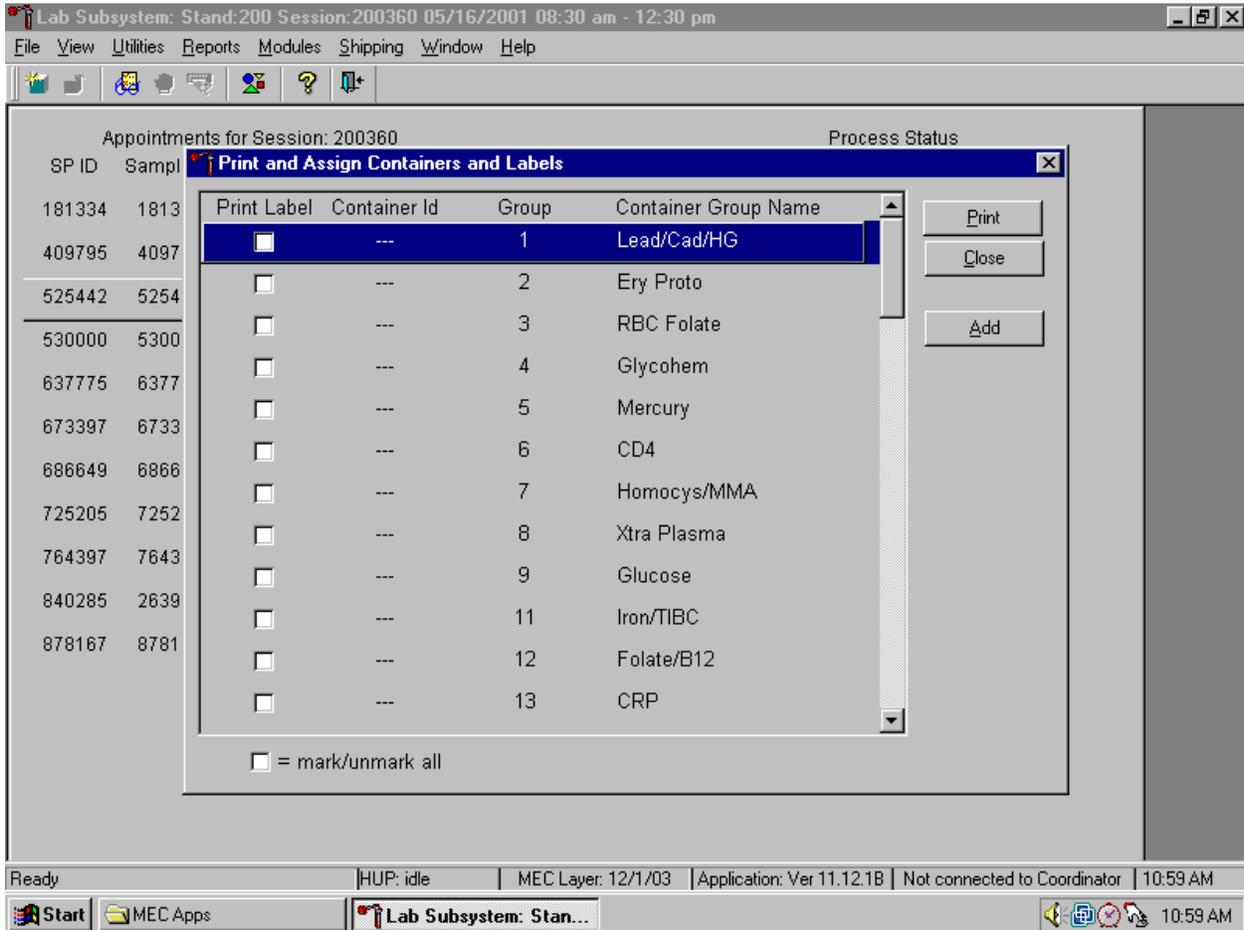
To print and assign new container ID numbers or labels using the {Print Labels} module, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, then drag the mouse arrow to {Print Labels}, {Containers}, {Create New Container Labels} and left click, or type [Alt] [F/f], [L/l], [C/c][C/c].

Print and assign new container ID numbers using the {Shipping} module.



To access the {Print New Container Labels} module, use the mouse to direct the mouse arrow to {Shipping} in the menu bar and left click, drag the mouse arrow to {Print New Container Labels}, and left click or type [Alt] [S/s], [P/p].

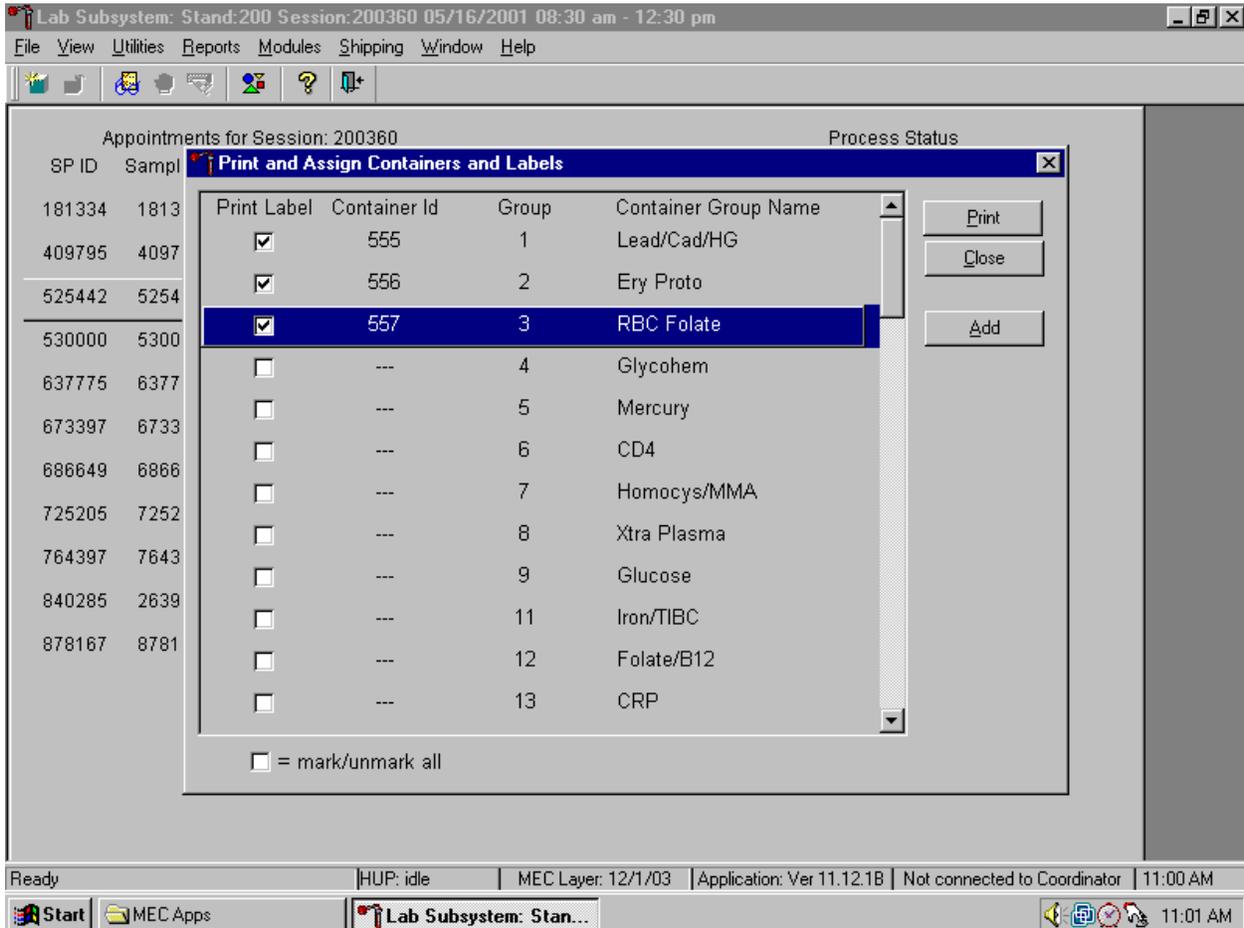
There are three instances when it is appropriate to use this module. At the start of each stand, create one new container label for each vessel ID or “group.” Use the same module to create a new label for a vessel after the last slot in an open container is filled. Use this module to print additional labels at any time.



The Print and Assign Containers and Labels window displays once the {Print New Container} module is accessed. The window includes checkboxes to mark or identify specific groups, new Container Ids that are assigned to the Groups, the number of the Group, and the Container Group Name or vessel name. The Group and corresponding Container Group Name listed in this screen represent the Group where the container has been “closed” and a new label has not been created. This screen also includes a “mark/unmark all” checkbox and three buttons: Print, Close, and Add. Use the Print button to print the container labels, use the Close button to exit the module without printing any

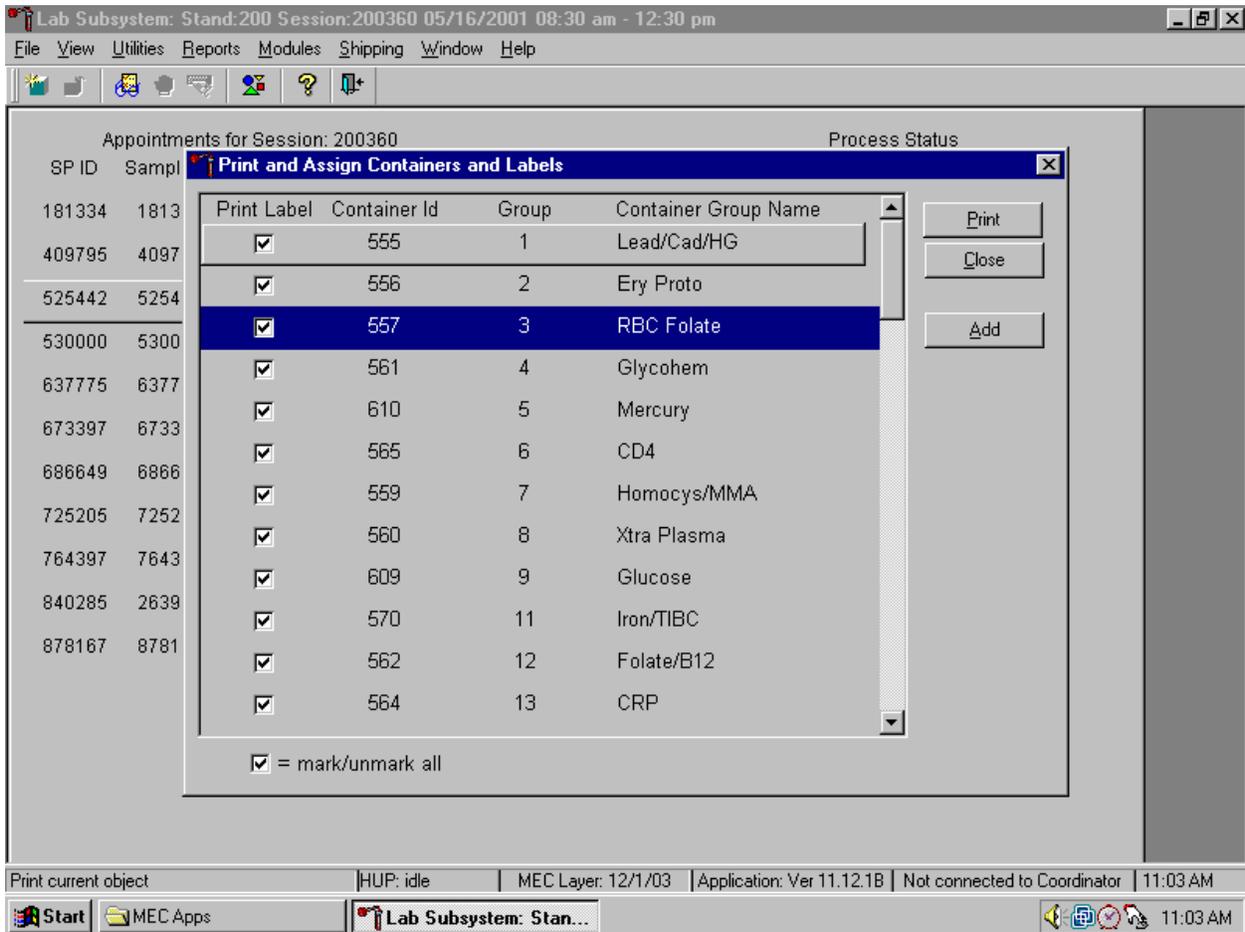
labels or assigning Container Ids to the Groups, and use the Add button to open another window that allows the user to add additional or multiple labels for any vessel.

Individually mark the Print Label checkbox to identify vessels that require labels.



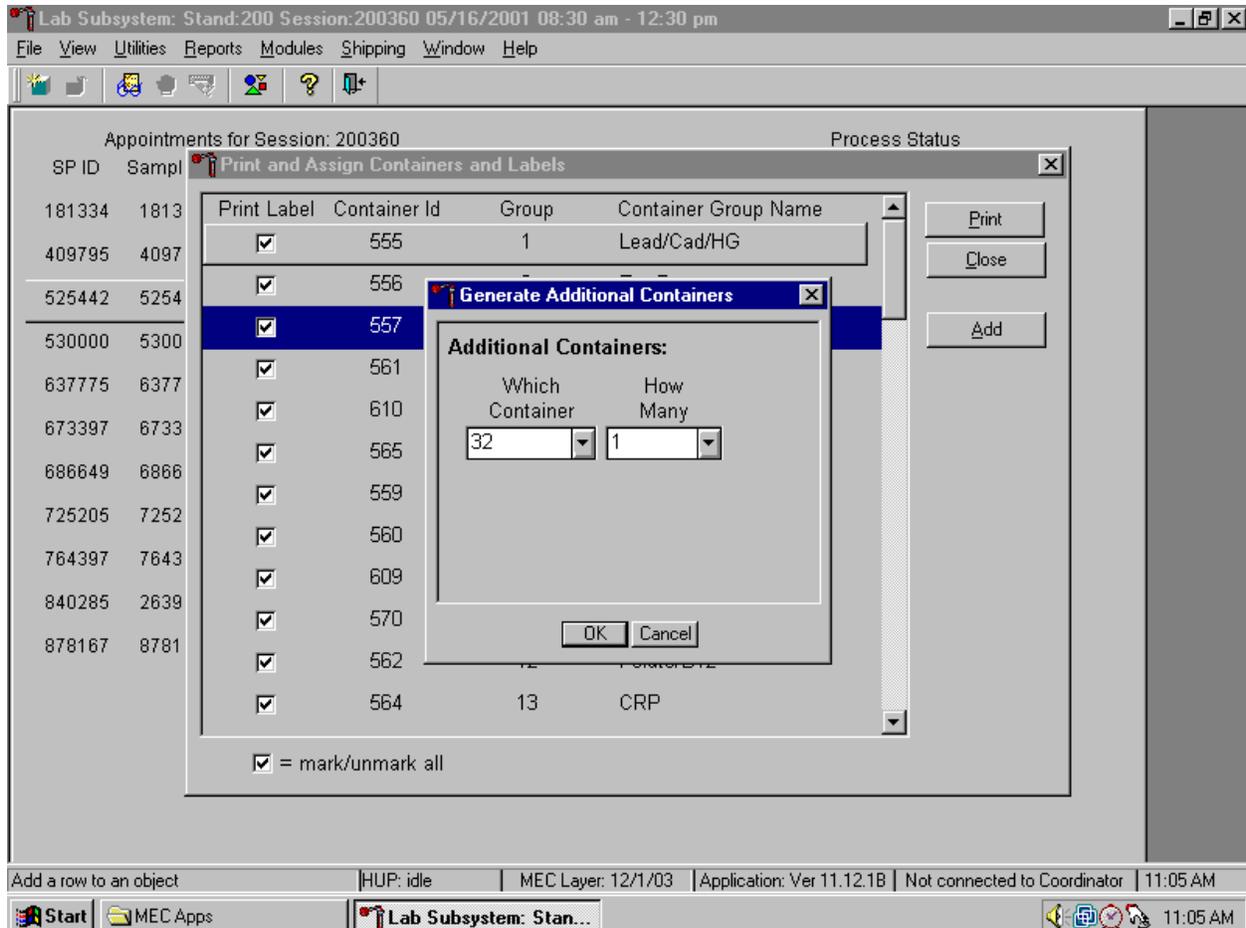
To begin the process of printing and assigning new Container Ids, mark the individual checkboxes that correspond to the Group of interest. To add a checkmark to the Print Label checkbox, use the mouse to direct the mouse arrow to the Print Label checkbox and left click.

Collectively mark all the Print Label checkboxes for all the Groups listed in the window.



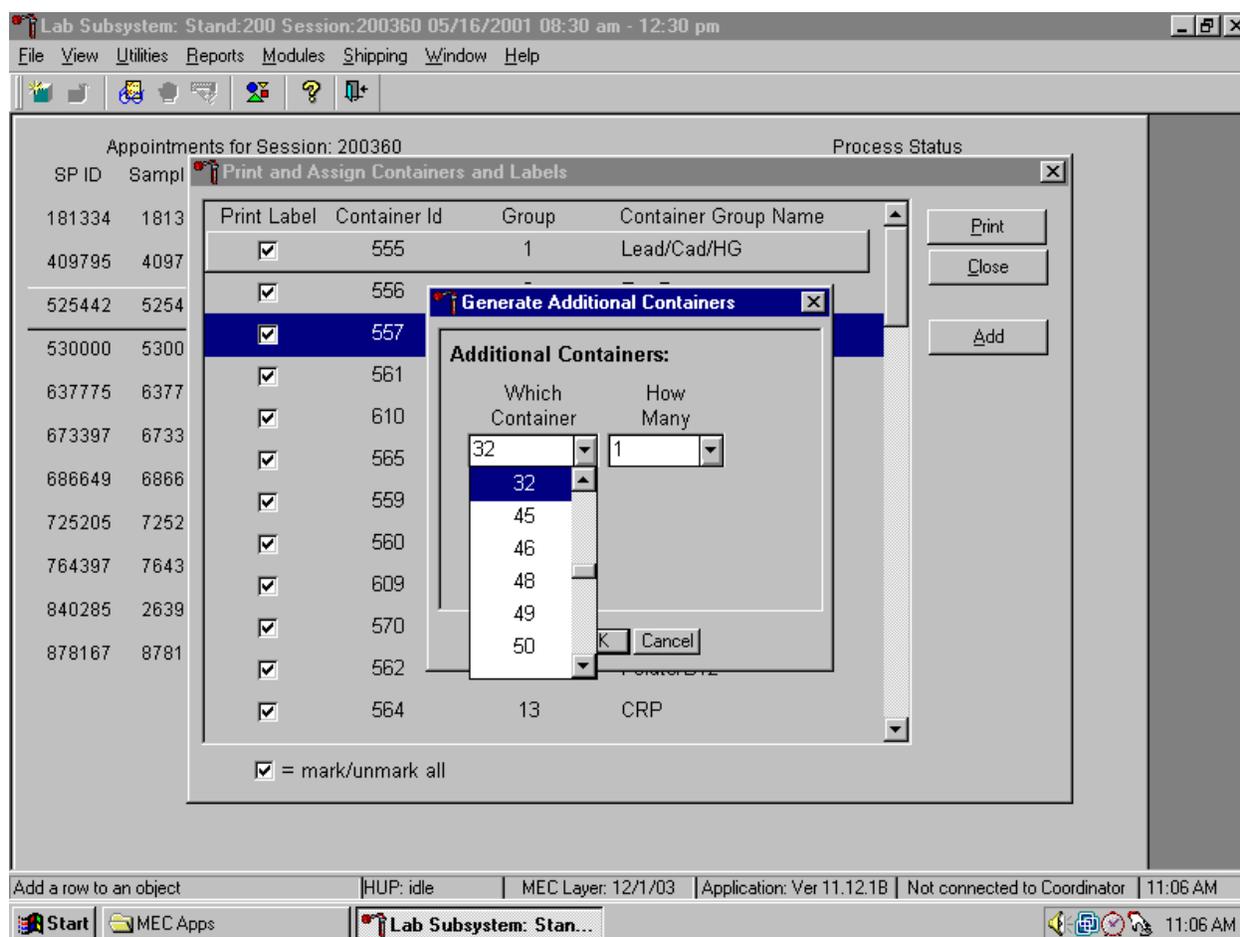
To collectively mark all the checkboxes, use the mouse to direct the mouse arrow to the mark/unmark all checkbox and left click. To collectively unmark all the checkboxes, use the mouse to direct the mouse arrow to the mark/unmark all checkbox and left click.

Access the Generate Additional Containers window to print additional labels for any Group at any time.



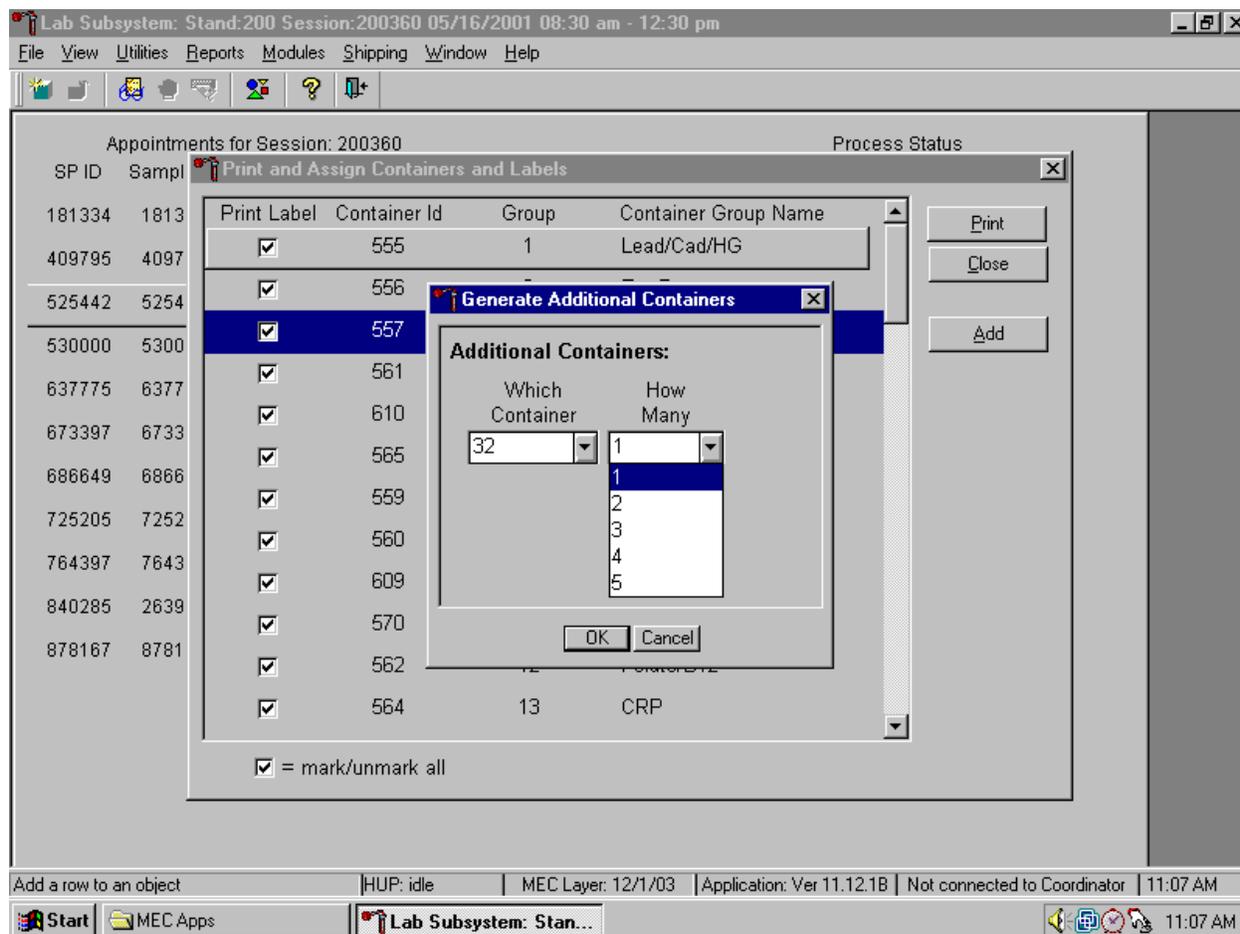
To access the Generate Additional Containers window, use the mouse to direct the mouse arrow to the Add button and left click, or type [Alt] [A].

The Generate Additional Containers window displays.



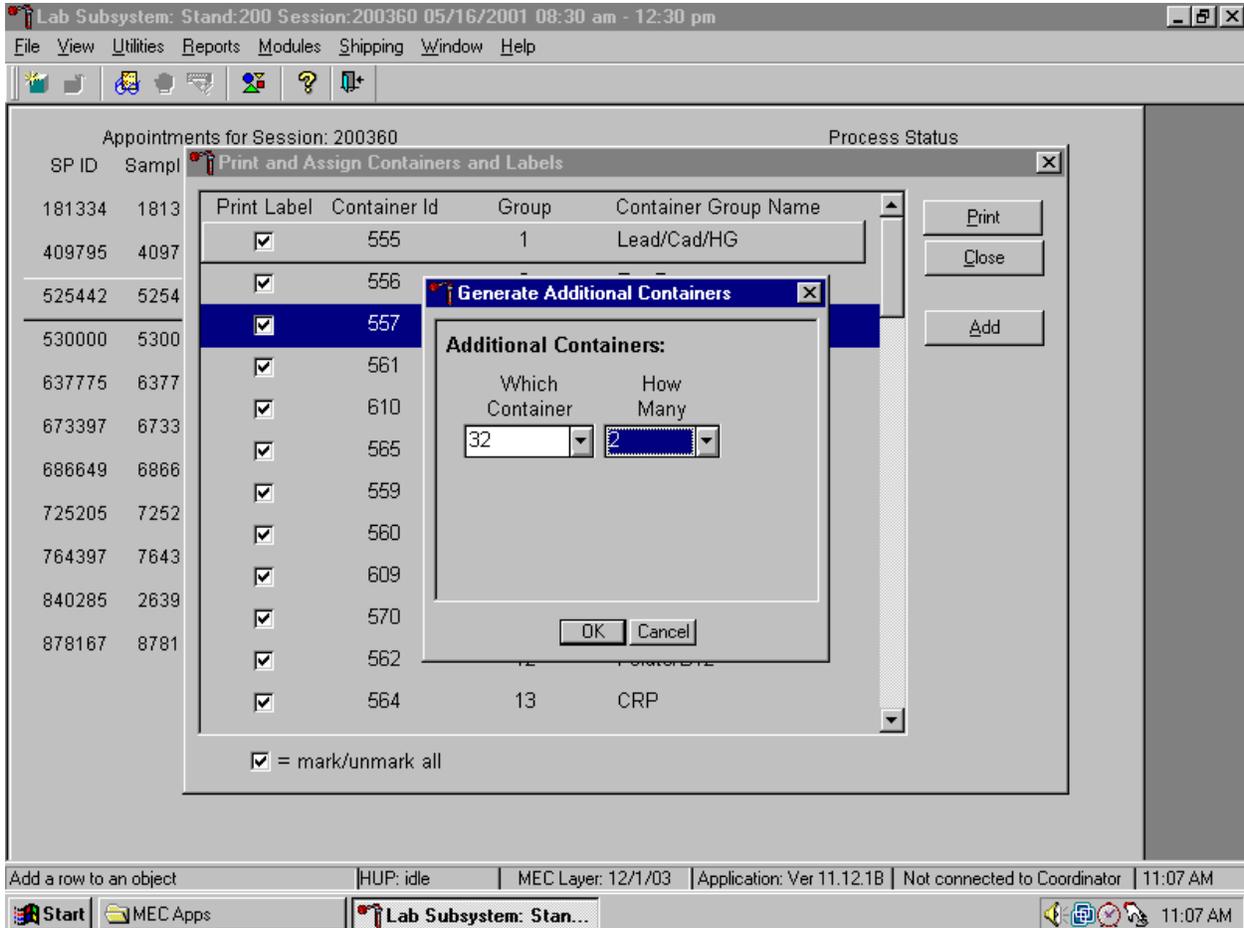
The Generate Additional Containers window includes two text boxes with dropdown lists: Which Container and How Many. The Which Container text box defaults to vessel 32. To select a vessel other than 32, use the mouse to direct the mouse arrow to the dropdown arrow and left click, drag the arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Select the number (1-5) of additional container labels.



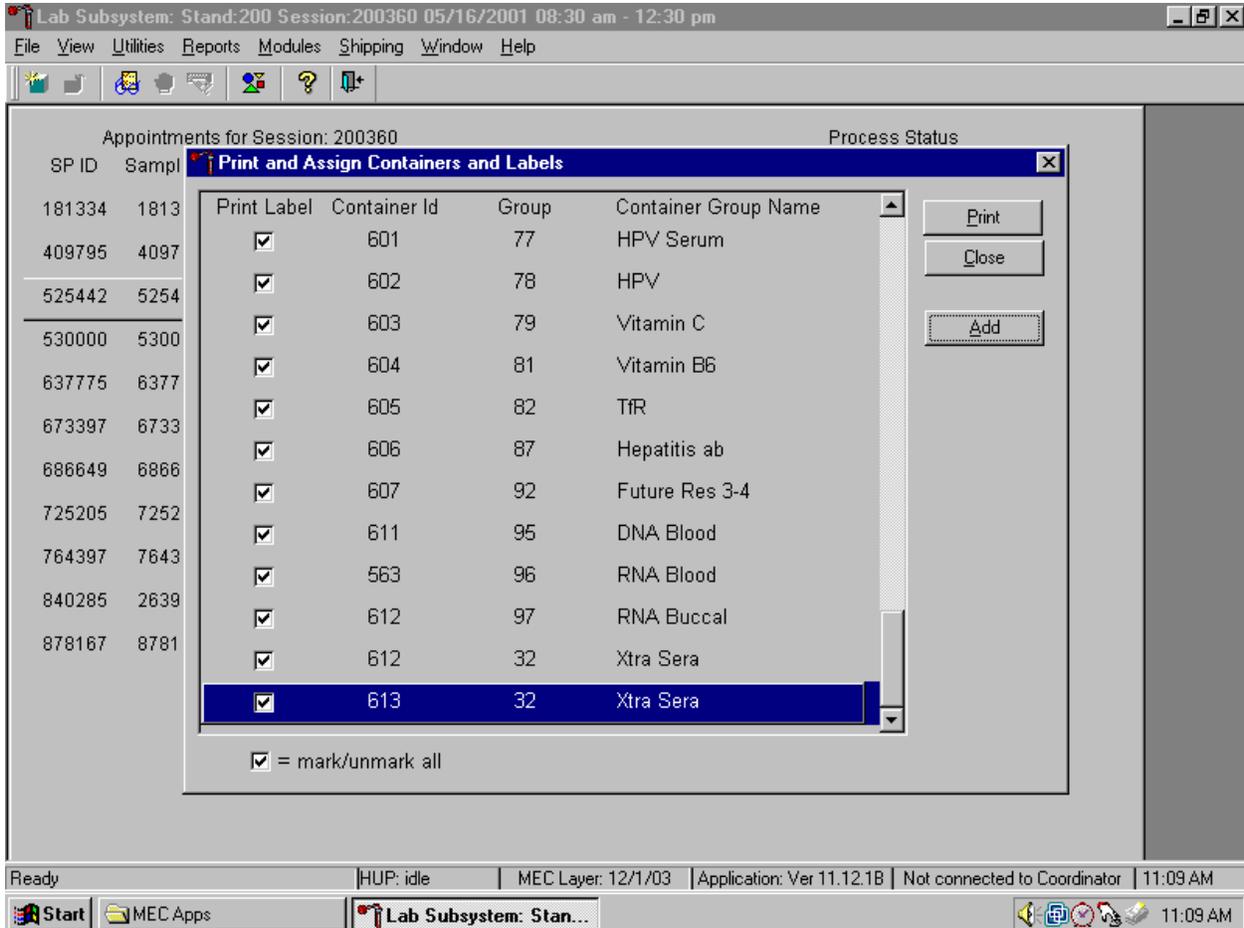
The How Many text box defaults to vessel 1. To select 2, 3, 4, or 5, use the mouse to direct the mouse arrow to the dropdown arrow and left click, then drag the arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Add these vessels to the Print and Assign Containers and Labels window or cancel the action.



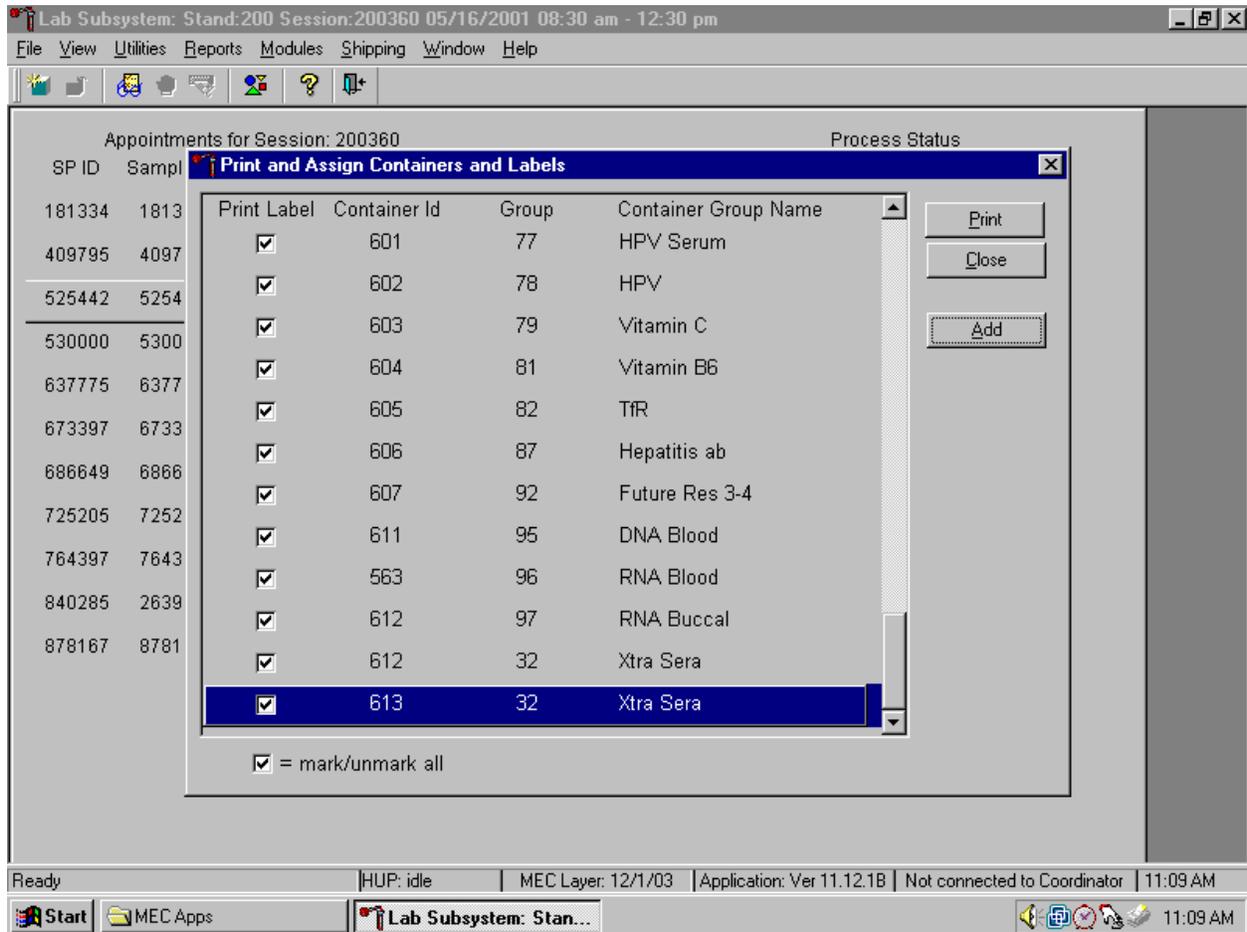
To accept the choices displayed in the Generate Additional Containers window, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter]. To close the window without creating a new container, use the mouse to direct the mouse arrow to the Cancel button and left click.

If the OK button is selected, then the containers are added to the bottom of the Print and Assign Containers and Labels window.



Review the information on the screen.

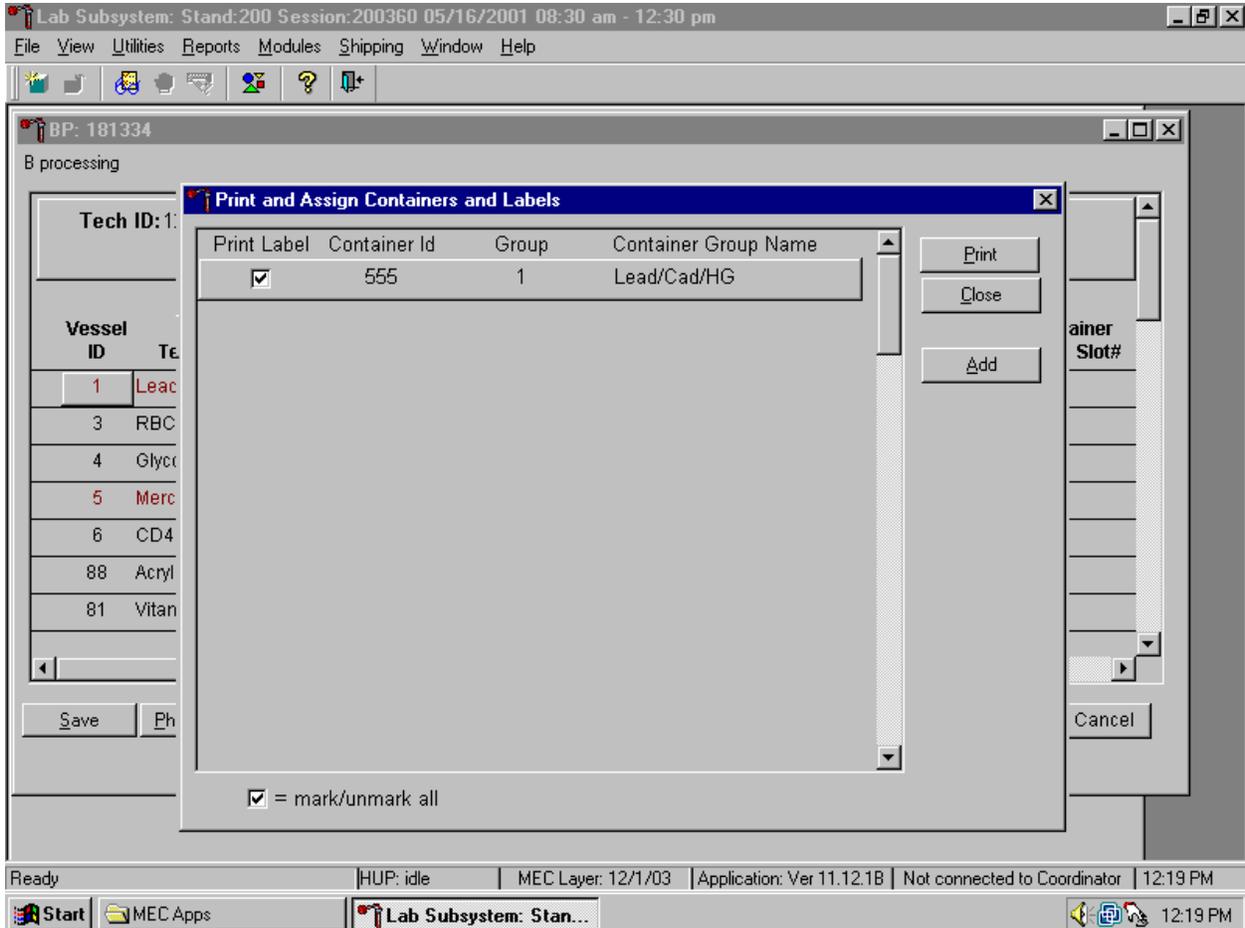
Complete the assignment process and print the labels.



After reviewing the screen, print the labels. To print the labels, use the mouse to direct the mouse arrow to the Print button and left click, or type [Alt] [P/p]. To exit the window without printing any labels, use the mouse to direct the mouse arrow to the Close button and left click, or type [Alt] [C/c].

Affix the container ID label(s) to the container(s) of the correct type.

When a container is full, the container will automatically “close.” Open a new container to replace the closed container by using the Print and Assign Containers and Labels window.



When a container is full, an opportunity to open a new container is automatically displayed on the “Print and Assign Container and Labels” window. Repeat the process of marking the checkbox and selecting the Print button.

## 9.6 Trash or Reprint Container Labels

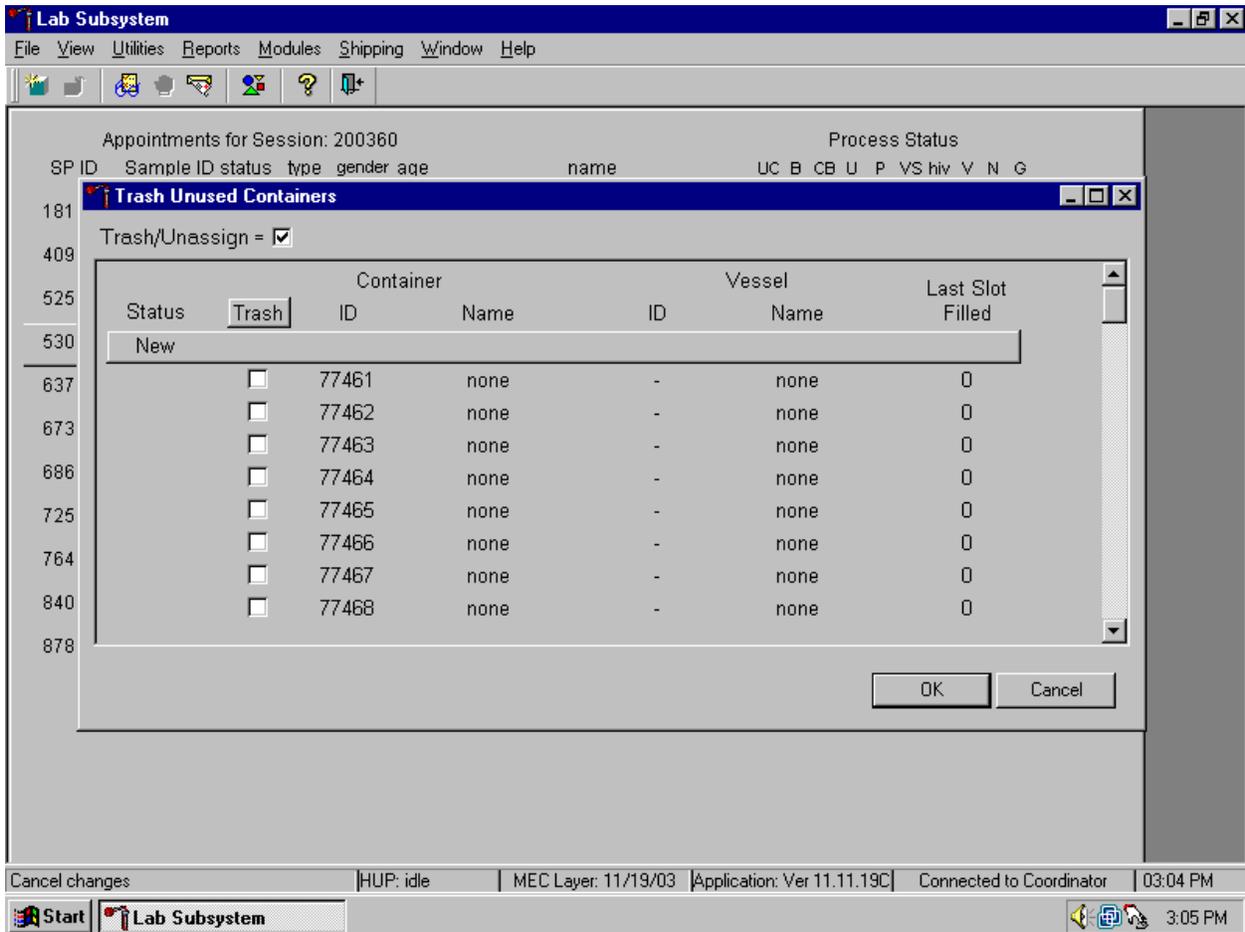
Each stand is allocated a maximum of 750 container IDs.

If unused container labels become lost or damaged, use the {Trash Container} module to delete the container IDs. Access the {Trash Containers} module.



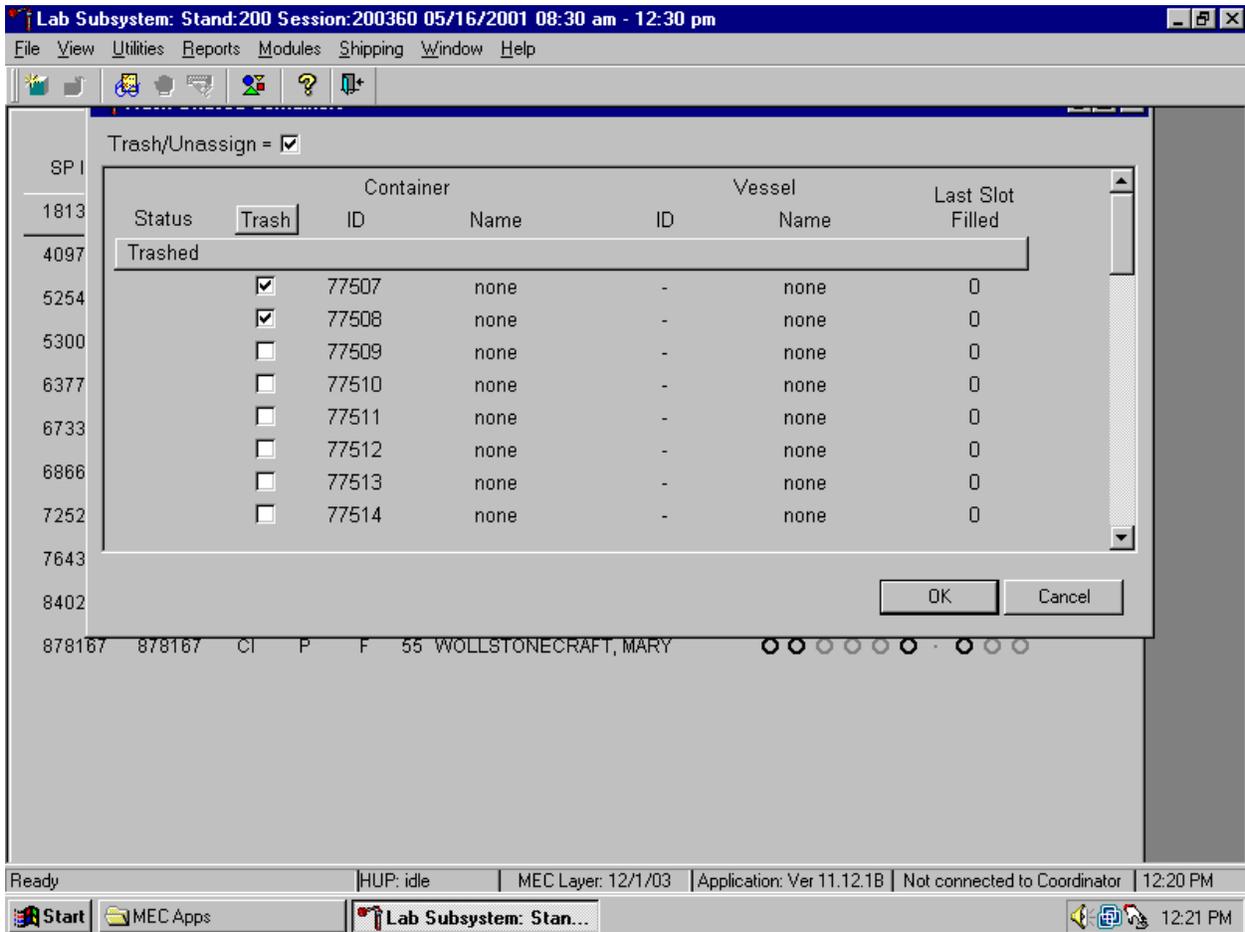
To access the {Trash Containers} module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Trash Containers}, and left click, or type [Alt] [S/s], [T/t].

The Trash Unused Containers window displays.



The status of each container ID is “New.” To individually mark the container IDs for deletion, use the mouse to direct the mouse arrow to the check boxes and individually left click on specific boxes or, to mark all outstanding container IDs for deletion, use the mouse to direct the mouse arrow to the Trash button and left click.

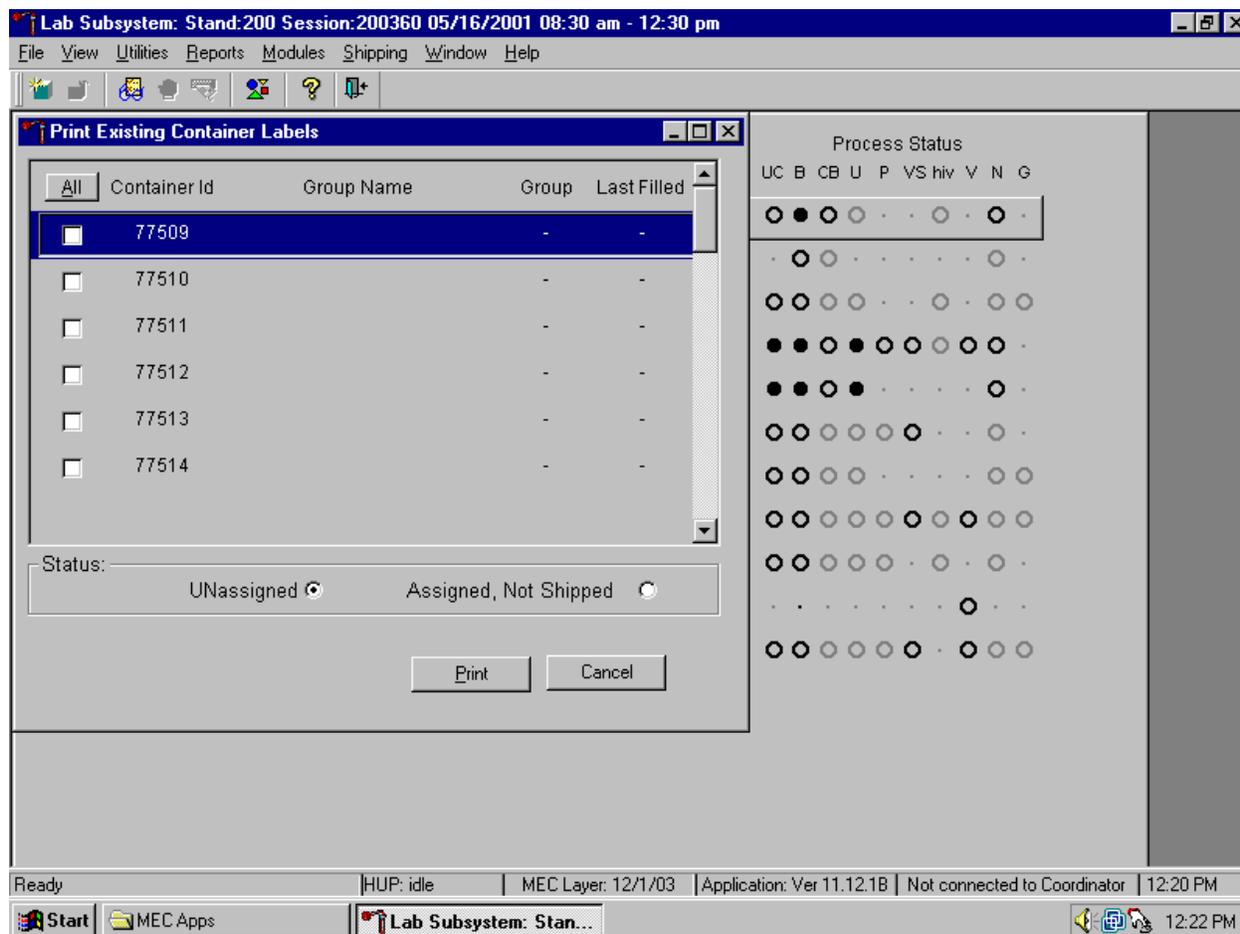
As the container IDs are marked for deletion, the status changes from “New” to “Trashed.”



To record these actions and execute the Trash Unused Containers function, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the {Trash Unused Containers} module without recording or executing the Trash Containers function, use the mouse to direct the mouse arrow to the Cancel button and left click.

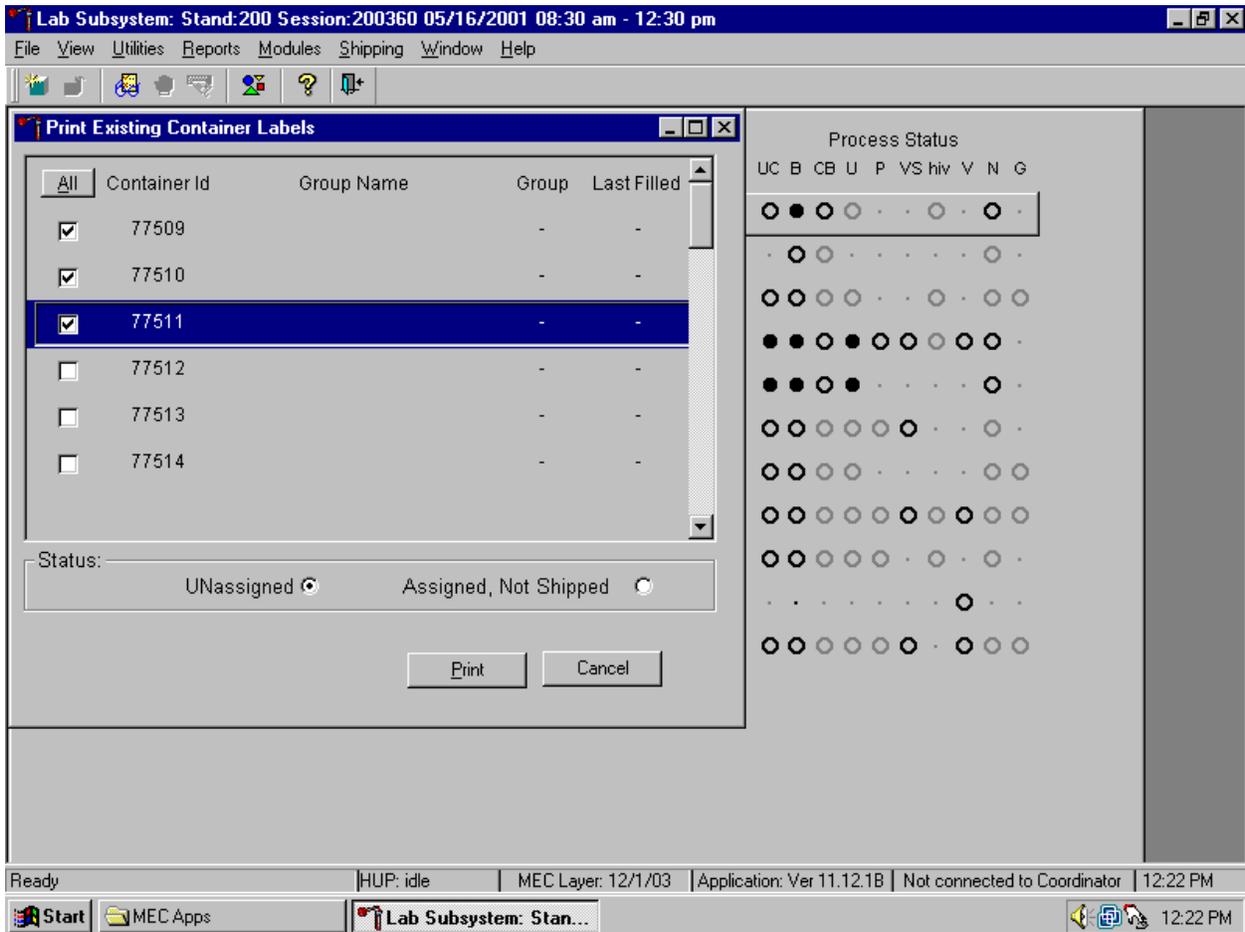


A Print Existing Container Label screen displays.



The Print Existing Container Label screen includes a checkbox associated with each trashed label, columns for container IDs (or labels), Size, Name, Vessel ID, and Last Filled, an ALL selection button, radio buttons or filters for “UNassigned”, and “Assigned, Not Shipped”, and Print and Cancel buttons.

A list of trashed container IDs is displayed if the radio button is set to UNassigned.



To individually mark or identify a trashed Container Id to be reprinted, use the mouse to direct the mouse arrow to an individual check box and left click. To mark all trashed Container Ids to be reprinted, use the mouse to direct the mouse arrow to the All button and left click. Check marks fill in all the check boxes. To unmark all container IDs, use the mouse to direct the mouse arrow to the All button a second time and left click.

Select the Print button to print the labels. To select the Print button, use the mouse to direct the mouse arrow to the Print button and left click. To exit the screen without printing the labels, use the mouse to direct the mouse arrow to the Cancel button and left click.



## 9.7 Shipping Overview

The integrity of laboratory specimens is critical to NHANES. Storage temperatures have been established for each analyte in consultation with the National Center For Health Statistics (NCHS) and contract laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their ultimate receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient dry ice, refrigerant packs, and sending specimens FedEx priority overnight.

Overnight delivery by FedEx can be delayed due to a weekend or holiday. This extraordinary circumstance usually occurs at the end of a stand or just before vacation. In any case, ship all specimens before vacations. The following actions are intended to mitigate unforeseen delay:

- Consider using medium shippers instead of small shippers for all laboratories east of the Mississippi when shipping from areas west of the Mississippi, and for all laboratories west of the Mississippi when shipping from areas east of the Mississippi. Substitute a larger shipper when shipping specimens in extreme summer heat or whenever professional judgment dictates added precautions.
- Use dry ice in blocks instead of pellets since blocks sublime at a slower rate.
- Increase the number of refrigerant packs from four to at least six per shipper.

The shipping technologist is primarily responsible for packing and shipping the specimens to various contract laboratories on a designated day. As necessary, other medical technologists assist in performing each of the steps listed below to complete the shipping procedures.

At the start of each stand, the laboratory staff creates address labels with the current MEC address to use on the Class 9 labels.

Shipping procedures:

- On the day before or the morning of a designated shipping day, create and print shipper labels (airbills) using FedEx Ship Manager.
- Prepare the Class 9 labels for shipments that use dry ice.

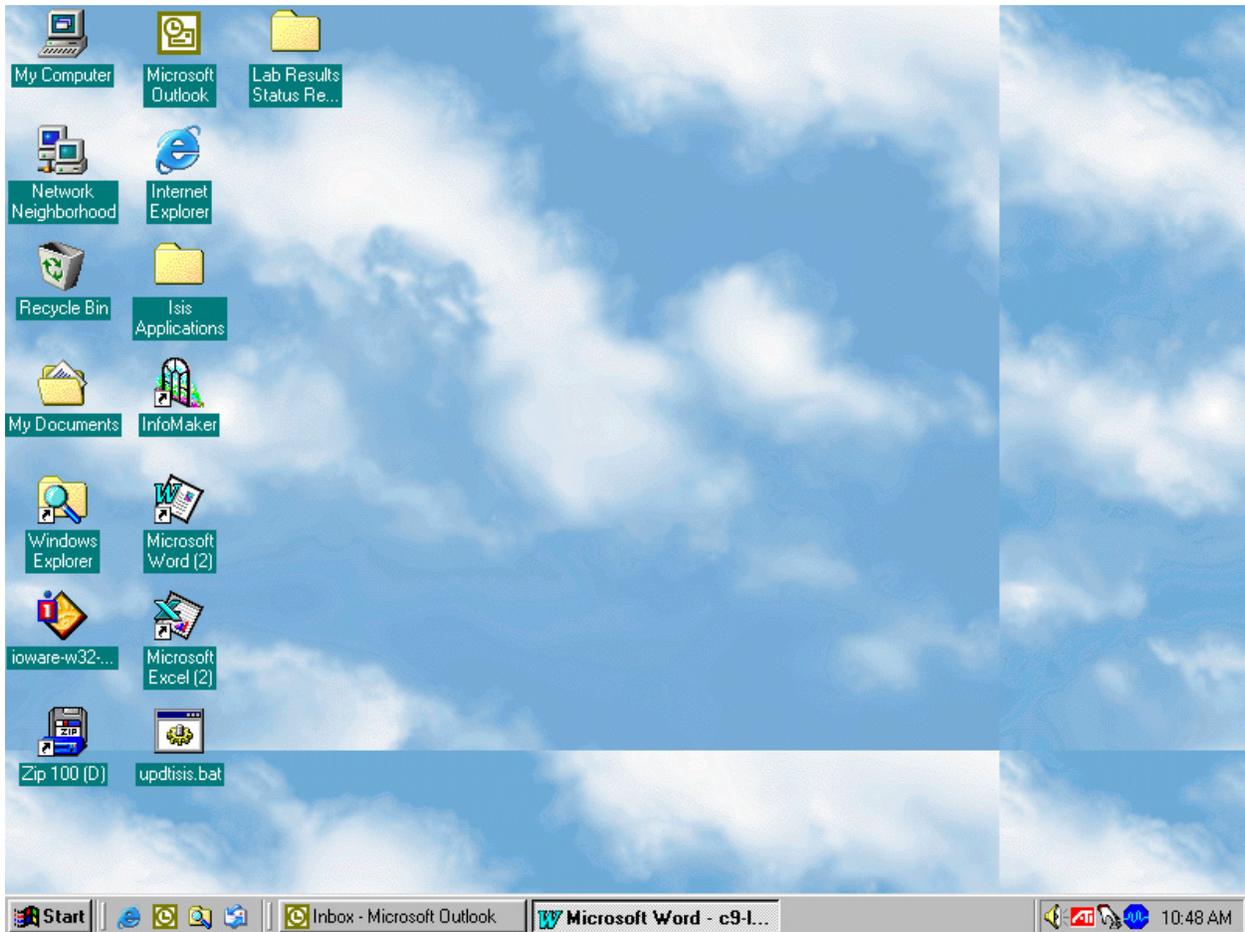
- On the morning of a shipping day, close all containers, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted “warning” labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.
- Pack the shippers with the containers, absorbent material, newsprint (padding), plastic bags, and a sufficient supply of dry ice or refrigerant packs as appropriate.
- Place the appropriate paper manifest and the preprinted FedEx return airbill in a 9 x 12 plastic bag and place the plastic bag on top of the Styrofoam shipper lid.
- Label each shipper with the appropriate FedEx label and warning labels.
- When the contract laboratory personnel receive the shippers, they unpack the specimens and return the shippers and refrigerant packs to either the field office (first 3-4 weeks of the stand) or the other concurrent stand (last 2 weeks of the stand).

## **9.8 Create Airbills using FedEx Ship Manager**

Create airbills using the Ship Manager application at FedEx.com. Each physical stand location will be designated as a department under the Passkey system. The department is set up by home office staff. The name of the department shows up as the department designation in all of the screens within Ship Manager. The department designation is “stand###” where ### is the stand number. The default point of contact for the department will always be Barbara Lindstrom. The department address will be the address of the MEC for the stand the department represents. The main contact telephone number for the department is 301-738-8324. The FedEx account number that the department is assigned to use is 129015748. The service option for the department has been restricted to FedEx Priority Overnight. Each department is assigned a default reference number for each package shipped; this is the project charge code for each stand. The User ID is designated “standxxx” where “xxx represents the stand number. The password is “labshipping.”

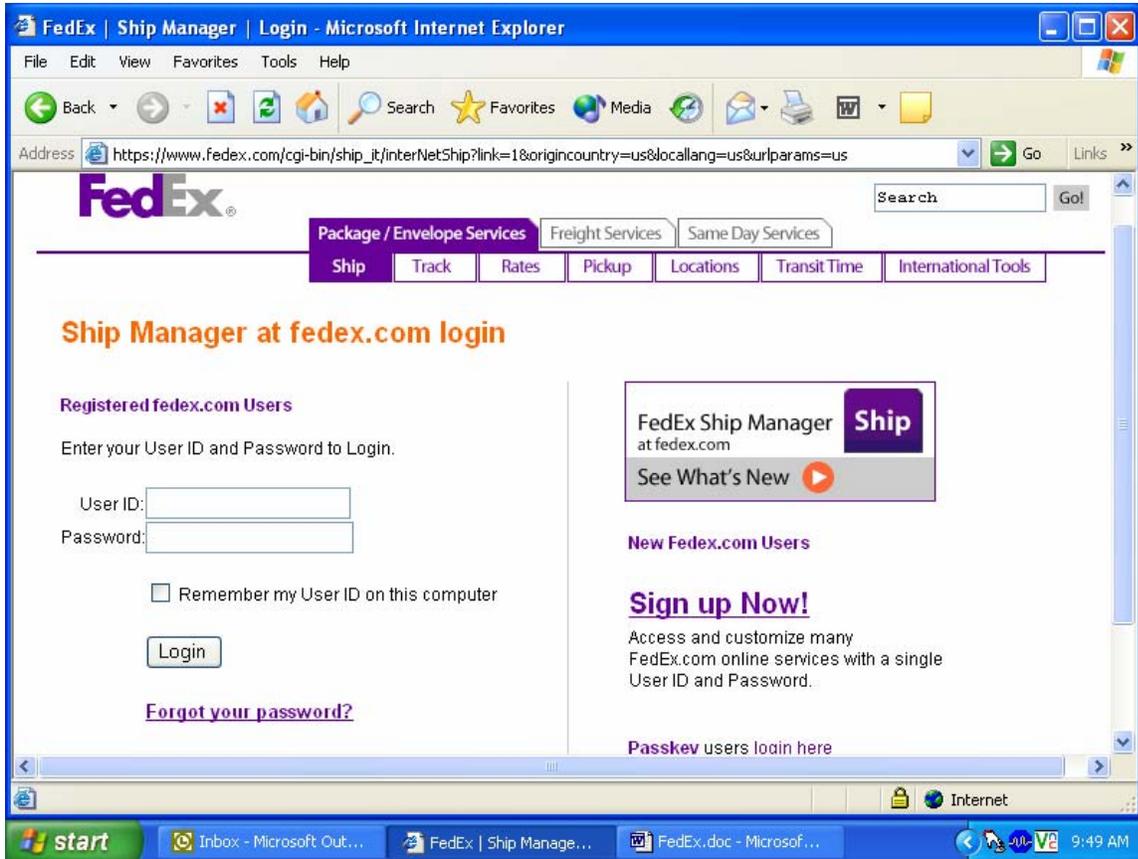
Access the FedEx web site using Explorer and logon to the application. Create one airbill for each shipment. Print the airbill, fold it in half, and insert it into a FedEx pouch. Attach the pouch to the shipper.

Use Internet Explorer to access the FedEx web site.



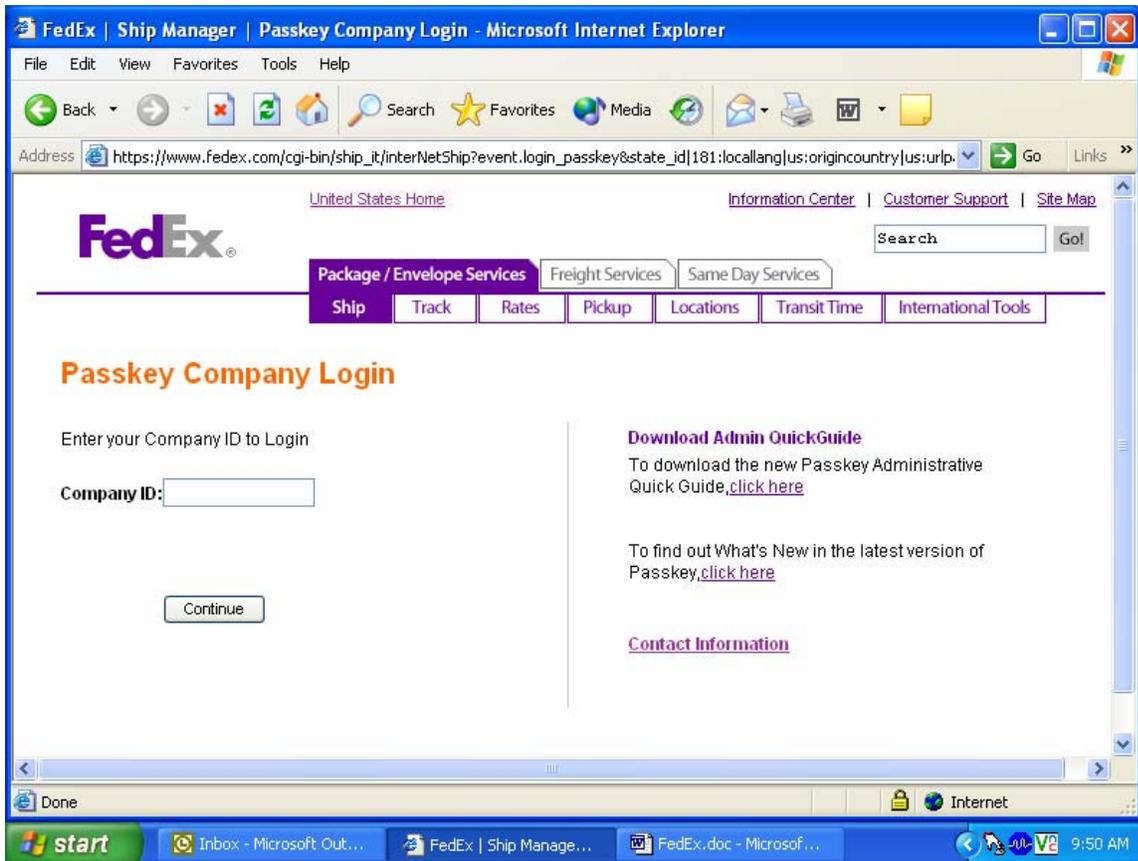
To access the Internet Explorer application, use the mouse to direct the mouse arrow to the Explorer icon on the desktop and double click.

Select the “Passkey users login here” link located in the lower right-hand corner of the screen.



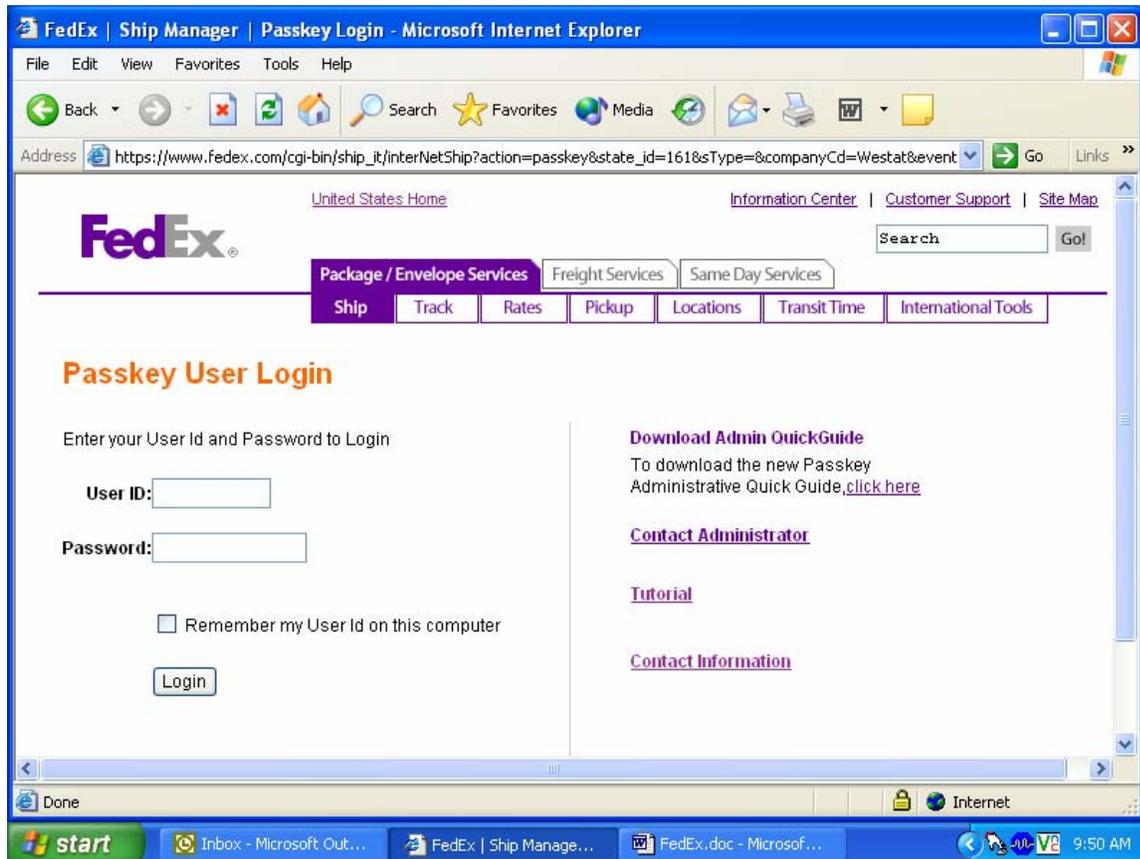
To select the Passkey users login here link, use the mouse to direct the mouse to the underlined link and left click.

Enter the Company ID in the text box.



To enter the Company ID, use the mouse to direct the mouse arrow to the white text box and left click. Type “Westat” and then use the mouse to direct the mouse arrow to the **Continue** button and left click.

Enter the User ID and password.



To enter the User ID, use the mouse to direct the mouse arrow to the User ID text box and left click, then use the keyboard keys to type “standXXX” where XXX represents the stand number. To move to the Password text box, use the mouse to insert the cursor in the Password text box and left click or type [Enter]. Enter the Password by using the keyboard keys to type “labshipping.” Both text boxes are case sensitive. To move to the shipping window, use the mouse to direct the mouse arrow to the **Login** button and left click or select [Enter].

The Ship window displays.

FedEx | Ship Manager | Shipping - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address [https://www.fedex.com/cgi-bin/ship\\_it/interNetShip](https://www.fedex.com/cgi-bin/ship_it/interNetShip) Go Links

fedex Ship Track/History Address Book Preferences Fast Ship Reports

<< Log out Home Quick help

**Recipient information** (Required fields in bold)

Recipient ID Select recipient ID

Company name Select company name

Contact name Select contact name

Country United States

Address 1

Address 2

City

State Select State

ZIP

Telephone

This is a residential address

Save in/update my address book

Add to my Fast Ship profiles

**Package and shipment details**

Service type Priority Overnight

Package type Your Packaging

Number of packages 1

Weight lbs

Dimensions Choose dimensions

Declared value US Dollars

**Billing details**

Bill shipment to Sender (prepaid)

Recipient/third party account #

Your reference 9851040913

**More shipment details**

Ship date Today

Additional shipment options Go to options

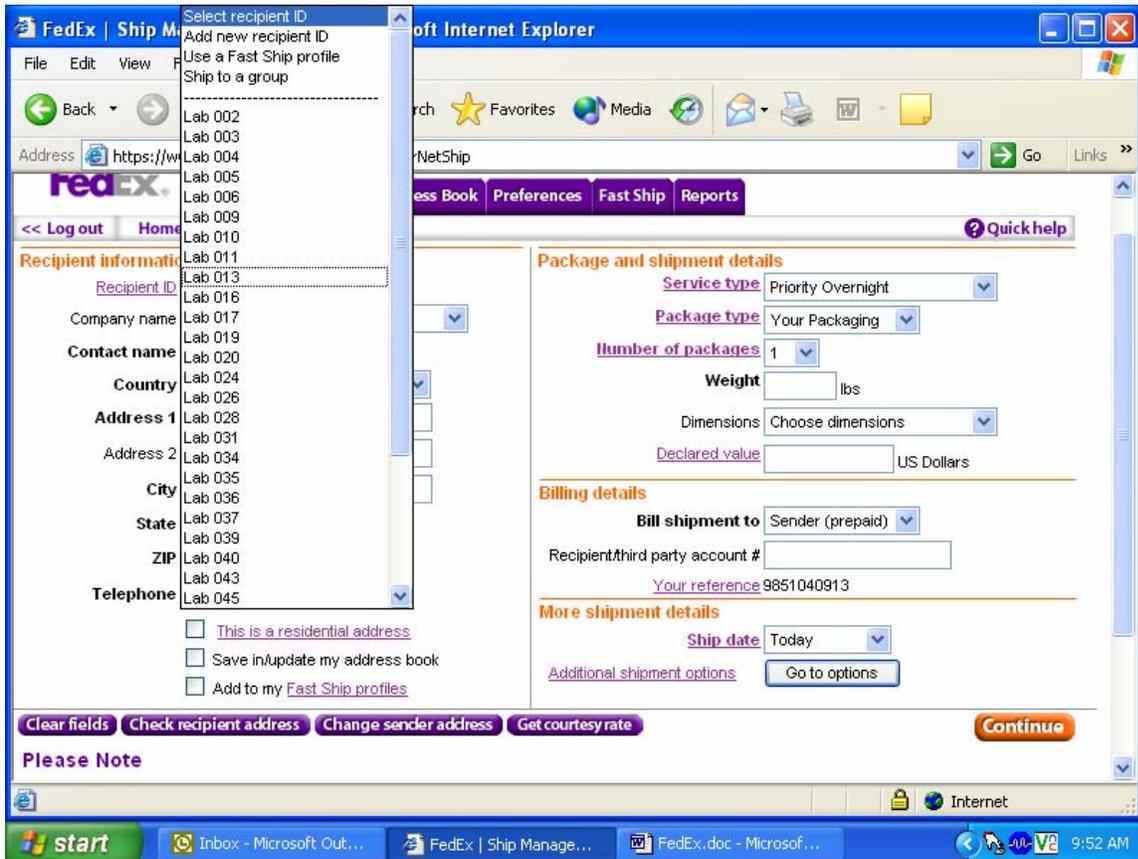
Clear fields Check recipient address Change sender address Get courtesy rate Continue

Please Note

start Inbox - Microsoft Out... FedEx | Ship Manage... FedEx.doc - Microsof... 9:51 AM

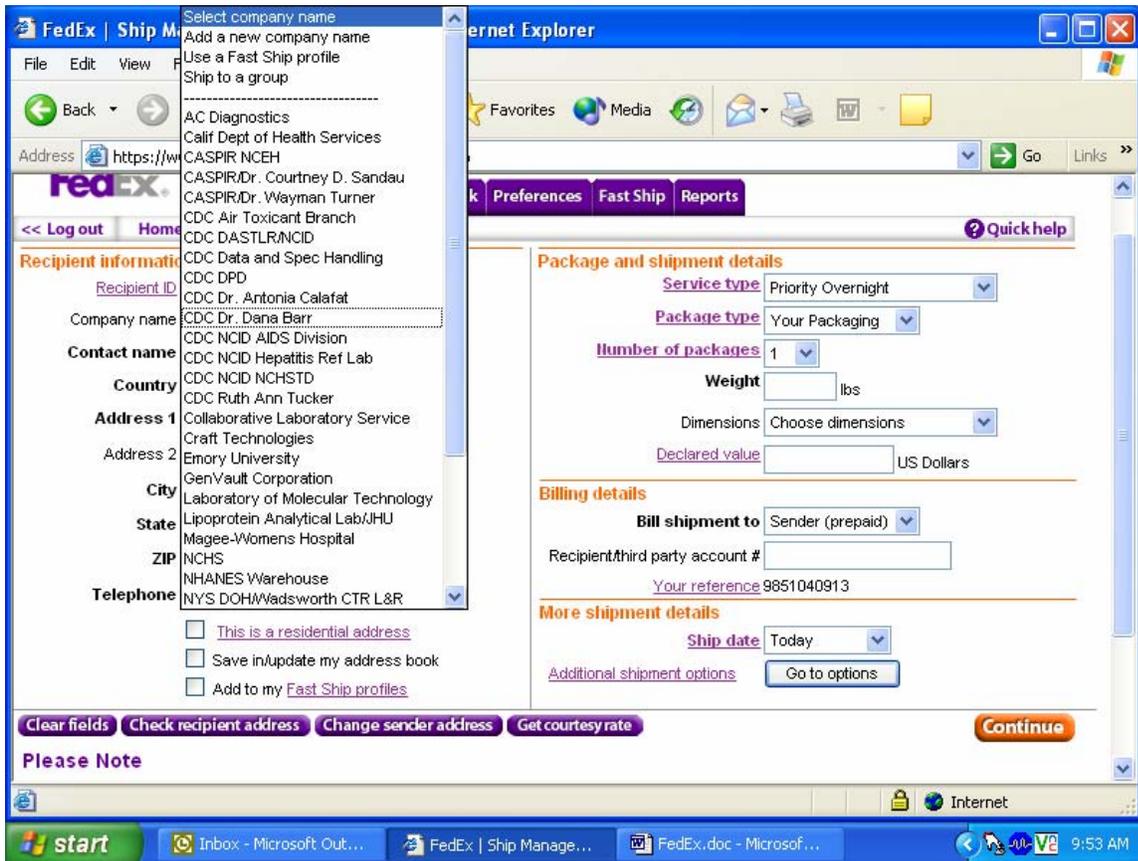
This page contains all of the information necessary to create an airbill. The recipient information is contained in the Address Book. *The Package and shipment details* and *Billing details* are preselected to default to the correct entries. The *More shipment details* defaults the shipping date to today and the **Go to option** button links to the special services section where the dry ice option is located.

The *Recipient information* section of the airbill contains all of the information necessary for each recipient. Select the entity to which the package is being shipped using one of three options. The *Recipient ID*, *Company name*, or *Contact name*.



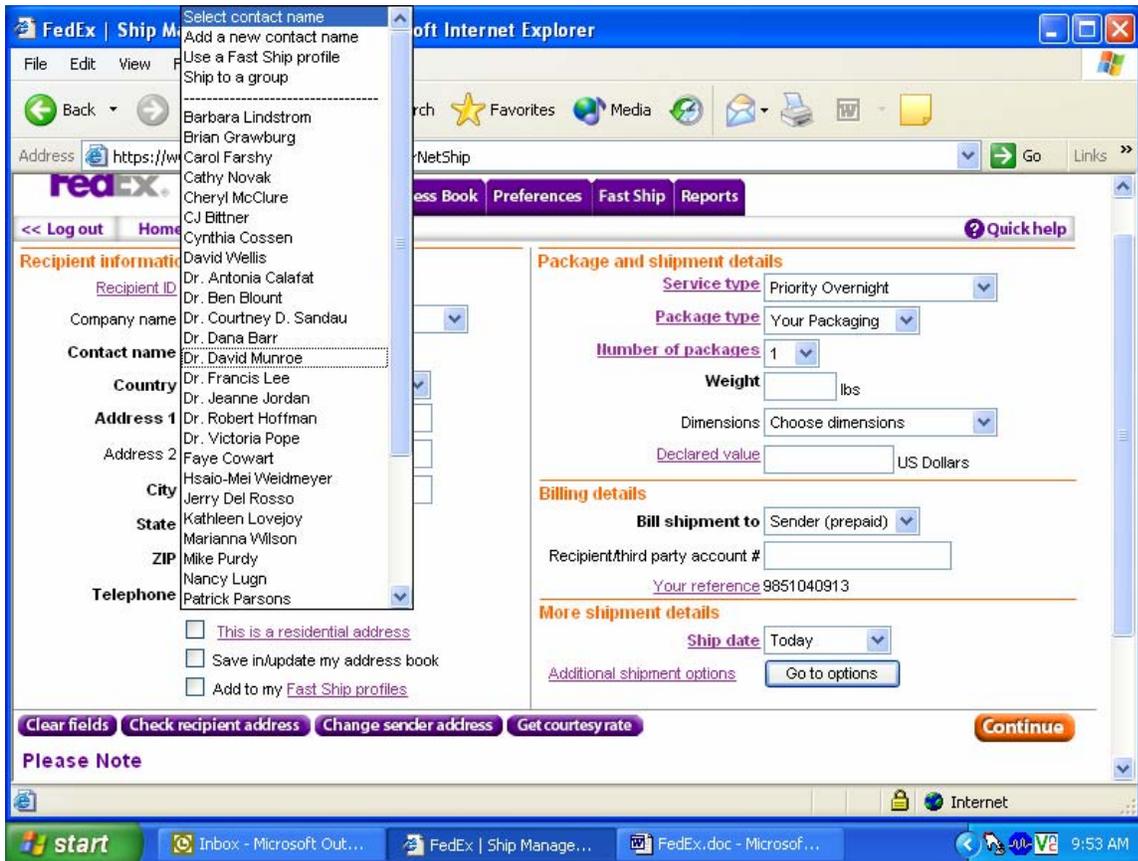
To select a recipient (or laboratory) by lab number, use the mouse to direct the mouse arrow to the down arrow on the right side of the Recipient ID text box and left click. Drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Select the entity to which the package is being shipped using the *Company name*.



To select a company (or laboratory) by name, use the mouse to direct the mouse arrow to the down arrow on the right side of the *Company name* text box and left click. Drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Select the entity to which the package is being shipped using the *Contact name*.



To select a laboratory by contact name, use the mouse to direct the mouse arrow to the down arrow on the right side of the *Contact name* text box and left click. Drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all the choices.

After a *Recipient ID*, *Company name*, or *Contact name* has been selected, the remainder of the text field automatically fills in using information contained in the address book.

The screenshot shows the FedEx Ship Manager web application. The browser window title is "FedEx | Ship Manager | Shipping - Microsoft Internet Explorer". The address bar shows "https://www.fedex.com/cgi-bin/ship\_it/interNetShip". The page has a navigation menu with "Ship", "Track/History", "Address Book", "Preferences", "Fast Ship", and "Reports". Below the navigation menu are "Log out" and "Home" links, and a "Quick help" icon.

The main content area is divided into several sections:

- Recipient information** (Required fields in bold):
  - Recipient ID: Lab 006
  - Company name: CASPIR NCEH
  - Contact name: Robert White
  - Country: United States
  - Address 1: 602 Webb Gin House Road
  - Address 2: Building C
  - City: Lawrenceville
  - State: Georgia
  - ZIP: 30045
  - Telephone: 7703395942
- Package and shipment details**:
  - Service type: Priority Overnight
  - Package type: Your Packaging
  - Number of packages: 1
  - Weight: lbs
  - Dimensions: Choose dimensions
  - Declared value: US Dollars
- Billing details**:
  - Bill shipment to: Sender (prepaid)
  - Recipient/third party account #:
  - Your reference: 9851040913
- More shipment details**:
  - Ship date: Today
  - Additional shipment options: Go to options

At the bottom of the form, there are several buttons: "Clear fields", "Check recipient address", "Change sender address", "Get courtesy rate", and "Continue".

Review the information for accuracy. If it is incorrect, then contact the laboratory supervisor.

Review the default information contained in the *Package and shipment details* and *Billing details* sections of the airbill.

#### Package and shipment details

**Service type** Priority Overnight ▼

**Package type** Your Packaging ▼

**Number of packages** 1 ▼

**Weight**  lbs

**Dimensions** Choose dimensions ▼

**Declared value**  US Dollars

---

#### Billing details

**Bill shipment to** Sender (prepaid) ▼

Recipient/third party account #

**Your reference** 9851040913

---

#### More shipment details

**Ship date** Today ▼

**Additional shipment options**

---

#### Package and shipment details

- The Service type should default to Priority Overnight.
- The Package type should default to Your Packaging.
- The Number of packages should default to “1.”
- **Enter the weight of the package.** To enter the weight, use the mouse to direct the mouse arrow to the Weight text box and left click. Use the numbers in the keyboard to enter the correct weight in pounds. Use whole numbers.
- Do not change the default (choose dimensions) in the *Dimensions* text box or enter a declared value in the Declared value text box.

#### Billing Details

- The *Bill shipment to* should default to Sender (prepaid).
- Do not enter a number in the *Recipient/third party account number* text box.
- Your reference should default to the project number for the stand.

Complete the options in the *More shipment details* section.

---

**Package and shipment details**

**Service type** Priority Overnight

**Package type** Your Packaging

**Number of packages** 1

**Weight**  lbs

**Dimensions** Choose dimensions

**Declared value**  US Dollars

---

**Billing details**

**Bill shipment to** Sender (prepaid)

Recipient/third party account #

**Your reference** 9851040913

---

**More shipment details**

**Ship date** Today

**Additional shipment options**

**at courtesy rate**

**Continue**

**ransmission time. Do not clic** ; **it may cause a**

[fedex.com Terms of Use](#) and the FedEx terms of shipping in the applicable [Express international shipments](#).

ntain undeclared Dangerous Goods. If you are uncertain of whether your ction for more information. To ship FedEx Express Dangerous Goods, you he Special services section.

rvice has been authorized for your department by your Passkey

The Ship date will default to Today. To change the date to tomorrow or any of the next 6 days, use the mouse to direct the mouse arrow to the down arrow on the right side of the Ship date text box and left click. Drag the mouse arrow to the desired choice and left click.

For shipments containing dry ice, select the **Go to options** button next to the Additional shipment options link.

**More shipment details**

**Ship date** Today

[Additional shipment options](#)

To select the **Go to options** button, use the mouse to direct the mouse arrow to the **Go to options** button and left click.

A second shipment options window displays.

**Special services**

- Deliver without signature
- Signature required (override recipient signature release)
- Saturday pickup
- Saturday delivery
- Hold at FedEx location
- Dry Ice
- Dangerous Goods

**Shipping Options**

Pickup/Drop-off

- Will use scheduled pickup at my location
- Will drop off at FedEx location
- Will contact FedEx to request pickup

**FedEx Express reference information**

Your reference 9851040913

P.O. number

Invoice number

Department number

**FedEx ShipAlert® - Express**

Email address	Shipment notification	Delivery notification
Sender nhaneslab@westat.com	<input type="checkbox"/>	<input type="checkbox"/>
Recipient rj0@cdc.gov	<input type="checkbox"/>	<input type="checkbox"/>
Other 1 <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other 2 <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

Add personal message (not to exceed 75 characters)

**FedEx InSight™** (a shipment visibility application) [Learn more.](#)

- Block shipment data (will prohibit the recipient and third party payer from viewing information about this shipment)
- Shipment contents  (shipment level detail for InSight customers only)

The options window includes checkboxes for special services, radio buttons for shipping options, text boxes for FedEx Express reference information, text boxes for FedEx ShipAlert® Express,

and check boxes for FedEx InSight™. Do not change any of the information in any of the sections except the Dry Ice option under *Special Services*.

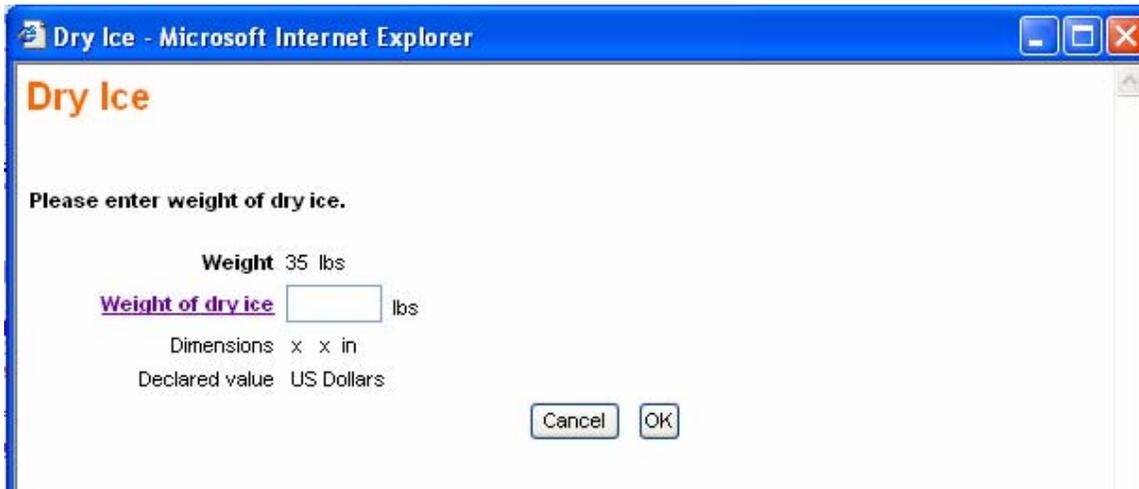
Select the Dry Ice check box.

**Special services**

- [Deliver without signature](#)
  - [Signature required](#) (override recipient signature release)
  - [Saturday pickup](#)
  - [Saturday delivery](#)
  - [Hold at FedEx location](#)
  - [Dry Ice](#)
  - [Dangerous Goods](#)
- 

To select the Dry Ice option, use the mouse to direct the mouse arrow to the Dry Ice check box and left click.

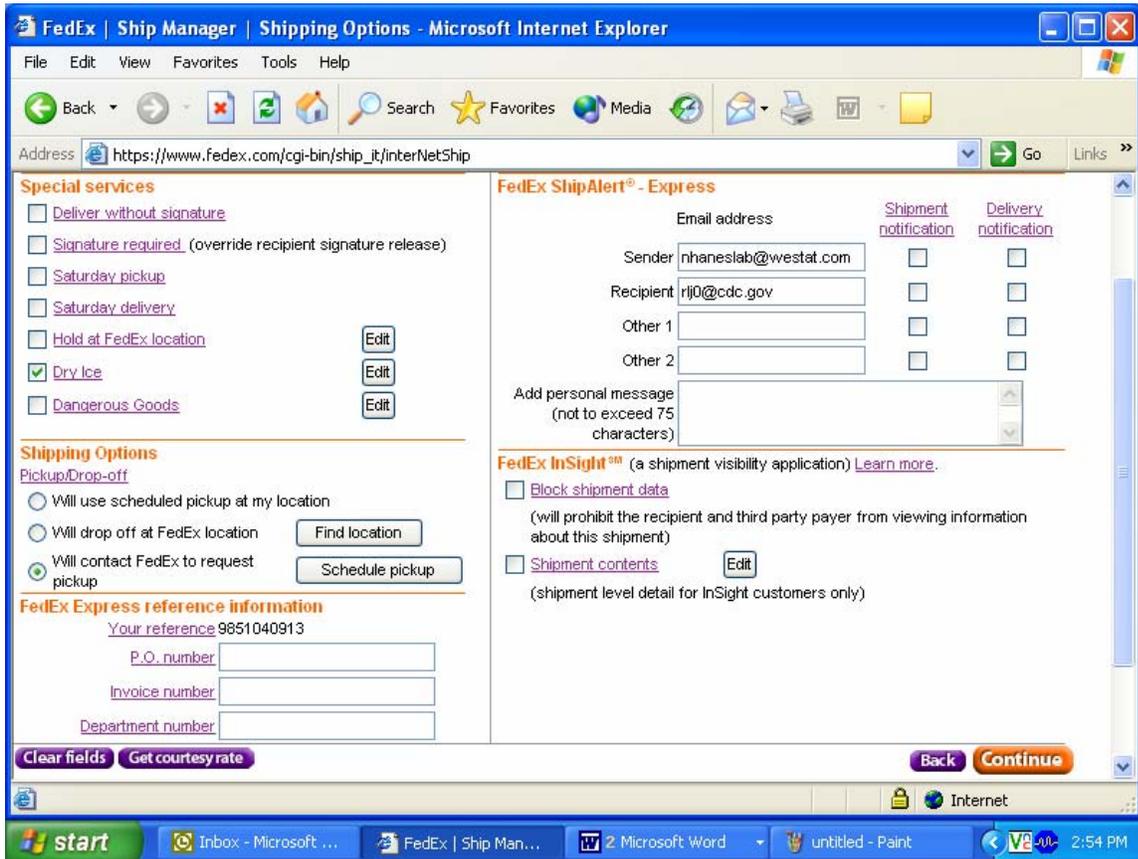
A second dry ice window displays. Enter the weight of the dry ice.



To enter the weight of the Dry Ice, use the mouse to the *Weight of dry ice* text box and left click. Type the weight, in pounds, into the text box using the keyboard keys. Use whole numbers. To exit this window and return to the special services window, use the mouse to direct the mouse arrow to the

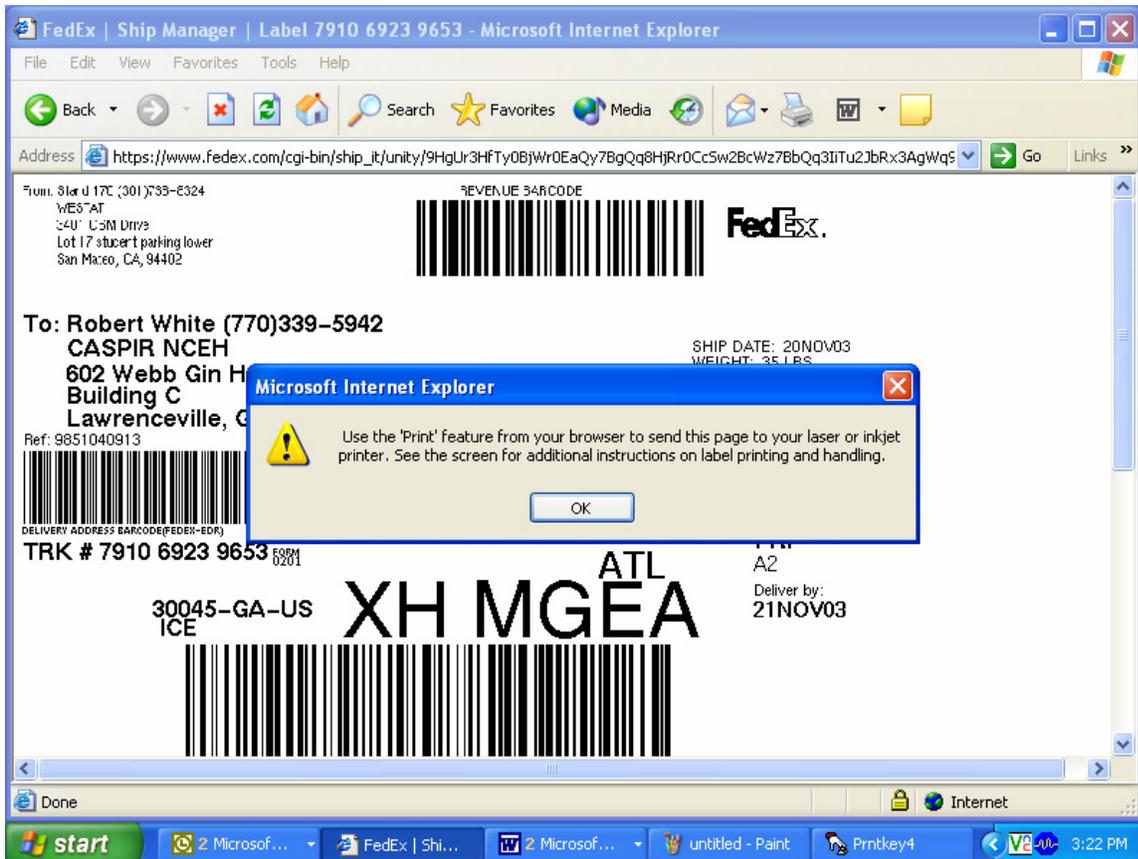
**Cancel** button and left click. To save the information and return to the special services window, use the mouse to direct the mouse arrow to the **OK** button and left click.

Continue to create the airbill.



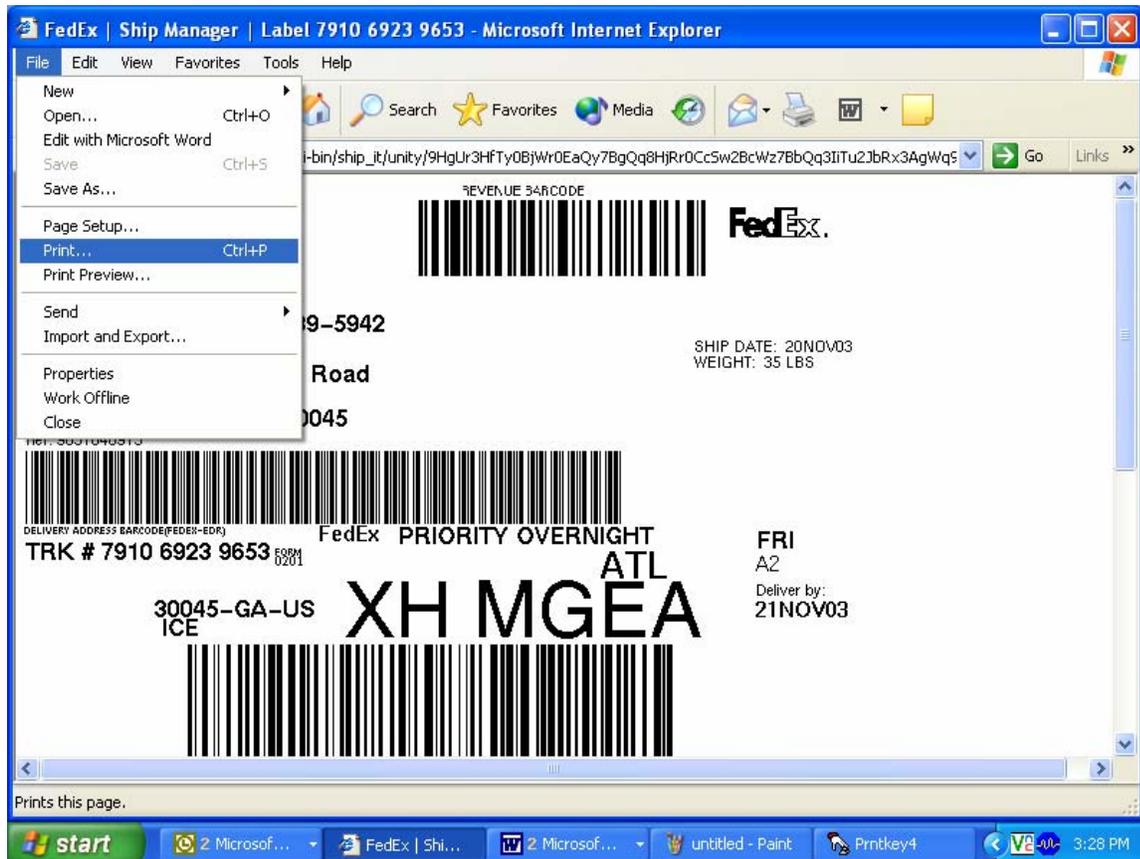
To edit the information in the dry ice window or to return to the dry ice window, use the mouse to direct the mouse arrow to the **Edit** Button to the right of the Dry Ice checkbox, and left click. To go back to the Recipient Information window, use the mouse to direct the mouse arrow to the **Back** button and left click. To clear the fields, use the mouse to direct the mouse arrow to the **Clear Fields** button and left click. To continue to create the airbill, use the mouse to direct the mouse arrow to the **Continue** button and left click. **Click the Continue button only once. Expect some delay due to transmission time. Do not click Stop or Reload; it may cause a duplicate shipment transaction to occur.**

Continue to create the airbill.



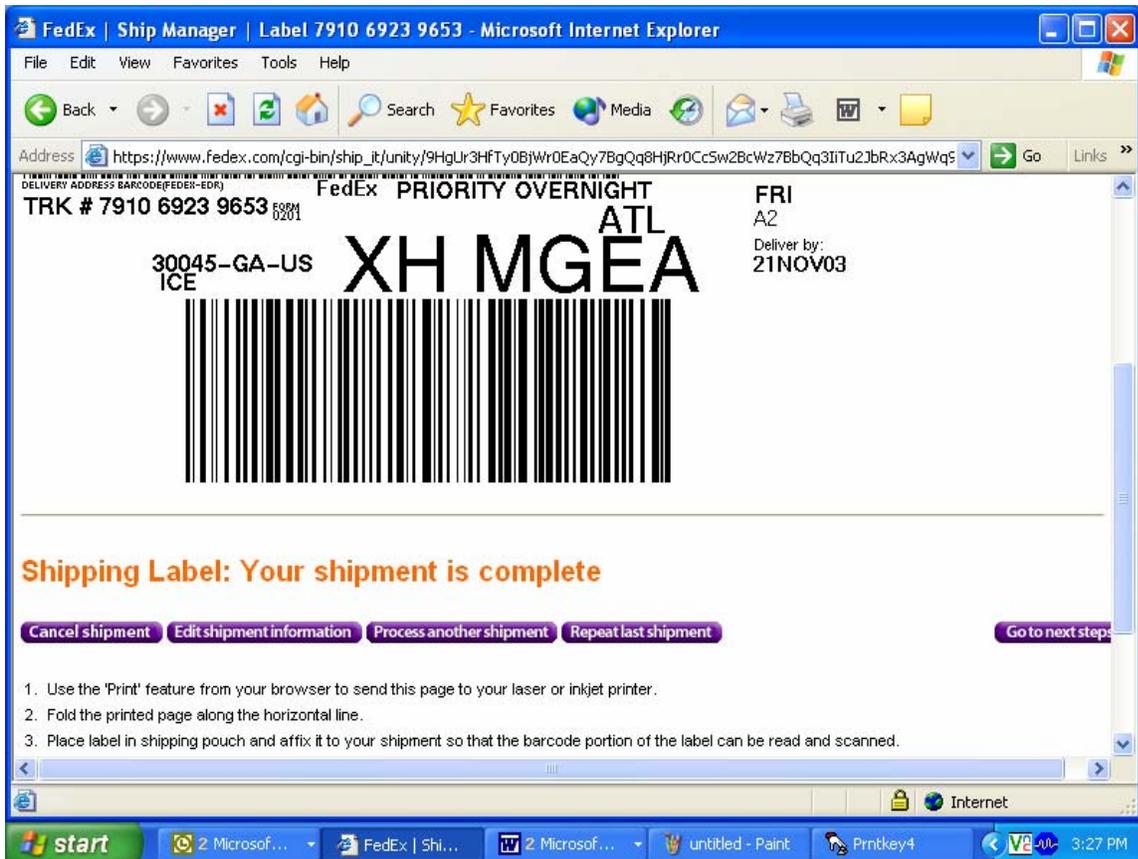
The airbill is created after the **Continue** button is selected. **Click the Continue button only once. Expect some delay due to transmission time. Do not click Stop or Reload; it may cause a duplicate shipment transaction to occur.** A popup window with an informational message displays. Follow the instructions contained in the popup window; “Use the ‘Print’ feature from your browser to send this page to your laser or inkjet printer. See the screen for additional instructions on label printing and handling.” To acknowledge the message, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter.]

Print the airbill.



To print the airbill, use the mouse to direct the mouse arrow to [File] in the top tile bar, drag the arrow to Print and left click, or type [Alt] [F] [P/p].

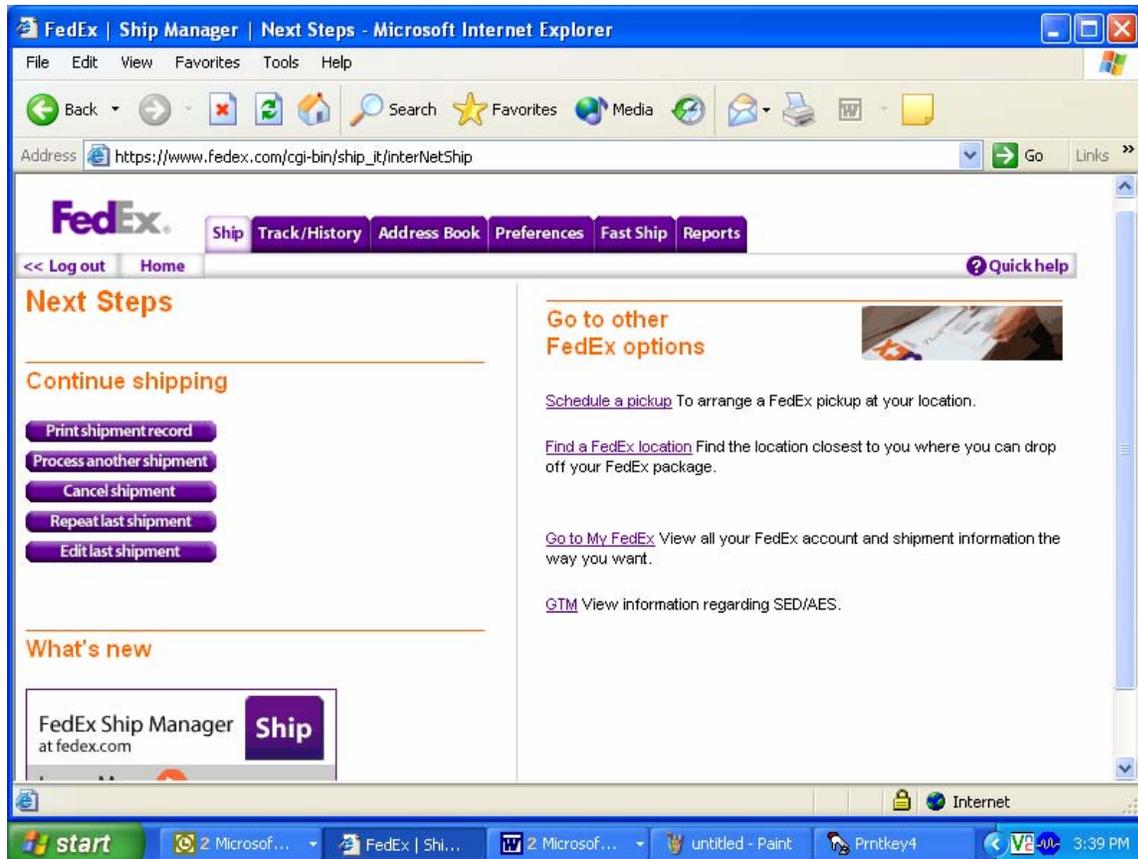
Scroll down to view the selections at the bottom of the window and follow the instructions.



Select one of the buttons to proceed. The choices are as follows:

- Cancel shipment – Moves to the Track/History page where the sample can be marked and cancelled.
- Edit shipment information – Opens a window that instructs, “If you have already printed the label for this shipment, please discard it. If you have entered ‘Shipment Contents’ information, this information will not be saved and will need to be re-entered. To confirm that you want to edit this shipment, click the “Yes” button.”
- Process another shipment – Moves to the Recipient information page.
- Repeat last shipment – Opens a warning window that instructs, “You have chosen to repeat a shipment that includes one or more of the following: freight booking number, package dimensions or shipment contents. It will be necessary to reenter some information to complete the repeat shipment.”
- Go to next step – proceeds to the Next Steps page with the same choices.

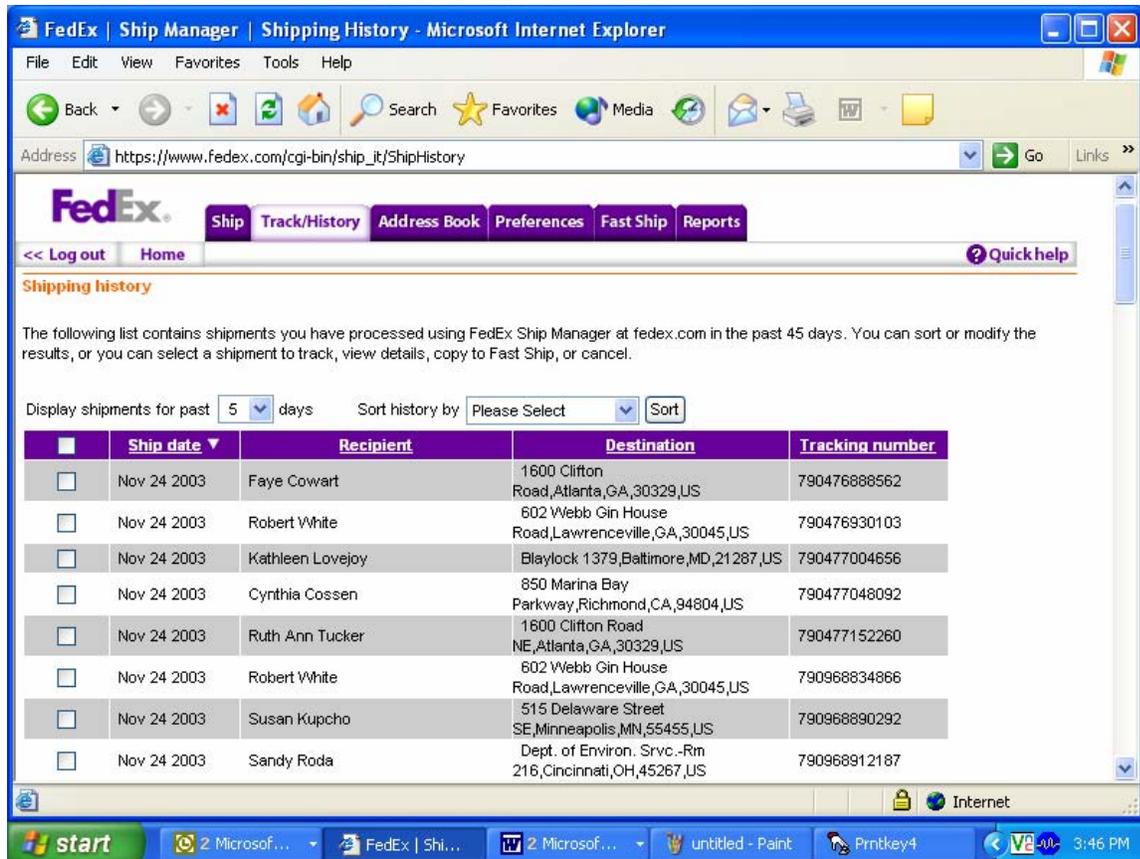
The Next Steps page displays if the **Go to next step** button is selected.



Complete the shipping process.

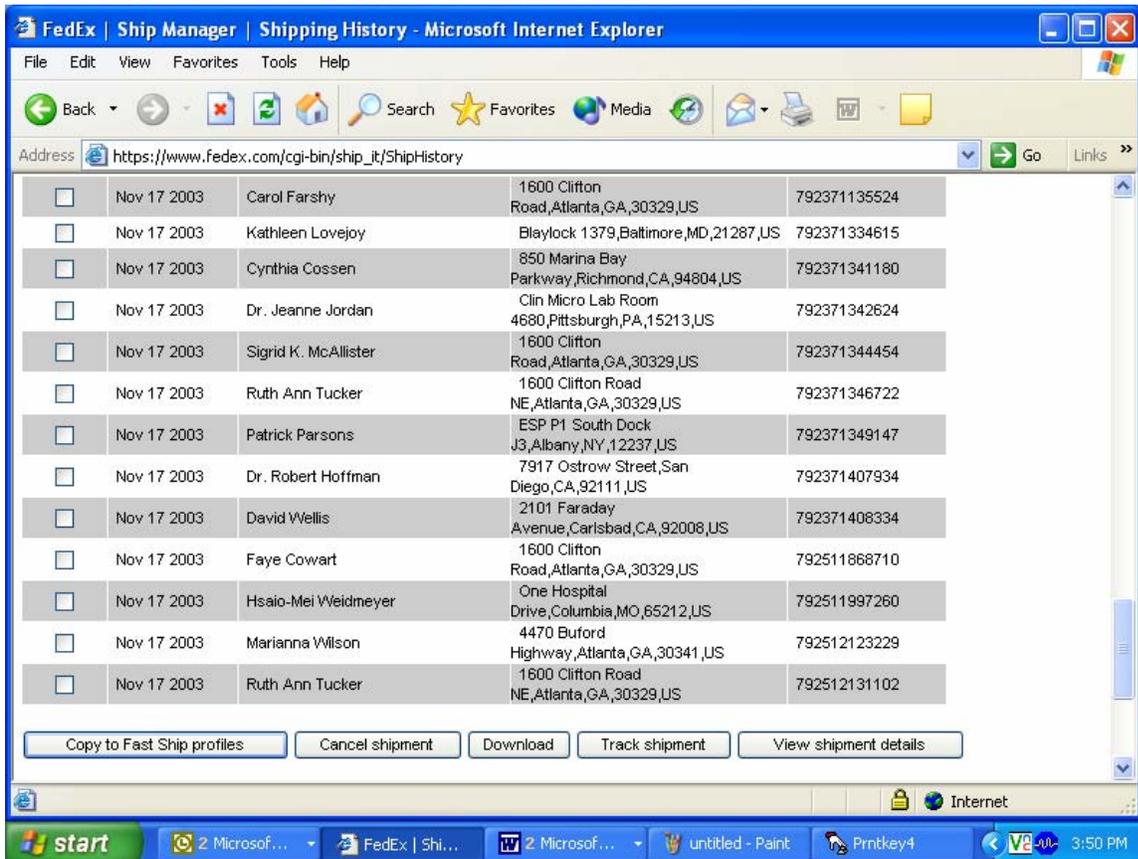
- Fold the printed page along the horizontal line
- Place label in shipping pouch and affix it to your shipment so that the bar code portion of the label can be read and scanned.

Track a shipment, cancel a shipment or view shipment histories using the Track/History file tab.



To access the Track/History window, use the mouse to direct the mouse arrow to the Track/History file tab at the top of the page and left click.

The Track/History window lists the shipments that have been processed using FedEx Ship Manager at FedEx.com in the past 45 days. Sort or modify the results, or select a shipment to track, view details, copy to Fast Ship, or cancel.

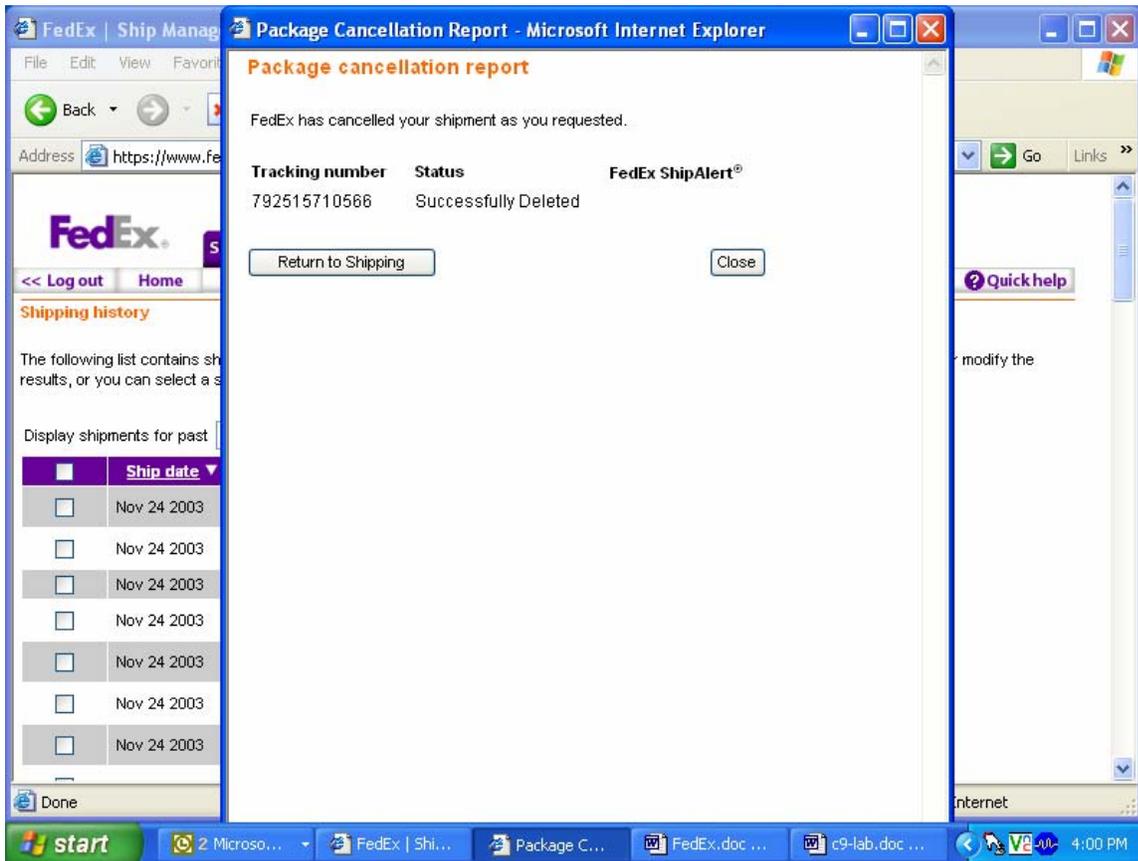


To mark one or more airbills, use the mouse to direct the mouse arrow to the check box and left click to insert a checkmark. Then select one of the actions listed along the bottom of the window:

- Copy to Fast Ship profiles – not applicable
- Cancel shipment – Opens a Package Cancellation Report window
- Download – Not applicable
- Track shipment – Opens a Track Shipments, Summary Results window that displays the tracking information for one or more shipments. The details include the Tracking Number, Status Date/Time, Destination, and Service type.

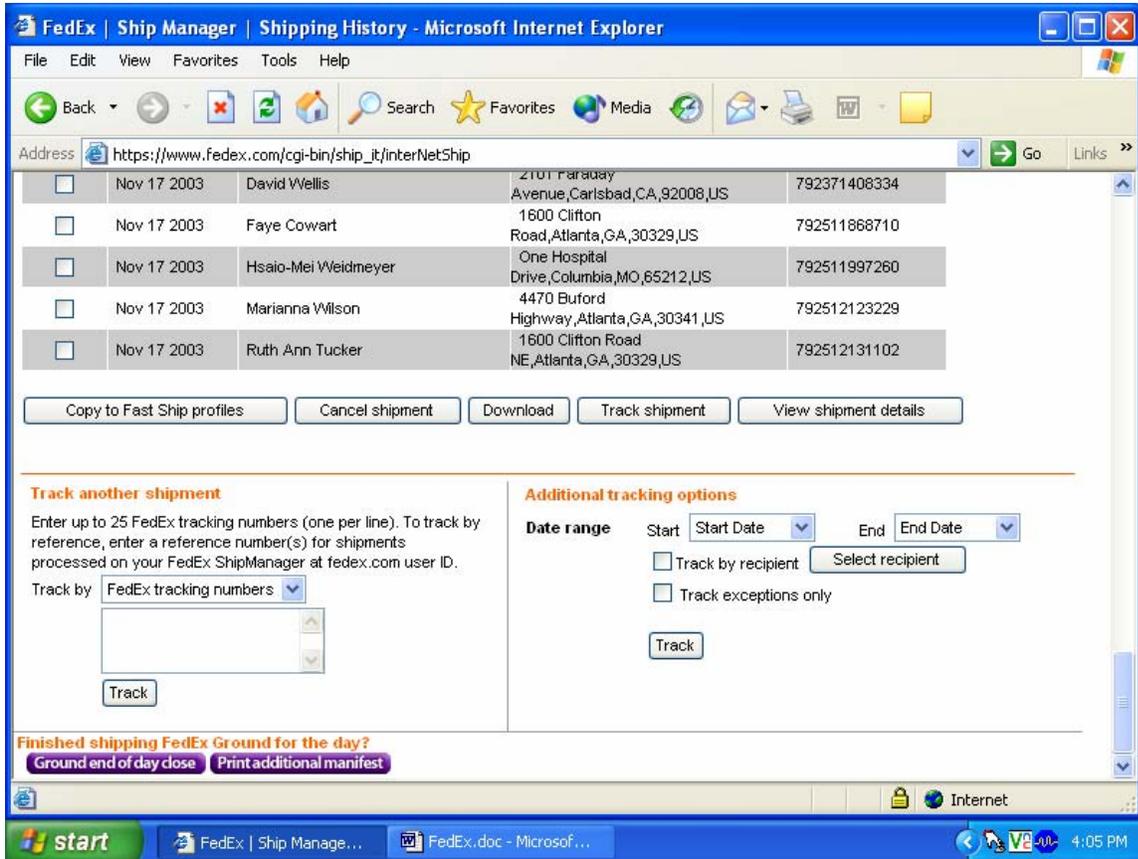
- View shipment details – Opens a window that displays the details for a shipment: Ship To, Tracking Number, Your Reference, Ship date, Service type, package type, Pick up/Drop off, Total Weight, Declared value, Courtesy Rate Quote, Special Services, and Shipment Type.

A shipment is cancelled as soon as the Cancel Shipment option is selected.



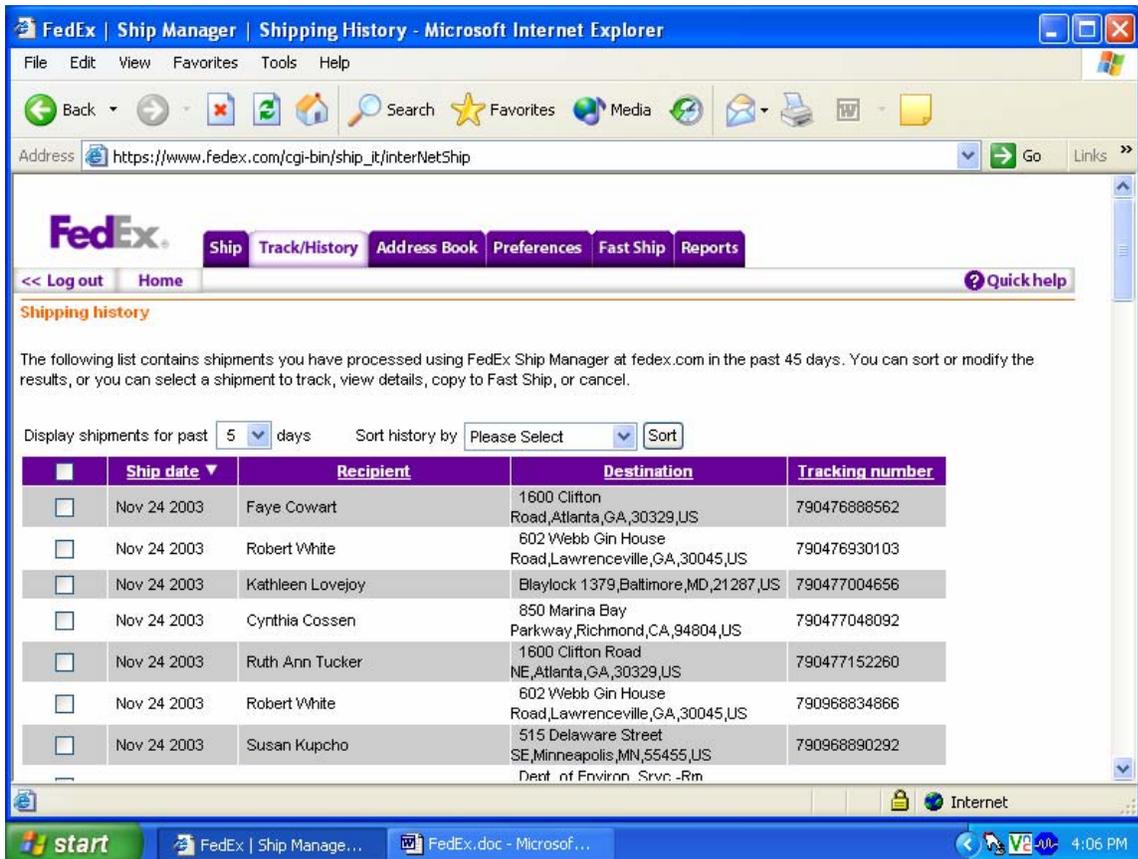
The Package cancellation report window confirms the status of the shipment. To return to the Recipient Information page, use the mouse to direct the mouse arrow to the **Return to Shipping** button and left click. To close the window and return to the Track/History window, use the mouse to direct the mouse arrow to the **Close** button and left click.

The bottom of the Track/History window includes a window to enter additional tracking numbers or additional tracking options.



Use the **Additional tracking option** to track using date filters, or checkboxes to track by recipient or by exceptions only.

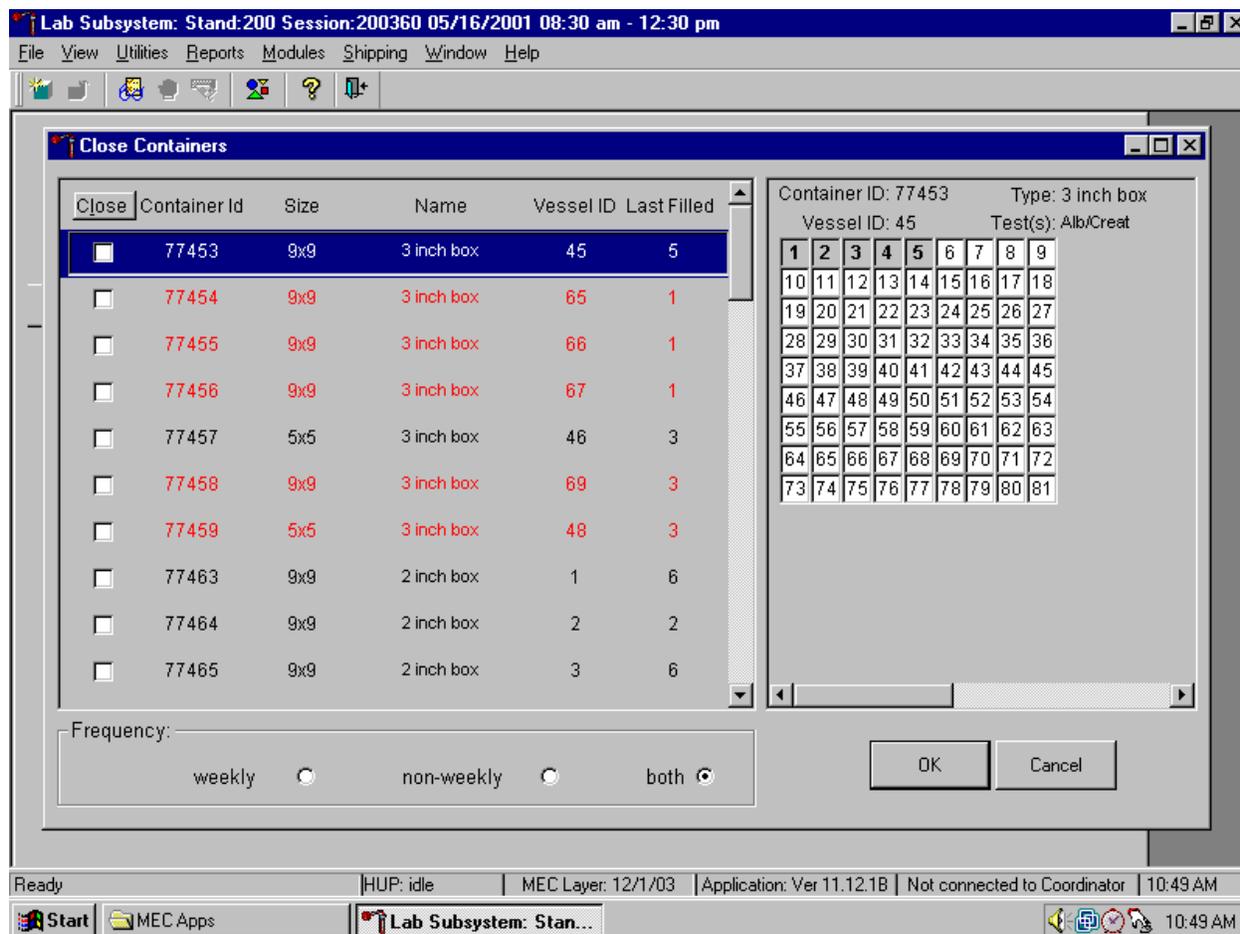
Log out of the application.



To log out of FedEx Ship Manager, use the mouse to direct the mouse arrow to the <<Log out header on the top left side of the window and left click.



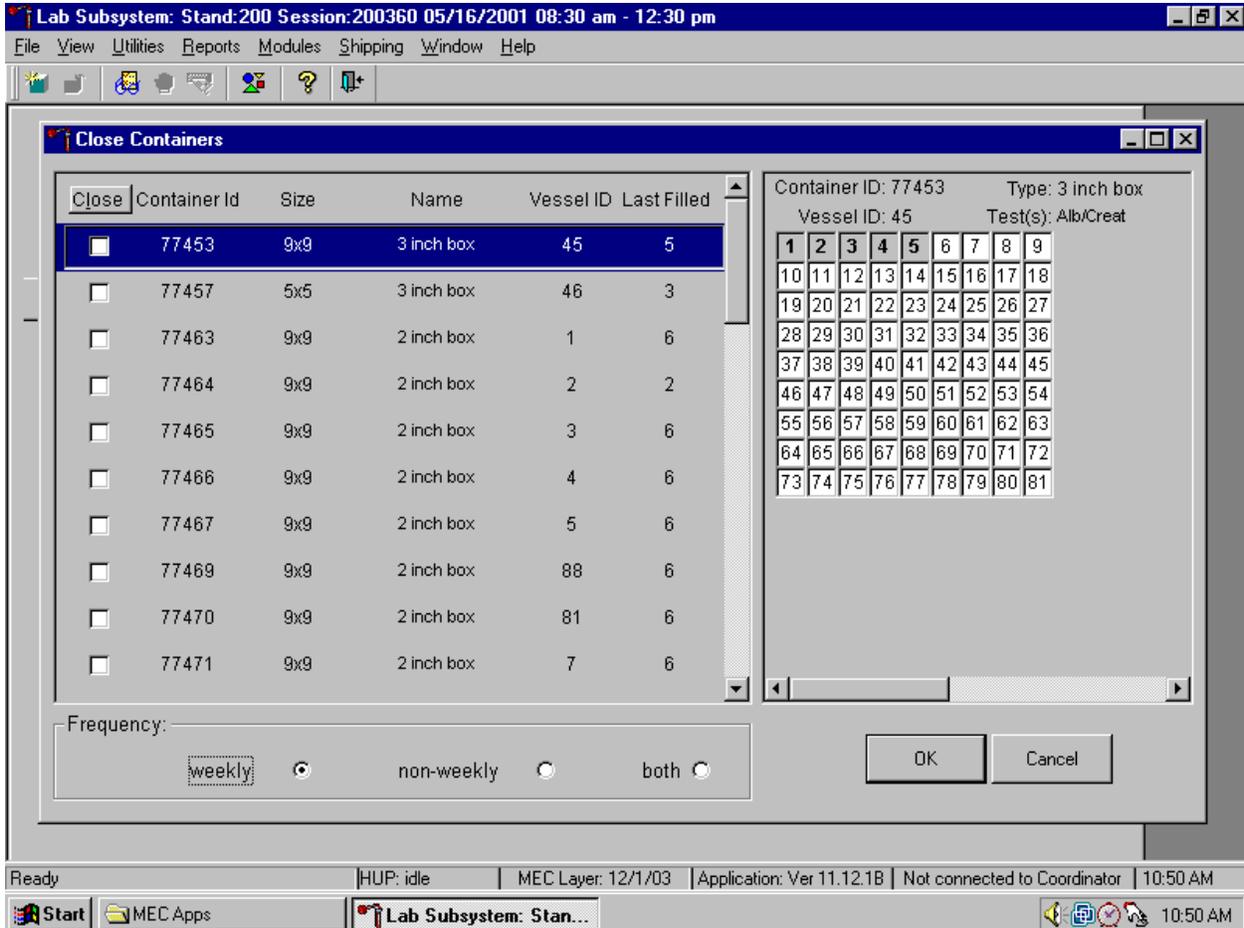
Individually close open containers or collectively close all open containers.



The left side of the Close Containers screen includes a check box for each open container and columns for the Container Id, Size, Name, Vessel ID, and number of the Last Filled slot. The container line in the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. Containers displayed in red indicate containers that can be shipped at the end of the stand or when they are full. The bottom of the screen includes three filters: weekly, non-weekly, and both.

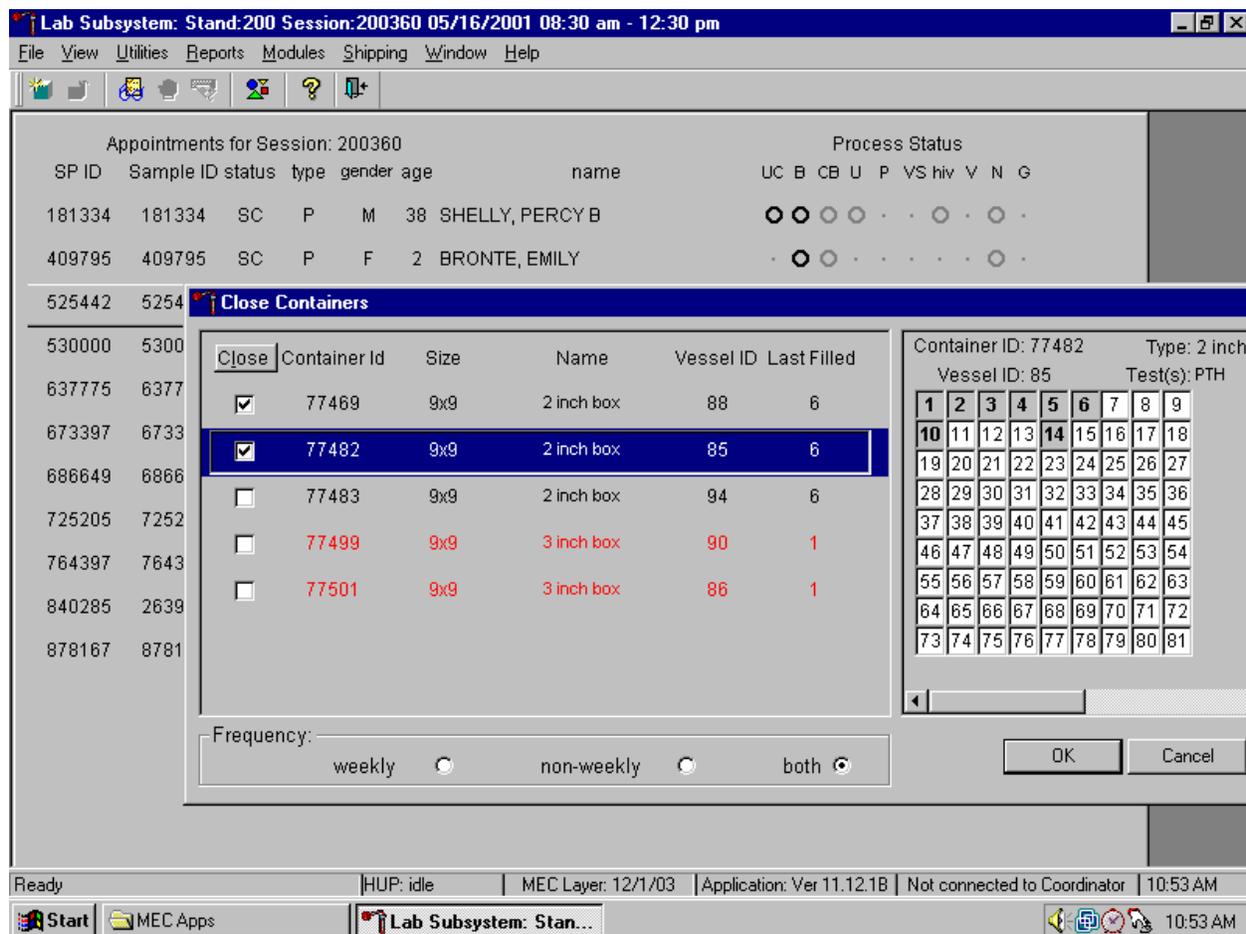
To move up and down the list, use the up and down keyboard arrows or use the mouse to direct the mouse arrow to any individual line. Use the vertical scroll bar to view all containers. To sort the lines by Container Id, Size, Name, Vessel ID or Last Filled, use the mouse to direct the mouse arrow to the column title and left click. The window will update and display the rows in the desired priority.

Use the filters to display containers that are shipped weekly, non-weekly, or both.



To select one of the three filters, use the mouse to direct the mouse arrow to the correct radio button and left click. The window updates to display those containers that meet the filter criteria.

Individually identify containers or select all containers.



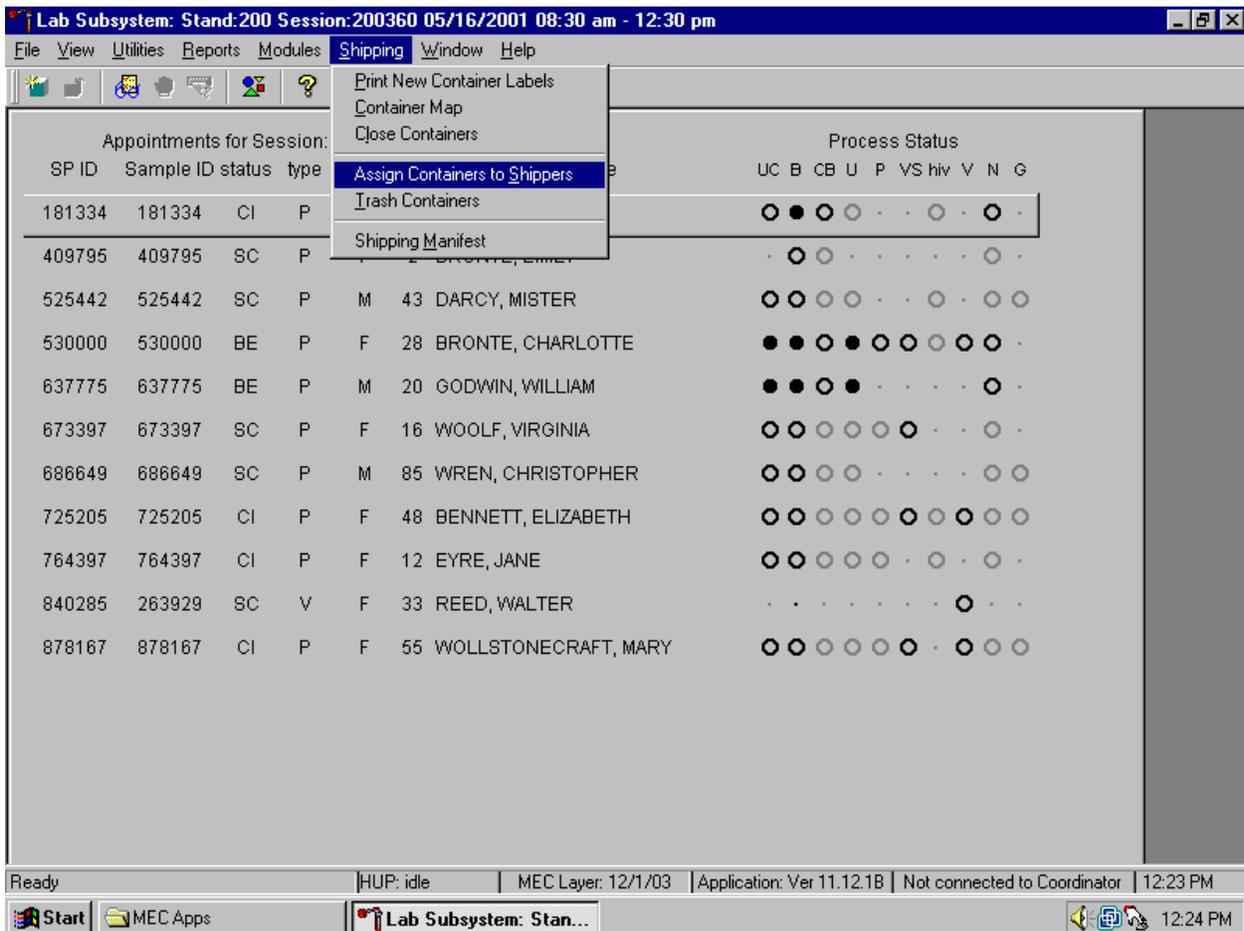
To mark individual containers, use the mouse to direct the mouse arrow to individual Close button check boxes and left click. To close all open containers, use the mouse to direct the mouse arrow to the Close button and left click. To remove the check marks, use the mouse to direct the mouse arrow to the Close button and left click a second time.

Verify the contents of each closed box by visually matching the contents of the box to the map. To record these actions, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the {Close Containers} module without recording these actions, use the mouse to direct the mouse arrow to the Cancel button and left click.

## 9.10 Assign Containers to Shippers

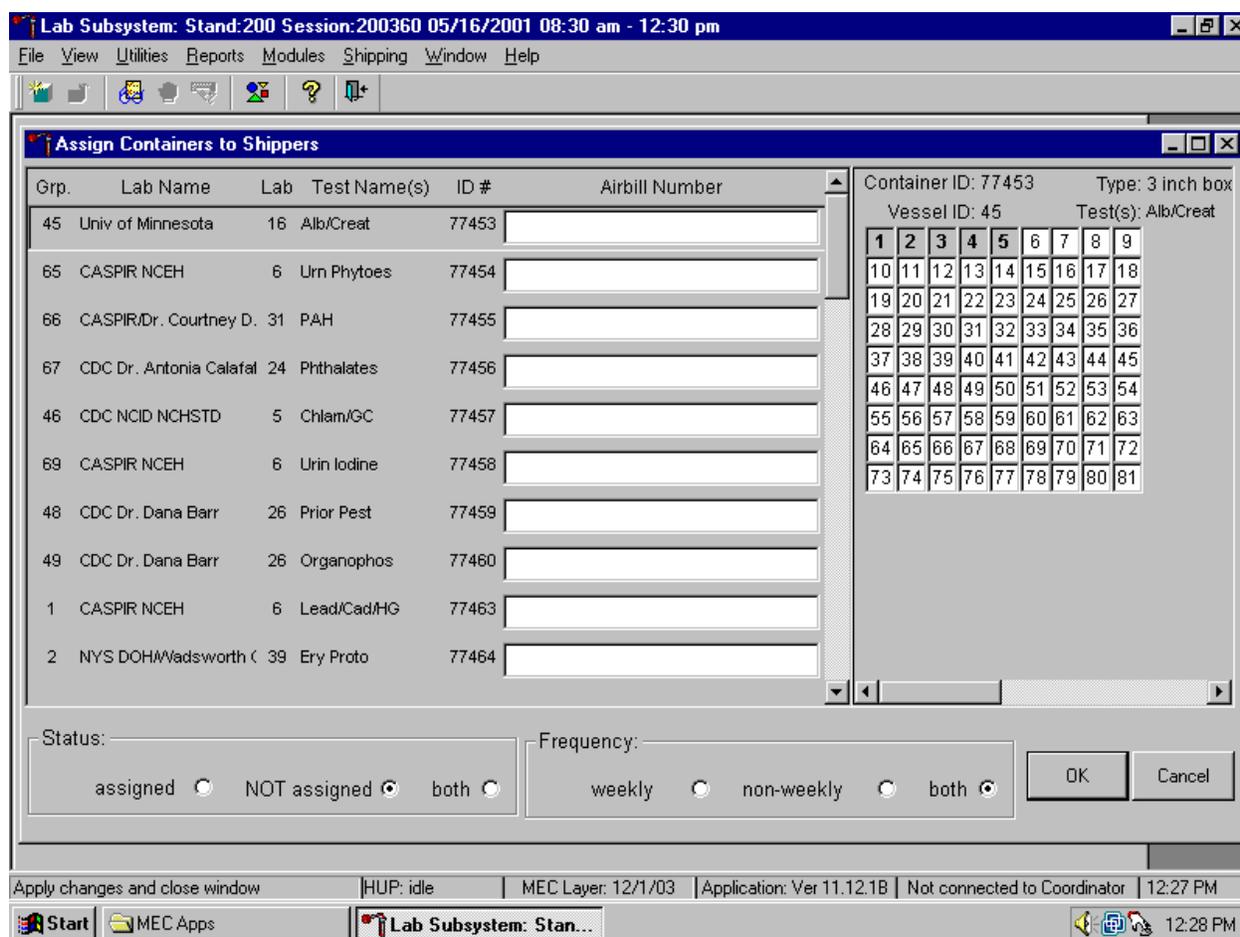
Assign closed containers to or associate closed containers with a specific airbill. To associate a specific closed container to the airbill for that laboratory, use the {Assign Container to Shippers} module.

Access the {Assign Containers to Shippers} module.



To access the {Assign Containers to Shippers} module, use the mouse to direct the mouse arrow to {Shipping} in the top menu bar, left click, drag the mouse arrow to {Assign Container to Shippers}, and left click or type [Alt] [S/s], [S/s].

The Assign Containers to Shippers window displays.



This left side of the screen includes columns for a group designation (which represents a number), Type of container, Lab designation, Test Name(s), Container ID number, and Airbill Number. The container line within the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. The left side of the bottom of the window contains three “Status” filters (radio buttons): “assigned,” “NOT assigned,” and “both.” The right side of the bottom of the window contains three “Frequency” filters (radio buttons): “weekly,” “non-weekly,” and “both.” Use the column titles to sort the rows. To sort the rows, use the mouse to direct the mouse arrow to the desired column title and left click. The window updates based on the selection.

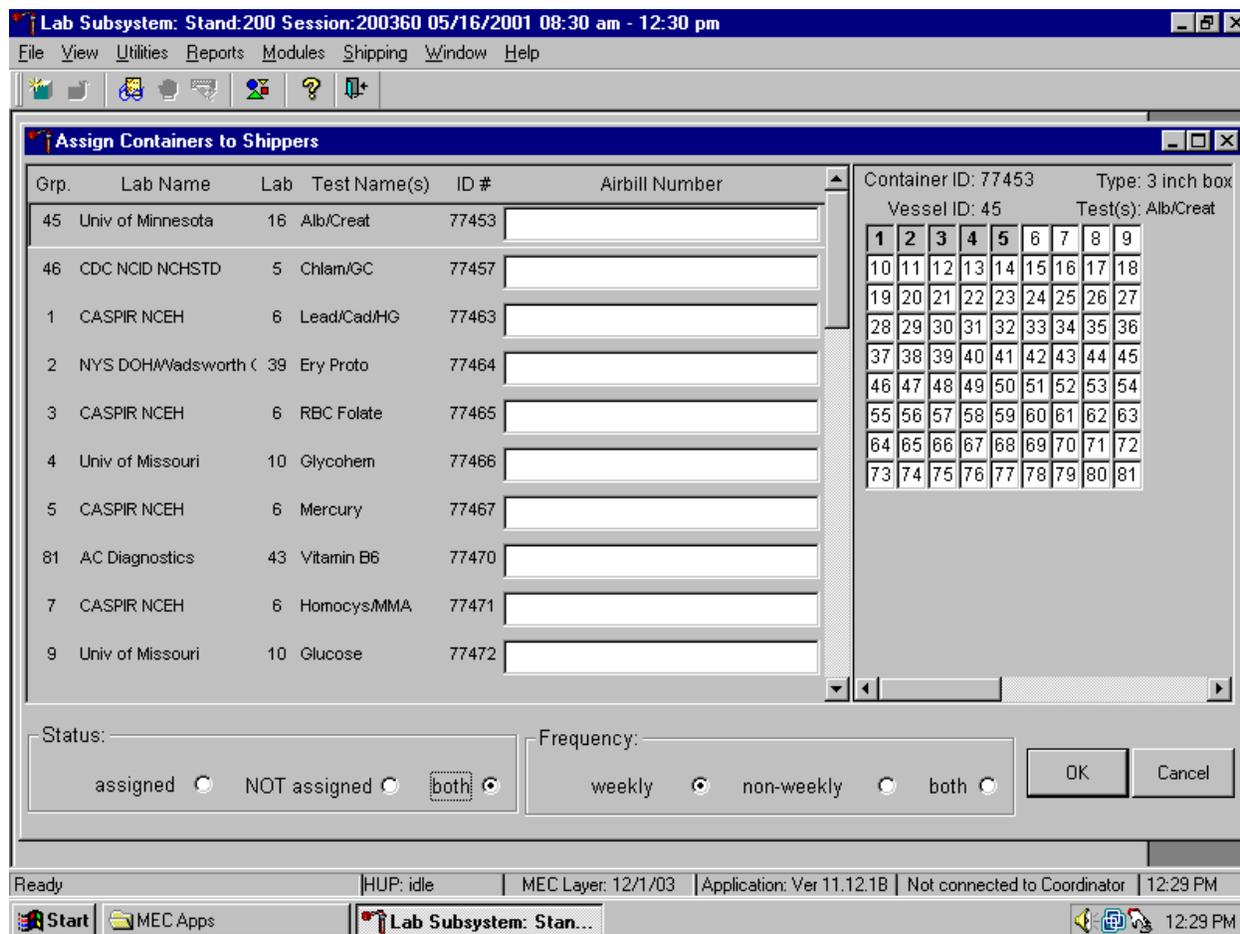
Enter an airbill number into each Airbill Number text box. There are three ways to enter the airbill number.

- Use the bar code gun to scan the bar code from the FedEx Ship Manager airbill. The bar code is located in the bottom of the top half of the folded airbill. It is the tallest bar code on the airbill. Hold the gun in the right hand, squeeze the trigger, and move the gun up and down to adjust the laser light so that it covers the width of the bar code. Once the gun successfully scans the bar code, an audible beep is emitted.
- Use the bar code gun to scan the bar code on the second page (Recipient's Copy) of the two-part Form ID 0215. This bar code is located on the lower left-hand side toward the bottom of the form. Hold the gun in the right hand, squeeze the trigger, and move the gun up and down to adjust the laser light so that it covers the width of the bar code. Once the gun successfully scans the bar code, an audible beep is emitted.
- Use the keyboard keys to type the airbill number from either the FedEx Ship Manager airbill or the FedEx airbill form 0215.

To assign a container to the corresponding airbill:

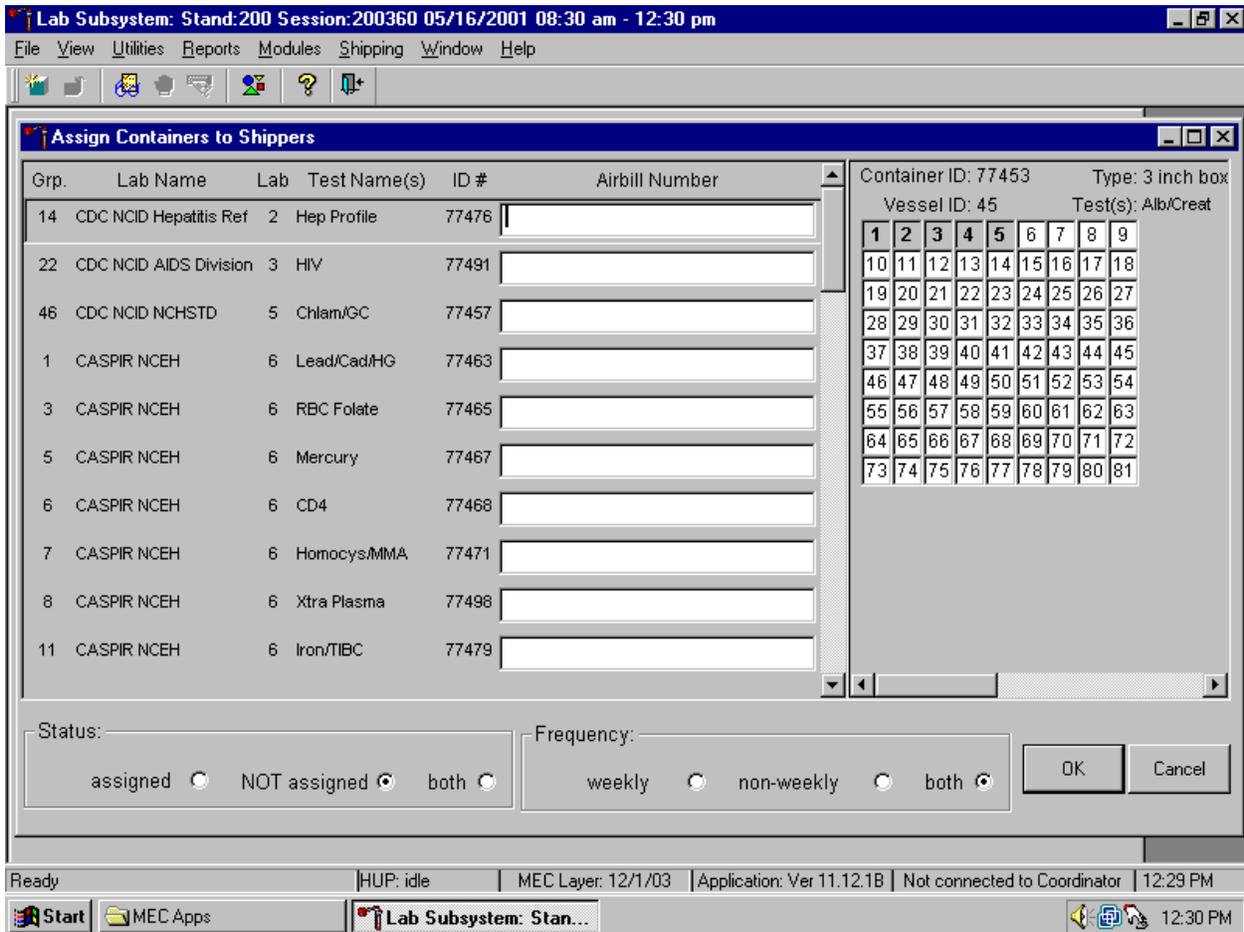
- Set the Status filter to: "NOT assigned";
- Set the Frequency to: weekly, non-weekly or both, depending on the shipping situation; and
- Sort the laboratories by Lab number.

Set the Status and Frequency filters.



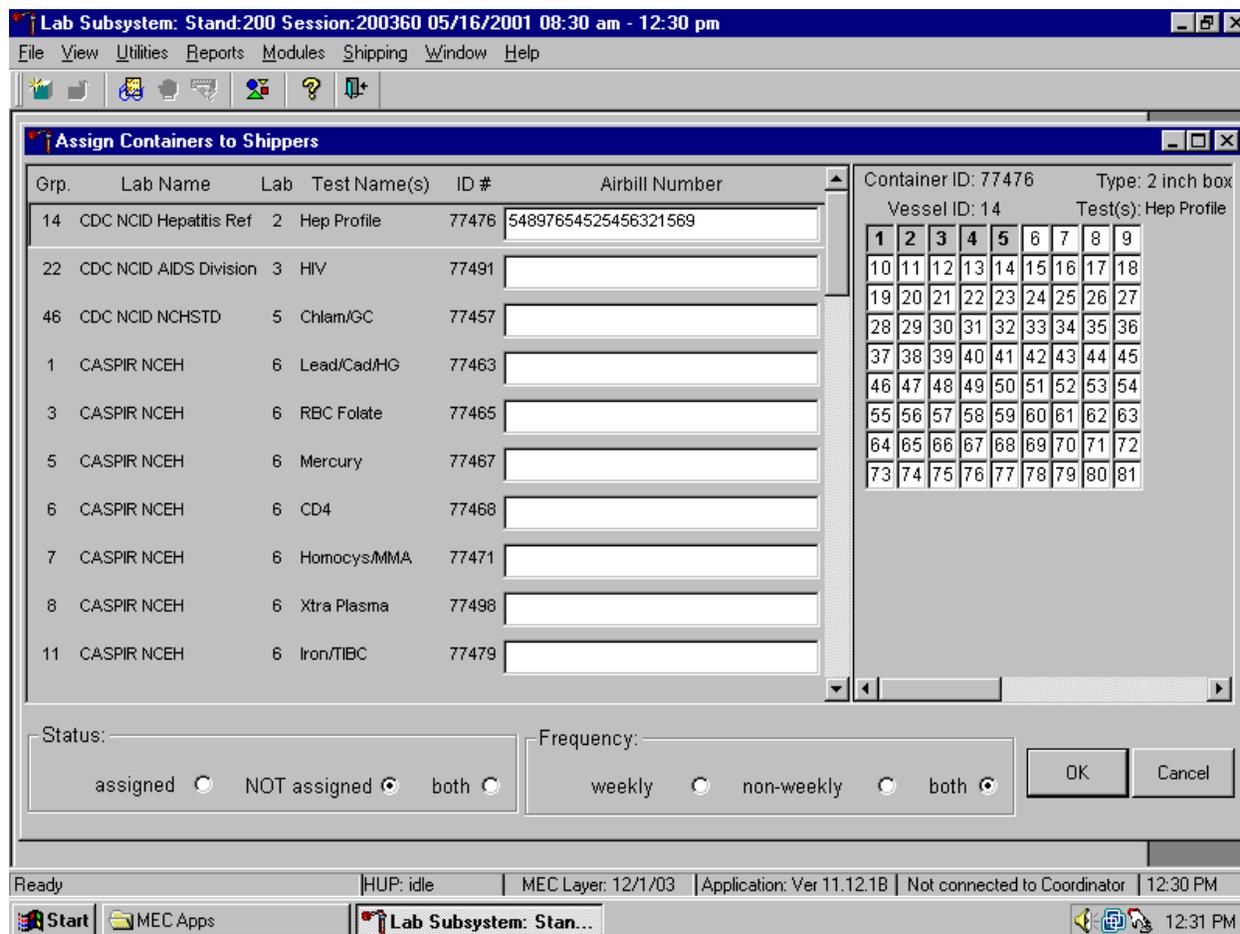
To select the Status filter, use the mouse to direct the mouse arrow to the assigned, NOT assigned or both radio button and left click. To select the shipping Frequency, use the mouse to direct the mouse arrow to weekly, non-weekly, or both, and left click.

Sort the rows by Lab number.



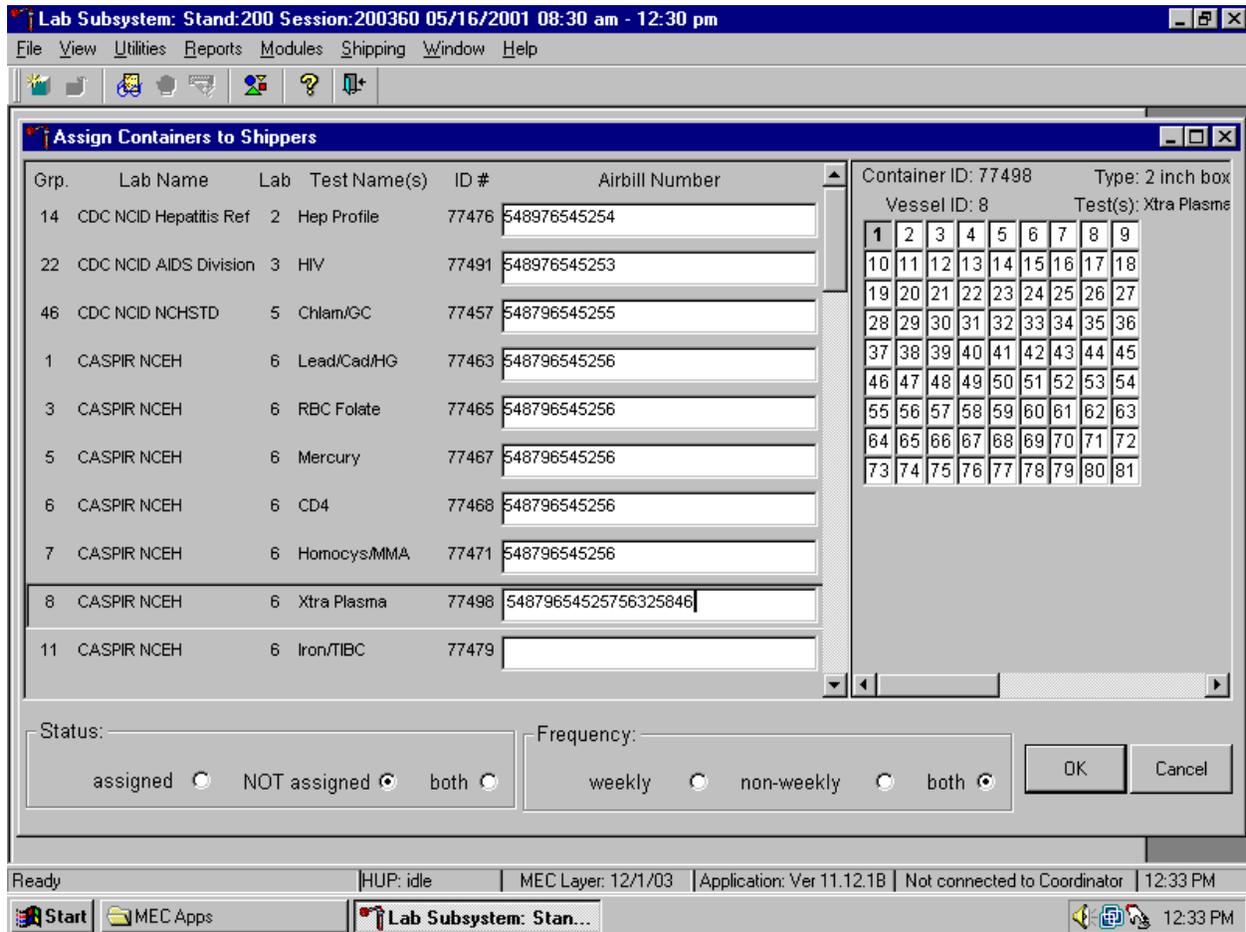
To sort the rows by lab number, use the mouse to direct the mouse arrow to the top header “Lab” and left click. All containers associated with a specific lab will be grouped together in ascending order.

Enter the airbill number into the Airbill Number text box.



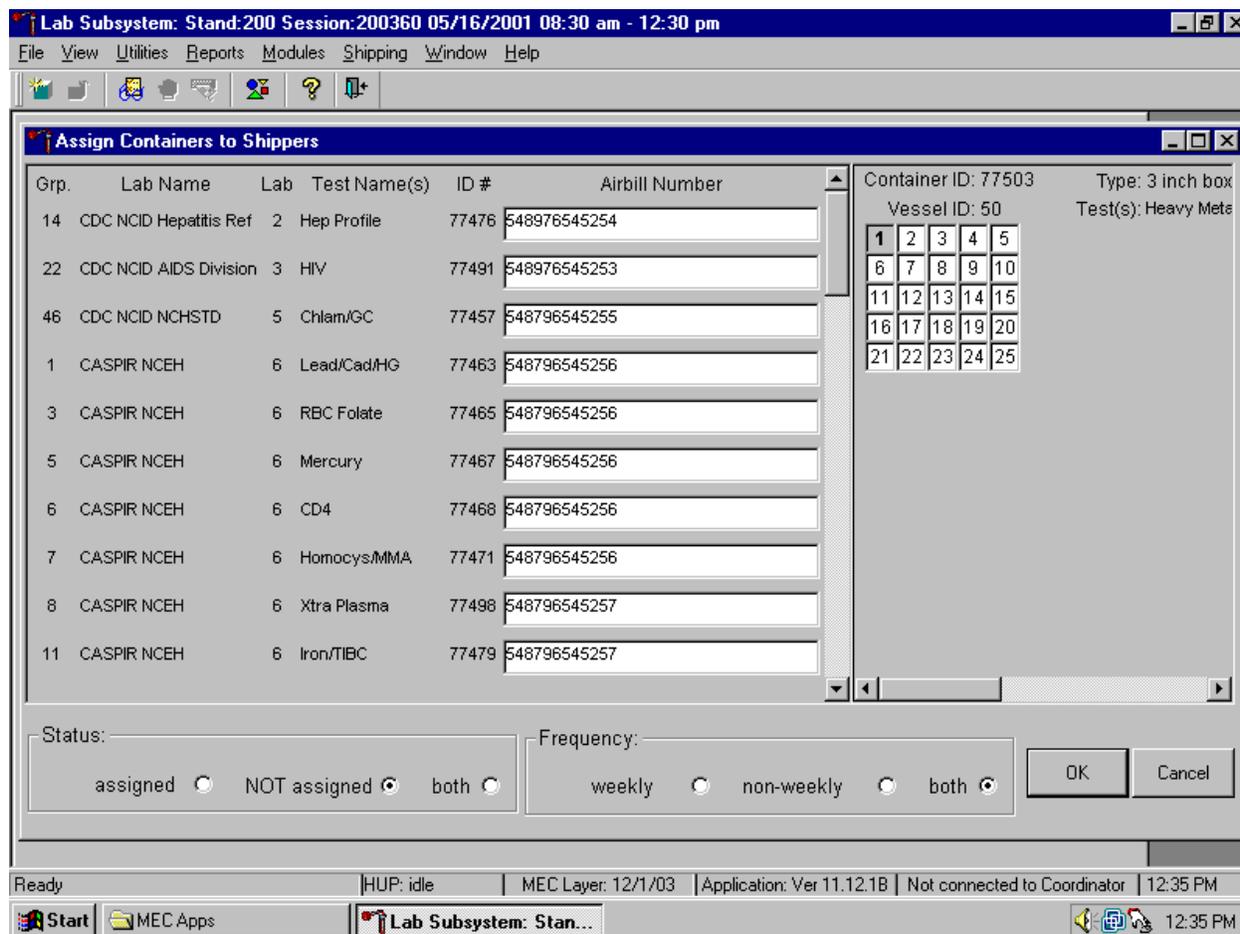
Place the cursor in the first Airbill Number text box. Use the bar code gun to scan the airbill number. The scanned number contains 20 extra digits. The actual 12-digit airbill number is embedded in the 32-digit scanned number. Select the [Tab] key to move to the next text box. Do not select the [Tab] key until the application has been allowed to enter the entire number into the text box. Once the [Tab] key is selected, the program edits the first airbill number to delete the extra numbers.

Continue the assignment process.



Continue scanning the bar codes and selecting the [Tab] key until all closed containers are assigned to airbills.

Complete the assignment process.



To record the assignment of containers to shippers, use the mouse to direct the mouse arrow to the OK button and left click. This step is required to save the information. To exit the {Assign Containers to Shippers} module without recording any assignments, use the mouse to direct the mouse arrow to the Cancel button and left click.

## 9.11 Create Shipping Manifests

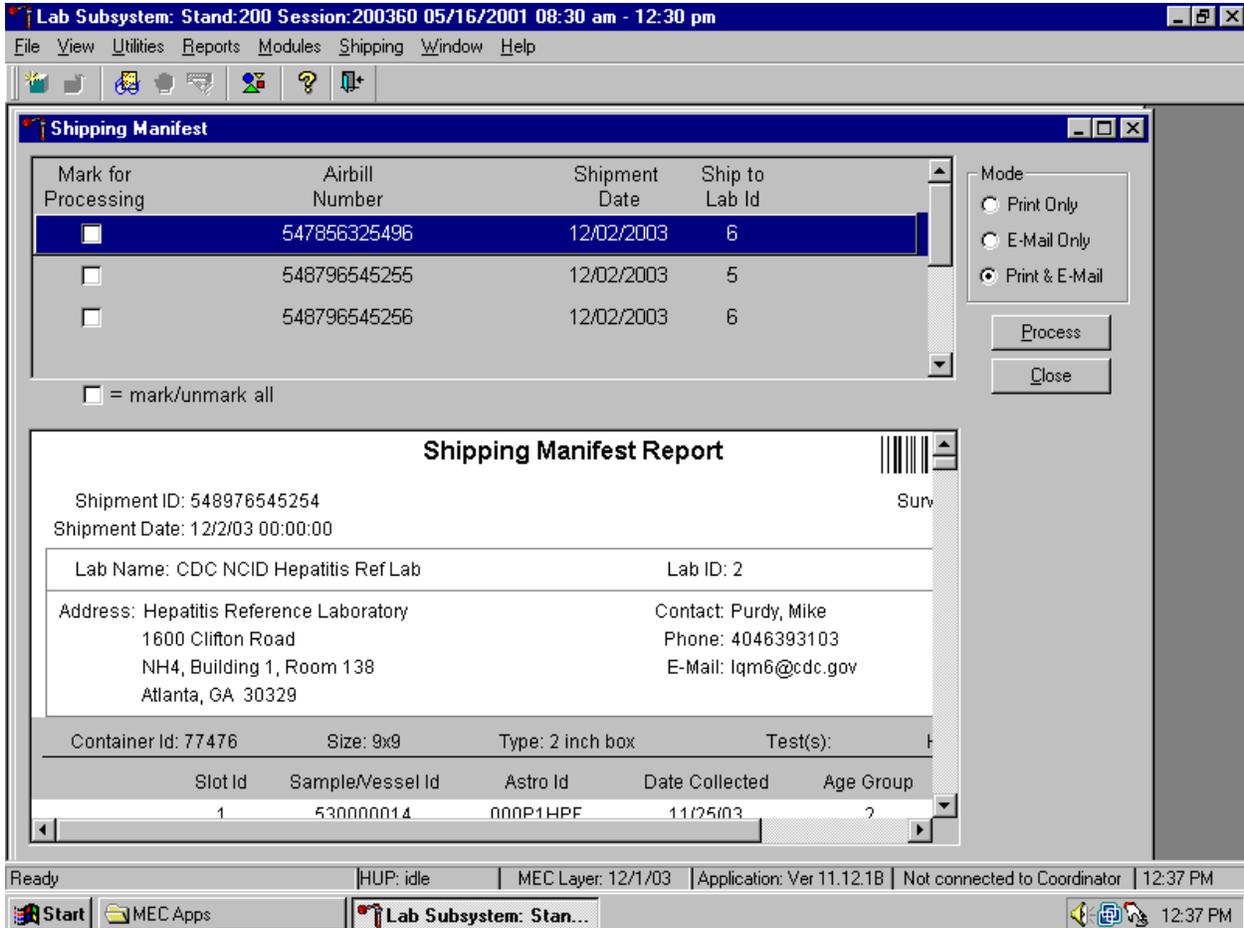
Each shipper must include a paper manifest, which lists the inventory of the specimens in the shipping boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed below to prepare the paper manifest and to send the electronic file.

Access the {Shipping Manifest} module.



To access the {Shipping Manifest} module, use the mouse to direct the mouse arrow to {Shipping} in the top menu bar, left click, drag the mouse arrow to {Shipping Manifest}, and left click or type [Alt] [R/r], [M/m].

A manifest window displays either after the {Shipping Manifest} module is accessed or after a positive response is recorded to the IC Informed Consent Exclusion window.



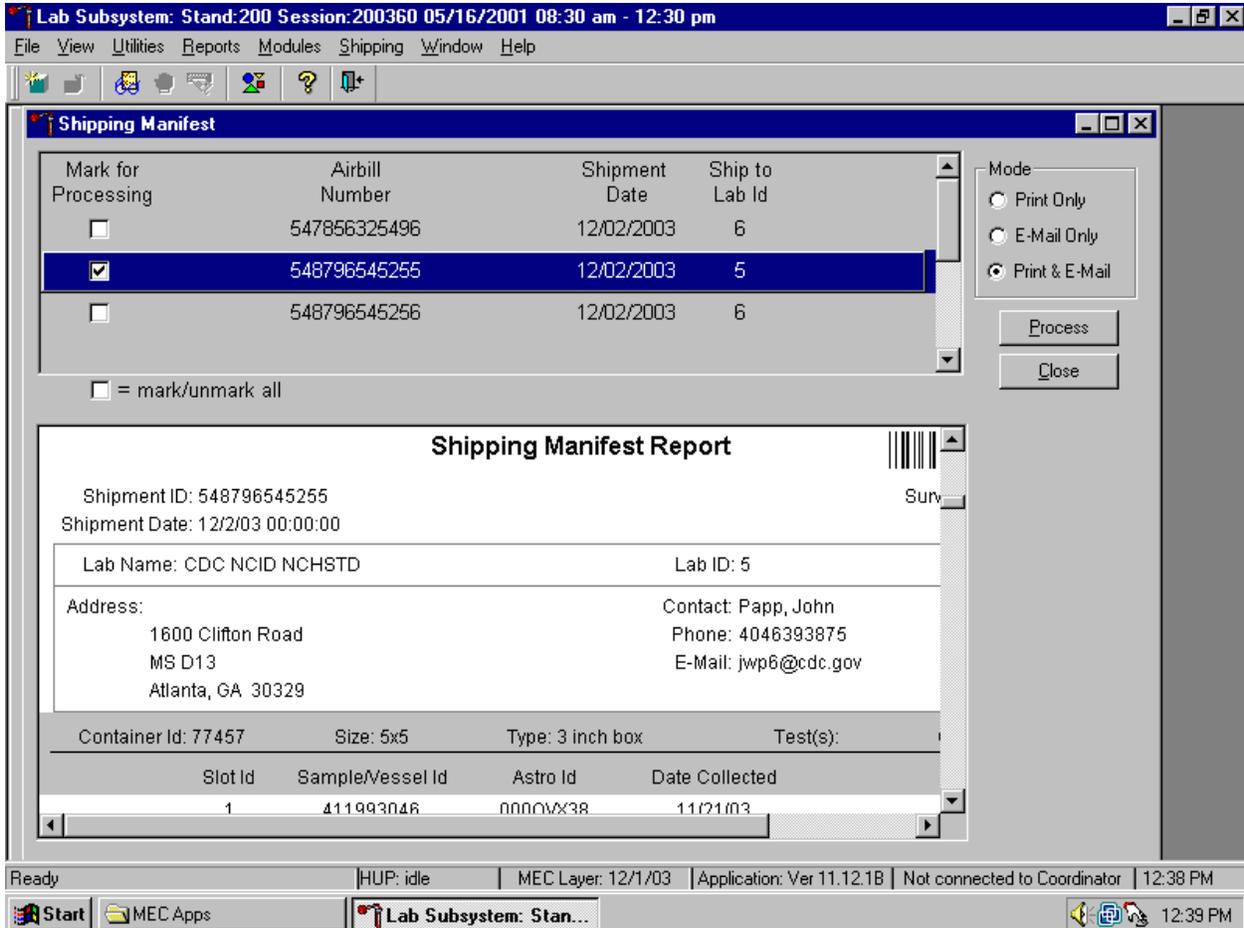
The upper portion of the Shipping Manifest Report contains one row for each Airbill assigned in the {Assign Container to Shipper} module. The row includes a processing checkbox, the Airbill Number, Shipment Date, and Ship to Lab ID, and one checkbox to mark or unmark all airbills.

The lower portion of the window includes the Shipment ID or airbill number, Shipment Date, Lab Name, Lab ID number, Address, Contact personnel, Survey Year, Container IDs associated with the shipment ID, container Size, container Type, Test(s) associated with the container, and a list by Slot ID of the Sample/Vessel ID, Astro ID, and Date Collected.

The right side of the window includes three radio buttons that correspond to three modes: Print Only, E-Mail Only, and Print and E-Mail, and two buttons: Process and Close.

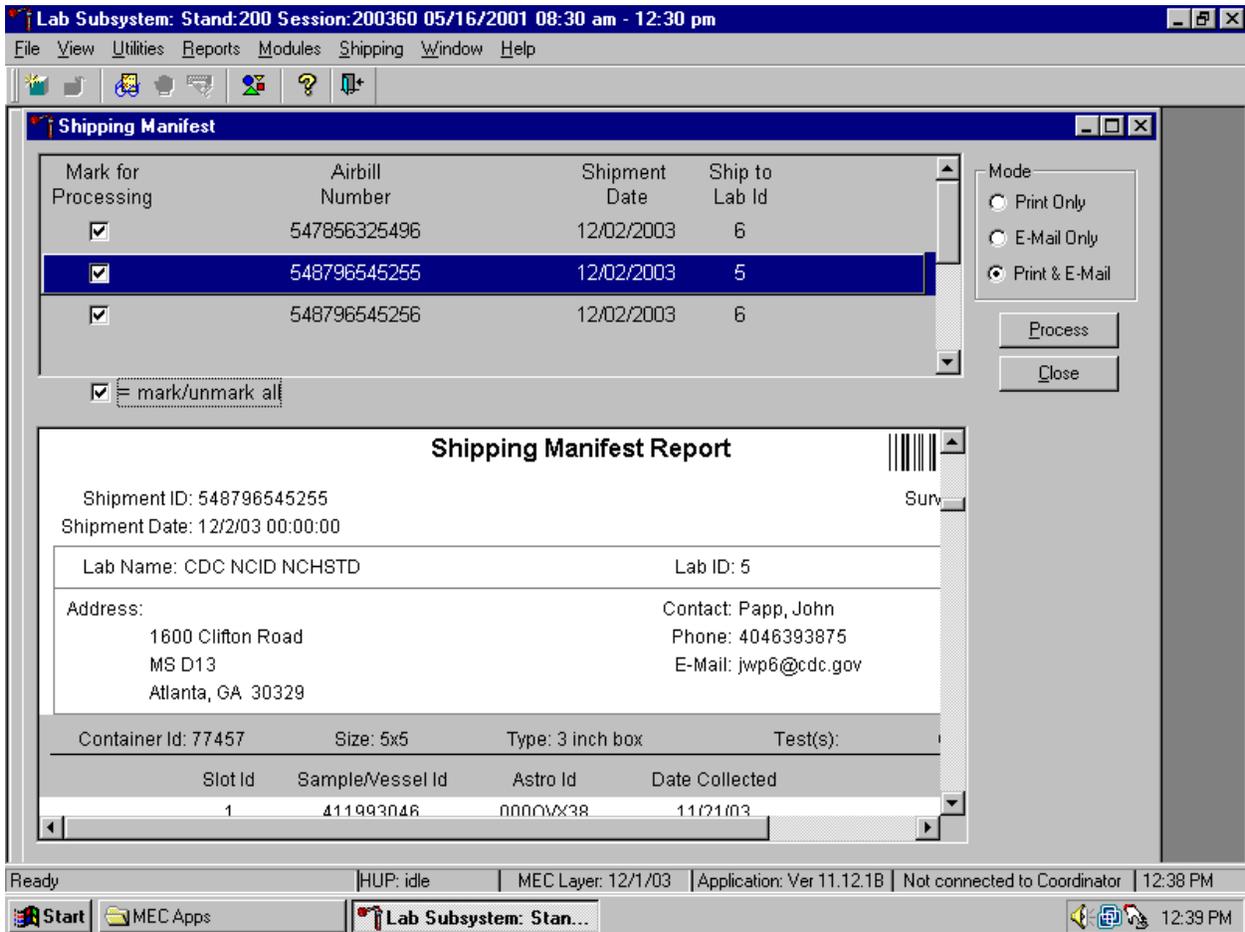
Set the Mode to “Print Only” to print the manifest(s), “E-mail Only” to send electronic files (manifests) to the analysis laboratory, or to “Print & E-mail” to print all manifests and send an electronic file to each laboratory. Select “Print & E-mail” as the default. Use “Print Only” and “E-mail Only” when necessary. To print the manifest and send the email file, use the mouse to direct the mouse arrow to the Process button and left click, or type [Shift] [P/p]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the Close button and left click, or type [Shift] [C/c]. Use the Reset button to clear the requirements and begin again.

Select one or more manifests by placing a checkmark in the Mark for Processing checkboxes.



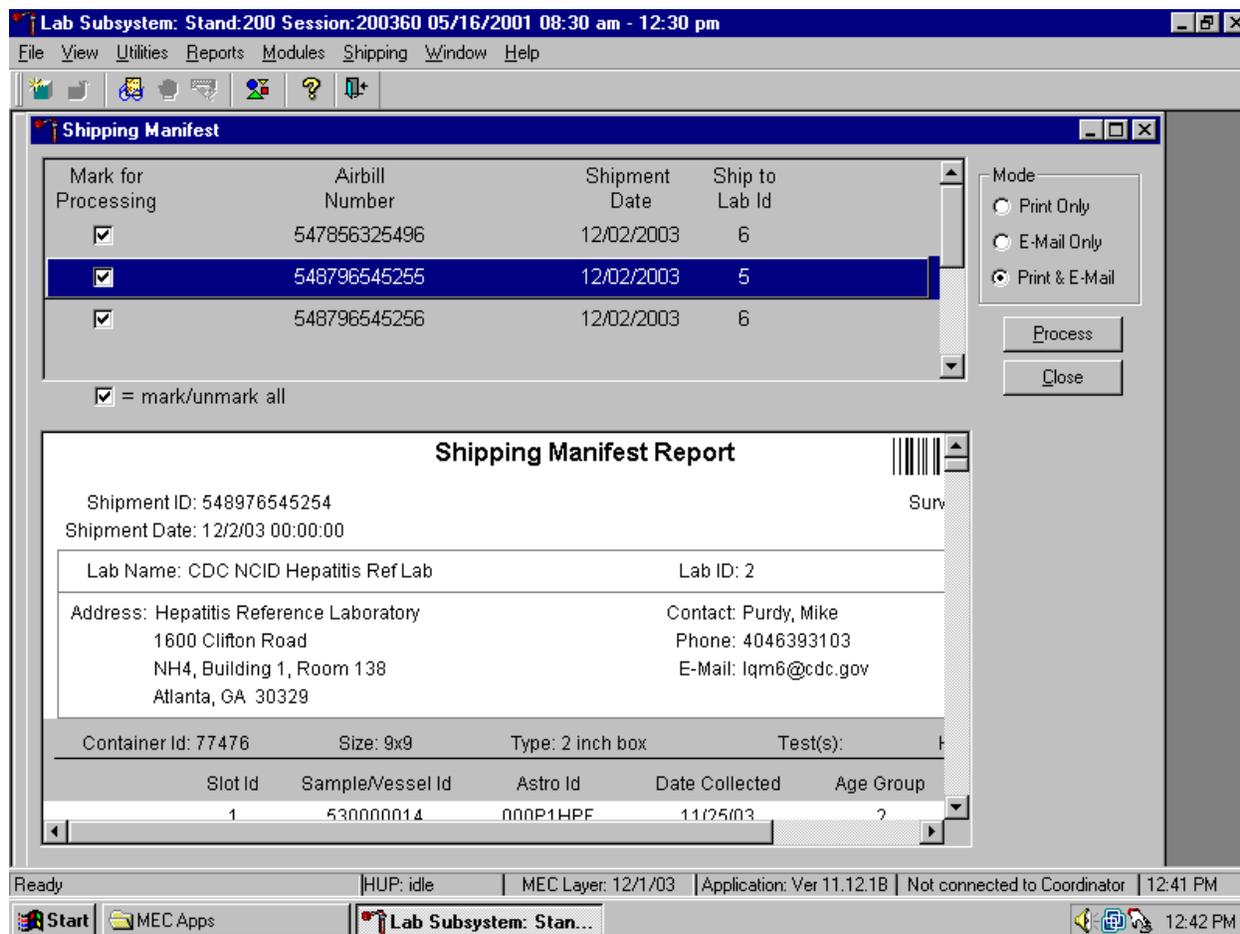
To select or mark one manifest for printing and e-mail, use the mouse to direct the mouse arrow to the checkbox and left click. Repeat this process to include other airbills. Use the scroll bar to display all existing airbills. The lower portion of the window updates to display only marked airbills.

Collectively mark or unmark all the airbills.



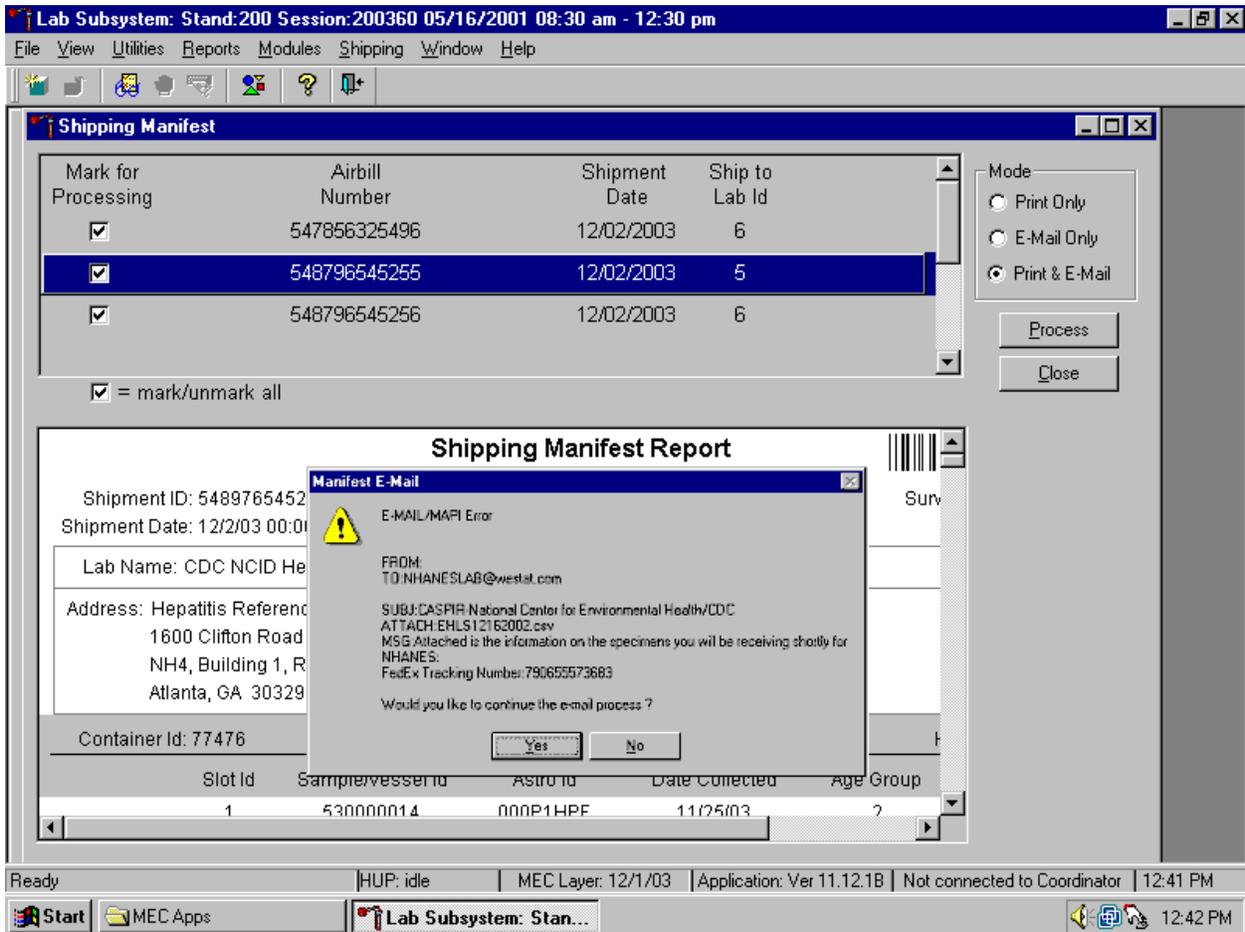
To collectively mark all the airbills, use the mouse to direct the mouse arrow to the mark/unmark all checkbox and left click. To collectively unmark all the airbills, use the mouse to direct the mouse arrow to the mark/unmark all checkbox and left click a second time. The lower portion of the screen will update to display the marked airbills.

Print the manifests(s), E-Mail the manifest(s) or Print and E-mail the manifest(s).



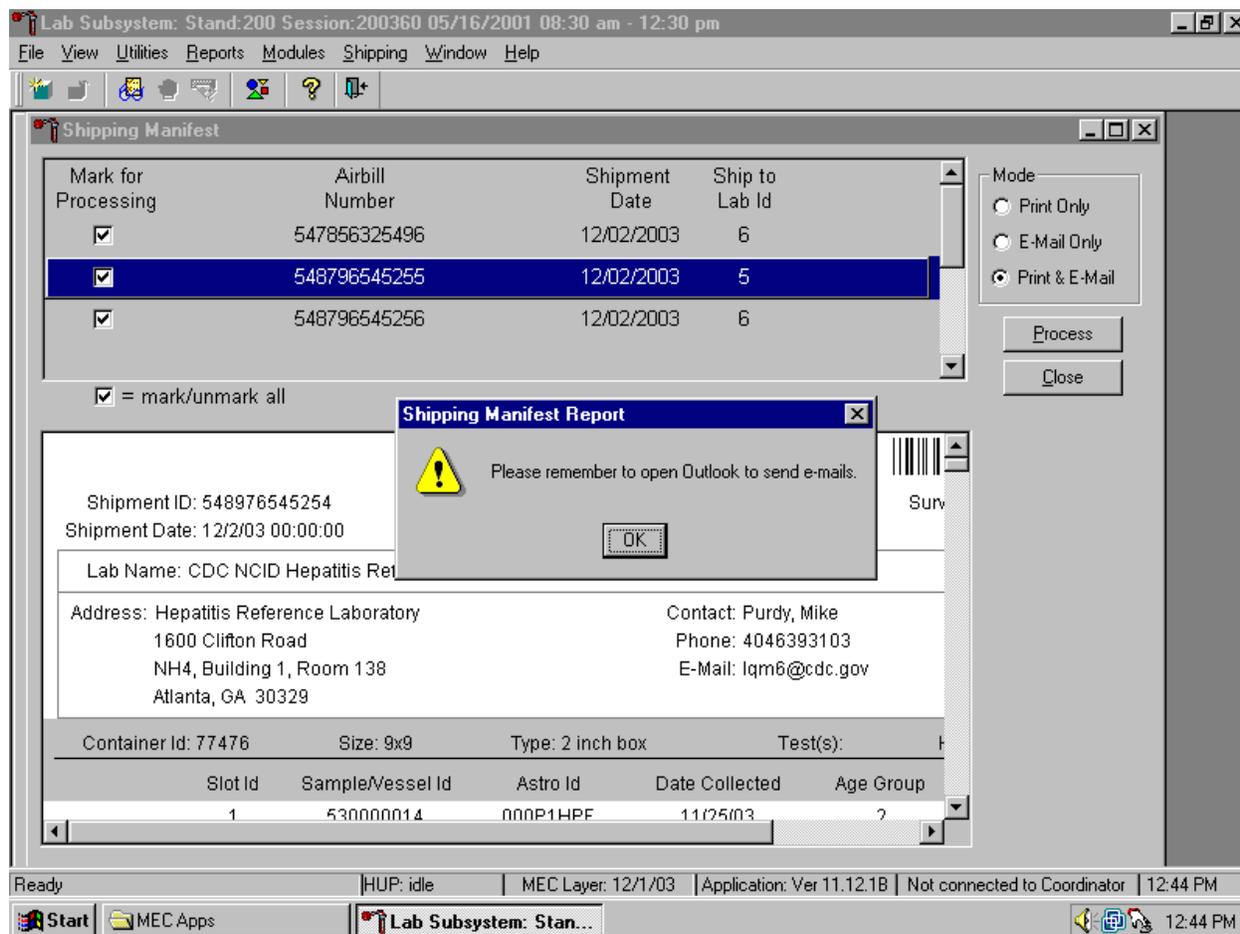
To print the manifest and send the email file, use the mouse to direct the mouse arrow to the Process button and left click, or type [Shift] [P/p]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the Close button and left click, or type [Shift] [C/c].

If the modem is not operating, a Manifest E-mail warning message text box displays.



Report this message to the data manager. Review the information in the warning text box. To continue to process the paper manifests, use the mouse to direct the mouse arrow to the Yes button and left click, or type [Y/y] or select [Enter]. To quit the manifest process, use the mouse to direct the mouse arrow to the No button and left click, or type [N/n].

After the Close button is selected, a Shipping Manifest Report message text box displays.



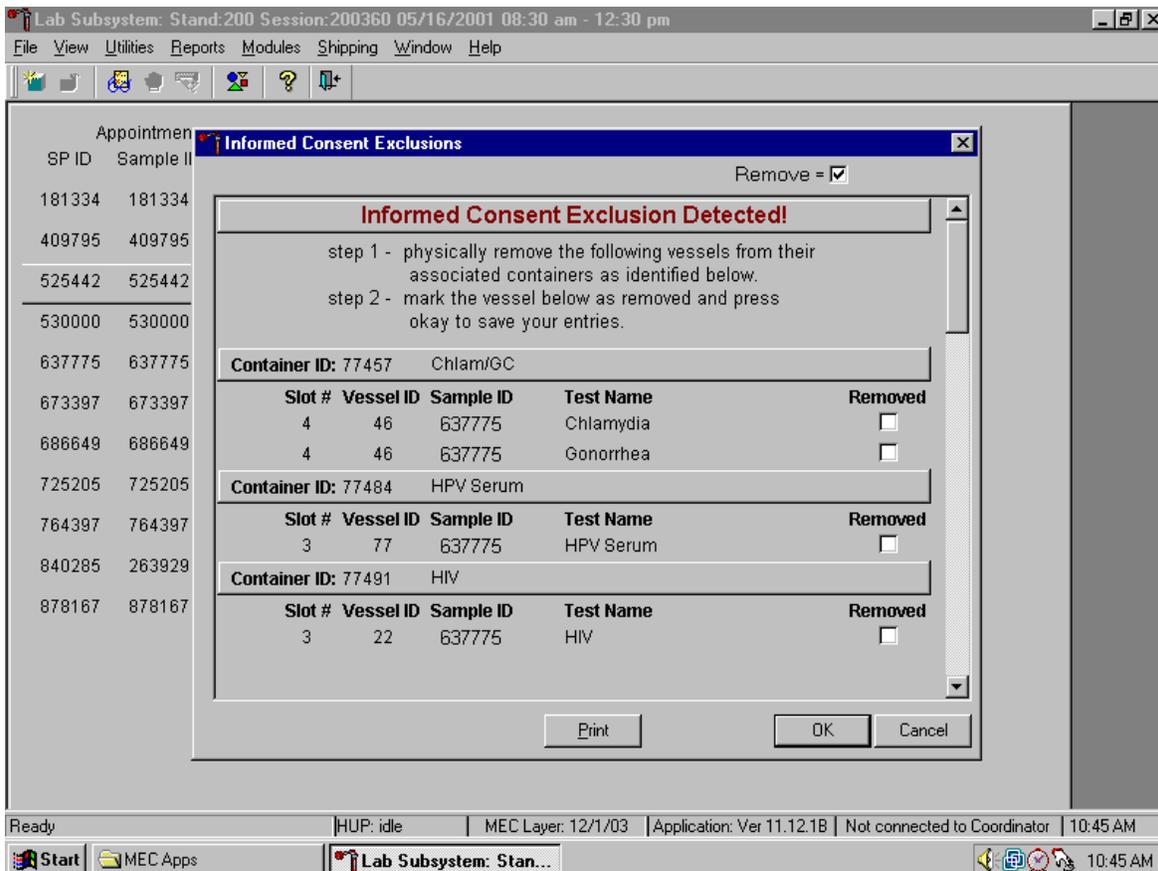
It is essential to open the Outlook email program to send the electronic files each time a manifest is created and a package is sent. It is the shipping technologist's responsibility to open the Outlook program immediately after shipping containers. Opening Outlook sends an email to each laboratory that receives a shipment. The email contains critical information and the contract laboratories rely on the electronic file contained in the email to prepare in advance for the shipment. Laboratories also use the airbill number in the email to track the shipment with FedEx. The data manager can explain the procedure to access and open Outlook. Do not transmit or send the electronic files more than once.

To acknowledge the reminder and to remove the message box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

## 9.12 Informed Consent Exclusions

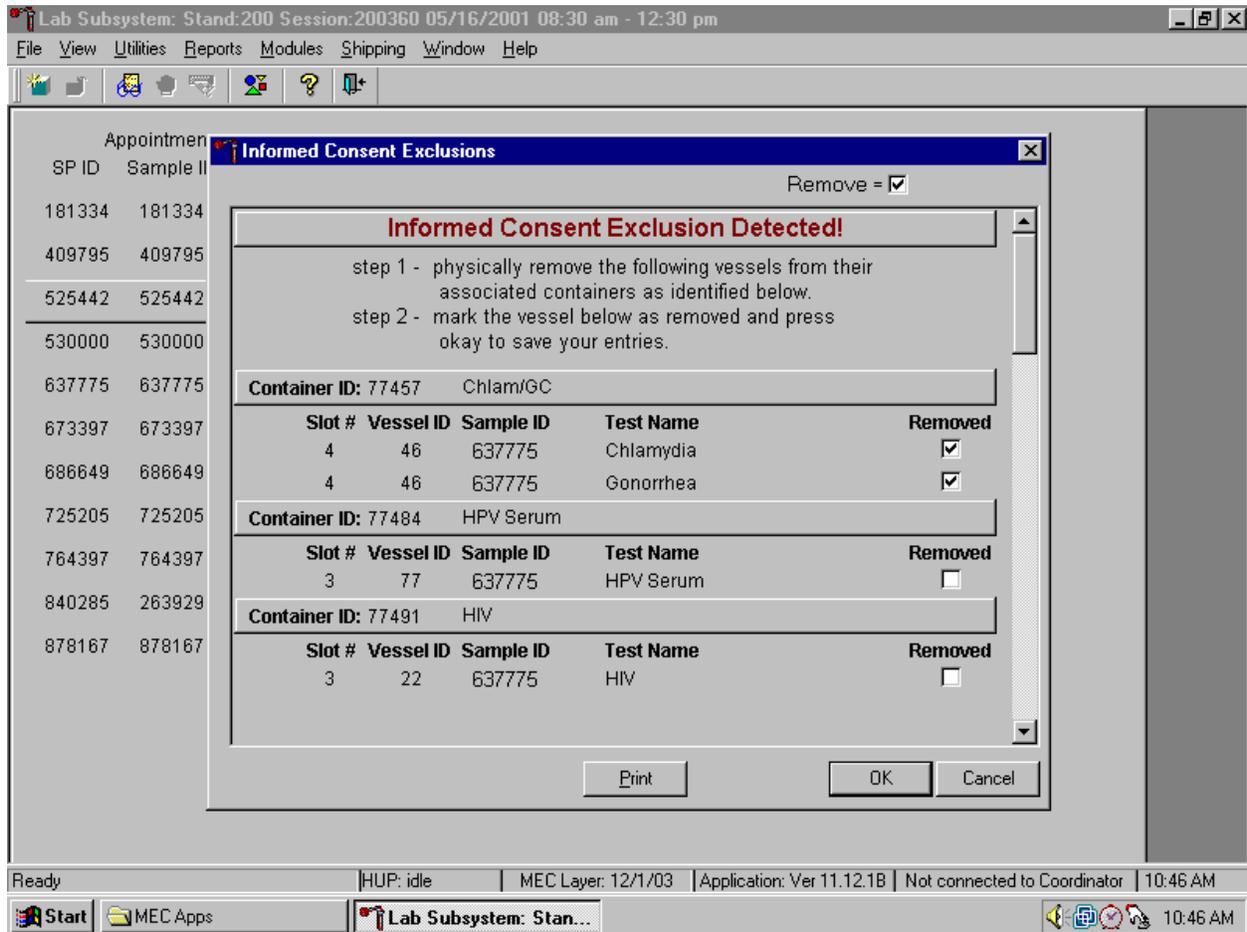
The Informed Consent Exclusions window displays either when the {Close Container} or {Shipping Manifest} module is accessed. It displays the following:

1. If SPs initially signed their consent form thereby agreeing to have their samples tested for vaginosis, trichomonas, HPV, PSA, STD testing;
2. And/or they consent to have their vessels stored for future research;
3. And they subsequently revoke either consent;
4. And the associated vessels have already been processed.



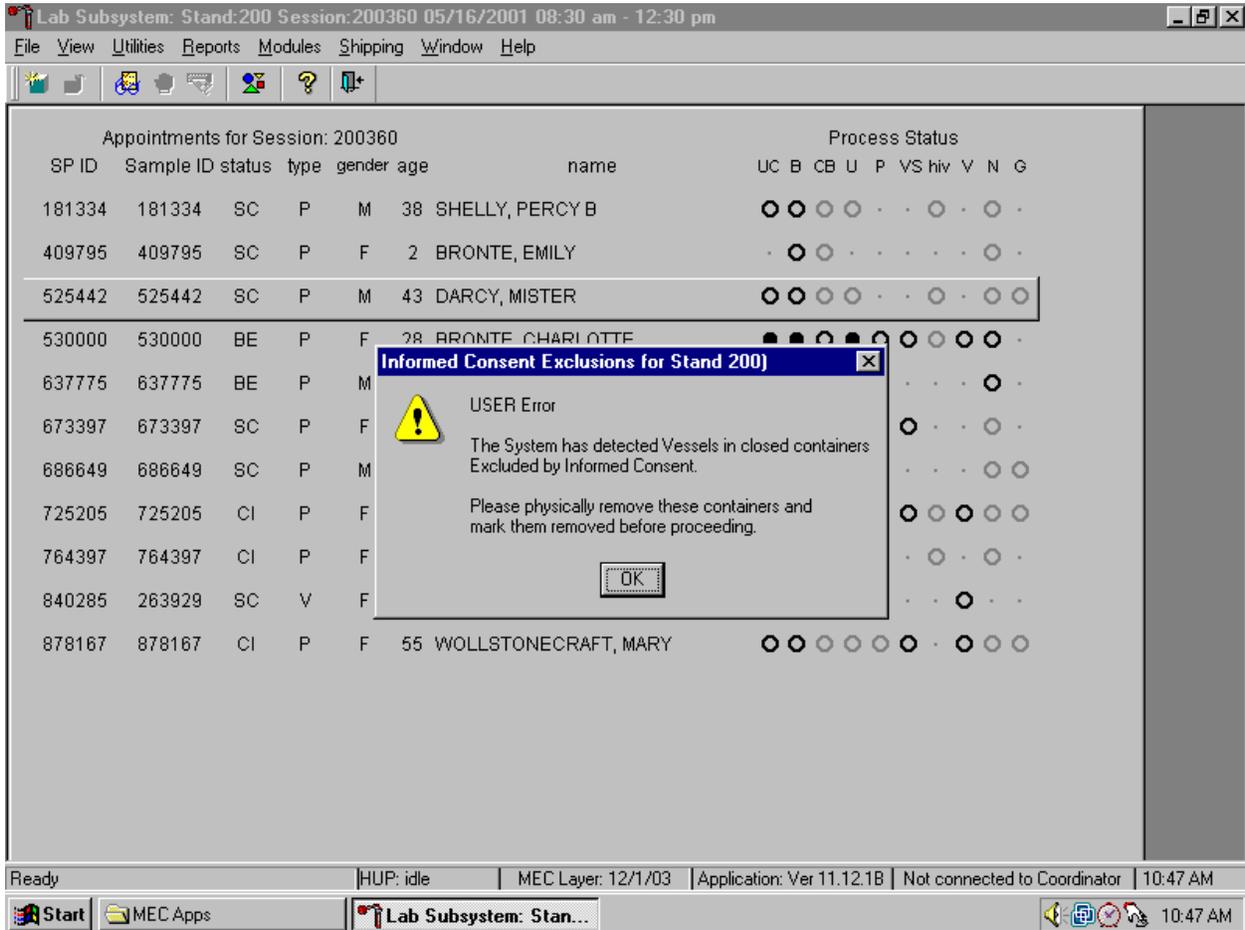
These vessels must be removed from the container and destroyed before the container is shipped. Follow the exact instructions indicated in the window – “Physically remove the following vessels from their associated containers as identified below.”

Affirm the actions taken to resolve these exclusions.



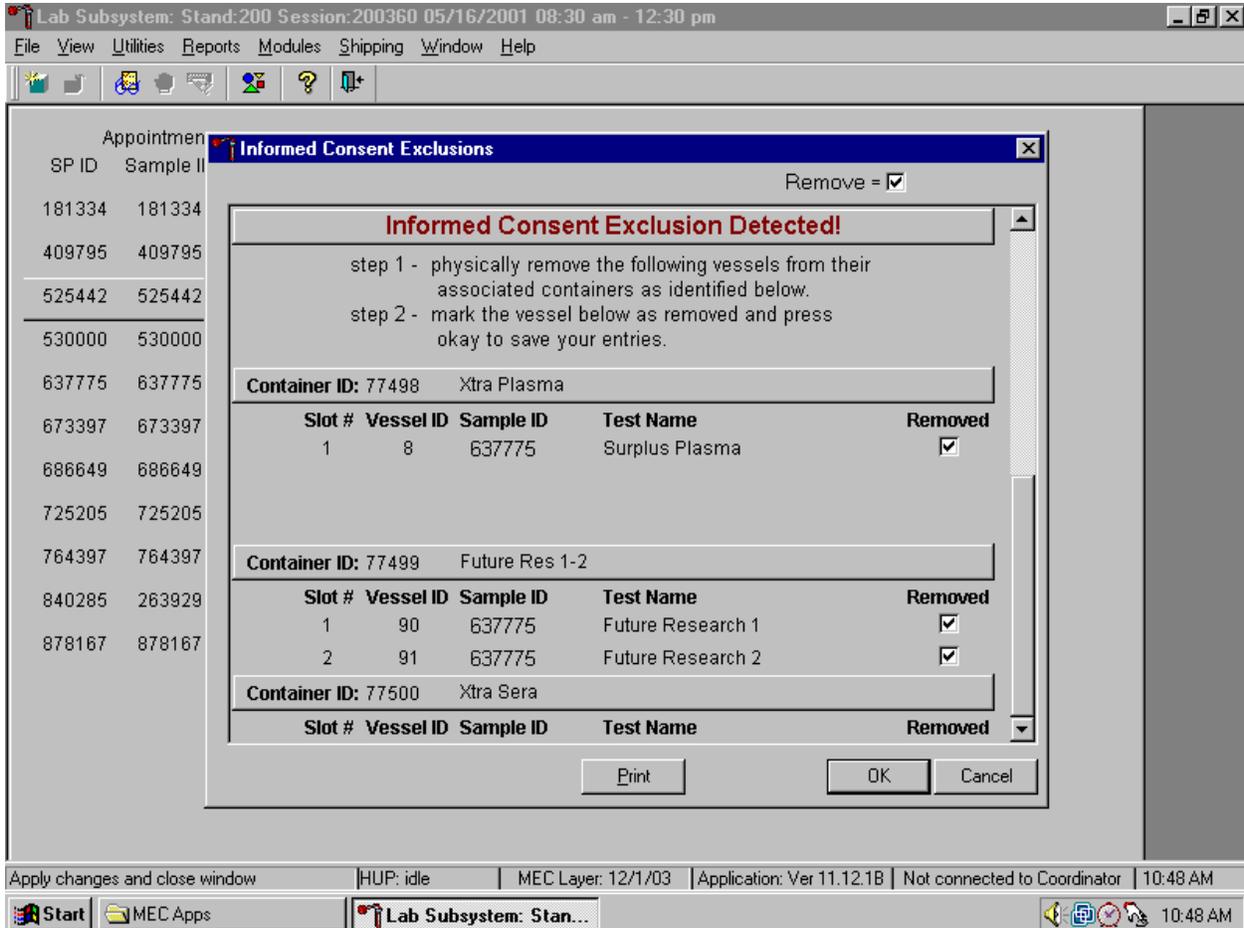
After following the exact instructions displayed in the window, record the actions taken to resolve the exclusions. To record these actions, use the mouse to direct the mouse arrow to the Removed check boxes and left click to insert a check mark. To record these actions in the database and to close the Informed Consent Exclusion window, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To remove the window and exit without saving the actions to the database, use the mouse to direct the mouse arrow to Cancel button and left click.

If all the vessels are not marked then a Warning popup box displays.



The system tracks each vessel in the {Informed Consent Exclusion} module to ensure that every vessel is marked. Follow the instructions in the popup box, "Please physically remove these containers, and mark them before proceeding. To acknowledge the message, use the mouse to direct the mouse arrow to the OK button and left click, or type [Enter].

If all the vessels were not marked, then access the {Informed Consent Exclusion} module a second time.



Follow the exact instructions displayed in the window, and then record the actions taken to resolve the exclusions. To record these actions, use the mouse to direct the mouse arrow to the Removed check boxes and left click to insert a check mark. To record these actions in the database and to close the Informed Consent Exclusion window, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

### **9.13 Packing Procedure for the Shippers**

Most of the shipments require dry ice to keep the specimens frozen during shipment. Some shipments require reusable refrigerant packs to keep specimens cold but not frozen. Store reusable refrigerant packs in the freezers. (Distribute the refrigerant packs across all freezers.) It is the chief medical technologist's responsibility to arrange for delivery of dry ice pellets or blocks for shipping specimens. Use sliced blocks whenever possible since these sublimate less than pellets. Well in advance of a scheduled shipment, the shipping technologist estimates how much dry ice to order for the shipment and informs the MEC manager. Store the dry ice in extra shipping containers. When handling dry ice, wear cryo gloves to avoid burning hands. Also, wear an eye shield when filling bags with ice chips or breaking blocks into chunks. Use the scale to ensure that each shipper has the required amount of dry ice. Exhibit 9-3 is a list of all contract laboratory addresses.

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. A complete description of these regulations is contained in Appendix A. The Federal regulations include the following:

#### For Liquids

- The primary receptacle(s) must be leakproof and must not contain more than 500 mL.
- There must be absorbent material placed between the primary and secondary packaging. If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them. The absorbent material must be in sufficient quantity to absorb the entire contents of the primary receptacles and there must be a secondary packaging, which must be leakproof.
- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40°C to +55°C (-40°F to 130°F).
- The outer packaging must not contain more than 4 L.

Exhibit 9-3. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
AC Diag Robert M. Hoffman, Ph.D. 7917 Ostrow Street San Diego, CA 92111 858-654-2555		Frozen	Robert M. Hoffman, Ph.D. 858-654-2555
Calif Dept of Health Services Attn: Cynthia Cossen 850 Marina Bay Parkway Richmond, CA 94804 510-307-8590		Frozen	Cynthia Cossen 510-307-8590
602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-339-5942	3/RBC Folate 5/Mercury 6/CD4 88/Acrylamide 7/Homocys/MMA 8/Xtra Plasma 70/Vitamin D 12/Fol/B12 99/Fer/TfR 17/Cotinine 79/Vitamin C 11/Iron/TIBC 15/Vit A/E/Car 32-40/Xtra Sera 90/91 Future Res1/2 92/93 Future Res3/4 69/Urn Iodine 86/Spc Arsenic 62/Urn Merc 50/Heavy Metal 51-52/Xtra Urine	Frozen	Richard Frome 770-339-5942
CASPIR/Dr. Courtney D. Sandau Attn: Dr. Courtney D. Sandau 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-4299	66/PAH	Frozen	Dr. Courtney D. Sandau 770-488-4299

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
CASPIR/Dr. Wayman Turner Attn: Cheryl McClure 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-7883	29/89/Pesis Pest	Frozen	Cheryl McClure 770-488-7883
CDC Air Toxicant Branch Attn: Ben Blount 4770 Buford highway NE Building 17, Loading Dock Atlanta, GA 30341 770-488-7962	54/VOC Blood 56/VOC Water	Refrigerated	Dr. Ben Blount 770-488-7962
CDC DASTLR/NCID Bldg 1, Room 3318 1600 Clifton Road, NE Atlanta, GA 30333 404-639-3224	74/Syphilis	Frozen	Victoria Pope, PhD 404-639-3224
CDC Data and Spec Handling Attn: Sigrid McAllister 1600 Clifton Road NE., MS G12 CLFT 4 B35 Atlanta, GA 30333 404-639-3241	76/MRSA	Refrigerated	Dr. Sigrid McAllister 404-639-3510
CDC DPD Attn: Marianna Wilson 4470 Buford Highway Bldg. 109, Rm 1304, MS F36 Atlanta, GA 30341 770 488-4431	20/Toxo	Frozen	Marianna Wilson 770-488-4331
CDC Dr. Antonia Calafat Attn: Dr. Antonia Calafat 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341-3724 770-488-7891	65/Urn Phytoestro 67/Phthalates	Frozen	
CDC/Dr. Dana Barr Attn: Dr Dana Barr 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341-3724 770-488-4598	48/Prior Pest 49/Organophos	Frozen	Dr Dana Barr 770-488-4598

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
CDC NCID AIDS Division Attn: Faye Cowart 1600 Clifton Road NE Building 1, Room 2367 Atlanta, GA 30333 404-639-3174	22/HIV	Frozen	Faye Cowert 404-639-3174
CDC NCID AIDS Division (R) Attn: Faye Cowert 1600 Clifton Road NE Building 1, Room 2367 Atlanta, GA 30333 404-639-3174	53/HIV Urine	Refrigerated	Faye Cowert 404-639-3174
CDC NCID Hepatitis Ref Lab Attn: Ed Simard Code NH4 1600 Clifton Road NE Building 1, Room 1389 Atlanta, GA 30329 404-371-5451	14/Hep Profile 87/Hepatitis ab	Frozen	Ed Simard 404-371-5451
CDC NCID NCHSTD Attn: Carol Farshy 1600 Clifton Road NE MS D13 Atlanta, GA 30329 404-639-2870	46/Chlam/GC	Frozen	Carol Farshy 404-639-2870
CDC/Ruth Ann Tucker Attn: Ruth Ann Tucker 1600 Clifton Road, MSG41 Atlanta, GA 30333 404-639-2183	77/HPV Serum	Frozen	Ruth Ann Tucker 404-639-2183
CDC/Ruth Ann Tucker (RT) Attn: Ruth Ann Tucker 1600 Clifton Road, MSG41 Atlanta, GA 30333 404-639-2183	78/HPV	Room Temperature	Ruth Ann Tucker 404-639-2183
Collaborative Lab Services Attn: Sue Vanness 1005 Pennsylvania Suite 102 Ottumwa, Iowa 52501 641 684-4621		Frozen	

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
Collaborative Lab Services (R) Attn: Sue Vanness 1005 Pennsylvania Suite 102 Ottumwa, Iowa 52501 641 684-4621		Refrigerated	
Emory University Attn: Dr. Francis Lee 46 Armstrong Street SE Room 219 Atlanta, GA 30303 404-616-4997	24/HSV	Frozen	Dr. Francis Lee Phone: 404-616-6229
Attn: Donna Virgil 600 North Wolfe Street Blaylock 1379 Baltimore, MD 21287 410-614-1145			410-614-1145
Magee-Womens Hospital (R) Clin Micro Lab Room 4680 300 Halket Street Pittsburgh, PA 15213 412-641-4104	72/Vaginosis 73/T vaginalis	Refrigerated	Dr. Jeanne Jordan 412-641-4104
NYS DOH/Wadsworth CTR L&R Attn: Patrick Parsons, PhD. ESP P1 South Dock J3 Albany, NY 12237 518-474-5475	2/Ery Proto 26/Selenium	Frozen	
Attn: Sandy Rhoda Dept of Env Services 3223 Eden Avenue Cincinnati, OH 45267-0056 513-558-1705	61/W Lead Dust		513-558-1705
Univ of Minnesota Attn: Susan Kupcho 515 Delaware St. S.E. Room 13-219 - MOOS Tower Minneapolis, MN 55455 612-624-6153	45/Alb/Creat	Frozen	Susan Kupcho 612-624-6153

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
Univ of Missouri Attn: Hsiao-Mei Wiedmeyer Department of Child Health One Hospital Drive Room M770 Columbia, MO 65212 573-882-2705	9/Glucose 23/Insul/Cpep	Frozen	Hsiao-Mei Wiedmeyer 573-882-2705
Univ of Missouri (R) Attn: Hsiao-Mei Wiedmeyer Department of Child Health One Hospital Drive Room M770 Columbia, MO 65212 573-882-2705	4/Glycohem	Refrigerated	573-882-2705
University of Washington Attn: Phyllis Daum 1959 NE. Pacific Avenue Room NW 176 Seattle, WA 98195 206-548-6149	13/CRP 19/Bn Alk Phos 75/PSA 94/PTH	Frozen	Phyllis Daum 206-548-6149
Brian Grawburg Craft Technologies, Inc. 4344 Frank Price Church Road Wilson, NC 27893-0923 252-206-7071	16/Vit A/E/Car	Frozen	Brian Grawburg 252-206-7071

For Solids

- The primary receptacles must be slit proof and must not contain more than 500 g.
- If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them and there must be a secondary packaging, which must be leakproof.
- The outer packaging must not contain more than 4 kg.

For Liquids and Solids

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

- Each completed package must be certified according to the regulations.
- Packages must have one side with dimensions of not less than 100 mm x 100 mm (4 in x 4 in) or packages must be in an overpack that has one side with dimensions of not less than 100 mm x 100 mm (4 in x 4 in).
- A Shipper's Declaration for Dangerous Goods is not required.
- An operator must report dangerous goods accidents or incidents to the appropriate authorities of the state of the operator and the state in which the accident or incident occurred, in accordance with the reporting requirements of those appropriate authorities.

The majority of diagnostic specimens can and must be packaged according to the following guidelines.

- **Substances shipped at ambient temperature or higher.** Primary receptacles include those of glass, metal, or plastic. Positive means of ensuring a leak-proof seal, such as heat seal, skirted stopper, or metal crimp seal must be provided. If screw caps are used, these must be reinforced with adhesive tape.
- **Substances shipped refrigerated or frozen (wet ice, prefrozen packs, dry ice (solid carbon dioxide).** Ice, dry ice (solid carbon dioxide), or other refrigerant must be placed outside the secondary packaging(s) or alternatively in an overpack with one or more completed packages. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after ice or dry ice has been dissipated. If ice is used, the packaging must be leakproof. If dry ice (solid carbon dioxide) is used, the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

Each package must be marked with each of the following:

- The proper shipping name of the contents and the corresponding UN numbers (dry ice is UN 1845).
- The full name and address of the shipper and the consignee.
- The NET Quantity of dry ice contained in each package or overpack must be shown. The quantity must be marked on each package or overpack adjacent to the UN number and Proper Shipping Name.
- Packages containing "Diagnostic Specimens": "DIAGNOSTIC SPECIMENS."
- Each package must also be marked to indicate that the shipper has determined that the packaging meets the applicable air transport requirements. The marking must be

durable, legible, and of such a size relative to the package as to be readily visible. The marking must include the symbol consisting of an aircraft within a circle and may include the words “Air Eligible.” The marking must be applied adjacent to the words “DIAGNOSTIC SPECIMENS.”

The hazard label is specified for each substance. All packages must bear the appropriate hazard label. The label identifying the primary hazard of the dangerous goods must bear the class number in the bottom corner of the label. For Class 9 goods (dry ice), the package is required to bear the Class 9 “Miscellaneous” dangerous goods label.

An “air waybill” must be completed for each consignment of dangerous goods. Dry ice shipments prepared in accordance with IATA regulations do not require a Shipper’s Declaration (FedEx page 79 F.).

For each shipment containing dangerous goods the shipper must do the following;

- Use only the correct form in the correct manner;
- Complete the form accurately and legibly; and
- Ensure that the shipment has been prepared in accordance with IATA regulations.

Each air waybill must include the following:

- Full name, address, telephone number, and ZIP code of the shipper;
- Full name, address, telephone number, and ZIP code of the recipient;
- The dry ice box must be checked and the dry ice information must be entered under the Special Handling section on the airbill; and
- Net quantity per package (kg) of dry ice.

### **9.13.1 Pack Boxed Specimens**

Store the blood and urine vessels in 2-, 3-, and 5-inch storage boxes. Separate the vessels with cardboard grids or foam inserts. Secure the top of the box to the bottom with a rubber band. Place the box in a pressure vessel, add one absorbent paper, and seal the pressure vessel.

Ship the vessels to the addresses listed in the Contract Laboratory addresses (see Exhibit 9-3).

### **9.13.2 Pack Medium Shipping Containers for Frozen Shipment**

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the shipper on the scale and tare.
- Place a layer 3-inches thick or at least 15 pounds of chipped dry ice or dry ice slabs in the bottom of a medium Styrofoam shipper.
- Place a single layer of newsprint between the box and the dry ice.
- Place the sealed pressure vessels containing the boxes on top of the dry ice.
- Pack the sides with crumbled newsprint.
- Tare the scale.
- Place enough chipped dry ice or dry ice slabs on top so that the Styrofoam container is filled with dry ice to 1/4" below the rim or add a minimum of another 15 pounds of dry ice.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and return preprinted label on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume the medium shipper weighs approximately 30 pounds.
- Record the weight of the dry ice (30 pounds for a medium shipper) on the FedEx Class 9 label.
- Secure the shipper with tape.
- Attach the airbill.

### **9.13.3 Pack Small Shipping Containers for Frozen Shipment**

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the shipper on the scale and tare.
- Place a layer 3-inches thick or at least 10 pounds of chipped dry ice or dry ice slabs in the bottom of a medium Styrofoam shipper.
- Place a single layer of newsprint between the box and the dry ice.
- Place the sealed pressure vessels containing the boxes on top of the dry ice.
- Pack the sides with crumbled newsprint.
- Tare the scale.
- Place enough chipped dry ice or dry ice slabs on top so that the Styrofoam container is filled with dry ice to 1/4" below the rim or add a minimum of another 10 pounds of dry ice.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and return preprinted label on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume the medium shipper weighs approximately 30 pounds.
- Record the weight of the dry ice (35 pounds for a small shipper) on the FedEx Class 9 label.
- Secure the shipper with tape.
- Attach the airbill.

### **9.13.4 Pack Medium Shipping Container for Refrigerated Shipment**

Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers.

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Seal the 9 x 12 zip closable plastic bag or the pressure vessel containing the boxes.
- Place at least two large frozen refrigerant packs in the bottom of a shipper.
- Place the sealed plastic bag containing the swabs or the pressure vessel containing the boxes on top of the refrigerant pack.
- Pack the sides with crumbled newsprint.
- Place two additional refrigerant packs on top of the container(s).
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place the appropriate shipping manifest and one return FedEx preprinted airbill into a 9 x 12 plastic bag and seal.
- Place the plastic envelope containing the appropriate shipping manifest and one FedEx preprinted airbill on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

### **9.13.5 Pack a Medium Shipper for Ambient Temperature Shipment**

Ship lead dust specimens at ambient temperature.

- Pack the bottom of the Styrofoam shipper with crumbled newsprint.
- Place the sealed boxes on top of the newsprint.
- Pack the sides with crumbled newsprint.
- Place more crumpled newsprint on top so that the shipper is filled to 1/4" below the rim.
- Place a plastic envelope containing the appropriate shipping manifest and the preprinted FedEx airbill on top of the Styrofoam lid.

- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the envelope (10 pounds) on the appropriate FedEx label.

### **9.13.6 Label Shippers**

For all destinations, include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 4 weeks of the stand. Include a preprinted FedEx return airbill label with the address for the concurrent stand during the last 2 weeks of the stand.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

1. Label shippers containing dry ice with a “Keep Frozen” label and a FedEx Class 9 – Miscellaneous Dangerous Goods label.
2. Label shippers containing refrigerant packs with a “Refrigerate” label.
3. Label shippers containing whole blood, serum, plasma, or urine with a “Biohazard” label.
4. All shippers with a DIAGNOSTIC SPECIMENS label.
5. All shippers with an Air Eligible label. The marking must be applied adjacent to the words DIAGNOSTIC SPECIMENS.
6. Complete the section of the FedEx label that requests the weight of the contents of the shipper, and if applicable, the section that requests the weight of the dry ice contained in the shipper.
7. Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
8. Add one additional strip of tape across the FedEx pouch.

## **9.14 Container Protocol and Weekly Shipping List**

Exhibit 9-4 illustrates the Container protocol and Exhibit 9-5 illustrates the FedEx weekly shipping list. Use the container protocol as an aid at the start of each stand when opening new containers. Use the weekly FedEx shipping list as an aid when creating airbills in FedEx Ship Manager.

Exhibit 9-4. Container protocol

**NHANES 2004 CONTAINER PROTOCOL**

Vessel ID	Test ID/Name	Sample Type	Vessel Type	Vessel Storage	Storage Unit
1	Lead/Cad/HG	WB	2 mL	9 x 9 two inch box	Freezer #1
2	Ery Proto	WB	2 mL	9 x 9 two inch box	Freezer #1
3	RBC Folate	WB	2 mL	9 x 9 two inch box	Freezer #1
4	Glycohem	WB	2-mL	9 x 9 two inch box	Refrigerator # 1
5	Mercury	WB	2 mL	9 x 9 two inch box	Freezer #1
6	CD4	WB	2 mL	9 x 9 two inch box	Freezer #1
88	Acrylamide	WB	2 mL	9 x 9 two inch box	Freezer #1
81	Vitamin B6	Plasma	2 mL	9 x 9 two inch box	Freezer #1
7	Homocys/MMA	Plasma	2 mL	9 x 9 two inch box	Freezer #1
8	Xtra Plasma	Plasma	2 mL	9 x 9 two inch box	Freezer #1
9	Glucose	Plasma	2 mL	9 x 9 two inch box	Freezer #1
70	Vitamin D	Serum	2-mL	9 x 9 two inch box	Freezer #1
12	Fol/B12	Serum	2 mL	9 x 9 two inch box	Freezer #1
13	CRP	Serum	2 mL	9 x 9 two inch box	Freezer #2
14	Hep Profile	Serum	2 mL	9 x 9 two inch box	Freezer #2
87	Hepatitis ab	Serum	2 mL	9 x 9 two inch box	Freezer #2
99	Fer/TfR	Serum	2-mL	9 x 9 two inch box	Freezer #2
11	Iron/TIBC	Serum	2 mL	9 x 9 two inch box	Freezer #2
17	Cotinine	Serum	2 mL	9 x 9 two inch box	Freezer #2
21	Lipids	Serum	2 mL	9 x 9 two inch box	Freezer #2
94	PTH2	Serum	2 mL	9 x 9 two inch box	Freezer #2
77	HPV Serum	Serum	2-mL	9 x 9 two inch box	Freezer #2
79	Vitamin C	Serum	2 mL	9 x 9 two inch box	Freezer #2
16	Rub/Mea/Var	Serum	2-mL	9 x 9 two inch box	Freezer 3
19	Bn Alk Phos	Serum	2 mL	9 x 9 two inch box	Freezer 3
20	Toxo	Serum	2 mL	9 x 9 two inch box	Freezer 3
18	Biochem	Serum	2 mL	9 x 9 two inch box	Refrigerator # 1
23	Insul/Cpep	Serum	2 mL	9 x 9 two inch box	Freezer #3
22	HIV	Serum	2 mL	9 x 9 two inch box	Freezer #3
24	HSV	Serum	2 mL	9 x 9 two inch box	Freezer #3
74	Syphilis	Serum	2 mL	9 x 9 two inch box	Freezer #3
75	PSA	Serum	2-mL	9 x 9 two inch box	Freezer #3
15	Vit A/E/Car	Serum	2 mL	9 x 9 two inch box	Freezer #3
26	Selenium	Serum	2 mL	9 x 9 two inch box	Freezer #3
29/89	Persis Pest	Serum	5 mL	9 x 9 three inch box	Freezer #3
90/91	Future Res 1/2	Serum	5 mL	9 x 9 three inch box	Freezer #3
92/93	Future Res 3/4	Serum	5 mL	9 x 9 three inch box	Freezer #3
32-40	Xtra Sera	Serum	2 mL	9 x 9 two inch box	Freezer #3
45	Alb/Creat	Urine	5 mL	9 x 9 three inch box	Freezer #4
46	Chlam/GC	Urine	14 mL	5 x 5 three inch box	Freezer #4
69	Urn Iodine	Urine	5 mL	9 x 9 three inch box	Freezer #4

Exhibit 9-4. Container protocol (continued)

Vessel ID	Test ID/Name	Sample Type	Vessel Type	Vessel Storage	Storage Unit
86	Spc Arsenic	Urine	5 mL	9 x 9 three inch box	Freezer #4
48	Prior Pest	Urine	14 mL	5 x 5 three inch box	Freezer #4
49	Organophos	Urine	14 mL	5 x 5 three inch box	Freezer #4
62	Urn Merc	Urine	14 mL	5 x 5 three inch box	Freezer #4
50	Heavy Metal	Urine	14 mL	5 x 5 three inch box	Freezer #4
65	Urn Phytoes	Urine	5 mL	9 x 9 three inch box	Freezer #4
66	PAH	Urine	5 mL	9 x 9 three inch box	Freezer #4
67	Phthalates	Urine	5 mL	9 x 9 three inch box	Freezer #4
51/52	Xtra Urine	Urine	5 mL	9 x 9 three inch box	Freezer #4
53	HIV Urine	Urine	5 mL	9 x 9 three inch box	Refrigerator #1
54	VOC Blood	WB	5 mL Gray	5 x 5 five inch with foam insert	Refrigerator #2
56	VOC Water	Water	10 mL glass vial	5 x 5 five inch with foam insert	Refrigerator #2
60/61	Lead Dust	Dust	50-mL	4 x 4 five inch box	Workstation 2
78	HPV	Genital swab	Epicentre swab	9 x 12 plastic bag	Workstation 2
72	Vaginosis	Genital swab	Glass slide	1 x 25 slide box	Workstation 2
73	T. Vaginalis	Genital swab	Puritan swab	9 x 12 plastic bag	Refrigerator #2
76	MRSA	Nasal swab	Culturette swab	9 x 12 plastic bag	Refrigerator #2

**Number of Boxes Per Week**

Number	Box type	Number	Box type
35	9 x 9 two inch box	2	5 x 5 five inch box (foam insert)
11	9 x 9 three inch box	1	1 x 25 slide box
7	5 x 5 three inch box	3	9 x 12 plastic bag
		1	4 x 4 five inch box

Exhibit 9-5. FedEx weekly shipping list

**NHANES 2003 FedEx Shipping List – Company Name**

Laboratory/Destination	Lab #	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
AC Diagnostics	43	81	Vitamin B6	Frozen	25	20	9
CASPIR NCEH	6	1	Lead/Cad/HG	Frozen	35	30	14
		3	RBC Folate				
		5	Mercury				
		6	CD4				
		88	Acrylamide				
		7	Homocys/MMA				
		8	Xtra Plasma				
		70	Vitamin D				
		12	Fol/B12				
		99	Fer/TfR				
		17	Cotinine				
		79	Vitamin C				
		90/91	Future Res1/2				
		92/93	Future Res3/4				
		32-40	Xtra Sera				
		69	Urn Iodine				
		86	Spc Arsenic				
		62	Urn Merc				
		50	Heavy Metal				
		65	Urn Phytoestro				
		51-52	Xtra Urine				
CASPIR/Dr. Courtney D. Sandau	31	66	PAH	Frozen	25	20	9
CASPIR/Dr. Wayman Turner	28	29/89	Persis Pest	Frozen	25	20	9
CDC Air Toxicant Branch (R)	4	54	VOC Blood	Refrigerated	10		
		56	VOC Water				
CDC DASTLR/NCID	36	74	Syphilis	Frozen	25	20	9
CDC Data and Spec Handling (R)	35	76	MRSA	Refrigerated	10		
CDC Dr. Antonia Calafat	24	67	Phthalates	Frozen	25	20	9
CDC Dr. Dana Barr	26	48	Prior Pest	Frozen	35	30	14
		49	Organophos				
CDC NCID AIDS Division	3	22	HIV	Frozen	25	20	9
CDC NCID AIDS Division (R)	3	53	HIV Urine	Refrigerated	10		
CDC NCID Hepatitis Ref Lab	2	14	Hep Profile	Frozen	25	20	9
		87	Hepatitis ab				
CDC NCID NCHSTD	5	46	Chlam/GC	Frozen	25	20	9
CDC Ruth Ann Tucker	37	77	HPV Serum	Frozen	25	20	9
CDC Ruth Ann Tucker (RT)	37	78	HPV	Room Temperature	1		
CDC DPD	17	20	Toxo	Frozen	25	20	9
Calif Dept of Health Service	19	16	Rub/Mea/Var	Frozen	25	20	9
Collaborative Lab Service	40	11	Iron/TIBC	Frozen	25	20	9
Collaborative Lab Service (R)	40	18	Biochem	Refrigerated	10		
Craft Technologies	45	15	Vit A/E/Car	Frozen	25	20	9

Exhibit 9-5. FedEx weekly shipping list (continued)

Laboratory/Destination	Lab #	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
Emory University	9	24	HSV	Frozen	25	20	9
Lipoprotein Analytical Lab/JHU	13	21	Lipids	Frozen	25	20	9
Magee Womens Hospital (R)	34	72 73	Vaginosis T vaginalis	Refrigerated	10		
NYS DOH/Wadsworth CTR L&R	39	2 26	Ery Proto Selenium	Frozen	25	20	9
Univ of Cincinnati (RT)	20	60 61	F Lead Dust W Lead Dust	Room Temperature	5		
Univ of Minnesota	16	45	Alb/Creat	Frozen	25	20	9
Univ of Missouri	10	9 23	Glucose Insul/Cpep	Frozen	25	20	9
Univ of Missouri (R)	10	4	Glycohem	Refrigerated	10		
Univ of Washington	11	13 19 75 94	CRP Bn Alk Phos PSA PTH2	Frozen	35	30	14
STP-710 or STP-740	STP-730	STP-740				9 x 12 Plastic bag	

**Bold/Black - Ship when full or at end of stand.**

Shaded = Verify correct assignment of container to FedEx airbill

**NHANES 2003 FedEx Shipping List – Lab Number**

Laboratory/Destination	Lab #	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
CDC NCID Hepatitis Ref Lab	2	14 87	Hep Profile Hepatitis ab	Frozen	25	20	9
CDC NCID AIDS Division	3	22	HIV	Frozen	25	20	9
CDC NCID AIDS Division (R)	3	53	HIV Urine	Refrigerated	10		
CDC Air Toxicant Branch (R)	4	54 56	VOC Blood VOC Water	Refrigerated	10		
CDC NCID NCHSTD	5	46	Chlam/GC	Frozen	25	20	9
CASPIR NCEH	6	1 3 5 6 88 7 8 70 12 99 17 79 90/91 92/93	Lead/Cad/HG RBC Folate Mercury CD4 Acrylamide Homocys/MMA Xtra Plasma Vitamin D Fol/B12 Fer/TfR Cotinine Vitamin C Future Res1/2 Future Res3/4	Frozen	35	30	14

Exhibit 9-5. FedEx weekly shipping list (continued)

Laboratory/Destination	Lab #	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
		69	Urn Iodine				
		86	Spc Arsenic				
		62	Urn Merc				
		<b>65</b>	Urn Phytoestro				
		50	Heavy Metal				
		<b>51-52</b>	Xtra Urine				
Emory University	9	24	HSV	Frozen	25	20	9
Univ of Missouri	10	9	Glucose	Frozen	25	20	9
		23	Insul/Cpep				
Univ of Missouri (R)	10	4	Glycohem	Refrigerated	10		
Univ of Washington	11	13	CRP	Frozen	35	30	14
		19	Bn Alk Phos				
		75	PSA				
		94	PTH2				
Lipoprotein Analytical Lab/JHU	13	21	Lipids	Frozen	25	20	9
Univ of Minnesota	16	45	Alb/Creat	Frozen	25	20	9
CDC DPD	17	20	Toxo	Frozen	25	20	9
Calif Dept of Health Service	19	16	Rub/Mea/Var	Frozen	25	20	9
Univ of Cincinnati (RT)	20	60	F Lead Dust	Room	5		
		61	W Lead Dust	Temperature			
CDC Dr. Antonia Calafat	<b>24</b>	<b>67</b>	Phthalates	Frozen	25	20	9
CDC Dr. Dana Barr	<b>26</b>	<b>48</b>	Prior Pest	Frozen	35	30	14
		<b>49</b>	Organophos				
CASPIR/Dr. Courtney D. Sandau	<b>31</b>	<b>66</b>	PAH	Frozen	25	20	9
CASPIR/Dr. Wayman Turner	<b>28</b>	<b>29/89</b>	Persis Pest	Frozen	25	20	9
Magee Womens Hospital (R)	34	72	Vaginosis	Refrigerated	10		
		73	T vaginalis				
CDC Data and Spec Handling (R)	35	76	MRSA	Refrigerated	10		
CDC DASTLR/NCID	36	74	Syphilis	Frozen	25	20	9
CDC Ruth Ann Tucker	37	77	HPV Serum	Frozen	25	20	9
CDC Ruth Ann Tucker (RT)	37	78	HPV	Room	1		
				Temperature			
NYS DOH/Wadsworth CTR L&R	39	2	Ery Proto	Frozen	25	20	9
		26	Selenium				
Collaborative Lab Service	40	11	Iron/TIBC	Frozen	25	20	9
Collaborative Lab Service (R)	40	18	Biochem	Refrigerated	10		
AC Diagnostics	43	81	Vitamin B6	Frozen	25	20	9
Craft Technologies	45	15	Vit A/E/Car	Frozen	25	20	9
STP-710 or STP-740		STP-730		STP-740		9 x 12 Plastic bag	

**Bold/Black - Ship when full or at end of stand.**

Shaded – Verify correct assignment of container to FedEx airbill



## QUALITY CONTROL AND QUALITY ASSURANCE – POLICIES AND PROCEDURES

National Health and Nutritional Examination Survey 1999-2004  
National Center for Health Statistics  
Centers for Disease Control and Prevention  
Public Health Service  
Department of Health and Human Services

Current revision: 01/06/2004

Approval: \_\_\_\_\_ Date: \_\_\_\_\_

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## **Abbreviations**

NCHS - National Center for Health Statistics

CDC - Centers for Disease Control and Prevention

NHANES - National Health and Nutrition Examination Survey

MEC - mobile examination center

LPM - NHANES Laboratory Procedures Manual

U.S. - United States

CBC - complete blood count

IRB - institutional review board

QC - quality control

QA - quality assurance

IQAP- Interlaboratory Quality Assurance Program

PT - proficiency testing

CLIA - Clinical Laboratory Improvement Amendments of 1988

HCFA - Health Care Finance Administration

ISIS - Integrated Survey and Information System

PC - personal computer

LAN - local area network

This policies and procedure quality control and quality assurance chapter is an adjunct to the Westat Policies Manual.

## **10.1 Safety**

### **10.1.1 Introduction**

NCHS and Westat maintain an ongoing Health and Safety Committee that acts in cooperation with the CDC Office of Health and Safety to assure safe working conditions for technologists in the NHANES mobile examination center (MEC). Safety precautions for all methods are documented in the Biosafety appendix in the *NHANES Laboratory Procedures Manual, 2003*. This manual is readily available to all laboratory staff. In addition to annual safety training, the NCHS Biomedical Engineer performs safety inspections at the beginning of each location. The technical supervisor assures that the primary laboratory analyst reads and is familiar with safety precautions.

## **10.2 Specimen Submission and Handling**

### **10.2.1 Introduction**

The goal of specimen submission and handling is to optimize the accurate and reliable measurement of analytes of interest. Each analytical procedure used in NHANES is documented in the *NHANES Laboratory Procedures Manual (LPM)*. Each method in the LPM specifies the procedure to be used for preparation of the sample person, specimen collection, labeling, processing, and preservation, and conditions for specimen transport that are appropriate for that method. The methods may refer to the NHANES blood collection protocol, or urine collection protocol, noting any special requirements specific to the particular method. These protocols are a starting point due to the special contamination requirements needed for collection of specimens analyzed for metals.

## **10.2.2 Identification of Specimens**

Personal identifiers (e.g., names) are not included on test specimens. NHANES uses a random internal specimen ID number to identify and track individual samples. The Integrated Survey and Information System (ISIS) system at Westat and the National Center for Health Statistics (NCHS) maintains information that links the specimen ID number to the sample person's name.

## **10.2.3 Questions on Specimen Submission and Handling**

The Chief Medical Technologist addresses questions concerning specimen collection including handling and testing.

## **10.3 Test Requisition**

### **10.3.1 Introduction**

Under a congressional mandate since 1960, NCHS has collected data on the health of the people of the United States through interviews and extensive physical examinations. As in previous NHANES programs, the survey's primary purpose is to produce descriptive statistics that can be used to measure and monitor the health and nutritional status of the civilian, noninstitutional U.S. population. Data collection for the entire survey of about 40,000 sample persons, of whom about 75 percent are expected to be examined, began in April 1999 and continues for about 6 years at about 90 locations (stands). NHANES performs a complete blood count on sample persons 1 year and older. A record of the test result report is maintained for a period of 7 years by Westat, the primary NHANES contractor and by NCHS for an indefinite period.

### **10.3.2 Laboratory Tests**

"Panic" or abnormally high CBC results are reported to the sample person. The report includes laboratory tests that will be performed. The NCHS Medical Officer or MEC physician involved

in the measurement may also confer with the sample person to obtain any other pertinent information, which might facilitate the laboratory measurement process.

### **10.3.3 Human Subjects Review**

The NCHS IRB as defined by the CDC institutional review board (IRB) criteria shall perform all laboratory analyses conducted on human specimens, which are part of a “survey,” only after approval of the survey.

## **10.4 Test Records**

### **10.4.1 Introduction**

The purpose of test records is to ensure correct and reliable identification of sample person specimens and to report accurate test results. The laboratory test record system is distinguished from the test report that is provided to the sample person.

### **10.4.2 Components of Test Records**

Test records include:

- Person performing the test (may be identified by initials);
- Printed or electronically stored output from instrumentation that the technical supervisor judges as necessary to document the analytical result;
- Date of specimen analysis;
- Date and time specimen was collected into the laboratory; and
- Condition of specimens that did not meet criteria for acceptable specimens (e.g., hemolyzed or insufficient quantity for test).

Test records are maintained for at minimum of 7 years. Records may be bound in laboratory notebooks, in loose-leaf form, or stored electronically.

## **10.5 Test Report**

### **10.5.1 Introduction**

The laboratory report is provided promptly to the sample person. This occurs as soon as the quality control has been reviewed and approved. The laboratory maintains confidentiality of the sample person results since it identifies samples only by a specimen ID number. Westat and NCHS maintain the link between the specimen ID number and the identity of the sample person.

### **10.5.2 Review, Approval, and Release of Test Results**

Upon completion of laboratory testing, results are reviewed by laboratory staff responsible for review of the quality control results to assure the measurement process was in-control for each of the sample person's analyses.

For NHANES surveys, the initial evaluation of quality control (QC) results is accomplished electronically by comparing the QC results to QC limits stored in a relational database. The laboratory staff performing the CBC reviews these QC performance results and ensures that only acceptable sample person's (SP's) data are reported.

Review and approval of the results by the MEC physician are documented. Review by the MEC physician includes an evaluation of the consistency of sample person results with information that may be available on the sample person (e.g., age, sex). All SP's samples are run in duplicate whenever possible. If inconsistent results are noted, and an adequate sample is available, the test is repeated a third time. If inconsistent results are again noted, the sample is run a fourth time. If the amount of sample is inadequate for repeat, then the sample person is informed verbally and in writing of the inconsistent result.

The paper hard copy of the results with the NCHS Medical Officer's signature is filed by Westat and kept with the test record for 7 years. The NCHS Medical Officer signs all laboratory reports before release.

Laboratory reports are released only to the authorized sample person. Each method includes a description of actions taken such as when results are markedly elevated or are “panic values.” The sample person is contacted immediately by the MEC physician with such results.

In addition to the written laboratory report, the data may be transmitted electronically in a suitable format; for example, a SAS data set or an ASCII file by email to the Westat home office and to NCHS.

### **10.5.3 List of Methods and Method Details**

NHANES maintains a *Laboratory Procedures Manual* (LPM) which includes detailed descriptions of each analytical procedure including analytical sensitivity, specificity, and accuracy, interfering substances, and other information.

### **10.5.4 Format of the Test Report**

The test report includes:

- The name and address of NCHS;
- The test result;
- Units of measurement;
- Reference range for each analyte, if available;
- The condition of specimens not meeting the laboratory’s criteria for acceptability; and
- Signature of the NHANES Medical Officer.

The laboratory report consists of:

- 1st page: a cover letter; and
- 2nd page: an analysis summary table.

A corrected laboratory report has the same format, except the words “corrected laboratory results” replaces the words “laboratory results” in the letter and title of the pages. In addition, in the text of the cover letter, the date of the previous laboratory report is noted.

#### **10.5.5 Format for Laboratory Report Cover Letter**

An example of the Laboratory Report cover letter (report of findings) is available upon request.

#### **10.5.6 Format for Listing of Laboratory Results**

An example of the laboratory results is available upon request.

### **10.6 Quality Control**

#### **10.6.1 Introduction**

Most quantitative analytical procedures involve several operations, or steps, and each operation is subject to some inaccuracy or imprecision or to the possibility of a mistake. The immediate aim of quality control is to ensure that the analytical values produced by a clinical laboratory are sufficiently reliable for their intended purpose. A broader objective is to ensure that all laboratories produce analytical values that meet acceptable standards of precision and accuracy.

Quality control in laboratory medicine is the study of those errors that are the responsibility of the laboratory, and the procedures used to recognize and minimize them. An alternate term, “quality assurance,” represents the techniques available to ensure with a specified degree of confidence that the result reported by the laboratory is correct. Both “precision control” (the agreement between replicate measurements) and “accuracy control” (the agreement between the mean estimate of a quantity and its true value) are evaluated to establish this degree of confidence.

A quality control program also monitors laboratory performance to detect excessive random or systematic error. Factors contributing to random error are those that affect the reproducibility of the measurement. These include instability of the instrumentation, variations in the temperature, and variations in reagents and calibrators, handling techniques such as pipetting, mixing, and timing, and operators. Terms used to describe random error include precision, imprecision, reproducibility, and repeatability. Systematic error describes the error that is consistently low or high. Factors that contribute to systematic error are independent of the analyte concentration. Examples of these factors include interfering substances or incorrect assignment of the amount of substance in the calibrator.

A good quality control program includes both internal (intralaboratory) and external (interlaboratory) surveillance and monitors the following five parameters:

- **Clerical Error:** This includes properly documented acknowledgment of transmittal and receipt of specimens (for example, “logging in”), proper labeling of all specimens, correct assignment of laboratory values to the proper SP ID number, and maintenance of proper records for all specimens for future reference.
- **Techniques:** This includes continued assurance that all personnel performing an assay understand the principles underlying a particular assay and are cognizant of the proper technique for that assay; that all personnel use the same technique for a particular assay; that there is ready access to a current technique manual; and that periodic review is undertaken to ensure use of the most current and reliable techniques.
- **Reagents and Materials:** This includes confirmation of commercial standards and controls before they reach the bench; proper labeling of reagents, particularly those prepared in the laboratory; ensuring all reagents in use are not outdated; having an adequate supply of current reliable reagents; proper calibration of equipment, such as pipettes; and proper washing of glassware.
- **Bench Performance:** This includes the use of controls and standards for each assay performed, a technique based on sound statistical principles which allows the technologist performing the assay to detect error outside of previously determined limits before reporting data; documentation of daily bench performance for detection of less obvious error (particularly those which tend to accumulate over time, so-called “drift”); and established procedures to be followed wherever error is found to exceed previously determined limits.
- **Instrumentation:** This includes periodic preventive maintenance of all instruments in use in the laboratory and documentation that each instrument is maintaining a previously determined level of each performance at each check.

In this context, QC procedures monitor and evaluate the quality of the analytical testing process of each method to ensure the accuracy and reliability of test results. Thus, QC procedures

referenced here refer to the analytical phase of testing and not to the preanalytic or postanalytic phases. Quality assurance (QA) addresses all three phases of measurement: preanalytic, analytic, and post-analytic. QC is therefore viewed here as one part of the overall QA process.

### 10.6.2 Method Specific QC Procedures

Specific QC procedures exist for each analytical laboratory procedure in the Laboratory Procedures Manual. The following are some general aspects of QC procedures.

### 10.6.3 QC Definitions

#### Internal (“Bench”) Quality Control

For purposes of this document, internal quality control is the evaluation of analytical performance that includes QC bench samples for which the analyst knows the expected measurement result. Internal commercial quality control materials contain predetermined amounts of analyte in the matrix, qualify under Clinical Laboratory Improvement Amendments (CLIA) as “calibration materials,” and may be used as a “calibration verification” as defined by CLIA.

- **External (“Blind”) Quality Control** – For purposes of this document, external quality control is the evaluation of analytical performance that includes QC samples for which the analyst does *not* know the expected measurement result. The analyst is “blind” to the expected measurement result. Examples include proficiency testing samples.
- **Interlaboratory Quality Assurance Program (IQAP)** – For purposes of this document, NHANES participates in Beckman Coulter’s® IQAP program. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance.
- **Proficiency Testing** – For purposes of this document, proficiency testing is one method of external quality control in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 3 months).
- **Analytical Run (sometimes referred to just as a run)** – An analytical run is a set of samples analyzed in a time within which the measurement system is considered to have stable accuracy and precision. The time for a run may not exceed 24 hours. An analytical run usually consists of both quality control specimens and sample person specimens.

- **Calibration** – Defined by CLIA as “the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.”
- **Calibration Material** – Defined by CLIA as “a solution which has a known amount of analyte weighed in or has a value determined by repetitive testing using a reference or definitive test method.” Many standards are therefore calibration materials.
- **Calibration Verification** – Defined by CLIA as “the assaying of calibration materials in the same manner as sample person samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for sample person test results.”
- **QC Requirements of Each Analytical Run** – Analysis of sample person samples is organized into analytical runs. The minimum QC requirement for an analytical run, which is analyzing sample person specimens, is that the run includes four internal (“bench”) QC specimens.

#### **10.6.4 Overview of the Relationship between Internal QC, Proficiency Testing, and External QC**

A Beckman Coulter® technical representative performs instrument setup, verification, and performs and verifies QC checks according to their procedure at the beginning of each stand. Medical technologists perform instrument calibration.

Most laboratory quality control programs include running internal (“bench”) QC with each analytical run to ensure each analytical run is in control. The  $X_B$  analysis is a QC method monitoring instrument performance. In addition, the laboratory participates in proficiency testing programs administered by an outside scientific group to be sure on a periodic basis that accuracy and precision are within acceptable limits. The IQAP compares NHANES 5C cell control results to other laboratories. These QC systems are used within NHANES. The linearity of the instrument is evaluated at least once a year.

In addition to these systems, NHANES uses calibration materials at the beginning of each stand to standardize the three Beckman Coulter® MAXM instruments and to provide additional objective evaluation of the quality of specimen analysis. S-CAL is a calibration material as defined by CLIA (i.e., “a solution, which has a known amount of analyte, weighed in or has a value determined by repetitive testing using a reference or definitive test method”) that is useful for monitoring method performance.

### 10.6.5 Internal (“Bench”) QC

The goal of internal QC is to provide a rapid feedback to the analyst on the performance of the measurement process to be sure analytical results and factors affecting analytical results are within acceptable limits. At least three internal QC specimens (5C® Cell control) are included in each analytical run. The QC material used as internal QC specimen has levels of the analyte, which are useful for monitoring method performance.

The 5C® Cell Control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. The 5C® cell control consists of human blood so repeated measurements to monitor daily performance of the instrument system is possible. The 5C® Cell Controls Tri-Pack contains three levels—normal, abnormal I, and abnormal II. When used with Beckman Coulter’s® blood diluent, Isoton III, they serve as a check on the accuracy of dilution, WBC counts, RBC counts, platelet counts, hemoglobin determinations, and differential counts.

The technologists run all three levels at the beginning of each session to monitor the precision of the instrument following procedures described in Chapter 7, Section X.B.

Standard Levy-Jennings QC charts are maintained for this internal QC specimen. A separate QC chart is to be maintained for each QC material used for this internal QC specimen. Standard criteria for run rejection based on statistical probabilities are used to declare a run either in-control or out-of-control. No results for a given analyte are reported from an analytical run that has been declared out-of-control for that analyte as assessed by internal (“bench”) QC. Rejection criteria are described in each method procedure in the LPM. Quality control results and remedial actions for out-of-control conditions are documented in a QC logbook.

In addition, a latex control (Latron®) is used to monitor the volume, conductivity, and light scatter (VCS) of the diff mode only. This control is run at the beginning of each day.

The Latron® control is a ready-to-use suspension of latex particles used to monitor differential parameters on the Beckman Coulter® MAXM. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter. The technologist runs the Latron® control immediately following the Latron® primer.

### **10.6.6 Interlaboratory Quality Assurance Program (IQAP)**

All MAXM instruments participate in Beckman Coulter's® Interlaboratory Quality Assurance Program (IQAP.) The Beckman Coulter® Data Management System saves results of 5C® cell controls in files. Technologists transfer the files to a disk and then send the disk to Beckman Coulter®, who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. The technologists perform this procedure on the last day of each month, at the end of each stand, or when a control lot expires using procedures described in Chapter 7, Section X.D.

### **10.6.7 Proficiency Testing**

Participation in the College of American Pathologist (CAP) proficiency-testing (PT) program is part of the comprehensive quality control program. Each MEC submits results for CAP specimens for evaluation. CAP compares the results to established values and issues a report.

The laboratory will satisfactorily participate in the HCFA-approved PT program for each method used to analyze human samples. Performance in the PT program along with documentation of remedial action taken for unacceptable performance is documented in a QC logbook that is available for review.

CAP samples are sent three times a year for hematology. Each shipment includes five 2.5-mL whole blood specimens. Duplicate Beckman Coulter® CBC determinations are performed on each whole blood sample using procedures described in Chapter 7, Section X. PT samples are handled and analyzed in a manner identical to SP samples. Results are recorded on the CAP forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS.

CAP samples are sent three times a year for qualitative serum and urine hCG. Each serum shipment includes five lyophilized sera specimens and each urine shipment contains five liquid specimens. PT samples are handled and analyzed in a manner identical to SP samples. Results are

recorded on the CAP forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS at the following address:

Brenda Lewis, MPH  
National Center for Health Statistics  
Room 900  
6525 Belcrest Road  
Hyattsville, MD 20782

### **10.6.8 Calibration Verification**

Calibration verification is defined by CLIA as “the assaying of calibration materials in the same manner as sample person specimens to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for sample person test results.” Thus, calibration verification assures that the accuracy of the measurement process across the reportable range is maintained over time. For methods approved by FDA, calibration verification is performed according to the manufacturer’s specification and at the frequency recommended by the manufacturer.

Note that the calibration materials must bracket the reportable range; that is, results should not be reported as a numerical value unless they are within the reportable range. If a result is higher than the upper end of the reportable range and the method permits sample dilution, the sample may be diluted to bring it within the reportable range. If dilution has been necessary, the reported value will exceed the upper end of the reportable range. Each analytical procedure specifies acceptable limits for results of analyses of the calibration materials based on the method precision of these materials.

The reliability of analytical values obtained when using a procedure often depends on the quality of the standards and the calibration procedure. The College of American Pathologists (CAP) suggests that automated instruments be calibrated using multiple analytical whole blood specimens or a certified, stabilized whole-blood type preparation. The International Committee for Standardization of Hematology (ICSH) by its definition requires that a calibrator “be based on or traceable to a reference preparation or material.”

Beckman Coulter® provides the S-CAL® calibrator to meet these requirements. The MAXM uses the S-CAL® kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. S-CAL® calibrates the WBC, RBC, Hgb, MCV,

Plt, and MPV parameters. It is a stabilized human-blood preparation. S-CAL® is an acceptable alternative to whole blood calibration. Hct, MCH, MCHC, RDW, and the DIFF parameters do not require calibration.

Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. The calibration procedure uses replicate measurements of S-CAL® calibrator. The S-CAL® divides the average result into the calibrator Assigned Value to give an Adjustment Factor. Then, it obtains and adjusts an instrument reading according to the Adjustment Factor.

S-CAL® is used to calibrate the Beckman Coulter® MAXM at the beginning of each stand (once every 6-8 weeks), after replacing any component dealing with dilution preparation, if the Beckman Coulter® representative suggests it, controls demonstrate unusual trends or are outside limits, or when the temperature varies by more than 10°F (5.5°C) from the room temperature during the last calibration.

Instructions for the performance of calibration procedures using S-CAL® calibration are in Section VII of Chapter 7.

#### **10.6.9 X<sub>B</sub> Analysis**

X<sub>B</sub> analysis is a QC method that monitors instrument performance by tracking the MCV, MCH, and MCHC parameters of SP's samples. These indices are very stable and show little variance between patient samples. This method displays the moving average of SP's samples and compares it to established target values. Target values are MCV = 88.5 (fL), MCH = 29.5 (pg), and MCHC = 33.5 (g/dL or g/100 mL). The technologist reviews and prints the X<sub>B</sub> current batch at the beginning on each session when printing the 5C Cell control results, using procedures described in Chapter 7, Section X. They review, print, file, and delete the Batch Means at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. They evaluate the percentage difference from the target limit to determine whether the batch is in- or out-of-control using procedures described in Chapter 7, Section X.E. The technologists refer to the troubleshooting section of the Beckman Coulter® manual if the batch is out-of-control.

### **10.6.10 Linearity**

The linearity controls verify the reportable range of Beckman Coulter® hematology systems. Linearity is performed at installation, at least yearly, and whenever experiencing an altitude change of 1 mile or more between locations using either Beckman Coulter® Lin-C™ or CAP LN9 survey material.

Beckman Coulter® Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent. Controls contain one each of Ultra Low Range, Low Range, Mid Range, and High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt. Beckman Coulter® Lin-C™.

CAP Hematology Calibration Verification/Linearity Survey (LN9) materials are shipped twice per year and consist of 18 3.0-mL liquid specimens. The medical technologist follows all CAP instructions in preparing and running the materials before performing the test. They fill out the CAP result form, make a copy for the logbook, send results to CAP, and send the copy back to the home office at the end of the stand.

### **10.6.11 Quality Control Records**

Records of all quality control results are maintained for at least 7 years. A QC logbook is maintained which documents quality control results, out-of-control conditions, and remedial actions taken to correct out-of-control conditions. The QC logbook also includes copies of results for Proficiency Testing.

## **10.7 Test Methods, Equipment, Reagents, Supplies, and Facilities**

### **10.7.1 Introduction**

Analytical procedures use equipment, reagents, materials, and supplies that are appropriate for achieving acceptable accuracy, precision, analytical sensitivity, and analytical specificity from the method. The documentation of individual analytical procedures included in the *Laboratory Procedures*

*Manual* (LPM) specifies acceptable equipment, reagents, materials, and supplies. If special requirements concerning water quality, temperature, humidity, electrical power, or other conditions are required for acceptable method performance, then these are described for each procedure in the LPM. Special procedures to monitor these requirements are also included in the documentation of the individual procedure. A lack of requirements in the documentation of the analytical procedure means that the expected day-to-day variation in any of these parameters is acceptable for proper method performance.

Documentation of problems with conditions required (e.g., water quality) for acceptable method performance is maintained in the logbook of the primary instrument used in the analysis. This documentation includes remedial action.

### **10.7.2 Labeling of Reagents, Solutions, Supplies**

Reagents, solutions, and other supplies are labeled to indicate the identity of contents, the concentration (if significant), the recommended storage requirements, the preparation and expiration date, and any other pertinent information required for proper use. Reagent, solutions, and other supplies are not used when they have exceeded their expiration date.

If a method uses a manufacturer's kit, components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

Beckman Coulter® reagents are monitored and documented in the Beckman Coulter® Data Management System and are additionally located on the daily instrument startup result sheet. A copy of all startup results is filed in the quality control notebook. The technologist documents any unusual occurrence or repair of the Beckman Coulter® MAXM on the Unusual Occurrence Log.

Logs are maintained for reagents other than the Beckman Coulter® reagents. The technologist documents reagent use by entering the reagent's name, date made, date put into use, expiration date, and tech ID on the Supply Use Control Log, and they send these logs back to the home office at the end of each stand.

### **10.7.3 Facilities**

Laboratories are arranged to ensure that adequate space, ventilation, and utilities are available for all phases of testing: preanalytic, analytic, and postanalytic.

## **10.8 Analytical Procedure Manual**

### **10.8.1 Introduction**

All procedures performed in the laboratory on human specimens are documented in the LPM. A copy of the LPM is maintained at the Westat home office and NCHS. The individual procedure is also available at or nearby the bench site where the procedure is performed.

### **10.8.2 Contents of the Analytical Procedure Documentation**

Each analytical procedure includes, when applicable:

- Requirements for specimen collection and processing including criteria for specimen rejection
- Step-by-step performance of the procedure including test calculations and interpretation of results
- Preparation of reagents, calibrators, controls, solutions, and other materials used in testing
- Calibration and calibration verification procedures
- The reportable range for sample person test results
- Quality control procedures
- Remedial action to be taken when calibration or control results are outside acceptable limits
- Limitation in methods, including interfering substances
- Reference range (normal values)

- Life-threatening or “panic values”
- Pertinent literature references
- Specimen storage criteria
- Protocol for reporting panic values
- Course of action if test system becomes inoperable
- Safety considerations for performing the method

### **10.8.3 Approval and Record Maintenance**

Each procedure is reviewed, approved, signed, and dated by the Clinical Consultant and Technical Supervisor and Laboratory Director of NHANES. Procedures are reapproved, signed, and dated if the Director changes. Each change in a procedure is approved, signed, and dated by the current Director. The procedure includes the dates of initial use and discontinuance, if discontinued. The procedure documentation is maintained for 7 years after discontinuance of the method.

### **10.8.4 Method Performance Specifications**

Method performance specifications for each analytical method is established or verified:

- Accuracy – accuracy of each analytical method will be determined by analysis of calibrators,  $X_B$  analysis and yearly linearity checks as described in the section of the LPM on quality control.
- Precision – precision of each analytical method is determined by analysis of QC reference materials as described in the section of this manual on quality control.
- Analytical specificity – analytical specificity is determined for each method including effects of potential interfering substances. This may be verified by testing the effect of potential interfering substances in method development, by analyzing reference materials, by comparing results on split samples with a method considered more definitive, and/or by analyzing a sample of persons ( $n > 20$ ) and examining the measurement output searching for interference. The appropriate procedures for verifying analytical specificity will vary by analytical method. Substances that interfere with the analysis in the reportable range are listed in the method procedure.

- Reportable range of test results – the reportable range of test results is described in the documentation of the analytical procedure.
- Reference range (normal range) – if available, the reference range of test results is described in the documentation of the analytical procedure and on the test report.
- Other pertinent performance specifications – other performance specifications that are required for adequate method performance are specified in the documentation of the analytical procedure.

## **10.9 Equipment Maintenance and Function Checks**

### **10.9.1 Introduction**

Laboratory equipment is checked regularly to ensure acceptable performance. Maintenance (including preventive maintenance) and function checks are documented in the Integrated Survey and Information System (ISIS). The frequency of maintenance and function checks follows manufacturer's recommendations, when available. Manufacturer's recommendations are included in the manuals that are located in notebooks in the laboratory.

Each analytical procedure outlines the equipment maintenance and function checks for proper method performance and acceptable results from the checks. These checks must be made at the interval specified in the documentation of the procedure. Failure of a function check is documented in the Unusual Occurrence Log.

### **10.9.2 Eppendorf Pipette Calibration**

The Eppendorf Research pro electronic pipettes are calibrated once per year. Pipettes are sent to the manufacturer and calibration certificates are kept on file at the home office.

### **10.9.3 Temperature Monitoring**

Temperature recordings are required for storage and preservation of reagents and sample material (analytical specimens), as well as quality control and reference materials.

Beckman Coulter® and Vacutainer have recommended the following storage conditions for reagents and tubes. Quality control temperature ranges have been established based on these recommendations.

Reagent	Manufacturer's recommended storage conditions	Established range
Coulter® reagents	2-25°C (36-77°F)	17-25°C (63-77°F)
Isoton		
Coulter Clenz		
Scatter Pack		
Lyse-S III		
S-Cal at room temperature	16-32°C (60-90°F)	17-25°C (63 to 77°F)
S-Cal at refrigerated temperature	2-8°C (35-46°F)	2-8°C (36 to 46°F)
Latron	2-30°C (36-86°F)	17-25°C (63 to 77°F)
5C Cell Control	2-8°C (36-46°F)	2-8°C (36 to 46°F)
Vacutainers	Not greater than 77°F	17-25°C (63 to 77°F)

The following ranges have been established for monitoring instrument quality control.

Instrument	Manufacturer's instrument range or limit	Established range
Beckman Centrifuge (Refrigerated)	-5 to +25°C (23-77°F)	2-8°C (36 to 46°F)
Beckman Centrifuge (Room temperature)	-5 to +25°C (23-77°F)	17-25°C (63 to 77°F)
Jewett Freezer	-8.9°C (16°F) Limit	-18 to -23°C (0 to -10°F)
Jewett Refrigerator	2-5°C	2-8°C (36 to 46°F)
LFBS	0.450	0.350 to 0.550
Phlebotomy Refrigerator	None	2-8°C (36 to 46°F)

Two thermometers monitor ambient temperature in the laboratory and one thermometer monitors ambient temperature in the phlebotomy room. The allowable temperature range for these rooms is 17-25°C (63 to 77°F).

The acceptable temperature range for refrigerators used for storage of CLIA-regulated specimens and reagents is 2-8°C and is checked and recorded daily. If temperatures are recorded automatically on a continuous monitoring system graph, the individual's initials are captured.

Freezer temperatures are monitored daily by visual inspection of either a thermometer or graphs and recorded. All freezers are monitored automatically by built-in visual systems (with thermographic or digital reading). The range of allowable temperature is -18 to -23°C. If this range is exceeded, the technologist contacts the MEC manager.

A separate automated continuous Sensaphone system monitors the room temperature and the internal temperature of the laboratory refrigerators and freezers. When the system detects a significant increase in the temperature, it begins calling designated staff. The MEC managers and data managers have been identified as those individuals responsible for responding to the call by typing in a response code. The temperature increase could be confined to one freezer or refrigerator, to multiple units, or all units. The temperature increase could be due to any number of circumstances such as a loss of power because a circuit breaker tripped, a compressor malfunctioned, or a system failed. The MEC manager or data manager implements corrective actions that are warranted to prevent loss of biological specimens.

Freezers and refrigerators are regularly monitored for excessive ice deposit, inoperative cooling fans, and frayed or worn electrical power connections. Problems are reported to the MEC manager.

## **10.10 Calibration and Calibration Verification**

### **10.10.1 Introduction**

Calibration and calibration verification are specified in the documentation of the CBC analytical procedure.

## **10.10.2 Comparison of Methods Performed on Multiple Instruments or at Multiple Sites**

At least once every 6 to 8 weeks, each of the three instruments is calibrated with S-Cal.

## **10.11 Remedial Actions**

### **10.11.1 Introduction**

Remedial actions are taken and documented when:

- Test systems perform outside acceptable performance specifications. Remedial action is documented in the appropriate QC manual.
- Results of control materials and calibration materials fail to meet quality control criteria. Remedial action is noted in the appropriate QC logbook.
- The laboratory cannot report sample person test results within its established period. If the reporting of data will exceed the agreed upon time frame, the MEC and final Report of Findings indicate that test results are not available.
- Errors in the reported SP test results are detected. When errors are detected in the reporting of sample person results, the MEC physician notifies the sample person by phone, followed by the issuance of a corrected report within a time period suitable to the sample person, but not to exceed 1 week. The corrected report clearly shows the corrected results in the title. Exact duplicates of the original as well as the corrected report are maintained for 7 years.

## **10.12 Integrated Survey Information System (ISIS)**

### **10.12.1 Introduction**

One of the purposes of the ISIS is to store sample person results for retrieval in a period acceptable for the intended use of the data. Sample person test results are stored in a database. The ISIS consists of the PC databases used for storing sample person results. This form for the ISIS facilitates the interfacing of varied and complex instrumentation used in many of the analytical procedures. The MEC LAN hardware serves as the hardware for the ISIS. The identification of the sample person result will be by specimen ID number, and the result is accessible by this number.

The minimum amount of data stored for each analytical result is the specimen ID number, the analyte name, and the measured result. If the specimen ID does not provide sufficient information to relate the measured result to the QC data for the run, then the run number and run date must also be stored. The specimen ID, run date, and run number should be sufficient information to relate the measured result to the quality control information for that run. Access to the ISIS database is password protected so that only the persons authorized by the Westat and NCHS may access the data.

#### **10.12.2 Integrated Survey and Information System Data Down Times**

Each laboratory method is able to run and temporarily store results even if the MEC LAN is inoperable.

#### **10.12.3 Maintenance of LAN Hardware**

After failure of a LAN component, ISIS should be able to be repaired or replaced within a day by a functioning component. LAN hardware is readily available. PC components and the infrequent problems with this hardware are readily correctable in this period. Westat participates in the standard service contract arranged for NHANES for service of failing or failed computer equipment.

#### **10.12.4 Backup Schedule of Integrated Survey and Information System Data**

ISIS data stored on LAN hard disk drives are backed up to tape once each weekday (Monday through Friday). If ISIS data are stored on local PC or minicomputer hard drives, they are archived to a second hard disk, tape, optical diskette, or CD-ROM at least once a week.

## **10.13 Communications and Complaints**

### **10.13.1 Introduction**

Good communication between the laboratory and persons reviewing laboratory analyses is essential for proper use of laboratory results. NHANES encourages collaborative relationships between technologists and physicians utilizing laboratory data. This collaborative interaction is the primary mechanism by which NHANES evaluates the effectiveness of laboratory protocols and other laboratory communications. If the laboratory has a persistent problem with meeting laboratory criteria (e.g., inadequate amount of specimen), the MEC manager, technical supervisor, or laboratory director will discuss the problem with the person in a collaborative spirit.

Similarly, complaints of laboratory performance are carefully considered. Usually, these complaints are fixed with minor adjustment or explanation. Each member of laboratory staff is responsive to complaints that have merit and relate to her/his responsibilities. Nontrivial complaints are reported to supervisors who will decide appropriate actions, including investigation and remedial action. The technical supervisor maintains documentation of nontrivial complaints concerning laboratory performance that are reported to her or him.

## **10.14 Quality Promotion**

### **10.14.1 Introduction**

High quality laboratory results are generated when all phases of the measurement process (i.e., preanalytic, analytic, and postanalytic) are conducted properly. Factors that promote high quality results include:

- Competent, well-trained, and motivated laboratory staff;
- Quality laboratory facilities;
- Well-maintained, high quality laboratory equipment;
- High quality laboratory analytical methods; and
- Clear commitment of management to quality laboratory results.

NHANES is committed to supporting each one of these factors in order to enhance quality.

## **10.15 Quality Assurance Program**

### **10.15.1 Introduction**

The goal of the NHANES Quality Assurance Program (QAP) is to monitor and evaluate the overall quality of the testing process including preanalytic, analytic, and postanalytic phases.

The initial database and reporting system design included the following requirements:

- All data are released in a timely manner relative to its intended use. All CBC results are provided to the SP in a preliminary Report of Findings when the SP checks out of the MEC. If the results are not available by the time the SP checks out of the MEC, they are reviewed by the MEC physician as soon as they are available, and the SP is notified by telephone of any abnormal results. A hard copy of the CBC results is included in the final Report of Findings sent to the SP 6-12 weeks after the MEC examination. In the case where no blood was drawn, the preliminary or final Report of Findings states, "Not enough blood drawn to test." In the case where no results were transmitted, the preliminary or final Report of Findings states, "Not Done."
- The preliminary and final Report of Findings are ISIS-generated and are based on results in the database; they are not predefined reports stored in the system. The format for the English and Spanish preliminary and final Report of Findings is tested annually to determine if the generic format is legible.
- The preliminary and final Report of Findings format includes reference ranges, units of measure, or notation for inadequate specimen. Sample preliminary and final English and Spanish Report of Findings are printed and the format is tested annually.
- NCHS is responsible for sending the final Report of Findings to each survey participant. Mailing labels are printed, the mailing label is matched to the final Report of Findings, and the final Report of Findings is inserted into the envelope. NCHS monitors communications from SPs who report that they have received the incorrect Report of Findings.
- All results are generated based on results stored in the database. The ISIS system prohibits the MEC technologist from changing data in the database after the SP has checked out of the MEC or if the MEC Report of Findings has been printed. All subsequent copies of results should match the original results. If any result is ever changed in the database, a back-end editing request system form is submitted, tracked, and maintained by ISIS.
- A comprehensive security system guards against unauthorized access. A complete description of this system is maintained by and is available through NCHS.

The basic mechanism for the QAP is the quality audit. The quality audit is conducted by the NHANES technical supervisor or laboratory director, who maintains documentation of the results of the quality audits, including remedial actions taken to address conditions that merited corrective action.

### **10.15.2 Quality Audit: Sample Person Test Management**

The quality audit for sample person test management is conducted at least yearly and consists of:

- A survey of the laboratory staff, and of the analytical procedures used in NHANES. The survey includes requests for information on:
  - Any changes which need to be made in sample person preparation, specimen collection, labeling, preservation, and transportation
  - Any changes which need to be made in completeness and relevance of sample person information obtained at the time the specimen is acquired, and the use and appropriateness of specimen rejection criteria based on their experience and interactions with persons requesting the tests
  - Laboratory-reporting errors encountered since the last survey
  - Whether the performance of the Integrated Survey and Information System (ISIS) is adequate for their measurement systems
  - Nontrivial complaints from outside the laboratory about performance of the lab

The technical supervisor and laboratory director assess the results of the audit and in consultation with Beckman Coulter®, implement corrective actions that are warranted.

### **10.15.3 Quality Audit: Quality Control**

Quality control addresses the analytic phase of measurement. The purpose of the internal (“bench”) quality audit is to ensure that the QC analyses were performed and appropriate actions were

taken when out-of-control conditions occurred. The quality audit of quality control shall be conducted at least yearly by technical supervisor and laboratory director and shall consist of:

- A review of a random 10 percent sample of 5C Cell and Latron control results. The review evaluates whether appropriate corrective action was performed and documented for out-of-control conditions.
- An analysis of the proficiency testing results. The analysis and review will assess PT performance and if unsatisfactory, whether the deficiencies have been adequately addressed. The technical supervisor and laboratory director compare results to determine the correlation coefficient. This correlation must be greater than 0.95 or the laboratory director may give written approval that the methods are sufficiently similar for the intended use of the data.
- The review of documents that demonstrate that at least once every 6 to 8 weeks S-Cal calibrator was run on three instruments.

The technical supervisor and laboratory director assess the results of the audit and, in consultation with Beckman Coulter®, implement corrective actions that are warranted.

#### **10.15.4 Quality Audit: Personnel**

Well-trained and competent personnel are essential components of good laboratory performance. The quality audit of personnel is conducted at least yearly by the technical supervisor and laboratory director and shall consist of:

- A review of the 5C Cell and Latron control (“bench”) results or IQAP QC results for 10 percent of the total control runs covering a period of not less than 1 year. The internal (“bench”) QC reflects the performance of persons performing the method. If out-of-control conditions occur with a frequency more than twice the expected statistical probability (e.g., 95% control limits would normally be exceeded by 5% of the analytical runs), the technical supervisor and laboratory director will assess whether the unacceptable performance is due to the performance of the person in question or other factors (e.g., failing equipment). If the personnel performance is the cause, the technical supervisor and laboratory director determine and implement appropriate remedial action (e.g., training).
- A review of all remedial action since the last audit to assess the effectiveness of the action. Acceptable performance of the method by the person involved for one month after remedial action is acceptable evidence of the effectiveness of remedial action.

- The technical supervisor and laboratory director audit the documentation of personnel training and evaluation to check whether the analyst has been appropriately evaluated in the last year (or 6 months if in first year performing a new method). The evaluation criteria are described in the Personnel Training and Evaluation section of the LPM (Chapter 10, Section 10.16).

The technical supervisor maintains documentation of the results of the audit.

#### **10.15.5 Quality Assurance Review with Staff**

The technical supervisor and laboratory director prepare a report of the results of quality audits within 3 weeks of the completion of the audit. The technical supervisor and laboratory director review pertinent information with appropriate staff to ensure effective remedial actions are taken. The technical supervisor and laboratory director also notify staff members who have been involved in the audit if performance was acceptable and no remedial action is needed. At least once every 6 months, the technical supervisor and laboratory director review the results of quality audits.

#### **10.16 Personnel Training and Evaluation**

The technical supervisor assures that persons performing laboratory tests receive appropriate training. The performance of persons performing laboratory tests is evaluated every 6 months for the first year testing is performed and annually thereafter. The evaluation shall consist of:

- Direct observation of test performance including sample person preparation (if applicable), specimen handling, specimen processing, and testing;
- Direct observation of the recording and reporting of test results;
- Review of QC results, IQAP, PT, Xb analysis, and linearity results and preventive maintenance records;
- Direct observation of performance of instrument maintenance and function checks;
- Assessment of testing performance using blind QC materials; and
- Assessment of problem-solving skills.

The technical supervisor maintains documentation of the evaluations for at least 7 years. If remedial action is warranted, the technical supervisor shall discuss the results of a personnel evaluation with the person evaluated and implement appropriate action (e.g., training).

## **11. OPERATIONAL ISSUES**

### **11.1 Start of Stand Activities**

The Westat warehouse manager sends supplies for all stands, schedules shipments so that they arrive on set-up day, and ships supplies requiring refrigeration so that they arrive the day before set up. The staff stores laboratory supplies in the laboratory cabinets or in MEC trailer compartments.

The advance arrangement staff may assist in completing some set-up activities. On set-up day, the phlebotomists and medical technologists work together to complete all activities. These tasks include assisting in unpacking the warehouse pallets and boxes, sorting the laboratory supplies by storage location, completing an inventory of all existing and new supplies, organizing and storing all inventoried supplies in MEC cabinets or trailer compartments, and setting up each work area by stocking the area with appropriate supplies. Medical technologists and phlebotomists perform maintenance on all instruments and equipment, and test equipment functions. Staff members notify the MEC manager if additional supplies are required and document all instrument and equipment malfunctions in the Unusual Occurrence Log.

Mark and store miscellaneous hardware in a safe location in the laboratory until the end of stand. Hardware includes wood blocks with Velcro, refrigerator and freezer bottle caps, temperature-recording pen protectors, restraining straps, wood boards, and carpeted counter supports and straps for the Beckman Coulter® MAXM instrument and printer.

#### **Phlebotomy Room**

- Phlebotomist's responsibilities include the following tasks:
  - Inventory consumables and nonconsumables.
  - Check the sink for hot and cold running water and proper drainage.
  - Remove the wood door and drawer blocks from the refrigerator and store for reuse at the end of the stand.
  - Turn on the refrigerator.

- Verify the refrigerator's operation.
- Check the function of the telephone intercom.
- Clean the refrigerator.
- Clean all work surfaces and storage areas.
- Stock and organize supplies.
- Record all lot numbers and expiration dates in the Supply Use Control Log.
- Check the computer operations.

### **Laboratory**

- Medical Technologists' responsibilities include the following tasks:
  - Inventory consumables and nonconsumables.
  - Check the sink and eyewash for cold running water and proper drainage.
  - Check telephone operation.
  - Check the wall thermometers for damage.
  - Remove the wood door blocks from the refrigerators and freezers and store.
  - Replace the freezer and refrigerator temperature probe solid bottle caps with the caps with holes and save solid caps for reuse at the end of the stand.
  - Place the temperature probes back into the bottles.
  - Plug in the refrigerators and freezers.
  - Verify freezer and refrigerator operation.
  - Reconnect the batteries inside the temperature-recording units.
  - Change temperature-recording charts, check pen ink, and save the black pen protector for use at the end of the stand.
  - Check light, blowers, and magnehelic pressure gauge reading in the LFBSC.
  - Release the Beckman Coulter restraining straps, remove the wood board, detach the bolted carpeted counter supports and store the straps, wood board, and counter supports until the end of the stand.

- Remove the restraining strap on the Beckman Coulter® printer and store the straps until the end of the stand.
  - Contact Beckman Coulter® at 1-800-526-7694 to schedule instrument verification by a service technician. Provide the current address and instrument system ID.
  - Perform all Beckman Coulter® beginning of stand operations as described in Chapter 7, Section VIII.F. This includes installing and priming all new reagents, performing a start-up procedure, and reviewing and verifying the system setup.
  - Calibrate the Beckman Coulter® MAXM. Complete the calibration before performing routine CBCs on SPs.
  - Refrigerate the serum and urine pregnancy controls, and Beckman Coulter® Latron and 5C Cell controls as soon as they arrive.
  - Clean all work surfaces and storage areas.
  - Stock and organize supplies.
  - Clean the interior and exterior of refrigerators, freezers, centrifuges, and LFBSC.
  - Perform centrifuge maintenance.
  - Open and label all new containers using the laboratory application.
  - Mentally step through labeling, blood processing, urine processing, pregnancy testing, complete blood count, and specimen storage to make sure all the necessary equipment is functioning and all supplies are available in the phlebotomy/laboratory area.
  - Document all readings and activities in the Laboratory QC module.
  - Call FedEx to check availability (1-800-463-3339).
- NCHS Biomedical Engineer (Annual) responsibilities include the following tasks:
    - Determine the rpm of the centrifuges using a strobe or tachometer.
    - Perform a timer check.
    - Verify that both centrifuges are operating at 4-8°C.
    - Enter the results in the Laboratory QC module.

## **11.2 End of Stand Activities**

For security reasons, lock all needles in the cabinet each day after examinations are complete. Turn off the centrifuges. Sign off from all computer terminals.

At the end of a stand, shut down all equipment and inventory all supplies. On teardown day, the phlebotomist and medical technologists work together to complete all activities. Carefully wrap all breakable supplies in preparation for the move. Lock all cabinets and drawers or secure with Velcro straps. Safely discard all biohazardous waste.

### **Packing Phlebotomy Room**

- Phlebotomist's responsibilities include the following tasks:
  - Inventory all consumables and nonconsumables.
  - Turn off and clean the refrigerator in phlebotomy.
  - Place wood blocks with Velcro strips on the refrigerator door to prevent the door from closing or moving. Be careful not to damage the rubber gasket on the door.
  - Pack the juice and crackers in labeled plastic boxes and store them inside the MEC.
  - Remove all loose supplies (clock, telephone handset, etc.) and equipment from the counter tops; pack loose supplies in boxes and label "Phlebotomy Room." If possible, place the boxes in the cupboards above the counter, under the bench, or in the corners on the floor in phlebotomy. If these areas are full, place the boxes in the designated compartments under the trailers. Do not store Vacutainer® tubes in these trailer compartments.
  - Lock the wall arm boards.
  - Bolt the room door in the open position.
  - Close all cabinets and lock them or secure with Velcro strips.
  - Place a dowel through the drawer handles or secure with a stretch cord.
  - Lock all needles in the cupboards or in compartments under the MEC.

- Lay the phlebotomy cart on its side on the floor.
- Give the Supply Use Control Log to the Chief Medical Technologist.

### **Packing the Laboratory**

- Medical Technologists' responsibilities include the following tasks:
  - Make an inventory of consumables and nonconsumables.
  - Perform the Beckman Coulter® end of stand procedures as described in Chapter 7.
    - Review, print, and clear the error file.
    - Download the IQAP files.
    - Print DMS database.
    - Print Latron and 5C Cell control cum statistics (files) and graphs.
    - Print  $X_b$  means and graph.
    - Perform daily shut down.
    - Bleach the apertures and flow cell.
    - Bleach, rinse, and drain reagent lines.
    - Turn off the power.
    - Rinse exterior of the BSV.
    - Wash exterior of the instrument.
    - Dispose of all opened reagents.
  - Check the expiration dates on the Beckman Coulter® Latron, Beckman Coulter® 5C Cell control, pregnancy test kit, and pregnancy controls. If unopened and they will not expire before the beginning of the next stand, pack them in a shipper with refrigerant packs, print a label using FedEx Ship, and ship back to the warehouse.
  - Unplug the refrigerators and freezers.
  - Clean refrigerators and freezers.

- Replace the freezer and refrigerator temperature probe bottle caps (with holes), with the bottle caps without holes, and save the caps with holes for reuse at the start of the next stand.
- Place wood blocks with Velcro strips on each refrigerator and freezer door to prevent the door from closing or moving. Be careful not to damage the rubber gasket on the door.
- Remove the temperature recording charts and send to the home office. Store the pen arm in the "Change chart" (#3) position. Replace the black pen tip protectors.
- Disconnect the batteries inside the temperature-recording units.
- Unplug the LFBSC.
- Close and lock centrifuge lids and turn off centrifuges.
- Pack all tube rockers securely in boxes or in drawers.
- Remove all small supplies from the counters and LFBSC and pack in boxes or cabinets.
- Close all cupboards and secure with Velcro strips.
- Remove the fire extinguisher from the wall and lay inside the laboratory sink.
- Clean all counters, the LFBSC, and equipment with 1:100 bleach solution.
- Place chairs upside down or lay them down on the floor.
- Attach Beckman Coulter's bolted carpeted supports to the counter. Secure the Beckman Coulter® by laying the wood board across the top of the instrument and tightening the straps. Place foam blocks behind the instrument to cushion it during transit. Place a strap around the bottom front of the instrument. (Do not apply too much pressure.)
- Secure the Beckman Coulter® printer by strapping it to the printer shelf.

## **Sending Laboratory Files and Supplies**

At the end of each stand, use FedEx Ship to create a label to send the following hard copy documentation to the technical supervisor at the home office:

- Temperature recording charts
- Beckman Coulter® Start Up printouts
- Beckman Coulter® Latron and 5C Cell Control printouts
- Calibration printouts
- Linearity printouts
- $X_b$  means and graphs printouts
- Latex CBC/Diff cumulative statistic and graph printouts
- Beckman Coulter® database printout
- Error file printout
- Proficiency testing copies (hematology and serum hCG)
- Unusual Occurrence Log(s)
- Supply Use Control Log(s) (lab and phlebotomy)
- Lead dust transmittals
- Dry ice receipts (at the discretion of the MEC manager)
- Biohazard receipts (at the discretion of the MEC manager)

At the end of each stand use FedEx Ship to create a label to send the following supplies to the warehouse supervisor:

- Unopened pregnancy test kits
- Unopened pregnancy urine controls – refrigerated
- Pregnancy serum controls – refrigerated
- Unopened Coulter® 5C Cell and Latron controls – refrigerated

Pack supplies using procedures described in Chapter 9.

### **11.3 Inventory Procedures and Supplies**

At the start and end of each stand, take a complete inventory. The warehouse uses this inventory to stock the MEC for the next stand.

#### **11.3.1 General Inventory Procedures**

- Since item units can change, verify the units each time you record a count. Examples of units are pack, each, bag, box, case, roll, tray, bottle, pair, and pouch.
- Do not redefine or reiterate the Unit of Measure.
- Do not write any notes, comments, etc. on the End of Stand Inventory Count Sheet. If you have any comments or concerns, attach a note to the inventory sheet.
- Remember to use items with older expiration dates first. Rotate items by first using items you have in the rooms, then items in the belly compartment. Place items you just received in the back of the stock, unless you need them immediately. Only restock your rooms with items that were just shipped to the stand when you are out of that item in your room. Many items such as gloves, alcohol prep pads, and electrodes, deteriorate over time.
- Do not purchase items listed on the inventory sheets. The warehouse stocks every item listed on the inventory sheets; purchasing items locally creates chaos with the Inventory Management System. Contact the warehouse manager before replacing items listed on the inventory with items purchased locally.
- Do not borrow items from other components. Usage is tracked by component. The “Counted By” tech ID is entered into the database to track inconsistencies and trends. Everyone is accountable for his or her component counts.

#### **11.3.2 End of Stand Inventory Procedures**

The End of Stand Inventory Count Sheet (EOSCS) includes the stand number, Site ID (MEC number), a “Counted By:” line, and Exam Supply columns for item number, general item description, Unit designation, and a Count box. The MEC manager prints these EOSCSs for every component. The MEC staff is responsible for accurately counting (inventorying) exam supplies and entering this number

into the Count box. The MEC staff gives the completed sheets back to the MEC manager who sends them to the warehouse manager. The warehouse manager enters the item counts into the Inventory Management System.

- Print only one name in the “Counted By” field. This is the person responsible for taking and verifying the inventory count.
- Place a number in each “Count” box.
- Do not count partial units; record whole numbers only in the “Count” field.
- Record a number in each count box; do not leave a count box blank.
- If the PAR for an item is more than one (1) and the box or container is open, do not count that container.
- If the PAR for an item is only one (1) unit and it is more than half empty, record a zero (0) as the count unit. Can the next stand get by without needing more? If not, record a zero (0) as the count unit.
- All active lot numbers and expiration dates are listed on the count sheets if they are applicable for that item. If you see a lot number and expiration date, you must put a number (even if it is zero) in this Count field.

### **11.3.3 Start of Stand Inventory Procedures**

The Start of Stand Pull Sheets (SOSPS) include the stand number, Site ID (MEC number), and Exam Supply columns for item number, general item description, Previous EOS Count number, Par level, Unit designation, and a Ship to Stand box. The warehouse manager uses this report to bring each item back to par level. For example, if the Previous EOS Count (captured by the IMS) is four and the Par level is five, the Ship to Stand Count box will contain the number one. The Warehouse Manager prints and packs one SOSPS for each component. The MEC staff is responsible for accurately reconciling the supplies and numbers in the SOSPS. The MEC staff gives the completed sheets back to the MEC manager who sends them to the warehouse manager. The warehouse manager reviews each sheet and sends additional supplies to the field if necessary.

- Reconcile the inventory for each item.
- Verify the Previous EOS Count for each item.

- Verify that the start of stand shipment contains the exact number of each item listed in the Ship to Stand box.
- If the counts are correct, place a check mark by each reconciled item.
- If there is a discrepancy, write the physical count on hand to the right of the Ship to Stand box.

#### **11.3.4 Consumables vs. Nonconsumables**

Inventory items are divided into two categories—consumable and nonconsumable. Take an inventory of both types of items at the end of each stand. The definition for a consumable item is anything that is typically consumed during an examination. Whereas some items may be used (consumed) in case of emergency, these are still considered nonconsumables since they are not typically consumed during the course of an exam.

#### **11.3.5 Shipping Excess Inventory Back to the Warehouse**

When shipping excess inventory back to the warehouse, please use the “Transfer Inventory to Warehouse Manifest” which is found on the IntraWeb and can be printed by the MEC manager or data manager. This form looks similar to the “End of Stand Count Sheets.” Print your name in the “Count By” field and indicate next to each item how many units are being shipped back to the warehouse. This information is entered into the Inventory Management System by the warehouse manager and is used to adjust the Stand inventory and usage information as well as increase the warehouse inventory counts.

#### **11.3.6 Tracking of Expired and Broken Inventory**

Complete the “Delete Expired/Broken Inventory Report” whenever inventory has expired and must be destroyed or has broken and is no longer usable. This report is found on the IntraWeb and should be completed and forwarded to the warehouse manager so that the expired or broken inventory can be removed from the stand inventory.

The chief medical technologist and the phlebotomist are responsible for notifying the MEC manager if additional supplies are needed during the stand. However, each technologist and phlebotomist is responsible for identifying any potential shortage of supplies at each workstation. Contact the warehouse manager directly at 301-330-7092.

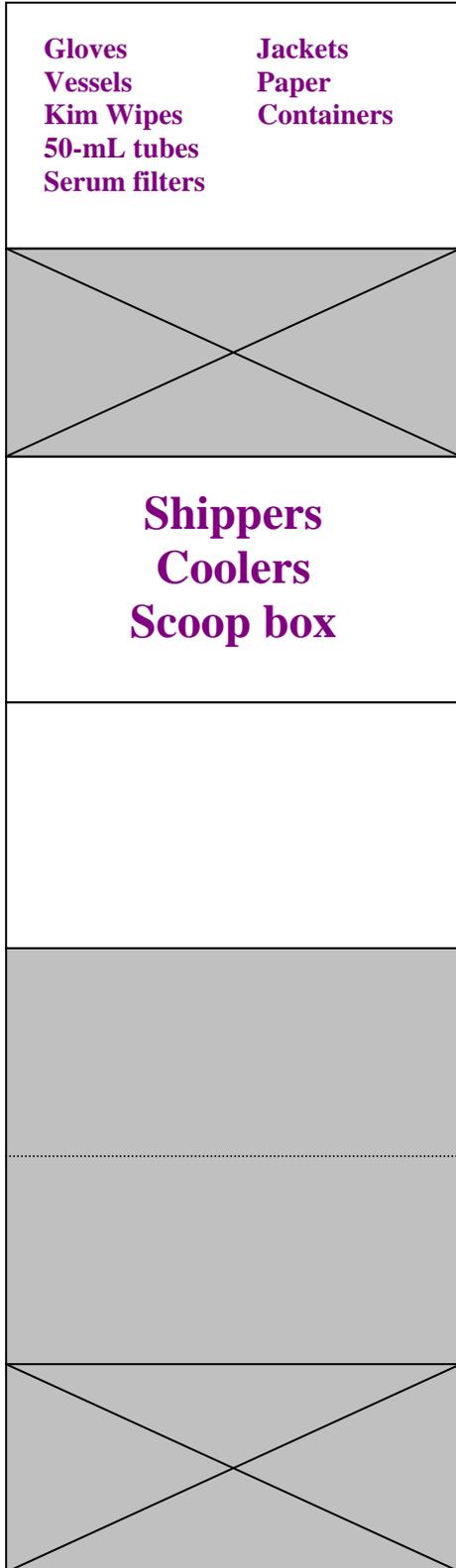
Exhibit 11-1. Equipment and supplies

Three Jewett freezers UCF5BH	Two Jewett refrigerators UC5B
Two Beckman Coulter GS 6R centrifuges	Five Jewett temperature monitoring units 8ER-1B
Two Thermolyne Vari-Mix M48700	Laminar flow biological safety cabinet
One Revco refrigerator (phlebotomy)	One Thermolyne Speci-Mix (phlebotomy)
Two solar wall thermometers (lab)	One solar wall thermometer (phlebotomy)
Temperature charts	Temperature chart pens
Thermometer (centrifuge calibration)	

Store supplies in the trailer compartments as indicated in the trailer maps (Figure 11-1).

Figure 11-1. MEC trailer compartment maps

### Trailer 1



### Trailer 4



## **11.4 Dry Run**

After setting up the phlebotomy and laboratory rooms at each new stand, the staff conducts a “dry run” session using volunteers to verify data collection and specimen collection and processing procedures. One purpose of the dry run session is to help identify any problem areas, particularly with equipment, and to resolve the problems before the stand begins. Another purpose is to provide the contract laboratories with blind split samples for quality control determinations. Two distinct IDs are assigned to each volunteer—the original SP ID and a second unique Sample ID. Document the results of the dry run session in a manner identical to an actual session except enter results twice, first using the SP ID, and second using the Sample ID.

### **Procedures**

- Prepare split samples for each volunteer.
- Send these split samples to contract laboratories for analysis with the first routine shipment.
- Collect the amount of blood specified in the Dry Run Venipuncture Protocol (see Exhibit 11-2). This amount is less than the blood required from a routine examinee.
- Collect 6-mL of urine and process as specified in Dry Run Urine Processing Protocol (see Exhibit 11-3, pg. 11-22).
- Process the blood as directed in the Dry Run Blood Processing Protocols (see Exhibits 11-4, 11-5, and 11-6, on pgs. 11-26 and 11-27).

### **11.4.1 Phlebotomy Protocol and Procedures**

The dry run venipuncture protocol is dependent on the last digit in the SP ID. If the last digit is an odd number, the volunteer’s protocol includes four 3-mL lavender, two 2-mL gray, and four 10-mL red top tubes. If the last digit is an even number, then the volunteer’s protocol includes two 3-mL lavender, two 2-mL gray, and four 10-mL red top tubes.

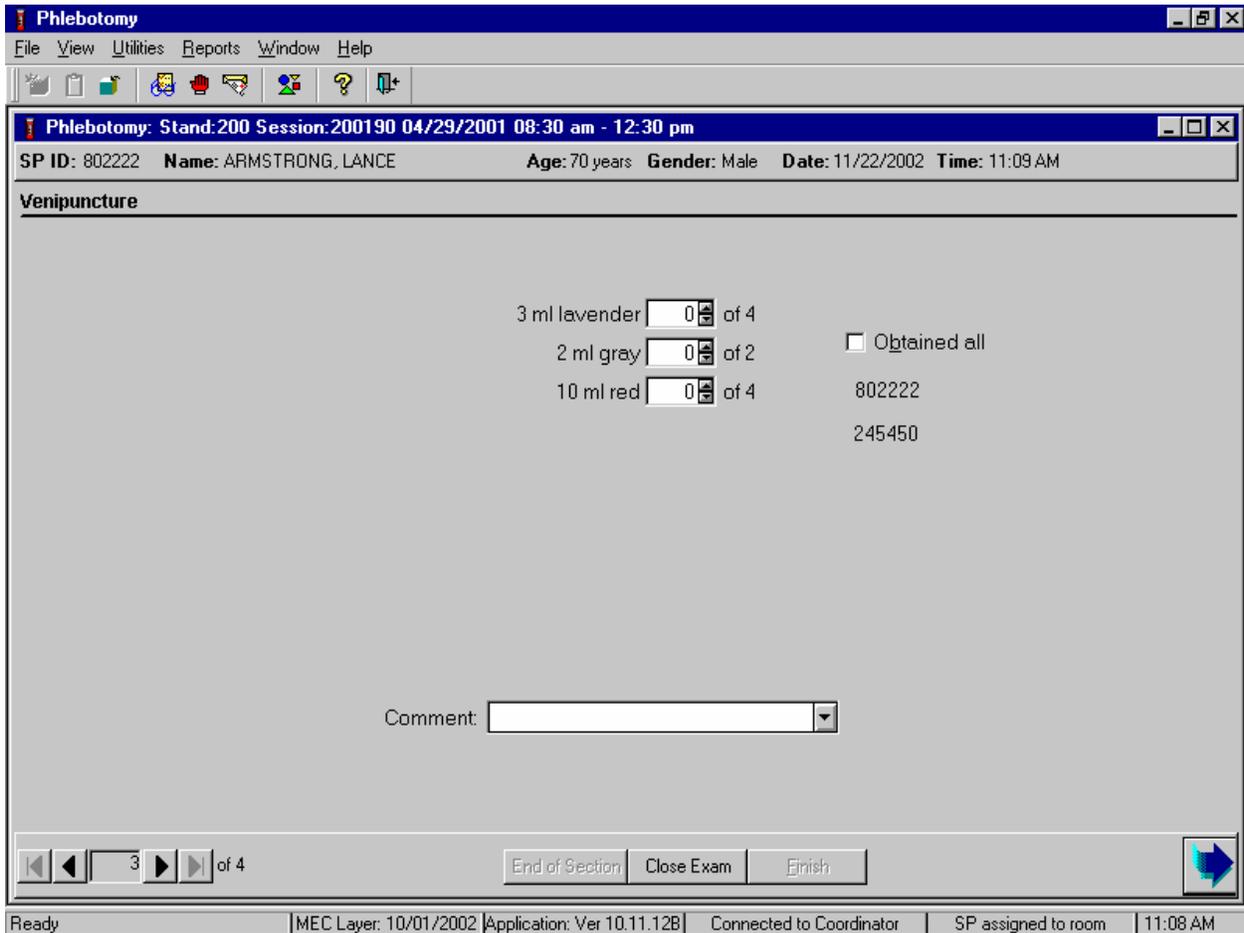
Exhibit 11-2. Dry run venipuncture protocol

Tube type (in priority order)	Last digit in SP ID = Odd	Last digit in SP ID = Even
3-mL Lavender	2	4
2-mL Gray	2	2
10-mL Red	4	4

On dry run day the phlebotomist refers to the following instructions to conduct the phlebotomy procedures:

- Access the phlebotomy application; open the exam and wand the dry run volunteer into the component.
- Conduct the phlebotomy interview and administer the fasting questionnaire as described in Chapter 4.
- Perform the venipuncture using procedures described in Chapter 4.

The last digit in the SP ID determines the dry run volunteer’s venipuncture protocol. The correct venipuncture automatically displays. Note that there are two IDs—an SP ID, and a Sample ID. Both the SP ID and the Sample ID display under the “Obtained all” check box.



Enter the venipuncture results using procedures described in Chapter 4. Enter any reasons for a tube not being drawn according to protocol, and any comments about the venipuncture. Refer to Chapter 4 for specific instructions.

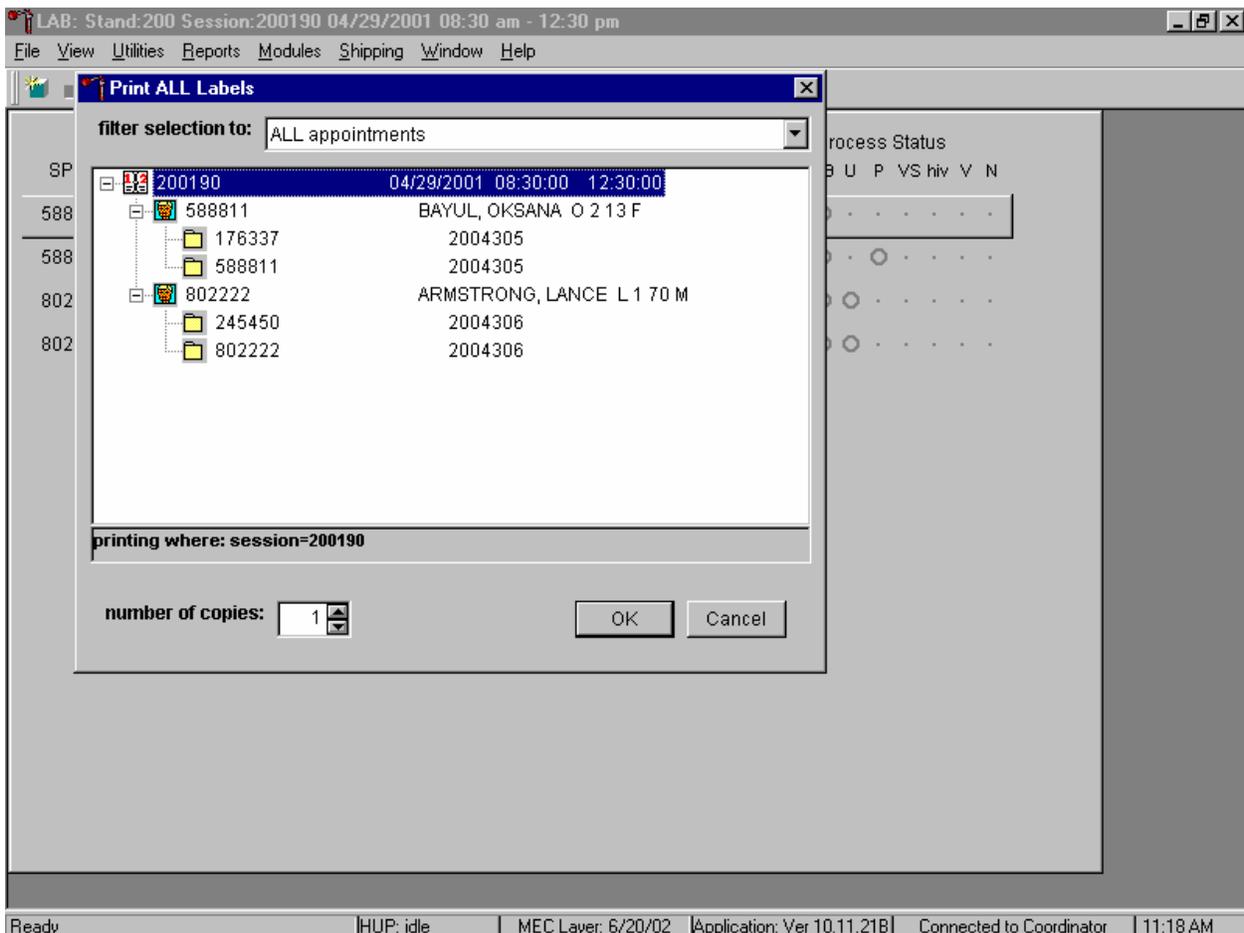
Label half of the tubes with the SP ID and the other half with the Sample ID. Label the Vacutainer® tubes for each volunteer as follows:

- Place the label with the original SP ID on one tube of the pair of 3-mL lavender tubes and the second label with the Sample ID on the other tube of the pair. Repeat this procedure for the second pair of 3-mL tubes if the dry run volunteer’s SP ID ends in an odd number.

- Follow the same procedure for the pair of 2-mL gray tubes.
- Place a label with the original SP ID on two of the four 10-mL red tubes and the second label with the Sample ID on the other two 10-mL red tubes. If only one tube is drawn, discard the tube. If less than four of the 10-mL red tubes are successfully drawn, label the first tube with the original SP ID and the second one with the Sample ID. If an odd number of tubes are drawn, discard the odd tube.

#### 11.4.2 Urine Processing and Pregnancy Testing

Access the laboratory application and logon using the MEC Logon window. Two distinct IDs are assigned to each volunteer—the original SP ID and a second unique Sample ID.



The Print All Labels pick list demonstrates that for each dry run volunteer, there are two entries, the original SP ID and the Sample ID. Volunteers with an original SP ID ending in an odd digit

are assigned to Urine or Blood Processing Protocol Group 1 and volunteers with an original SP ID number ending in an even digit are assigned to Urine or Blood Processing Protocol Group 2.

There are two sets of urine and blood vessel labels and one pregnancy label (if eligible) for each dry run volunteer. The correct vessel labels automatically print based on the protocol. Print labels using procedures described in Chapter 9. Place urine and pregnancy labels at workstation 2. Each volunteer has two unique blood processing racks—one with labels containing the SP ID and the second with labels containing the Sample ID. Assemble and label the blood processing racks for each dry run volunteer using procedures described in Chapter 9.

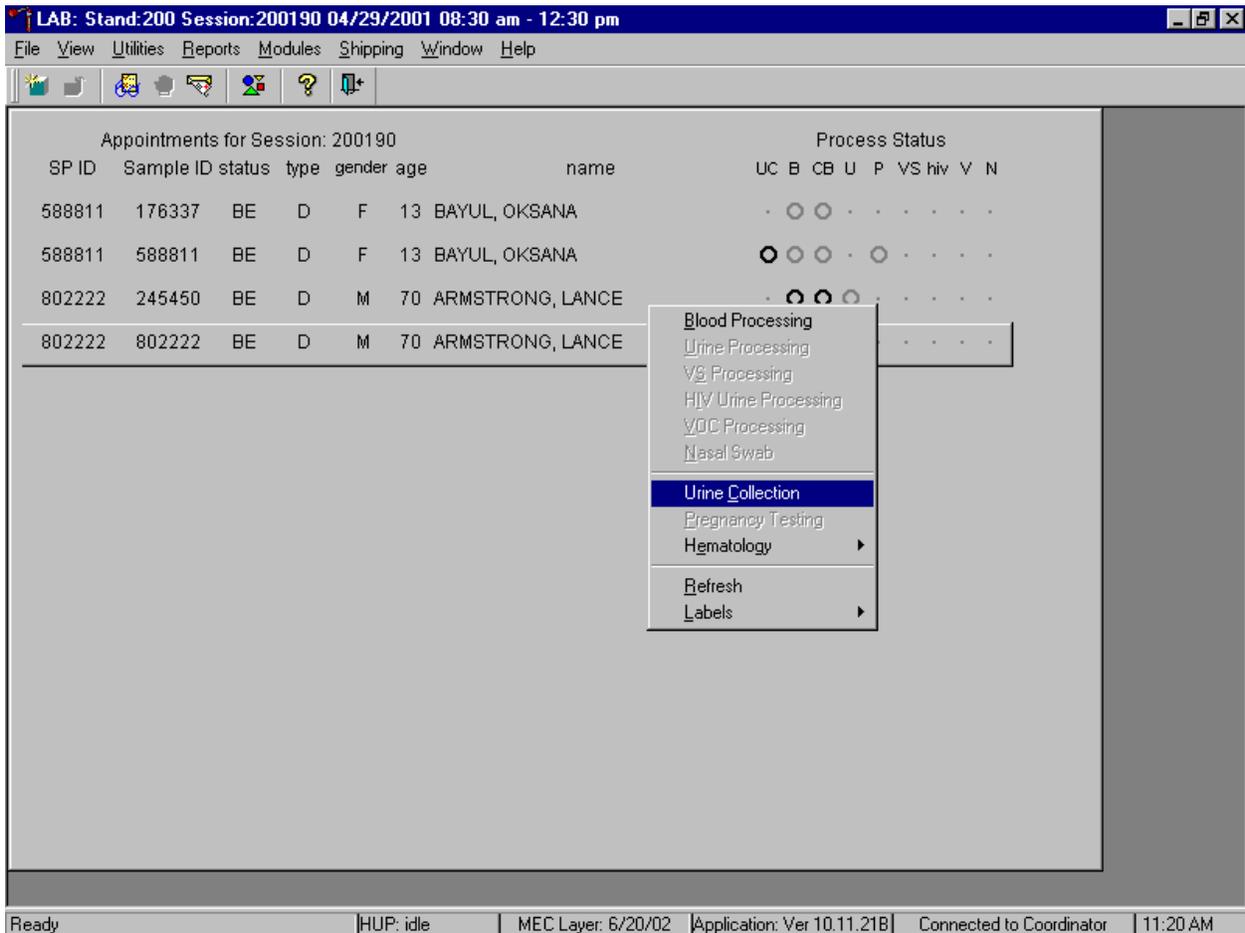
Review the laboratory heads-up display. Use the heads-up display to view the modules for which the dry run volunteer is eligible and the current process status.

Appointments for Session: 200190							Process Status								
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N
588811	176337	CI	D	F	13	BAYUL, OKSANA	.	○	○	.	.	.	.	.	.
588811	588811	CI	D	F	13	BAYUL, OKSANA	○	○	○	.	○	.	.	.	.
802222	245450	BE	D	M	70	ARMSTRONG, LANCE	.	○	○	○	.	.	.	.	.
802222	802222	BE	D	M	70	ARMSTRONG, LANCE	○	○	○	○	.	.	.	.	.

The heads-up display lists each dry run volunteer twice. Note the difference between the SP ID and the Sample ID and the types of tests for which the dry run volunteer is eligible. Dry run volunteers are eligible only for urine collection and processing, CBC, blood processing, and the pregnancy test. The urine and blood protocols constitute a limited subset of the primary SP's test protocol. Each test has the same age and gender restrictions as a primary SP. Dry run volunteers are never eligible for future research vessels (surplus serum, plasma, or urine), MRSA - nasal swab, HIV serum or urine, CD4, urine mercury, or any subsamples, including VOC. Notice that one urine collection result and one pregnancy test are required for each dry run volunteer.

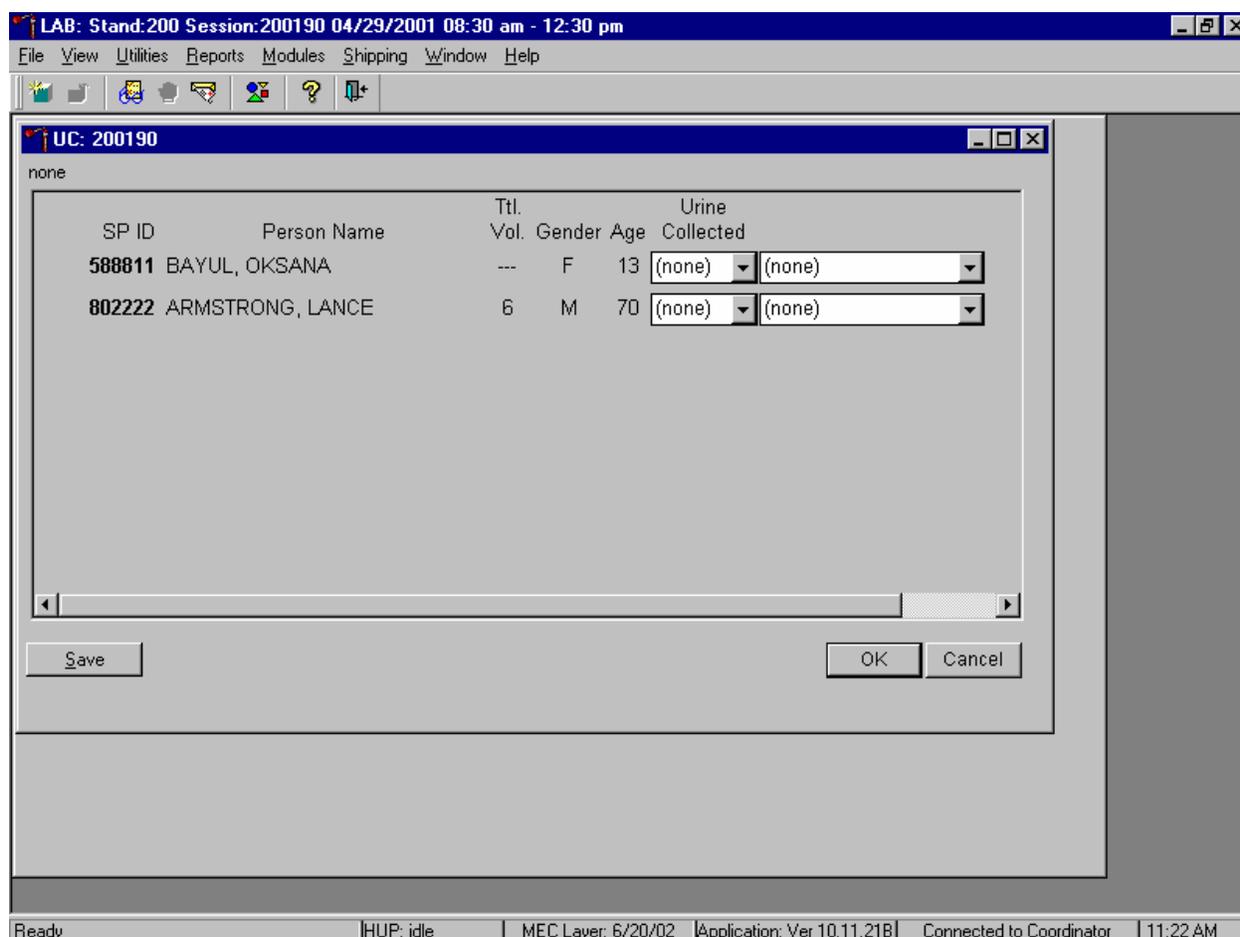
Collect approximately 8-mL urine from all dry run volunteers. The MEC coordinator instructs each volunteer to void at the same time that the volunteer changes clothes or ideally, within 45 minutes after arrival at the MEC. After collection, the coordinator or local assistant transports the initial specimen to the laboratory. Dry run volunteers assigned to protocol group 1 (SP ID ending in an odd digit) do not require any urine at this time, since they are not eligible for any tests. Discard urine if it is not required.

Document the urine collection in the laboratory application.



To select the correct dry run volunteer's record, locate the record in the heads-up display that contains the urine collection circle. To access the urine collection module, use the up and down keys to move up and down the list until the correct record is highlighted or drag the mouse arrow to the correct volunteer and right click. Continue by dragging the mouse arrow to {Urine Collection} then left click or type [C/c].

The urine collection window displays.



The urine collection window contains columns for the SP ID, Person Name (last, first), Ttl Vol. (total volume required to complete the protocol), Gender, Age, and Urine Collection and Comments result fields. Only dry run volunteers who have checked into the MEC session are available for processing. This result field for checked-in volunteers is indicated in black while the result text box for volunteers who have not checked into the MEC session is gray. Use the scroll bar to view all volunteers scheduled into the session.

Evaluate the sufficiency of the quantity of urine received in the laboratory. Use the gradations on the urine collection cup to estimate the amount of urine received. Record the urine collection result for each volunteer by typing [Y/y] for “Yes,” [N/n] for “No” [Y/y] a second time for “Yes/QNS.” Alternatively to record the collection result, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to “Yes,” “No,” or “Yes/QNS” and left click. A “Yes/QNS” result notifies the coordinator, who then asks the dry run volunteer to provide an additional urine specimen. Refrigerate all insufficient urine samples. If additional urine is obtained, pool the urine, mix, and process.

Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each dry run volunteer. Enter “No” in the result field for all volunteers who have not produced a urine sample. Record a result other than “(none)” for all records. Record a comment for all insufficient urine collections.

Save each result after entering it in the Urine Collected result field. To save a result to the database without exiting the module or removing the window, use the mouse to direct the arrow to the Save button and left click or press [Enter] when it is highlighted. To save a result to the database and exit the module and to remove the window, use the mouse to direct the mouse arrow to the OK button and left click. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to the Cancel button and left click. To exit the module or close the window after saving results to the database and without recording any further actions, use the mouse to direct the mouse arrow to the X in the upper right hand corner of the module and left click.

Use the urine processing labels printed in advance to label the SP's urine vessels. The correct protocol (Exhibit 11-3) is determined in advance by assigning dry run volunteers with an original SP ID number that ends in an odd digit to Protocol Group 1 and assigning dry run volunteers with an original SP ID number that ends in an even digit to Protocol Group 2. Protocol group 1 does not require any urine. There are two sets of labels for each dry run volunteer. Label one set of vessels with the first set of labels (SP ID) and the second set of vessels with the second set of labels (Sample ID).

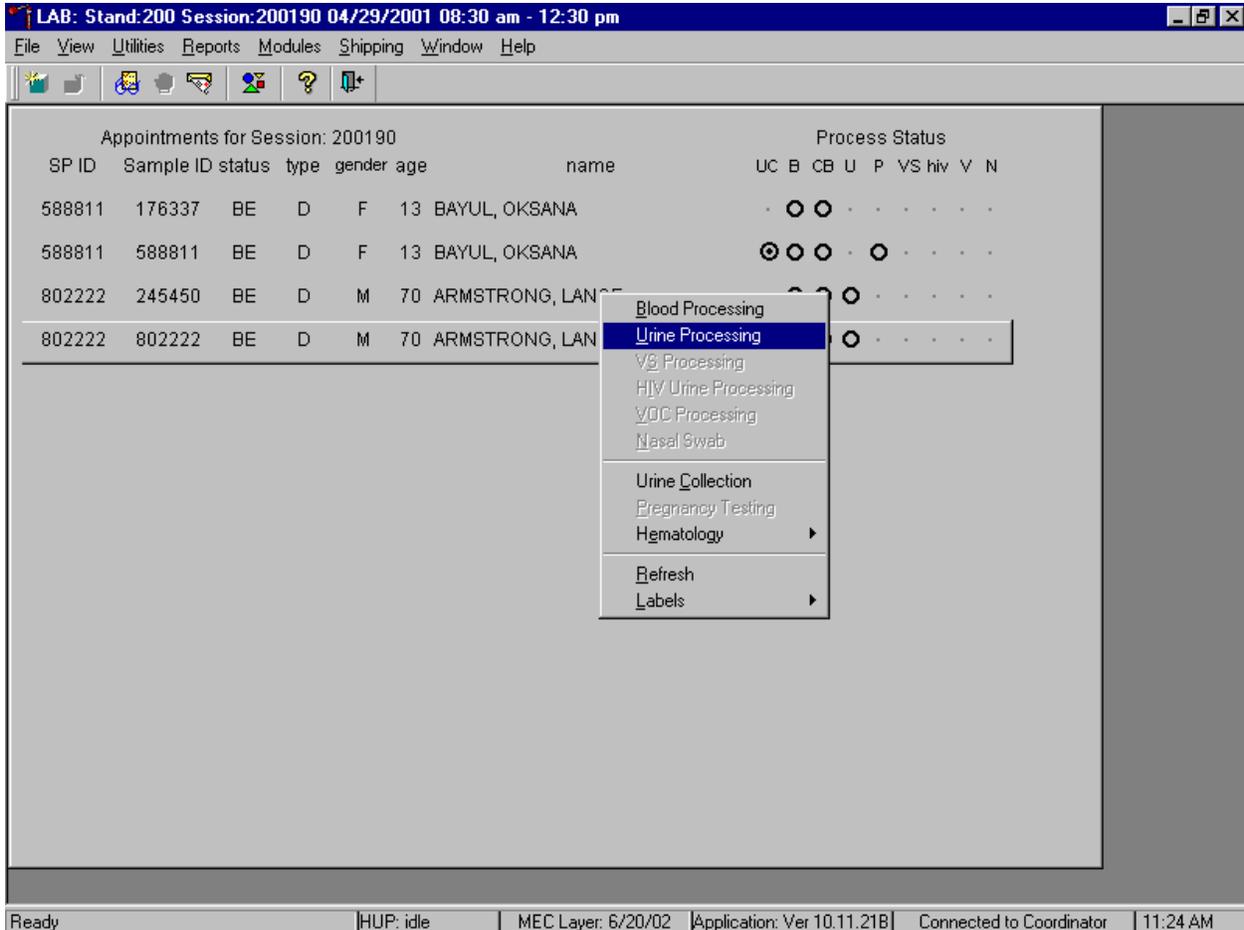
Exhibit 11-3. Dry run urine processing protocol

ID	Assay	Group 1-Odd	Group 2-Even	Sample size mL	Vessel
45	Alb/Creat		6	3	5-mL Cryovial

#### **Procedures for Dry Run Volunteers**

- Label one 5-mL cryovial for the first test - #45. Label one tube with the volunteer's original SP ID. Label the other tube with the volunteer's second Sample ID.
- Pour 3-mL urine into the vessels.
- Enter the results of urine processing for the original SP ID and again for the second Sample ID.

After filling the urine specimen vessels for each dry run volunteer, use the Urine Processing module to enter the urine processing results.



To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct volunteer, right click, drag the mouse arrow to {Urine Processing} and right click or right click and type [U/u]. Alternatively to access the Urine Processing module, use the up and down keys to move up and down the list until the correct volunteer is highlighted, right click, drag the mouse arrow to {Urine Processing}, and right click or right click and type [U/u].

The volunteer's urine processing screen displays.

LAB: Stand:200 Session:200190 04/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

UR: 802222

none

Tech ID: 1126    Sample ID: 802222    Name: ARMSTRONG, LANCE    Gender: M    Age: 70  
 SP ID: 802222    SubSample: 6    Fasting\_Req: 4

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0077087	7

Save    OK    Cancel

Apply changes and close window | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.21B | Connected to Coordinator | 11:26 AM

To mark an individual urine vessel as collected or Filled – “Yes,” use the mouse to direct the mouse arrow to the “Yes” radio button and left click. As each vessel is marked as Filled – “Yes,” it is automatically assigned to a slot in an existing (open) container. To mark an individual urine vessel as not collected or Filled – “No,” use the mouse to direct the mouse arrow to the “No” radio button and left click. As each vessel is marked as Filled “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column. To collectively mark all vessels as Filled – “Yes,” use the mouse to direct the mouse arrow to the Filled button above the radio buttons, left click, and drag the arrow to {Fill All} and left click or type [Shift] [F/f]. To mark all vessels as Filled – “No,” use the mouse to direct the mouse arrow to the Filled button above the radio buttons, left click, drag the mouse arrow to {Not Filled All} and left click or type [Shift] [F/f], [N/n]. Use the quality comment code to indicate if blood is present. Store each filled vessel in the assigned slot in the assigned container. To record this action or to

save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

Access the Sample ID record on the heads-up display and record the processing results. Remember to process vessels in pairs and if the quantity of urine is insufficient to fill both vessels; do not record either vessel as filled.

Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink. Flush the sink with water. Discard urine cup in the biohazard trash.

The urine-processing technologist performs the pregnancy test on female dry run volunteers aged 8-59 years and documents the results following the procedures in Chapter 6.

### **11.4.3 Hematology**

The technologist at workstation 2 runs two CBCs, in duplicate, for each dry run volunteer after the blood processing technologist processes whole blood from the 3-mL lavender tubes according to the Whole Blood Processing Protocol (see Exhibit 11-4). Run the first CBC in duplicate on the first 3-mL lavender tube with the original SP ID on the tube. Evaluate results, and save the data using procedures described in Chapter 7.

Run the second CBC in duplicate on the second 3-mL lavender tube using the second Sample ID. Evaluate results, and save the data using procedures described in Chapter 7.

### **11.4.4 Blood Processing and Storage**

Print blood-processing labels using procedures described in Chapter 9. There are two sets of labels for each dry run volunteer. Prepare two blood processing racks using the blood-processing template for age 12+.

Treat each set of venipuncture tubes and prelabeled blood processing racks as two independent and separate dry run volunteers. Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID, then process the second set of venipuncture tubes and blood processing vessels using the second Sample ID.

For volunteer's whose SP ID ends in an even or an odd digit, process each of the 3-mL lavender top tubes for Lead/Cad/HG, Ery Proto, RBC Folate, Glycohem, and Mercury using the same procedures described in Chapter 8. Match the first 3-mL lavender tube with the SP ID to the corresponding blood processing rack. Match the second 3-mL lavender tube with the sample ID to the corresponding blood processing rack. Reserve the remaining whole blood in the 3-mL lavender tubes for the CBC.

Exhibit 11-4. Dry run processing protocol – whole blood

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG	Both	0.5	Whole Blood	3-mL lavender	2-mL
2	Ery Proto (age 14-49 females)	Odd	0.4	Whole Blood	3-mL lavender	2-mL
3	RBC Folate	Even	0.1	Whole Blood	3-mL lavender	2-mL
4	Glycohem	Odd	0.4	Whole Blood	3-mL lavender	2-mL
5	Mercury	Even	0.3	Whole Blood	3-mL lavender	2-mL

When the SP ID ends in an even digit, process the plasma in each of the other two 3-mL lavender top tubes for Vitamin B6 and Homocys/MMA as described in Chapter 8. When the SP ID ends in an even or an odd digit, process each of the 2-mL gray top tubes for Glucose using the same procedures described in Chapter 8.

Exhibit 11-5. Dry run processing protocol - plasma

ID	Test Name	Groups	Sample (mL)	Sample Type	Collection Type	Vessel Type
81	Vitamin B6	Even	0.5	Plasma	3-mL lavender	2-mL
7	Homocys/MMA	Even	1.0	Plasma	3-mL lavender	2-mL
9	Glucose	Both	0.5	Plasma	2-mL Gray	2-m:

Process pooled serum for the dry run volunteers using the Dry run blood processing protocol – serum (Exhibit 11-6).

Exhibit 11-6. Dry run blood processing protocol - serum

ID	Test Name	Groups	Sample (mL)	Sample Type	Collection Type	Vessel Type
70	Vitamin D	Even	0.5	Serum	10-mL Red	2-mL
12	Folate/B12	Odd	1.0	Serum	10-mL Red	2-mL
13	CRP	Odd	0.5	Serum	10-mL Red	2-mL
14	Hep profile	Even	1.5	Serum	10-mL Red	2-mL
99	Fer/TfR (12-49 females)	Odd	0.4	Serum	10-mL Red	2-mL
11	Iron/TIBC (12-59 females)	Even	1.0	Serum	10-mL Red	2-mL
17	Cotinine	Even	1.8	Serum	10-mL Red	2-mL
21	Lipids	Both	1.0	Serum	10-mL Red	2-mL
94	PTH2	Odd	1.0	Serum	10-mL Red	2-mL
79	Vitamin C	Even	0.1	Serum	10-mL Red	2-mL
16	Rub/Mea/Var (12-49)	Odd	0.1	Serum	10-mL Red	2-mL
19	Bn Alk Phos (8-49)	Odd	0.5	Serum	10-mL Red	2-mL
20	Toxo (12-49)	Odd	0.5	Serum	10-mL Red	2-mL
18	Biochem	Both	0.8	Serum	10-mL Red	2-mL
23	Insul/Cpep	Odd	1.0	Serum	10-mL Red	2-mL
26	Selenium	Even	0.5	Serum	10-mL Red	2-mL

- Fill each vessel as described in the blood processing protocol.
- Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID. Continue to use the labeled vessels in the prepared rack.
- Process the second set of venipuncture tubes and blood processing vessels using the second Sample ID. Continue to use the labeled vessels in the prepared rack.
- Use the same techniques for spinning and separating the blood as described in Chapter 8.

- Check the vessel labels before filling the vessel making sure that each vessel has the correct SP ID or Sample ID.

Match the two processing racks to each other. Record the blood processing results.

LAB: Stand:200 Session:200190 04/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BP: 245450

Tech ID:1126 Sample ID: 245450 Name: ARMSTRONG, LANCE Gender: M Age: 70  
 SP ID: 802222 SubSample:6 Fasting\_Req: 4

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
5	Mercury	0.3	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

BP: 802222

Tech ID:1126 Sample ID: 802222 Name: ARMSTRONG, LANCE Gender: M Age: 70  
 SP ID: 802222 SubSample:6 Fasting\_Req: 4

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad/HG	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
81	Vitamin B6	0.2	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.21B | Connected to Coordinator | 11:33 AM

Enter results for those vessels where both vessels are filled for the whole blood, plasma, and serum protocol. Enter the results of blood processing using the correct Sample ID and SP ID numbers and procedures described in Chapter 8, Section 8.8. Store the blood vessels in a manner identical to blood vessels processed during a regular session.

### **11.4.5 Shipping Dry Run Specimens**

Ship the split sample blood and urine vessels with samples from the regular sessions following procedures described in Chapter 9.

## **11.5 Centrifuges – Equipment Maintenance**

Technologists are responsible for inspecting the centrifuges at the beginning of each stand, and inspecting and cleaning the centrifuges at the end of each stand and whenever necessary. Clean the interior of the chamber with a mild soap, as time permits. Rinse thoroughly and dry completely.

1. Inspect the rotor yolk and buckets.

Inspect for rough spots or pitting, white powder deposits or heavy discoloration. If any of these signs are evident, do not use the rotor. Use the second centrifuge and notify the NCHS engineer. Check the condition of the O-ring in the tie-down nut; replace it if it is worn or damaged.

2. Clean the rotor.

Use mild detergent, diluted 10 to 1 with water and a soft brush to clean the rotor yolk and tie-down nut. Thoroughly rinse the cleaned rotor and components with water and air-dry upside down. When the rotor is dry, lubricate the bucket sockets and pins by saturating a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk. Before reinstalling the rotor, lightly lubricate the drive hole of the rotor with Anti-Seize to prevent the rotor from sticking, as follows:

Apply the lubricant onto a swab.

Draw the coated swab through a paper towel to remove excess lubricant.

Lightly coat the inside of the drive hole with the lubricant remaining on the swab.

3. Clean the buckets:

- Remove the O-ring.
- Clean the bucket and O-ring with a mild detergent diluted 10 to 1 with water, then rinse thoroughly, and dry completely.

- Coat the O-ring with a light film of silicone vacuum grease. Place the O-ring on the ledge inside the bucket.
  - Once a week and after every cleaning, lubricate contact areas between the buckets and the pins on the rotor. Saturate a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk.
4. Inspect and clean Aerosolve canisters.
- Inspect the O-ring for nicks, abrasions, or other damage. Coat the O-ring with a light film of silicone vacuum grease before installing. Place the O-ring in the groove.
  - Inspect the canister and lid threads and bottom of canister for heavy crazing or cracks.
  - Inspect the tube racks for heavy scratches or cracks and inspect the rubber cushions for damage or for imbedded glass from broken tubes.
  - Clean the canisters, lids, and racks with a mild detergent, diluted 10 to 1 with water, and a soft brush. Thoroughly rinse the cleaned components with water and air-dry upside down. Coat the O-ring with a light film of silicone vacuum grease before reinstalling it into the groove.

The NCHS biomedical engineer certifies both centrifuges annually. The NCHS engineer determines the rpm of the instruments using a strobe light or a tachometer. The engineer records multiple readings for each centrifuge. The Beckman GS-6R centrifuge should exceed 3,750 rpm to ensure adequate centrifugal force development. The engineer checks each centrifuge timer against a stopwatch and records the values in the Laboratory QC module – NCHS QC.

Document beginning and end of stand cleaning procedures in the Laboratory QC module.

## **11.6 Refrigerators and Freezers – Equipment Maintenance**

The freezers require proper ventilation in order to operate efficiently and the air around the freezers must be free to circulate. Vents in the counters allow the heat from the freezers to rise and dissipate. Keep the vents open and do not obstruct the airflow. Do not store anything between the freezers or between the counter supports and the freezer.

Quality control procedures for the refrigerators and freezers include cleaning them at the beginning and end of the stand and whenever necessary. Continuously monitor the temperatures of refrigerators and freezers on a daily basis and record the results in the Laboratory QC module. Additionally, monitor temperatures using the automated recording instrument procedure that follows. Before putting a new chart on the recording device, date the chart and record the assigned instrument number.

- Change the tempscribe chart weekly.
- Save and send the used charts to the home office at the end of each stand.
- Document these activities in the Laboratory QC module.
- Change recording pens when necessary.
- Document any necessary unscheduled maintenance in the Unusual Occurrence Log.

### **Cleaning**

Wear rubber gloves when cleaning. Use warm soapy water and avoid the use of abrasive cleansers. After cleaning the unit, disinfect the interior and exterior by cleaning with a 1:10 solution of bleach and water.

## **11.7 Use of the Temperature Recording Instrument**

The Jewett Instrument is a microprocessor-based, AC operated temperature recording device, which automatically monitors the interior temperature of the refrigerator and freezers. The device continuously graphs this record on a circular paper chart so that 7 days of temperature data can be inspected easily. When this recorder functions under normal conditions and receives proper care, it renders lasting accurate service.

The NHANES engineer is responsible for mounting, installing, and calibrating the recorder as specified in the manufacturer's Operating Manual. The results of the recorder should be monitored at the beginning of each day. Replace charts on a weekly basis, and replace batteries and pens, as needed.

To monitor the results of the recorder, look at the chart for each refrigerator and freezer at the beginning of each day, read the temperature indicated on the chart, and record it in the Laboratory QC module. Record the highest temperature shown on the chart since the last reading.

The allowable temperature range for the refrigerators is 2° to 8°C, (36° to 46°F) and the allowable temperature range for the freezers is –18 to 23°C (0 to -10-°F). Note that if the temperature for a refrigerator or freezer exceeds the allowable temperature range, document this in the Unusual Occurrence Log, and inform the MEC manager immediately. Transfer contents of the refrigerator or freezer to a temperature controlled environment.

Maintenance of the Jewett Temperature Recorder involves chart installation on a weekly basis, replacement of the cartridge pen, and replacement of the batteries as needed (approximately once a year).

To install the new chart:

1. Press and hold the Change Chart push button switch for 1 second until the pen begins to move to the left of the chart.
2. To remove the chart, unscrew the knob at the center of the chart.
3. Position the new chart so that the correct timeline coincides with the timeline groove on the chart plate, then replace the knob and screw tightly against the chart.
4. Again, push the Change Chart push button switch for 1 second until the pen begins to move back onto the chart.
5. Check to make sure the pen is marking on the paper. If not, lightly adjust the pen arm to establish contact with the paper.

The Jewett temperature recorder uses a standard cartridge pen that requires no filling. It consists of a self-contained ink reservoir with a porous plastic stylus that snaps around the outer edge of the pen. Use the two screws at the top of the pen arm to adjust the length to ensure that the pen tracks the timeline on the chart. Check the length after each pen replacement and adjust accordingly if required. If the stylus does not touch the chart, make adjustments by slightly bending the pen arm in the center. Do not use more pressure than is necessary to create a fine line.

**NOTE:** As the ink supply runs out, the ink color becomes lighter. Replace the pen when this occurs.

If AC power fails, the LED changes to a flashing green to alert the user of the power failure. The 9-Volt battery allows the recorder to sense and record temperatures for a minimum of 12 hours.

Occasionally, a recorder may malfunction. Contact technical service at 800-879-7767. The manufacturer offers the following troubleshooting guide:

LED status	Chart rotation	Pen location	Battery status	AC power status	Cause	Repair
Green	OK	OK	OK	OK	Normal	None required
Flashing Green	OK	OK	Low	Off	AC failure or low battery	Check power source and transformer – Replace battery if necessary.
Green	OK	Inner hub	OK	OK	Probe failure	Check connection on board – Replace probe

## 11.8 Use of the Class II Type A Biological Safety Cabinet

The Class II Laminar Flow Biological Safety Cabinet (LFBSC), with proper technique, provides an effective partial containment system for safe manipulation of moderate- and high-risk microorganisms. The vertical laminar airflow barrier prevents contaminated air from entering or escaping from the open-front work chamber, protecting the cabinet contents and the technologist. A high-efficiency filter system decontaminates both the incoming air and the exhaust.

### Installation, Certification, and Maintenance

The NCHS biomedical engineer arranges for a certified engineer to perform the required annual certification that includes replacement of HEPA filters as necessary.

The basic concept of the LFBSC is to take air through a blower system, pressurize a plenum, and force air through a filter. Built-in supply and exhaust blowers come with separate HEPA filters. The recirculating airflow pattern directs a portion of the HEPA filtered air straight down over the central work area driving the airborne contaminants into the surrounding grills, allowing a pollution free environment for particular specifications. If a filter is defective, the filtration system no longer filters and becomes a

vacuum cleaner, taking in gross contamination and exploding it through the defective filter onto and around the critical work area. The filter of the LFBSC is a permanent part of the disposable plenum. A manometric gauge is calibrated in “inches of water gauge” pressure (w.g.). The gauge indicates when the supply HEPA filter is clogged. As the filter loads with particulate matter, the amount of pressure registered on the gauge will increase. The initial pressure reading is approximately 0.4 w.g.  $\pm$  0.05 w.g. depending on the altitude from sea level. Check and record the reading on the gauge every day. If the gauge registers an increase in pressure of more than 0.1 w.g., notify the NCHS engineer. The NCHS engineer will arrange to have the airflow pressure and the HEPA filter system checked. If the HEPA filter is no longer effective, the engineer or MEC manager discards the entire filter and plenum and substitutes a new replacement unit.

Clean the LFBSC at the beginning and end of each stand. Lift the front glass and wash both the interior and exterior glass. Remove all contents from the interior of the cabinet. Remove and wash the front grill. Lift the cover to the table and wash the base underneath. Put table cover and grill back into cabinet. Lock front glass into place. Document these activities in the Laboratory QC module. Take and record the pressure reading in the Laboratory QC module at the beginning of stand and at the start of each session.

Document all unscheduled maintenance for the LFBSC in the Unusual Occurrence Log.

## **11.9 Ambient Air Temperature**

Two thermometers monitor ambient temperature in the laboratory. Quality control procedures for ambient air temperatures involve checking these thermometers for damage, monitoring the temperature each session, and documenting any unusual occurrences. Check the two wall thermometers for damage at the beginning of each stand. Notify the MEC manager of any damage.

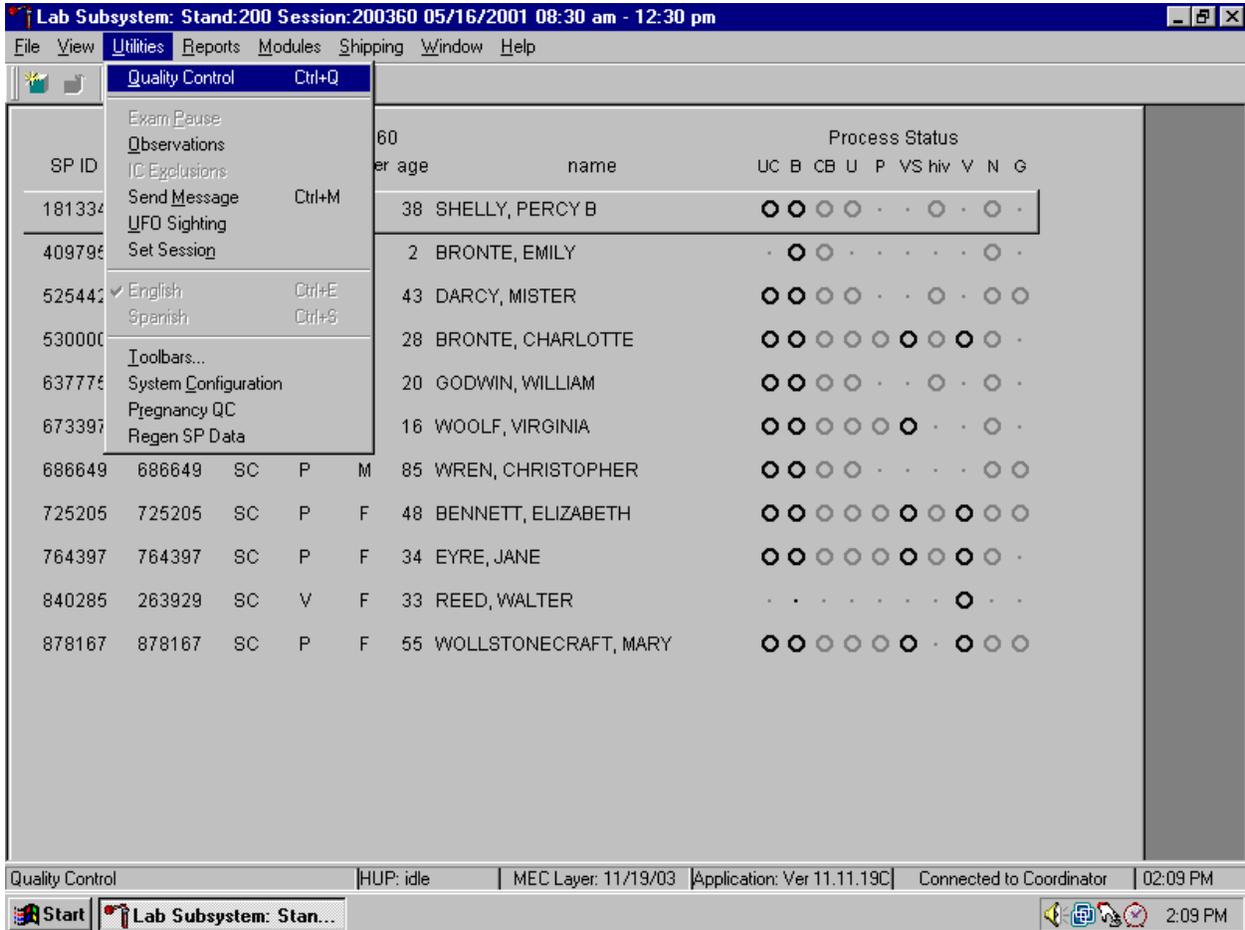
The allowable ambient temperature range for the laboratory is 17° to 25°C (63° to 77°F).

**NOTE:** If the room temperature is out of allowable range since the last reading, document this in the Unusual Occurrence Log and inform the MEC manager immediately.

## 11.10 Laboratory/Phlebotomy Quality Control Module

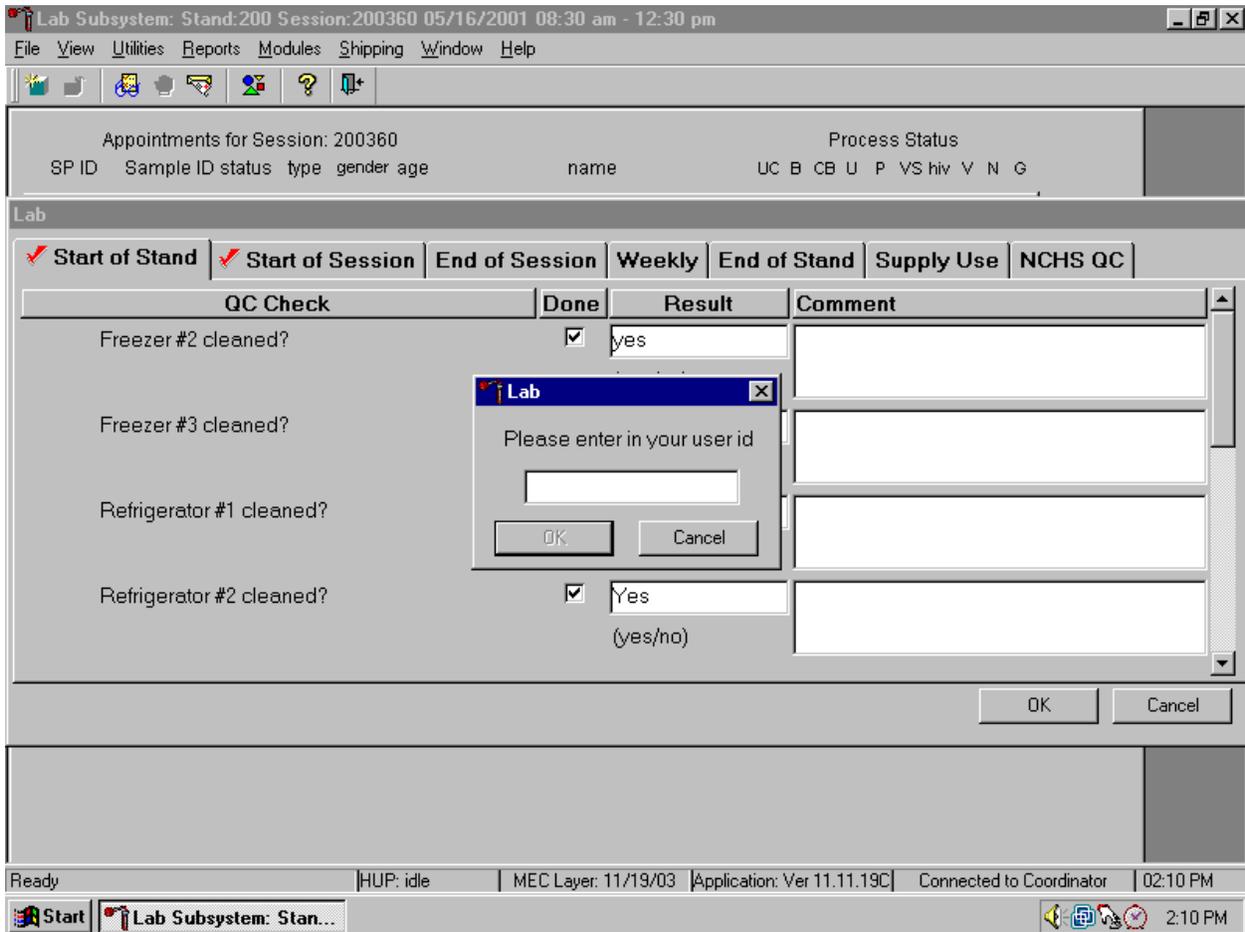
Document all instrument quality control activities in the Laboratory QC module.

Access the Laboratory or Phlebotomy QC module.



To access the QC module, use the mouse to direct the mouse arrow to {Utilities}, drag the arrow to {Quality Control}, and left click or type [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

Enter the required user ID.



Enter user ID as last name\_first initial and [Enter] or type in the user ID and use the mouse to direct the mouse arrow to the OK button and left click. To exit without entering a user ID, use the mouse to direct the mouse arrow to the Cancel button and left click.

Enter quality control activities and readings.

Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 200360 Process Status

SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
-------	-----------	--------	------	--------	-----	------	----	---	----	---	---	----	-----	---	---	---

**Lab**

Start of Stand
  Start of Session
  End of Session
  Weekly
  End of Stand
  Supply Use
  NCHS QC

QC Check	Done	Result	Comment
Urine processing ambient air temperature reading (17 to 25 °C)	<input type="checkbox"/>	degrees C	
Blood processing ambient air temperature reading (17 to 25 °C)	<input type="checkbox"/>	degrees C	

OK Cancel

Apply changes and close window | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:11 PM

Start | Lab Subsystem: Stan... | 2:11 PM

Select the correct activity (Start of Stand, Start of Session, End of Session, Weekly, End of Stand, Supply Use, or NCHS QC) by using the mouse to direct the mouse arrow to the correct heading on the top of the file and left click. At each stand, perform and record weekly activities on the same weekday as set up.

Mark activities as done and enter the result.

The screenshot shows a software window titled "Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main area is divided into sections. At the top, there's a header for "Appointments for Session: 200360" and "Process Status". Below that is a table with columns: "SP ID", "Sample ID", "status", "type", "gender", "age", "name", "UC", "B", "CB", "U", "P", "VS", "hiv", "V", "N", "G". A blue bar labeled "Lab" is below the table. Underneath, there are several tabs: "Start of Stand", "Start of Session", "End of Session", "Weekly", "End of Stand", "Supply Use", and "NCHS QC". The "Start of Stand" and "Start of Session" tabs are checked. Below the tabs is a table with columns: "QC Check", "Done", "Result", and "Comment".

QC Check	Done	Result	Comment
Urine processing ambient air temperature reading (17 to 25 °C)	<input checked="" type="checkbox"/>	20 degrees C	
Blood processing ambient air temperature reading (17 to 25 °C)	<input checked="" type="checkbox"/>	21 degrees C	

At the bottom right of the main area are "OK" and "Cancel" buttons. The status bar at the bottom shows "Apply changes and close window", "HUP: idle", "MEC Layer: 11/19/03", "Application: Ver 11.11.19C", "Connected to Coordinator", and "02:12 PM". The Windows taskbar at the very bottom shows the Start button, the application window "Lab Subsystem: Stan...", and the system tray with the time "2:12 PM".

To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the done column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box.

Enter the response or reading in the Result text box.

The screenshot shows a software window titled "Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm". The interface includes a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. Below the menu is a header section for "Appointments for Session: 200360" with a "Process Status" field. A table with columns "SP ID", "Sample ID", "status", "type", "gender", "age", "name", and "UC B CB U P VS hiv V N G" is partially visible. The main area is titled "Lab" and contains a series of tabs: "Start of Stand", "Start of Session", "End of Session", "Weekly", "End of Stand", "Supply Use", and "NCHS QC". The "Start of Session" tab is active. Below the tabs is a table with the following structure:

QC Check	Done	Result	Comment
Urine processing ambient air temperature reading (17 to 25 °C)	<input checked="" type="checkbox"/>	20 degrees C	
Blood processing ambient air temperature reading (17 to 25 °C)	<input checked="" type="checkbox"/>	29 degrees C	Air conditioner not working - notified MEC Manager

At the bottom right of the main area are "OK" and "Cancel" buttons. The status bar at the bottom of the window displays: "Apply changes and close window", "HUP: idle", "MEC Layer: 11/19/03", "Application: Ver 11.11.19C", "Connected to Coordinator", and "02:12 PM". The Windows taskbar at the very bottom shows the Start button, the application icon, and the system tray with the time "2:13 PM".

Enter "Yes" or "No" for text responses, whole numbers for rpm measurements, minutes, and seconds for timer readings, three decimals for w.g., and whole negative and positive numbers for thermometer readings in the Result text box. Select [Tab] or [Enter] to move to the Comment text box. Type any actions associated with an unexpected result in the Comment text box. Select [Tab] to move to the next line.

## Enter Phlebotomy QC.

QC Check	Done	Result	Comment
Room Temp. Reading	<input checked="" type="checkbox"/>	26 17°C - 25°C	Notified MEC Manager and Chief Medical Technologist
Disinfect Counters	<input checked="" type="checkbox"/>	Yes	

To record a check mark in the Room Temp. Reading check box, use the mouse to direct the mouse arrow to the check box in the Done column and left click, then select [Tab] to move to the Result text box. Enter the temperature in the Result text box and select [Tab] to move to the Comment text box. If the reading is outside the established range (17-25°C); document the actions taken to resolve the situation in the Comment text box. Select [Tab] to move to the next QC item. To record a check mark in Disinfect Counters check box, use the mouse to direct the mouse arrow to the check box in the Done column and left click, then select [Tab] to move to the Result box. Type “Yes” or “No” in the Result box and select [Tab] to move to the Comment text box. If the result is unexpected, such as “No,” document the actions taken to resolve the situation in the Comment text box. To save these actions in the database, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the QC

module without saving these actions in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

Enter the lot numbers and expiration dates in the Supply Use activity. This activity lists every inventory item associated with the component. It is not necessary to record the pregnancy test kit and the serum and urine pregnancy control lot numbers and expiration dates since these are captured in the Pregnancy QC module.

Lab Subsystem: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 200360 Process Status

SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N	G
-------	-----------	--------	------	--------	-----	------	----	---	----	---	---	----	-----	---	---	---

**Lab**

Start of Stand
  Start of Session
  End of Session
  Weekly
  End of Stand
  Supply Use
  NCHS QC

QC Check	Done	Result	Comment
Timer	<input checked="" type="checkbox"/>		05/02,05/31/04
Solar Thermometer	<input checked="" type="checkbox"/>		12/02, 12/31/04
Metaphosphoric Acid - Weeks 4 - 6	<input type="checkbox"/>		
Metaphosphoric Acid - Weeks 1 - 3	<input checked="" type="checkbox"/>		Week 1, 10/08/03 Week 2, 10/12/03

OK Cancel

Apply changes and close window | HUP: idle | MEC Layer: 11/19/03 | Application: Ver 11.11.19C | Connected to Coordinator | 02:16 PM

Start | Lab Subsystem: Stan... | 2:17 PM

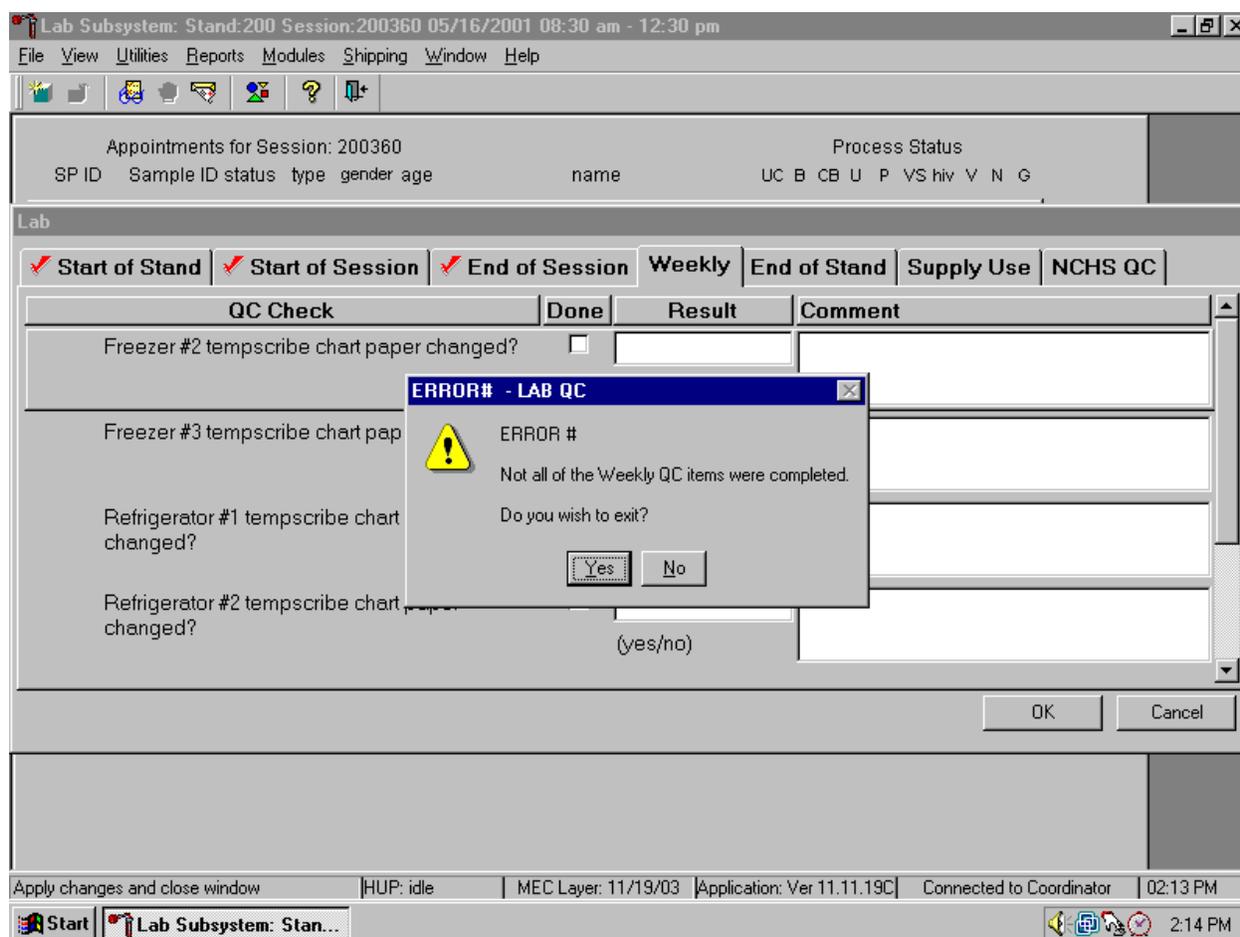
Mark each check box and record the lot and expiration date of each item in the Comments text box at the start of the stand and whenever a new lot is put into use. To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the done column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box. Do not enter the response or reading in the Result text box. Select [Tab] or [Enter] to move to the Comment text box.

- For the ascorbic acid and MPA, record the stand week (Week 1, Week 2, etc), add a comma, and record the date the reagent was reconstituted using the MM/DD/YY format.
- For the timers and thermometers, record the calibration date (12/02), add a comma, and record the expiration date using the MM/DD/YYYY format.
- For items with lot numbers, record the lot number, add a comma, and record the expiration date using the MM/DD/YY format.

There is no frequency requirement for this activity within the QC application. Update the information each time a new lot is put into use

To save the results to the database, use the mouse to direct the mouse arrow to the OK button and left click; to exit the QC module without saving the results, use the mouse to direct the mouse arrow to the Cancel button and left click. Once results are saved to the database, they cannot be changed, except for the information contained in the Supply Use Comments text box.

A warning message text box displays if required QC is incomplete.



A warning message text box displays when an attempt is made to access a laboratory module if the required QC activities have not been performed or if some activities are incomplete. Respond to the message text box. To exit the QC module, use the mouse to direct the mouse arrow to the Yes button and left click or type [Y/y] or select [Enter]. To remain in the QC module, use the mouse to direct the mouse arrow to the No button and left click or type [N/n]. Continue to perform the required QC activities and record the results.

A red check mark on the top of the file header indicates that all QC activities associated with that requirement were successfully recorded and saved to the database.

## **11.11 Unusual Field Occurrence (UFO)**

Document any unusual occurrence using the Unusual Field Occurrence utility. The hard copy Unusual Occurrence Log (see Exhibit 11-7) is available as a back up. Record the date, Tech ID number, an explanation of the incident, and the steps to resolve the incident. Be sure to record the model and the serial number of the instrument.

This new utility takes the place of the existing Tiger Log and hard copy Unusual Occurrence Log. MEC staff and the MEC manager use the UFO Utility to document any unusual occurrences that occur during an examination session. This includes equipment issues, SP issues, and protocol issues, trailer issues, supply or inventory issues, etc. This module has been incorporated into the Utility menu bar option of each application. A separate standalone module has been installed on the MEC manager workstation for use by the MEC manager and data manager. Nightly checks are made to see if there were any occurrences and, if there were, then home office staff are notified. Home office staff link to a web-based review module that will allow them to review, comment, and update the status of each occurrence.

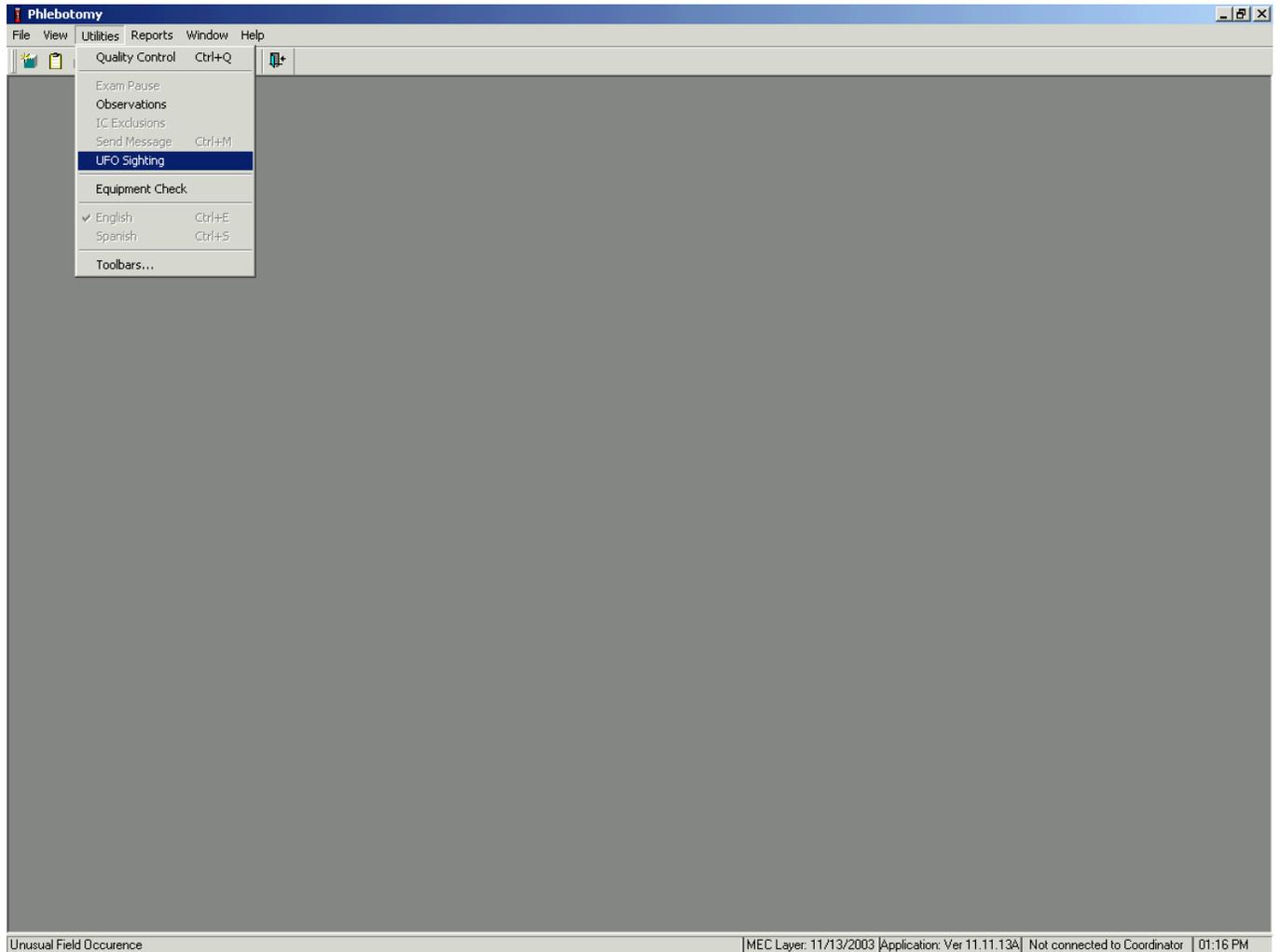
To the extent possible, the use of screen-prints when describing errors will be eliminated (for example there is no real need to print Dr. Watson errors) and system generated error messages will be automatically captured to the extent possible. Should staff feel that a screen print would be useful for describing the occurrence, they can take a screen print and store it locally. Should ISIS or home office staff need to review the screen print, they can proxy into the MEC and retrieve the screen shot.

The advantages of the UFO module are as follows:

- Allows for better tracking, review, and followup of MEC occurrences and unusual occurrences;
- Provides for a better tie to tech QC and data QC by allowing the ability to search on all unusual occurrences by Tech, by SP\_ID (very helpful when reviewing component data occurrences); and
- Provides the ability to track types of occurrences by a particular MEC or MEC workstation (for example if there are several Dr. Watson messages occurring on the MEC 1 Anthropometry workstation).

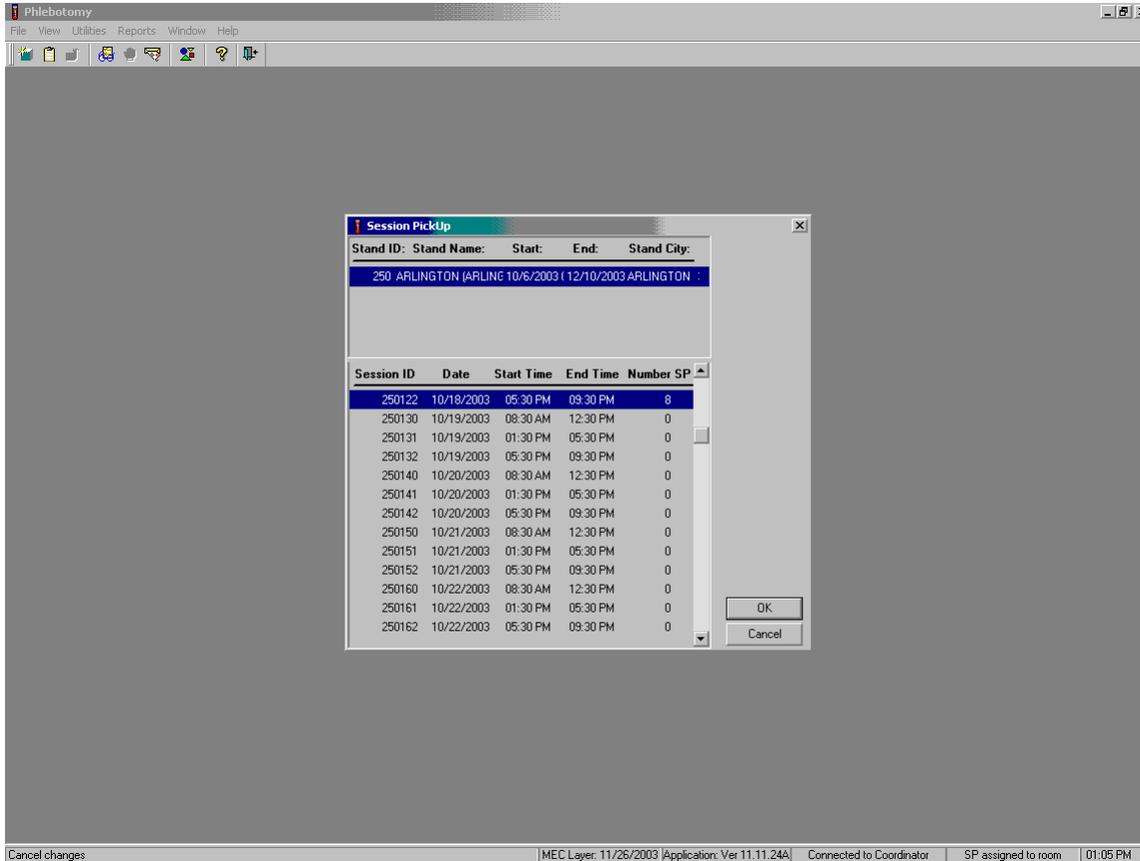
## 11.11.1 MEC UFO Utility

Log onto the application and access the UFO utility.



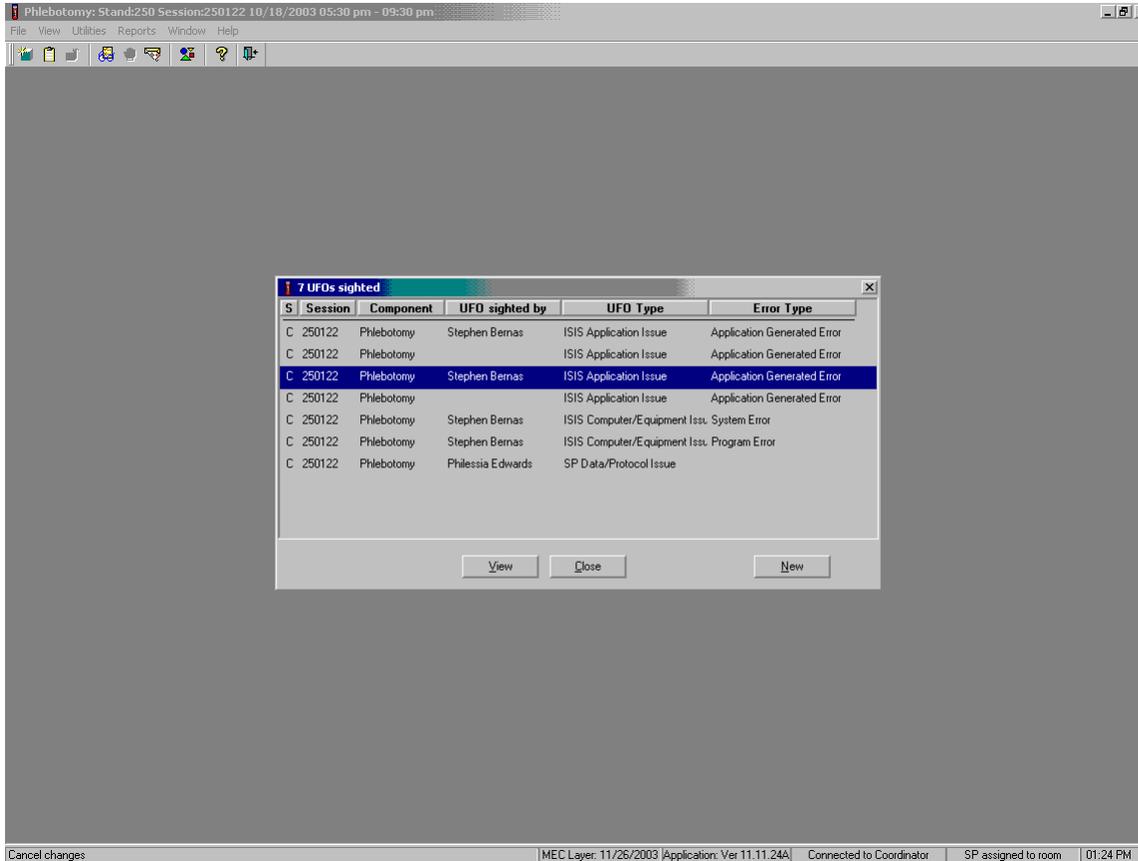
To access the UFO Sighting module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {UFO Sighting}, and left click.

Access the UFO Screen by the standard MEC Pick list that allows you to pick the Stand and Session where the unusual occurrence transpired.



The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

The UFO screen includes six column headers and three buttons. This screen is blank if no occurrences have been recorded for the selected session.



The 6 column headers are:

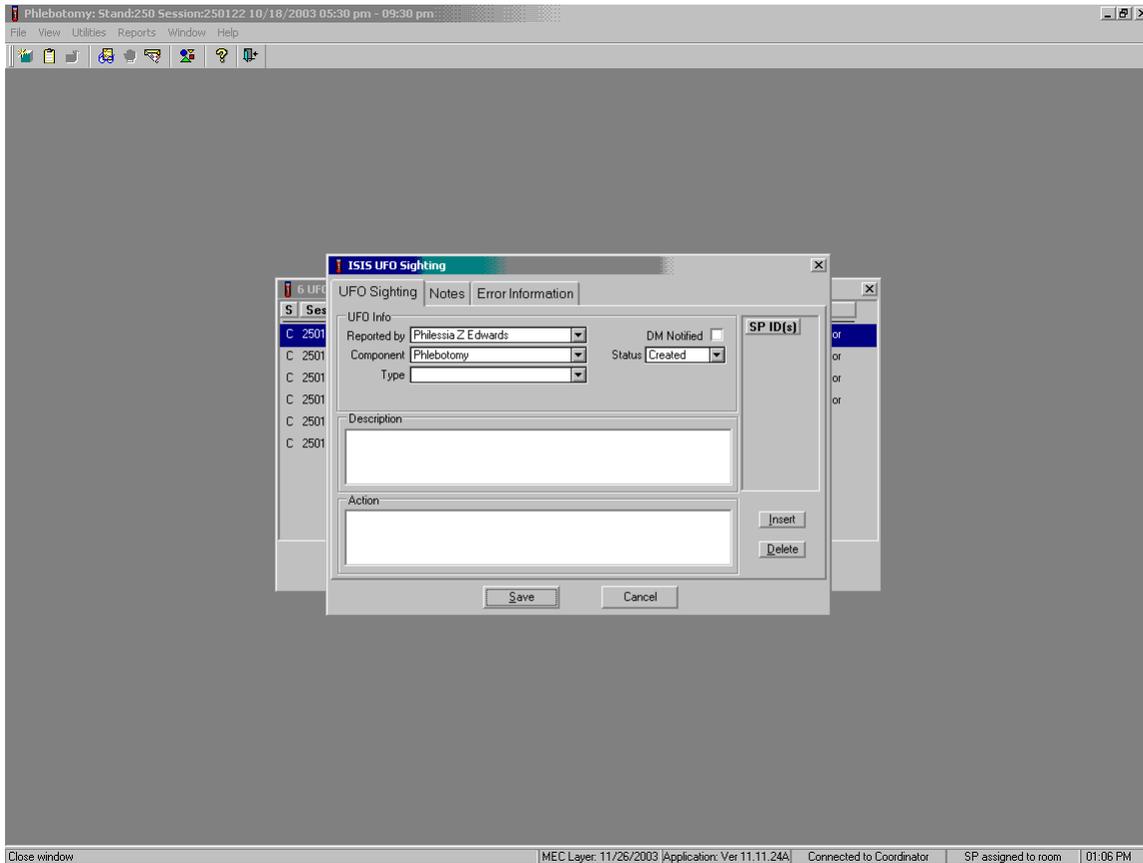
- S – Status (created, reviewed, finalized)
- Session – The session number in which the UFO occurred
- Component – default
- UFO sighted by – default
- UFO Type – pick list
- Error Type – pick list if occurrence is an ISIS Application Issue

The three buttons are:

- View – Displays existing occurrences for this session and component.
- Close – Closes the window.
- New – Allows the user to add an occurrence

### 11.11.1.1 Add a New Occurrence

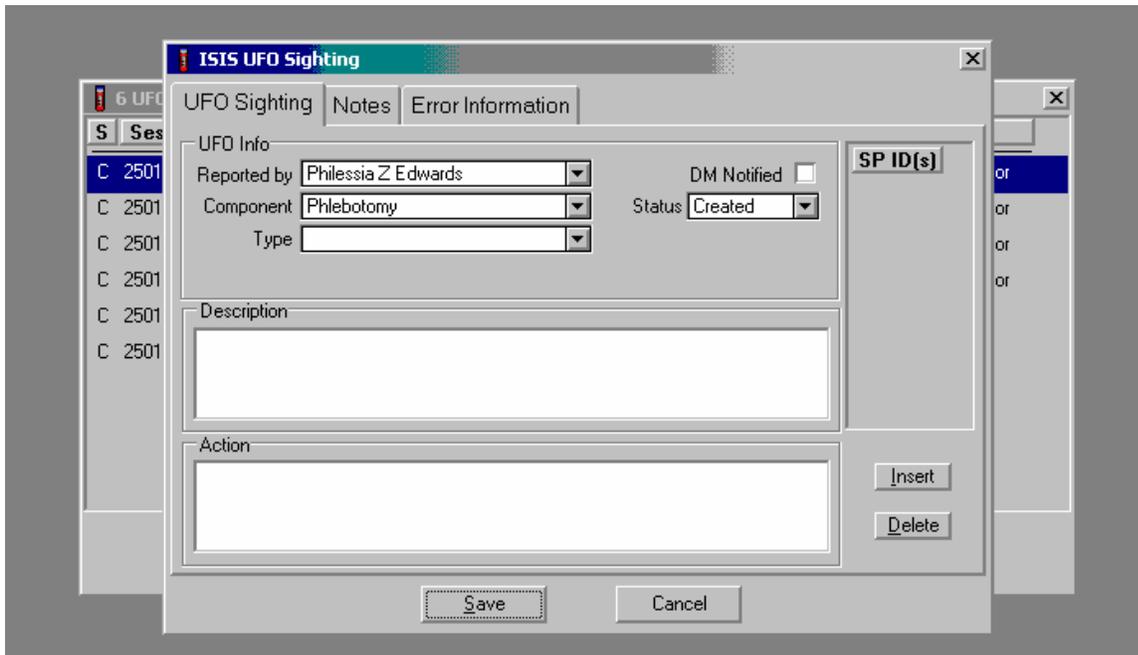
If the **New** button is selected, then an ISIS UFO Sighting window displays.



There are three file header tabs:

- **UFO Sighting**      Use the UFO sighting tab to access and enter the information. This is the default selection.
- **Notes**              Use the Notes to document subsequent action(s)
- **Error Information**    The module automatically captures the Error Information when an application error is generated.

Use the UFO Sighting tab to access and enter the information.

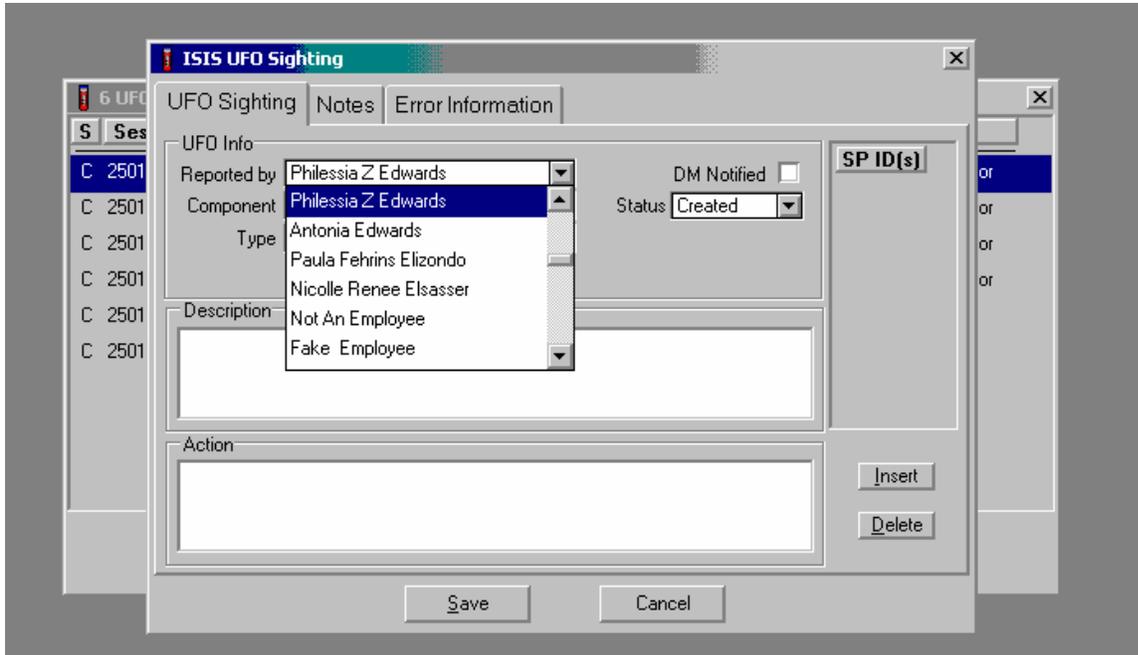


The UFO Sighting screen contains:

- Three drop-down lists:
  1. Reported by
  2. Component
  3. Type
- A checkbox for DM (data manager) notified
- A status drop-down list
- A description text box
- An action text box
- An SP ID(s) selection column with **Insert** and **Delete** buttons
- **Save** and **Cancel** action buttons

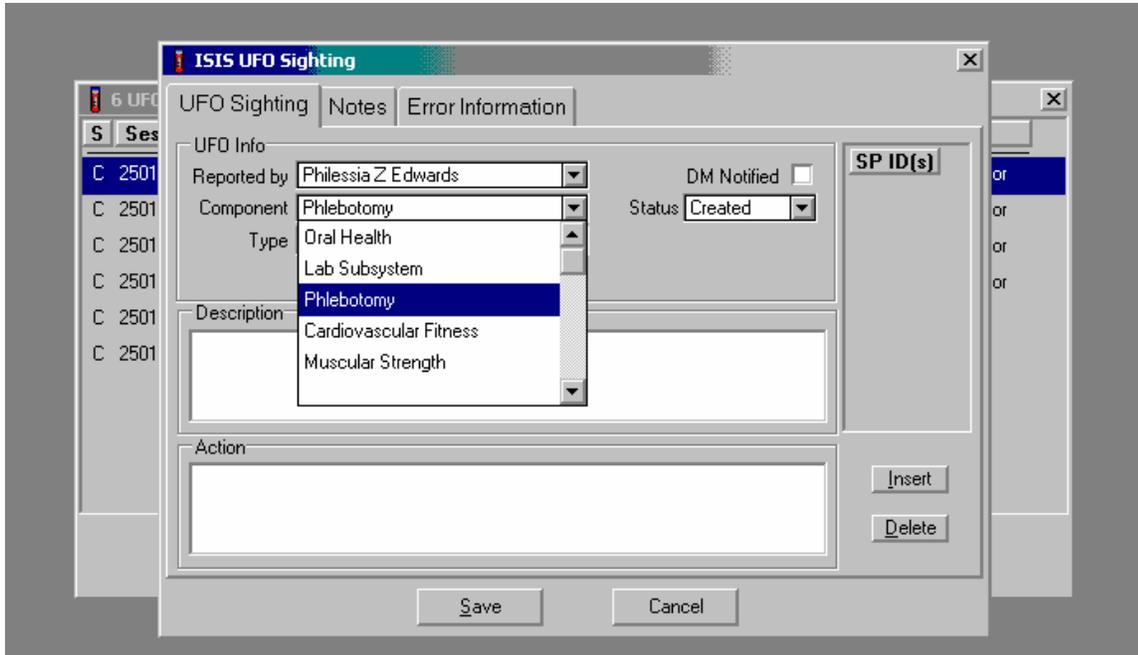
The UFO Sighting screen defaults the Reported by and Component text boxes to the user who logged onto the application and the application in use.

If necessary, change the Reported by default by using the drop-down lists to select the correct Reported by from the drop-down list.



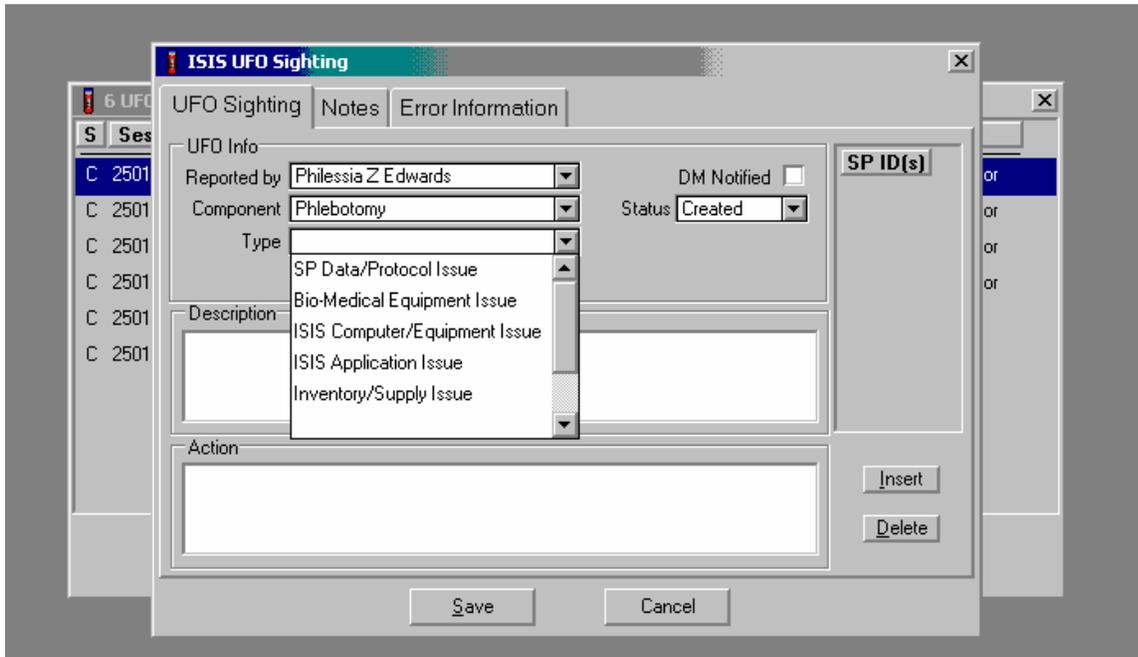
To select a different individual, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the choices, and drag the mouse arrow to the correct choice and left click.

If necessary, change the Component default by using the drop down lists to select the correct Component from the drop-down list.



To select a different individual, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the choices, and drag the mouse arrow to the correct choice and left click.

Select a Type of occurrence.



Occurrence Types are defined as follows:

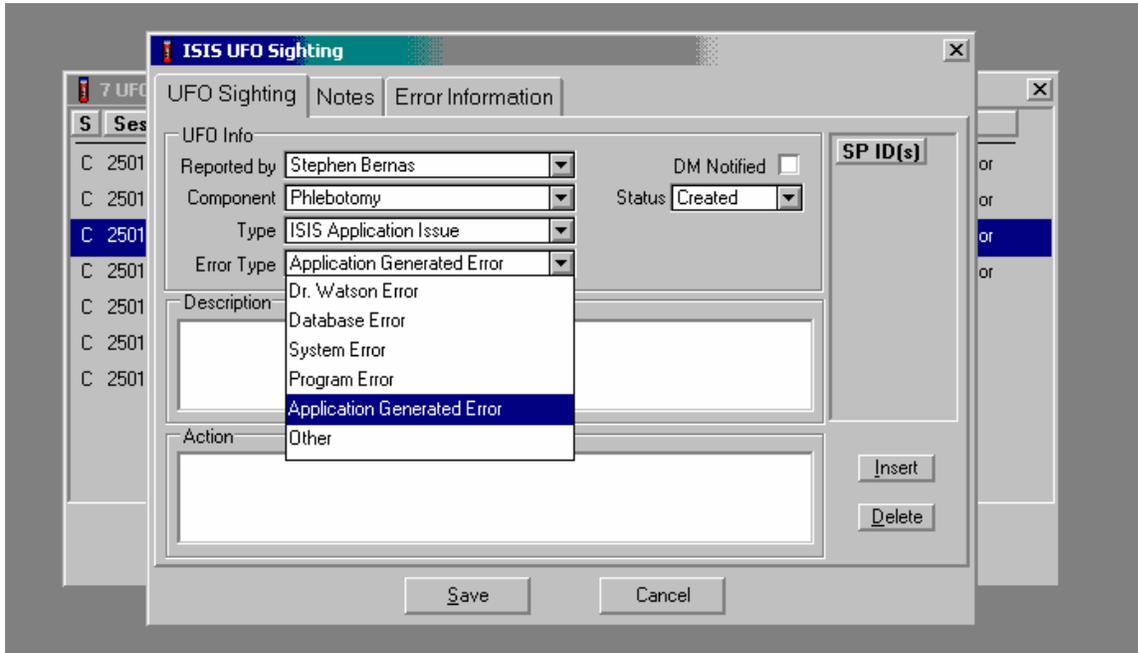
- SP Data/Protocol Issue
- Bio-Medical Equipment Issue
- ISIS Computer/Equipment Issue
- ISIS Application Issue
- Inventory/Supply Issue
- MEC Trailer Issue
- Other

Use the scroll bar to view all the various types. To select an Occurrence Type, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the choices, and drag the mouse arrow to the correct choice and left click.

### Examples of the Different Types of Issues

Occurrence Type	Definition	Example
SP Data/Protocol Issue	Use this type to document issues that are related to one or more specific SPs in the session or are related to the protocol.	The tubes displayed in the venipuncture screen of the phlebotomy application are incorrect.
Bio-Medical Equipment Issue	Use this type to document issues that are related to a specific piece of biomedical equipment.	The cable to the Parks machine has stopped working and needs to be replaced.
ISIS Computer/Equipment Issue	Use this type to document issues that are related to ISIS computer equipment only.	The laboratory workstation 3 hard drive fails and needs to be replaced.
ISIS Application Issue	Use this type to document issues related to specific applications.	The dietary interviewers get an informational popup messages that indicates that was an error creating a Phone Follow-up Appointment. They are unable to set the appointments so they sent an email request with the information to have these scheduled.
Inventory/Supply Issue	Use this type to document issues with inventory or supplies.	The Phlebotomy component is running low on 3-mL red top tubes and they need the warehouse to send more with the weekly shipment.
MEC Trailer Issue	Use this type to document issues related to the MEC trailers.	The air conditioner in trailer 3 is not working so the MEC manager documents the number of the ETS issue here.
Other	Use this type to document any other type of issue not captured by the first 6.	The telephone lines were not functioning when the MEC manager came to the MEC before the Morning Session.

If the Type of occurrence is an ISIS Application Issue, then an Error type is required.



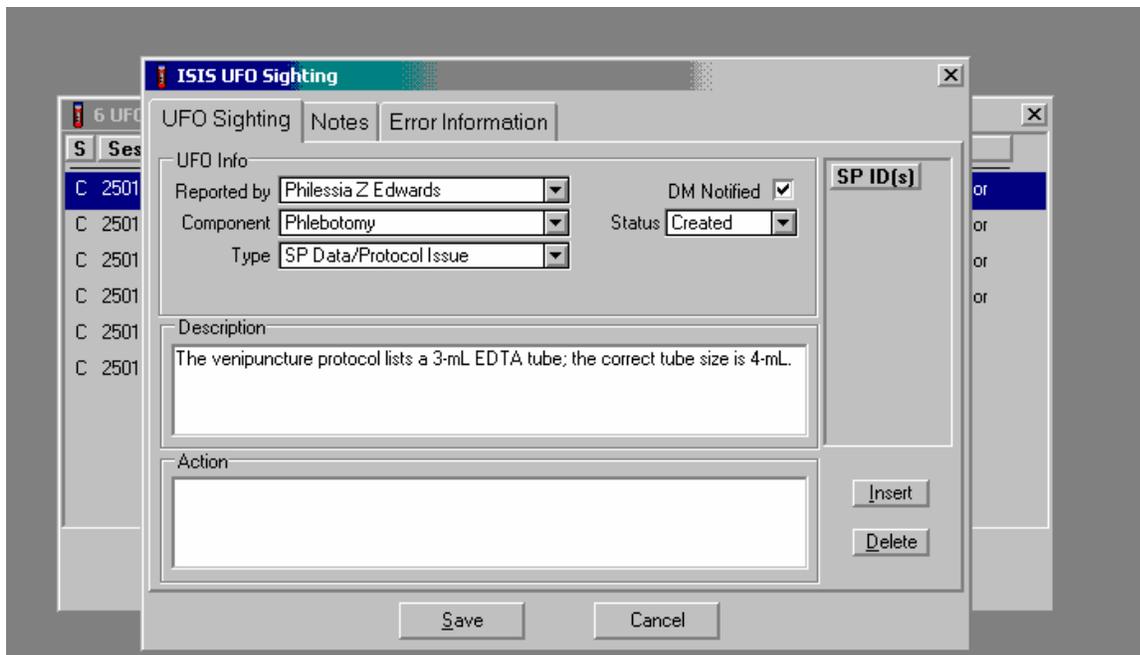
An additional Error Type text box displays if the Occurrence Type is an Application Issue. To select an Error Type, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the choices, and drag the mouse arrow to the correct choice and left click.

Error Types are defined as follows:

- Dr. Watson Error
- Database Error
- System Error
- Program Error
- Application Generated Error
- Other

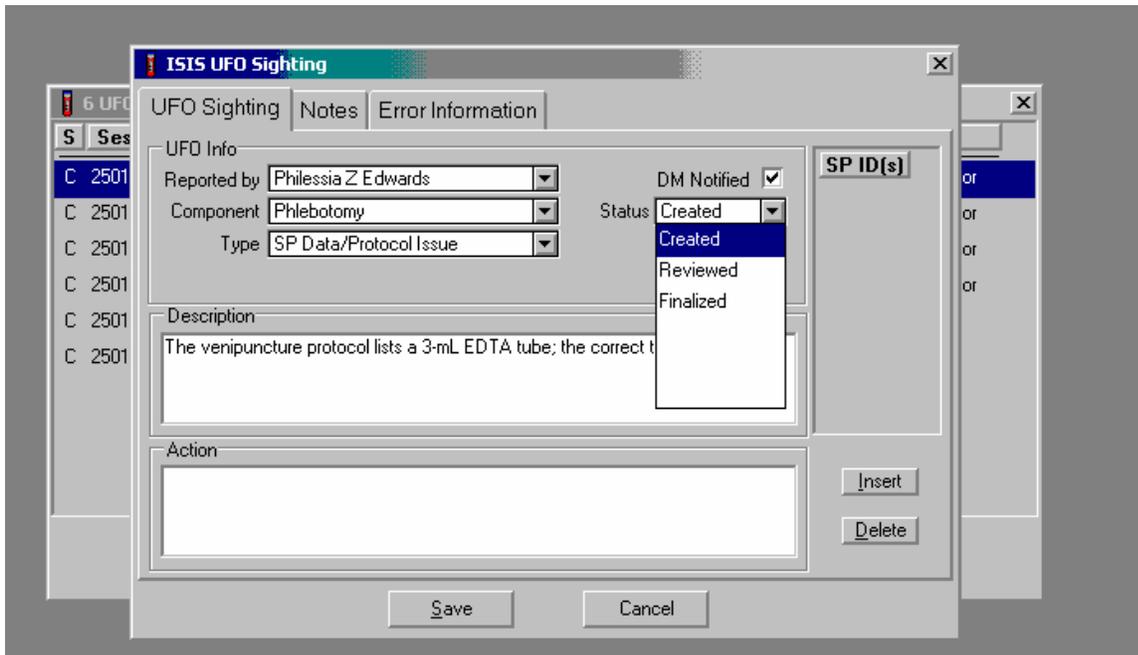
The MEC Exam Layer has been modified to capture database, system and program error messages, and store this information into a database table for review. A UFO will be generated automatically for ISIS Application Issues and Application Generated Errors. When a system problem is encountered, look to see if a UFO was already generated, and then update the other information as appropriate. **Note:** The data manager and MEC manager have access to an additional **Insert Comment** button in their module.

Notify the data manager of all occurrences except for Inventory/Supply issues unless the Inventory/Supply issue is related to their responsibilities.



Add a check mark to the DM Notified checkbox once the data manager has been notified. To record a check mark in the checkbox, use the mouse to direct the mouse arrow to the center of the checkbox and left click.

Record a status for an occurrence.



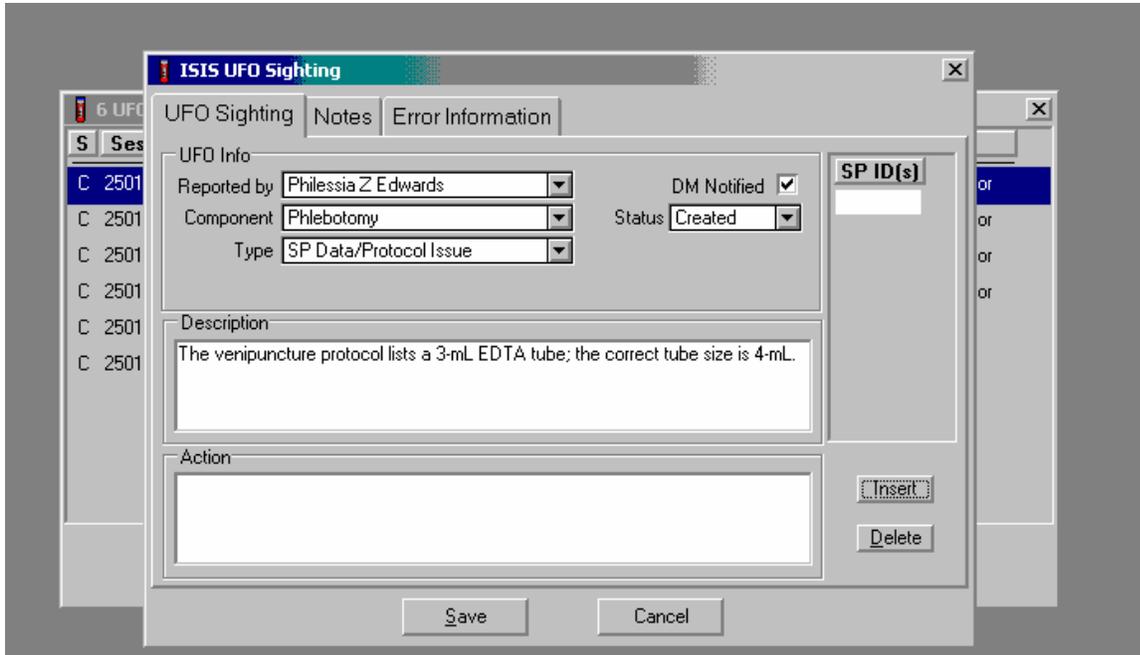
Assign a status to the New occurrence. The choices are: Created, Reviewed, and Finalized. The Status of an occurrence will default to Created for all new occurrences. To select a different status, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the choices, and drag the mouse arrow to the correct choice and left click.

Enter a description of the occurrence in the Description text box.

The screenshot shows the 'ISIS UFO Sighting' application window. The 'UFO Sighting' tab is selected. The 'Reported by' field contains 'Philessia Z Edwards', 'Component' is 'Phlebotomy', and 'Type' is 'SP Data/Protocol Issue'. The 'DM Notified' checkbox is checked, and the 'Status' is 'Created'. The 'Description' text box contains the text: 'The venipuncture protocol lists a 3-mL EDTA tube; the correct tube size is 4-mL.' The 'Action' text box is empty. The 'SP ID(s)' field is empty. The 'Insert' and 'Delete' buttons are visible on the right side of the window. The 'Save' and 'Cancel' buttons are at the bottom.

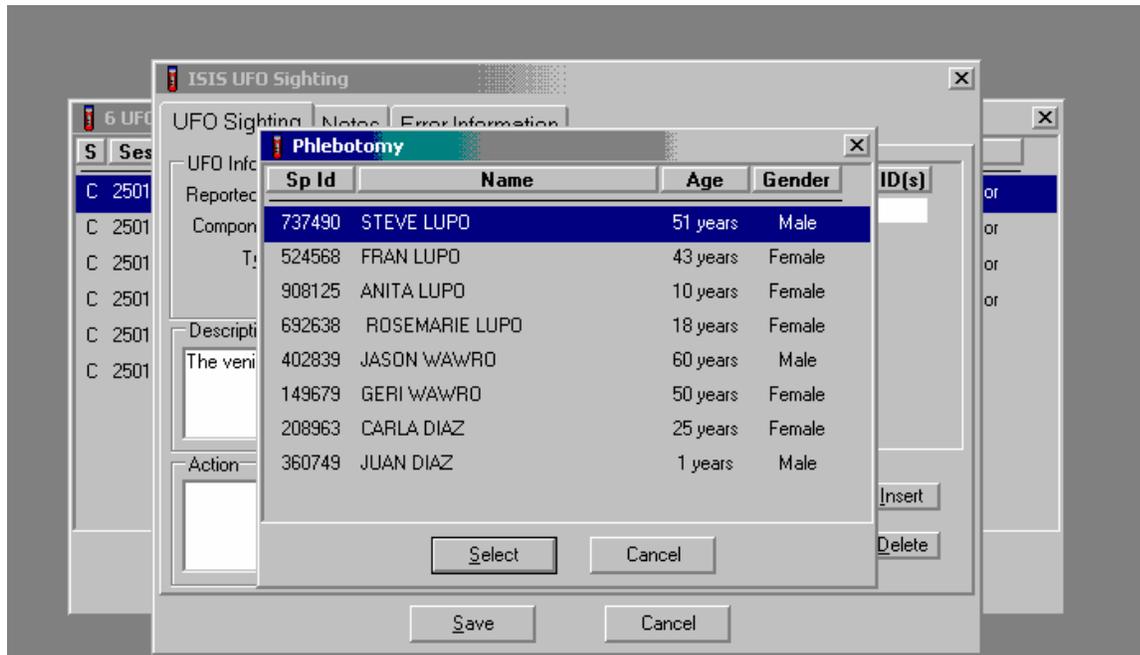
Type a description of the occurrence into the Description text box. Provide enough information and background to allow the reviewer to understand the details of the occurrence. For example, provide key strokes, when possible.

It is possible to link a particular occurrence with a specific SP ID or link an occurrence to more than one SP scheduled into the session.



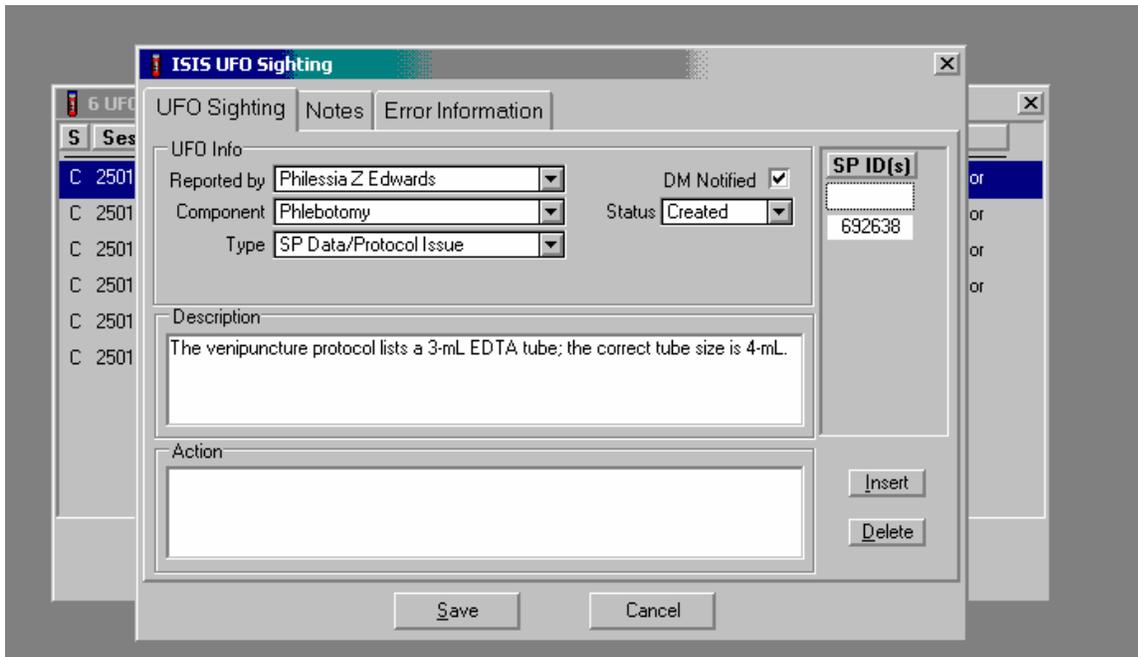
To link one or more SP ID(s) to a new occurrence, use the mouse to direct the mouse arrow to the **Insert** button and left click or type [Alt] [I/i]. This action adds a blank SP ID text box in the SP IDs column.

Enter the SP ID(s) into the SP ID text box using a pick list.



To view a pick list of the SPs scheduled into the existing session, use the mouse to direct the mouse arrow to place the cursor in the center of the text box and double click. A pick list displays that includes the SP ID, Name, Gender, and Age of all the SPs scheduled into the session. To select or highlight a SP, drag the mouse arrow to the correct SP and left click or use the up and down arrows to move up and down the list. Verify that the SP ID, name, and age are correct. To continue, use the mouse to direct the mouse arrow to the **Select** button and left click, or select [Enter]. To cancel these actions, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Repeat the process to add additional SPs to the list.



To add additional SPs to the list, select the **Insert** button to bring up the pick list of SPs and repeat the previous process.

Review the information on the screen for accuracy.

The screenshot shows the 'ISIS UFO Sighting' application window. The 'UFO Sighting' tab is selected. The 'UFO Info' section contains the following data:

Field	Value
Reported by	Philessia Z Edwards
Component	Phlebotomy
Type	SP Data/Protocol Issue
DM Notified	<input checked="" type="checkbox"/>
Status	Created

The 'SP ID(s)' column lists the following IDs:

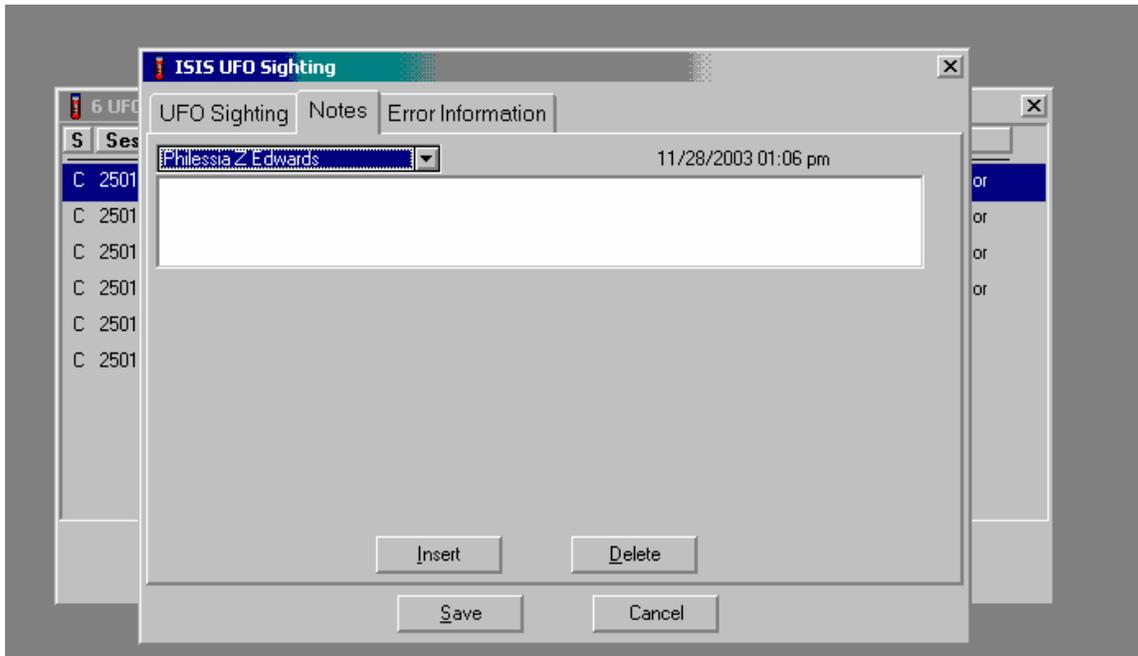
- 908125
- 692638

The 'Description' field contains the text: "The venipuncture protocol lists a 3-mL EDTA tube; the correct tube size is 4-mL."

To delete the SP ID(s) listed in the SP ID column, use the mouse to direct the arrow to the **Delete** button and left click or type [Alt] [D/d]. To save the information to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [Alt] [S/s]. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to **Cancel** button and left click.

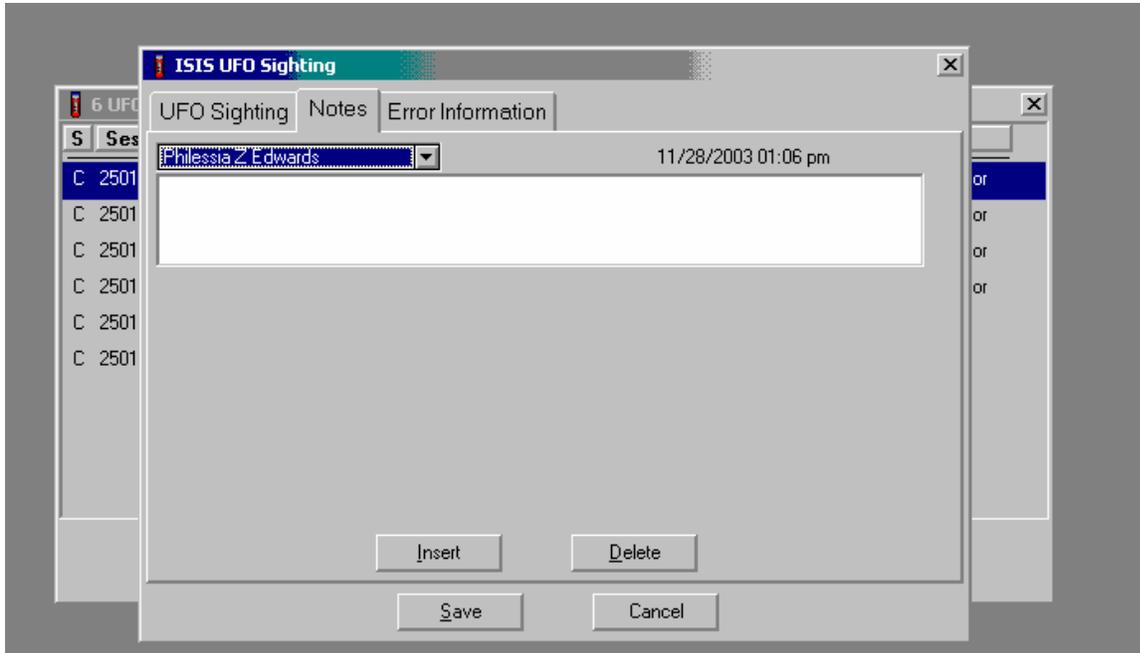
### 11.11.1.2 Add Notes to a New or Existing Occurrence

Use the Notes tab to enter comments about a new or existing occurrence.



To move to the Notes screen, use the mouse to direct the mouse arrow to the Notes text in the top file header and left click. A blank Notes text box displays.

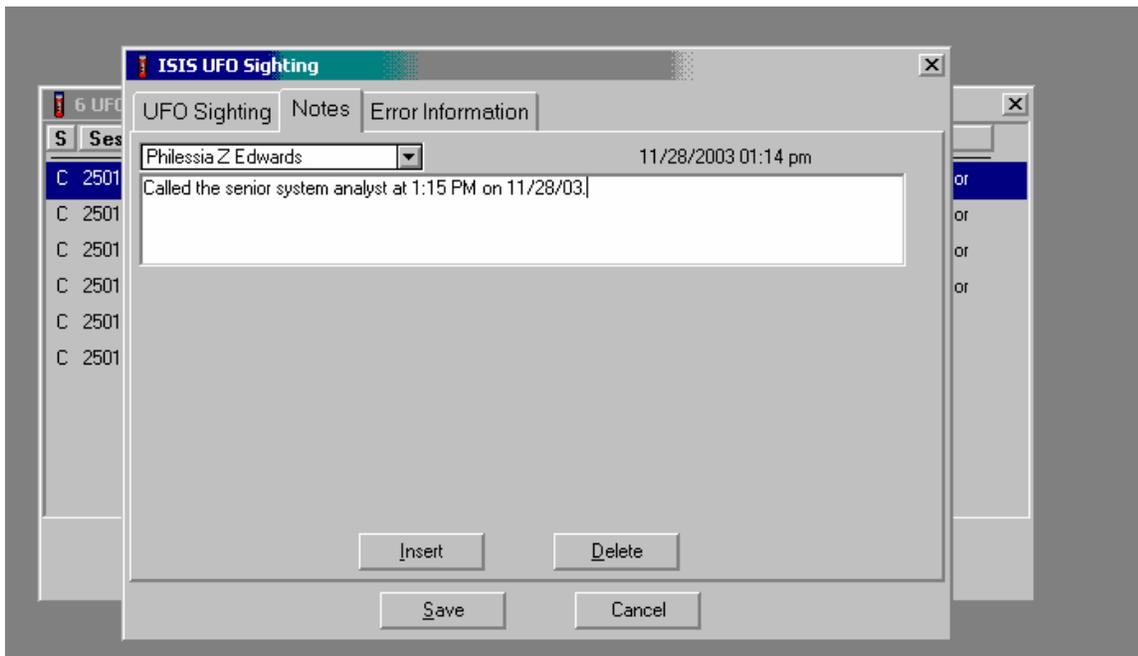
The Notes screen includes the current date and time, a text box to capture the identify of the person entering the notes, and a blank text box to enter a comment.



The identity text box will default to the identity of the person who logged onto the application. The current date and time are displayed on the screen. To change the identity of the person entering the note(s), use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the choices, and drag the mouse arrow to the correct choice and left click. Use the scroll bar to view the entire list.

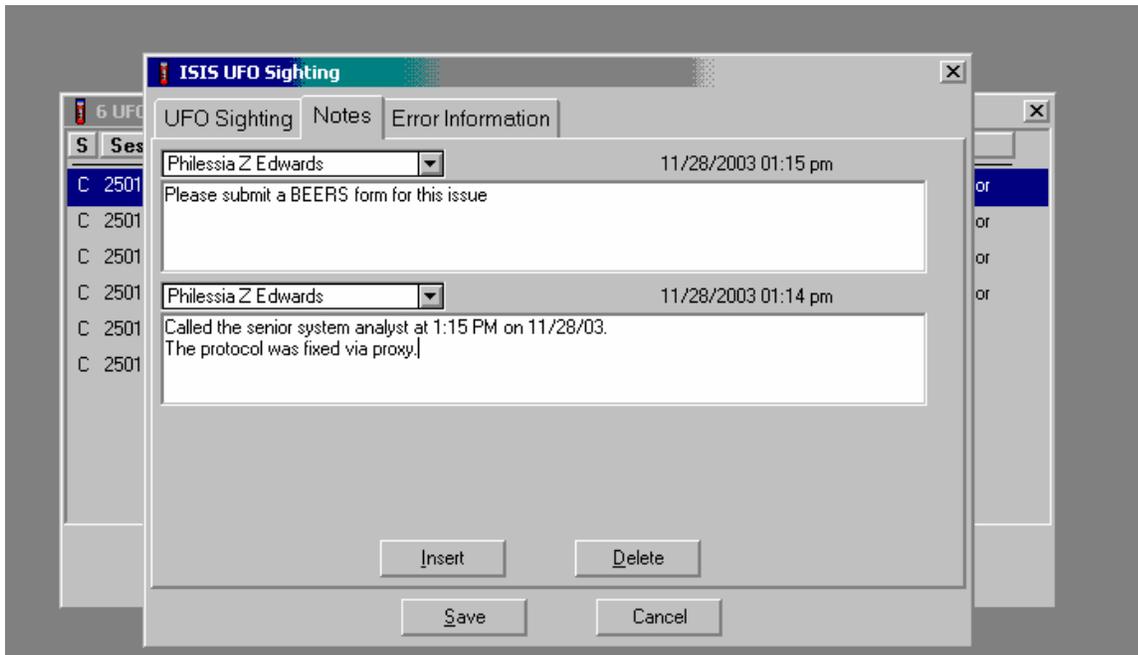
Use the Notes text box to record information into the large text box. Examples of the types of notes that are appropriate are indications that:

- A back-end edit was completed or is needed for SP Data Protocol Issues;
- An Equipment Tracking System Issue (the ETS ID should be noted) was entered for biomedical, ISIS equipment, or MEC trailer issues; and
- An Issue Tracking System form is requested to address specific application issues.



To add a note to the occurrence, use the mouse to direct the mouse arrow to the large blank text box, and left click. Type a comment or note using the keyboard keys.

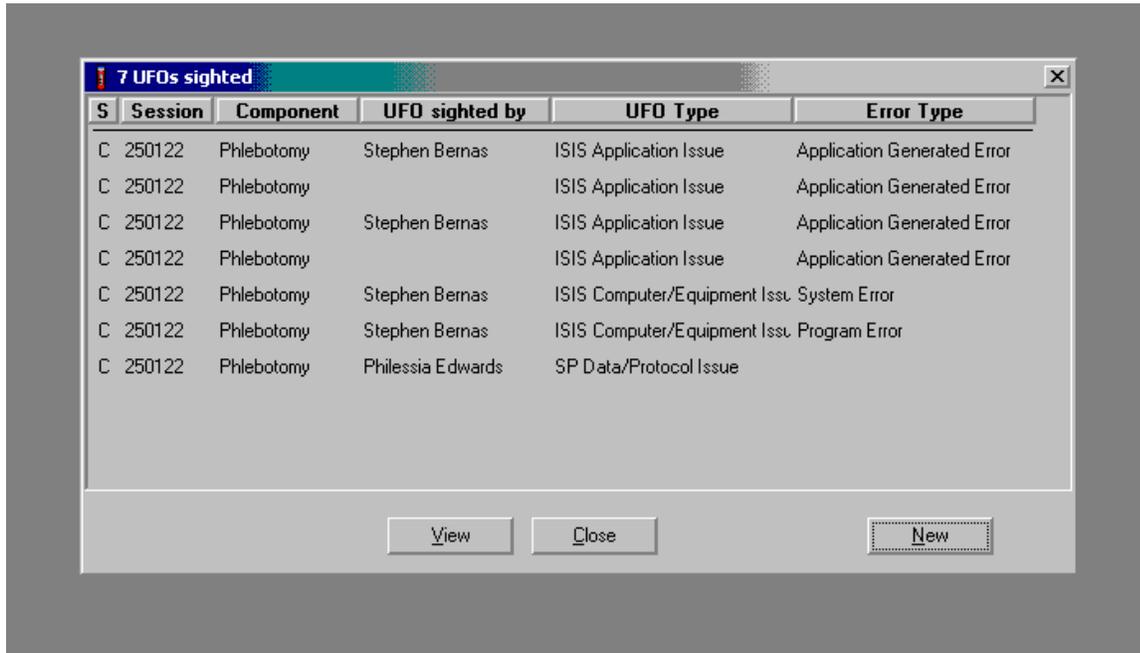
It is possible to add additional notes.



To insert an additional Notes text box, use the mouse to direct the mouse arrow to the **Insert** button and left click or type [Alt] [I/i]. To return to the UFO Sighting screen, use the mouse to direct the mouse arrow to either the UFO Sighting tab or the Error Information tab and left click. To delete the Notes text box(es), use the mouse to direct the mouse arrow to the **Delete** button and left click or type [Alt] [D/d].

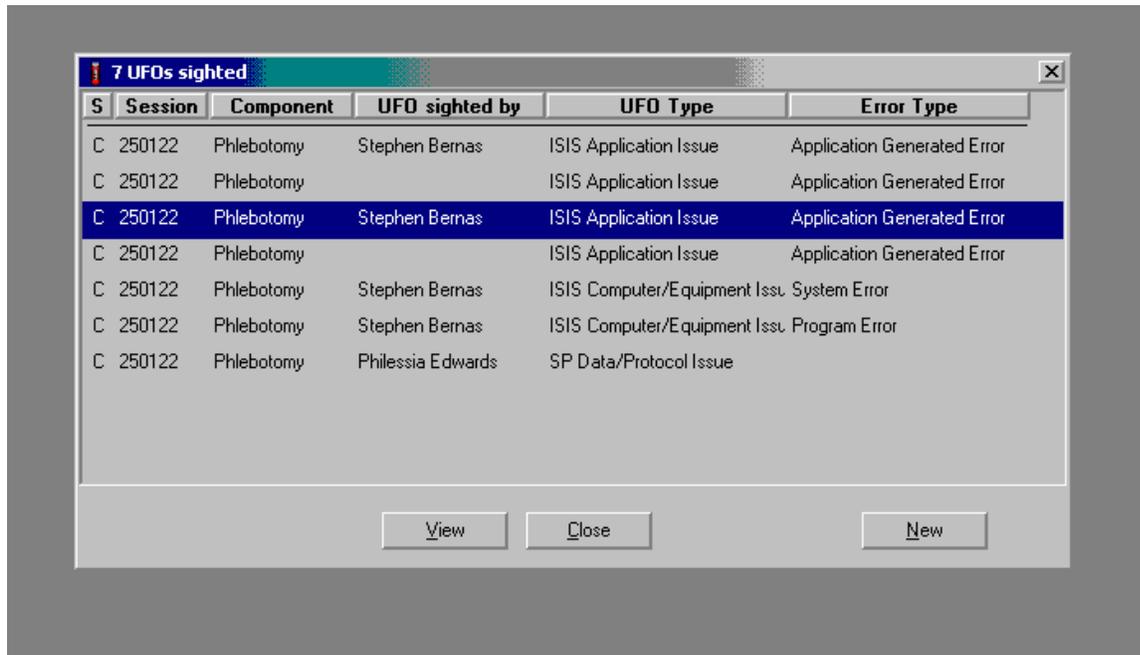
### 11.11.1.3 Review Error Information

When a Program Error is detected, the UFO module automatically captures the error. If necessary, restart the program. Access the UFO module.



The UFO screen for the component will contain a list of all the occurrences entered or captured during a session. It is possible to access and view (and edit) the details for each occurrence listed or to add a new occurrence.

Highlight or select an occurrence.



To select an occurrence to view, use the mouse to direct the mouse arrow to highlight the occurrence and left click. To access the occurrence, use the mouse to direct the mouse arrow to the **View** button or type [Alt] [V/v]. To close the window, use the mouse to direct the mouse arrow to the close button and left click or type [Alt] [C/c]. To add a new occurrence, use the mouse to direct the mouse arrow to the **New** button and left click, select [Enter], or type [Alt] [N/n].

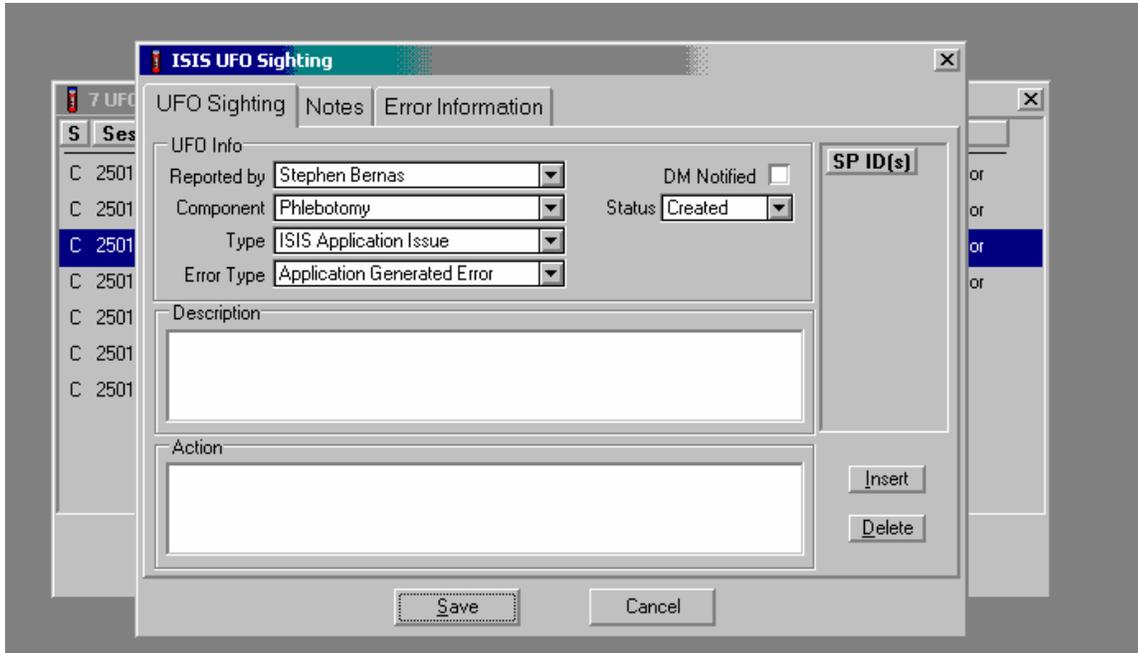
The Reported by text box will be blank if the ISIS System automatically captured ISIS Application Issue and the Error Type is an Application Generated Error. Assign an identity in the Reported by .text box.

The screenshot shows the 'ISIS UFO Sighting' application window with the 'Error Information' tab selected. The window contains the following fields and controls:

- UFO Info:**
  - Reported by: A text box with a drop-down arrow.
  - Component: A drop-down menu showing 'Phlebotomy'.
  - Type: A drop-down menu showing 'ISIS Application Issue'.
  - Error Type: A drop-down menu showing 'Application Generated Error'.
  - DM Notified: A checkbox.
  - Status: A drop-down menu showing 'Created'.
- SP ID(s):** A vertical list of text boxes, each with a drop-down arrow. The second item from the top is highlighted in blue.
- Description:** A large text area.
- Action:** A large text area.
- Buttons:** 'Save', 'Cancel', 'Insert', and 'Delete'.

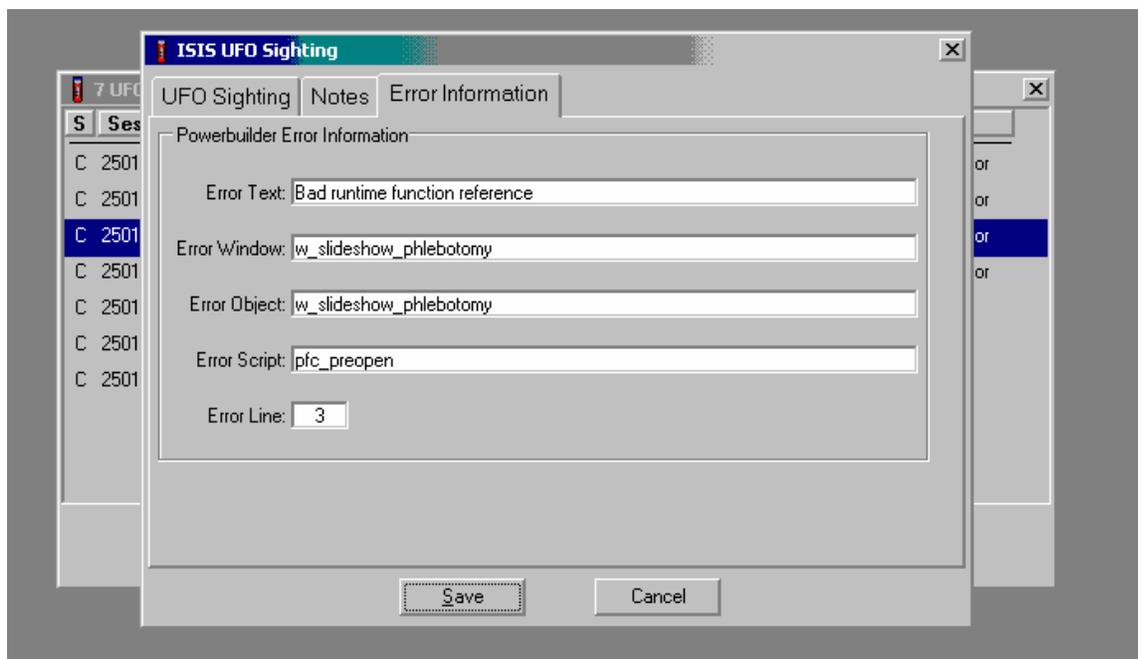
To add an identity to the Reported by text box, use the mouse to direct the mouse arrow to the drop-down arrow on the Reported by drop-down list, left click to display the choices, drag the mouse arrow to the correct choice, and left click.

Edit the information contained in the UFO Sighting window, add a Note, or view the Error Information that was automatically captured by the UFO module.



To move to the Notes or Error Information screen, use the mouse to direct the mouse arrow to the Notes or Error Information tab in the top file header and left click.

View the details on the Error Information file screen.



Review the information. To Save the information, use the mouse to direct the mouse arrow to the **Save** button and left click or type, [Alt] [S/s]. To exit the module without saving the information to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click or type, [Alt] [C/c].

#### 11.11.1.4 Hard Copy Unusual Occurrence Log

Document all unusual occurrences in the UFO utility. The hard copy Unusual Occurrence Log (see Exhibit 11-7) is available as a backup.

Exhibit 11-7. Hard copy Unusual Occurrence Log

**NHANES  
Unusual Occurrence Log**

Stand Number \_\_\_\_\_

Beginning Stand Date \_\_\_\_\_

**Technologist Name and ID**

\_\_\_\_\_

**Date**

\_\_\_\_\_

**Time**

\_\_\_\_\_

**Comments or Issue**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Action Taken**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Resolution**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Reviewed by** \_\_\_\_\_

**Date reviewed** \_\_\_\_\_

Enter information into the appropriate line(s):

- Stand Number;
- Beginning Stand Date;
- Technologist Name and ID;
- Date;
- Time;
- Comments or Issue;
- Action Taken; and
- Resolution.

**NOTE:** Do not enter any text in the Reviewed by or Date reviewed lines.

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

#### **11.12 Hard Copy Supply Use Control Log**

Document the lot number and expiration dates for all Vacutainer® tubes, needles, and reagents in the Supply Use Control activity of the Quality Control module. A hard copy Supply Use Control Log (Exhibit 11-8) is available as a backup.

Enter information into the appropriate column(s):

- Reagent or Supply Name;
- Beginning Stand Date;
- Lot Number;

Exhibit 11-8. Hard copy Supply Use Control Log

**NHANES  
Supply Use Control Log**

Stand Number \_\_\_\_\_

Beginning Stand Date \_\_\_\_\_

Reagent or Supply Name	Lot Number	Date in Use	Expiration Date	Technologist ID

- Date in Use;
- Expiration Date; and
- Technologist ID.

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

### **11.13 Eppendorf Pipette Care, Sterilization, Maintenance, and Calibration**

The MEC laboratory has four Eppendorf Research pro electronic pipettes: one 5-100 $\mu$ L, two 50-1000 $\mu$ L, and one 100-5000 $\mu$ L. The lab also uses 100  $\mu$ L and 1000  $\mu$ L Biopur pipette tips and 5-mL bulk pipette tips. Charge the pipettes in the 4-stand charger.

- Do not clean the display or any of the labeling using acetone or aggressive solutions.
- Do not allow any liquid to enter the device.
- Authorized service personnel may carry out repairs only.
- Use original spare parts and accessories (battery, pipette tips) only.

#### **Care**

Wipe the outside of the pipette with a moist cloth. The use of water with wetting agent is also permitted.

**WARNING: DO NOT ALLOW ANY LIQUID TO ENTER THE PIPETTE.**

Rinse (with distilled water) and dry only the lower part of the pipette. The pipette may be wiped clean with 60% isopropanol.

Disassemble the lower half of the Research pro if the pipette is very contaminated or if very aggressive chemicals are dispensed. Rinse the individual parts in distilled water and then dry the parts. Lightly lubricate the piston using silicone grease.

After opening the pipette, check that position of the piston and execute a motor reset. Trigger the motor reset by holding down the Reset key until **R** appears in the display.

### **Sterilization**

Disassemble only the lower half of the pipette. The individual parts of the lower part must be disassembled further into separate pieces. Please review the diagrams on page 27 of the Research Pro Instruction Manual before attempting to disassemble any pipette.

To loosen the lower part of the pipette (for all pipettes except the 5,000  $\mu\text{L}$ ):

- Hold down the ejector and pull off the ejector sleeve. Force may be required.
- Unscrew the lower part using the key. During disassembly, do not damage the piston.
- Unscrew the piston. If necessary, first loosen the piston at the upper end using flat-nose pliers. The piston is moved to the lowest position.

To loosen the lower part of the 5,000  $\mu\text{L}$  pipette:

- Hold down the ejector and pull off the ejector sleeve. Force may be required.
- Unscrew the cylinder. The piston is held in place magnetically. During reassemble, do not damage the piston.
- Pull the piston out of the upper part.

Assemble in reverse order. Engage the magnetic coupling of the 5,000  $\mu$ L piston as shown in the diagram on page 27 of the Instruction Manual. Check that the dispensing function of the pipette is working correctly.

## **Maintenance and Calibration**

Apart from general care and occasional discharging (when the battery symbol starts flashing) and recharging of the pipette, no special maintenance is necessary if the pipette is used correctly. The lower part of the pipette may be replaced. Part B: “Ordering information/service parts,” describes the process for replacing the seals in the lower part.

The pipettes are calibrated at least once per year, when the staff is on their break in June/July or December. When instructed, send the pipettes to the warehouse. The warehouse manager will contact the service department at Brinkmann Instruments at 800-645-3050, Ext 404 to schedule the calibration; send the pipettes to Brinkmann, and then back to the field.

A complete list of troubleshooting information is included on pages 28 and 29 of the Instruction Manual.

### **11.14 Power Loss and Laboratory Operations**

Three scenarios may occur if power is lost to the MEC. Scenario 1 occurs when power is lost during an exam session and there is no backup generator. Scenario 2 occurs when power is lost when the MEC is not conducting a session. Scenario 3 occurs when power is lost but there is a backup generator available. Procedures to address each scenario are described in detail.

#### **11.14.1 Scenario 1 - Power Loss during Exam Session with No Backup Generator**

If a power loss occurs during a MEC session, action must be taken to either continue processing the blood or preserve the integrity of the processed specimens. The phlebotomist should not draw blood during a power loss because of safety concerns due to insufficient light.

## Centrifuges

- **Overview** - There are two centrifuges in each MEC: one centrifuge is operated at ambient temperature and the second is operated at refrigerated (2-6°C) temperature. All blood tubes can be spun in the refrigerated centrifuge but the lavender tube for vessel 7 must be spun in the refrigerated centrifuge. The plasma from vessel 7 must be off the cells within 30 minutes or the lavender blood tube must be kept refrigerated.
- While power is generally required to open or unlock the centrifuge door, an emergency access procedure will allow the technologists to open the door to retrieve the blood tubes if a power failure occurs.
- **Consequences** – All blood tubes can remain in the locked centrifuge for up to 4 hours except for the lavender blood tube for vessel 7. If the plasma from this tube is not separated and frozen within 30 minutes, the data from this vial are lost.
- **Actions**
  1. It is not possible to routinely spin all tubes in one centrifuge; if a power loss is anticipated, spin all tubes in the refrigerated centrifuge.
  2. Use the emergency access procedure to retrieve the blood tubes from the centrifuge. Aliquot the serum and plasma into the vessels if the serum or plasma has sufficiently separated from the cells.
    - Move the secondary latch lever to UNLOCK position.
    - Insert a 5-mm (3/16 in.) or smaller screwdriver into the override key slot in the front panel (See Figure 4-1 on page 4-4 of the Operations Manual).
    - Turn the screwdriver clockwise until you hear a “click” or until the door pops open.

## Laminar flow hood

- **Overview** - The technologists require the laminar flow hood to process the blood for two reasons: (1) the hood provides an uncontaminated or clean environment for processing environmental blood specimens; (2) the hood is required to provide a full-face shield in case of an accidental blood splash. In addition, the outlet in the hood provides power to the electronic pipettes. The electronic pipette is required to perform an accurate dilution for vessel 3 (RBC Folate.)
- **Consequences** – The environmental specimens may become contaminated. The pipette will lose battery power after ~60 minutes.

- **Actions**

1. Complete an Unusual Occurrence Log to document the SP IDs of the samples processed without a fully functioning hood. This information is subsequently recorded in an annual summary for NCHS.
2. Attach the comment “equipment failure” to vessels 1, 5, and 29.
3. Use the backup full-face shields when processing blood.
4. Process vessel 3 immediately so specimens are not lost due to battery failure.

### **Freezers and refrigerators**

- **Overview** – There are four freezers and two refrigerators in each MEC lab. The freezers are located under the counter that holds the two large centrifuges and they are numbered 1 to 4 from left to right. Refrigerator #1 is located to the right of the laminar flow hood and refrigerator #2 is located to the right of the Coulter MAXM. There is one wall-mounted Jewett temperature-recording unit for each freezer and refrigerator. These units are blue and they contain a round paper chart with a red pen tracing. Each unit is marked with a label that matches the corresponding freezer or refrigerator. Refrigerant gel packs are distributed and stored in the freezers. Most specimens are stored in various plastic vials and the vials are placed in cardboard boxes with grids; the cardboard boxes are then stored in the freezers and refrigerators. In addition, some blood tubes (vessels 54 and 55), swabs (vessels 73 and 76), the VOC water (vessel 56), and the Coulter and pregnancy controls are stored in the refrigerator.
- **Consequences** – Specimen integrity is affected if frozen specimens thaw or if refrigerated specimens reach ambient temperature. Some analytes are more sensitive than other analytes. The temperature-monitoring chart provides a constant read out of the actual temperature. A full freezer takes approximately 3 hours to rise from -20°C to -10°C; a 1/2 filled freezer takes 2 hours and 25 minutes to rise to -10°C; and a 1/4 filled freezer takes 1 hour and 45 minutes to rise to -10°C. Once the temperature reaches -10°C the staff has approximately 30 minutes before the specimens thaw.
- **Actions**
  1. Do not open the freezer or refrigerator doors, if possible.
  2. Refrigerators - After 30 minutes or when the temperature recording chart reading reaches 7°C, add 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator. Do not add dry ice to the refrigerators; this will cause the refrigerator to explode.

3. Freezers – Contact the local dry ice company and order 200 pounds of dry ice. Obtain four large ice chests or coolers; each cooler should hold the boxes from one freezer and 50 pounds of dry ice. Within 2 hours or when the temperature recording chart reading reaches  $-10^{\circ}\text{C}$ , move the containers (boxes) to the ice chests and add 50 pounds of dry ice to each ice chest. Alternatively, move the containers to Styrofoam shippers and distribute the dry ice across the shippers. Do not add dry ice to the freezers; this will cause the freezer to explode.

### **Coulter MAXM**

- **Overview** - The Coulter consists of the MAXM, the monitor, hard drive, and printer. The MAXM will not function without the hard drive and monitor. The blood components for the CBC (complete blood count) are stable for a maximum of 24 hours when stored at room temperature.
- **Consequences** – None.
- **Actions** – None.

**NOTE:** The data manager should disable the Sensaphone system before a scheduled power loss.

### **11.14.2 Scenario 2- Power Loss when the MEC is Not Conducting Exams**

If the power loss occurs when the MEC is not conducting a session, the freezers and refrigerators require action to protect the integrity of the specimens. The lab staff can continue to ship if all the ISIS processes are complete. If the ISIS processes are not complete, the lab staff can still pack the shippers and complete the ISIS process once power is restored.

### **Freezers and refrigerators**

- **Overview** – All three MECs now have the Sensaphone system installed. The Sensaphone system monitors the room temperature and the internal temperature of the refrigerators and freezers in the MEC laboratory. When the system detects a significant increase in the temperatures, it begins calling designed staff. The MEC managers and data managers have been identified as those individuals responsible for responding to the call by typing in the response code. The temperature increase could be confined to one freezer or refrigerator, to multiple units, or all units. The temperature increase could be due to any number of circumstances such as a loss of

power because a circuit breaker tripped, or due to a compressor malfunction or failure. Whoever enters the code must act to prevent loss of biological specimens. The Sensaphone temperature trigger was established to allow 30 minutes of travel time. After 30 minutes, frozen specimens may begin to thaw.

- **Consequences** – Same as scenario #1.

- **Actions**

1. Examine each recording unit chart to verify which unit(s) is/are affected. The red pen line on the affected freezer or refrigerator chart should show a distinct movement toward the center of the graph.
2. Refrigerators - If one refrigerator has been affected, move all the specimens to the other refrigerator. If both refrigerators have been affected, keep the specimens cold by adding 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator. Do not add dry ice to the refrigerators; this will cause the refrigerator to explode.
3. Freezers – If only one freezer has been affected, move all the specimens from the affected unit to an unaffected unit. If more than one freezer has been affected and there is sufficient space in the unaffected freezers to accommodate the specimens, move the specimens to the other unaffected freezers. If there is insufficient space to accommodate the frozen specimens in the unaffected units or if all four freezers are affected, try to reach the chief medical technologist or any of staff medical technologists to assist. Contact the local dry ice company and order 200 pounds of dry ice. Obtain four large ice chests or coolers; each cooler should hold the boxes from one freezer and 50 pounds of dry ice. Within 2 hours or when the temperature recording chart reading reaches  $-10^{\circ}\text{C}$ , move the containers (boxes) to the ice chests and add 50 pounds of dry ice to each ice chest. Alternatively, move the containers to Styrofoam shippers and distribute the dry ice across the shippers. Do not add dry ice to the freezers; this will cause the freezer to explode.
4. Leave a note on the unit indicating the new location of the specimens.
5. Unplug the affected unit. Each plug is bound to an extension cord or is labeled and assigned to a corresponding wall outlet.

### 11.14.3 Scenario 3- Power Loss with a Backup Generator

If the power loss occurs when the MEC is conducting a session and there is a backup generator available, continue to monitor the temperature of the freezers and refrigerators and assess the situation with the MEC manager. If the temperature approached the established thresholds:

- Retrieve the generator from the trailer belly compartment;
- Retrieve the power strip;
- Plug the freezers into the power strip;
- Start the generator; and
- If both refrigerators have been affected, keep the specimens cold by adding 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator.

If a power loss occurs and the MEC is not conducting a session, the freezers and refrigerators require action to protect the integrity of the specimens. The Sensaphone system alerts the MEC and data managers that the temperature of the freezers and/or refrigerators has exceeded established thresholds. The MEC or data managers must respond to the call, travel to the MEC immediately, and do the following:

- Retrieve the generator from the trailer belly compartment;
- Retrieve the power strip;
- Plug the freezers into the power strip;
- Start the generator; and
- If both refrigerators have been affected, keep the specimens cold by adding 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator.

## **12. PROTOCOL FOR VOLATILE ORGANIC COMPOUNDS (VOC) STUDY**

### **12.1 Overview**

The purpose of the VOC study is to determine the prevalence of exposures to chemicals called Volatile Organic Compounds (VOCs). A one-half subsample of primary SPs aged 20-59 years are randomly selected to participate in this study. This selection occurs when the SP ID is generated at the time the MEC appointment is made. This can occur in the home during the home interview or in the field office when the field office staff schedules the appointment with the SP.

The home interviewer introduces the potential selected SP to the VOC component and leaves one water collection kit for each eligible SP in the household. The field office staff sends a reminder notice with the reminder letter to each SP.

The office manager uses the Appointment Schedule for VOC Appointments with Time Constraints report (#71) to identify VOC SPs. The field office staff makes the reminder calls for MEC-appointed SPs and confirms the appointment date and time. They enter the appointment time in the Appointment Management System (AMS) and add any comments or other pertinent information. If the SP does not come to the MEC (no show) for their scheduled MEC exam, the field office attempts to contact the SP to reschedule the SP into another MEC session.

When the SP comes to the MEC for their exam, the phlebotomist collects one additional tube of blood, collects the water vessel, and administers a questionnaire. Labels for the blood tubes and water samples print on the Intermec printer in the phlebotomy room. If the SP does not bring their water vial to the exam, the field office staff contacts the SP and schedules a VOC appointment using the VOC Reconciliation Report located on the NHANES ISIS IntraWeb (isisweb). The MEC staff or other designated representative collects the water and transports the water vial back to the MEC. The medical technologist processes it using the laboratory application. The MEC manager manages the medical technologist's schedule.

The laboratory processes, stores, and ships the SP’s VOC blood tube and water vial. The blood sample must be refrigerated within 15 minutes after completion of the venipuncture. The blood and water vessels are shipped once a week via next day courier in insulated containers with enough ice packs to maintain their refrigerated temperature.

## 12.2 Supplies

The VOC equipment and supplies are listed in Exhibit 12-1.

Exhibit 12-1. Equipment and supplies - VOC

10-mL gray top Vacutainer ® blood tube	Water collection kit 10-mL vial Instructions “Write collection date and time here” sticker Small zip closable bag
VOC questionnaire – English	Blue absorbent pad
VOC questionnaire – Spanish	#740 SafTPak pressure vessel
5-inch box with 5 x 5 foam grid	Refrigerant gel pack
9 x 12 plastic bag	Cardboard shipper
Packing tape	Absorbent pad

The VOC water vial is a 10-mL glass Wheaton glass vial that contains 125 µL quench buffer. Quench buffer is water with 1 M phosphate buffer and 0.1 M sodium thiosulfate.

At the start of each stand, the warehouse staff prepares and ships 275 water collection kits for the field office and 25 water collection kits for the MEC. The warehouse staff enters the current field office telephone number in the blank space on the water collection instructions and places it and one 10-mL glass water collection vessel into a zip closable bag. The warehouse staff attaches one pink “Write collection date and time here” sticker to the outside of the bag. The phlebotomist stores the collection kits in the phlebotomy cabinet. The field office staff stores their collection kits in the field office. Do not discard any remaining water vials at the end of each stand; ship them back to the warehouse.

Use the following information to introduce the component and water collection process to the SP.

- The NHANES survey includes a special study that is looking at a group of chemicals. These chemicals are in things that we use every day. If you are selected for this special study or if you are potentially eligible for this study, I will leave a water collection kit with you. This kit contains a glass water vial in a plastic bag and instructions for collecting the water. Collect the water sample according to the instructions and bring it with you when you come to the mobile examination center for your examination. The small amount of liquid in the vial is not harmful to anyone in your household. A tap water sample is needed for the measurement of some chemicals, which may be present in chlorinated water. (See Exhibits 12-2 and 12-3.)

CDC prescreens the gray-top tubes used for the VOC protocol for this study. The following is the procedure for preparing the 10-mL gray Vacutainer® VOC blood collection tubes and a statement of their purpose. Dr. David Ashley at the CDC provided this procedure.

**Procedure for preparing the 10-mL gray Vacutainer® tubes:**

- Because of the volatile organic compounds present in commercial Vacutainers® with rubber stoppers, it is necessary to decontaminate the tubes before blood collection. CDC laboratory personnel carry out this decontamination procedure. The vacuum is released and the glass tube with anticoagulant and the stopper are placed in a vacuum oven. These materials are then decontaminated under vacuum at 70° C for 2 weeks. The Vacutainers® are reassembled and tested for lack of contamination. A vacuum is reapplied to each Vacutainer® and they are sterilized in a Gamma-ray sterilizer to kill any microbiological organisms that may have entered the tubes.
- This procedure is necessary to acquiring a volatile organic compound measurement that is a true measure of an individual's internal dose level of VOCs.

Since the date on the Vacutainer® is a guarantee that the vacuum is reliable, this date has no reference to the current materials sent from CDC to NCHS. The laboratory at CDC will ensure that the Vacutainers® sent to the NHANES staff have been prepared on a date within the timeframe necessary for their use. Notify the technical supervisor if the tubes begin to lose their vacuum but continue to use the tubes until replacements arrive.

Exhibit 12-2. Water collection instructions – English

**Water Collection Instructions**

(To be given to each SP with the glass tube.)

Instructions for collecting tap water sample:

1. Collect the water sample from the bathtub or an outside faucet **ONLY**.
2. Turn on the cold water (all the way on).
3. Let the cold water run for 3 minutes (all the way on) and then decrease the flow to a trickle.
4. Take the black cap off the glass tube. (If the white liner in the cap falls out, put it back into the cap. The shiny side should be facing up.)
5. Carefully fill the glass tube with water until it is almost full.
6. Screw the black cap tightly on the tube.
7. Turn the tube upside down to make sure it does not leak. (If the tube does leak, then remove the cap and try tightening the cap again.)
8. Write the date and time that the water was collected on the bright pink label on the outside of the plastic bag.
9. Put the water vial back into the plastic bag.
10. Bring the water sample with you when you come to the mobile examination center.

Call the Field Office at \_\_\_\_\_ if you have questions.

Exhibit 12-3. Water collection instructions – Spanish

Instrucciones para recolectar la muestra de agua de la llave:

1. Tome la muestra de agua de la (bañadera/bañera/tina) o de una llave de afuera **SOLAMENTE**.
2. Abra la llave del agua fría (totalmente abierta).
3. Deje correr el agua fría por 3 minutos (totalmente abierta) y después disminuya el chorro de agua hasta que sea un goteo o un hilo de agua.
4. Quite la tapa negra del tubo de vidrio. (Si la cubierta blanca de la tapa se sale, póngala nuevamente en el interior de la tapa. El lado brillante debe quedar a la vista.)
5. Cuidadosamente llene el tubo de vidrio con agua hasta que esté casi lleno.
6. Ponga la tapa negra bien apretada al tubo.
7. Dé vuelta el tubo al revés para asegurarse que no está goteando. (Si el tubo gotea, entonces saque la tapa y trate de ponerla bien apretada nuevamente).
8. Escriba la fecha y la hora en que el agua fue recolectada en la etiqueta rosada brillante en la parte de afuera de la bolsa de plástico.
9. Ponga el tubo de vidrio nuevamente dentro de la bolsa de plástico.
10. Traiga la muestra de agua con usted cuando vuelva al centro móvil de examen.

Llame al Centro de Operaciones en \_\_\_\_\_ si desea hacer alguna pregunta.

### **12.3 Home Interviewer and Field Office Responsibilities**

The home interviewer will leave one water collection kit (water vial and collection instructions in a zip closable bag) for each interviewed SP aged 20-59 in the household. The interviewer should review the collection instructions and explain that the SP may be selected to participate in a special study involving VOCs.

The field office staff will inform the SP that they have been selected for this special study when they schedule the appointment and/or make the reminder call and instruct the SP to bring their water sample with them when they come to the MEC. The field office adds a reminder notice (Exhibits 12-4 and 12-5) to the reminder letter sent to selected SPs.

If the SP does not keep their appointment, the field office staff should remind the SP to bring their water when they reschedule the appointment.

Exhibit 12-4. Reminder notice – English

**\*\*\*REMINDER\*\*\***

Please remember to collect a tap water sample according to the instructions in the water collection kit and bring your water sample to the mobile examination center when you come for your exam.

Exhibit 12-5. Reminder notice – Spanish

**\*\*\*RECORDATORIO\*\*\***

Por favor recuerde recolectar una muestra de agua de la llave según las instrucciones en el paquete de recolección de agua y traiga su muestra de agua al centro móvil de examen cuando venga para su examen.

## 12.4 Background

NCHS has developed the following “talking points” to describe the VOC special study.

*Component:* Volatile Organic Compounds (VOC)

*Who Examined:* Selected participants aged 20-59

*Examination:* A water sample

A blood sample

A questionnaire

*Results:* Reported only if levels are high

*Why we do this:*

- There are chemicals and pollutants in the air we breathe every day. Since many of these chemicals have no odor or color, we do not know they are there. Some of these chemicals are known or thought to cause health problems. In 1990, the Clear Air Act Amendment required the government to take a closer look at these hazardous air pollutants.
- For this test, we are interested in a group of chemicals called volatile organic compounds, or VOCs. They are commonly used in the manufacture of many household items and things we use every day. Some examples of products that contain VOCs are: household cleaners, furniture polish, gasoline, hair spray, nail polish and remover, air fresheners, mothballs, and paint.
- We have very little information on the levels of VOCs in the air that we breathe. Our survey is the first time that national levels are being collected to measure how much of these chemicals people are exposed to. We expect that the levels of these chemicals will be low, but need to collect information to determine what the true levels are. From the information collected, we will be able to describe what the levels are in the U.S. and compare them with high levels from places like waste sites and factories.
- If you are selected to be part of this test, you will be asked to bring a sample of water from your home when you come to the MEC for your examination. At that time, we will take one additional tube of blood. We will ask you about some of your activities during the three days before you came into the MEC. There are no harmful chemicals in the water vial that can affect you or any people in your household.
- This is an important test because it is not currently known how much of these chemicals are in the air that people breathe.

In addition, use the following information to encourage SPs to participate.

- This study is an epidemiologic data analysis of a population-based study of personal exposures to volatile organic compounds among a subset of participants in a statistically designed national survey.
- The NCEH is collaborating with the National Center for Health Statistics (NCHS) on a study to collect environmental exposure data for a subset of the U.S. population, as part of a comprehensive nationally-based health study.
- The purpose of the national survey is to obtain nationally representative data on the health and nutritional status of the population.
- The subjects in the collaborative NCHS-NCEH study are selected to be a representative subset of the larger study population. Thus, they will provide household and personal data about themselves to the survey regarding socioeconomic, behavioral, demographic, and occupational factors.

The primary aims of the study are:

- 1 To characterize the distribution of exposures to selected VOCs within a subpopulation.
- 2 To examine the relationship between personal exposures to the VOCs and socioeconomic, behavioral, demographic, and occupational characteristics.
- 3 To investigate possible associations between personal exposures to VOCs and some selected indicators of health status for which data are collected as part of the larger study.
- 4 To investigate the relationships between local sources of VOCs in subject communities (such as tap water) and personal exposures using available data.

The purpose of the analysis will be to assess exposures to the group of VOCs being monitored, as well as exposures to particular VOCs, and to explore potential linkages between exposures and economic, behavioral, and other factors. A tap water sample is needed for the measurement of certain VOCs, which may be present in chlorinated water.

Associations of VOC exposures with potential health outcomes may not be possible to demonstrate because of the size of the sample. However, the opportunity exists to investigate health status markers among the data points collected as part of the larger study to elucidate any patterns, which are consistent with published studies of health outcomes.

## **12.5 VOC MEC Exam**

VOC data collection consists of the following: one 10-mL blood tube, a tap water sample, and answering the questionnaire questions.

The coordinator assigns the SP to the phlebotomy room. In phlebotomy, the phlebotomist logs the SP into the application, and performs venipuncture to collect the protocol-dictated tubes, which includes the 10-mL gray top VOC blood tube. Labels print automatically for the blood tubes. The phlebotomist collects the water sample from the SP, transfers the collection date and time from the pink label on the outside of the bag to the white paper label on the glass tube, and administers a short questionnaire. Labels for the water sample print on the Intermec printer in the phlebotomy room.

A volunteer from the MEC staff or a designated representative conducts a VOC home visit to collect the water vial if the SP does not bring the tap water sample with them when they come to the MEC for their exam. Use the VOC Reconciliation Report to view the SPs and the status of their water collection. Schedule an appointment with the SP. Before conducting the home VOC water collection, access the laboratory application and print the water vial label. For each home VOC water collection, take at least two spare water collection kits. Document the collection date and time on the paper label on the water vial. Transport the water vial back to the MEC, and process the specimen using the heads-up display in the Laboratory application. Store the specimens in refrigerator #2.

### 12.5.1 Complete the VOC Section of the Phlebotomy Exam

Access the Phlebotomy application. Log onto the application. Open the Phlebotomy examination. Log the SP into the component. Verify the information. Conduct the phlebotomy interview, administer the fasting questionnaire, and proceed to the Venipuncture protocol screen.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and help. The main content area is titled "Venipuncture" and displays the following information:

SP ID: 248274    Name: EYRAMYA, AUNTIE    Age: 39 years    Gender: Female    Date: 11/11/2002    Time: 02:56 PM

**Venipuncture**

4 ml lavender  of 3  
2 ml gray  of 1     Obtained all  
7 ml red  of 1    248274  
15 ml red  of 3  
10 ml red  of 2  
10 ml gray  of 1

Comment:

Navigation:   3 of 4   

System tray: Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 02:57 PM

The window displays the appropriate venipuncture protocol for VOC SPs. Draw one 10-mL gray top tube as part of the venipuncture protocol using procedures described in Chapter 4. Thoroughly mix the 10-mL gray top tube immediately after drawing the tube and place the tube on the specimen rocker until the tubes are labeled and passed through to the window to the laboratory.

Immediately after completing the venipuncture, enter the results of the blood draw.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and navigation. The main window displays patient information: "SP ID: 248274", "Name: EYRAMYA, AUNTIE", "Age: 39 years", "Gender: Female", "Date: 11/11/2002", and "Time: 02:56 PM". Below this is a section titled "Venipuncture" with a list of blood tubes and their collection status:

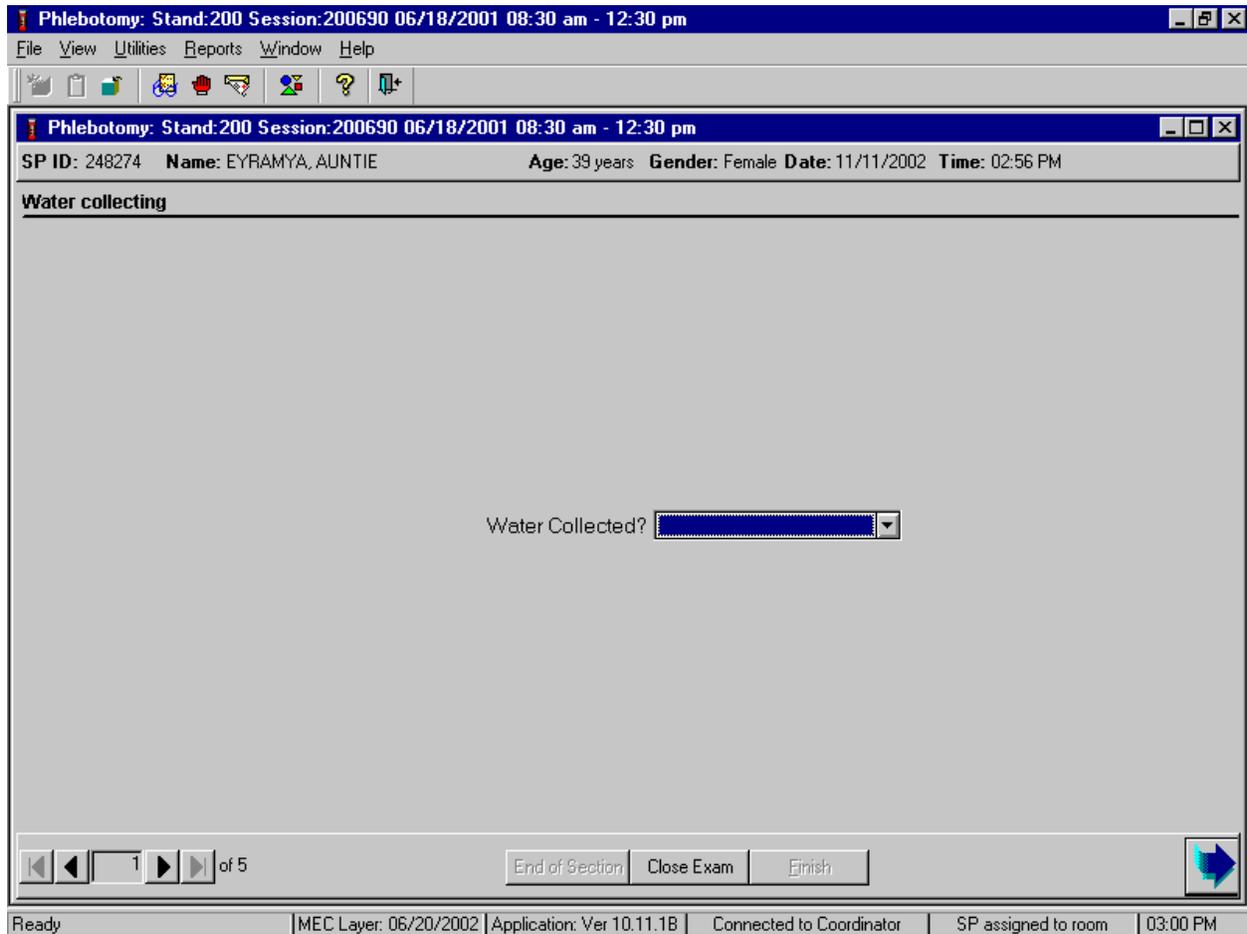
4 ml lavender	<input type="text" value="3"/>	of 3	<input checked="" type="checkbox"/> Obtained all 248274
2 ml gray	<input type="text" value="1"/>	of 1	
7 ml red	<input type="text" value="1"/>	of 1	
15 ml red	<input type="text" value="3"/>	of 3	
10 ml red	<input type="text" value="2"/>	of 2	
10 ml gray	<input type="text" value="1"/>	of 1	

Below the list is a "Comment:" field with a dropdown arrow. At the bottom of the window is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a blue arrow icon. The status bar at the very bottom shows "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "02:58 PM".

Label the blood tubes by placing the bar-coded label on the tube. Pass the blood through the window to the laboratory. Review the venipuncture status.

The slide navigation bar provides a means to move forward and back through an examination. To move forward to the water collection slide, use the mouse to direct the mouse arrow to the black right arrow with the line on the right side on the navigation bar and left click.

Record the water collection.



The Water Collecting screen displays immediately after the venipuncture section status screen.

Continue to record the water collection result.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 248274 Name: EYRAMYA, AUNTIE Age: 39 years Gender: Female Date: 11/11/2002 Time: 02:56 PM

Water collecting

Water Collected?

- Yes
- Needs to be collected
- SP refusal

1 of 5

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 03:00 PM

If the SP brings their water vial to the MEC, record “Yes.” If they did not bring their water vial to the MEC, record “Needs to be collected,” and if the SP refuses to allow the medical technologist to collect the water during a home visit, record “SP refusal” To record one of these results in the text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code. Label the water vial with the paper label containing the vessel id 56. Transfer the collection date and time from the pink label on the outside of the bag to the white paper label on the glass tube. Pass the water vial through the window to the laboratory. Administer the questionnaire.

The phlebotomist administers the VOC SP's questionnaire after collecting the blood and/or water. The questionnaire collects data about the SP's home, activities, amount of time spent in various locations, and exposure to different chemicals over the past 76 hours. Administer the questionnaire by reading each question to the VOC SP. Record the VOC SP's response to each question either by selecting the response from a list of acceptable responses or by entering a numeric value in the space indicated. A description for each of the questions from the VOC questionnaire and specifications for answers are listed below.

All SPs are eligible for the VOC questionnaire.

- If the SP refuses to answer any of the VOC questions in the questionnaire, then record each response as "refused."

Record the various text and numeric responses by using one of the following two methods.

- Record text responses either by typing the first letter of the choice, or select (highlight) the correct choice by using the mouse to direct the mouse arrow to the drop-down list, left click, drag the mouse arrow to the correct choice, and left click when the correct choice is highlighted. Select [Tab] to move to the next question.
- Record numeric responses by using the keyboard's numeric keys to enter the number and select [Tab] to move to the next question.

Begin to administer the VOC questionnaire. Ask each question exactly as presented on the window.

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 248274 Name: EYRAMYA, AUNTIE Age: 39 years Gender: Female Date: 11/11/2002 Time: 02:56 PM

**VOC Questionnaire 1-3**

I would like to ask you a few questions about your home. Does your home have an attached garage?

Is the source of water for your home from a private well?

Do you store paints or fuels inside your home? Include your basement (and attached garage, if applicable.)

Do you use toilet bowl deodorizers inside your home?

Do you use moth balls or crystals inside your home?

2 of 5

End of Section Close Exam Finish

Ready MEC Layer: 06/20/2002 Application: Ver 10.11.1B Connected to Coordinator SP assigned to room 03:01 PM

**Q1: I would like to ask you a few questions about your home. Does your home have an attached garage? [Yes, No, Refused, Don't know]**

<p>Q1: This question refers to the residence where the SP spent the last 76 hours and specifically refers to whether or not the home has a garage and if it does, if it is attached or not.</p>	<p>Home refers to the building where the SP lives. This can be a mobile trailer, apartment, townhouse, single, or multiple family building. An attached garage refers to a building or wing of a building in which a car is parked that is also attached or connected as a part to the home. Select "Yes," if the home has an attached garage, "No" if it does not; "Refused" if the SP refuses to answer the questions; and "Don't know" if the SP is unsure.</p>
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**Q2: Is the source of water for your home from a private well? [Yes, No, Refused, Don't know]**

<p>Q2: This question asks the SP to report the source of water used in their home.</p>	<p>Include all types of wells.</p> <p><b>BORED WELLS:</b> An earth auger rotated, by hand or power, bores the hole and carries the earth to the surface. Casing is usually steel, concrete, or plastic pipe</p> <p><b>DUG WELLS:</b> Historically, dug wells were excavated by hand shovel to below the water table until incoming water exceeded the digger's bailing rate. The well was lined with stones, brick, tile, or other material to prevent collapse, and was covered with a cap of wood, stone, or concrete. Modern large-diameter dug wells are dug or bored by power equipment and typically are lined with concrete tile.</p> <p><b>DRIVEN-POINT (sand point) WELLS:</b> Constructed by driving assembled lengths of pipe into the ground with percussion equipment or by hand.</p> <p><b>DRILLED WELLS:</b> Constructed by either percussion or rotary-drilling machines. Drilled wells that penetrate unconsolidated material require installation of casing and a screen to prevent inflow of sediment and collapse.</p> <p>If the SP indicates if the source of water is from any of these types of private wells, select "Yes." If the SP reports that the source of water is from a municipal or city source, select "No." If the SP refuses to answer the question, select "Refused" and if the SP does not know select "Don't know."</p>
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**Q3: Do you store paints or fuels inside your home? Include your basement (and attached garage.) [Yes, No, Refused, Don't know]**

<p>Q3: This question asks the SP to decide if they currently have any paints or fuels stored inside their home. Include the basement and attached garage if the SP reports having an attached garage.</p>	<p>Include areas of the home like the basement and attached garage. Do not include separate storage facilities like barns or sheds on the same property. Include all paints, both indoor and outdoor, and fuels like propane or butane. Do not include wood or coal. If the SP indicates they store paint or fuels in any of these locations select "Yes." If the SP reports they do not store these items in these locations select "No." If the SP refuses to answer the question, select "Refused" and if the SP does not know select "Don't know."</p>
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**Q4: Do you use toilet bowl deodorizers inside your home? [Yes, No, Refused, Don't know]**

<p>Q4: This question asks the SP to report if they use toilet bowl deodorizers inside the toilets in their home.</p>	<p>Include all types of deodorizers such as rim cage that clips onto the toilet rim, deodorant blocks, deodorant gels, and wall mounted "para" block deodorant packaged in cardboard hanger that hangs on the wall or fits in separate wall-hanging plastic container (extra). Consider brand names such as Bully, 2000 Flushes, Vanish, X-14, Ty-D-Bol, Toilet Duck, Clorox, Lime A Way and Sno Bol. If the SP indicates they use any of these deodorizers select "Yes." If the SP reports they do not use any of these items select "No." If the SP refuses to answer the question, select "Refused" and if the SP does not know select "Don't know."</p>
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**Q5: Do you use moth balls or crystals inside your home? [Yes, No, Refused, Don't know]**

Q5: This question asks the SP to report if they use moth balls or moth crystals inside their home.	One traditional way to prevent fabric damage by moths is to pack sweaters and blankets in moth balls or moth crystals. Moth balls or moth crystals are naphthalene or camphor. They produce a characteristic odor. Naphthalene, also known as tar camphor, is a white crystalline solid with a distinctive mothball odor. Naphthalene is available to the public as a pest repellent and is frequently contained in moth balls, moth flakes, and toilet bowl deodorizers. Select “Yes,” if the SP reports that they use both balls or moth crystals, “No” if they do not; “Refused” if the SP refuses to answer the question; and “Don't know” if the SP is unsure.
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 248274 Name: EYRAMYA, AUNTIE Age: 39 years Gender: Female Date: 11/11/2002 Time: 02:56 PM

**VOC Questionnaire 2-3**

Now I am going to ask you a few questions about your activities over the last three days. This means today, yesterday, or the day before yesterday.

In the last three days, did you pump gas into a car or other motor vehicle yourself?

If, yes, how long ago, in hours, did you pump gas into a car?

In the last three days, did you spend any time at a swimming pool, in a hot tub, or in a steam room?

If, yes, how long ago, in hours, has it been since you spent time in a swimming pool, in a hot tub, or in a steam room?

In the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

In the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

In the last three days, did you take a hot shower or bath for five minutes or longer?

If, yes, how long ago, in hours, has it been since your last shower or hot bath?

3 of 5

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 03:03 PM

Read the script to the SP. “Now I am going to ask you a few questions about your activities over the last three days. This means today, yesterday, or the day before yesterday.”

**Q6. In the last three days, did you pump gas into a car or other motor vehicle yourself?  
[Yes, No, Refused, Don't know]**

<p>Q6: This question asks the SP to report if they pumped gas into a car or other motor vehicle during the last 3 days.</p>	<p>Include any grade of gasoline but do not include natural gas. Include pumping gas into a container, such as a lawn mower container. Do not record "Yes" if the SP reports being a passenger in a car into which gas was pumped. If the SP reports actually pumping gas into any car or motor vehicle, select "Yes." If the SP reports they did not pump gas into a car or other motor vehicle, select "No." If the SP refuses to answer, select "Refused." If the SP does not know if they pumped gas into any car or other motor vehicle, select "Don't know." If the answer to Q6 is "yes," then Q7 becomes enabled.</p>
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**Q7: If, yes, how long ago, in hours, did you pump gas into a car? [Yes, No, Refused, Don't know]**

<p>Q7: This question asks the SP to report the number of hours between the time they pumped gas into a car and the current time.</p>	<p>Enter the number of hours reported by the SP. If the number of hours is less than 1, enter 0. In general, round &lt;30 minutes down to nearest whole number, if &gt;30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since SPs are required to answer this question, get the SP's best estimate. This number cannot be greater than 76 since the time reference for this question is the last 3 days.</p>
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**Q8: In the last three days, did you spend any time at a swimming pool, in a hot tub, or in a steam room? [Yes, No, Refused, Don't know]**

<p>Q8: This question asks the SP to report if they spent any time at a swimming pool, in a hot tub, or in a steam room during the last 3 days.</p>	<p>Determine if the SP spent any time at a swimming pool, in a hot tub, or in a steam room. The SP did not have to swim in the pool. If the SP reports being at or in a swimming pool, hot tub, or steam room, select "Yes." If the SP reports that they were not at a swimming pool, hot tub, or steam room, select "No." If the SP refuses to answer, select "Refused." If the SP does not know or cannot recall, select "Don't know." If the answer to Q8 is "yes," then Q9 becomes enabled.</p>
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**Q9: If, yes, how long ago, in hours, has it been since you spent time in a swimming pool, in a hot tub, or in a steam room. [Yes, No, Refused, Don't know]**

<p>Q9: This question asks the SP to report the number of hours between the time they were in a swimming pool, hot tub, or steam room and the current time.</p>	<p>Enter the number of hours reported by the SP. If the number of hours is less than 1, enter 0. In general, round &lt;30 minutes down to nearest whole number, if &gt;30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since SPs are required to answer this question, get the SP's best estimate. This number cannot be greater than 76 since the time reference for this question is the last 3 days.</p>
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**Q10: In the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week? [Yes, No, Refused, Don't know]**

<p>Q10: This question asks the SP to report if they visited a dry cleaning shop or wore clothes that had been dry cleaned within the last week.</p>	<p>The dry cleaning process cleans clothing with chemical solvents having little or no water. Determine if the SP visited a dry cleaning shop during the last 3 days or if they wore clothes that had been dry-cleaned within the last week or 7 days. If the SP meets either criterion, select "Yes." If the SP reports that they were not at a dry cleaners in the last 3 days and have not worn clothes dry-cleaned within the last week, select "No." If the SP refuses to answer, select "Refused." If the SP does not know or cannot remember if they were at a dry cleaning shop in the last 3 days or wore clothes dry-cleaned within the last week, select "Don't know."</p>
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**Q11: In the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe? [Yes, No, Refused, Don't know]**

<p>Q11: This question asks the SP to report if they have spent 10 or more minutes near any person who was smoking cigarettes, cigars, or a pipe in the last 3 days.</p>	<p>Include any brand of cigarette, any size of cigar, or any style of pipe. If the SP meets any of these criteria, select "Yes." If the SP reports that they have not been around any of these sources of smoke, select "No." If the SP refuses to answer, select "Refused." If the SP does not know or cannot recall if they spent any time near someone who was smoking these forms of tobacco while using the exposure badge, select "Don't know."</p>
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**Q12: In the last three days, did you take a shower or bath for five minutes or longer? [Yes, No, Refused, Don't know]**

Q12: This question asks the SP to report if they took a hot shower or bath for at least 5 minutes during the last 3 days.	Determine if the SP took a hot shower or bath for at least 5 minutes in the last 3 days. If the SP reports taking a hot shower or bath for a total of at least 5 minutes, select "Yes." If the SP reports taking a cold or warm shower or a hot shower or bath for less than 5 minutes, select "No." If the SP refuses to answer, select "Refused." If the SP does not know or cannot recall taking a hot shower or bath for at least 5 minutes, select "Don't know." If the answer to 12 is "yes," then Q13 becomes enabled.
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**Q13: If, yes, how long ago, in hours, has it been since your last shower or hot bath? [Yes, No, Refused, Don't know]**

Q13: This question asks the SP to report the number of hours between the time they took a hot shower or bath and the current time.	Enter the number of hours reported by the SP. If the number of hours is less than 1, enter 0. In general, round <30 minutes down to nearest whole number, if >30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since SPs are required to answer this question, get the SP's best estimate. This number cannot be greater than 76 since the time reference for this question is the last 3 days.
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm

SP ID: 248274 Name: EYRAMYA, AUNTIE Age: 39 years Gender: Female Date: 11/11/2002 Time: 02:56 PM

VOC Questionnaire 3-3

In the last three days, did you breathe fumes from any of the following:

Paints

Degreasing cleaners

Diesel fuel or kerosene

Paint thinner, brush cleaner, or furniture stripper

Drycleaning fluid or spot remover

Fingernail polish or fingernail polish remover

Glues or adhesives used for hobbies or crafts

Varnish or stain

Refused  Don't Know

4 of 5

End of Section Close Exam Finish

Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 03:05 PM

Continue to enter responses for each item.

**Q14: In the last three days, did you breathe fumes from any of the following? [Yes, No, Refused, Don't know]**

Q14: This question asks the SP to report if they breathed fumes from a variety of sources during the last 3 days.	Individually determine if the SP breathed fumes from each source. Record each answer. If the SP reports breathing fumes from an item in the last 3 days, select "Yes." If the SP reports s/he did not breath fumes in the last 3 days, select "No." If at any point during the interview the SP refuses to answer any further questions, select the "Refused" square. If the SP does not know or cannot recall breathing fumes during the last 3 days, select "Don't know" or if the SP reports they do not know the answer to all the remaining choices, select the "Don't know" square. Select the bright blue arrow to proceed to the last window.
Paints	Include all interior and exterior paints, spray paints used in arts and crafts, and oil-based artist paints.
Degreasing cleaners	Consider all degreasing cleaners such as Formula 409® Cleaner Degreaser and Simple Green All-Purpose Industrial Degreaser/Cleaner.
Diesel fuel or kerosene	Diesel fuel is a crude oil. Kerosene is a hydrocarbon oil, chiefly of the methane series, used for burning in lamps. It is also called coal oil.
Paint thinner, brush cleaner, or furniture stripper	These items contain turpentine.
Dry-cleaning fluid or spot remover	Consider all spot removers like K2R.
Fingernail polish or fingernail polish remover	Nail polish and nail polish remover contain acetone.
Glues or adhesives used for hobbies or crafts	Glue is a viscid cement or adhesive preparation and is usually an impure gelatin derived from boiling certain animal substances. Hobby glue contains a significant amount of toluene.
Varnish or stain	Varnish is a solution of certain gums or resins in alcohol, linseed oil, etc., and it is used to produce a shining, transparent coat on a surface. Stain is a dye or pigment used in staining.

To move to the section status screen, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

Each item requires a recorded response.

The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and help. Below the toolbar, a header bar displays patient information: "SP ID: 248274", "Name: EYRAMYA, AUNTIE", "Age: 39 years", "Gender: Female", "Date: 11/11/2002", and "Time: 02:56 PM". The main content area is titled "VOC Questionnaire 3-3" and contains the question: "In the last three days, did you breathe fumes from any of the following:". Below the question is a list of items with dropdown menus: "Paints", "Painters", "Asphalt", "Nail polish remover", "Glues or adhesives used for hobbies or crafts", and "Varnish or stain". Each dropdown menu currently shows "No". At the bottom of the list are two checkboxes: "Refused" and "Don't Know". An error message dialog box is overlaid on the questionnaire, titled "Phlebotomy" and containing a red "X" icon, the text "Please answer the question", and "Glues or adhesives used for hobbies or crafts". An "OK" button is visible in the dialog box. The bottom of the window features a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, and a status bar with "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "03:06 PM".

If the bright blue arrow in the navigation bar or [Enter] is inadvertently selected before all questions have been answered, an error message text box displays. Review the text and, to remove the message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. Enter responses for each item.

Verify the section status for the VOC section of the phlebotomy exam.

The screenshot displays a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar shows patient information: "SP ID: 248274 Name: EYRAMYA, AUNTIE Age: 39 years Gender: Female Date: 11/11/2002 Time: 02:56 PM". The main area is titled "VOC status" and contains a form with the following elements:

- A "Status" section with three radio buttons: "Complete" (selected), "Partial", and "Not Done".
- A "Comments" field with a dropdown arrow.
- An "Other text" field with a text input area.

At the bottom of the window, there is a navigation bar with a page indicator "5 of 5", buttons for "End of Section", "Close Exam", and "Finish", and a blue arrow button. The system tray at the very bottom shows "Ready", "MEC Layer: 06/20/2002", "Application: Ver 10.11.1B", "Connected to Coordinator", "SP assigned to room", and "03:06 PM".

The section status is dependent on the status of the water collection vial. The VOC blood tube result is reflected in the venipuncture section status. If the water collection is marked as “Yes” or “Needs to be collected,” the VOC section status is complete. If the water vial is marked as “SP refusal,” then the VOC section status is not done. The VOC questionnaire does not affect the VOC section status.

Use comment codes to explain a not done section status.

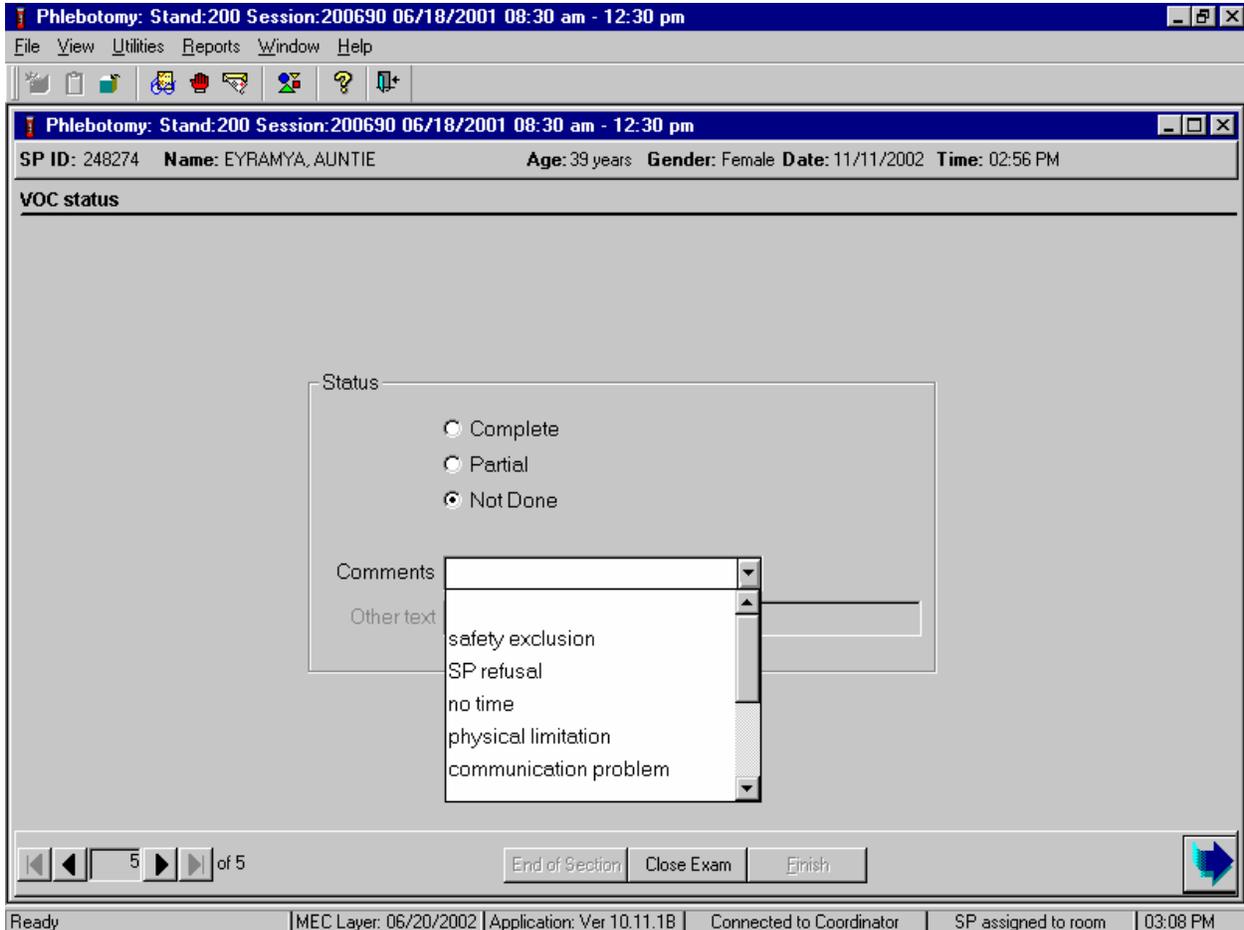
The screenshot shows a software window titled "Phlebotomy: Stand:200 Session:200690 06/18/2001 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar displays patient information: "SP ID: 248274 Name: EYRAMYA, AUNTIE Age: 39 years Gender: Female Date: 11/11/2002 Time: 02:56 PM". The main area is titled "VOC status" and contains a dialog box with the following elements:

- Status:** Three radio buttons:  Complete,  Partial, and  Not Done.
- Comments:** A dropdown menu.
- Other text:** A text input field.

At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a blue arrow icon. The system tray at the very bottom shows: "Ready | MEC Layer: 06/20/2002 | Application: Ver 10.11.1B | Connected to Coordinator | SP assigned to room | 03:08 PM".

Comment codes are used to describe the reason for a not done section status.

Choose and enter the appropriate comment code when the examination status is partial or not done.



To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice and left click. Alternatively to select a comment code, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click. If "Other, specify" is chosen, type a short explanation in the "Other text" text box.

Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	This is SP initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam.
no time	Not applicable
physical limitation	Not applicable
communication problem	Not applicable
equipment failure	Not applicable
SP ill/emergency	The SP became ill or an emergency occurred and the test could not be performed on the SP.
interrupted	Not applicable
other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

To complete the VOC section of the phlebotomy exam, use the mouse to direct the mouse arrow to the Finish button in the navigation bar, and left click or press [Enter] when the Finish button is highlighted.

## 12.6 VOC Water Collection

If the SP does not bring their water sample to the MEC, the field office staff **MUST** attempt to schedule an appointment with the SP so that a designated representative can collect the water from the bathtub faucet. Get permission from the SP to collect the water from an outside faucet if the SP is not available for the home visit.

The medical technologist performs a weekly data search to identify SPs who not did bring their water sample to the MEC when they came to the mobile examination center for their exam. Select one MEC exam day per week to perform the search. Access and print the VOC Reconciliation Report from the NHANES ISIS IntraWeb. Work with the MEC manager to coordinate the collection with the field office staff. The field office staff accesses the Appointment Management System to locate the pertinent information needed to contact the SP to schedule the collection visit. They contact the SP and establish an acceptable collection date and time. In preparation for the collection, print one label for each water vial using the Laboratory application. Locate the original MEC exam session into which the SP was scheduled, access the Print VOC Water processing module under the File, Print Labels menu. Select the correct SP and print the label. The collector takes several spare water collection kits to the SP's home. The designated representative collects the tap water sample, labels the vial, records the collection date and time on the label, and transports the sample back to the MEC. Process the specimen using the Laboratory application. Use the Set Session functionality to access the SP's original MEC exam session, access the VOC Processing module, and mark the vial as Filled—"Yes," or Filled—"No."

If the MEC staff or designated representative is unable to collect the water vial, then the medical technologist must access the VOC processing module, mark the VOC water vial as Filled—"No," and add a comment. The two comment choices are "SP refusal" and "Unable to locate." The VOC Reconciliation Report captures and displays this comment in the "Water Collected in Lab" column. The "Water Collected in Lab" column should never contain "null"; this means that no comment has been entered. A comment is required for vessel 56 whenever it is marked as Filled—"No" in the processing module. It is the medical technologist's responsibility to review and reconcile all data in the VOC Reconciliation Report before the end of each stand.

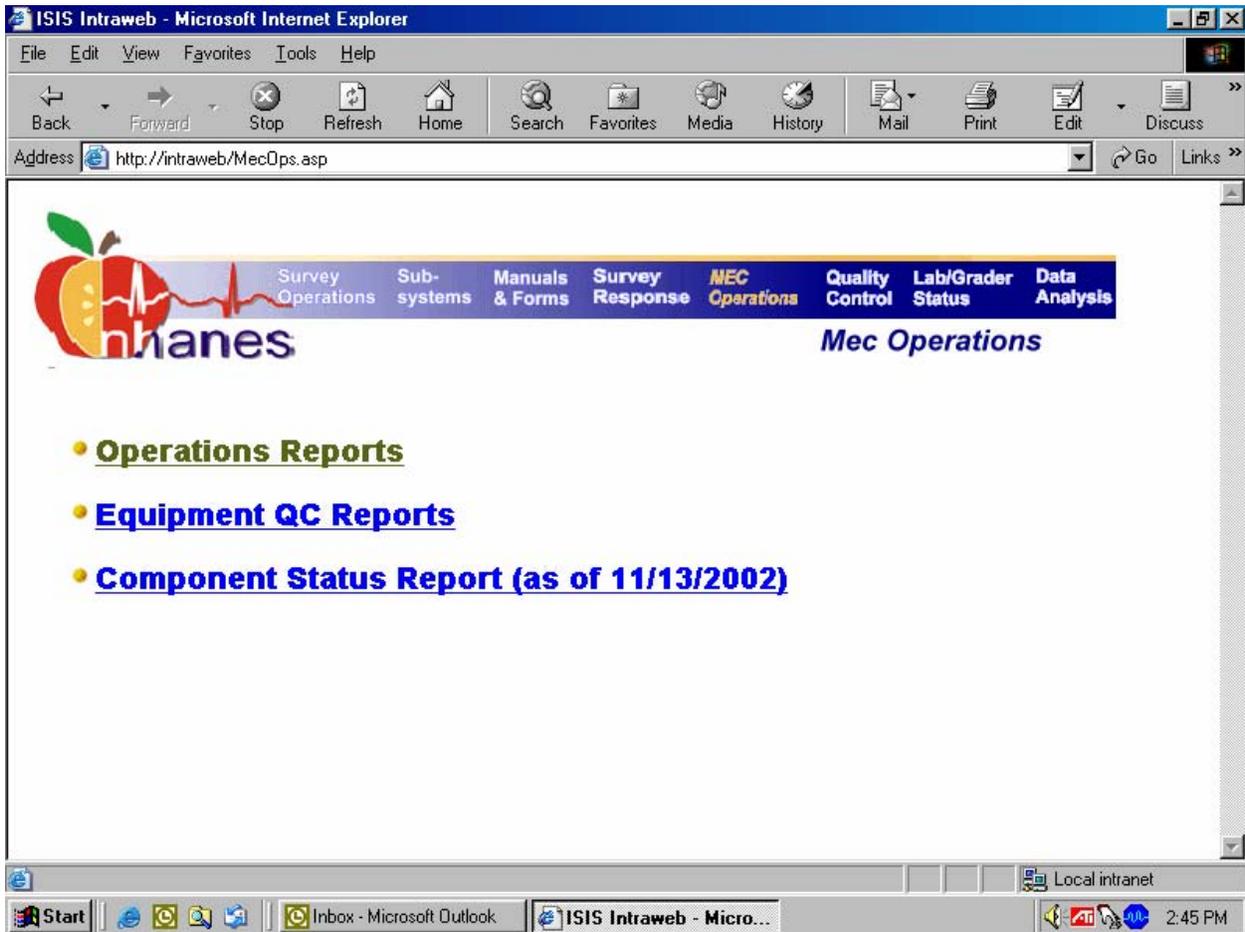
## 12.6.1 Preparing to Collect Vessel 56

Access the VOC Reconciliation Report on the ISIS Intraweb.



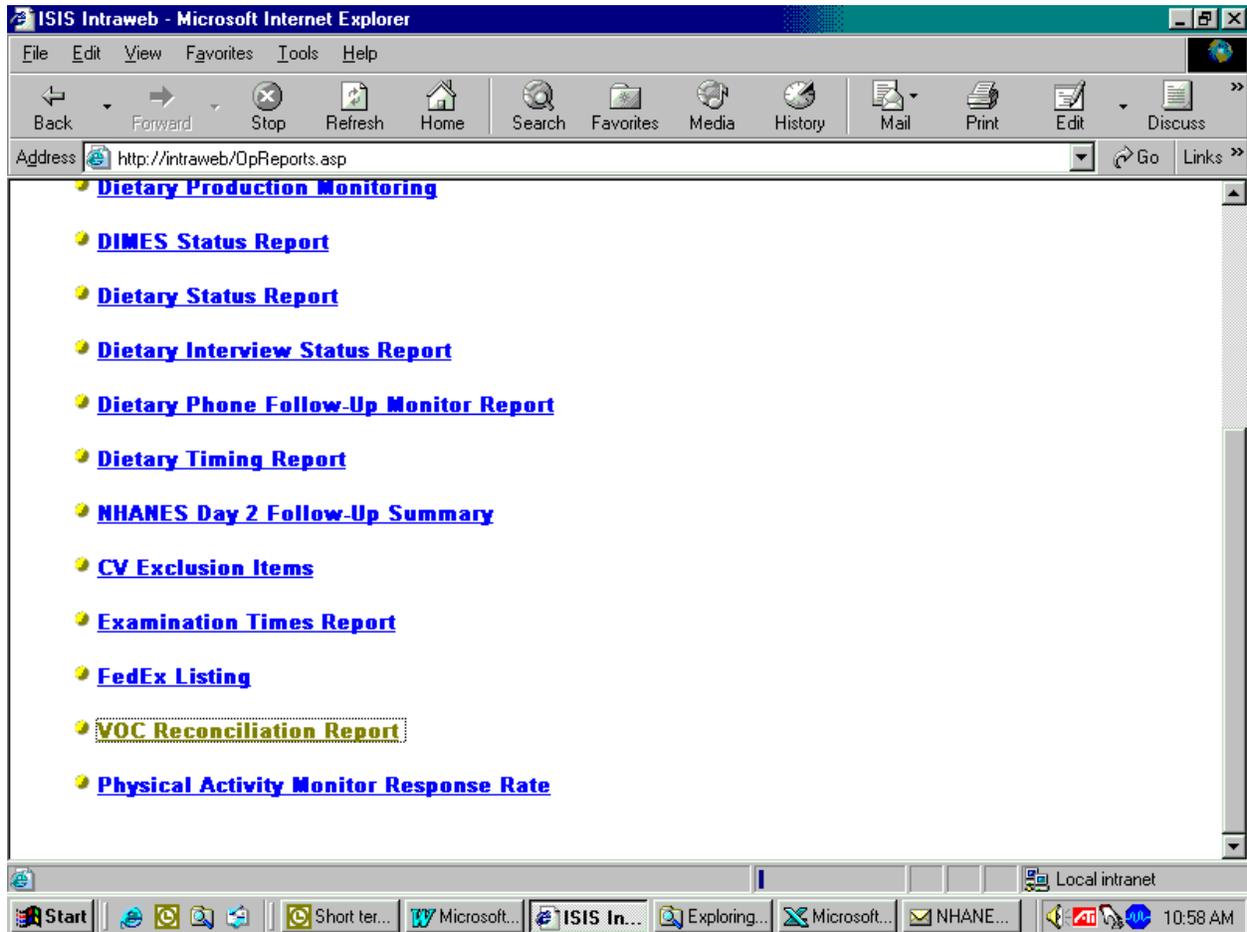
Begin to access the VOC Reconciliation Report on the Intraweb by opening Internet Explorer. To access the "ISIS Intraweb," use the mouse to direct the mouse arrow to Favorites in the top tile bar, drag the arrow to the Intraweb selection, and left click.

Continue to access the Intraweb.



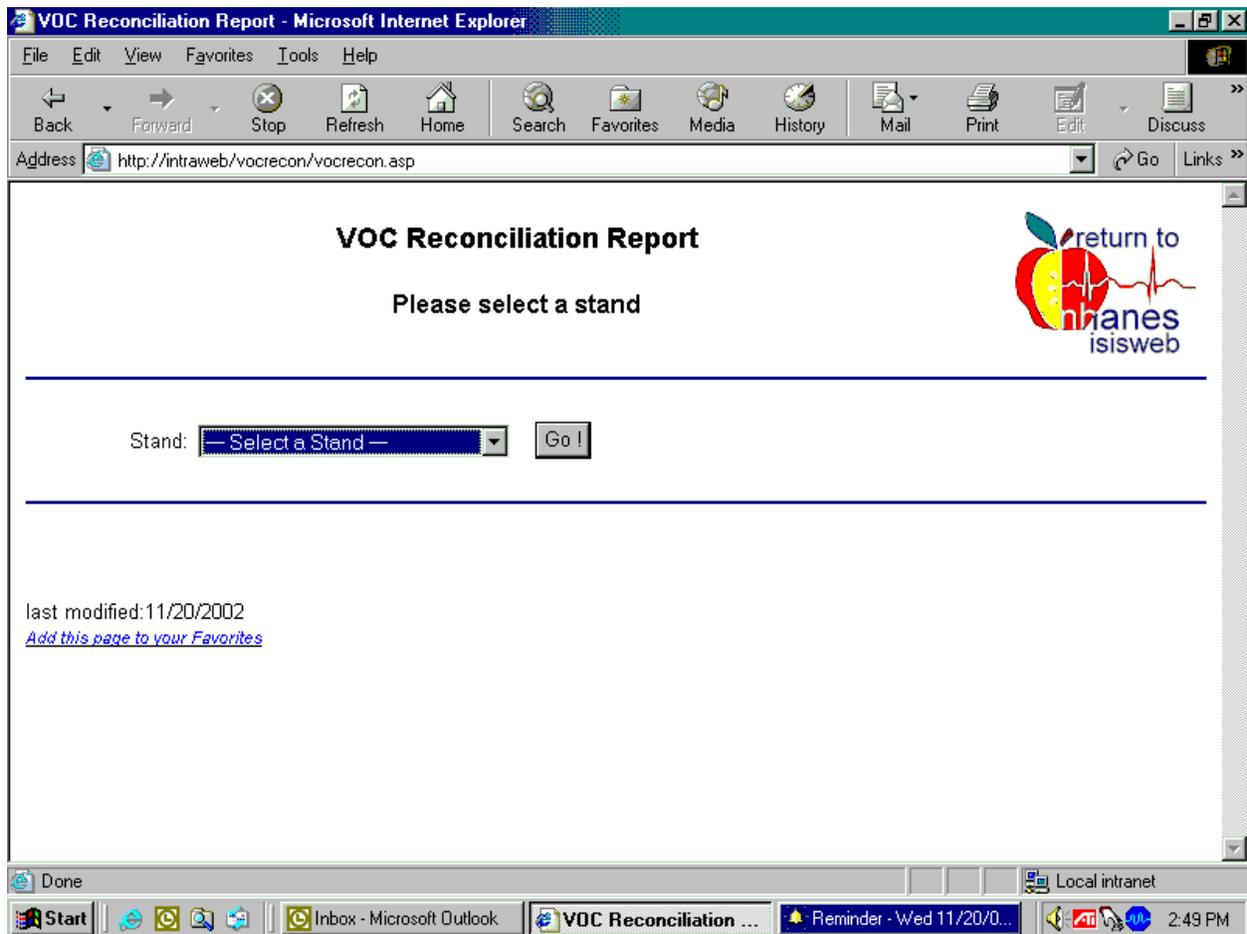
To continue to access the VOC Reconciliation Report, use the mouse to direct the mouse arrow to the MEC Operations header and left click. The Operations Reports link displays.

Continue to access the links in the Intraweb.



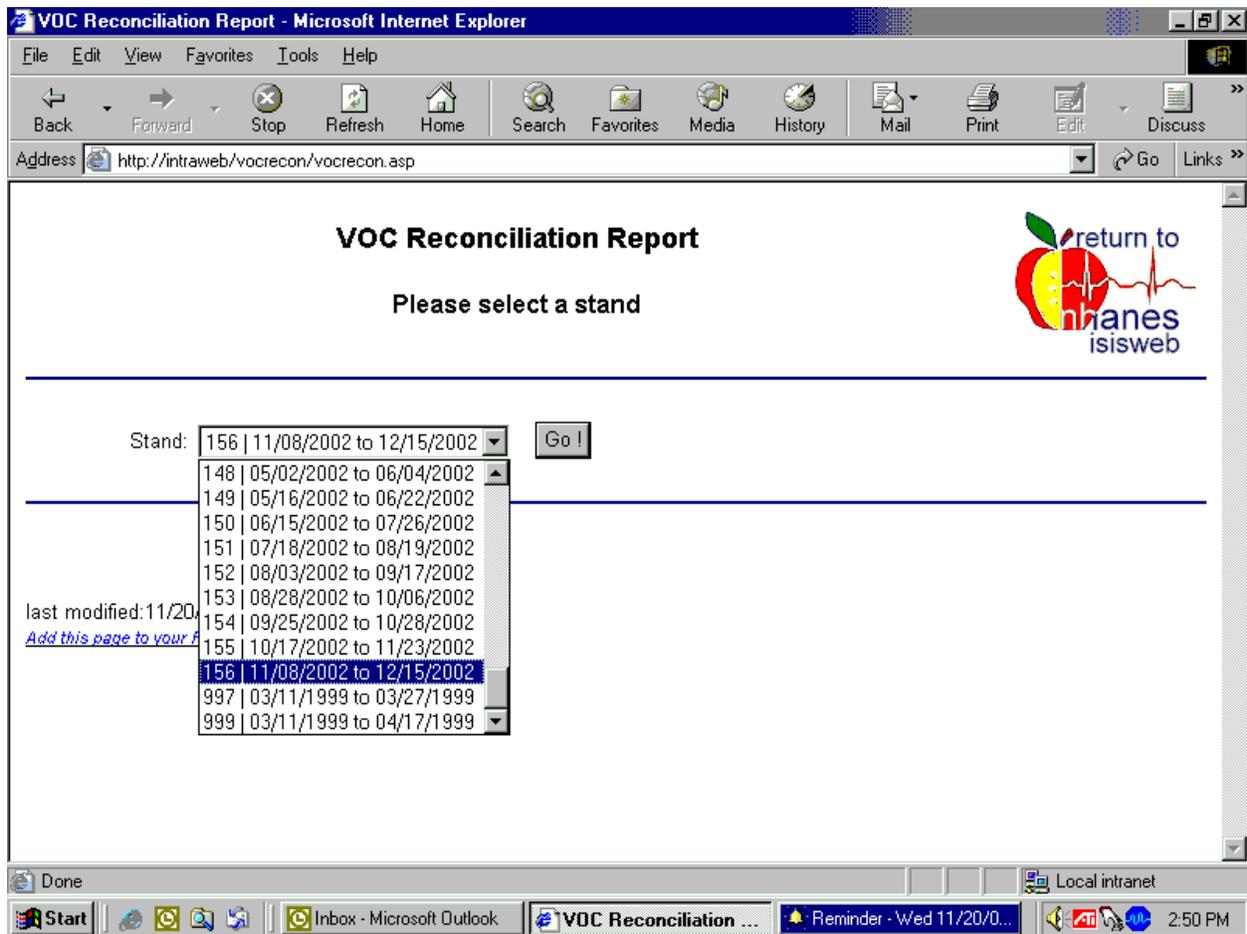
To continue to access the VOC Reconciliation Report, use the mouse to direct the mouse arrow to the VOC Reconciliation Report underlined link and left click. The stand pick list displays.

Define the search by selecting the stand.



To select the correct stand, use the mouse to direct the mouse arrow to the arrow on the right side of the drop-down list, drag the arrow to the correct stand, and left click. Use the scroll bar on the right side of the selection list to view a complete list of all the stands.

Continue to define the search by selecting the stand.



To select the correct stand, drag the mouse arrow to the correct stand and left click once the selection is highlighted. To begin the search, use the mouse to direct the mouse arrow to the Go button and left click.

The VOC Reconciliation Report displays.

**VOC Reconciliation Report**

Stand: 199

SP Name	SP ID	Stand/Segment Serial/Person/Family	Session ID	Exam Date	Water Collected in Phlebotomy	Water Collected in Lab
Mary Smith	287091	199-12-18-1 1	199290	11/08/02	Yes	Collected
Fred Jones	654879	199-6-10-1-1	199290	11/08/02	Needs to be collected	Collected
Sally McNeil	942117	199-13-3-1-1	199291	11/08/02	Yes	Collected
Elizabeth Williams	345962	199-23-14-1- 1	199300	11/09/02	Yes	Collected
Franklin Butterworth	677864	199-22-10-1- 1	199300	11/09/02	Yes	Collected
Missy Loundon	214864	199-3-7-1-6	199301	11/09/02	Yes	Collected
Wallter Bridges	109457	199-3-7-1-1	199301	11/09/02	Yes	Collected
Doris Granger	238577	199-17-15-1- 1	199311	11/10/02	Needs to be collected	Collected
Melissa Jackson	466648	199-24- 5400-1-1	199320	11/11/02	Yes	Collected
					Needs to be	

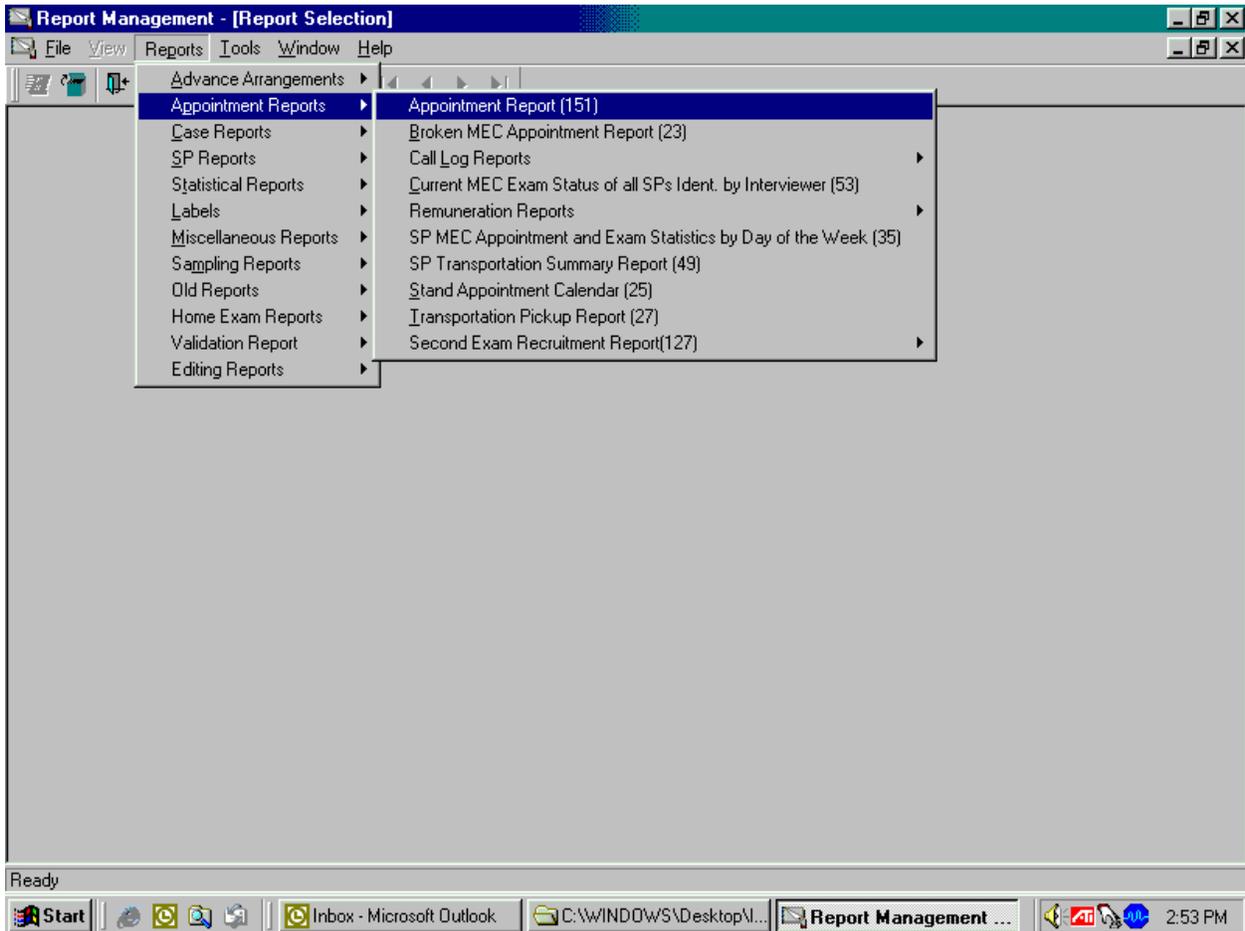
The VOC Reconciliation Report list the SP's name (first, last), SP ID, Stand-Segment-Serial Person-Family, Session ID (the original session in which the SP was examined), the Exam Date, the status of the Water Collection in Phlebotomy (Yes, Needs to be collected, or SP refusal), and the status of the Water Collection in Lab (Collected, Not Collected, Unable to locate, SP refusal). Determine which SPs need to have their water vial collected based on the information in the last two columns. Collect water on SPs whose "Water Collected in Phlebotomy" status is "Needs to be Collected" and whose "Water Collected in Lab" status is "Not Collected." Do not attempt to contact SPs whose "Water Collected in Phlebotomy status is "SP Refusal."

Highlight the segment. The segment is the first number or numbers after the stand number, and it is located in the third column from the left.

Look at the stand map, locate the segments, and arrange the driving route. The field office has segment folders available that are helpful for trailer courts, apartment complexes, and rural areas.

Arrange the “Appointment Reports” for each SP based on the route. The MEC manager routinely prints these reports for the coordinator. Each SP is listed on a separate page. Ask the coordinator to save and provide the page for each SP who does not bring their water to the exam session.

Alternatively, ask the data manager or MEC manager to print the appointment report for each SP. This report is located in the Report Management application; select the Reports, Appointment Reports, and Appointment Report (151) drop-down lists to access this information.



Open the Report Management application, and log on. To select the Appointment Report, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, drag the mouse arrow to {Appointment Reports}, then {Appointment Report (151)} and left click.

The Report Management application displays the begin and end date filters. Insert the dates and select the Retrieve button.

The Appointment Report displays.



The Appointment Report lists all the SPs in the stand. It contains the SP's telephone number, address, language, and relationships.

Select the SPs listed on the VOC Reconciliation Report by using the filters.



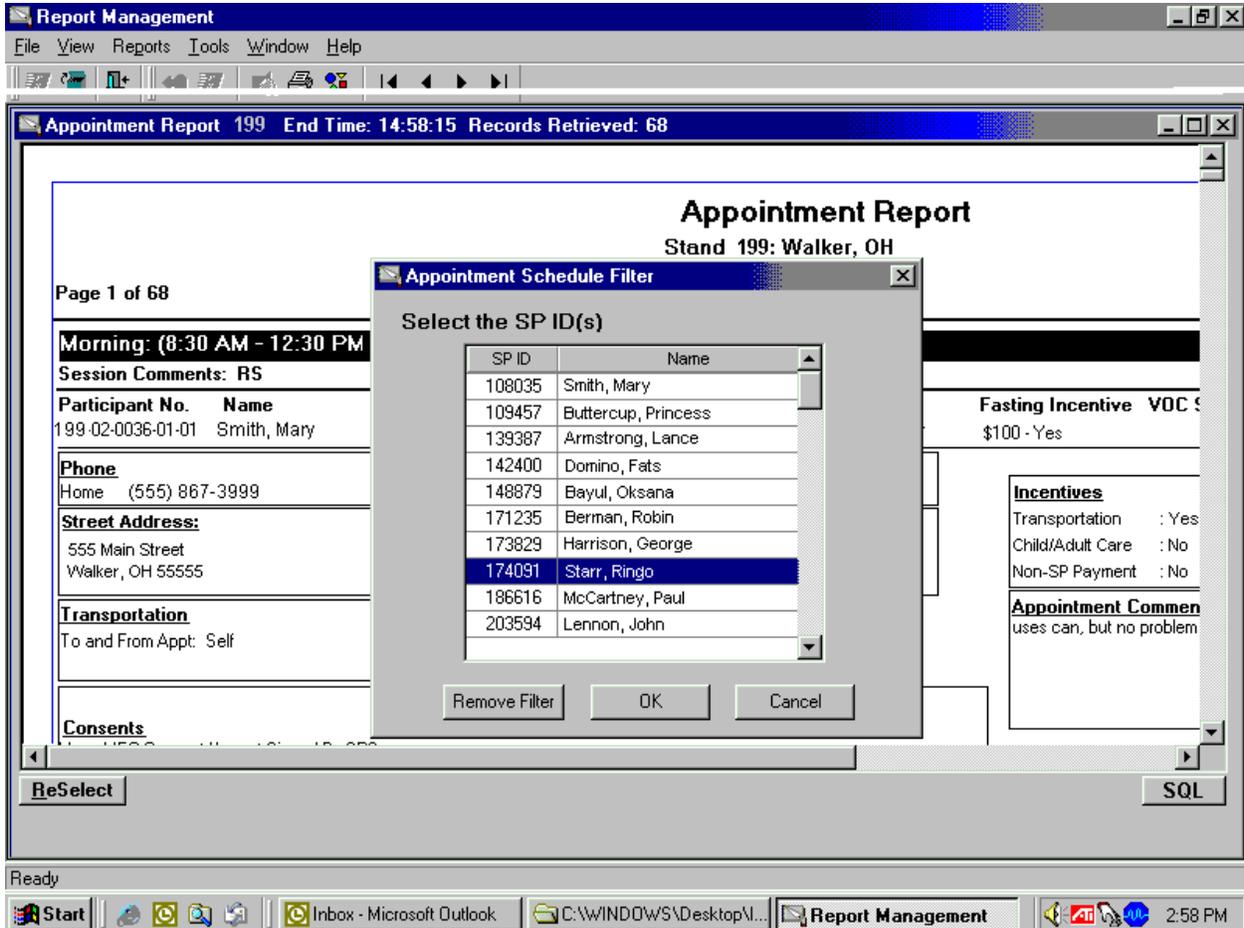
To select individual SPs, use the mouse to direct the mouse arrow to {View} in the top menu bar, drag the mouse arrow to {SP Filter} (at the bottom), and select the correct SP.

The Appointment Schedule Filter displays.



The SPs are listed in numerical order based on their SP ID.

Choose the correct SP; they are listed in SP ID order. The SP ID for each SP is located in the 2nd column on the VOC Reconciliation Report.



To select a specific SP, use the mouse to direct the mouse arrow to the correct SP and left click to select or highlight the choice. Use the scroll bar to view the entire list. Once the correct SP is highlighted, use the mouse to direct the mouse arrow to the OK button and left click.

To print the Appointment Report, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the mouse arrow to {Print} and left click.

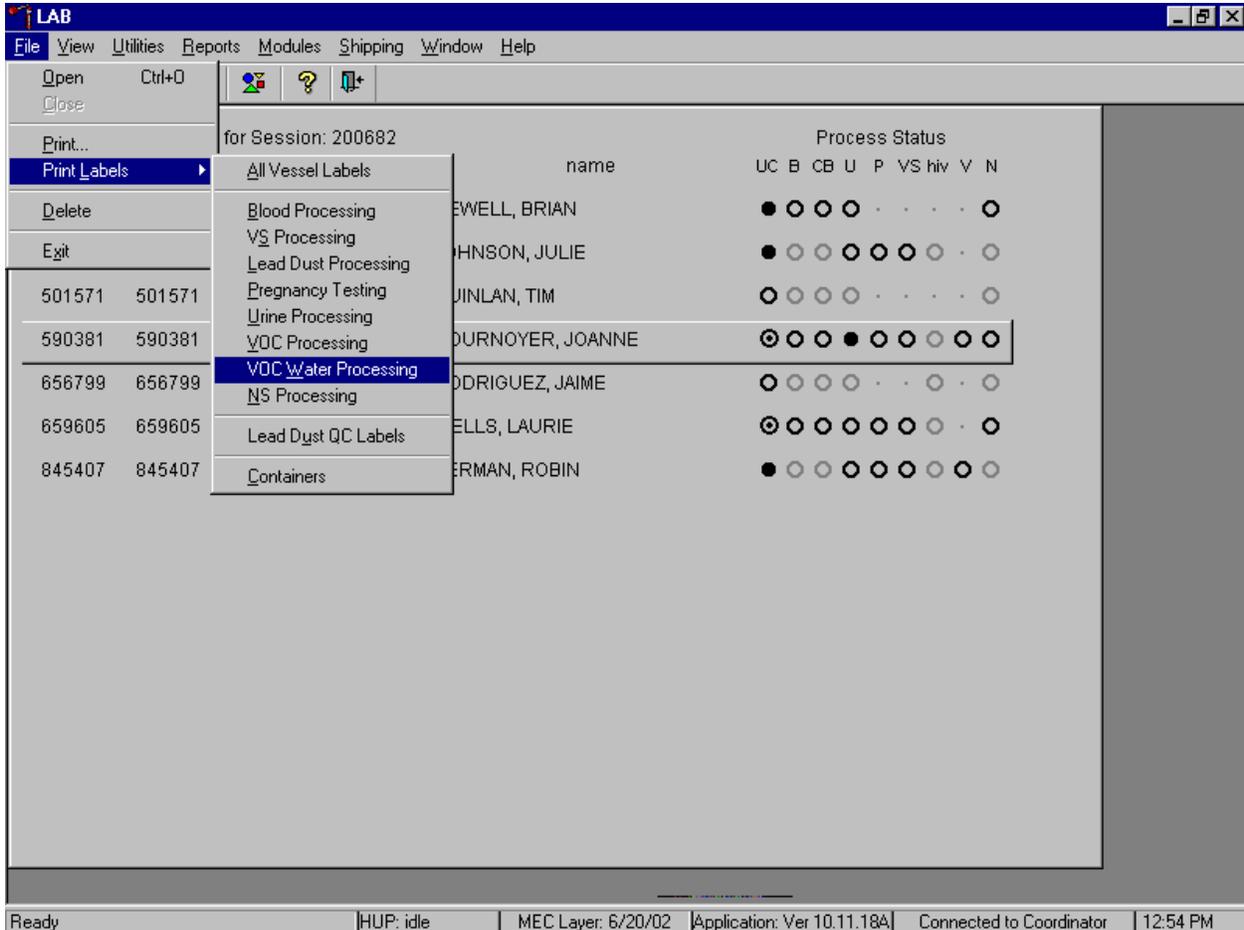
Write down any directions or special arrangements on the Appointment Report.

A field office staff member will call the SP to schedule an appointment to collect the water. The staff member can ask permission for the designated collector to collect the water from an outside faucet if the SP is not available. If the SP still has the collection vial, he or she can collect the sample and leave it on the porch or in another obvious predetermined location. If there are other SPs in the household who are scheduled for a future MEC exam, it is acceptable to arrange for them to collect and bring the other sample with them.

### **12.6.2 Collecting Vessel 56**

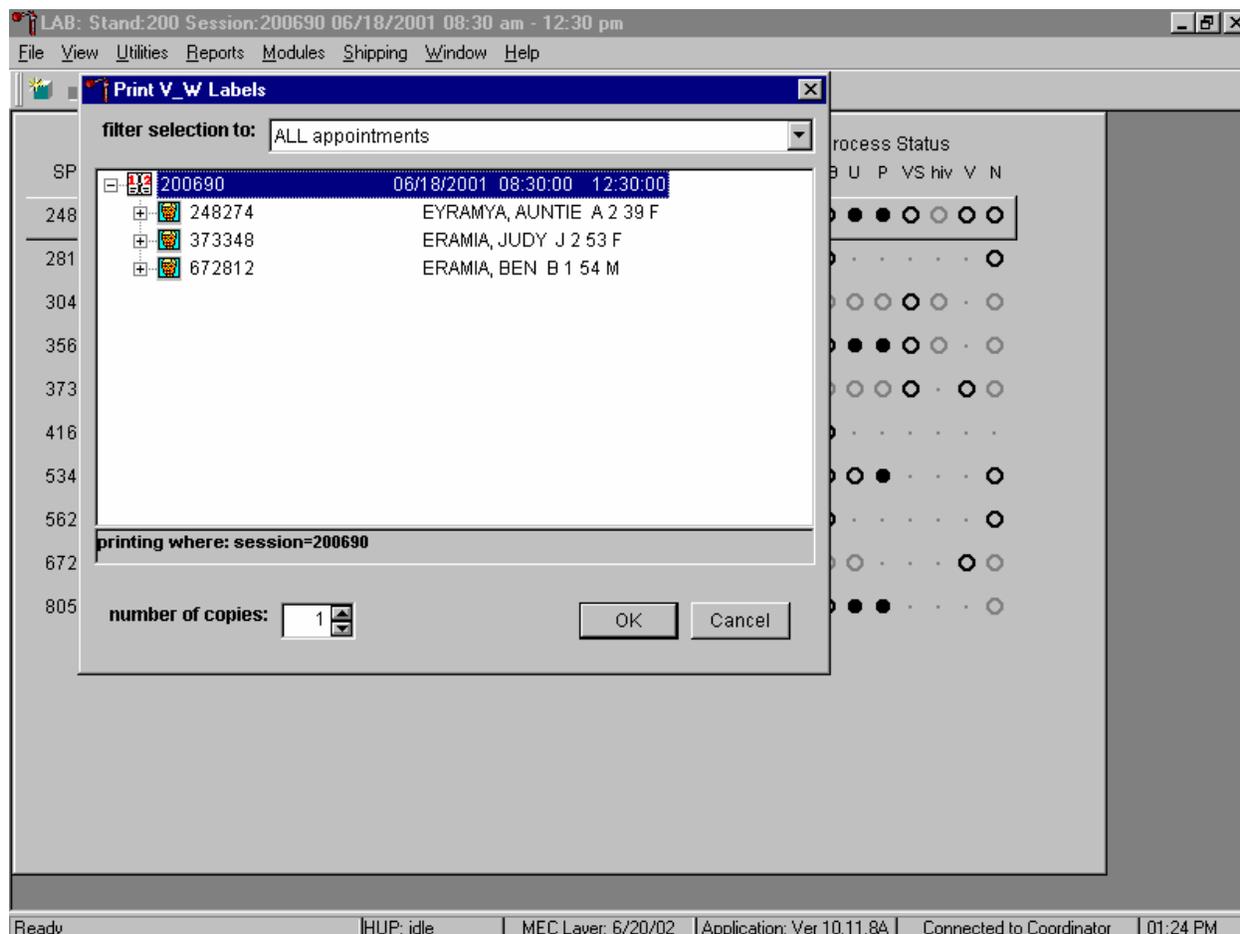
In preparation for the collection, print one label for each water vial using the Laboratory application. Locate the original MEC exam session into which the SP was scheduled; access the {Print VOC Water processing} module under the {File}, {Print Labels} menu. Select the correct SP and print the label. Get the water collection kits from the phlebotomy room. Take several spare water collection kits to the SP's home. Take the collection kits, appointment reports, maps, segment folders, and a pen. Record the mileage at the start of the collection process and at the end of the collection process. The MEC manager will provide the formula for reimbursement. Collect the tap water sample, label the vial, record the collection date and time on the label, and transport the sample back to the MEC.

Access the Print Labels module in the Laboratory application. Print vessel labels for the VOC Water Processing vessels for specific SPs in a MEC session.



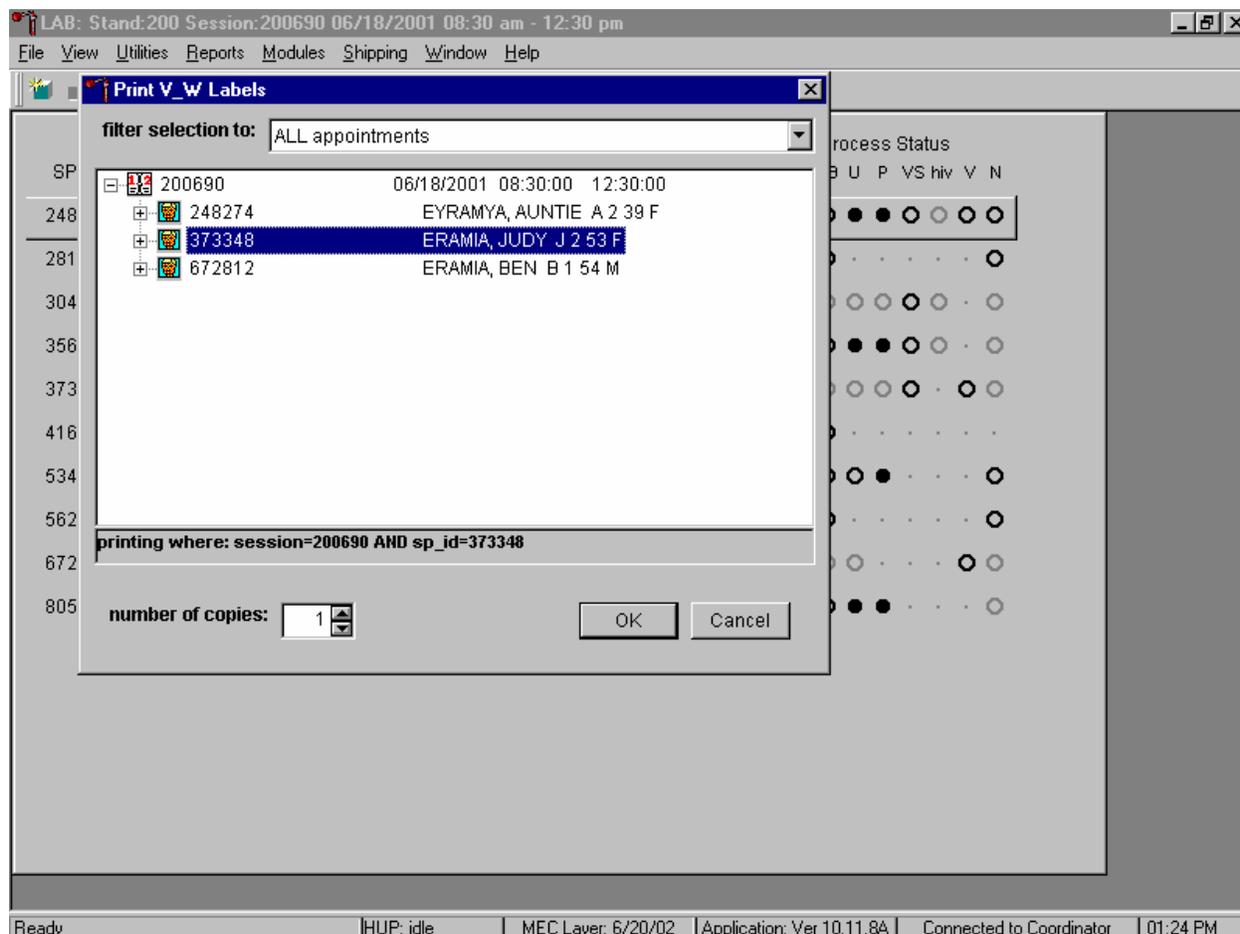
To print vessel labels for the VOC Water Processing modules, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Print Labels}, then to {VOC Water Processing}, and left click or type [Alt] [F/f], [L/l], [W/w].

Print VOC Water Processing vessel labels for all SPs in a MEC session.



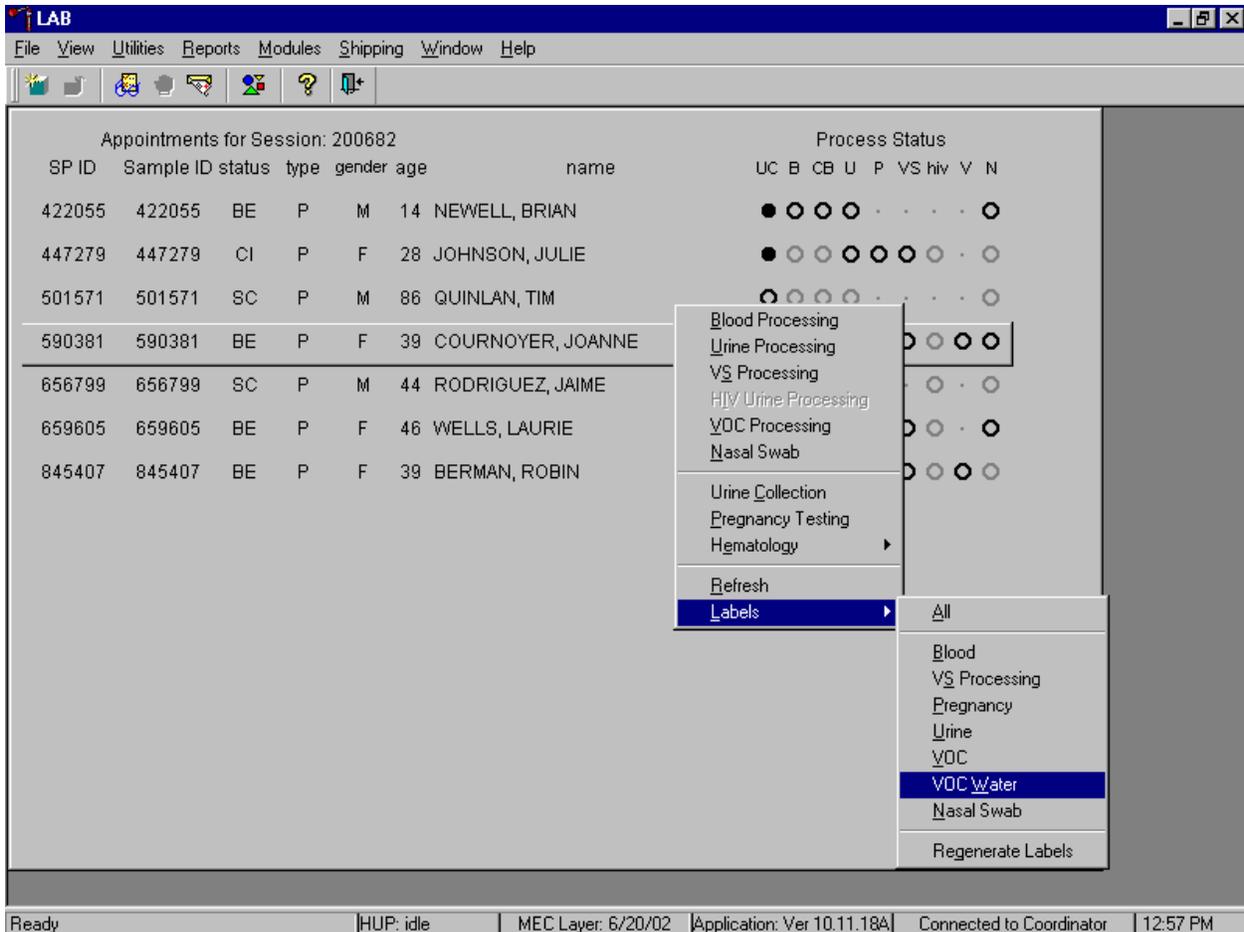
To print vessel labels for one specific module for all SPs, in a MEC or session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print VOC Water Processing vessel labels for one SP in a MEC session.



To print vessel labels for one specific module for one SP, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print labels for a particular MEC SP using the heads-up display. Print labels for one specific module for one SP in a MEC session using the heads-up display.



To print labels for one specific module for an SP using the heads-up display, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then {VOC Water} and right click or and type [L/I], V/v]. Alternatively, to print labels using the heads-up display, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, then drag the mouse arrow to {Labels} and then {Voc Water}, or left click or type [L/I] [V/v].

### 12.6.3 After Returning to the MEC

After collection, note the date and time of the collection on the tube label. If the label is missing, write it on the bag label and transfer it to the lab label after returning to the MEC.

### 12.7 Processing VOC Specimens (Vessels) in the Laboratory

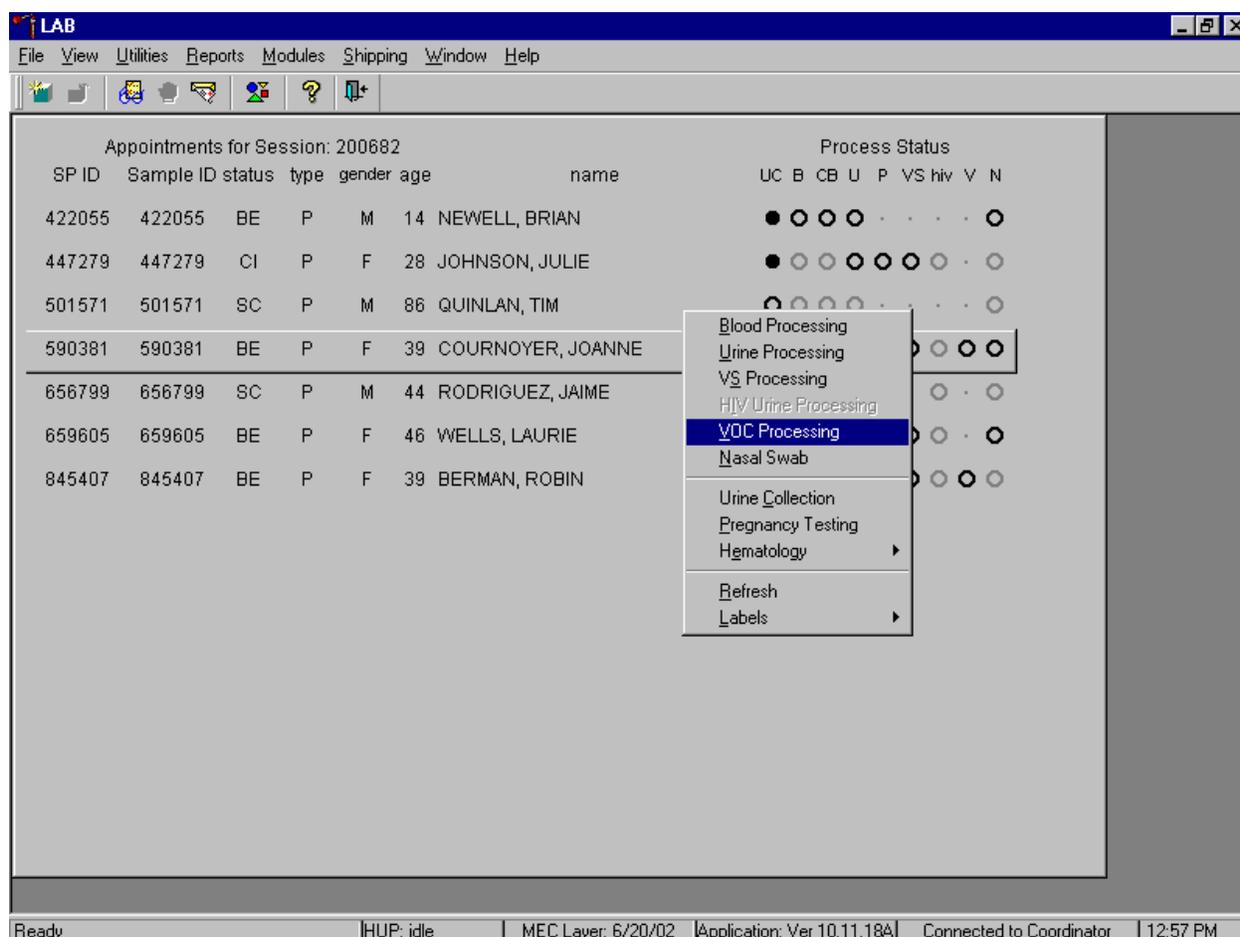
Open the Laboratory application, select the correct session, and review the heads-up display. If the VOC water was collected in the home, then use the Set Session functionality to access the SP's original MEC exam session, access the VOC Processing module and mark the vial as Filled—"Yes," or Filled—"No."

Table 12-1 illustrates the VOC processing and storage protocol.

Table 12-1. VOC processing and storage protocol

Vessel No	Assay	Age in years	Sample size mL	Collection type	Container
54	VOC Blood	20-59	10	10-mL Gray top	5 x 5 5-inch box with foam insert
56	VOC Water	20-59	10	10-mL Glass	5 x 5 5-inch box with foam insert

Access the VOC processing module.



To access the VOC processing module, use the mouse to direct the mouse arrow to the correct SP and right click, drag the mouse arrow to {VOC Processing} and right click or right click and type [V/v]. Alternatively, to access the VOC processing module, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, then drag the mouse arrow to {VOC Processing} and left click or type [V/v].

The VOC processing window displays.

LAB

File View Utilities Reports Modules Shipping Window Help

VOC: 590381

none

Tech ID: 1126    Sample ID: 590381    Name: COURNOYER, JOANNE    Gender: F    Age: 39  
 SP ID: 590381    SubSample: 1    Fasting\_Req: 3

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
54	VOC Blood	10.0	VW	10 ml	gray top	<input type="radio"/> Yes <input type="radio"/> No			
56	VOC Water	10.0	H2	10 ml	glass vial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    OK    Cancel

Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.18A | Connected to Coordinator | 12:58 PM

The VOC processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting\_Req, columns for Vessel ID, Test Name, Sample Volume, Type (blood tube, whole blood, plasma, serum, clots, VW, H2), Vessel Volume, Vessel Name, Container ID/Slot #, Filled buttons and a Comments drop-down list.

Mark each vessel as Filled–“Yes” or Filled–“No.”

The screenshot shows a software window titled 'LAB' with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. Below the toolbar is a sub-window titled 'VOC: 590381' with a 'none' label. The sub-window contains a form with the following fields:

Tech ID: 1126    Sample ID: 590381    Name: COURNOYER, JOANNE    Gender: F    Age: 39  
 SP ID: 590381    SubSample: 1    Fasting\_Req: 3

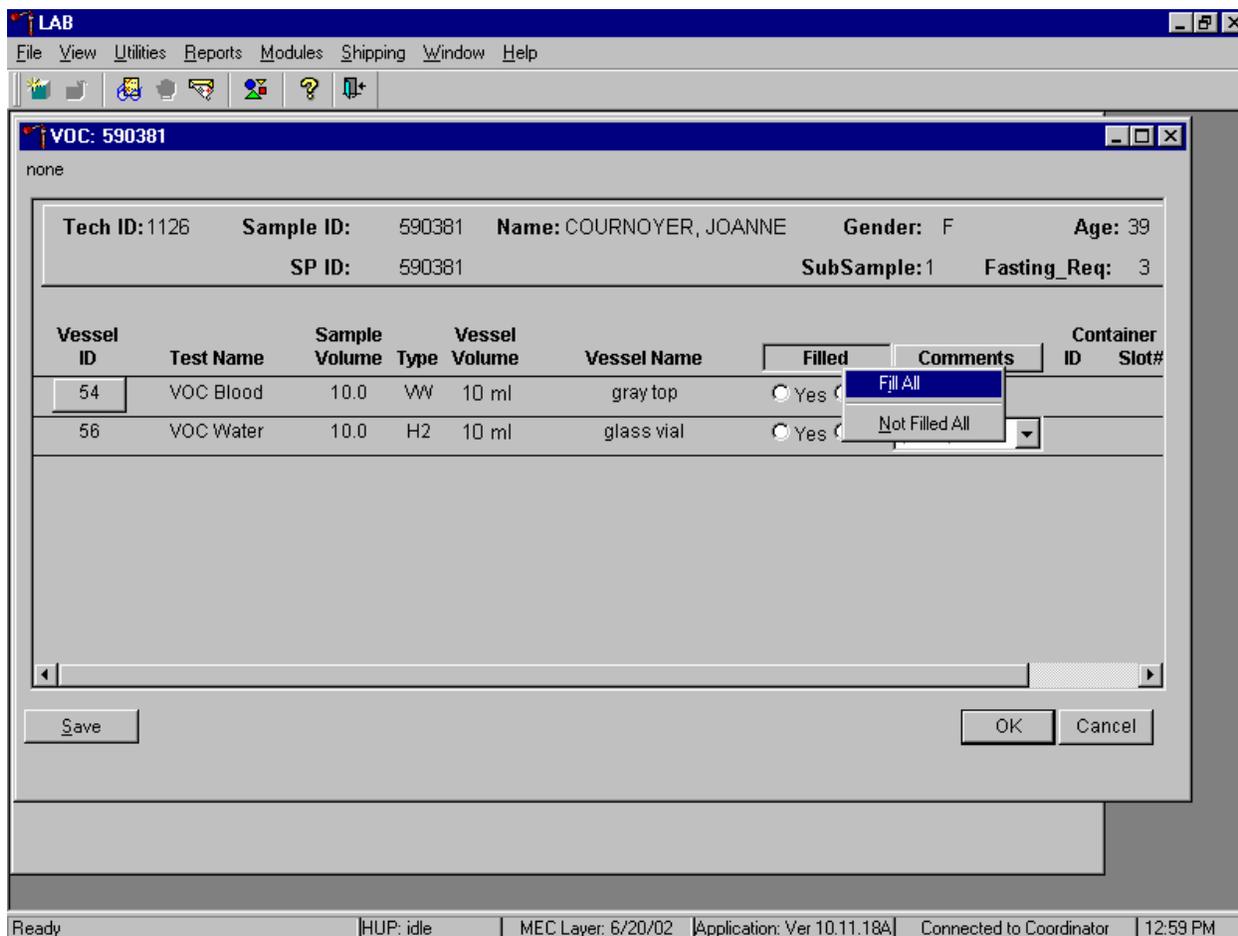
Below the form is a table with the following columns: Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Filled (Yes/No radio buttons), Comments, Container ID, and Slot#.

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
54	VOC Blood	10.0	WW	10 ml	gray top	<input checked="" type="radio"/> Yes <input type="radio"/> No		0077096	2
56	VOC Water	10.0	H2	10 ml	glass vial	<input checked="" type="radio"/> Yes <input type="radio"/> No		0077097	2

At the bottom of the sub-window are buttons for 'Save', 'OK', and 'Cancel'. The status bar at the bottom of the main window shows: Ready | HUP: idle | MEC Layer: 6/20/02 | Application: Ver 10.11.18A | Connected to Coordinator | 12:59 PM

To individually mark each vessel as filled or not filled, use the mouse to direct the mouse arrow to the Yes or No radio button for a specific vessel ID (or test), and left click. As each vessel is marked as “Filled,” it is automatically assigned to a slot in an existing (open) container. Store each vessel in the correct slot in the correct container. To record these actions or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To record these actions or to save these data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions and to exit the module, use the mouse to direct the mouse arrow to the Cancel button and left click.

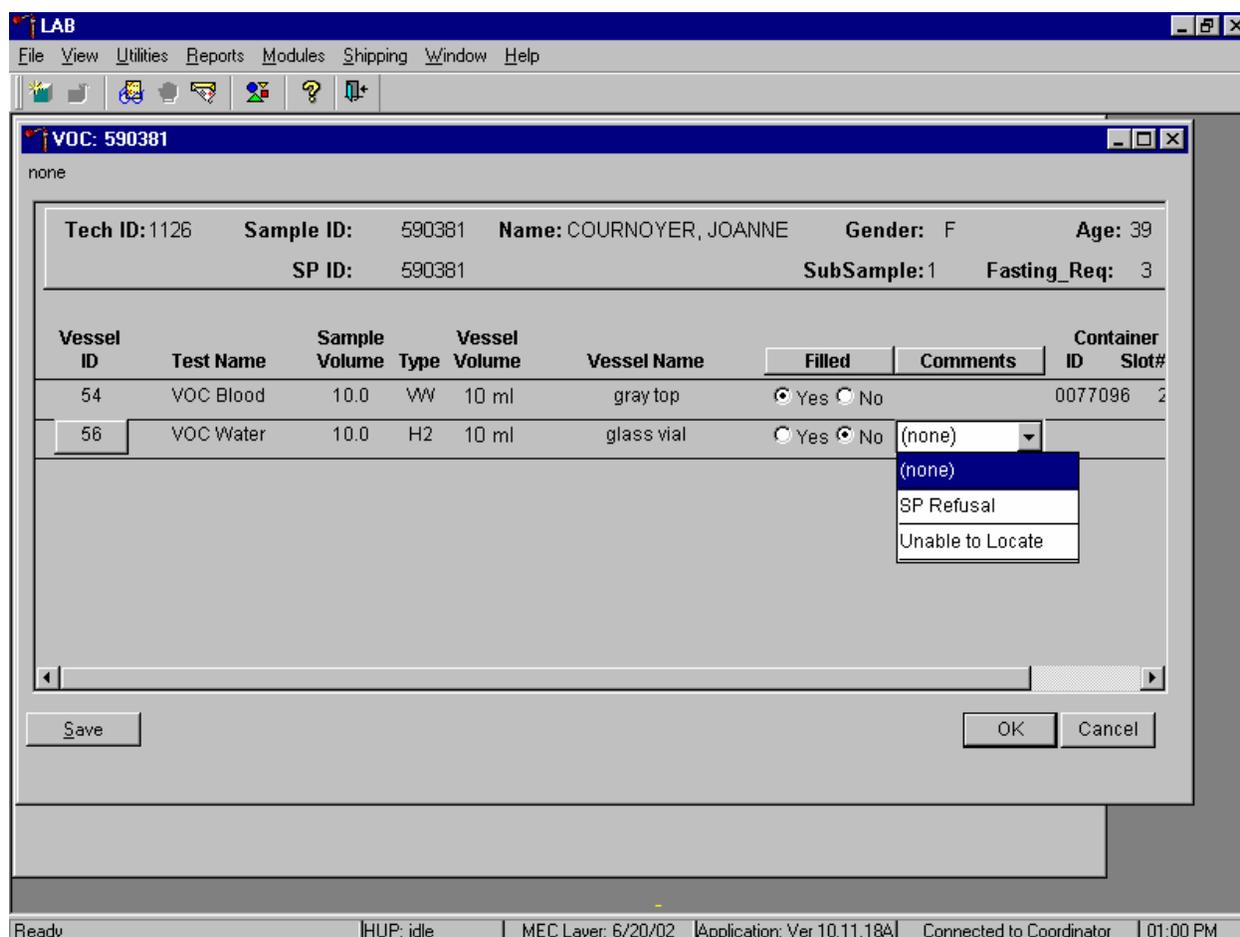
Collectively mark both vessels as Filled–“Yes.”



To collectively mark both vessels as Filled–“Yes,” use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {All}, and left click. As each vessel is marked as “Filled,” it is automatically assigned to a slot in an existing (open) container. Alternatively, to collectively mark both vessels as Filled–“Yes,” type [Shift] [F/f], [I/i], and [A/a.]

There are no quality comment codes available to describe the quality of the specimen.

Attach a comment to an individual Filled–“No” vessel.



To attach a Filled–“No” comment to an individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments text box to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

All vessels marked as Filled–“No” require a comment or explanation. Enter comment codes to describe the reason that a vessel is marked as Filled–“No.”

Comment for not filled vessels	Use when:
SP refusal	The SP refuses to allow the medical technologist to contact them to collect the water.
Unable to locate	The medical technologist is unable to locate the SP to arrange to collect the water from the SP’s home.

Review the heads-up display. Verify that the heads-up display is updating correctly. Check the slot assignment of containers associated with vessels 54 and 56, at the end of each session. Verify the contents of each container against the container map.

## 12.8 Shipping VOC Specimens

Ship VOC blood and water vessels to one contract laboratory (Exhibit 12-6) in a double-sided Styrofoam shipper or hard-sided cooler using wet refrigerant packs. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 12-7, the VOC shipping protocol, illustrates the specifications for the shipment of biological specimens to the contract laboratory.

Exhibit 12-6. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) Telephone number
CDC/Air Toxicant Branch 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341	54/VOC Blood 56/VOC Water	Refrigerated	Dr. Ben Blount 770-488-7962

Exhibit 12-7. VOC shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
CDC/Air Toxicant Branch	54/VOC Blood	Refrigerated	5 x 5 5-inch box with foam insert	Weekly
CDC/Air Toxicant Branch	56/VOC Water	Refrigerated	5 x 5 5-inch box with foam insert	Weekly

The integrity of laboratory specimens, including the VOC vessels, is critical to NHANES. Storage temperatures have been established for each analyte in consultation with NCHS and contact laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their ultimate receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient refrigerant packs, and sending specimens FedEx priority overnight.

The shipping technologist is primarily responsible for packing and shipping the specimens to all laboratories on a designated day. As necessary, other medical technologists, the phlebotomist, and the medical technologist assist in performing each of the steps listed below to complete the shipping procedures.

- On the day before a designated shipping day, create and print shipper labels (airbills) using FedEx Ship software.
- On the morning of a shipping day, close all containers following the protocol listed in Exhibit 12-8. Also, import FedEx airbill numbers into the shipping module, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted “warning” labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.
- Pack the containers for vessels 54 and 56 in the VOC shipper in the following order:
  - Cold packs at -20°C
  - Padding
  - Container for vessel 56 (VOC Water)
  - Container for vessel 54 (VOC Blood tube)
  - Padding
- Place the appropriate paper manifest and the FedEx return airbill in a 9 x 12 plastic bag and place the plastic bag on the Styrofoam lid of shipper and place the lid on the shipper.
- Label each shipper with the appropriate FedEx label and warning labels.

Exhibit 12-8. Container protocol

Vessel ID	Test ID/Name	Sample type	Vessel type	Vessel storage	Storage unit
54	VOC Blood	WB	10-mL Gray top	5 x 5 5-inch box (Foam insert)	Refrigerator #2
56	VOC Water	Water	10-mL glass vial	5 x 5 5-inch box (Foam insert)	Refrigerator #2

When the contract laboratory personnel receive the shippers and/or hard-sided coolers, they unpack the specimens and return the shippers, coolers, and refrigerant packs to either the field office (first 3-4 weeks of the stand) or the NHANES warehouse (last 2 weeks of the stand).

Follow the instructions in Chapter 9, Section 9.8, to create one airbill for CDC/Air Toxicant Branch. Follow instructions in Section 9.9 to close containers for vessels 54 and 56. Follow instructions in Section 9.10 to assign the airbills to the shippers. Vessels 54 and 56 are assigned to the same shipper.

Each shipper must include a paper manifest, which lists the inventory of the specimens in the storage boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed in Chapter 9, Section 9.11, to prepare the paper manifest and to send the electronic file.

### **12.8.1 Pack Medium Shipping Container for Refrigerated VOC Shipment**

Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers.

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the container associated with vessel 54 into a pressure vessel (STP-740) and seal.
- Place the container associated with vessel 56 (VOC Water) in a 9 x 12 plastic bag.
- Place at least two large frozen refrigerant packs in the bottom of a shipper. (Place enough cold packs to cover the bottom of the shipper; lay them flat, not on their edges.)
- Cover the cold packs with a blue insulation pad.
- Place the container associated with vessel 56 (VOC Water) on top of the insulating material. The water samples are not as temperature sensitive as the blood samples.
- Place the sealed pressure vessel containing the blood samples associated with vessel 54 on top of the container associated with vessel 56 (VOC water).

- Add another layer of insulated material.
- Pack the sides with crumbled newsprint.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place the appropriate shipping manifest and one return FedEx preprinted airbill into a 9 x 12 plastic bag and seal.
- Place the plastic envelope containing the appropriate shipping manifest and one FedEx preprinted airbill on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

## **12.9 Label Shippers**

For all destinations, include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 4 weeks of the stand. Include a preprinted FedEx return airbill label with the address for the concurrent stand during the last 2 weeks of the stand.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Label shippers containing refrigerant packs with a “Refrigerate” label.
- Label shippers containing whole blood, serum, plasma, or urine with a “Biohazard” label.
- Complete the section of the FedEx label that requests the weight of the contents of the shipper, and if applicable, the section that requests the weight of the dry ice contained in the shipper.
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Add one additional strip of tape across the FedEx pouch.

## **12.10 The MEC Environment**

Maintaining a stable interior environment is critical to many laboratory analytes and processes. Environmental contamination of specimens can result if specimens are exposed to outdoor air and/or contaminants. For this reason, the windows in the MEC should generally be kept closed. This is especially important when actively processing specimens in the laboratory. Confine smoking outside the MEC to areas where there are no air intake vents and there is no possibility of second-hand smoke entering the interior of the MEC. Adjust thermostats to maintain a comfortable MEC environment; opening and closing windows to adjust the temperature inside the MEC is not an alternative.

Exceptions to this policy are allowed under certain circumstances. Windows and/or bay doors can be opened when:

- An SP is uncomfortable and requires brief exposure to fresh air.
- The blood processing technologist is not processing specimens and the laboratory has dry ice inside the MEC.
- The MEC is not in session and the medical technologist is shipping specimens with dry ice.
- The blood processing technologist is not processing specimens and opening the laboratory bay door is required to provide access to the FedEx courier.
- The blood processing technologist is not processing specimens and opening the laboratory bay door is required to dispose of biohazardous trash.
- Performing setup and teardown activities. (This is done before any laboratory processing has occurred at the beginning of a stand and after all laboratory processing is complete at the end of a stand.)

## **12.11 How to Deal With System Failure**

If the computer system fails, conduct the VOC questionnaire using a hard-copy document (Exhibits 12-9 and 12-10), and note the time and number and type of specimens collected (water and/or blood). Complete the questionnaire and enter the collection and questionnaire results after the system is operational. These documents are available in the blank forms directory in the MEC and the shared directory in the field office. Contact the data manager with questions about how to access and print these documents.

SP Name _____	Date  __ _  -  __ _  -  __ _ _ _ _
SP ID  __ _ _ _ _ _ _ _ _	Time  __ _  :  __ _  AM PM
	TECH ID  __ _ _ _

**Exhibit 12-9. VOC QUESTIONNAIRE  
ENGLISH**

Q1. I would like to ask you a few questions about your home. Does your home have an attached garage?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q2. Is the source of water for your home from a private well?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q3. Do you store paints or fuels inside your home? Include your basement (and attached garage, if applicable.)

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q4. Do you use toilet bowl deodorizers inside your home?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q5. Do you use moth balls or crystals inside your home?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

"Now I am going to ask you a few questions about your activities over the last three days. This means today, yesterday, or the day before yesterday."

Q6. In the last three days, did you pump gas into a car or other motor vehicle yourself?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q7. If, yes, how long ago, in hours, did you pump gas into a car?

|||  
HOURS

Q8. In the last three days, did you spend any time at a swimming pool, in a hot tub, or in a steam room?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q9. If, yes, how long ago, in hours, has it been since you spent time in a swimming pool, in a hot tub, or in a steam room?

|||  
HOURS

Q10. In the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q11. In the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q12. In the last three days, did you take a hot shower or bath for five minutes or longer?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q13. If, yes, how long ago, in hours, has it been since your last shower or hot bath?

□□  
HOURS

Q14. In the last three days, did you breathe fumes from any of the following:

	<u>YES</u>	<u>NO</u>	<u>DK</u>	<u>REFUSED</u>
a. Paints .....	1	2	7	9
b. Degreasing cleaners .....	1	2	7	9
c. Diesel fuel or kerosene .....	1	2	7	9
d. Paint thinner, brush cleaner, or furniture stripper .....	1	2	7	9
e. Drycleaning fluid or spot remover .....	1	2	7	9
f. Fingernail polish or fingernail polish remover .....	1	2	7	9
g. Glues or adhesives used for hobbies or crafts .....	1	2	7	9
h. Varnish or stain .....	1	2	7	9

SP Name _____	Date  __ _  -  __ _  -  __ _ _ _ _
SP ID  __ _ _ _ _ _ _ _ _	Time  __ _  :  __ _    AM PM
	TECH ID  __ _ _ _

**Exhibit 12-10. VOC QUESTIONNAIRE  
SPANISH**

Q1. Quisiera hacerle algunas preguntas acerca de su hogar. ¿Tiene su hogar un garaje unido?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q2. ¿Es la fuente de agua para su hogar de un pozo privado?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q3. ¿Guarda pinturas o combustibles dentro de su hogar? Incluya el sótano (y el garaje unido al hogar, si corresponde).

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q4. ¿Usa desodorante para la taza del (inodoro/excusado/wáter) dentro de su hogar?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q5. ¿Usa bolas o cristales de naftalina para las polillas dentro de su hogar?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

“Ahora le voy a hacer algunas preguntas acerca de sus actividades durante los últimos tres días. Esto significa hoy, ayer, o anteayer.”

Q6. En los últimos tres días, ¿le echó gasolina usted mismo a un carro u otro vehículo de motor?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q7. Si, sí, ¿cuánto tiempo hace, en horas, que usted le echó gasolina a un carro?

|||  
HORAS

Q8. En los últimos tres días, ¿pasó algún tiempo en una (alberca/piscina), en una bañera caliente, o en un cuarto de vapor?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q9. Si, sí, ¿cuánto tiempo hace, en horas, desde que usted pasó algún tiempo en una (alberca/piscina), en una bañera caliente, o en un cuarto de vapor?

|||  
HORAS

Q10. En los últimos tres días, ¿visitó una lavandería de lavado en seco o usó ropa que había sido lavada en seco dentro de la última semana?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q11. En los últimos tres días, ¿pasó 10 minutos o más cerca de una persona que estaba fumando (cigarro/cigarrillo), (puro/cigarro/tabaco) o pipa?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q12. En los últimos tres días, ¿se dio una ducha o un baño caliente por cinco minutos o más?

YES ..... 1  
 NO ..... 2  
 REFUSED ..... 7  
 DON'T KNOW ..... 9

Q13. Si, sí, ¿cuánto tiempo hace, en horas, desde la última vez que se dio una ducha o un baño caliente?

□□□  
 HORAS

Q14. En los últimos tres días, ¿aspiró los gases de alguno de los siguientes artículos?:

	<u>YES</u>	<u>NO</u>	<u>DK</u>	<u>REFUSED</u>
a. Pinturas.....	1	2	7	9
b. Desengrasantes o limpiadores.....	1	2	7	9
c. Combustible de diesel o querosén.....	1	2	7	9
d. Líquido para diluir pintura, limpiar brochas, o quitar la pintura de los muebles .....	1	2	7	9
e. Líquido para lavar en seco o para quitar manchas .....	1	2	7	9
e. Esmalte para las uñas o líquido para quitar el esmalte de las uñas .....	1	2	7	9
g. Goma de pegar o adhesivos que se usan para pasatiempos o artesanías. ....	1	2	7	9
h. Barniz o tintura.....	1	2	7	9

## 13. VAGINAL SWAB (VS) PROCESSING

### 13.1 Introduction

The purpose of collecting vaginal swabs is to obtain suitable biological specimens to test for human papillomavirus (HPV), perform a pH test and make a gram stain to test for bacterial vaginosis (BV), and to test for *Trichomonas vaginalis* (TV). Human papillomavirus infection is one of the most common sexually transmitted infections in the United States. Cervical infection with certain types of HPV is a major risk factor for cervical cancer in women. The “high-risk” types of HPV (e.g., HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) are associated with cervical cancer and the “low-risk” types (e.g., HPV 6, 11, 42, 43, 44) with genital warts. No national surveillance system exists to measure the full burden of HPV infection, and no reliable national population estimate of HPV exists. NHANES offers a unique opportunity to assess the prevalence of HPV infection in the general population.

Reducing the prevalence of HPV infection is a Developmental Healthy People 2010 objective: “Reducing the number of new HPV cases can help minimize the overall number of cases of high risk subtypes associated with cervical cancer in females.” Detection and typing of HPV DNA in vaginal swabs (in conjunction with testing of NHANES sera for HPV 16 antibody) will allow evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. HPV vaccine development is underway, and knowledge of the national prevalence of HPV infection will be critical for planning vaccination strategies in the United States. Studies have demonstrated that recovery of HPV from self-collected swabs is comparable to that from physician-collected cervical samples. The HPV Hybrid Capture® II DNA results will be reported to survey participants via the same reporting system as for STD/HIV testing. This system is a respondent-initiated toll-free phone call to NCHS. Results are given to persons tested after a password is provided to verify identity. The HPV-16 serology and the HPV DNA typology will not be reported.

Recent studies have linked bacterial vaginosis and trichomoniasis to adverse pregnancy and gynecologic outcomes such as preterm labor and delivery, low birth weight, premature rupture of membranes, post-Cesarean endometritis, and post-abortal and post-hysterectomy infections. No reliable national population estimate of BV or trichomoniasis exists. NHANES is assessing the prevalence of BV and TV infections in the general population, identifying and confirming risk factors, and monitoring trends in prevalence as detection and treatment programs are established and expanded.

Primary female SPs aged 14-49 collect swabs for HPV, BV, and TV, and primary female SPs aged 50-59 collect the HPV swab only. The physician collects the appropriate preprinted labels from the grid in the label/ship area at the start of each session. Each label includes the test name, 6-digit SP ID concatenated with the vessel ID, and the corresponding bar code. The physician counsels each eligible SP and introduces them to the vaginal collection technique. The physician uses one of two prepared collection kits. The first collection kit is designed for SPs aged 14-49 and it includes illustrated collection instructions and three swabs—one Epicentre® Dacron swab with a foam tip in a transport tube with a green dot, one cotton swab in a red-capped tube, and one Puritan® Dacron swab in a plastic transport tube. The second collection kit is designed for SPs aged 50-59 and it includes illustrated collection instructions and one Epicentre® Dacron swab with foam tip in a transport tube with a green dot. The physician removes the appropriate swab(s) from the collection kit and labels the Epicentre® Dacron swab with the foam tip with the label displaying the vessel ID #78, the red-capped tube containing the cotton swab with the label displaying the vessel ID #72, and the Puritan® swab, which is a Dacron swab with a white plastic shaft, with the label displaying the vessel ID #73. The physician then places the swab(s) back into the collection kit and gives the collection kit to the eligible SP.

The SP self-collects the appropriate swabs in the mobile examination center (MEC) bathroom, places each swab back into its original container and places the swabs back into the plastic bag. The SP hands the plastic bag containing the swab(s) to the assistant coordinator. The assistant coordinator delivers the plastic bag to the laboratory.

The laboratory staff verifies the SP ID and the vessel ID (#78) on the label of the Epicentre® Dacron swab with the foam tip, records the collection in the VS module, and stores the swab at room temperature. The laboratory staff prints one additional glass slide label as part of each eligible SP's set of processing labels. The laboratory staff tests the pH of the vaginal fluid on the cotton swab (vessel ID #72) and makes a gram stain from the same cotton swab. They record these results in the VS module and store the glass slide at room temperature. The SP ID and the vessel ID on the label of the Puritan® Dacron swab (vessel ID #73) are verified in the laboratory, the collection is recorded in the VS module, and the swab is refrigerated. The laboratory staff ships the specimens to the contract laboratories weekly.

The laboratory staff also processes serum for vessels 77 (HPV Serum) on SPs aged 14-59 as part of a SP's blood processing profile. The vessels are stored at -20°C and shipped to a contact laboratory once per week.

### 13.2 Supplies

The supplies needed for VS processing and storage are listed in Exhibit 13-1.

Exhibit 13-1. Equipment and supplies – VS processing and storage

PH paper, EM ColorpHast range 4-7	Zip closable bag (9 x 12 clear)
Slides, Microscope – Single Side Frosted 3 x 1	Large padded envelope
Micro slide box – Blue	Medium shipper
Refrigerant gel pack	

### 13.3 Protocols

Exhibit 13-2 illustrates the SP’s protocol for VS processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 13-2. VS processing protocol

ID	Test name	Ages	Sample	Sample type	Vessel type	Person types
78	HPV	50-59 females	1 swab	Vaginal swab	Epicentre® Dacron swab with a green dot	Primary only
78	HPV	14-49 females	1 swab	Vaginal swab	Epicentre® Dacron swab with a green dot	Primary only
72	Vaginosis	14-49 females	1 swab	Vaginal swab	Cotton swab	Primary only
73	T vaginalis	14-49 females	1 swab	Vaginal swab	Puritan® Dacron swab	Primary only

### 13.4 Labeling Vessels

The appropriate bar code labels automatically print for each SP based on the SP’s age, sex, and person type. The label/ship technologist at workstation 3 prints the labels at least one session in advance. The printing procedure is described in Chapter 9.

One vessel #78 label prints for primary SPs aged 50-59. A total of four labels print for each primary SP aged 14-49; one label prints for vessel #72, one for vessel #73, one for vessel #78, and one

additional label for the glass slide. Place all the vessel labels on the grid in the label/ship area except for the one additional glass slide label that prints for vessel #72. The physician collects the labels from the grid before each session begins.

One additional label prints for the gram stain slide. This label contains the words “Vaginosis,” the SP ID concatenated with the vessel ID (#72), and a bar code that is shifted toward the bottom of the label’s white opaque area. Place this label at workstation 2 with the other urine vessel and pregnancy test labels.

### 13.5 VS Protocol

Process the Epicentre® Dacron swab with the foam tip and the green dot for:

- HPV

Process the cotton swab in the red-capped tube for:

- pH
- Gram stain slide

Process the Puritan® Dacron swab in the transport sleeve for:

- *Trichomonas vaginalis*

Process the HPV swab for HPV if the laboratory receives only the Epicentre® Dacron swab. Do not use the Epicentre® Dacron swab for the pH, gram stain, or as a substitute for vessel #73, the Puritan Dacron swab. If the laboratory receives only the Puritan® Dacron swab in the transport sleeve, perform the pH, make the gram stain, and process the swab for *Trichomonas vaginalis*. If the laboratory receives only one red-capped swab, perform the pH, and make the gram stain; do not process the red-capped swab for TV or HPV.

Verify that the correct swab is in the correct tube before processing the specimens. If the swabs are in the incorrect tubes, remedy the situation before proceeding. Table 13-3 summarizes the VS

processing protocol. Process the Epicentre® Dacron swab first, the red-capped cotton swab next and the Puritan Dacron swab third.

Access the VS Processing module for a SP.

- Vessel 78 – HPV
  - Verify that the tip of the Dacron swab in the clear plastic tube is foam and that the top of the tube is marked with a green dot. Verify that the SP ID on the label matches the SP ID on the processing screen. Record the processing results in the VS module and store the swab at room temperature.
- Vessel #72 – Vaginosis
  - Verify that the SP ID on the label matches the SP ID on the processing screen. Perform a pH on the cotton swab in the red-capped tube. Touch the pH strip to the side of the cotton tip. Use the fluid on the tip of the swab if necessary. Record the pH to one decimal.
  - Cut (trim) the label at the margin between the opaque and clear sections and discard the clear portion. Label one glass slide with the vessel 72 label. Make a smear for gram stain using the cotton swab in the red-capped tube. Roll the swab across the surface of the frosted-edge glass slide. (Do not dab the tip of the cotton swab on the slide.) Allow the slide to air dry. Record the processing results. Store the glass slide at room temperature in a slide box.
  - Discard the red-capped cotton swab that was used for the pH and gram stain in the biohazard trash.
- Vessel #73
  - Verify that the shaft of the swab inside the plastic transport sleeve is white plastic and not wood. Verify that the SP ID on the label matches the SP ID on the processing screen. Record the processing result. Store the Dacron swab in the transport sleeve in a 9 x 12 plastic bag (container) and place in refrigerator #2.

Remember if the laboratory receives only the Epicentre® Dacron swab, process and store the swab for HPV; do not use this swab for the pH or the gram stain and do not send it for TV. If the laboratory receives only the Puritan® Dacron swab in the transport sleeve, perform the pH, make the gram stain, and send the swab for TV. If the laboratory receives only one red-capped swab, perform the pH, and make the gram stain; do not process the red-capped swab for TV or HPV.

### 13.6 Record Processing Results

The protocol includes a serum vessel (HPV Serum #77) for primary SPs aged 14-59. The volume requirement is 0.5-mL of serum; the storage vessel is a 2-mL cryovial, and it is stored in a 2-inch box with a 9 x 9 grid. The vessel is processed after the PTH vessel (#85) and before the Vitamin C vessel (#79.) The serum vessel is displayed on the blood-processing screen in the correct priority and is recorded in the same manner as the other vessels. This vessel is frozen and shipped to CDC/Ruth Ann Tucker weekly.

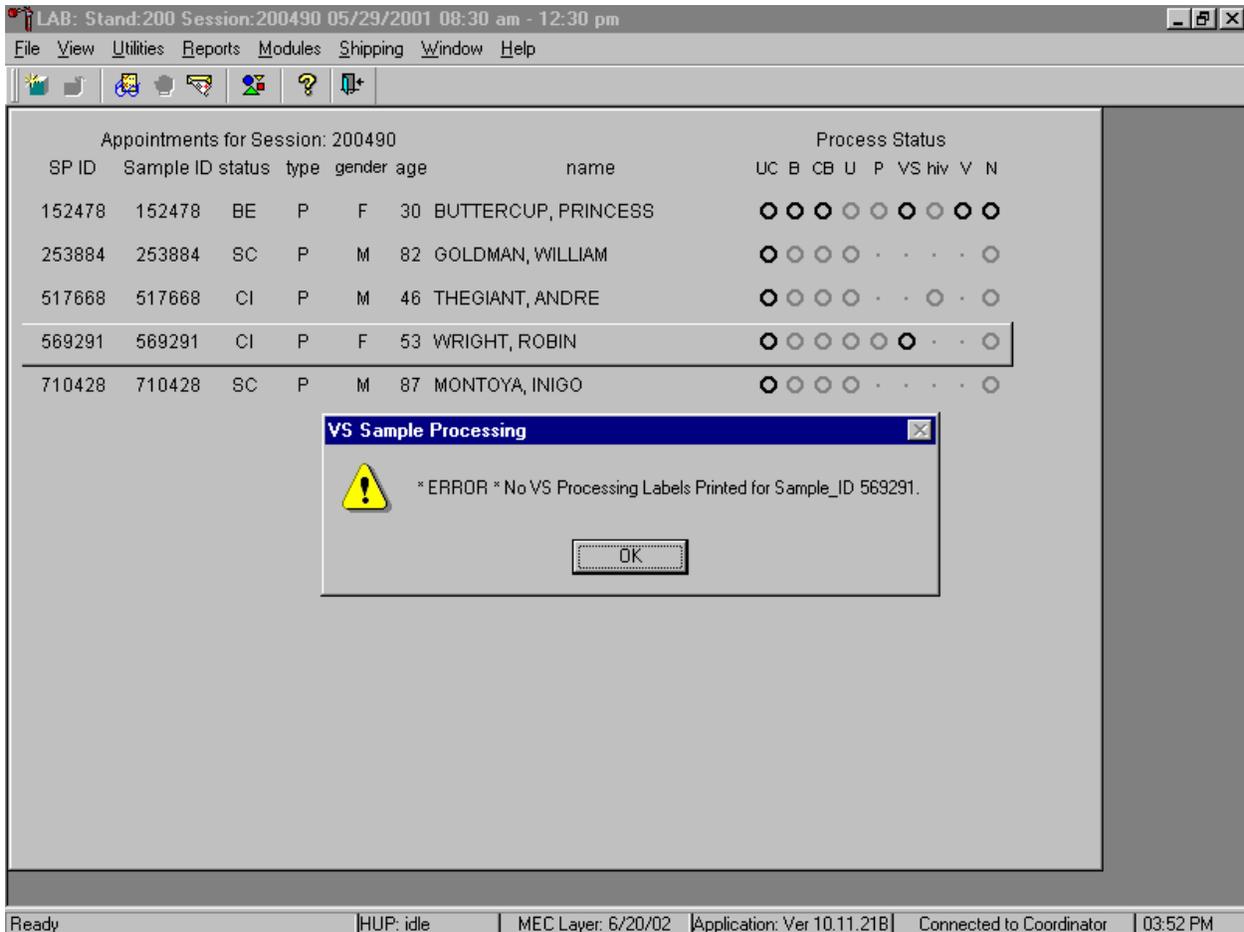
Select the correct SP and access the Blood Processing module.

The screenshot shows a software window titled "LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm". The interface includes a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar with various icons. The main area displays a table of appointments for session 200490. A context menu is open over the first row, listing options such as "Blood Processing", "Urine Processing", "VS Processing", "HIV Urine Processing", "VOC Processing", "Nasal Swab", "Urine Collection", "Pregnancy Testing", "Hematology", "Refresh", and "Labels".

Appointments for Session: 200490							Process Status								
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N
152478	152478	BE	P	F	30	BUTTERCUP, PRINCESS									
253884	253884	SC	P	M	82	GOLDMAN, WILLIAM									
517668	517668	CI	P	M	46	THEGIANT, ANDRE									
569291	569291	CI	P	F	53	WRIGHT, ROBIN									
710428	710428	SC	P	M	87	MONTOYA, INIGO									

To select an SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the Blood Processing module, drag the mouse arrow to {Blood Processing} and left click or left click and type [B/b].

If labels have not been printed in advance, a Blood Processing message text box displays.



Blood processing cannot occur unless labels have been printed in advance. To remove the Blood Processing message text box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

Record processing results for vessel 77 in the Blood Processing module.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm - [BP: 152478]

File View Utilities Reports Modules Shipping Window Help

none

Tech ID: 1226    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

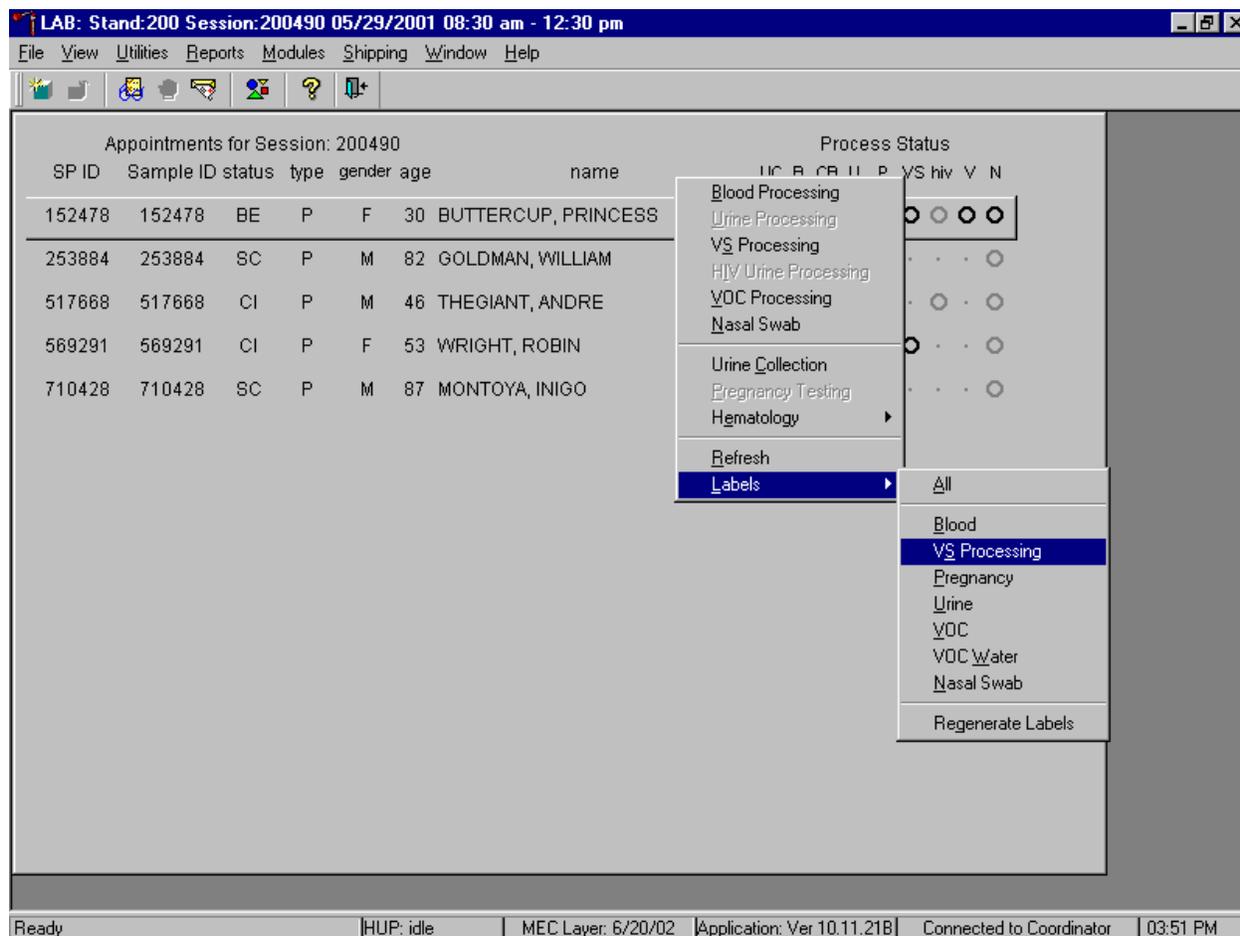
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
24	HSV	0.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
74	Syphilis	0.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
77	HPV Serum	0.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
70	Vitamin D	0.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
29	Persis Pest	4.0	S	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save    Phlebotomy    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    03:50 PM

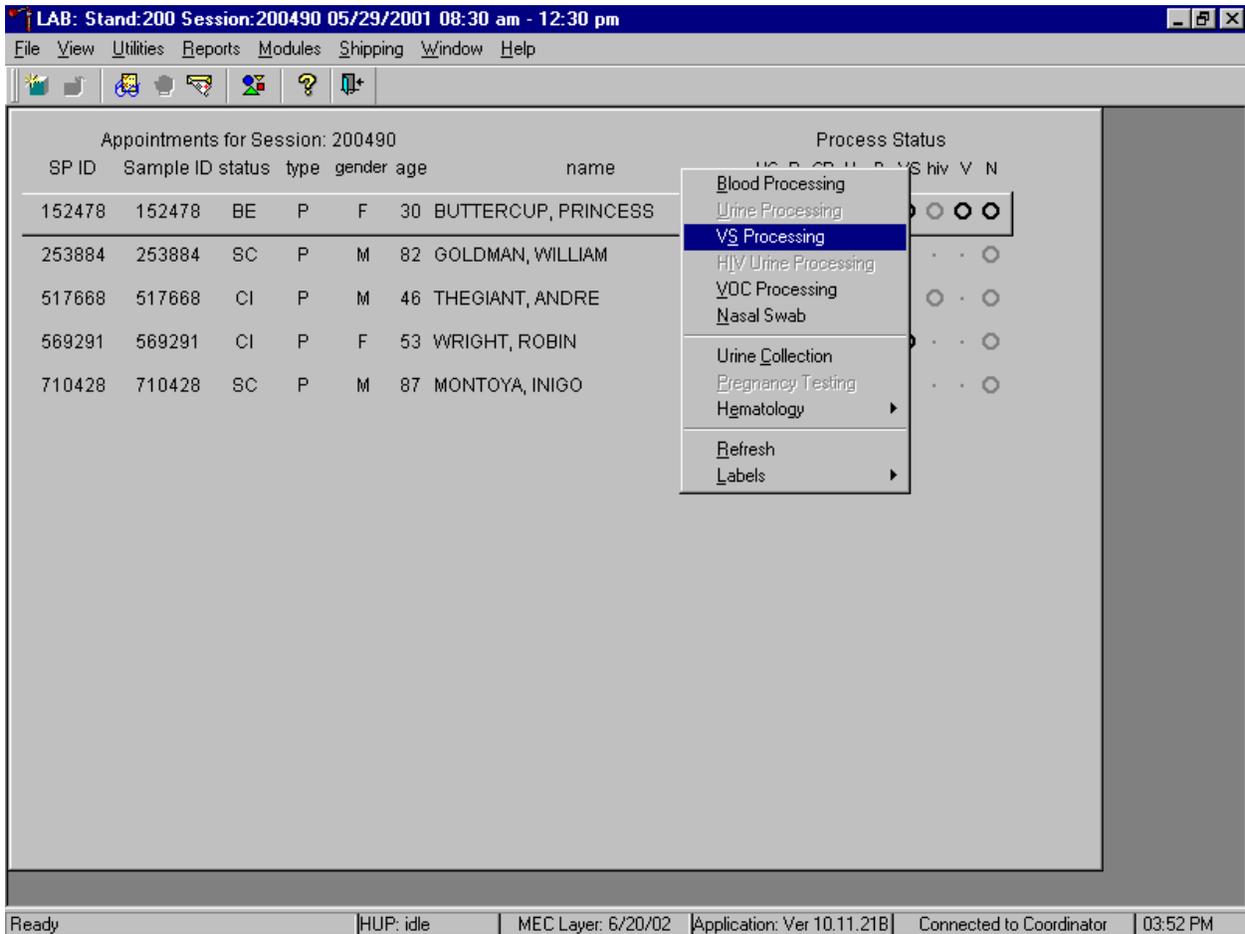
Primary SPs aged 14-59 are eligible for the HPV serum test. Pool the serum and aliquot 0.5-mL into a prelabeled 2.0-mL cryovial. Mark the vessel as Filled—"Yes" or Filled—"No" using procedures described in Chapter 8. Store the vessels in a 2-inch tall container with a 9 x 9 grid. Pack the container in a medium shipper, add sufficient dry ice, and ship weekly to CDC/Dr. Ruth Ann Tucker. Use existing procedures described in Chapter 9 to pack, label, and ship the shipper.

Print additional VS labels for a particular SP using the heads-up display.



To print additional labels for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then drag the arrow to {VS Processing} and right click. Alternatively, to print additional labels, use the mouse to direct the mouse arrow to the correct SP, right click, and type [L/1] [S/s] for VS processing labels. The labels print in the Label/Ship area.

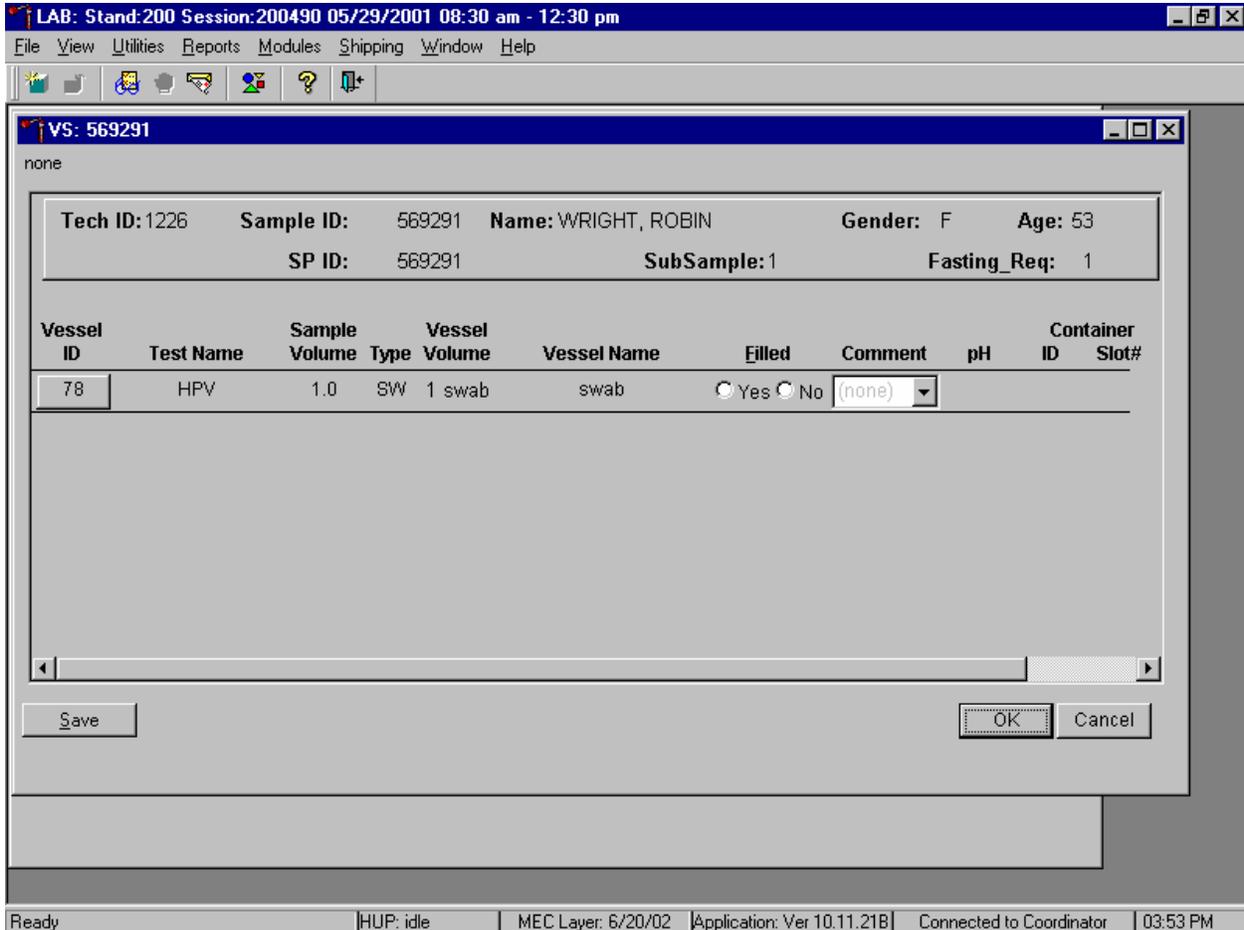
Select the correct SP and access the VS Processing module.



Use the scroll bar to view all SPs scheduled into the session. The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.

To select a SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the VS Processing module, drag the mouse arrow to {VS Processing} and left click or right click and type [S/s]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to correct module and left click or type [S/s].

One of two unique processing windows display, depending on the SP's age. Document processing results for SPs aged 50-59.



The VS Processing window contains the following information for a SP ages 50-59: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample (designation), and Fasting\_Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Sample Type (SW = swab), Vessel Volume, Vessel Name, Filled (Yes or No) radio buttons, Comment drop-down box, pH (inactive for SPs ages 50-59) and Container ID and Slot#. There is one row associated with vessel 78. Use radio buttons to record the processing results, Filled—"Yes" or Filled—"No," if necessary, attach a comment using the Comment drop-down box, and store the vessel in the assigned Container ID and Slot#.

Mark vessel 78 as Filled—"Yes" if the swab was collected.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

VS: 569291

none

Tech ID: 1126    Sample ID: 569291    Name: WRIGHT, ROBIN    Gender: F    Age: 53  
SP ID: 569291    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No			0077098	4

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    03:54 PM

To mark vessel 78 as collected or Filled—"Yes" use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As a vessel is marked as Filled—"Yes," it is automatically assigned to a slot in an existing (open) container. A comment is not required to exit this screen.

Mark vessel 78 as Filled—"No" if the swab was not collected.

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)			

To mark vessel 78 as not collected or Filled—"No" use the mouse to direct the mouse arrow to the "No" radio button and left click. To record an "inadequate sample" comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, drag the mouse arrow to "inadequate sample" and left click. Alternatively, to record the comment "inadequate sample," [Tab] to advance to the Comment text box and type [I/I] and [Enter]. A comment is not required to exit this screen.

Document processing results for SPs aged 14-49.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

VS: 152478

none

Tech ID: 1226    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

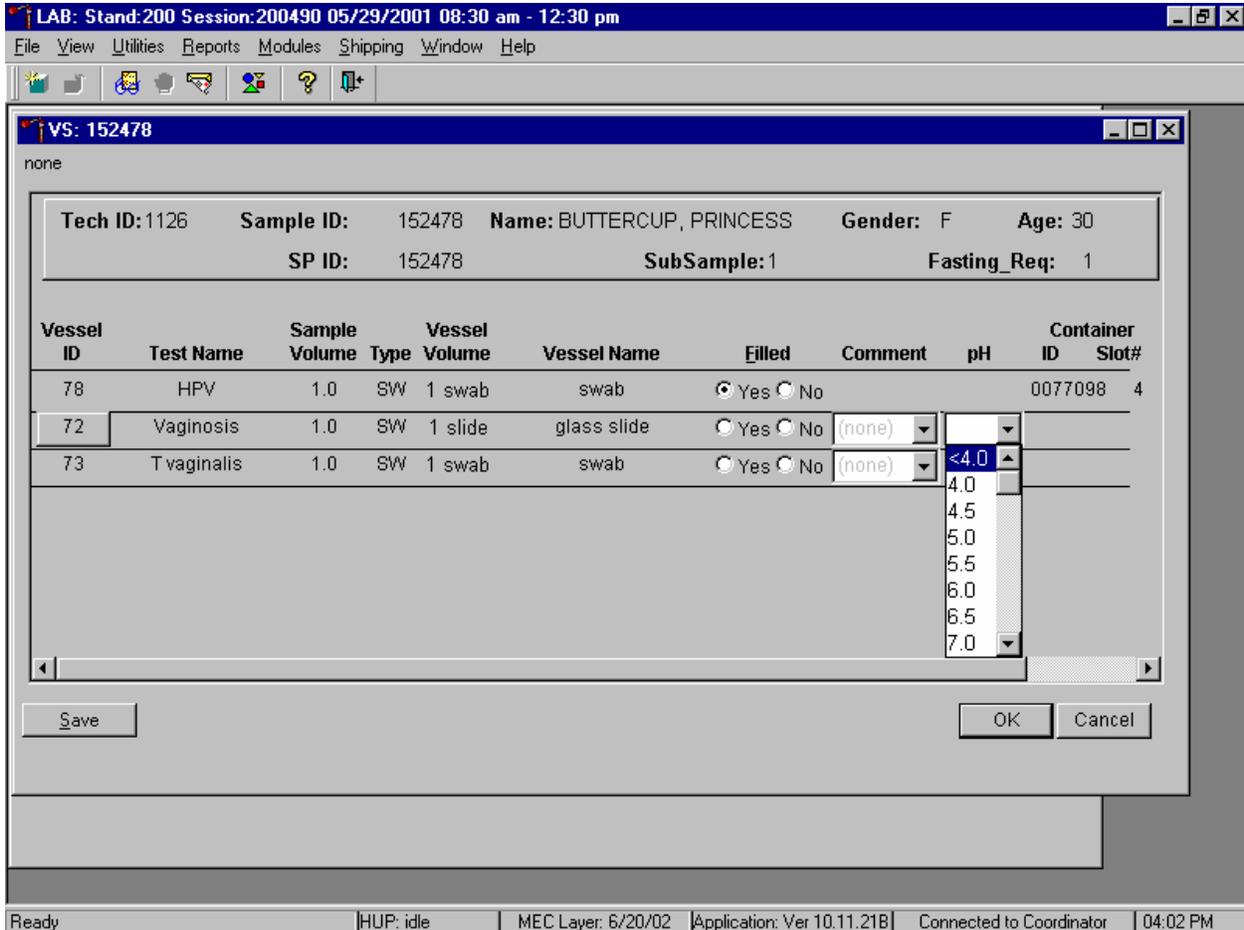
Vessel ID	Test Name	Sample Volume	Sample Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)			
72	Vaginosis	1.0	SW	1 slide	glass slide	<input type="radio"/> Yes <input type="radio"/> No	(none)			
73	T vaginalis	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)			

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:01 PM

The VS Processing window contains the following information for a SP ages 14-59: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample (designation), and Fasting\_Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Sample Type (SW = swab), Vessel Volume, Vessel Name, Filled (Yes or No) radio buttons, Comment drop-down box, pH (inactive for vessels 78 and 73) and Container ID and Slot#. There are three rows, one each for vessels 78, 72, and 73. Record the pH for vessel 72, use radio buttons to record the processing results for each vessel by marking either the Filled-”Yes” or Filled-”No” radio button and, if necessary, attach a comment using the Comment drop down-box, and store the vessels in the assigned Container ID and Slot#.

Record the pH either before or after recording any of the vessels as Filled—"Yes" or Filled—"No."



To record the pH, use the mouse to direct the mouse arrow to the pH drop-down list, left click to display the choices, drag the mouse arrow to the correct value, and left click. Use the scroll bar to view all the possible values. Alternatively, to record the pH, type [Tab], [Tab], and [Tab] to advance to the pH text box, and type the whole number value using the keyboard's numeric keys. To enter a decimal value, type the whole number value a second time.

Individually mark vessels 78, 72, and 73 as Filled–"Yes" if the respective swabs were collected.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

VS: 152478

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No			0077098	4
72	Vaginosis	1.0	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	<4.0	0077105	3
73	T vaginalis	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		0077099	4

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:02 PM

To mark vessels 78, 72, and/or 73 as collected or Filled–"Yes" use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As a vessel is marked as Filled–"Yes," it is automatically assigned to a slot in an existing (open) container. A comment is not required to exit this screen.

Individually mark vessels 78, 72 and 73 as Filled—"No" if the respective swabs were not collected.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

VS: 152478

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No			0077098	4
72	Vaginosis	1.0	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	<4.0	0077105	3
73	T vaginalis	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)			

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:03 PM

To mark vessel 78, 72, or 73 as not collected or Filled—"No" use the mouse to direct the mouse arrow to the "No" radio button and left click.

Enter a quality control comment for vessel(s) 78, 72, and/or 73 when the swab is dry and the judgment is that the SP did not attempt to collect the sample(s).

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

VS: 152478

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

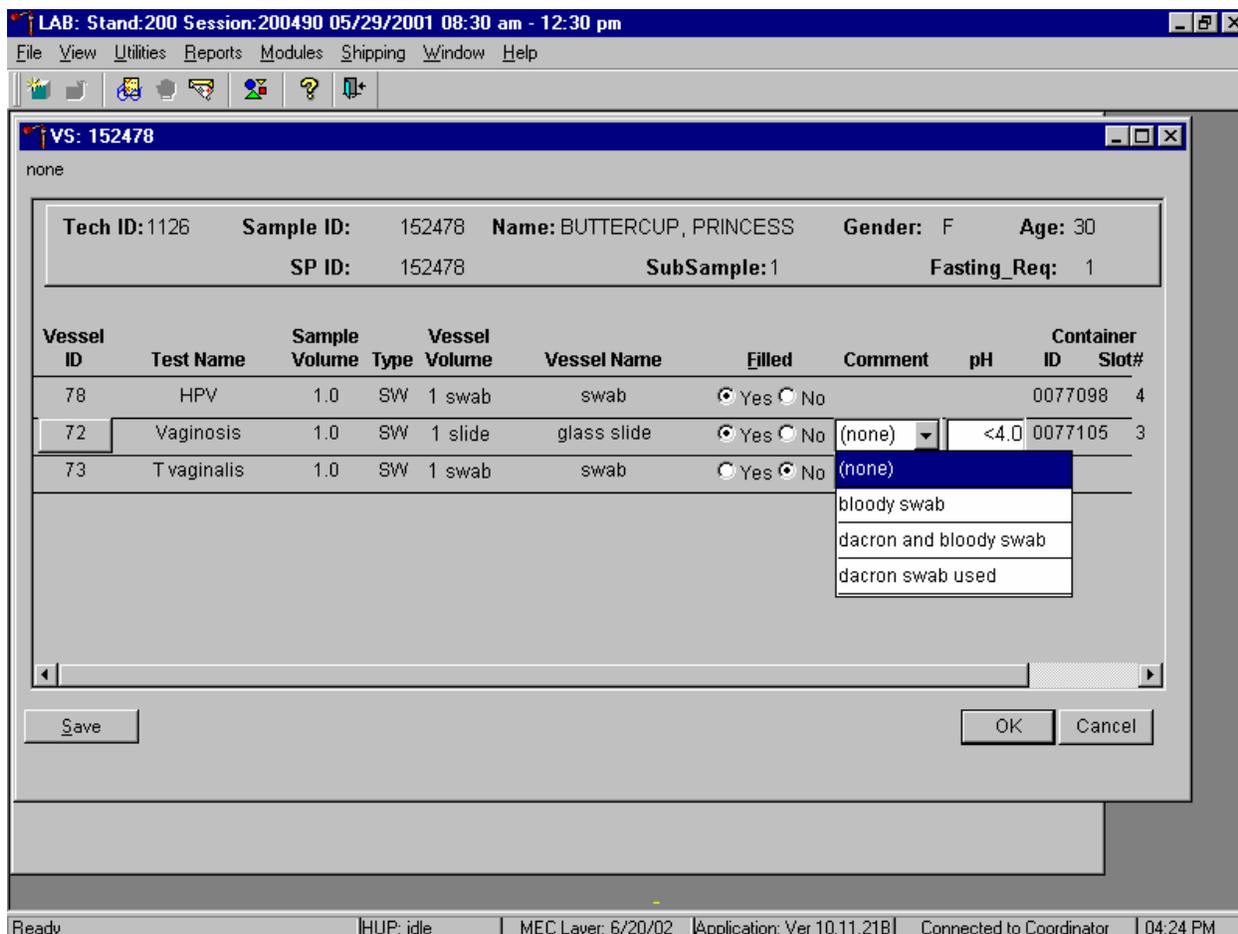
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)			
72	Vaginitis	1.0	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		105	3
73	T vaginalis	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	inadequate sample			

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:23 PM

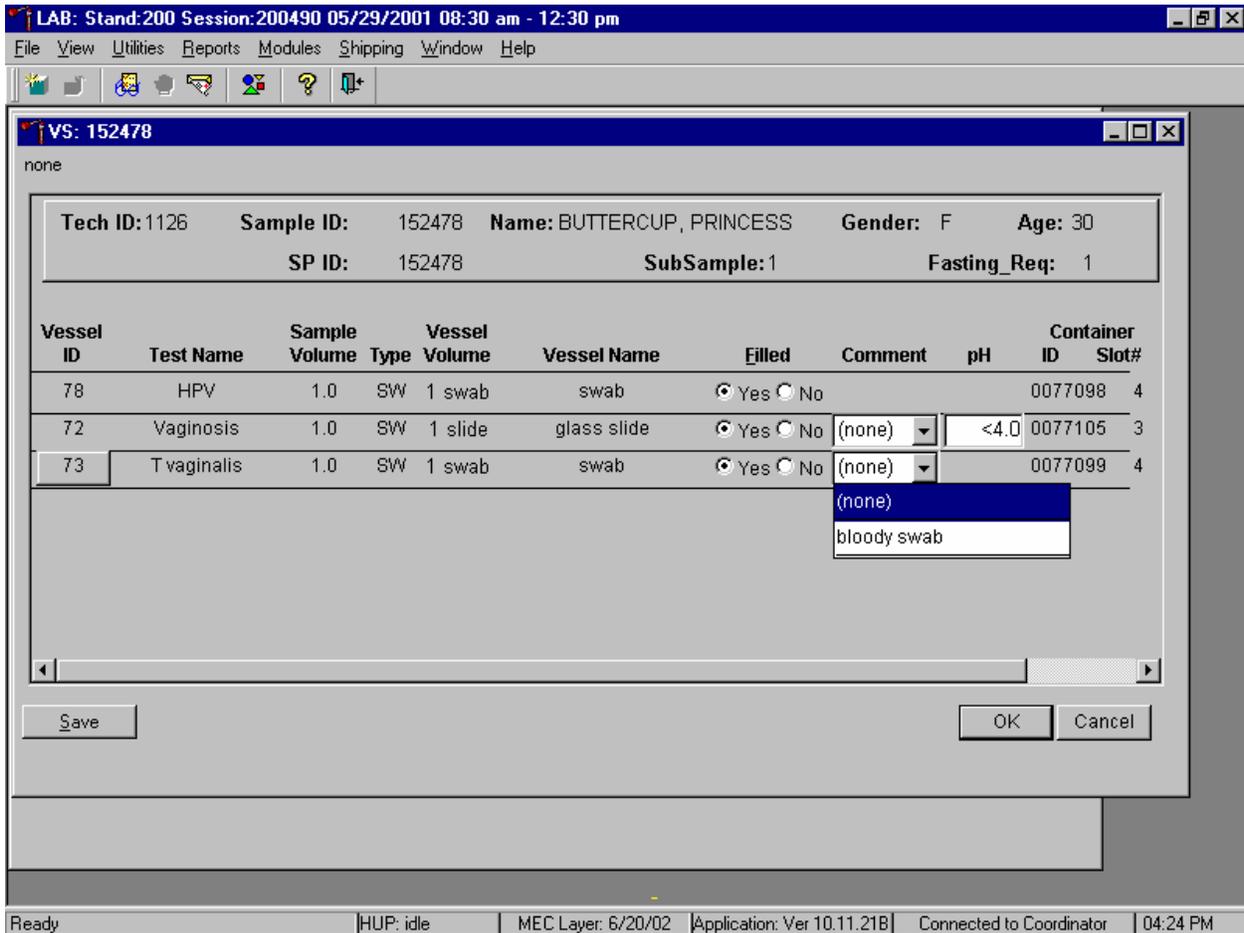
To record an “inadequate sample” comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, drag the mouse arrow to “inadequate sample” and left click. Alternatively, to record the comment “inadequate sample,” [Tab] to advance to the Comment text box and type [I/I] and [Enter]. A comment is not required to exit this screen.

For vessel 72, record the comment “dacron swab used” when appropriate.



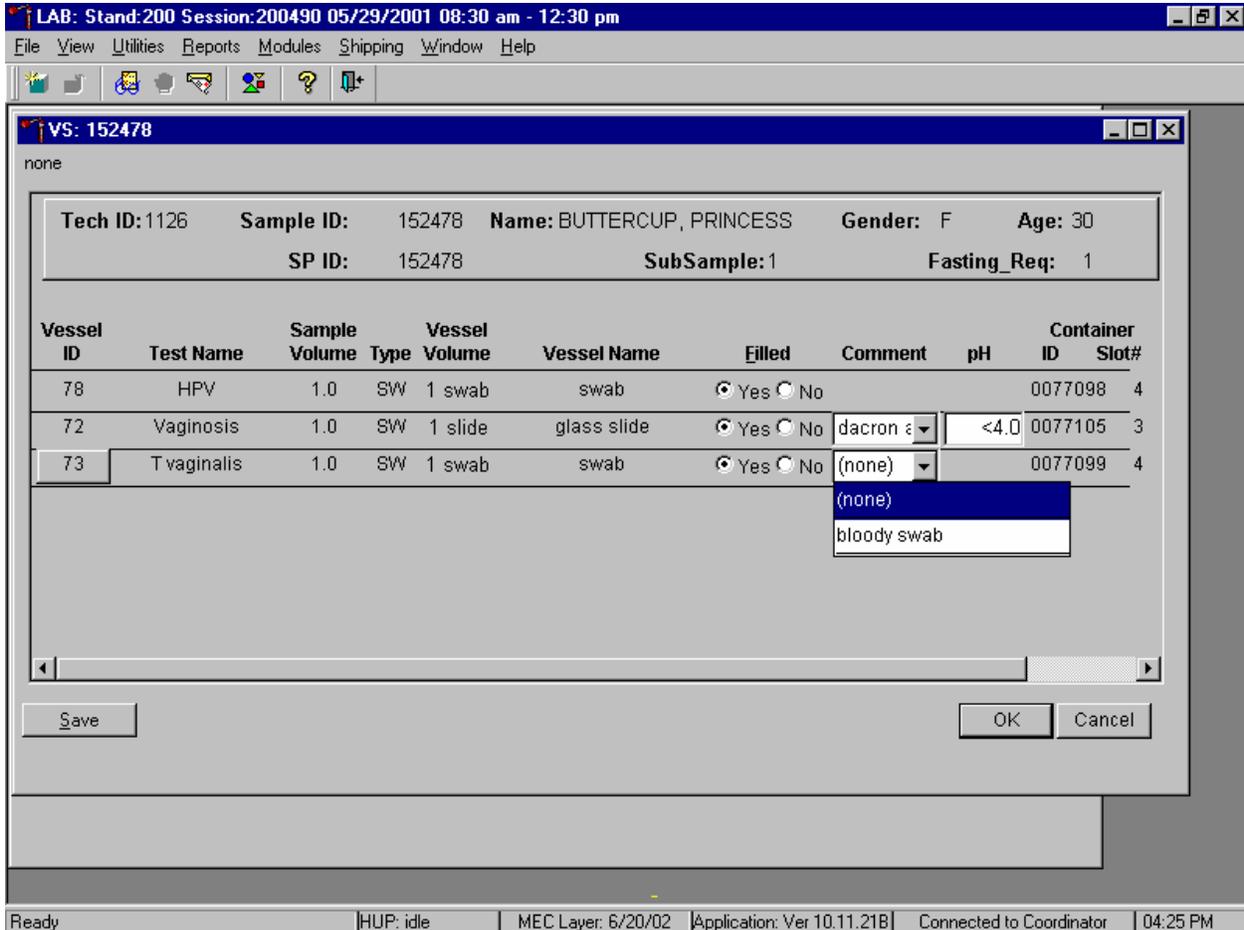
Mark vessel 72 as Filled–“Yes” but record the comment “dacron swab used” to indicate when the laboratory did not receive a cotton swab in the red screw cap tube and when the Puritan® Dacron swab was used for the pH and the gram stain slide. To record this comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, drag the mouse arrow to “dacron swab used” and left click. Do not type [D/d] and [Enter] to record the comment “dacron swab used,” because only the first identical portion of the comment is visible in the text box.

The comment “Dacron swab used” is not available for vessels 78 and 73 when the vessels are marked as Filled–”Yes” because it is not permissible to use the cotton swab for either the HPV or the *T vaginalis* test.



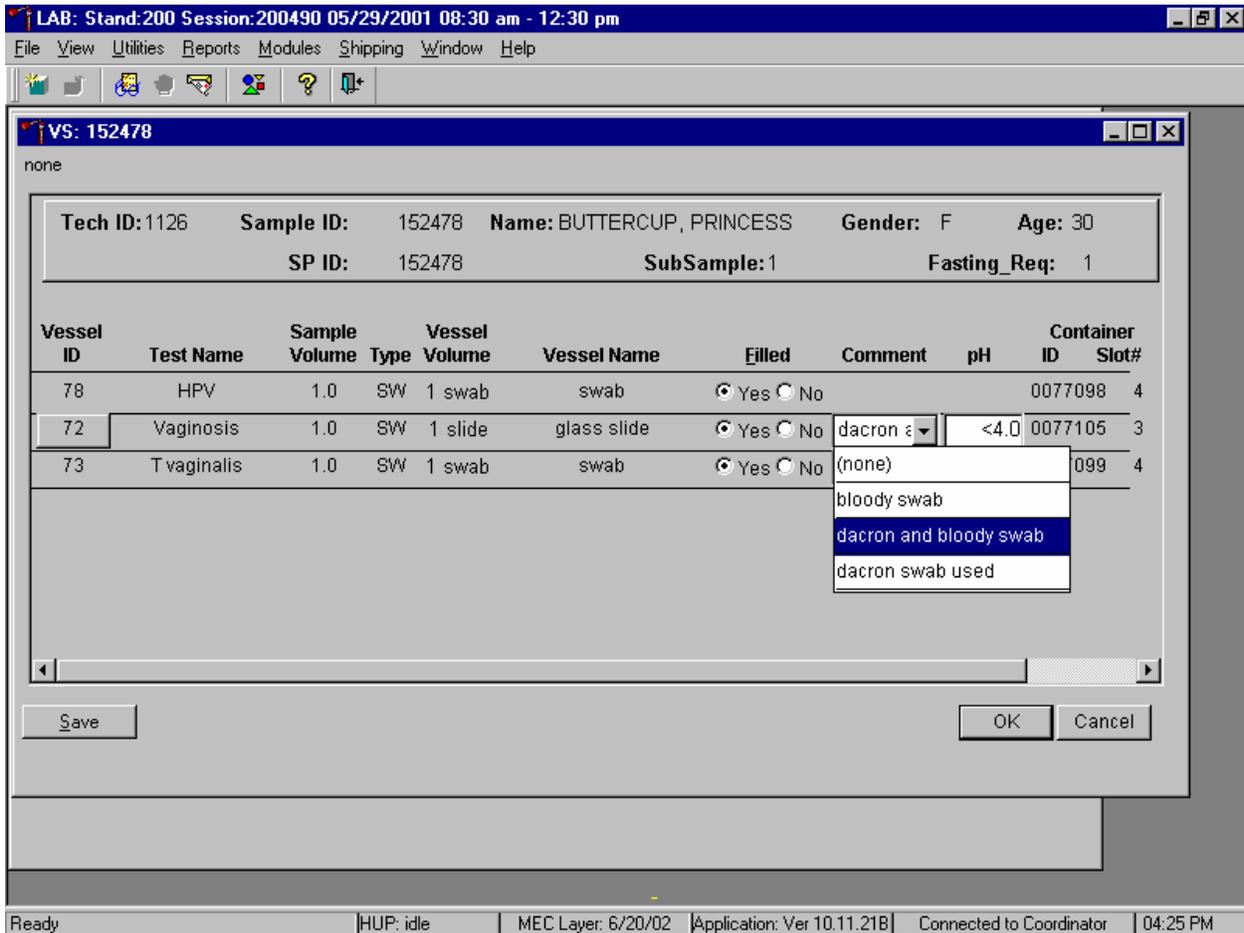
Never use the cotton (red-capped) swab for the T vaginalis (vessel 73) test. Never use either the cotton (red-capped) swab or the Puritan® Dacron swab for the HPV (vessel 78) test.

For vessels 72 and 73, record the quality comment code “bloody swab” to indicate if blood is present.



To enter the quality control comment “blood present” for a Filled–”Yes” vessel 72 and/or 73, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {bloody swab} and left click.

For vessel 72 record the quality comment code “dacron and bloody swab” to indicate when the Puritan® Dacron swab was used for the pH and gram stain because a cotton swab was not available and there was blood present.



To enter the quality control comment “dacron and bloody swab” for a Filled–“Yes” vessel 72, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {dacron and bloody swab} and left click.

Store the glass slide in the assigned slot in the slide box at room temperature, store the Epicentre® Dacron swab in the assigned 9 x 12 plastic bag at room temperature, store the Puritan® Dacron swabs in the assigned 9 x 12 plastic bag in refrigerator #2, review the information in the VS-Processing window, and save the data to the database.

LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

VS: 152478

none

Tech ID: 1126    Sample ID: 152478    Name: BUTTERCUP, PRINCESS    Gender: F    Age: 30  
 SP ID: 152478    SubSample: 1    Fasting\_Req: 1

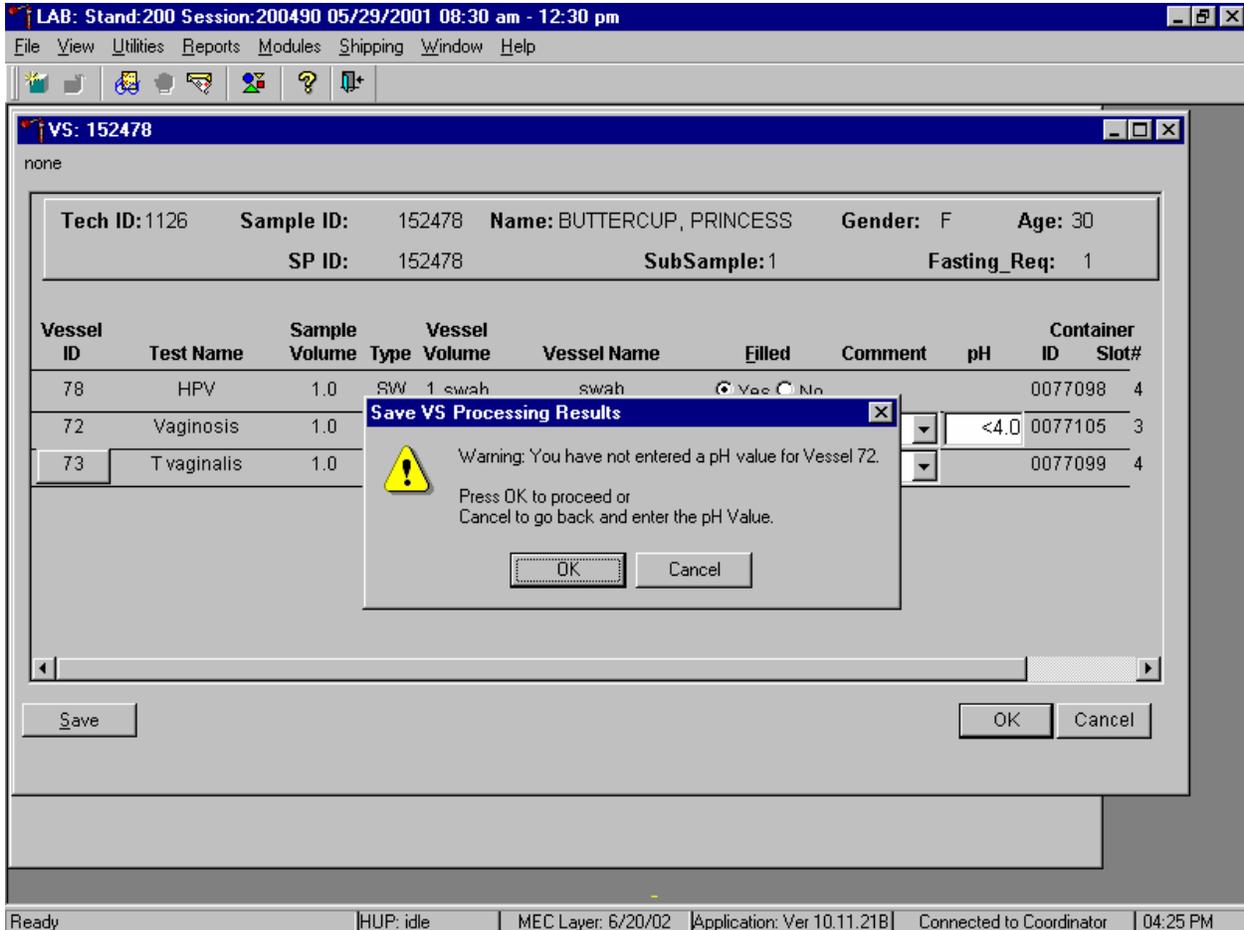
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No			0077098	4
72	Vaginosis	1.0	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none) ▼	<4.0	0077105	3
73	T vaginalis	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none) ▼		0077099	4

Save    OK    Cancel

Ready    HUP: idle    MEC Layer: 6/20/02    Application: Ver 10.11.21B    Connected to Coordinator    04:25 PM

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [S/s]. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

If the Save or the OK button is selected and the pH has not been recorded, a Save VS Processing Results warning message box displays requesting a value for this test.



To remove the warning message box and return to the heads-up screen, use the mouse to direct the mouse arrow to the OK button and left click. To remove the warning message box and return to the current processing screen, use the mouse to direct the mouse arrow to the Cancel button and left click.

The process status circle in the heads-up fills in completely for SPs who have all three swabs recorded as collected or Filled–"Yes." The process status circle partially fills in for SPs who have at least one vessel marked as Filled–"Yes" and when any of the other vessels are left unmarked.

Do not enter a result until the swabs arrive in the laboratory. At the end of each session, review the results for each SP. Access each record and enter Filled–"No" for all vessels for SPs for whom no swabs were received.

### 13.7 Specimen Storage

Record the processing result for the Epicentre® Dacron swab and store the swab in a 9 x 12 plastic bag at room temperature. Perform the BV pH measurement, make the gram stain slide, store the glass slide in a plastic slide box, and store the slide box at room temperature at workstation 2. Record the processing results for the Puritan® Dacron swab, store the swab in a 9 x 12 plastic bag, and refrigerate the swab (in the transport sleeve) in refrigerator #2.

Store vessels in numbered storage containers according to test as indicated in Exhibit 13-3.

At the beginning of each stand, generate and print a series of bar-coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process "opens" a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in slide boxes are assigned according to a standard left to right procedure. Store each vessel in the appropriate slot in the correct container immediately after processing. Check the slot assignment of containers associated with vessels 78, 72, and 73, at the end of each session by accessing the Container Map report. Verify the contents of each container against the container map.

Exhibit 13-3. Storage protocol for VS

Shipping Location	Vessel	Condition	Vessel Storage
CDC/Ruth Ann Tucker	78 HPV	Room temperature	9 x 12 plastic bag
Magee Womens Hospital	72 Vaginosis	Room temperature	1 x 25 slide box
Magee Womens Hospital	73 T vaginosis	Refrigerated	9 x 12 plastic bag

### 13.8 Shipping Procedures

The technologists ship vessels 78, 72, and 73 to two contract laboratories. Vessel 78 is shipped in a padded envelope at room temperature. Vessels 72 and 73 are shipped together in double-sided Styrofoam and corrugated cardboard shipper using wet ice (refrigerant gel packs). Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 13-4, the Shipping protocol illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Ship the Epicentre® Dacron swab for HPV (vessel 78) in a padded envelope at room temperature weekly. Pack the plastic slide box in a padded envelope and place this envelope and the Puritan® Dacron swabs in a small shipper with sufficient refrigerant gel packs to maintain refrigerated conditions and ship weekly.

Exhibit 13-4. Shipping protocol

Location	Vessels	Test	Vessel storage	Shipping frequency
CDC/Ruth Ann Tucker	78	HPV	Room Temperature	Weekly
Magee Womens Hospital	72 73	Vaginosis <i>T vaginalis</i>	Refrigerated	Weekly

#### 13.8.1 Pack and Ship Vessels 72 and 73 in a Refrigerated Medium Shipping Container

These instructions apply to vessels 72 and 73. Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant gel packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers. Exhibit 9-3 in Chapter 9 contains a list of all contract laboratory addresses.

Pack the specimen containers tightly in the Styrofoam container to prevent movement.

- Place a rubber band around the slide box (vessel 72) to prohibit the slides from falling out of the slide box.

- Place the container for vessel 72 (Vaginosis slide box) into a padded envelope and seal.
- Place at least two large frozen refrigerant packs in the bottom of a shipper.
- Place the sealed plastic bag containing the swabs (vessel 73) on top of the refrigerant pack. Place the sealed padded envelope containing the slide box on top of the sealed plastic bag containing the swabs.
- Pack the sides with crumbled newsprint.
- Place two additional refrigerant packs on top of the container(s).
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place the appropriate shipping manifest and one return FedEx preprinted air bill into a 9 x 12 plastic bag and seal.
- Place the plastic envelope containing the appropriate shipping manifest and one FedEx preprinted air bill on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

### **13.8.2 Pack and Ship Vessel 78 at Room Temperature**

Ship the container (9 x 12 plastic bag) for vessel 78 (HPV swab) at room temperature.

- Place the plastic bag containing the specimens into a large padded envelope.
- Place the appropriate shipping manifest into a 9 x 12 plastic bag and seal.
- Place a plastic envelope containing the appropriate shipping manifest into the padded envelope and seal.
- Assume that the package weighs 1 pound.
- Record the total weight of the envelope (1 pound) on the appropriate FedEx label.

### 13.8.3 Label Shippers

Include one preprinted FedEx air bill in the shipment to Magee Womens Hospital.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Label shippers containing refrigerant packs with a “Refrigerate” label.
- Complete the section of the FedEx label that requests the weight of the contents of the shipper.
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Add one additional strip of tape across the FedEx pouch.

### 13.9 How to Deal With System Failure

If the computer system fails, record results on a preprinted VS Processing worksheet (Exhibit 13-5). Complete a workstation 2 worksheet for each SP while processing the VS specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 13-5. VS Processing worksheet

#### VS PROCESSING

SP ID \_\_\_\_\_

ID	Name	Ages Gender	Sample mL	Sample Type	pH	Filled ✓	Slot #
78	HPV	14-59 females	1 swab	Epicentre® Dacron Swab			
72	Vaginosis	14-49 females	1 swab	Cotton swab			
72	Vaginosis	14-49 females		Glass slide			
73	T. vaginalis	14-49 females	1 swab	Puritan® Dacron swab			

## 14. LEAD DUST PROCESSING AND QUALITY CONTROL

### 14.1 Overview

Field interviewers collect lead dust samples in households with children aged 1-5. Associate a dust sample with a specific SP when it is collected; collect the sample in the room where the SP spends most of his or her time. There are five possible sample types: floor, floor replicate, windowsill, windowsill replicate, and field blank. Collect both floor and windowsill samples in each eligible home. In 10 percent of homes, collect one replicate sample. This replicate is randomly selected as either a floor or windowsill. In those households chosen for a replicate sample, the interviewer must also collect a field blank.

Each lead dust sample consists of one dust collection wipe in a 50-mL skirted conical tube. Label lead dust samples in the field with preprinted randomly assigned specimen identification numbers. Place samples from each household in a sample storage bag and return to the field office. Store samples at room temperature in a box with a lid to prevent excessive exposure to light. The MEC manager delivers lead dust samples and the corresponding Lead Dust Transmittal form to the MEC weekly. Samples are relabeled, assigned to specific slots in storage containers, and shipped weekly to the analysis laboratory. Send the Lead Dust Transmittal form back to the home office at the end of each stand.

The warehouse maintains a supply of spiked positive controls. At the start of each stand, the warehouse manager sends four spiked positive samples to the MEC. Process one pair of spiked samples; designate one control as a floor sample and designate the second positive control as a window sample. Process this pair of samples at the start of weeks 1 and 3. Print labels for these specimens, process, and insert the relabeled samples into the assigned slot in the storage containers.

Blood lead levels are reported to all SPs who were tested. The test is performed on all primary SPs age 1+, all dry run volunteers age 12+, and VIP guests aged 1+. If the blood level is greater than the threshold, which is age dependent, an early reporting letter is sent to the SP. If the result is less than the threshold, it is reported in the final Report of Findings. If the lead level of the household lead dust wipes exceeds Federal guidelines, a report is sent to the household along with EPA (Environmental Protection Agency) or HUD Housing and Urban Development) informational brochures. Only abnormal lead dust levels in an environment sample is reported to an SP, but all blood levels are reported.

## 14.2 MEC Laboratory Lead Dust Processing

The conical tubes that hold each lead dust sample are labeled in the field with bar-coded labels that contain a preprinted randomly assigned specimen identification number and an indication of the sample type. Once these tubes reach the MEC, the laboratory staff matches the vessels to the Lead Dust Transmittal form, prints laboratory labels that contain the sample ID associated with each SP and the vessel ID, removes the original field office label, and labels each sample with the new MEC laboratory label. Process the relabeled samples using the Lead Dust Processing module, store the samples at room temperature, and ship weekly. Field blanks and spiked positive controls are blinded to the analysis laboratory. They are labeled with “virtual” sample IDs as designated by ISIS.

The supplies needed for lead dust processing and storage are listed in Exhibit 14-1.

Exhibit 14-1. Equipment and supplies

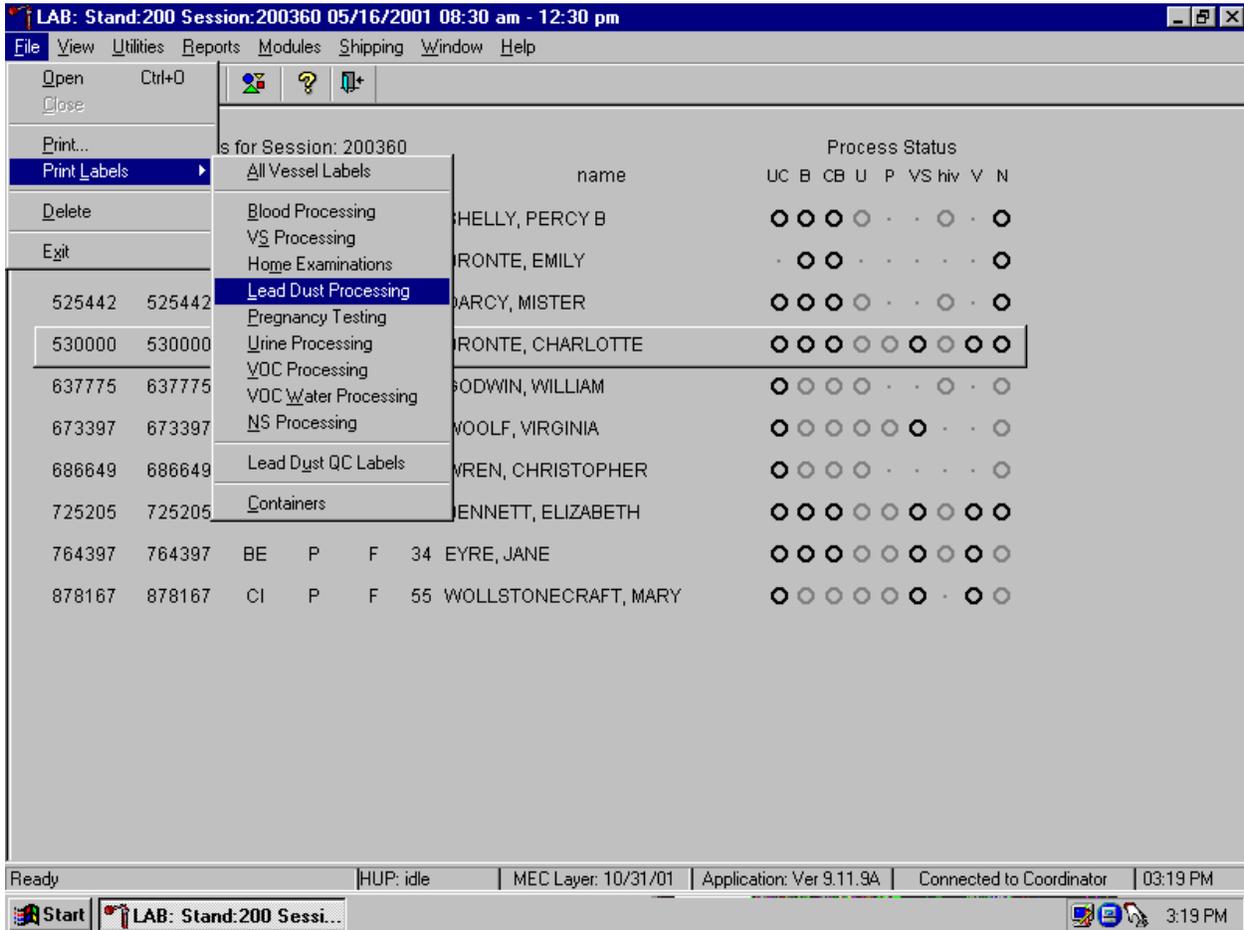
5.25 x 5.25 five-inch box with 4 x 4 grid	Rubber bands
Medium shipper	9 x 12 plastic bags

The lead dust vessel protocol is displayed in Exhibit 14-2.

Exhibit 14-2. Laboratory lead dust vessel protocol

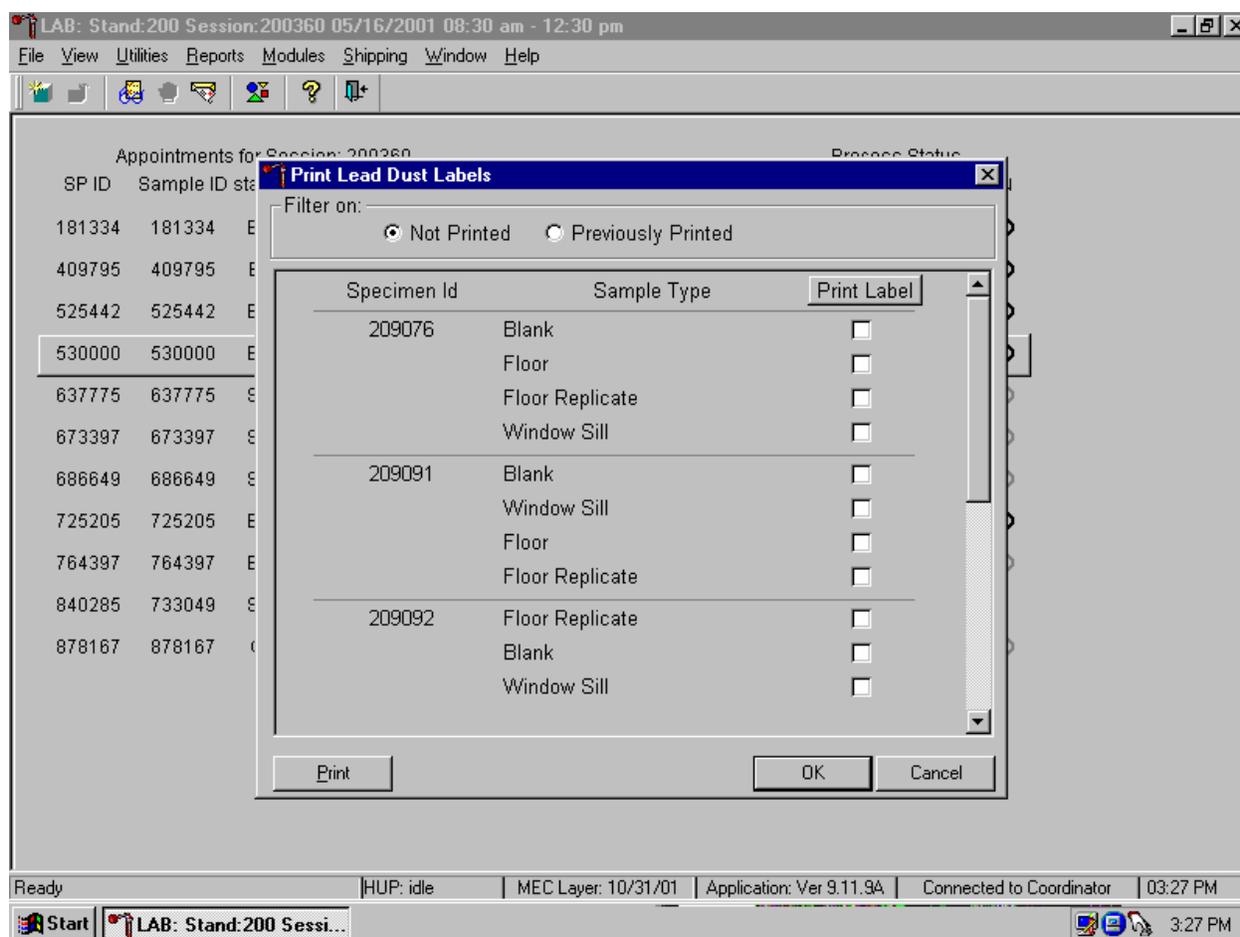
Vessel ID	Test Name	Sample Type	Vessel Type	Vessel Storage
60	Lead Dust Floor	Wipe	50-mL Conical tube	4 x 4 five-inch box
61	Lead Dust Windowsill	Wipe	50-mL Conical tube	4 x 4 five-inch box

Physically match the vessels listed on the Lead Dust Transmittal form to the actual lead dust samples. If there are discrepancies, contact the field office manager to reconcile the inconsistencies. Print laboratory labels for lead dust samples collected in the home. Access the Lead Dust Processing label module.



To access the Lead Dust Processing label module, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, drag the arrow to {Print Labels}, then to {Lead Dust Processing}, and left click or type [Alt] [F/f], [L/l], [L/l].

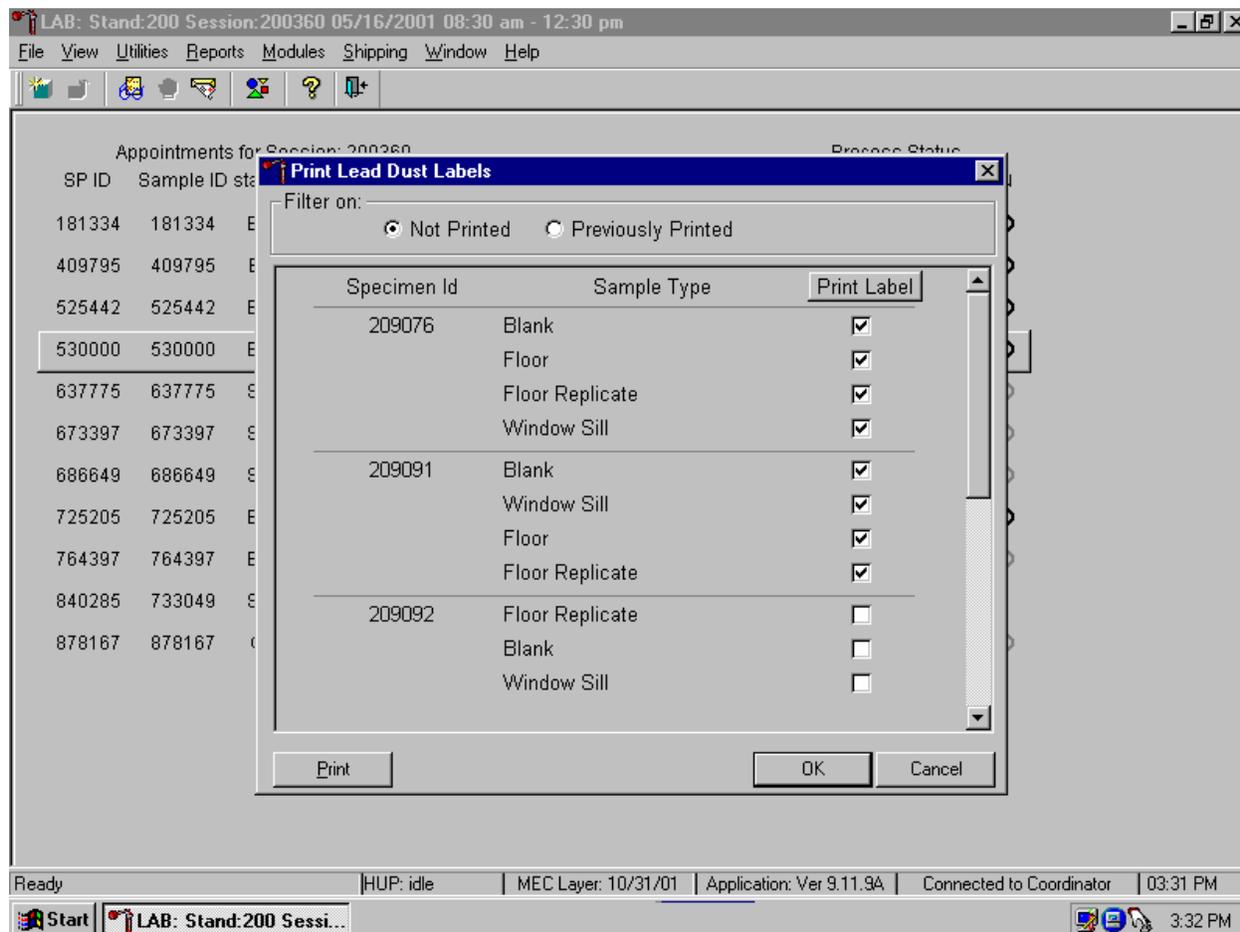
The Print Lead Dust Labels window displays.



The Print Lead Dust Labels window contains a filter that selects or displays samples for which labels have not been printed or samples for which labels have been previously printed, the Specimen ID for each set of samples, the sample types collected, and a check box to mark each sample as requiring a label. Generally, set the filter to Not Printed to view samples that require labels. The labels are sorted in the following order: floor, sill, floor replicate, sill replicate, and field blank.

Physically match each sample's specimen ID and sample type to the data displayed in the window. Use the scroll bar to view all Specimen IDs and sample types.

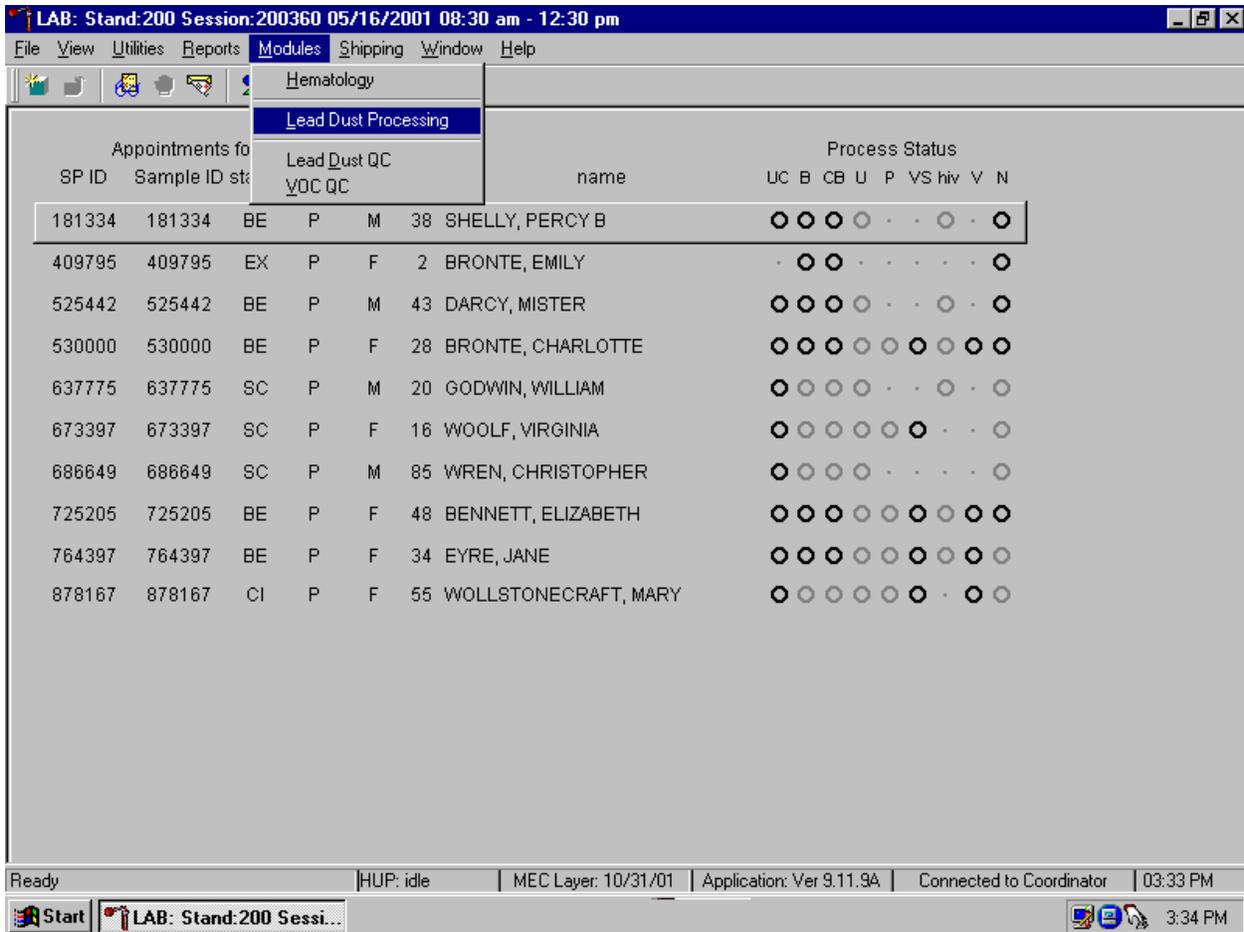
Mark the checkbox for each Specimen ID and sample type.



To mark each sample type for each Specimen ID, use the mouse to direct the mouse arrow to each individual checkbox and left click. To mark all Sample Types for all Specimen IDs at one time, use the mouse to direct the mouse arrow to the Print Label box at the top of the checkbox column and left click. To remove all checkmarks, use the mouse to direct the mouse arrow to the Print Label box and left click a second time. After physically matching all the samples in the window to the samples from the field office and marking the corresponding checkbox, print the labels. To print the labels, use the mouse to direct the mouse arrow to the Print button and left click. Labels print on the Datamax printer. The window deletes or removes the marked Specimen ID and Sample Types and refreshes to display only those Specimen IDs and Sample Types for which labels have not been printed. Alternatively, to print the labels, use the mouse to direct the mouse arrow to the OK button and left click. The window deletes or removes the marked Specimen ID and Sample Types and refreshes to display only those Specimen IDs and Sample Types for which labels have not been printed. To close the window without saving any data in the

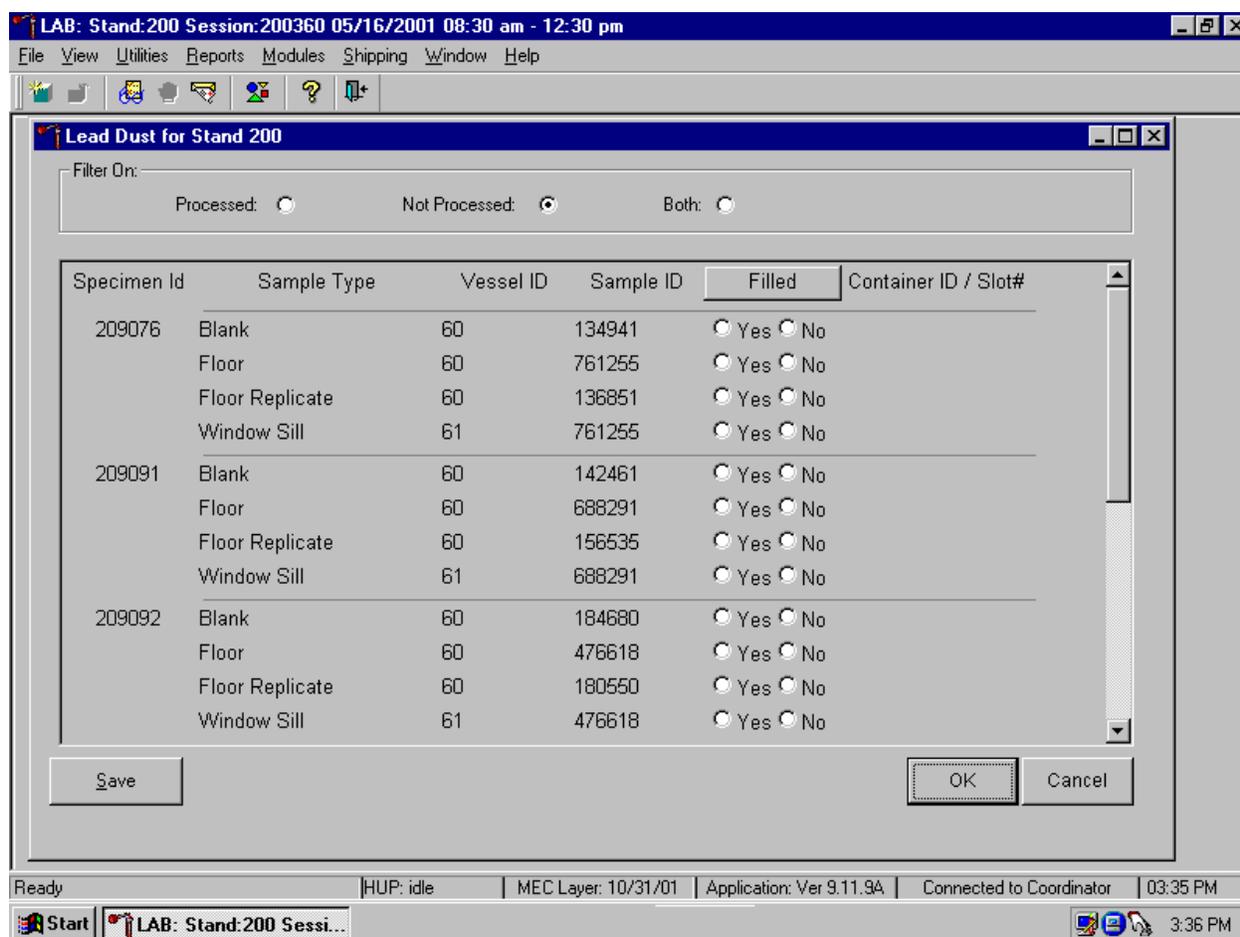
database or printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Process the lead dust samples.



To access the Lead Dust Processing module, use the mouse to direct the mouse arrow to {Modules} in the top menu bar, left click, drag the arrow to {Lead Dust Processing} and left click or type [Alt] [M/m], [L/l].

The Lead Dust processing window displays.

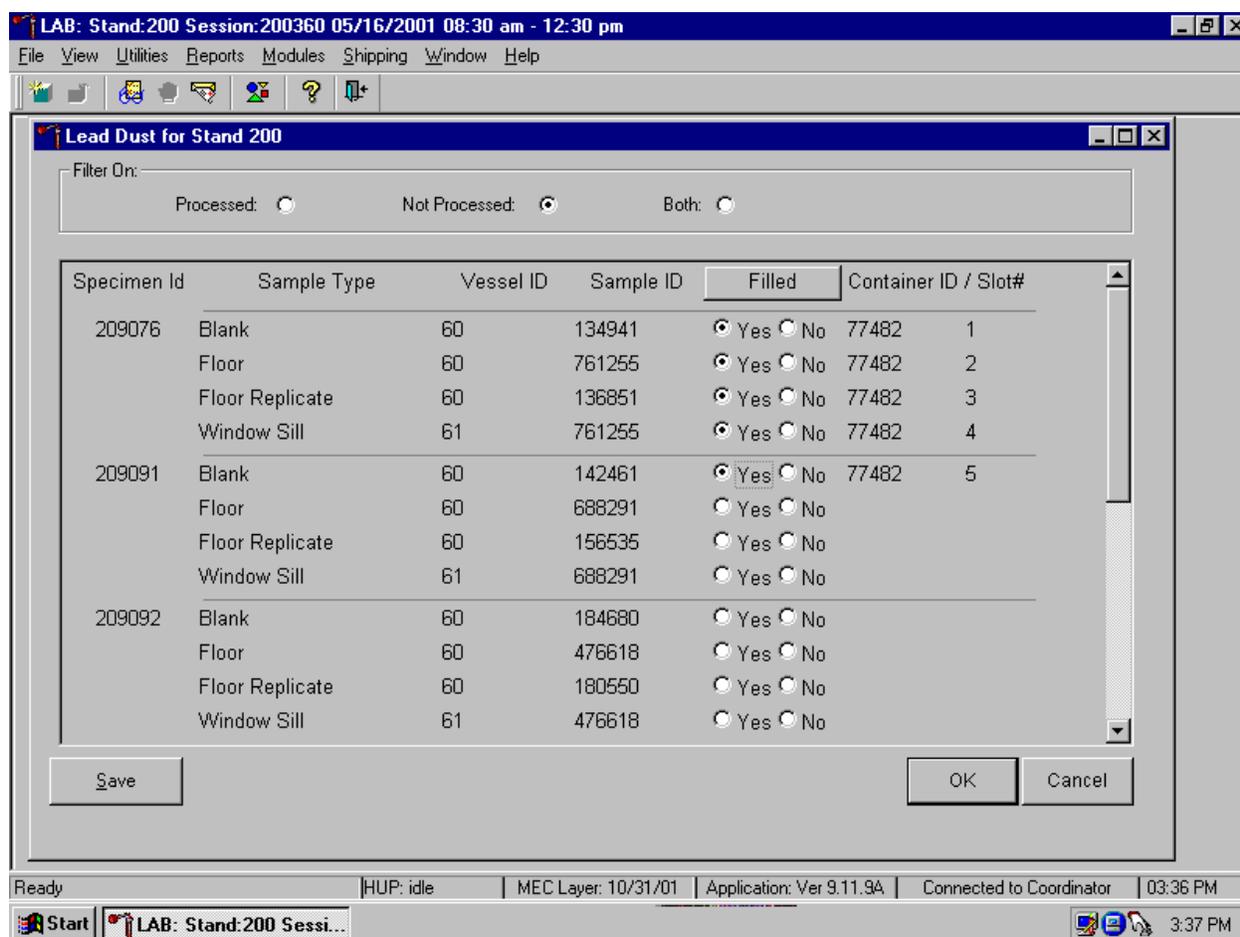


The Lead Dust for Stand XXX window contains a filter that selects or displays processed samples, not processed samples, or both previously processed and not processed samples. Generally, set the filter to Not Processed to view samples that require processing. The labels are sorted in the following order: floor, sill, floor replicate, sill replicate, and field blank.

This window contains column titles for Specimen Id, Sample Type, Vessel ID (either 60 or 61), Sample ID, a Filled button, and a Container ID/Slot # column.

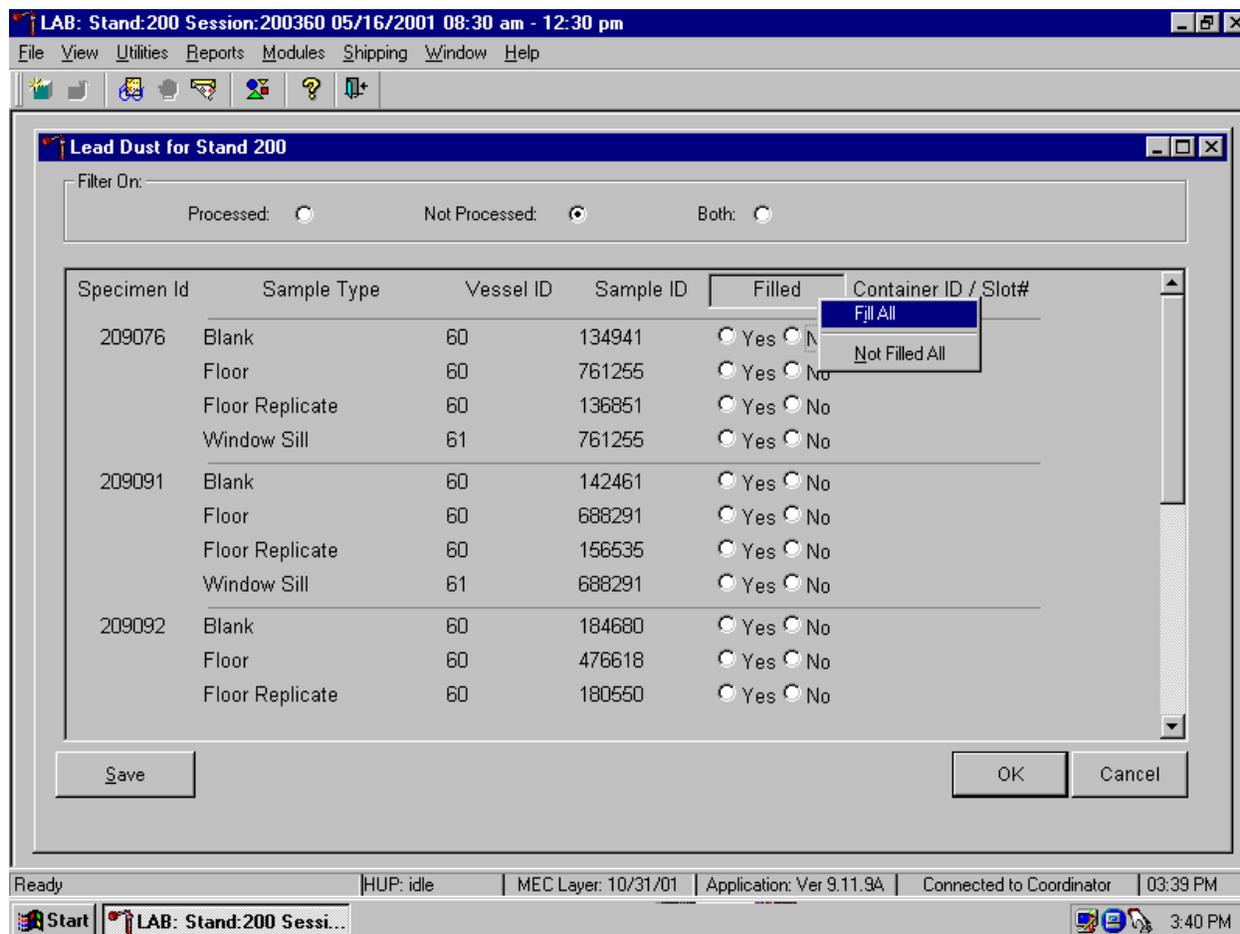
Match the samples to the Datamax laboratory labels. The laboratory label contains the Sample ID concatenated with the Vessel ID and includes the text, “W Lead Dust” for windowsill samples or “F Lead Dust” for floor samples. Remove the field office label, relabel each sample with the laboratory label, and mark the vessel as collected or filled.

Individually mark each vessel as filled, Yes or No.



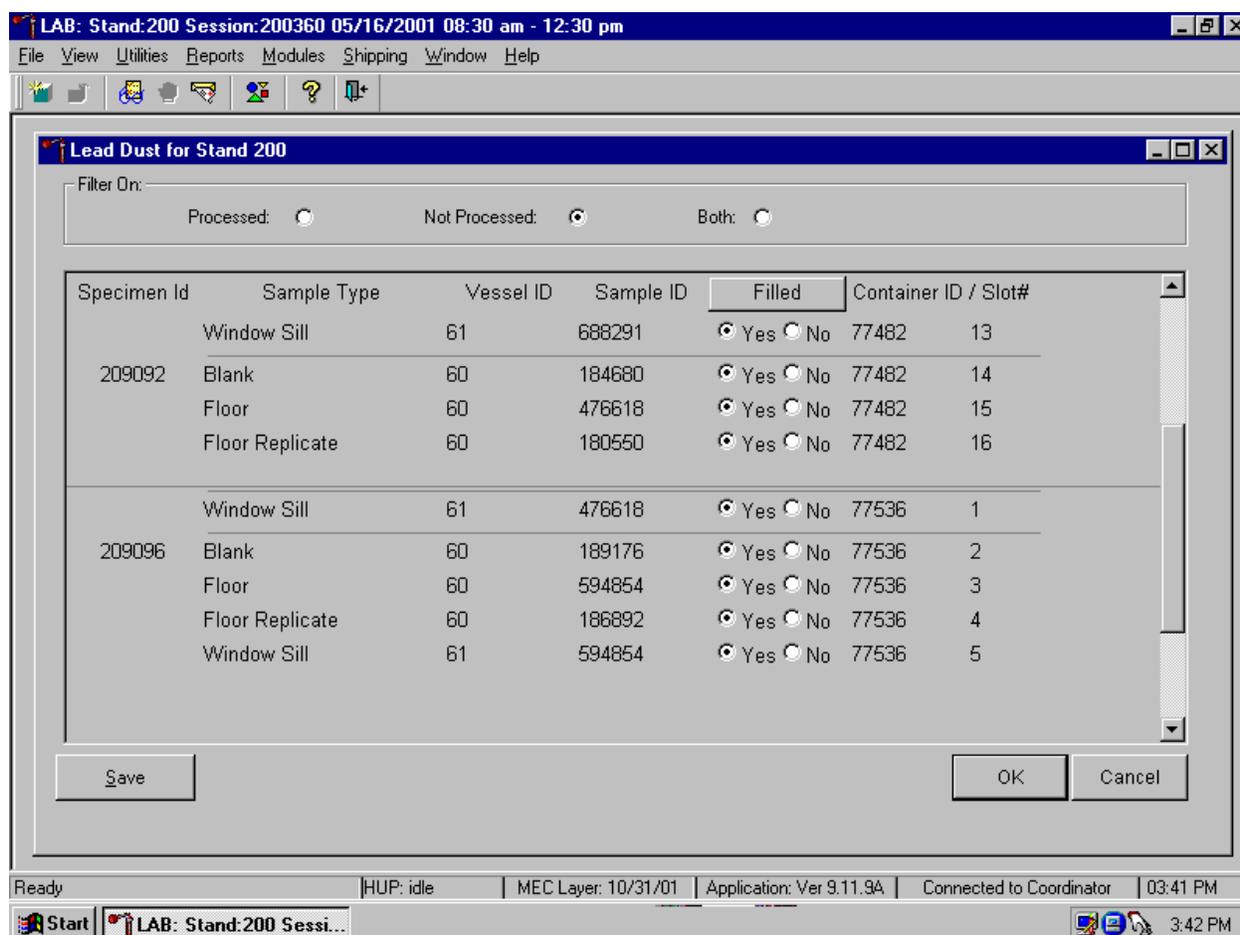
To mark individual lead dust vessel as collected or “filled,” use the mouse to direct the mouse arrow to the center of the Filled radio button and left click. As each vessel is marked as Filled–”Yes,” it is automatically assigned to a slot in an existing (open) container.

Collectively mark all vessels as Filled or Not Filled.



To collectively mark all vessels as filled, use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click and drag the arrow to {Fill All} or type [F]. To mark all vessels as Not Filled, use the mouse to direct the mouse arrow to the Filled box, left click and drag the arrow to {Not Filled All} or type [N/n].

Continue to process all lead dust vessels.

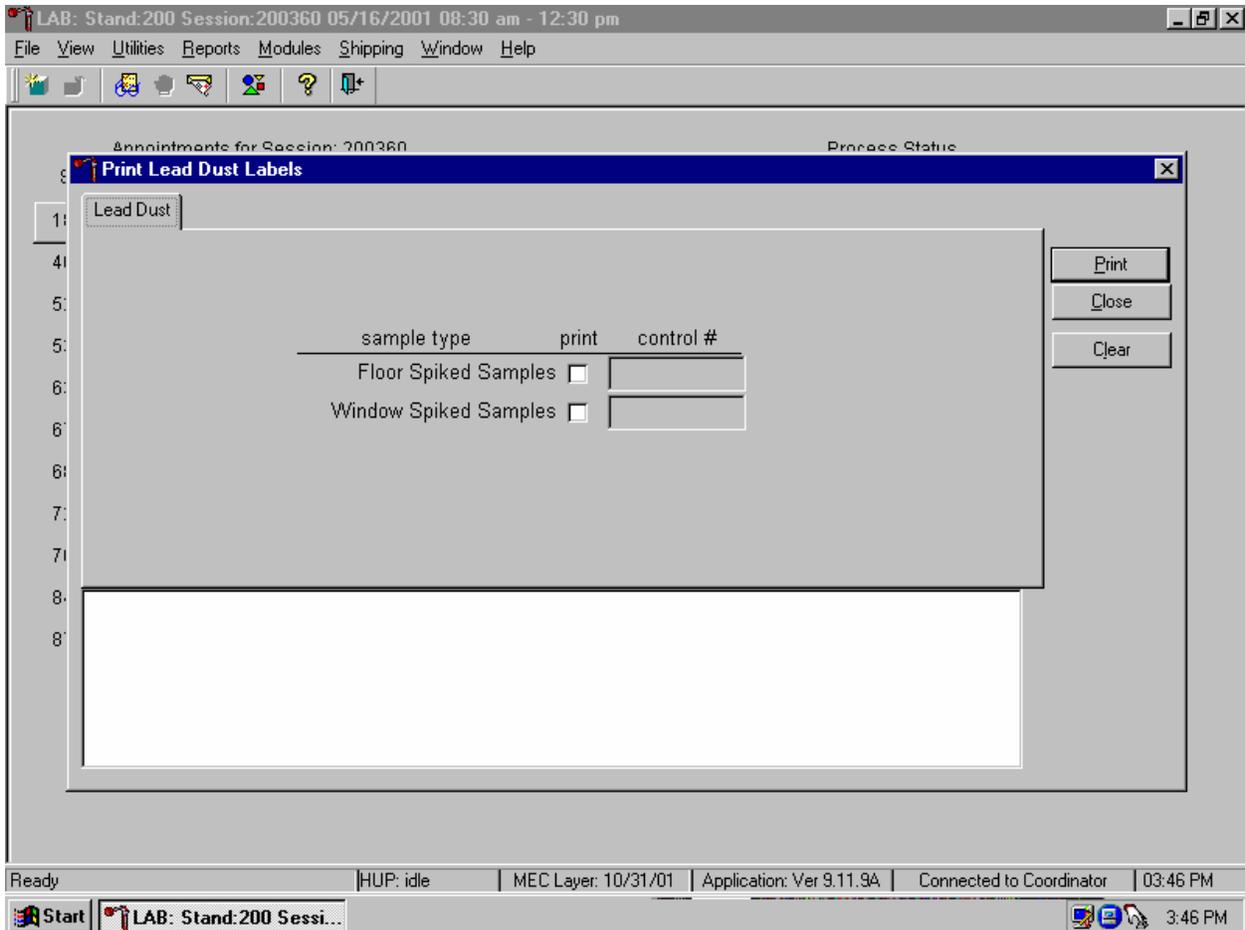


Store each filled vessel in the assigned slot in the designated container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

Check the slot assignment of the lead dust container at the end of each processing session by accessing the Container Map Report. Verify the contents of each container against the container map.

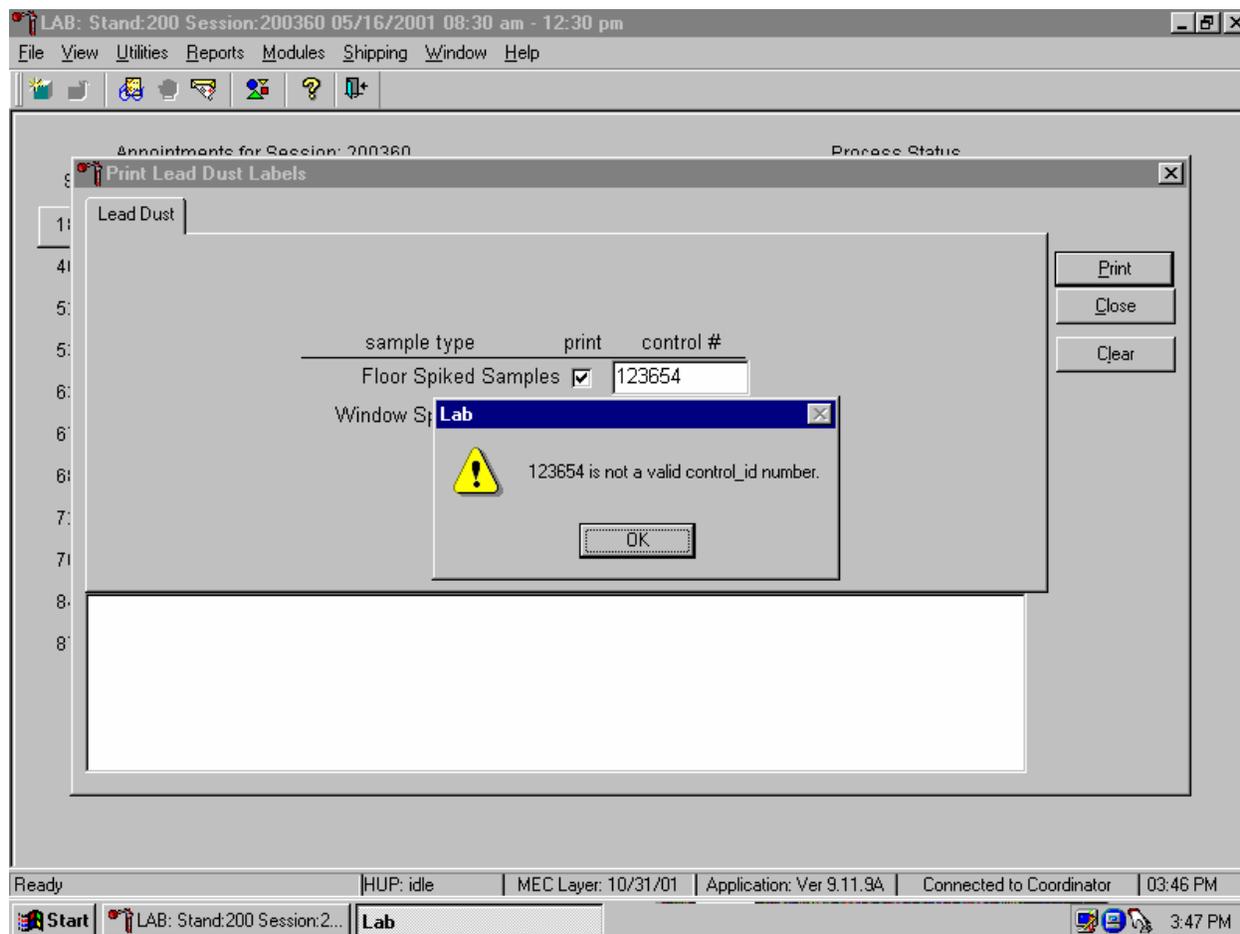


The Print Lead Dust Labels window displays. Use this module to print two types of lead dust QC labels – floor spiked samples and window spiked samples.



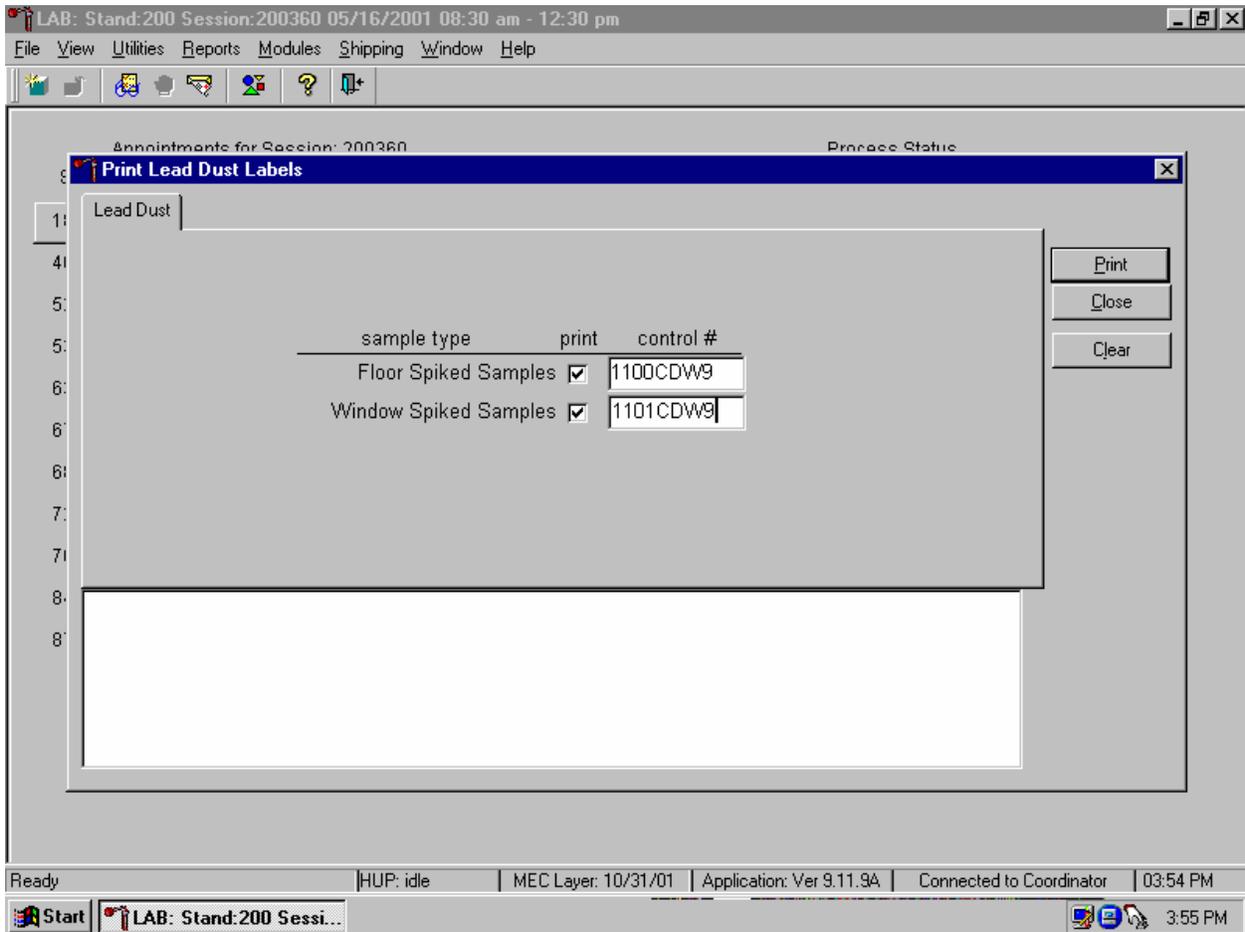
The Print Lead Dust Labels module contains rows for Floor and Window Spiked Samples, a print checkbox, a shaded control # text box, and Print, Close, and Clear buttons.

Continue the Print Lead Dust QC Label process.



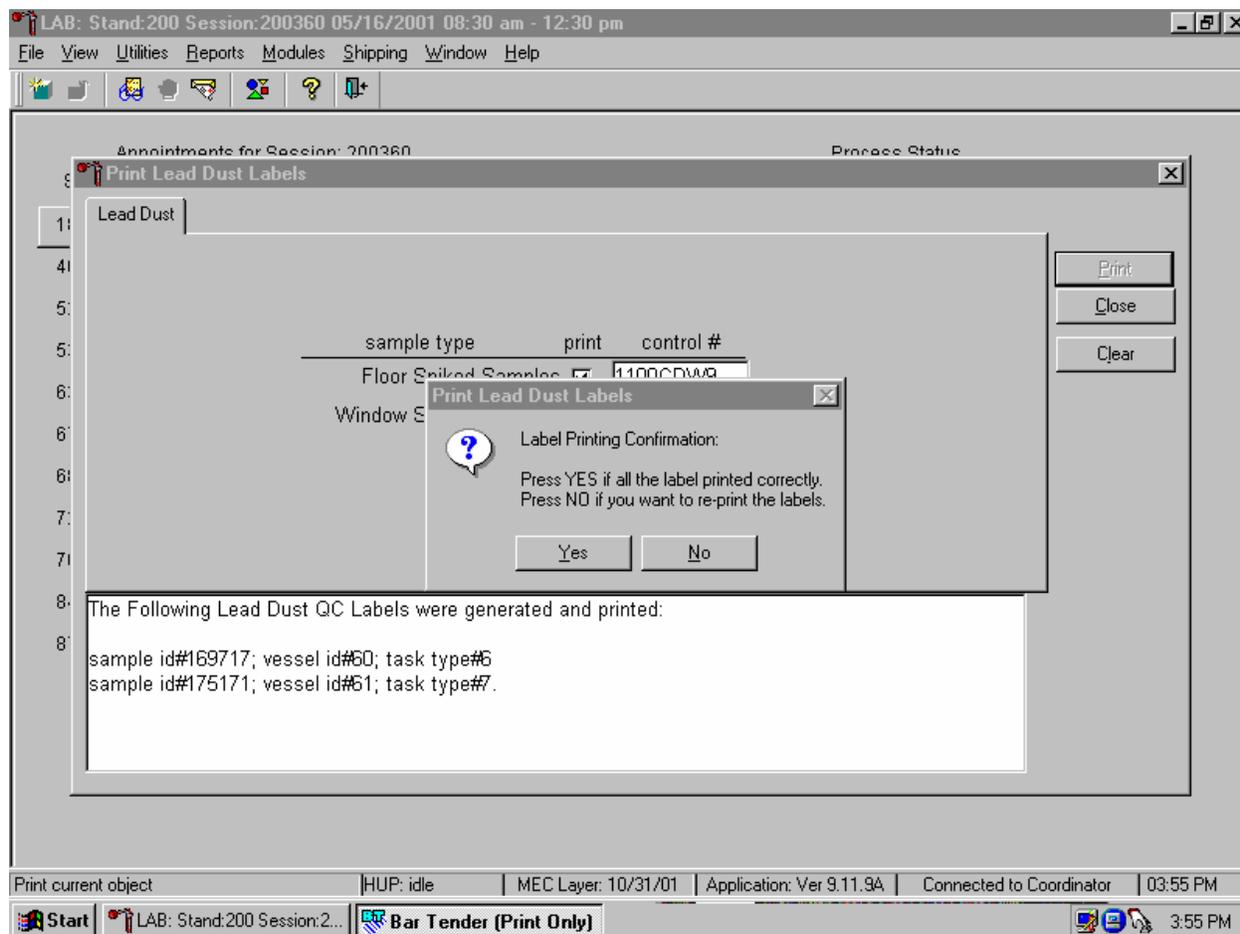
To mark the print checkbox, use the mouse to direct the mouse arrow to the print checkbox and left click to insert a checkmark. Once the checkbox is marked with a checkmark the control # text box is activated. Type the combination number and letter identifier located on the paper label into the control # text box. The application performs a validity check to ensure that the number matches the numbers in the database. If the number does not match, a Lab warning popup box displays. To remove the popup box, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter.]

Type the correct number into the control # text box.



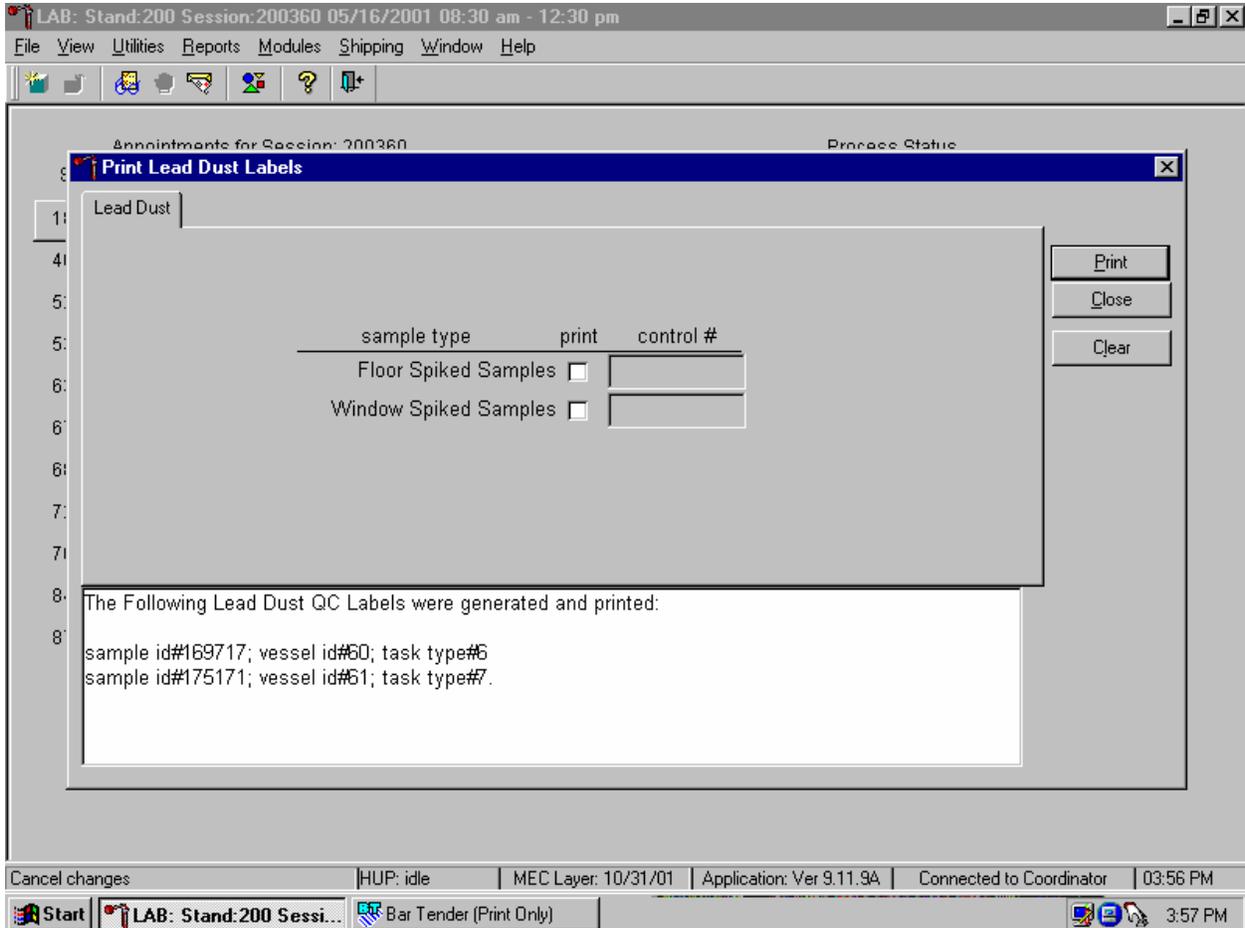
If the number matches a stored number in the database, no message is displayed. To print the labels, use the mouse to direct the mouse arrow to the Print button and left click or type [P/p]. Labels print on the Datamax printer. These labels are indistinguishable from routine vessel labels.

Confirm that the labels printed correctly before continuing.



The Print Lead Dust Labels message box displays. If all the labels printed correctly, use the mouse to direct the mouse arrow to the Yes button and left click or type [Y/y]. If any of the labels did not print correctly and/or to reprint the labels, use the mouse to direct the mouse arrow to the No button and left click or select [N/n].

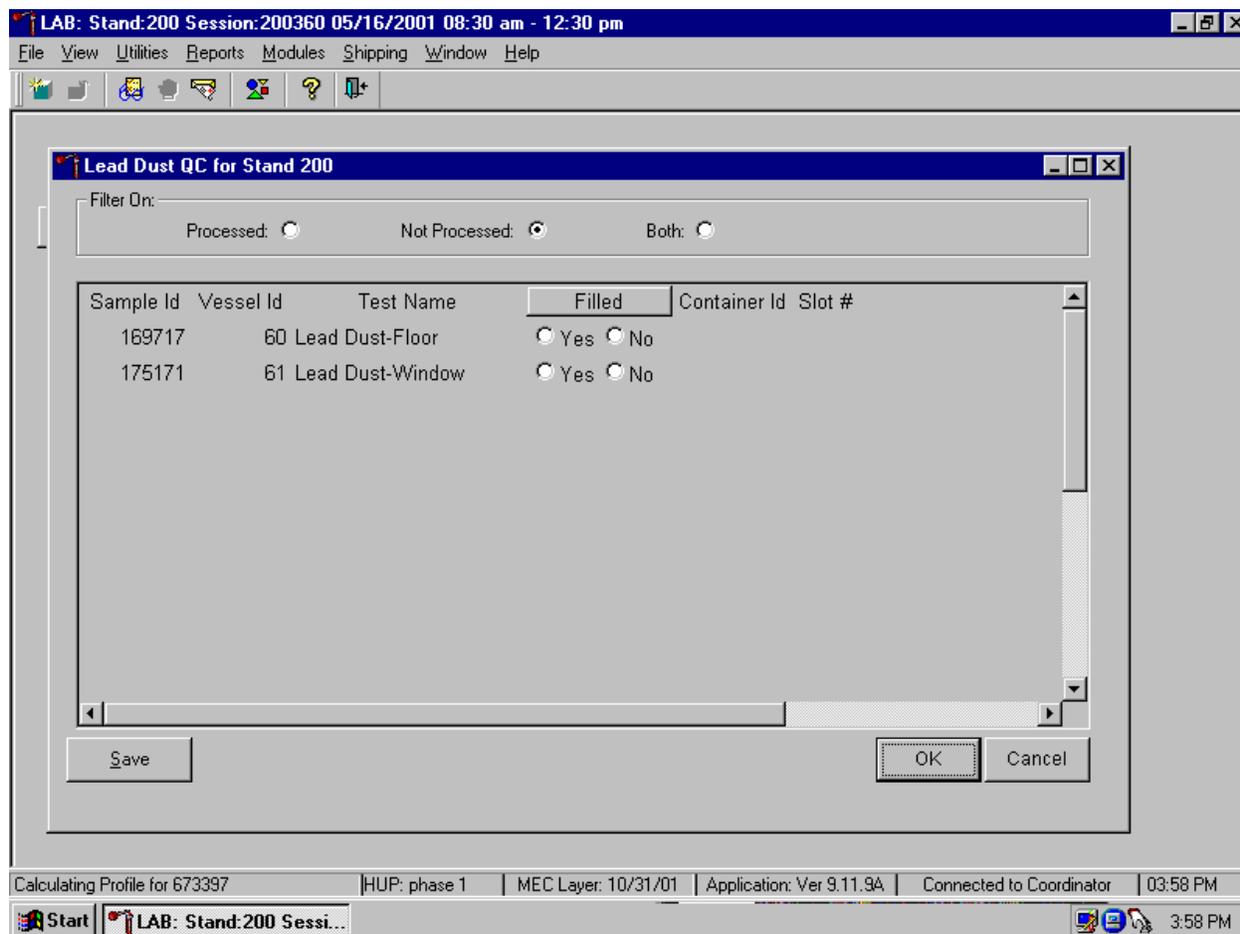
Verify the information contained in the lower white section of the Print Lead Dust Labels window.



The lower white section of the Print Lead Dust QC Labels window displays the virtual sample ID #, vessel ID # and sample type #. To close the window, use the mouse to direct the mouse arrow to the Clear button and left click or type [Shift] [C/c].



The Lead Dust QC processing screen displays.

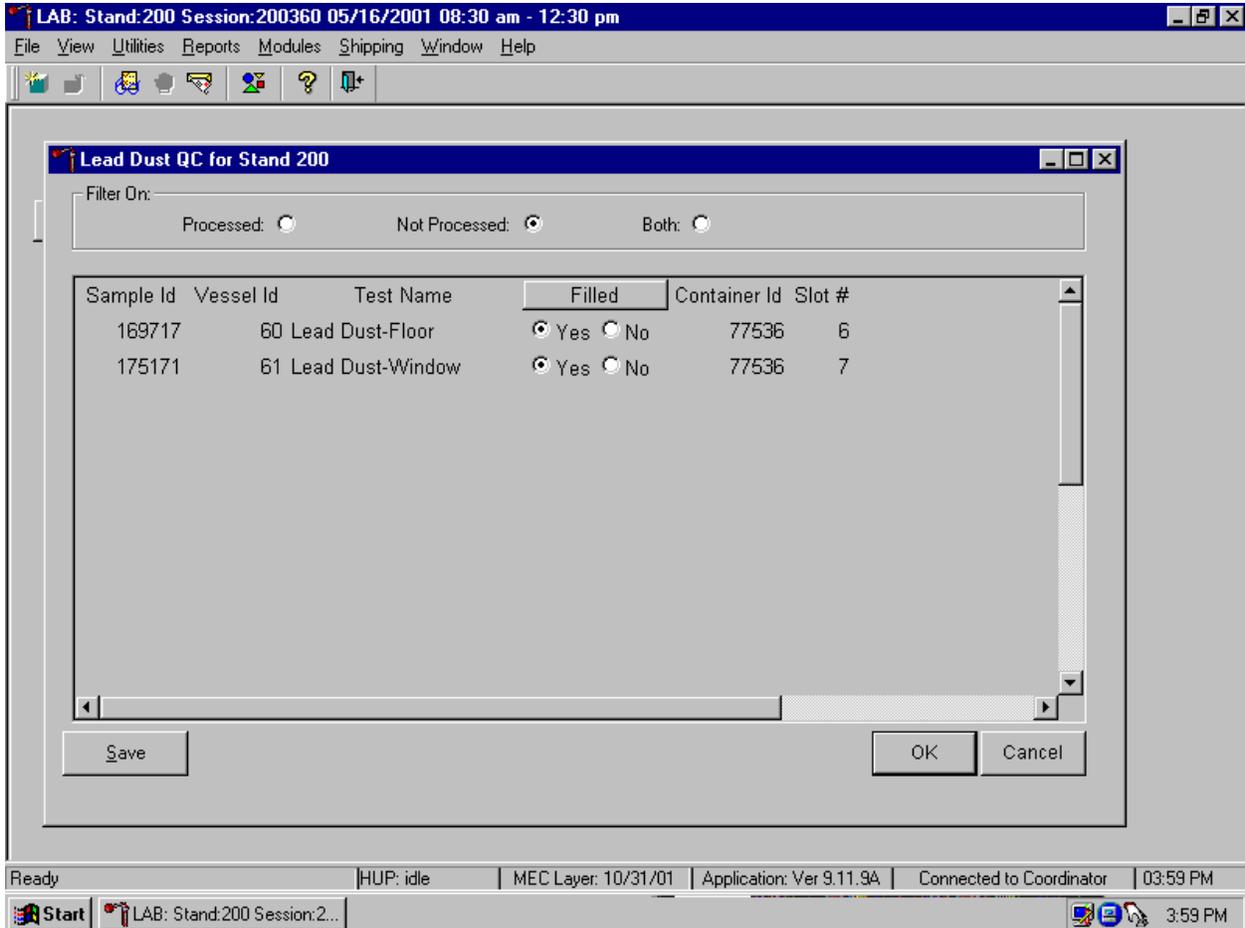


The Lead Dust for Stand XXX window contains a filter that selects or displays Processed samples, Not Processed samples, or Both previously processed and not processed samples. Generally, set the filter to Not Processed to view samples that require processing.

This window contains columns for the Sample Id, Vessel Id (either 60 or 61), Test Name (either Lead Dust-Floor or Lead Dust-Window), a Filled box (radio buttons for Yes and No), and Container Id/Slot # column.

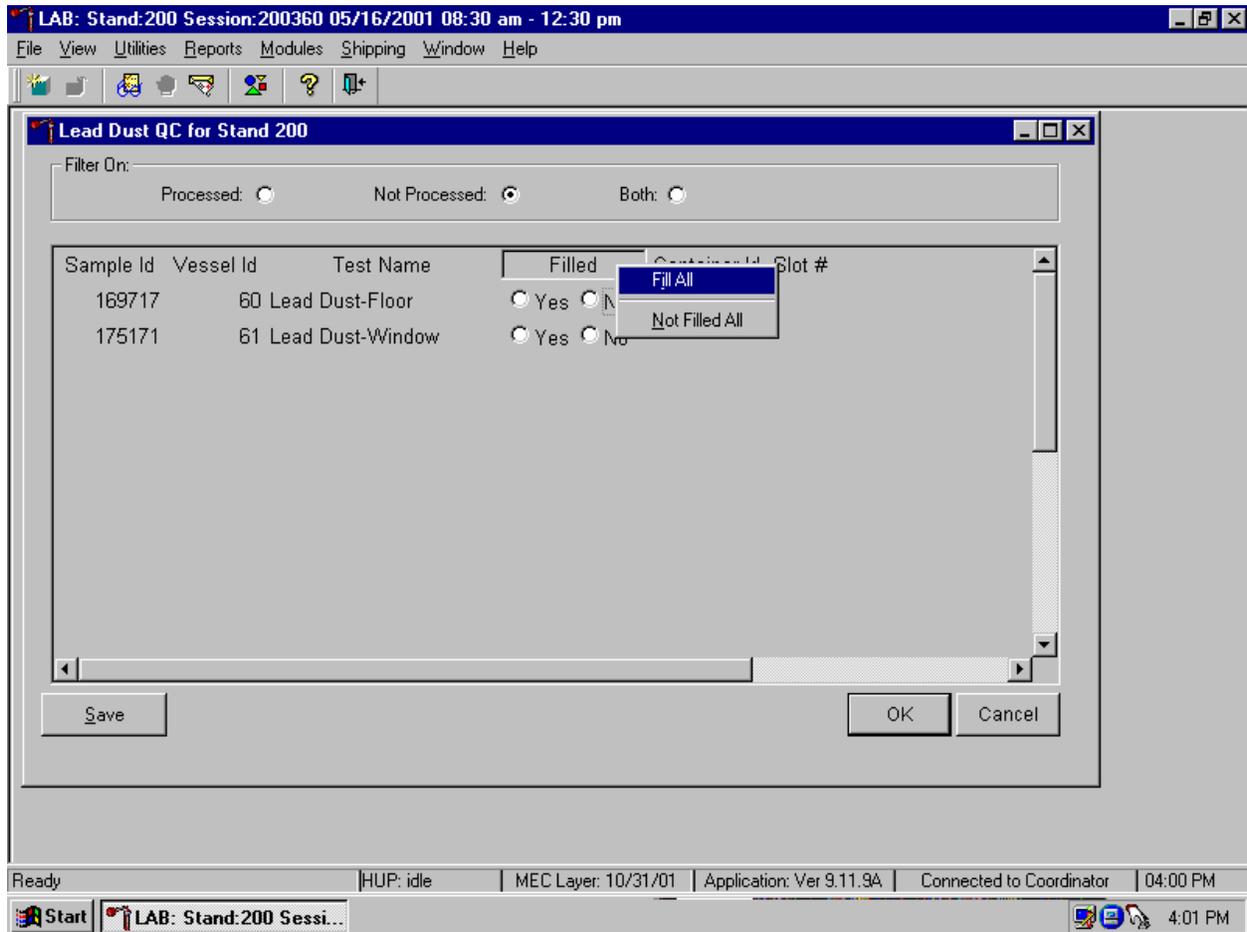
Match the samples to the Datamax labels. Remove the original QC label from the vessel and discard. Place the new laboratory label on the vessel lengthwise.

Mark the Lead Dust-Floor and Lead Dust-Window QC vessels as collected or Filled--"Yes" or "No."



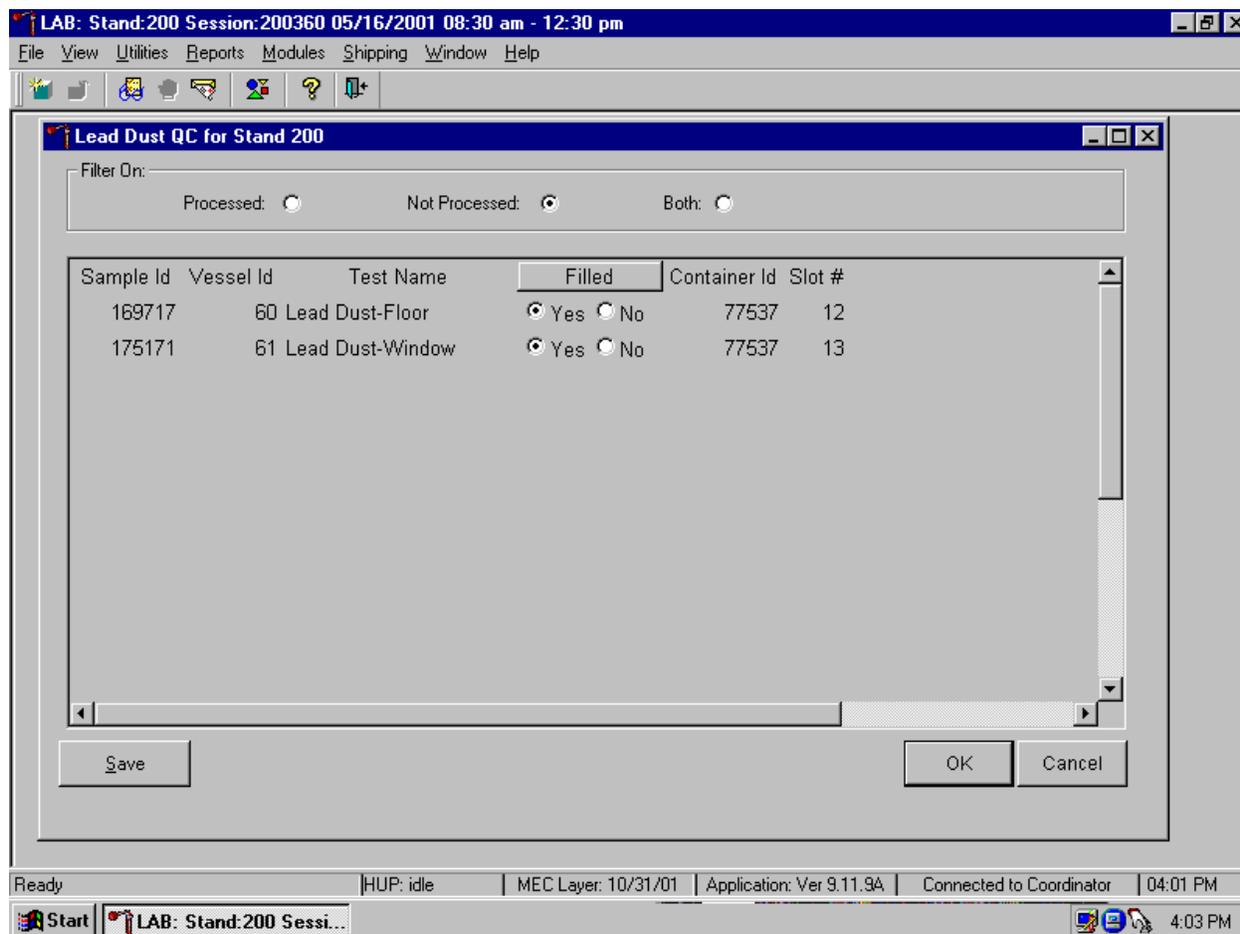
To mark the individual lead dust QC vessel as collected or "Filled," use the mouse to direct the mouse arrow to each Yes radio button and left click. As each vessel is marked as Filled--"Yes," it is automatically assigned to a slot in an existing (open) container. To mark the individual lead dust QC vessel as not collected or Filled--"No," use the mouse to direct the mouse arrow to each No radio button and left click.

Collectively mark both vessels as Filled or Not Filled.



To collectively mark both vessels as Filled, use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click and drag the arrow to {Fill All} or type [F/f]. To mark both vessels as Not Filled, use the mouse to direct the mouse arrow to the Filled box, left click and drag the arrow to {Not Filled All} or type [N/n].

Store each filled vessel in the assigned slot in the assigned container.



To record this action or to save this data to the database and remove the information from the screen, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without recording any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

Only vessels for which labels have been printed are capable of being processed.

The screenshot shows a software window titled "LAB: Stand:200 Session:200360 05/16/2001 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main area displays a table of appointments for session 200360. The table has columns for SP ID, Sample ID, status, type, gender, age, name, and Process Status (UC, B, CB, U, P, VS, hiv, V, N). A dialog box titled "plc\_preopen" is overlaid on the table, displaying a warning icon and the text: "Unable to retrieve Lead Dust QC. Please make sure you have generated Lead Dust QC labels." with an "OK" button.

Appointments for Session: 200360							Process Status								
SP ID	Sample ID	status	type	gender	age	name	UC	B	CB	U	P	VS	hiv	V	N
181334	181334	BE	P	M	38	SHELLY, PERCY B	○	○	○	○	○	○	○	○	○
409795	409795	EX	P	F	2	BRONTE, EMILY	○	○	○	○	○	○	○	○	○
525442	525442	BE	P	M	43	DARCY, MISTER	○	○	○	○	○	○	○	○	○
530000	530000	BE	P	F	28	BRONTE, CHARLOTTE	○	○	○	○	○	○	○	○	○
637775	637775	SC	P	M	28	GODMAN, WILLIAM	○	○	○	○	○	○	○	○	○
673397	673397	SC	P	M	28	GODMAN, WILLIAM	○	○	○	○	○	○	○	○	○
686649	686649	SC	P	M	28	GODMAN, WILLIAM	○	○	○	○	○	○	○	○	○
725205	725205	BE	P	M	28	GODMAN, WILLIAM	○	○	○	○	○	○	○	○	○
764397	764397	BE	P	M	28	GODMAN, WILLIAM	○	○	○	○	○	○	○	○	○
878167	878167	CI	P	F	55	WOLLSTONECRAFT, MARY	○	○	○	○	○	○	○	○	○

If the Lead Dust QC module is accessed and labels have not been printed, a message text box displays. To remove the text box, use the mouse to direct the mouse arrow to the OK button and left click. Access the Lead Dust QC Label module to print the QC labels and then proceed to process the QC samples.

#### 14.4 Packing and Shipping Procedure

Ship lead dust specimens to the University of Cincinnati in a double-sided Styrofoam and corrugated cardboard shipper at room temperature. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information. Include a preprinted

FedEx return airbill label with the current field office address for the first 3 or 4 weeks of the stand. Include a preprinted FedEx return airbill label with the Westat warehouse address for the last 2 weeks of the stand.

Laboratory	Test	Temperature	Container	Frequency
University of Cincinnati	Lead Dust	Room temperature	4 x 4 five-inch box	Weekly

### **Pack a Medium Shipper for Ambient Temperature Shipment**

Ship lead dust specimens at ambient temperature.

- Pack the bottom of the Styrofoam shipper with crumbled newsprint.
- Place the sealed boxes on top of the newsprint.
- Pack the sides with crumbled newsprint.
- Place more crumpled newsprint on top so that the shipper is filled to 1/4" below the rim.
- Place a plastic envelope containing the appropriate shipping manifest and the preprinted FedEx airbill on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the envelope (10 pounds) on the appropriate FedEx label.
- Seal the container with several tape strips.

### **Label Shippers**

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Complete the section of the FedEx label that requests the weight of the contents of the shipper.
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Place one additional tape strip across the FedEx pouch.

## 15. NASAL SWAB (NS) COLLECTION AND PROCESSING

### 15.1 Introduction

The purpose of collecting a nasal swab is to obtain a suitable biological sample to culture for the presence of *Staphylococcus aureus* (*S. aureus*). *Staphylococcus aureus* is one of the most common causes of skin and soft tissue infection in both the health care and community settings. Antimicrobial resistance in *S. aureus* has increased dramatically, particularly in the hospital, where the rapid emergence of methicillin-resistant *S. aureus* (MRSA) has left only one intravenous antimicrobial, vancomycin, as a treatment option. The appearance of *S. aureus* isolates with resistance to vancomycin (VISA) has led to concern that this organism may become untreatable with currently available antimicrobials. Previously limited to hospitals, MRSA infections have been increasingly reported in the community, and it is unclear whether resistance is spreading from hospitals or another unidentified source. Risk factors for MRSA infection include hospitalization, antimicrobial use, underlying medical illness, and proximity to individuals with MRSA infection or colonization, including health care workers. The carrier state is asymptomatic, and transmission of MRSA can occur from any individual colonized with MRSA. In order to estimate the potential for spread of MRSA in the community, it is important to measure the MRSA carriage rate through a population-based study. However, no prospective, population-based prevalence study has been done to measure the prevalence of MRSA in the community, and no national surveillance exists to provide a reliable national population estimate. Therefore, NHANES participants who consent are cultured for MRSA.

The phlebotomy application consists of four sections: venipuncture, VOC, nasal swab collection, and physical activity monitor (PAM) recruitment. The MEC coordinator assigns an SP to the phlebotomy room. The phlebotomist logs onto the phlebotomy application and logs the SP into the component. The application presents the correct section screens according to the SP's appointment type, age, and selection for inclusion in the VOC subsample. Primary SPs age 1+ are eligible for venipuncture; selected primary SPs aged 20-59 are eligible for the VOC subsample, primary SPs age 1+ are eligible for nasal swab collection and primary SPs age 6+ are eligible for the PAM. The phlebotomist collects the blood tubes, collects the VOC water sample, administers a VOC questionnaire, collects a nasal swab, recruits the SP to wear a PAM, records all results in the phlebotomy application, escorts the SP back to the coordinator, and transports the specimens to the MEC laboratory. The medical technologists log the

specimen into the MEC laboratory using the laboratory application, store the specimens, and ship them to contract laboratories weekly.

The nasal swab collection section displays after the venipuncture and VOC sections of the phlebotomy application if the SP is eligible for both. If the SP is not eligible for VOC, then the nasal swab section displays immediately after the venipuncture section of the phlebotomy application since all primary SPs age 1+ are eligible for both venipuncture and nasal swab collection.

Collect a nasal swab on all primary SPs age 1+. Swab both nares using a BBL™ CultureSwab™.

## **15.2 Procedure Summary**

Log the SP into the component, peel open the swab pack, remove the white plug, remove the swab, insert swab 2 cm into one naris, and rotate against the anterior nasal mucosa for 3 seconds. Repeat this procedure using the same swab in the second naris, return the swab to the transport sleeve, label the swab, record the collection results, and transport the specimen to the laboratory.

## **15.3 Equipment and Supplies**

BBL™ CultureSwab™ #220099 (Liquid Stuart – single swab, plastic shaft)

Each BBL™ CultureSwab™ unit comprises a single peel pouch containing a rayon-tipped swab applicator used to collect the sample and a tube containing transport medium into which the swab applicator is placed after sampling. The BBL™ CultureSwab™ transport medium is nonnitritious, buffered with phosphates, and provides a reduced environment due to its formulation with sodium thioglycollate. Organisms in the sample material are protected from drying by moisture in the transport medium. The medium is designed to maintain the viability of organisms during transport to the laboratory.

Store the BBL™ CultureSwab™ at 5-25°C. Do not freeze or overheat. Do not use after the expiration date, which is clearly printed on the outer box and on each individual sterile pouch unit and the specimen transport tube label.

#### 15.4 Collection Procedure

If the SP has nasal discharge:

- Ask the SP to attempt to clear the discharge by “blowing” his or her nose. Allow one attempt.
- Assist children whenever necessary.
- Do not try to clear the discharge with swabs, as this might be excessively traumatic.

Use the following script to introduce the SP to this procedure.

*“Staph” (Staphylococcus aureus) is a type of germ or bacteria. Many people have the Staph germ living inside their nostril and it does not harm them. We would like to find out how many people have different kinds of Staph.”*

*“To test for Staph, I will gently place a cotton tipped swab (like a “Q-tip”) into the tip of your nostril and rub the swab against the inside surface. Then I will repeat this procedure using the same swab in the other nostril. This will last only a few seconds at most. It should not be uncomfortable, except that it may tickle your nose.”*

1. Put on clean gloves if this is the only section for which the SP is eligible. It is not necessary to change gloves after the venipuncture and before the nasal swab collection procedures.
2. Peel open the BBL™ CultureSwab™ sterile pouch at the point marked “PEEL HERE.”
3. Remove cap from the transport tube.
4. Remove the white plug.
5. Remove the swab.
6. Insert the swab approximately 2 cm (approximately ¾ inches) into the naris.
7. Rotate the swab against the anterior nasal mucosa for 3 seconds.

8. Using the same swab, repeat for other naris.
9. Place swab back into the transport tube.
10. Invert the BBL™ CultureSwab™, and crush ampule at midpoint. Ensure that the swab is in contact with the moistened pledget by securing the transport cap.
11. Label the swab with the SP's preprinted label.
12. Remove and discard gloves.
13. Pass the labeled specimen through the pass-through window to the laboratory.

### **15.5 Record Collection Results**

Access the phlebotomy application, open an exam, logon using the Logon window, and log the SP into the phlebotomy component. Log the SP into the component. Conduct the phlebotomy interview, administer the fasting questionnaire, and perform the venipuncture. Collect the VOC water vial and administer the VOC questionnaire, if applicable. Collect the nasal swab, record the collection results, and then proceed through the PAM section, if applicable.

If the SP is not eligible for VOC then the nasal swab section displays immediately after the venipuncture section.

The screenshot shows a software window titled "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and navigation. The main window header displays "Phlebotomy: Stand:200 Session:200220 05/02/2001 08:30 am - 12:30 pm". Below this, patient information is shown: "SP ID: 967050 Name: BLACK, JOAN Age: 28 years Gender: Female Date: 11/21/2003 Time: 02:12 PM". The section title is "Nasal Swab Collection".

The main content area contains the following text:

'Staph' (Staphylococcus aureus) is a type of germ or bacteria. Many people have the Staph germ living inside their nostril and it does not harm them. We would like to find out how many people have different kinds of Staph.

To test for Staph, I will gently place a cotton tipped swab (like a 'Q-tip') into the tip of your nostril and rub the swab against the inside surface. Then I will repeat this procedure using the same swab in the other nostril. This will last only a few seconds at most. It should not be uncomfortable, except that it may tickle your nose.

Below the text are two dropdown menus:

Nasal Swab Collected?

Number of nares swabbed

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Einish". A status bar at the very bottom shows: "Ready | MEC Layer: 11/14/2003 | Application: Ver 11.11.14A | Connected to Coordinator | SP assigned to room | 02:39 PM".

The nasal swab collection screen consists of an introductory script, one text box to record the collection results, and a second text box to record the number of nares that were swabbed.

Collect the nasal swab and record the result.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar, a status bar displays "Phlebotomy: Stand:200 Session:200220 05/02/2001 08:30 am - 12:30 pm". The main content area is titled "Nasal Swab Collection" and contains the following text:

'Staph' (Staphylococcus aureus) is a type of germ or bacteria. Many people have the Staph germ living inside their nostril and it does not harm them. We would like to find out how many people have different kinds of Staph.

To test for Staph, I will gently place a cotton tipped swab (like a 'Q-tip') into the tip of your nostril and rub the swab against the inside surface. Then I will repeat this procedure using the same swab in the other nostril. This will last only a few seconds at most. It should not be uncomfortable, except that it may tickle your nose.

Nasal Swab Collected?

Number of nares swabbed

At the bottom of the form, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom of the window shows "Ready", "MEC Layer: 11/14/2003", "Application: Ver 11.11.14A", "Connected to Coordinator", "SP assigned to room", and "02:39 PM".

To record the collection result, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, to record the response, type the first letter of the correct choice and [Tab.] For example, type [Y/y] for “Yes” or [N/n] for “No.” Select [Tab] to move to the next text box.

Record the number of nostrils that were swabbed.

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:200 Session:200220 05/02/2001 08:30 am - 12:30 pm

SP ID: 967050 Name: BLACK, JOAN Age: 28 years Gender: Female Date: 11/21/2003 Time: 02:12 PM

**Nasal Swab Collection**

'Staph' (Staphylococcus aureus) is a type of germ or bacteria. Many people have the Staph germ living inside their nostril and it does not harm them. We would like to find out how many people have different kinds of Staph.

To test for Staph, I will gently place a cotton tipped swab (like a 'Q-tip') into the tip of your nostril and rub the swab against the inside surface. Then I will repeat this procedure using the same swab in the other nostril. This will last only a few seconds at most. It should not be uncomfortable, except that it may tickle your nose.

Nasal Swab Collected? Yes

Number of nares swabbed Both

Both  
One  
Both

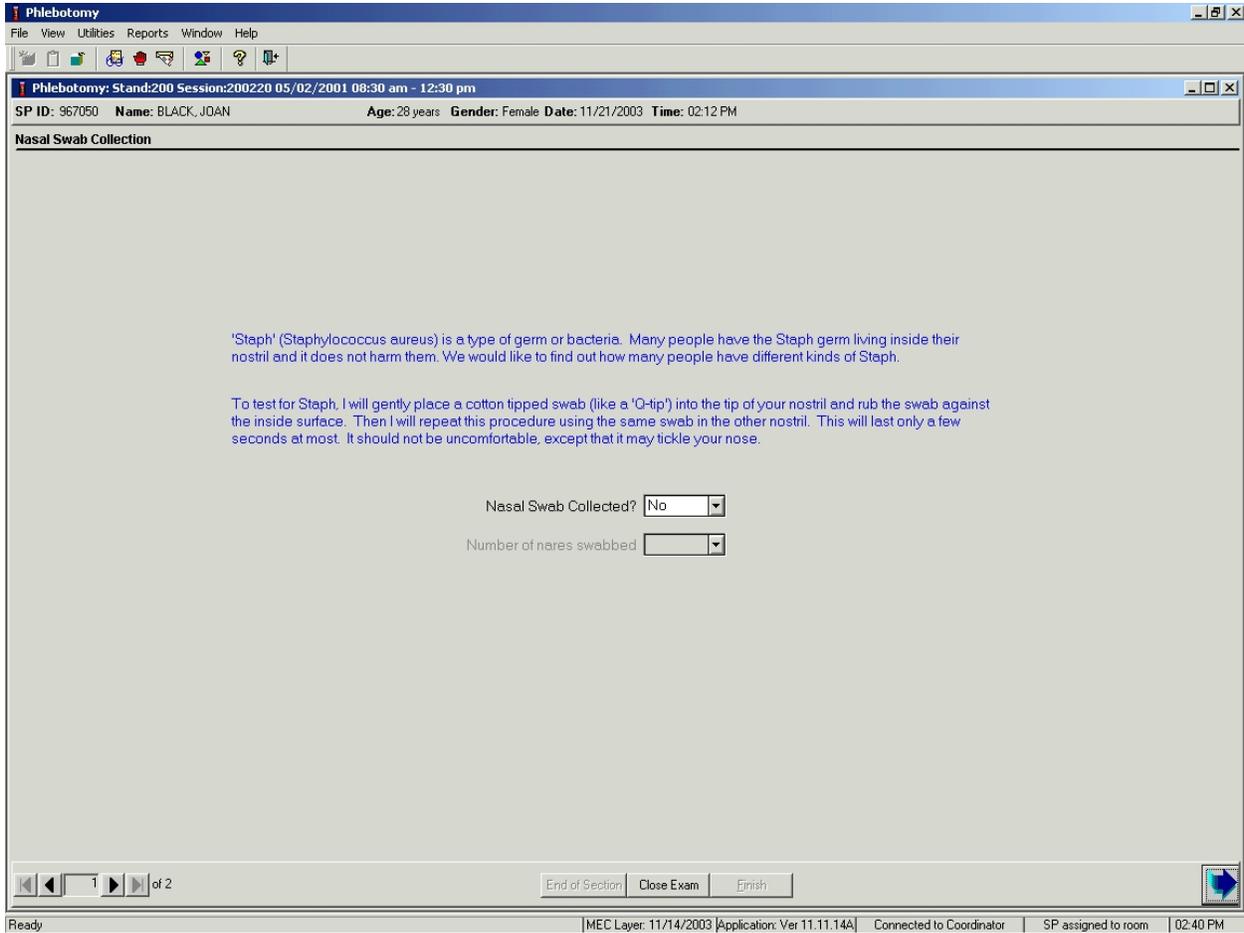
1 of 2

End of Section Close Exam Finish

Ready | MEC Layer: 11/14/2003 | Application: Ver 11.11.14A | Connected to Coordinator | SP assigned to room | 02:39 PM

After entering a “Yes” response in the Nasal Swab Collected text box, select [Tab] to move to the Number of nares swabbed text box. The Number of nares swabbed text box defaults to “Both.” To change the Number of nares swabbed result from “Both” to “One,” use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to “One,” and left click. Select [Enter] to move to the Nasal Swab Collection Status screen or use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar to move to the next screen.

If a “No” response is recorded in the Nasal Swab Collected text box, the Number of nares swabbed text box is disabled.



Select [Enter] to move to the Nasal Swab Collection Status screen or use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar to move to the next screen.

Review the status screen.

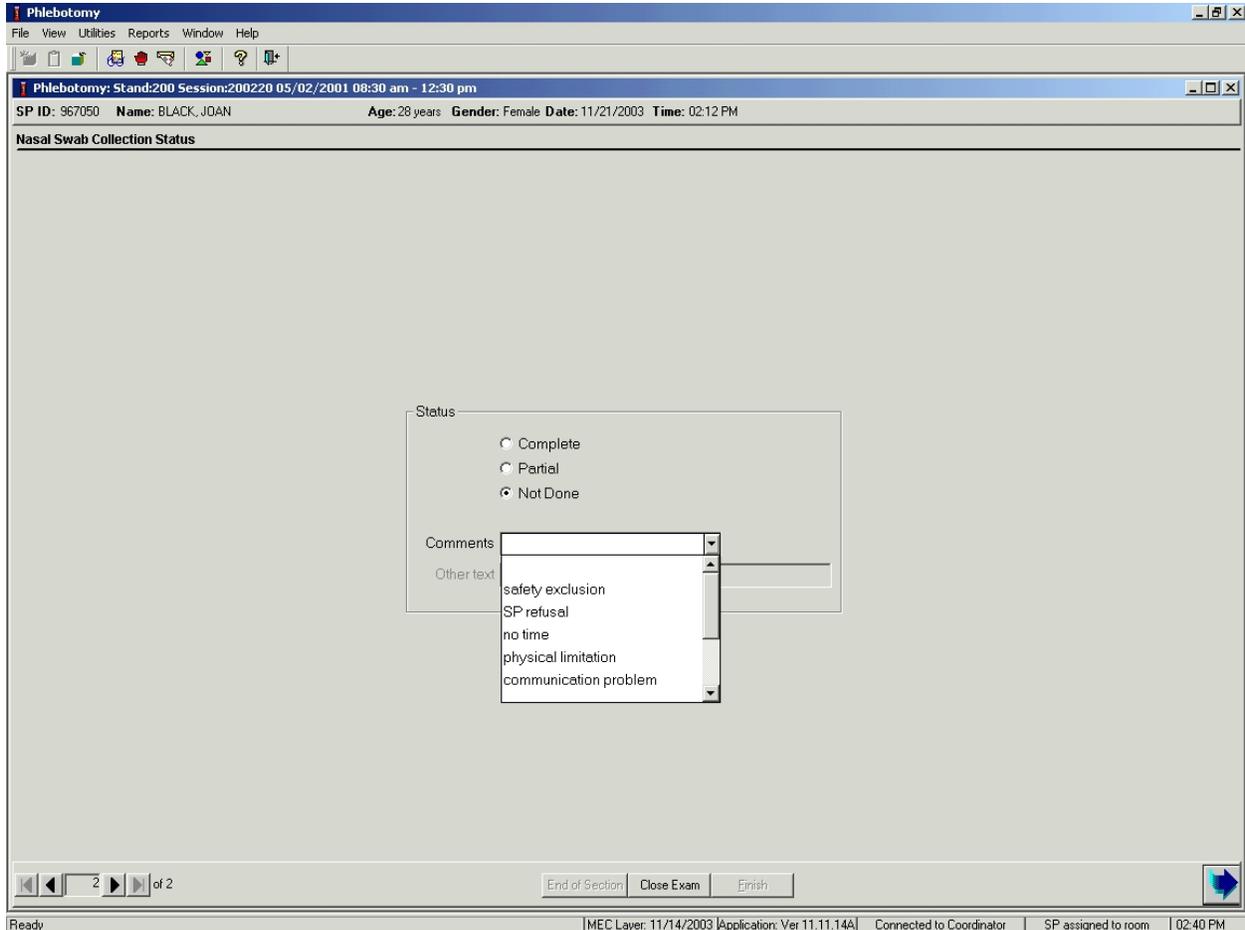
The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main content area is titled "Nasal Swab Collection Status" and contains a form with the following fields:

- Status:** A group box containing three radio buttons:  Complete,  Partial, and  Not Done.
- Comments:** A text input field with a dropdown arrow on the right.
- Other text:** A larger text input field below the comments field.

At the bottom of the window, there is a navigation bar with a "2 of 2" indicator, buttons for "End of Section", "Close Exam", and "Einish", and a blue arrow icon. The Windows taskbar at the very bottom shows the system tray with the text: "Ready | MEC Layer: 11/14/2003 | Application: Ver 11.11.14A | Connected to Coordinator | SP assigned to room | 02:40 PM".

Component status codes indicate the degree of component examination completion. There are two standard codes for the nasal swab section. The section exam status is complete if either naris or both nares were swabbed, and not done if neither naris was swabbed.

Choose and enter the appropriate comment code when the nasal swab collection section status is not done.



To record a comment in the Comments text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	The SP refuses to have a nasal swab collected. This is an SP initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator can code the exam. If the SP refuses after starting the exam, the examiner will code the exam.
no time	Not applicable
physical limitation	Not applicable
communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
equipment failure	Not applicable
SP ill/emergency	The SP became ill or an emergency occurred and the test could not be performed on the SP.
interrupted	Not applicable
other, specify	If the reason for a Not Done status code is not explained by one of the existing comment codes, choose Other, specify and type a free text comment in the text field.

When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click to progress to the end of the exam or select [Enter] when this blue arrow is highlighted.

## 15.6 Process the Nasal Swab in the Laboratory

The supplies needed for nasal swab collection, processing, and storage are listed in Exhibit 15.1.

Exhibit 15-1. Equipment and supplies – Nasal swab processing and storage

BBL Culture swab	Zip closable bag (9 x 12 clear)
Refrigerant gel packs	Medium shipper

### 15.6.1 Processing Protocol

Exhibit 15-2 illustrates the SP's protocol nasal swab processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 15-2. Nasal swab processing protocol

ID	Test name	Ages	Sample	Sample type	Vessel type	Appointment type
76	MRSA	1+	1 swab	Nasal swab	Culturette swab	Primary

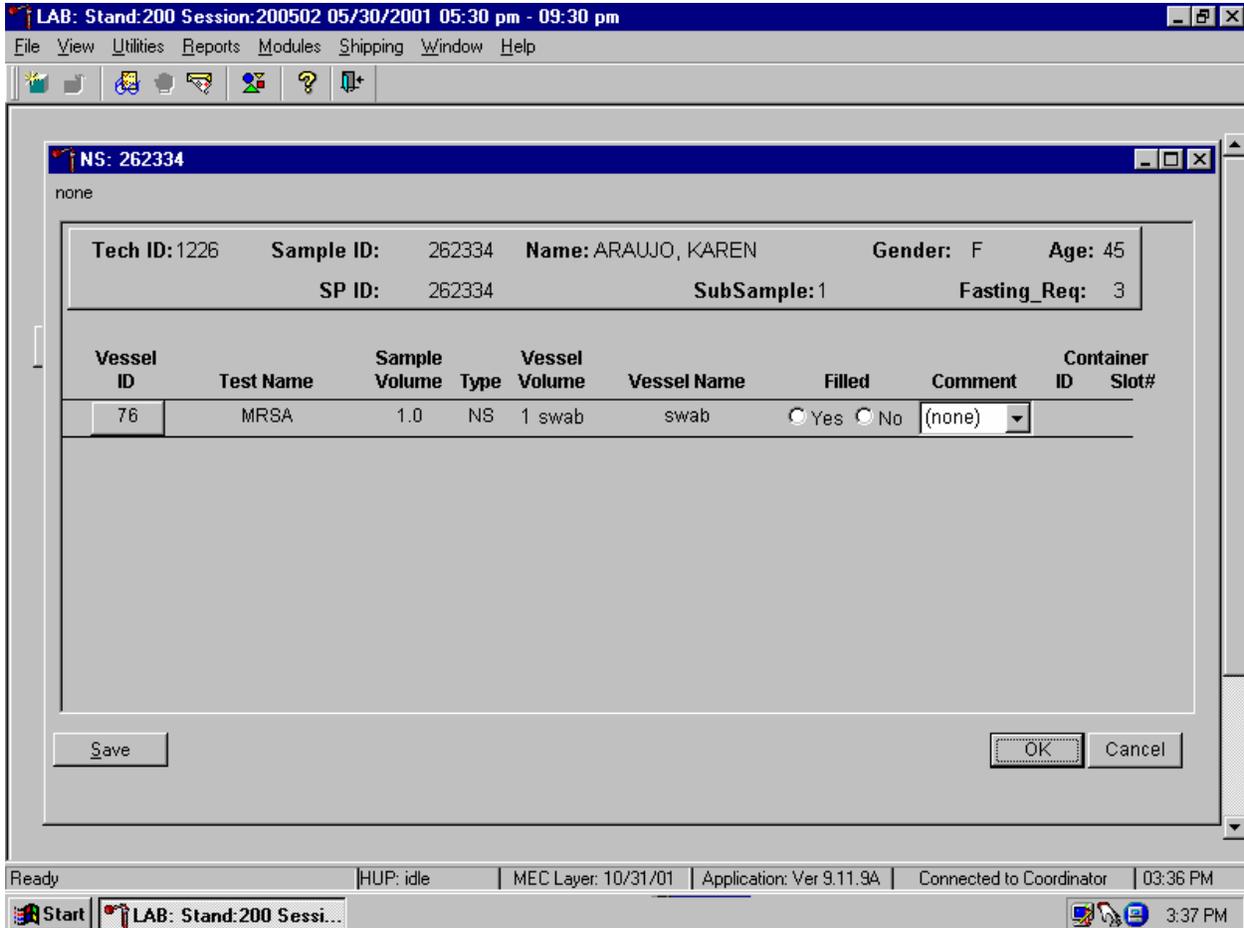
### 15.6.2 Labeling Vessels

The appropriate bar code labels automatically print when the specimen is recorded as collected in phlebotomy.

### 15.6.3 Record Processing Results

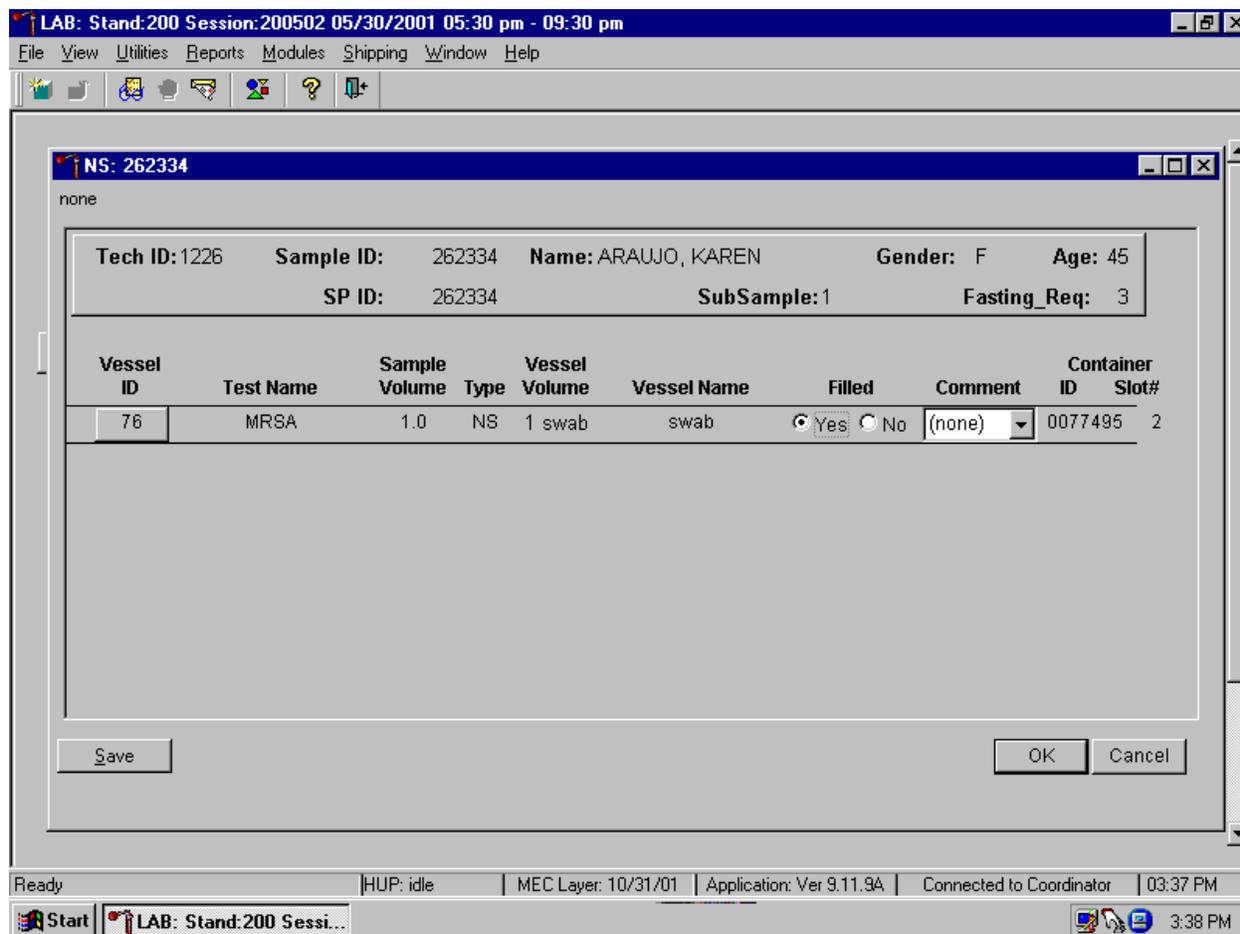
Open and log onto the laboratory application. Use the heads-up display to view the SPs scheduled into the session, the modules for which they are eligible, and their current process status.

The nasal swab (NS) processing window displays once the Nasal Swab processing module is selected for a SP.



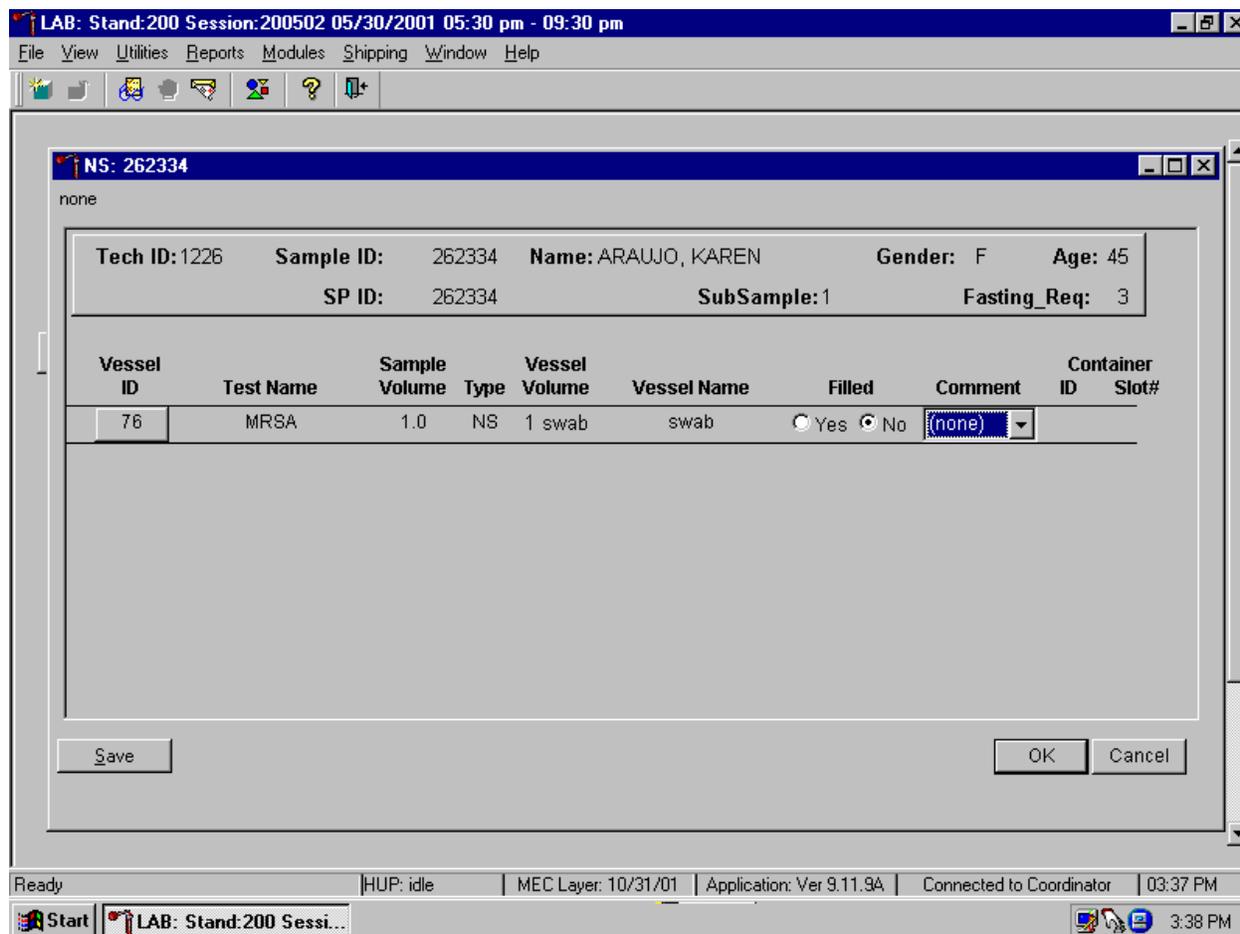
The nasal processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting\_Req, columns for Vessel ID, Test Name, Sample Volume, Type (NS), Vessel Volume, Vessel Name, Container ID/Slot #, and Filled “Yes” and “No” radio button and a Comment text box.

Mark each vessel as Filled “Yes.”



To mark an individual NS vessel as collected or “filled,” use the mouse to direct the mouse arrow to the center of the “Yes” radio button, and left click. As each vessel is marked as Filled – “Yes,” it is automatically assigned to a slot in an existing (open) container. Write the slot assignment number on the label of each swab.

Mark each vessel as Filled – “No.”



To mark an individual NS vessel as not collected or Filled – “No,” use the mouse to direct the mouse arrow to the “No” radio button and left click. There are no comments available for either a Filled – “Yes” or Filled – “No” result.

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button, and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter]. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

## 15.7 Specimen Storage

Record the nasal swab processing results and store the nasal swab in a 9 x 12 plastic bag in the refrigerator at workstation 2 (Exhibit 15-3).

Exhibit 15-3. Storage protocol for nasal swab

Shipping Location	Vessel	Condition	Vessel Storage
CDC/Data and Specimen Handling	76 MRSA	Refrigerated	9 x 12 plastic bag

## 15.8 Shipping Procedures

Ship vessel 76 to the CDC/Data and Specimen Handling in a medium shipper using refrigerant packs. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 15-4, the Shipping protocol, illustrates the specifications for the shipment of this biological specimen to the contract laboratory.

Ship the nasal swab in a medium shipper with sufficient refrigerant gel packs to maintain refrigerated conditions and ship weekly.

Exhibit 15-4. Shipping protocol

Location	Vessel	Test	Vessel storage	Shipping frequency
CDC/Data and Specimen Handling	76	MRSA	Refrigerated	Weekly

### 15.8.1 Pack and Ship Vessel 76 in a Refrigerated Medium Shipping Container

These instructions apply to vessel 76. Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant gel packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all

refrigerated containers in Styrofoam shippers. Exhibit 9-3 in Chapter 9 contains a list of all contract laboratory addresses.

Pack the specimen containers tightly in the Styrofoam container to prevent movement.

- Seal the 9 x 12 zip closable plastic bag.
- Place at least two large frozen refrigerant packs in the bottom of a shipper.
- Place the sealed plastic bag containing the swabs (vessel 76) on top of the refrigerant pack.
- Pack the sides with crumbled newsprint.
- Place two additional refrigerant packs on top of the container(s).
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place the appropriate shipping manifest and one return FedEx preprinted air bill into a 9 x 12 plastic bag and seal.
- Place the plastic envelope containing the appropriate shipping manifest and one FedEx preprinted air bill on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

### **15.8.2 Label Shippers**

Include one preprinted FedEx air bill in the shipment to CDC/Data and Specimen Handling.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Label shippers containing refrigerant packs with a “Refrigerate” label.
- Complete the section of the FedEx label that requests the weight of the contents of the shipper.

- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Add one additional strip of tape across the FedEx pouch.

## **15.9 How to Deal With System Failure**

If the computer system fails, record results on a preprinted Nasal Swab Processing worksheet (Exhibit 15-5). Complete a workstation 2 worksheet for each SP while processing the urine, MRSA, and/or BV specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 15-5. Nasal Swab Processing worksheet

**NASAL SWAB PROCESSING**  
MRSA Vessel 76

SP ID	Name	Age	Filled ✓	Container	Slot #

**15.10 References**

Chin, J. (2000). *Control of Communicable Diseases Manual*, 17<sup>th</sup> edition, American Public Health Association.

## 16. PHYSICAL ACTIVITY MONITOR

### 16.1 Introduction

The purpose of the Physical Activity Monitor component (PAMC) is to assess the physical activity levels of NHANES examinees 6+ years of age. Approximately 4,000 individuals are expected to participate in this component annually. NHANES examinees wear a physical activity monitor (PAM) to examine physical activity patterns over a 7-day monitoring period. The monitors detect locomotion-type activities such as walking or jogging. The monitors provide a means of capturing nonstructured activities that are often difficult for survey respondents (SPs) to self-report. Minors are included in this study because they are an important target population group for the NHANES nutrition assessment component. Physical activity data are linked to other household interview and health component data and are used to track changes that occur in body weight, functional status, bone status, and health status over time.

From a public health perspective, there is compelling data to show that physical inactivity is an independent risk factor for coronary heart disease (Berlin and Colditz, 1990). In the United States, a significant percentage of deaths from coronary heart disease, colon cancer, and Type 2 diabetes are attributable to sedentary lifestyle (Blair and Morrow, Jr., 1998). Even moderate-intensity activity is beneficial to overall health (Pate, JAMA, 1995) because it contributes to improved glucose tolerance and blood lipid profile levels. Additionally, NHANES 1999-2000 data demonstrates continued increases in the prevalence of obesity and overweight among all age groups of Americans.

The American College of Sports Medicine, the Centers for Disease Control and Prevention, the American Heart Association, the National Institutes of Health, and the President's Council on Physical Fitness and Sports recommend regular, moderate-intensity physical activity. *The U.S. Surgeon General's Report on Physical Activity and Health* reported that more than 60 percent of Americans do not engage in regular physical activity and that 25 percent do not engage in any activity (DHHS, 1996). The report reaffirmed the importance of regular moderate or vigorous-intensity activity. Until now, it has been difficult to assess actual physical activity levels in free-living populations because the cost and complexity of performing the monitoring tasks required to obtain this information were prohibitive. Furthermore, physical activity data on children, particularly children in the 6-11 year age group are lacking. Proxy information on physical activity levels among youth are not useful because children spend large amounts of time away from home and they engage in sporadic periods of activity that are difficult to

document, let alone quantify. Reliable, accurate methods are now available to assess physical activity levels in large groups of free-living individuals.

NHANES uses the CSA/MTI accelerometer model 7164 to monitor physical activity. The CSA/MTI monitor has a long record of accomplishment in clinical and community-based physical activity studies. The monitor enables researchers to examine the duration of physical activity at varying levels of intensity. In addition, the monitors have a step counter feature that provides another objective measure of physical activity. For example, some countries have set physical activity recommendations for population groups that are based upon a certain number of steps traveled per day.

### **16.1.1 Overview of the Phlebotomist's Responsibilities**

The MEC phlebotomist completes the blood collection procedure, which consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw. The phlebotomist also collects one additional blood tube on and administers a questionnaire to SPs selected for the VOC special study, collects a nasal swab to test for Methicillin-Resistant *Staphylococcus aureus* (MRSA), and then recruits SPs age 6+ to wear the physical activity monitor for 7 days. The phlebotomist instructs the SP to wear the PAM under or against light clothing on the right hip, during waking hours for seven (7) full days, beginning the day after their MEC examination. The phlebotomist initializes the monitor using the Reader Interface Unit (RIU), places it on a removable elastic belt that has a Velcro closure and fits the belt on the SP. The monitors are water resistant, but not waterproof and should be removed before swimming, showering, or bathing. The phlebotomist provides verbal and written instructions to the SP to reinforce these precautions.

The phlebotomist affixes a self-sticking label on the PAM. This label includes the participant's name to minimize confusion when multiple study participants reside in the same household. The NHANES logo and a toll-free "800" telephone number is embossed on the monitor case. Assistance will be provided by telephone if questions or problems arise during the study. English and Spanish speaking staff members are available to answer questions that arise during the study.

## **16.1.2 Overview of the Home Office Responsibilities**

Upon completion of the 7-day test period, survey participants mail the PAM device to the NHANES warehouse using a postage-paid padded envelope. Separate return mailing envelopes are provided for each survey participant's PAM device. Once the monitor is received at the home office, the warehouse staff downloads the data and cleans and calibrates each monitor. The warehouse staff checks the battery life and installs new batteries, when indicated. Monitors are revised.

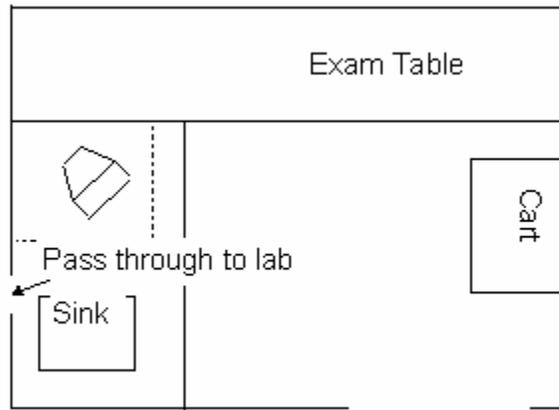
Participants receive a reminder post card at the end of the data collection period (7-8 days after the MEC exam). Upon receipt of the monitor back at the home office, a remuneration check for forty (\$40) dollars is mailed to the participant.

If the monitor is not returned within 12 days post-MEC exam, reminder contacts are initiated by the Westat phone center offices in Gaithersburg, MD. Monitors not returned within 12 days after MEC exam constitute a broken appointment. If a monitor is overdue, then a reminder notice displays at the end of the Dietary Phone Follow-up (DPFU) Interview. The dietary interviewer reminds the SP that they have a PAM monitor outstanding.

## 16.2 Equipment and Supplies

The phlebotomy room contains an exam table, a sink, data terminal, thermal transfer label printer, refrigerator, supply cart, and cabinets. Figure 16-1 illustrates the floor plan for the phlebotomy room.

Figure 16-1. Floor plan for phlebotomy room



At the start and end of each stand, take a complete inventory using procedures described in Chapter 11, Section 11.3.

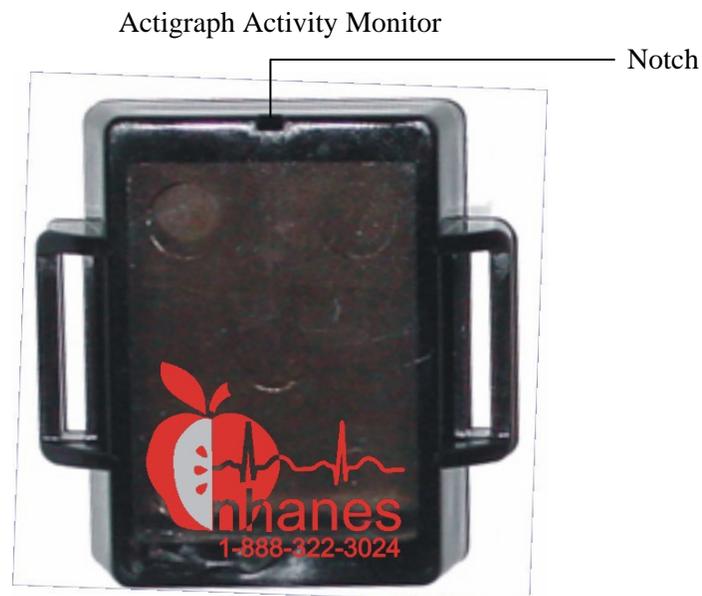
The equipment and supplies used in the PAMC are listed in Exhibit 16-1.

Exhibit 16-1. Equipment and supplies – physical activity monitor

<b>MEC</b>	
PAMC kits	Reader Interface Unit
Physical activity monitor	Lister scissors
Elastic belt with Velcro® closure (80 inches)	Intermec labels
Information sheet	Intermec thermal transfer ribbon
2 Informational flyers from NCHS	Padded mailers
<b>Warehouse</b>	
Screwdriver	Reader interface Unit
Duracell batteries	Calibrator

### 16.2.1 Actigraph Monitors

The activity monitor (Actigraph) is a single axis accelerometer that has been programmed to detect normal human motion and reject motion from other sources (see picture below). The data collected by the monitor is a series of numbers representing a level or intensity of activity in a set period of time (1-minute intervals). The accelerometer sensor element is not located in the center of the case but it is located at the end of the case opposite the end of the notch. For this reason, consistent orientation of the monitor on the belt and the belt on the SP is critical. The monitor runs on a CR2430 coin-cell lithium battery.



### 16.2.2 Reader Interface Unit

The activity monitor interfaces with a computer using a reader interface unit (RIU) connected to the computer in the phlebotomy room. The activity monitor must be placed correctly on the RIU in order for the monitor to be initialized. The activity monitor should be placed with the back cover and screws facing up. The notched end of the activity monitor should be directly over the finger access slot in the front wall of the RIU.

### **16.2.3 Warehouse Responsibilities**

The warehouse staff assembles PAMC kits. Each PAMC kit consists of one activity monitor, one elastic belt, one information sheet, and two copies of an informational flyer in a padded return envelope. The padded envelope is labeled with a business reply postage-paid label.

### **16.3 Overview**

The coordinator tracks each SP through the MEC using the coordinator system. This system tracks the SP throughout the exam, including arrival, location during the session, and exit. The coordinator uses this system to direct the SP to the appropriate workstations in the MEC and to determine if all the appropriate examinations are complete. The MEC coordinator monitors exam component status using responses from examination stations.

The NHANES dietary interview proxy rules apply to the PAM component for wearing and removing the monitors during the study. Proxies (preferably a parent or guardian) assist survey participants who are 6-11 years of age at the time of the examination. Respondents 12 years of age and older receive instructions on how to wear their monitor and remove the monitor before going to bed.

Each SP receives a bar-coded ID bracelet upon arrival at the MEC. The bracelet remains on the SP throughout the session. This bracelet contains the SP's ID number in bar code and eye-readable format. The phlebotomist "wands" the bracelet bar code with a bar code scanner (wand) to log the SP into the phlebotomy component. If necessary, the ID number can be entered manually by reading it from the bracelet.

The phlebotomist is responsible for completing sections within the Phlebotomy exam:

- Venipuncture
- VOC special study
- Nasal swab collection
- Physical activity monitor

Access the phlebotomy application and open the phlebotomy exam. Log the SP into phlebotomy by scanning the bar code on the SP ID bracelet or manually typing the SP ID when the SP arrives in phlebotomy.

Complete the blood collection procedure, which consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw. Collect one additional blood tube on and administer a questionnaire to SPs selected for the VOC special study, collect a nasal swab to test for Methicillin-Resistant *Staphylococcus aureus* (MRSA), and then recruit SPs age 6+ to wear the physical activity monitor for 7 days. Explain the purpose of this component and how to wear and return the monitor. Instruct the SP to wear the PAM under or against light clothing on the right hip, during waking hours for seven (7) full days, beginning the day after their MEC examination. Initialize the monitor, place it on a removable elastic belt that has a Velcro closure, and fit the belt on the SP. The monitors are water resistant, but not waterproof and should be removed before swimming, showering, or bathing. Provide verbal and written instructions to the SP to reinforce these precautions.

### **16.3.1 PAMC Kits**

Each SP will receive a Velcro® stretch belt onto which the monitor is attached. The belts come in one size – 80 inches. The phlebotomist cuts the belt to the approximate size, places the monitor on the belt, fits the belt on the SP, and trims the belt.

Each SP will be given:

- One monitor on a Velcro® elastic belt.
- Two copies of an informational flyer on survey letterhead explaining the activity monitor.
- One copy of an information sheet that summarizes the details relating to the monitor.
- One padded envelope (with the postage-paid sticker) to use when returning the monitor.

## 16.4 Gaining Cooperation

The coordinator introduces the SP to the examination and briefly explains the examination process. The coordinator can answer any general questions the SP has about the phlebotomy exam, including the PAMC. However, the phlebotomist must be prepared to answer all the questions the SP poses about the phlebotomy procedures. In addition, the phlebotomist must convince the SP of the importance of cooperating in the PAM component. (SPs do not receive any results.)

If a SP initially refuses the component, then ask questions to determine the reason for the refusal and try to address any concerns the SP has in order to have them complete the component. Provide reassurance and encouragement. If they still refuse, code the exam as an SP refusal. If the SP is planning to be out of the country for the next few weeks, assess their ability to remember to return the monitor. To address SP's concerns effectively, know the following information about the procedures used for the study:

### Safety

- There is no reason to exclude mentally impaired or handicapped individuals who are mobile. A proxy respondent can assist mentally challenged individuals with their monitors. Exclude individuals who use a wheelchair.
- There are no known risks associated with use of the monitors. The activity monitor is not waterproof but if the monitor accidentally gets wet, this does not pose a danger. The Actigraph is powered by a 3-volt watch battery, which does not present a shock hazard when worn in a wet environment. The battery is housed securely inside the device and a special screwdriver is required to open the device. The PAM device does not emit radiation, electrical current, vibration, or heat and it can be worn under clothing without causing discomfort or embarrassment.

**Note to MEC staff:** Do not attempt to open the monitor. The screws are tiny and delicate. The home office staff has special equipment to use when opening the cases.

- There is a small risk of accidental choking if the device is removed from the web belt and left within reach of small children or pets. The CSA/MTI device dimensions are 2 inches x 1.5 inches x ½ inch. The device is intended to be worn or stored securely fastened to a long, ¾ -inch wide belt at all times. There is no reason for the device to be removed from the belt.
- The other potential hazard is that the waist belt could catch on something. The belt should be securely fastened to the waist-hip area. Information about potential safety

concerns will be included in written materials that are given to the survey participants and proxies and included in the scripts that are used by staff in the MEC.

- The PAM will not interfere with a pacemaker.

#### 16.4.1 Answering Questions

**1. Will the monitor harm me in any way?**

No, the monitor will not harm you in any way. A small watch battery that is securely housed in the device powers the monitor. The monitor does not emit radiation, electrical current, vibration, or heat and it can be worn under your clothing without causing discomfort or embarrassment.

**2. I play a team sport and we are not allowed to wear jewelry. How do I explain this to my coach?**

We are providing you with two copies of an informational flyer to show anyone who asks about your participation in this study. Keep the letter with you, so you can respond to questions.

**3. What do I need to do if I have to go through a metal detector (at airport, school, government building)?**

Please take the belt off and put it in the bin to be screened. This will not harm the monitor in any way. In addition, please keep the informational flyer we provided to show security personnel.

**4. I swim a lot, what do I need to do?**

Do not wear the monitor while swimming. The monitors should not get wet.

**5. What do I do if I lose the envelope?**

Call the toll-free number we provided you and another mailer envelope will be sent to your home.

**6. I will be out-of-town during the next week.**

It is OK to participate while you are out-of-town. You can mail the monitor back to us from any location within the United States.

## 16.4.2 Background

It is helpful to understand the NCI research activities in the area of physical activity. Use this information to answer questions.

The Division of Cancer Control and Population Sciences conducts a variety of epidemiological, surveillance, and behavioral research activities to explore the association between physical activity and a number of cancer sites. The Division's research objectives are posted on their web site: [http://dccps.nci.nih.gov/DECC/dwpa\\_pa.html](http://dccps.nci.nih.gov/DECC/dwpa_pa.html). The areas of research that are especially relevant to NHANES include:

- The characteristics of physical activity such as frequency, intensity, and types of activities people engage in—topics that are included in NHANES questionnaires are of interest.
- Methodological research interests include development of improved, standardized methods for assessment of physical activity, especially those for lifetime history, adolescent, and young adult physical activity.
- The association of physical activity with site-specific cancer for diverse populations defined by age, income, education, and race or ethnicity

In the area of surveillance, and as noted in the *Surgeon General's Report on Physical Activity and Health* (1996):

- Develop methods to monitor patterns of regular, moderate physical activity.
- Improve the validity and comparability of self-reported physical activity in national surveys.

Behavioral research targets the following:

- Examine the impact of physical activity and physical activity interventions on other cancer-related risk behaviors.
- Examine the impact of psychosocial sequelae of survivorship on weight, weight management, physical activity, and diet.

## **16.5 Exclusions**

There are only a few reasons to exclude a SP from this component. They are as follows:

- The SP's girth is too large to accommodate the belt. This includes pregnant SP when the belt will not fit around their waist. Pregnancy alone is not an exclusion. The SP is excluded only if their waist is too big for the belt.
- The SP is in a wheelchair.
- The SP had recent abdominal surgery.

## **16.6 Recruiting SPs Who Do Not Speak English**

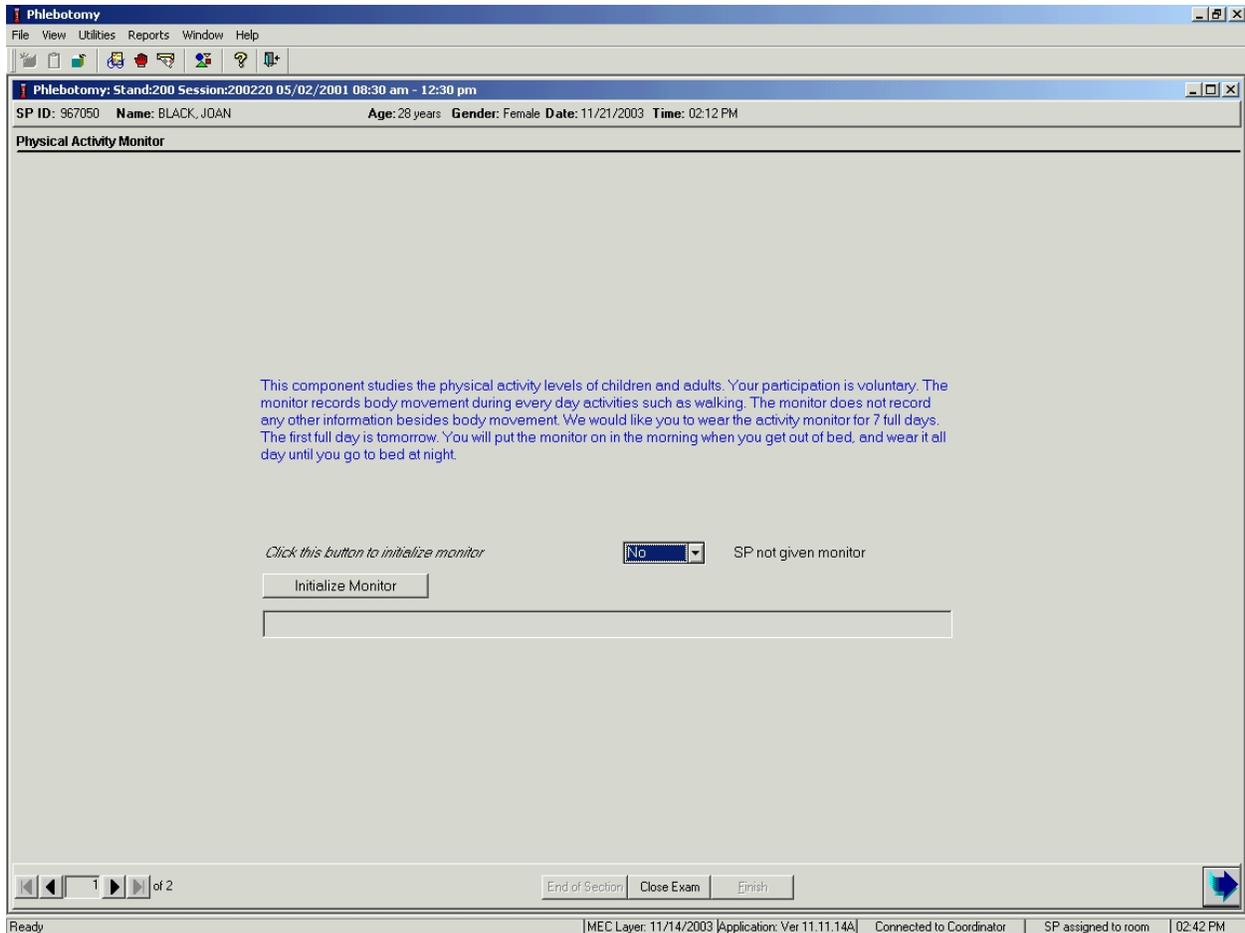
When the phlebotomist attempts to recruit a SP who does not speak English and the phlebotomist does not speak the language of the SP, a translator who does speak the language of the SP assists the phlebotomist.

The translator stays with the phlebotomist and the SP for the entire procedure. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the procedure.

## 16.7 Recruit the SP

Introduce the PAM as the “next component” in the phlebotomy exam. Simply state that the SP has been selected for this component.

The Physical Activity Monitor slide displays after the nasal swab section status slide.



The Physical Activity Monitor slide includes a script, an Initialize Monitor button, an SP not given monitor drop-down list, and a blank progress bar. Read the script as displayed. Additional talking points are displayed on the wall-mounted summary script. Use the following summary scripts (Exhibits 16-2 and 16-3) to reinforce the important points.

Exhibit 16-2. PAM script – English

**Physical Activity Monitor**

- This component studies the physical activity levels of children and adults.
- The monitor records body movement during everyday activities such as walking.
- Your participation is voluntary.
- The monitor runs on a watch battery, is safe, and will not cause discomfort when worn.
- Wear the monitor all day, every day, for 7 days except when you shower, bathe, or go swimming.
- Put the monitor on when you get up in the morning and take it off before you go to bed.
- Your first full day wearing the monitor is tomorrow, however we would like you to start wearing the monitor when you get dressed before leaving here today.
- The monitor is worn on a belt. I will place the monitor on the belt and fit the belt on you.
- It is best to keep the monitor fastened on the belt to reduce the chance of losing it.
- Mail the monitor back to our home office at the end of the 7-day period.
- Place the monitor in the postage-paid padded envelope and drop the envelope in any United States Postal Service mailbox as soon as possible.
- Please do not return the belt.
- When we receive the monitor we will mail you a check for \$40.
- If the monitor is not returned you will not be paid.
- Two copies of an information letter about the study are included. These are included in case you need to provide schools, camps, or work offices with information about the study.
- When passing through metal detectors at airports and work sites, it would be best to remove the monitor and put it in a separate bin for scanning. If questioned about the monitor, please show the information letter to security personnel.
- If you have questions, please call our office using the toll-free number that is listed on the bottom of the information and instruction sheets.

Exhibit 16-3. PAM script – Spanish

**Monitor de Actividad Física**

- Este componente estudia los niveles de actividad física de niños y adultos.
- El monitor registra los movimientos del cuerpo durante actividades diarias, tal como caminar.
- Su participación es voluntaria.
- El monitor funciona con una pila de reloj, es seguro y no le causará incomodidad mientras lo lleva.
- Use el monitor todo el día, todos los días por 7 días excepto cuando se ducha, se baña, o va a nadar.
- Póngase el monitor cuando se levanta en la mañana y quíteselo antes de acostarse.
- Su primer día completo para llevar el monitor es mañana, sin embargo quisiéramos que empezara a llevar el monitor cuando se vista antes de irse hoy de aquí.
- El monitor se lleva con un cinturón. Pondré el monitor en el cinturón y le ajustaré el cinturón.
- Es mejor llevar el monitor abrochado al cinturón para reducir la posibilidad de perderlo.
- Mande por correo el monitor a nuestra oficina al fin del período de 7 días.
- Ponga el monitor en el sobre abullonado con porte prepago que le dieron y ponga el sobre en cualquier buzón del Servicio Postal de Estados Unidos lo antes posible.
- Por favor no devuelva el cinturón.
- Cuando recibamos el monitor le mandaremos un cheque por \$40.
- Si no devuelve el monitor no se le pagará.
- Hemos incluido dos copias de una carta informativa acerca del estudio. Estas se incluyen en caso de que usted necesite proporcionar información acerca del estudio a escuelas, campamentos, u oficinas de trabajo.
- Cuando pase por un detector de metales en aeropuertos y lugares de trabajo, lo mejor será que se quite el monitor y lo ponga en un recipiente para que lo pasen por el escáner. Si le preguntan acerca del monitor, por favor muestre la carta informativa al personal de seguridad.
- Si desea hacer alguna pregunta, por favor llame a nuestra oficina usando el número gratis que está anotado en la parte de abajo de las hojas informativas y de instrucción

## **16.8 Complete the PAM Section of the Phlebotomy Exam**

The activity monitor interfaces with a computer using a reader interface unit (RIU) connected to the computer in the phlebotomy room. Once the SP has agreed to participate, the phlebotomist puts the monitor in the RIU cradle and selects the initialization button. The activity monitor must be placed correctly in the RIU cradle in order for the monitor to be initialized. The activity monitor should be placed with the back cover and screws facing up. The notched end of the activity monitor should be directly over the finger access slot in the front wall of the RIU. When initializing and downloading make sure the PAM is inserted properly into the RIU; the Light Emitting Diode (LED) should be visible when the PAM is inserted correctly. The flashes of the LED are observable as a reflection in the mirrored surface located in the ejection port of the RIU. To extend battery life, remove the PAM from the RIU after completing the initialization or data download.

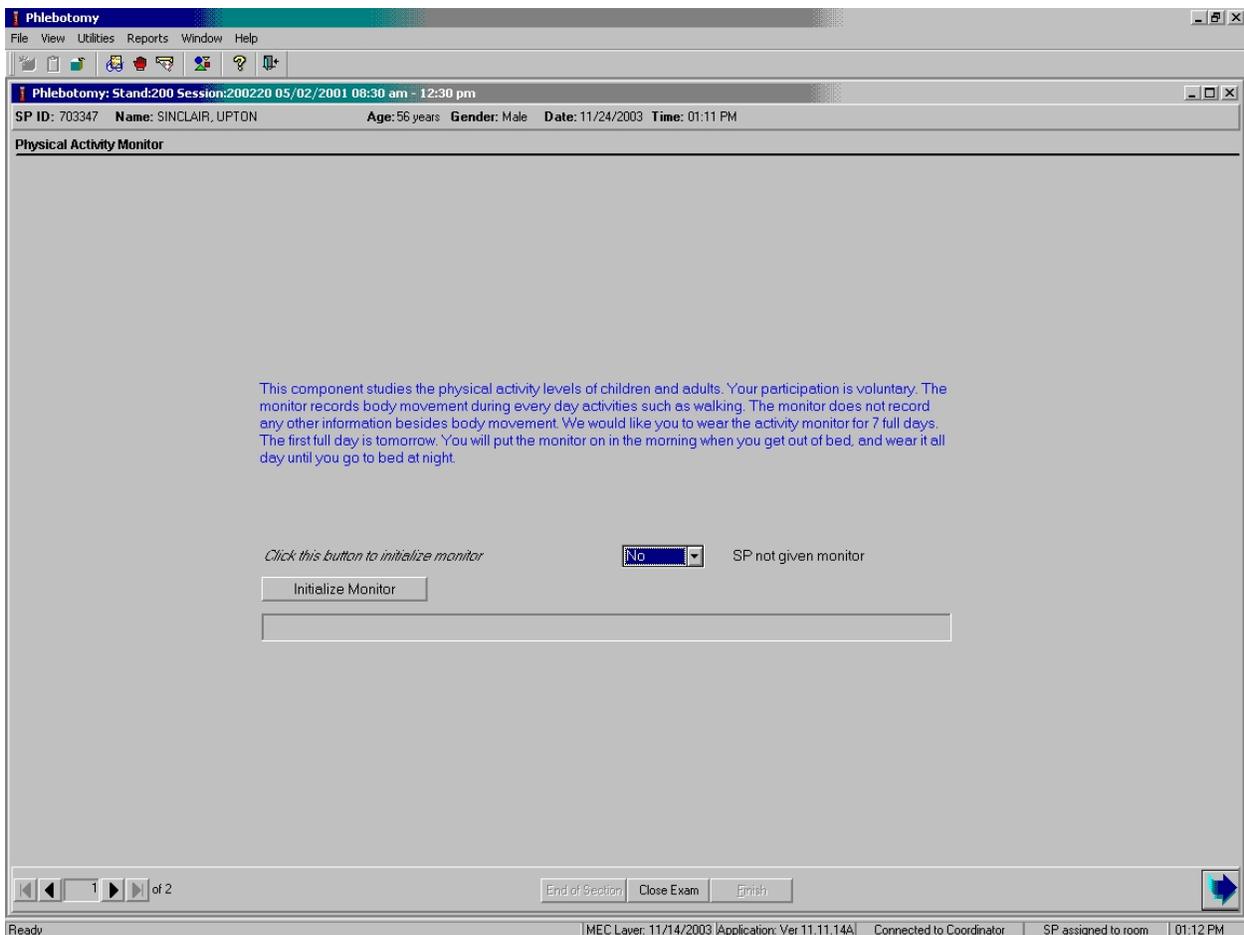
There are three messages the phlebotomist may see while initializing. The first comes up if the monitor has already been initialized during the session. The program will not allow the same monitor to be initialized twice in a session. The second potential message appears if the monitor is not seated in the cradle correctly. It displays a message that indicates that it cannot read the serial number. This last message informs the phlebotomist the initialization is complete. If there are no problems with the initialization, this is the only message the phlebotomist will see. One additional popup window flashes on the screen. It indicates that the application is creating the Pf\_appt (phone follow-up appointment). Do not press the Initialize button again.

If the SP agrees to participate and the monitor initializes successfully, the section status is Complete. If the SP is excluded or declines (refuses) to participate, then select "yes" from the SP not given monitor dropdown list; the section status is Not Done. Select and record the appropriate the comment for this Not Done section status.

## 16.8.1 Initialize the Monitor

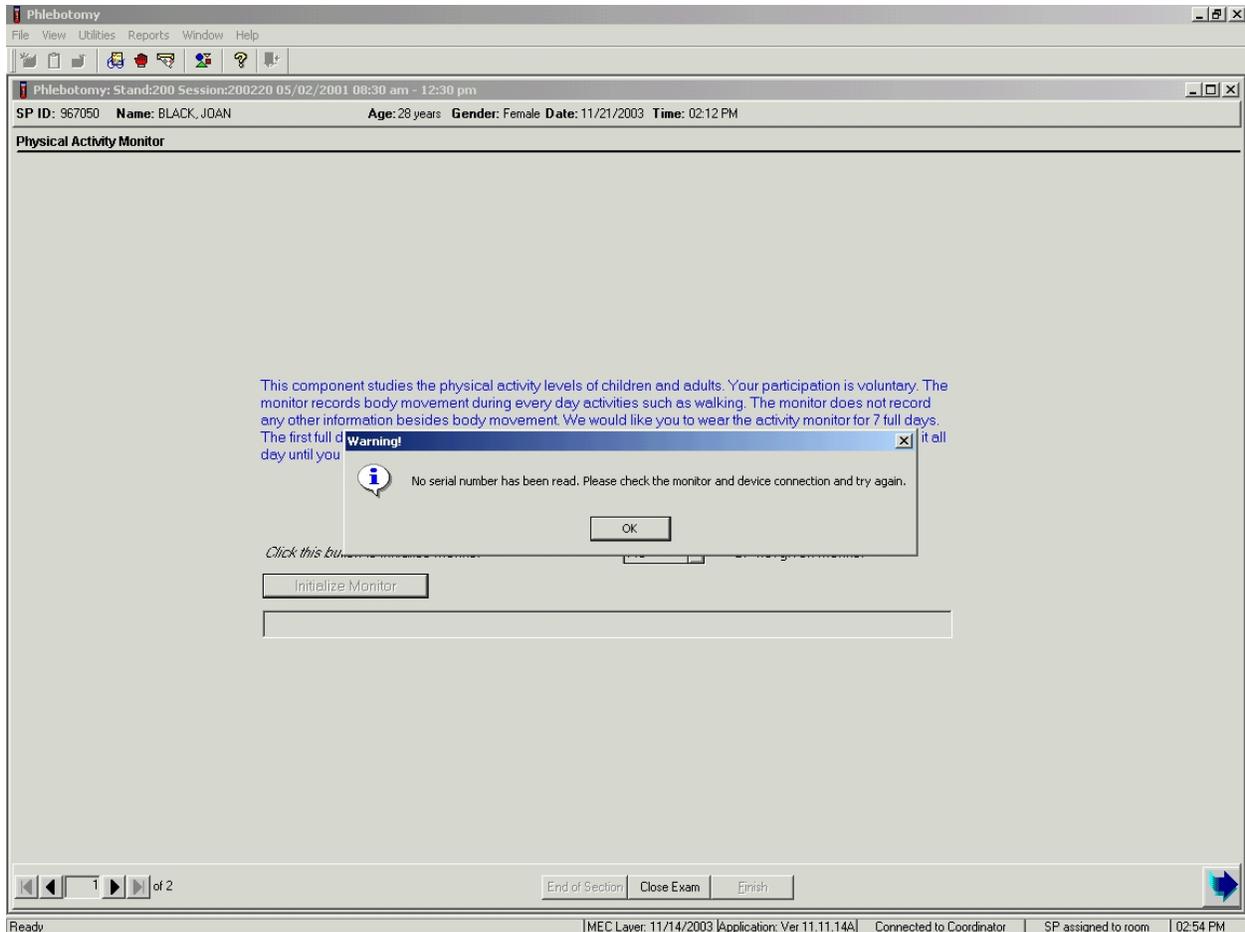
If the SP is eligible for the PAMC then the Physical Activity Monitor (initialization) slide will display after the nasal swab status slide.

Visually inspect the monitor. Read the script and introduce the SP to the component. To initialize the device, place the PAM in the RIU with the screws facing up and the notched end over the finger access slot in the front of the unit.



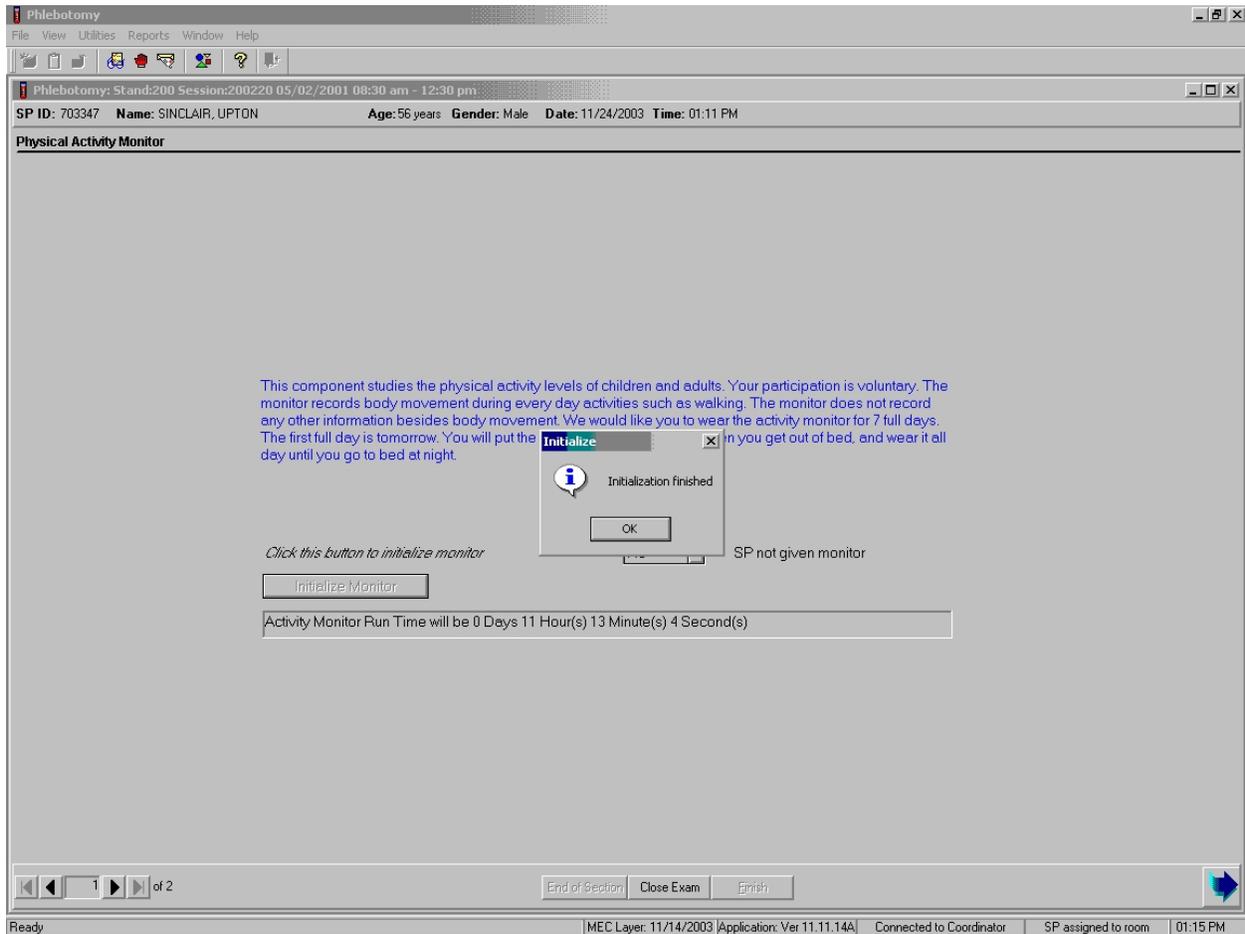
To initialize the PAM, use the mouse to direct the mouse arrow to the Initialize Monitor button and left click. The RIU may or may not display a series a red flashes as the monitor is being initialized. The Initialize Monitor button will gray out while the monitor is being initialized. The read-only progress bar displays the initialization steps.

If the initialization is unsuccessful, a warning message displays.



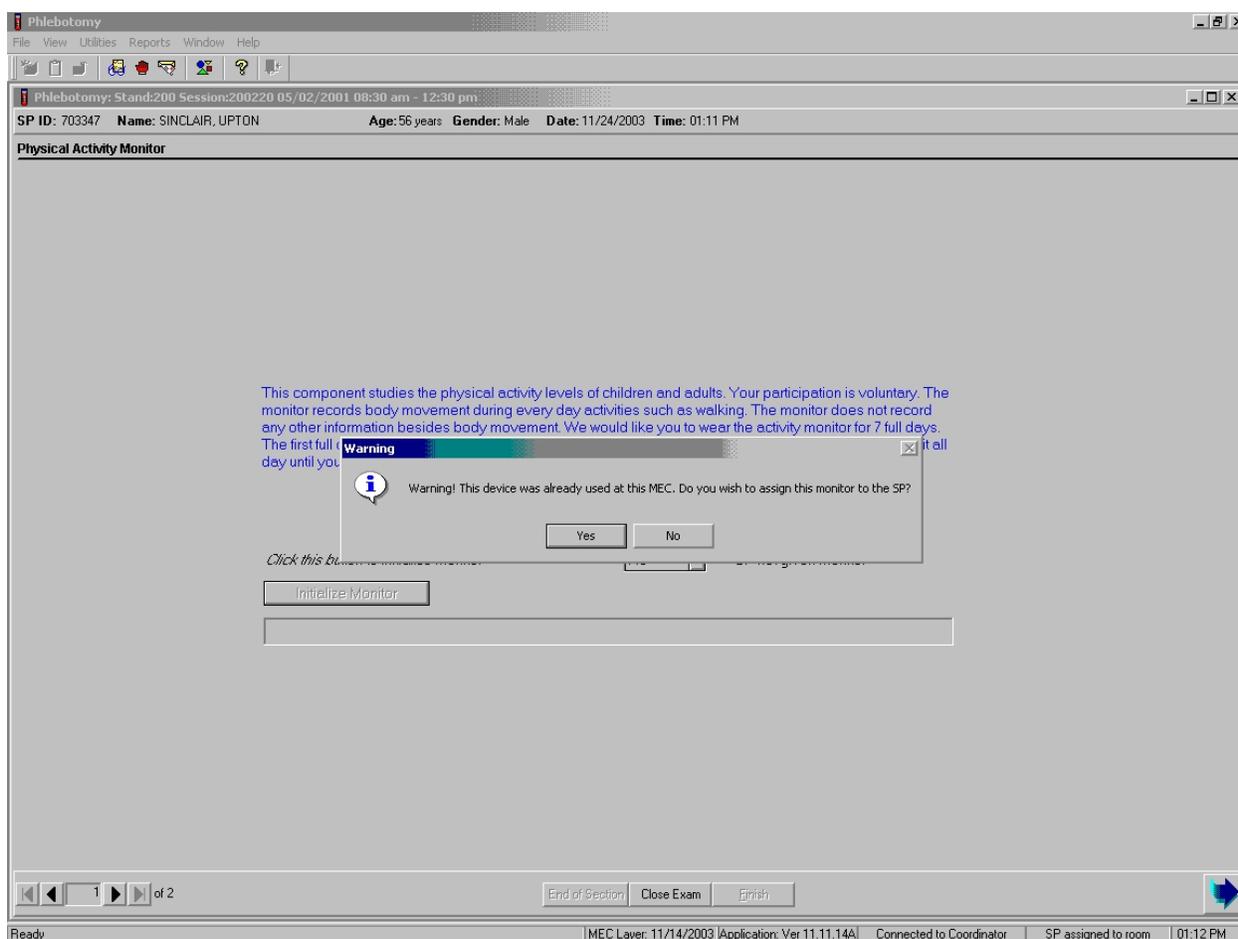
Review the message in the warning window and follow the instructions. To remove the warning message, use the mouse to direct the mouse arrow to the OK button and left click. Check the placement of the monitor in the RIU and select the Initialize Monitor button again. If the second attempt is unsuccessful, repeat the process with another monitor.

If the initialization is successful, an initialize informational window displays.



To remove the Initialize window, use the mouse to direct the mouse arrow to the OK button and left click. To move forward to the PAM section status slide, use the mouse to direct the mouse arrow to the bright blue button in the lower right hand corner and left click. Do not select [Enter] because it fires off another initialization sequence.

It is acceptable to initialize the same monitor more than once.



Verify that the monitor has not been assigned to another SP. To remove the warning message box and assign the monitor to the SP, use the mouse to direct the mouse arrow to the Yes button and left click or type [Enter]. To remove the warning message and skip the assignment of this monitor to this Sp, use the mouse to direct the mouse arrow to the No button and left click.

Once the monitor has been initialized, the Intermec printer in the phlebotomy room prints one bar-coded label. The label contains an up directional arrow, the SP's name, and a bar code. Place the label on the back (side with the screws) of the monitor with the arrow pointed toward the notched end of the monitor.

## 16.8.2 SP Not Given Monitor

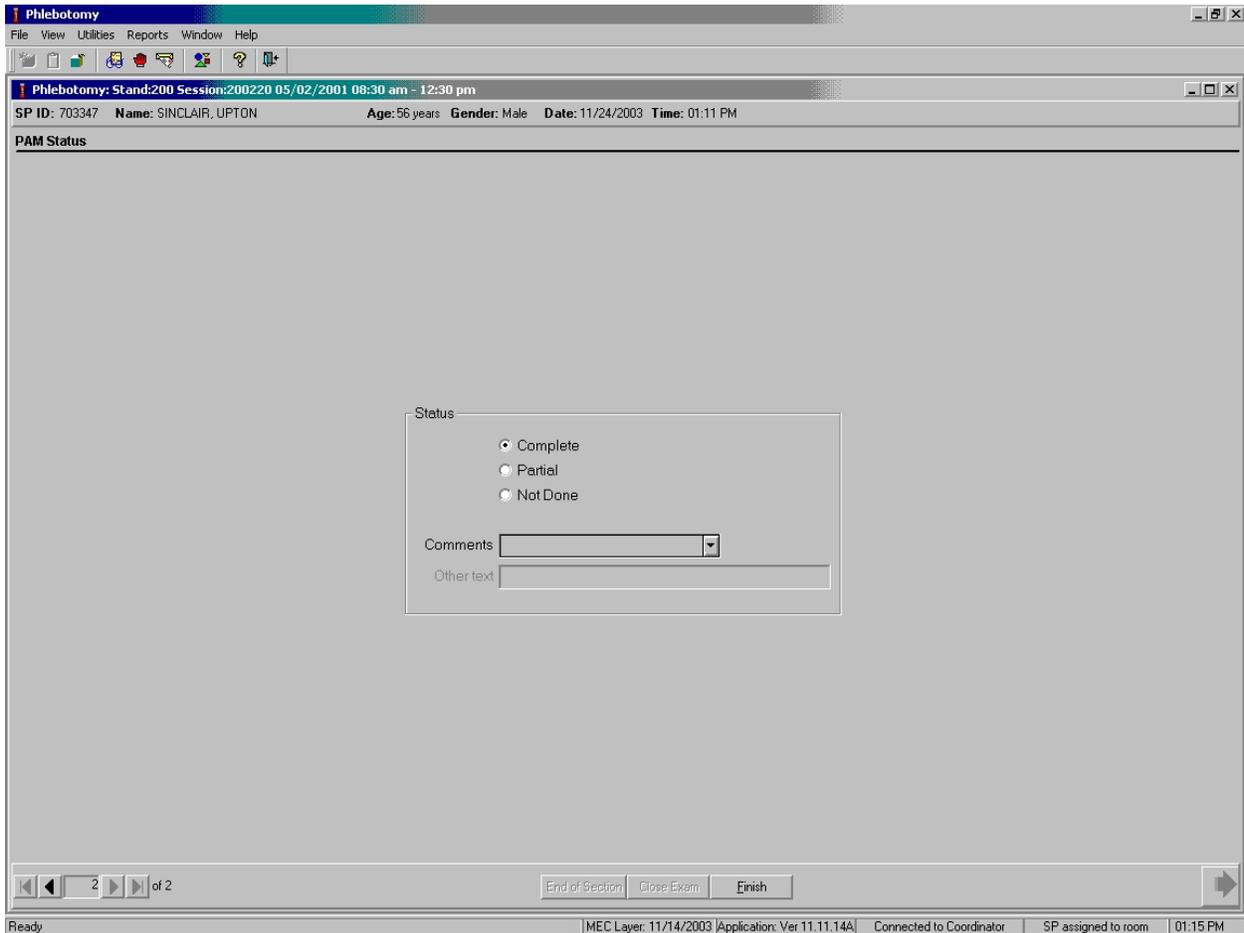
The SP not given monitor text box will default to “No”, indicating that the SP is not excluded. If the SP is excluded or the recruitment is unsuccessful, select “yes” from the SP not given monitor drop-down list.

The screenshot displays the Phlebotomy software interface. At the top, the window title is "Phlebotomy". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains various icons. The main content area has a header bar with "Phlebotomy: Stand:200 Session:200220 05/02/2001 08:30 am - 12:30 pm". Below this, a status bar shows "SP ID: 967050 Name: BLACK, JOAN Age: 28 years Gender: Female Date: 11/21/2003 Time: 02:12 PM". The main section is titled "Physical Activity Monitor" and contains the following text: "This component studies the physical activity levels of children and adults. Your participation is voluntary. The monitor records body movement during every day activities such as walking. The monitor does not record any other information besides body movement. We would like you to wear the activity monitor for 7 full days. The first full day is tomorrow. You will put the monitor on in the morning when you get out of bed, and wear it all day until you go to bed at night." Below the text is a button labeled "Initialize Monitor" and a drop-down menu with "Yes" selected, followed by the text "SP not given monitor". At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the very bottom shows "Ready", "MEC Layer: 11/14/2003", "Application: Ver 11.11.14A", "Connected to Coordinator", "SP assigned to room", and "02:58 PM".

To record "Yes" in the SP not given monitor text box, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to "Yes", and left click or type [Y/y]. To move forward to the PAM section status slide, use the mouse to direct the mouse arrow to the bright blue button in the lower right hand corner and left click or select [Enter].

### 16.8.3 Section Status

Review the section status slide for SPs who agree to participate.



The section status is Complete if the SP agrees to participate and the monitor is successfully initialized. To complete the PAM section of the phlebotomy exam, use the mouse to direct the mouse arrow to the Finish button in the navigation bar and left click or press [Enter] when the Finish button is highlighted.

Review the section status slide for SPs who are excluded or who do not agree to participate.

The screenshot shows a software window titled "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window header displays "Phlebotomy: Stand:200 Session:200220 05/02/2001 08:30 am - 12:30 pm". Below this, patient information is shown: "SP ID: 967050 Name: BLACK, JOAN Age: 28 years Gender: Female Date: 11/21/2003 Time: 03:02 PM". The "PAM Status" section is the primary focus, containing a "Status" field with three radio button options: "Complete", "Partial", and "Not Done". The "Not Done" option is selected. Below the status field are two input areas: "Comments" with a dropdown menu and "Other text" with a text box. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the very bottom shows "Ready", "MEC Layer: 11/14/2003", "Application: Ver 11.11.14A", "Connected to Coordinator", "SP assigned to room", and "03:09 PM".

The section status is Not Done if “Yes” is entered in the SP not given monitor text box.

Choose and enter the appropriate comment code when the section status is Not Done.

The screenshot shows the Phlebotomy software interface. At the top, the window title is "Phlebotomy". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains various icons. The main window displays patient information: "Phlebotomy: Stand:200 Session:200220 05/02/2001 08:30 am - 12:30 pm", "SP ID: 967050", "Name: BLACK, JOAN", "Age: 28 years", "Gender: Female", "Date: 11/21/2003", and "Time: 03:02 PM". Below this is a "PAM Status" section. A dialog box is open, titled "Status", with three radio buttons: "Complete", "Partial", and "Not Done". The "Not Done" option is selected. Below the radio buttons is a "Comments" section with a drop-down list showing "SP refusal". Below that is an "Other text" section with a text input field containing "safety exclusion". The drop-down list is open, showing a list of comment codes: "SP refusal", "no time", "physical limitation", and "communication problem". The "SP refusal" option is highlighted. At the bottom of the dialog box, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The bottom status bar of the software shows "Finish slide show", "MEC Layer: 11/14/2003", "Application: Ver 11.11.14A", "Connected to Coordinator", "SP assigned to room", and "03:11 PM".

To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice and left click. Alternatively, to select a comment code, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click. If "Other, specify" is chosen, type a short explanation in the "Other text" text box.

Comment Code	Use when:
safety exclusion	The SP had recent abdominal surgery.
SP refusal	The SP refuses to participate. This is SP initiated nonresponse due to refusal. The SPs refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam.
no time	Not applicable
physical limitation	The SP's girth is too large to accommodate the belt. This includes pregnant SPs when the belt will not fit around their waist. Pregnancy alone is not an exclusion. The SP is excluded only if their waist is too big for the belt.
communication problem	Not applicable
equipment failure	Use the comment if the Reader Interface Unit fails or breaks.
SP ill/emergency	Use the comment when the SP faints or is about to faint or the SP became ill or an emergency occurred and the test could not be performed on the SP.
interrupted	Not applicable
Error (technician/software/supply)	Use this comment when there are phlebotomist errors or software or supply issues. Complete an Unusual Occurrence Form.
Wheelchair bound	Use this comment if the SP is in a wheelchair.
other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

To complete the PAM section of the phlebotomy exam, use the mouse to direct the mouse arrow to the Finish button in the navigation bar and left click or press [Enter] when the Finish button is highlighted.

## **16.9 Fitting, Wearing, and Returning the Monitor**

Place the Intermec label on the monitor, the monitor on the belt, and fit the belt on the SP. It is acceptable to place the belt and monitor on the top of a lumbar support (girdle) and on the left side as long as the monitor will not be damaged during routine wear. Keep a placebo monitor on a belt in the room as a demo and visual aid.

The information sheet has a toll-free number for the SP to call if they have questions. The information sheet is printed on light green paper and has English text on one side and a Spanish translation on the other. Each SP receives one copy.

Review and give one copy of the information sheet to the SP. Calculate the last day that the SP will wear the monitor; add 8 days to the exam date since the SP wears the monitor for 7 days beginning with the first day after their MEC exam. Record this date on the first line on the information sheet.

*The last day you will wear the monitor is \_\_\_\_\_*  
(Example - If the SP's MEC exam date is January 6, add 8 days and write January 13 on the line.)

Review and give two copies of the informational flyer describing the component to the SP. This information flyer has a toll-free number for the SP to call if they have questions. The informational flyer is printed on NHANES letterhead and has English text on one side and Spanish on the other. Each SP receives two copies.

Complete the following steps for each SP:

- Place the label on the monitor.
- Estimate the correct length and trim the belt before beginning to place the monitor onto the belt.
- Put the monitor on the belt with the proper side up.
- Ask the SP to stand.
- Close the door for privacy.
- Fit the belt with the monitor attached around the SP's waist. The belt should be buckled snugly around the SPs waist so that the monitor rests on the **right** side of the SPs body, close to their right hip, and the Velcro® closure is centered. The belt and the monitor should be worn under the SPs clothing.
- Trim the belt so that 4 inches remain. Be sure to trim the correct end of the belt. Leave the "easy-peel" end intact and trim the other end.
- Calculate the last day that the SP will wear the monitor; add 8 days to the exam date since the SP wears the monitor for 7 days beginning with the first day after their MEC exam. Record this date on the first line on the information sheet.

- Review the information sheet and informational flyer with the SP.
- Place the monitor (on the belt) back into the padded mailer.
- Place the hard copy documents back into the padded mailer.
- Place the mailer in the basket with the SP's street clothes.
- Instruct the SP to put the monitor/belt on when they change into their street clothes.
- When the SP is ready to exit the MEC, check the placement of the monitor.

Instruct the SP to wear the monitor everyday for 7 days. The SP should put the activity monitor on as soon as they get out of bed in the morning and wear it all day until they go to sleep at night. The monitor should not get wet, so the SP should take the monitor off while showering, bathing, or swimming. Although no injury will be caused if the SP gets the monitor wet, it might cause the instrument to malfunction. When passing through metal detectors, the SP should remove the monitor and put it in a separate bin for scanning.

#### **16.10 Final Actions and Instructions**

The coordinator will let the phlebotomist know when the SP is ready to leave the MEC. The phlebotomist should check with the SP to make sure they put the belt containing the monitor on their waist and check the monitor placement, making sure the belt is secure around the SP's waist and that the monitor is on the SP's right hip.

Each SP should exit the exam center with the following items:

- The activity monitor (SP should put this on when getting dressed.); the phlebotomist should check the SP before leaving the MEC);
- The padded envelope;
- Two copies of the informational flyer on survey letterhead (Exhibits 16-4 and 16-5); and
- An information sheet (Exhibits 16-6 and 16-7).

Instruct the SP to mail the monitor back to the home office after the SP has completed the 7-day period. Instruct the SP to place the monitor into the postage-paid padded envelope, seal the envelope, and place it in any United States Postal Service mail receptacle. The SP should keep or discard the belt. If the monitor is not received at the home office 12 days after the MEC exam date, the home office will initiate a series of mail and telephone contacts to ask the SP to return the monitor.

#### **16.11 SP Remuneration**

Once the monitor is received at the home office, the SP will be sent a check in the mail for \$40. If the monitor is not returned, the SP will not receive the \$40. If the monitor is lost, it is not replaced.

## 16.12 Informational Flyer – English and Spanish

### Exhibit 16-4. Informational flyer - English

The Centers for Disease Control and Prevention (CDC) conducts the National Health and Nutrition Examination Survey (“NHANES”) to study the health of the U.S. population. As part of this study, a group of survey participants will wear physical activity monitors such as the one pictured here. The activity monitor records body movements during normal daily activities such as walking or jogging. The activity monitor records no other information.



**A photograph of the NHANES Physical Activity Monitor**

Manufacturing Technology Incorporated of Fort Walton Beach, Florida manufactures the activity monitors. Over 5,000 of these monitors have been used in other studies. A 3-volt watch battery powers the monitors. The monitors are safe, durable, and comfortable to wear. The National Center for Health Statistics Institutional Review Board reviewed the survey procedures and a description of the equipment for safety.

Survey participants will wear the activity monitors for 7 days during waking hours including activities such as school, camp, or work, whenever possible. The monitors are worn on a waist belt. The monitors are removed before going to bed or when the survey participant bathes, showers, or goes swimming.

If you have additional questions, please call the NHANES Survey Toll-Free Information Line Number: 1-888-324-3092.

#### Exhibit 16-5. Informational flyer – Spanish

Los Centros para el Control y Prevención de Enfermedades (“CDC”) hacen la Encuesta Nacional de Examen de Salud y Nutrición (“NHANES”) para estudiar la salud de la población de Estados Unidos. Como parte de este estudio, un grupo de participantes en la encuesta usará monitores de actividad física tal como el de esta ilustración. El monitor de actividad registra los movimientos del cuerpo durante las actividades normales tales como caminar o trotar. El monitor de actividad no registra ninguna otra información.



**Fotografía del Monitor de Actividad Física de NHANES**

“Manufacturing Technology Incorporated” de Fort Walton Beach, Florida fabrica los monitores de actividad. Se han usado más de 5.000 de estos monitores en otros estudios. Los monitores son seguros, durables, y cómodos de llevar. Los monitores funcionan con una pila de reloj de 3 voltios. La Junta Revisora Institucional del Centro Nacional de Estadísticas de Salud revisó la seguridad de los procedimientos de investigación y una descripción del equipo para encuestar.

Los participantes de la encuesta llevarán los monitores de actividad física por 7 días durante las horas que estén despiertos, incluyendo actividades tales como la escuela, campamento o trabajo, cuando sea posible. El monitor se lleva con un cinturón. El monitor se quita antes de acostarse o cuando el participante se baña, se ducha, o va a nadar.

Si desea hacer preguntas adicionales por favor llame al número gratis de la Línea de Información de NHANES: 1-888-324-3092.

## 16.13 Information Sheet – English and Spanish

Exhibit 16-6. Information sheet – English

### Physical Activity Monitor Information Sheet

The last day you will wear the monitor is \_\_\_\_\_

Mail back the monitor the next day using the padded envelope that was given to you.

**This component studies the physical activity levels of children and adults.**

#### ➤ What is an activity monitor?

An activity monitor is a small machine that records information about physical activity patterns. The monitor is safe. It uses a watch battery to power the monitor. The monitor records body movement during everyday activities such as walking. The monitor is safe to wear and will not cause discomfort while you wear it. Most people forget they are wearing it because it is lightweight and small enough to fit under clothing without being seen. Many studies with children and adults have used activity monitors. We hope to learn more about the activity levels of people who participate in NHANES.

#### ➤ What am I supposed to do with the activity monitor?

We ask that you wear the monitor every day for 7 days. Wear the monitor all day except when you shower, bathe, or go swimming. Your first full day wearing the monitor is tomorrow; however, we would like you to start wearing the monitor when you get dressed before leaving here today. Please put the monitor on when you get up in the morning and take it off before you go to bed. Please keep the monitor away from small children and pets to avoid accidents. When the monitor is not being worn, put the monitor where children and pets cannot reach it.

#### ➤ How am I supposed to wear the activity monitor?

The monitor is worn on a belt. Attach the belt snugly around your waist so that the monitor rests on the right side of your body – close to your right hip. You will ideally wear the monitor under your clothes. It is best to keep the monitor fastened on the belt to reduce the chance of losing it.

You will wear it at all times except when in the water, for instance, taking a bath or shower, or swimming. Please do not get the monitor wet. Water could damage the monitor. If you forget to take the monitor off before bathing or swimming, you will not be harmed.

#### ➤ What do I do after I have worn the monitor for 7 days?

Mail the monitor back at the end of the 7-day period. Place the monitor in the postage-paid padded envelope that you were given and drop the envelope in any United States Postal Service mailbox as soon as possible. Please do not return the belt. When we receive the monitor, we will mail you a check for \$40. If the monitor is not returned, you will not be paid.

Exhibit 16-6. Information sheet – English (continued)

➤ **What if I get questions about the monitor?**

Two copies of an information letter about the study are included. These are included in case you need to provide schools, camps, or work offices with information about the study. When passing through metal detectors at airports and work sites, it would be best to remove the monitor and put it in a separate bin for scanning. If questioned about the monitor, please show the information letter to security personnel.

➤ **Who do I contact if I have questions?**

If you have questions about the monitor, please call our office toll-free at **1-888-322-3024**.

## Hoja de Información del Monitor de Actividad física

El último día que usted usará el monitor es el \_\_\_\_\_

Devuelva el monitor al día siguiente usando el sobre abullonado que le dieron.

**Este componente estudia los niveles de actividad física de los niños y de los adultos.**

➤ **¿Qué es un monitor de actividad?**

Un monitor de actividad es una pequeña máquina que registra la información acerca de patrones de actividad física. El monitor es seguro. Funciona con una pila de reloj. El monitor registra los movimientos del cuerpo durante las actividades de todos los días tal como caminar. El monitor es seguro y no le causará incomodidad mientras lo usa. La mayoría de las personas se olvidan que lo están usando porque es liviano y lo suficientemente pequeño como para usarlo debajo de la ropa sin que se vea. Muchos estudios con niños y adultos han usado monitores de actividad. Esperamos aprender más acerca de los niveles de actividad de las personas que participan en NHANES.

➤ **¿Qué debo hacer con el monitor de actividad?**

Pedimos que usted use el monitor diariamente por 7 días. Use el monitor todo el día excepto cuando se ducha, baña, o va a nadar. Su primer día completo para usar el monitor es mañana, sin embargo, quisiéramos que empezara a llevar el monitor cuando se vista antes de irse hoy de aquí. Por favor póngase el monitor cuando se levante en la mañana y quíteselo antes de acostarse. Por favor mantenga el monitor lejos del alcance de los niños y animales domésticos para evitar accidentes. Cuando no esté llevando el monitor, ponga el monitor donde los niños y los animales domésticos no puedan alcanzarlo.

➤ **¿Cómo debo llevar el monitor de actividad?**

El monitor se lleva con un cinturón. Póngase el cinturón ajustado alrededor de la cintura de modo que el monitor quede al lado derecho de su cuerpo – cerca de la cadera derecha. Lo ideal sería que llevara el monitor debajo de la ropa. Lo mejor es mantener el monitor ajustado con el cinturón para reducir la posibilidad de perderlo.

Usted lo llevará en todo momento excepto cuando está en el agua, por ejemplo mientras se baña o se ducha, o nada. Por favor no moje el monitor. El agua puede dañar el monitor. Si a usted se le olvida quitarse el monitor antes de bañarse o nadar, no se hará daño a usted mismo(a).

➤ **¿Qué debo hacer después de haber llevado el monitor por 7 días?**

Devuelva por correo el monitor al fin del período de 7 días. Ponga el monitor en el sobre abullonado con porte prepago que le dieron y ponga el sobre en cualquier buzón del Servicio Postal de Estados Unidos lo antes posible. Por favor no devuelva el cinturón. Cuando recibamos el monitor le mandaremos un cheque por \$40. Si no devuelve el monitor no se le pagará.

Exhibit 16-7. Information sheet – Spanish (continued)

➤ **¿Qué puedo hacer si alguien me pregunta acerca del monitor?**

Hemos incluido dos copias de una carta informativa acerca del estudio. Estas se incluyen en caso de que usted necesite proporcionar información acerca del estudio a escuelas, campamentos, u oficinas de trabajo. Cuando pase por un detector de metales en aeropuertos y lugares de trabajo, lo mejor será que se quite el monitor y lo ponga en un recipiente para que lo pasen por el escáner. Si le preguntan acerca del monitor, por favor muestre la carta informativa al personal de seguridad.

➤ **¿Con quién me comunico si deseo hacer alguna pregunta?**

Si desea hacer alguna pregunta acerca del monitor, por favor llame gratis a nuestra oficina al **1-888-322-3024**.

## **16.14 Home Office Responsibilities**

Upon completion of the 7-day test period, survey participants mail the PAM device to the NHANES warehouse using a postage-paid padded envelope. Separate return mailing envelopes are provided for each survey participant's PAM device. Once the monitor is received at the home office, the warehouse staff downloads the data and cleans and calibrates each monitor. The warehouse staff checks the battery life and installs a new battery when the remaining battery life reaches 1,000 hours. Each PAM should cycle through 10 SPs before the battery life reaches 1,000 hours.

### **16.14.1 Battery Replacement**

The battery used in the activity monitor is a lithium coin cell designated in the industry as a CR2430. Battery life is typically in excess of 4,000 hours. Actual battery life is dependent on the frequency of data downloads and the capacity of the particular manufacturer's battery. The battery life remaining, as reported by the activity monitor, is an estimate and should be interpreted as such. The voltage of a lithium battery cannot be used to predict battery life. The activity monitor estimates the remaining battery life by keeping track of total hours of operation since the last battery replacement. The 4,000-hour battery life is a safe estimate of run time for a 220-mah capacity battery (typical of the CR2430 series).

If the PAM is accidentally left in the RIU for long periods (where the LED flashes constantly), then battery life will be less than the expected 4,000 hours. Collected data will **not** be lost if the battery dies while the monitor is in the field. The activity monitor stops collecting data when the battery dies. Installing a new battery will allow the data to be downloaded.

Replace the battery when the remaining battery life reaches 1,000 hours.

To replace the battery, follow these steps:

#### **Step 1**

- Using a small Phillips head screwdriver, carefully remove the four screws that retain the cover on the PAM. (If the screwdriver is allowed to slip in the head of the screw,

damage to the screw head will occur. If this happens, send the PAM to the factory for removal of the damaged screw.)

- After all four screws have been removed; carefully pry off the plastic cover to expose the battery and holder. It is helpful to use one of the loose screws to extract the cover. This is done by catching the threads in one of the holes and pulling away from the case. Do not attempt to remove the circuit boards from the metal box or touch the sensor. Touching the sensor, even lightly, can damage it.

## **Step 2**

- Remove the battery by inserting a small common blade jeweler screwdriver between the battery and the holder. Note that this terminal position is near the sensor. Use gentle force to release the battery. This method prevents damage to the small nibs that retain the battery. Use minimal force to avoid permanently deforming the battery holder's retaining ears.

## **Step 3**

- Insert a new battery into the holder by snapping it into place. The positive (+) terminal faces up. Using a conductivity object, such as a brightly finished jeweler screwdriver or a paper clip, temporarily short the new battery by bridging the gap at the same location where the battery was pried out. This action ensures proper startup of the activity monitor processor by forcing a power-on reset. Do not skip this step.
- Ensure that the battery holder nibs are in good shape and that they will retain the battery tightly in the holder. Nibs that are worn or spread away from the battery render the holder unreliable and will require service at the factory.

## **Step 4**

- Align the sealing gaskets (if used) before installing the cover. Carefully place the cover over the box. Verify that the sides of the box are facing the interior of the lid's shield. It may be easier to temporarily remove the metal box from the plastic case and place the box onto the cover.

## **Step 5**

- Place the box/lid assembly into the plastic case taking care that the holes in the box are oriented towards the notch. After all the screws have been started, snug each one up very lightly while seating the cover between the thumb and forefinger.

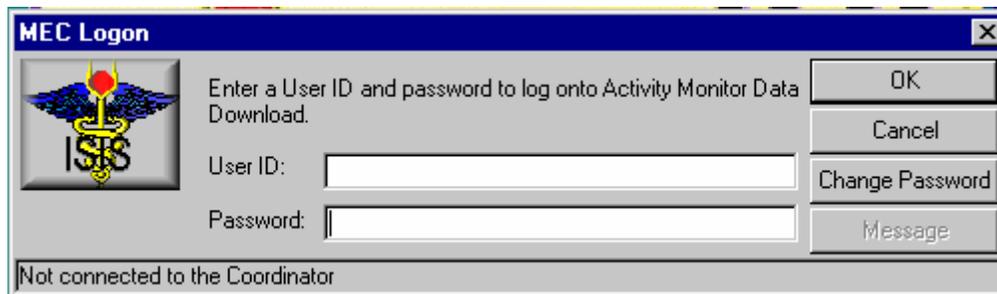
## 16.14.2 Cleaning

The activity monitor is water-resistant but is not waterproof. Care must be taken not to immerse it into water. Remove the label after downloading the data and clean the polycarbonate case with a Sani-Wipe cloth. Soap and water or Isopropyl alcohol may be used in an emergency. Do not use cleaning solvents or immerse the case into any liquid. Chlorinated fluorocarbon cleaners will damage the plastic case.

## 16.14.3 Download the Data and Calibrate the Monitor

Open and log onto the download application. Download the data from the monitor by placing the monitor into the RIU. Access {File} and then {Open} in the top tile bar to open the data download window. Follow the instructions on the screen.

Open the application by double clicking on the Data Download application icon on the desktop. The MEC Logon window displays.



MEC Logon

Enter a User ID and password to log onto Activity Monitor Data Download.

User ID:

Password:

OK

Cancel

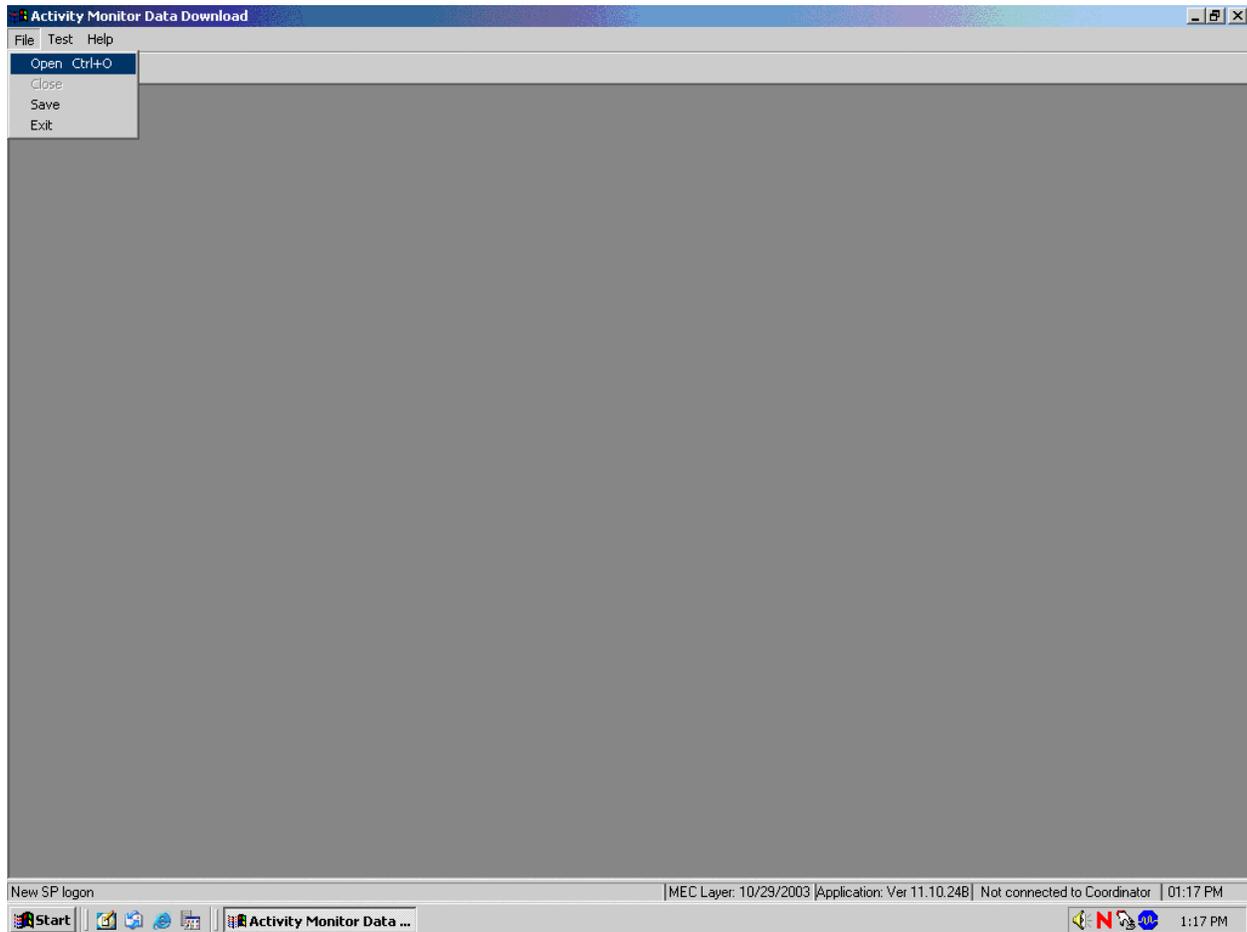
Change Password

Message

Not connected to the Coordinator

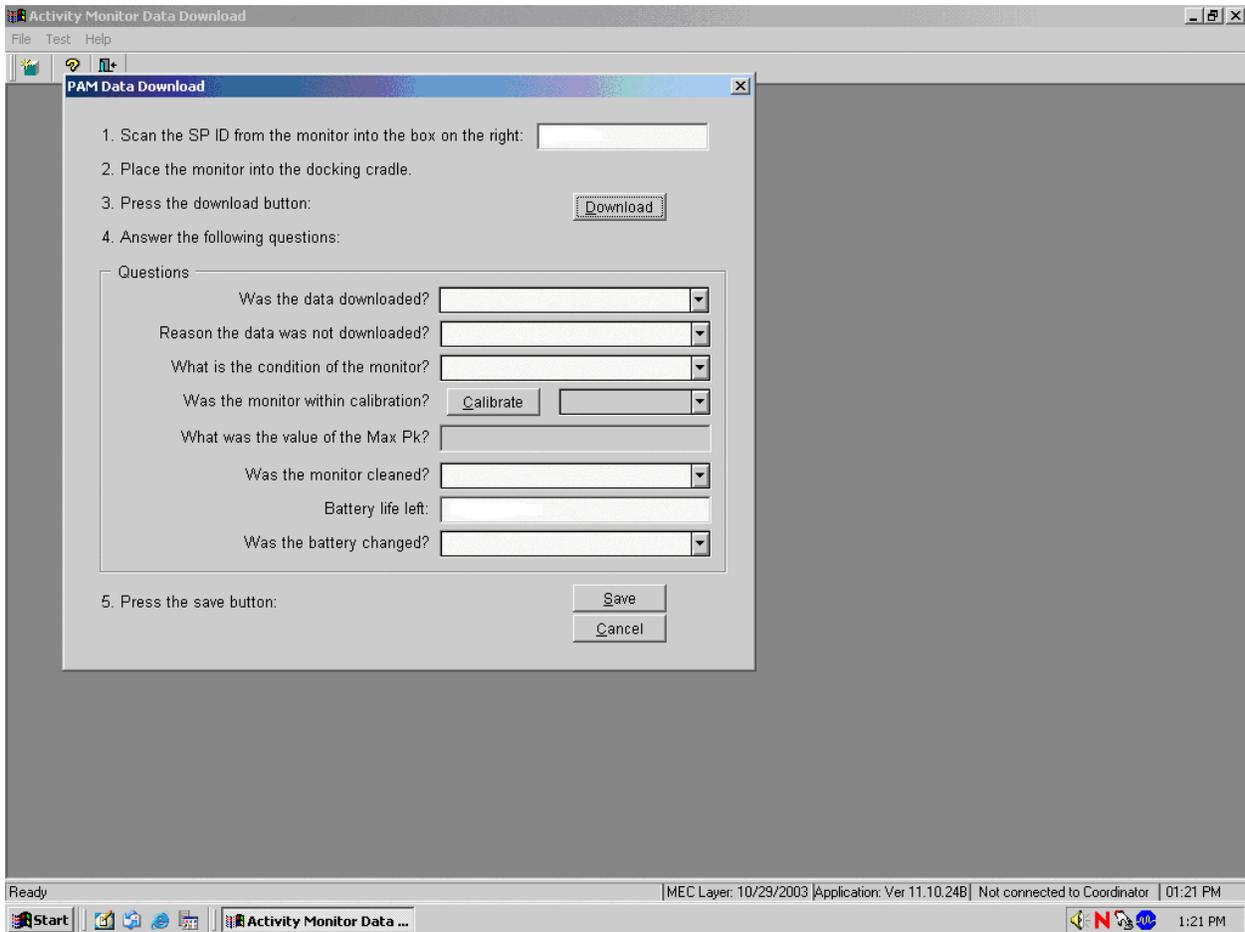
To log onto the Data Download application, type last name, underscore, first initial (Last Name\_First Initial) in the User ID space, and then select [Tab] or [Enter]. Enter the password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the OK button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the Cancel button and left click.

Open an exam.



The PAM screen displays. To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o].

The PAM Data Download window displays.



The PAM Data Download window contains a list of steps and action buttons. Scan or type the SP ID from the back of the monitor into the first text box. The application performs a validity check to verify that the SP ID matches the list of recruited SP IDs. Place the monitor into the docking cradle in the RIU with the notched side down, toward the front of the RIU and with the screws facing up. Press the Download button and observe the brown status line while the data is downloaded. Remove the monitor when the data download is complete. Answer the questions in the Questions box. If the answer to the first question, "Was the data downloaded" is "Not downloaded," then the second question is enabled.

## Calibrate the Monitor

To calibrate a monitor:

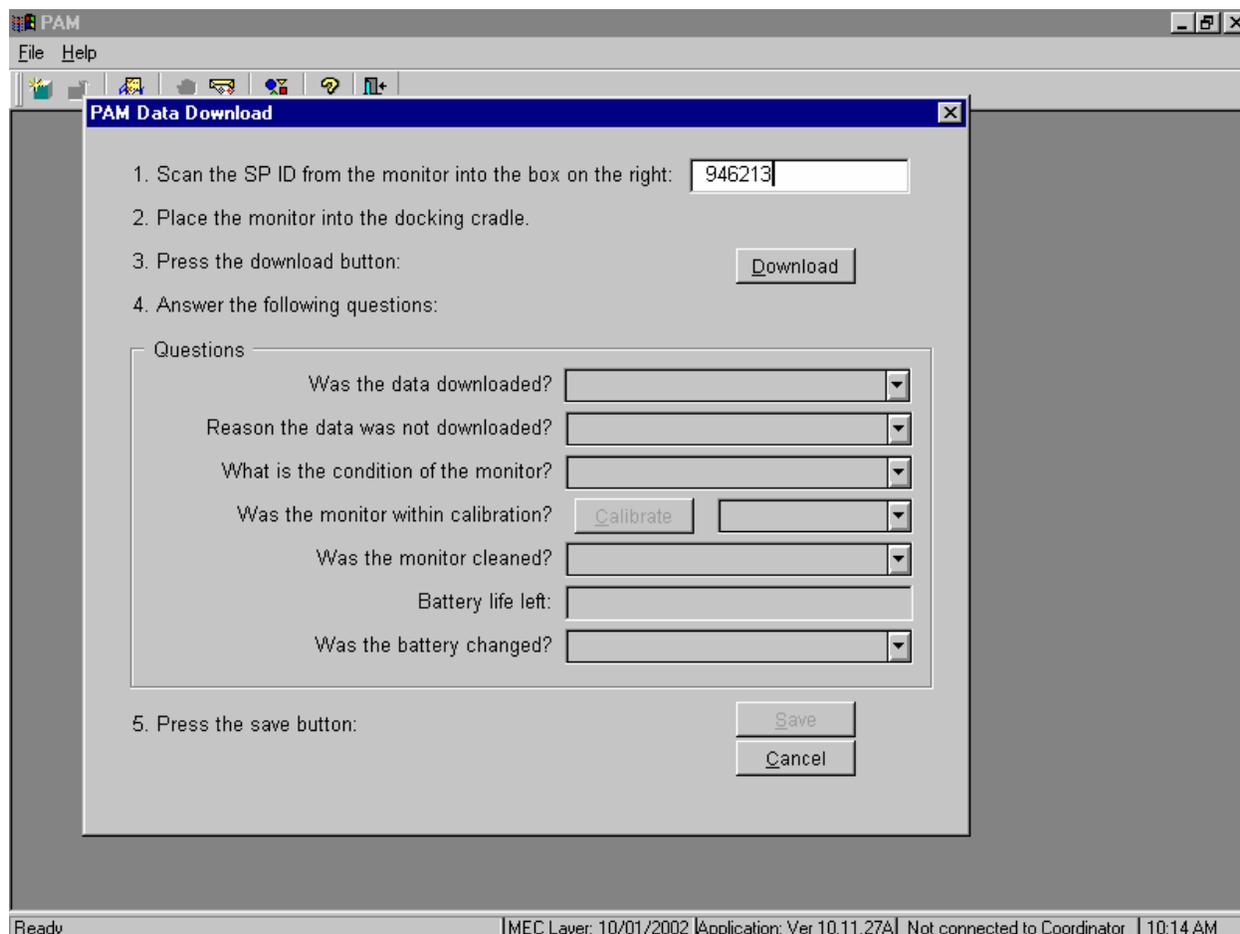
1. Position the calibration unit cradle with the open side facing the up position.
2. Gently slide the monitor into the calibration cradle with the screws to the back and the smooth side toward the front and the notches down. The LED should flash red.
3. Begin the calibration by selecting the Calibrate button. This action launches the MTI calibration program.
4. Select the Serial Communication port number “2” when the calibration program asks for the port number.
5. The calibration unit rotates or spins the monitor during the actual calibration.
6. Watch the calibration graph as the monitor is calibrating.

Evaluate the calibration data. The calibration program displays a Max Pk number after the calibration is complete. This number must be between 0.57 and 0.63.

- If the number is between 0.57 and 0.63 then no adjustment is necessary and the monitor is calibrated.
  - If the number is  $<0.57$  or  $>0.63$ , then the monitor is not in calibration and must be sent to MTI for repair.
7. Press the [Enter] key to exit the calibration program.

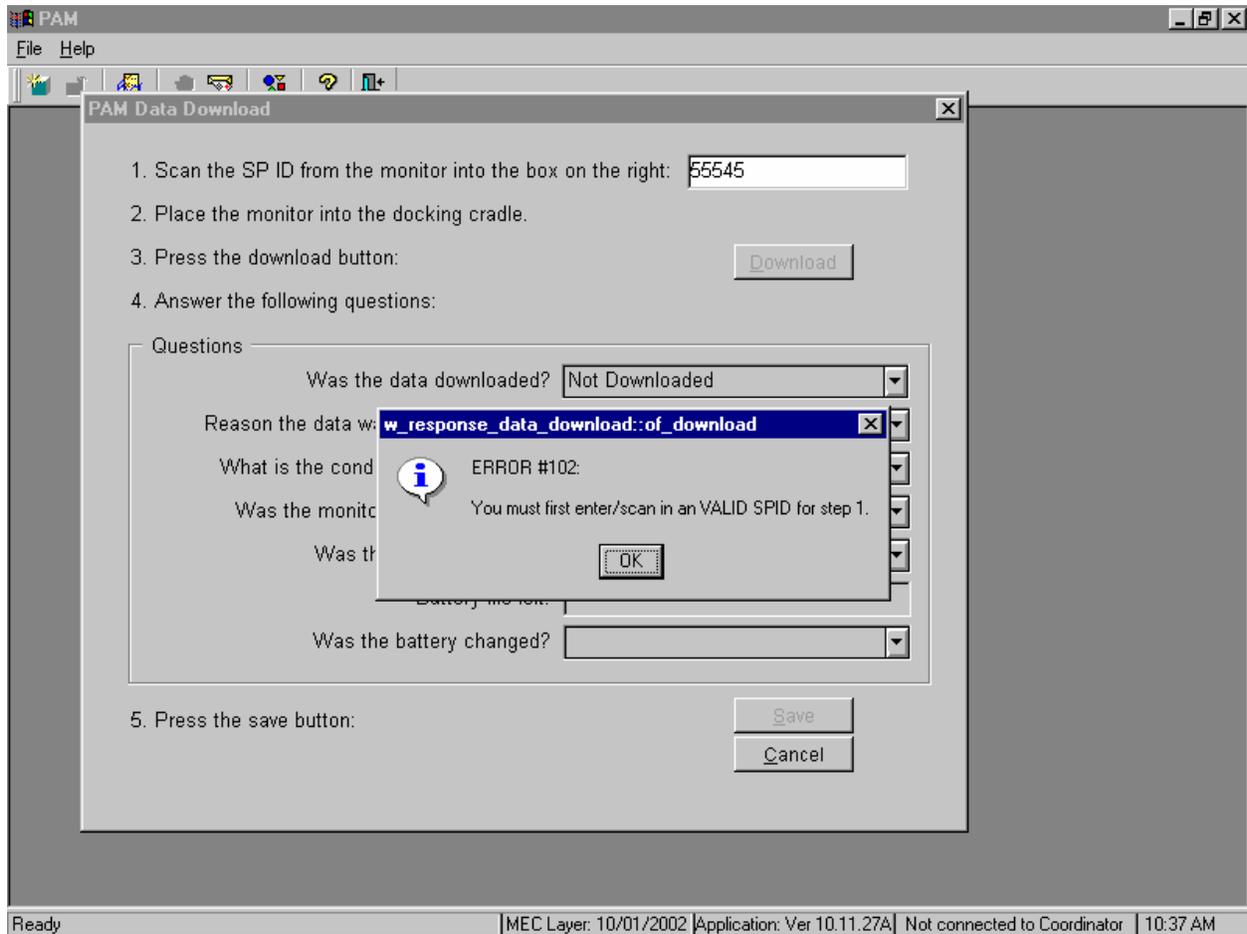
Answer the next two questions and review the Battery life left number. If the battery life is less than or equal to 1000 then change the battery and record this action in the last question text box. Select the Save button to save the answers to the questions and the data to the database, or select the Cancel button to repeat all of these actions, including the download.

Insert the SP ID into the text box.



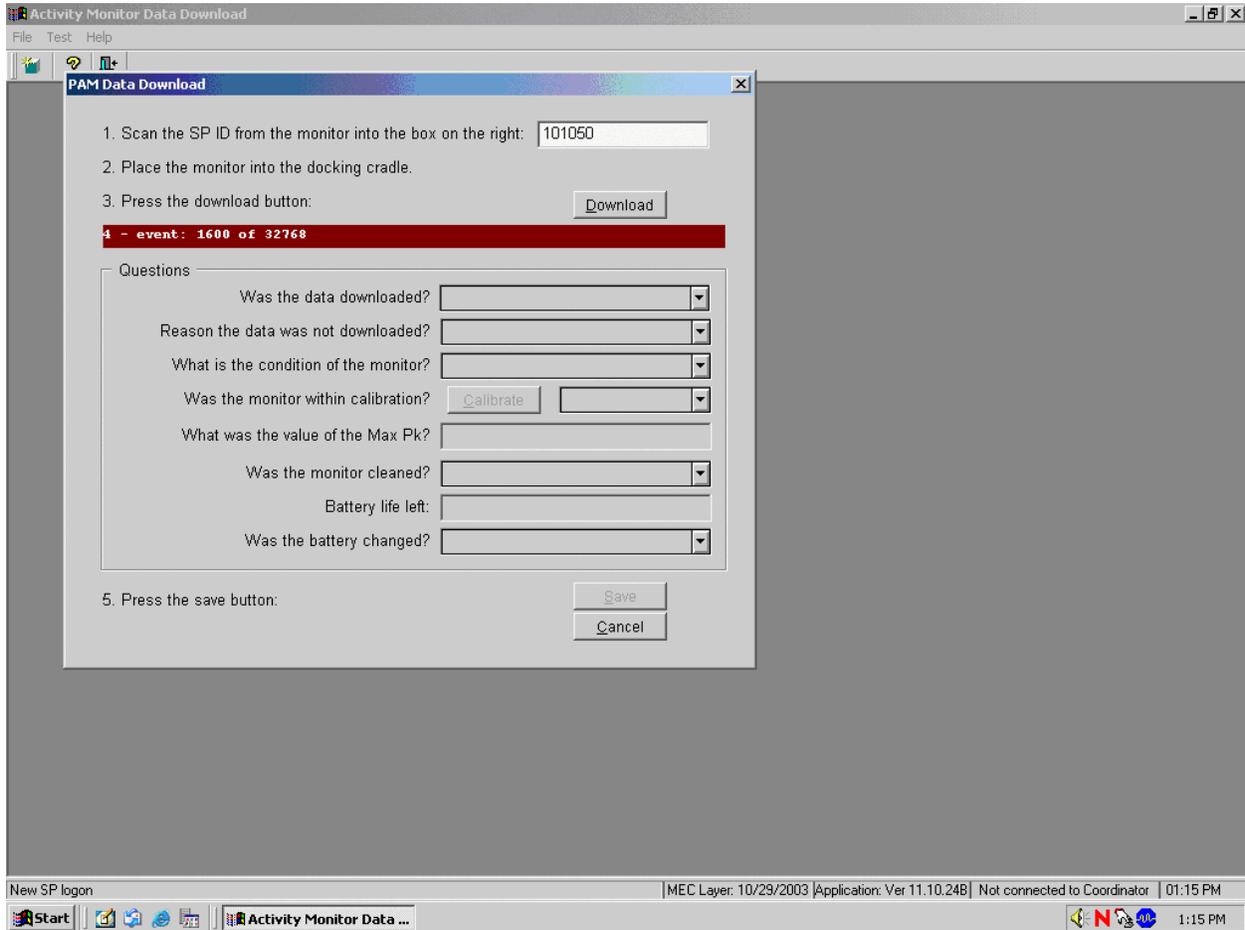
To insert the SP ID into the first text box, (Scan the SP ID from the monitor into the box on the right.) use the bar code gun to scan the bar code on the label located on the back of the monitor. Alternatively, use the keyboard numbers to type the number into the text box. If there is no label or if the label is unreadable, contact the senior system analyst. The analyst can search the database to locate the SP ID that matches the serial number that is printed on the end of the monitor case.

If the SP ID does not match a recruited SP ID, then an informational text box displays.



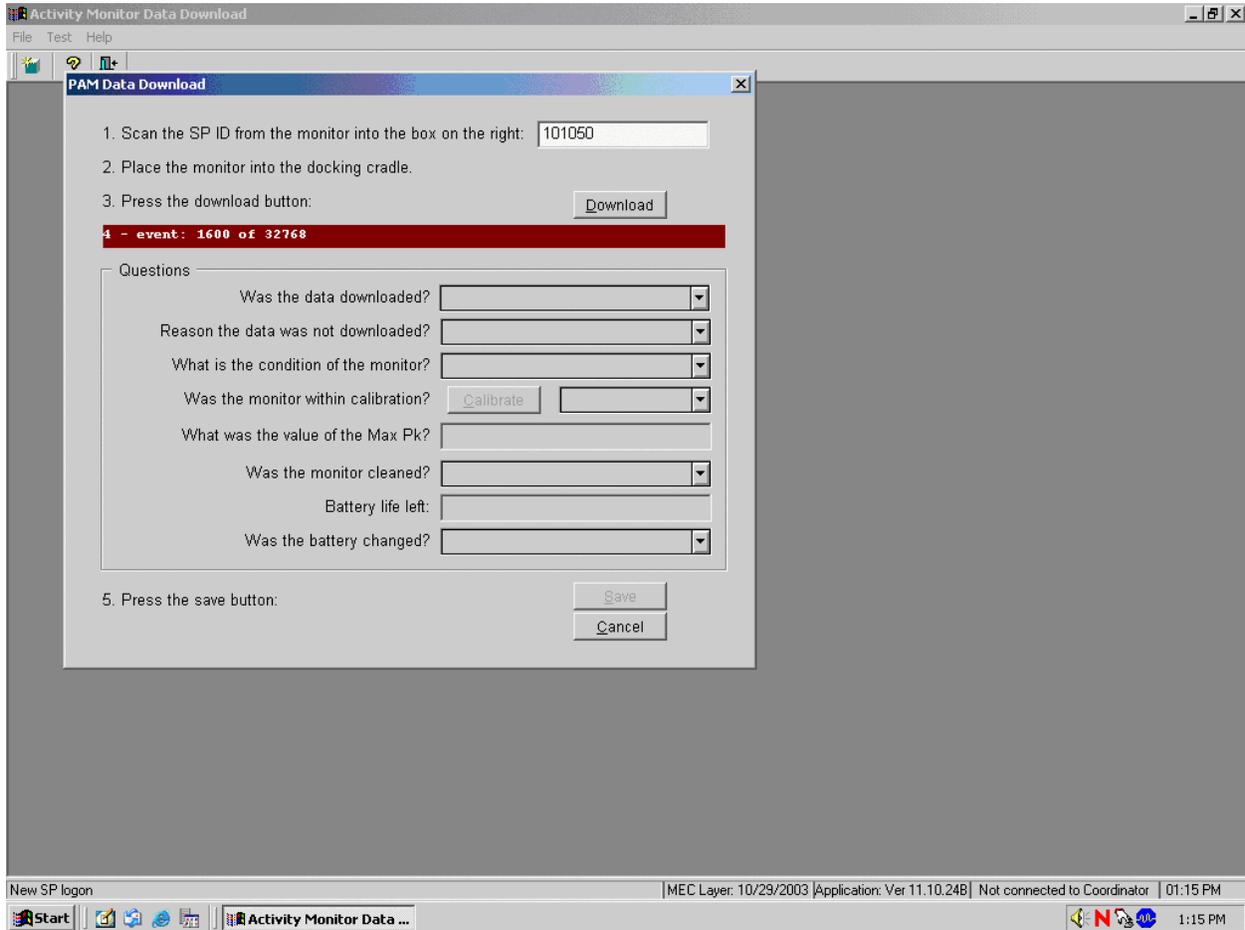
To remove the informational text box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. Reenter the SP ID.

Download the data.



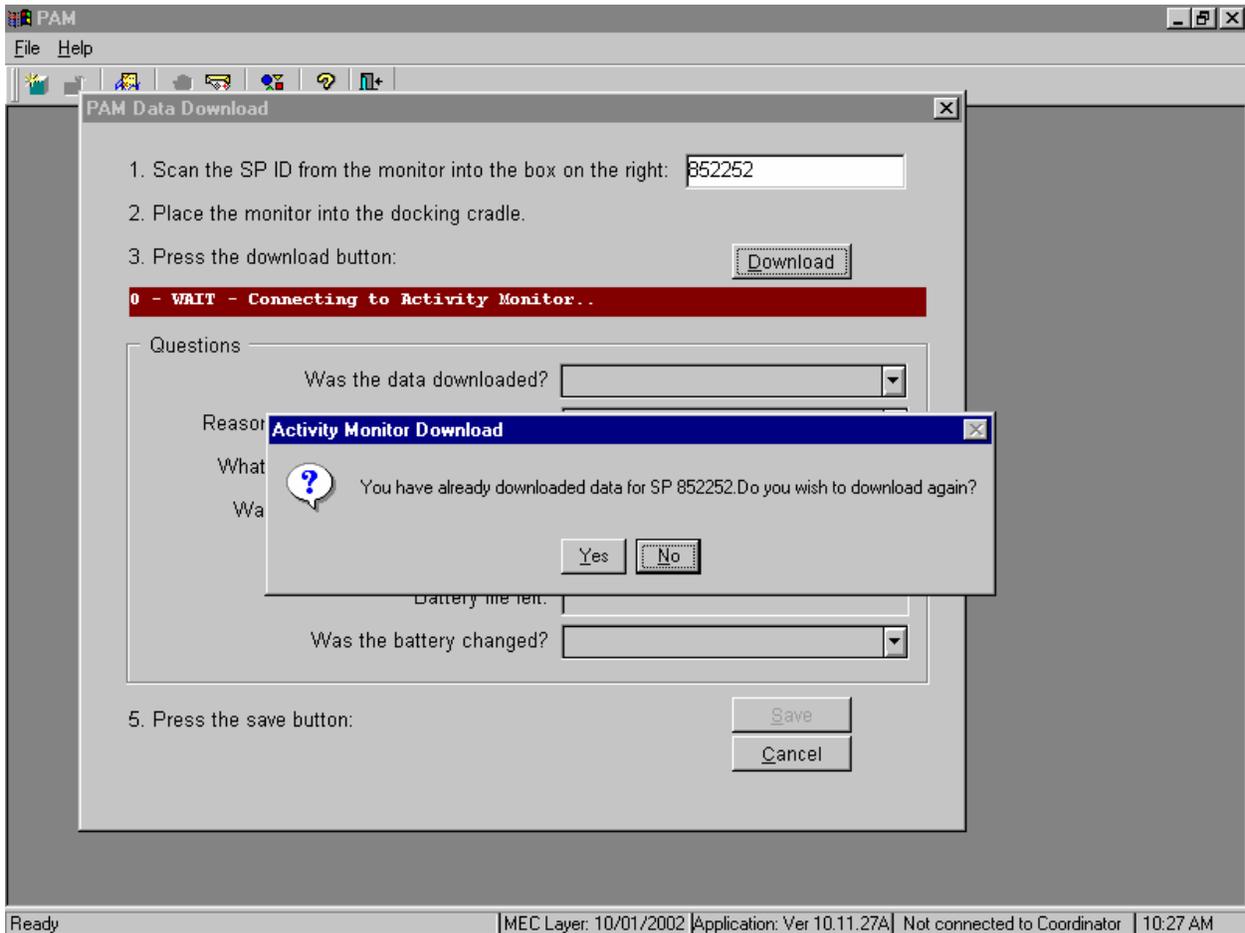
Place the monitor into the RIU docking cradle as described in Section 16.8. To begin the data download process, use the mouse to direct the mouse arrow to the Download button and left click.

Watch the brown status line while the data is downloading.



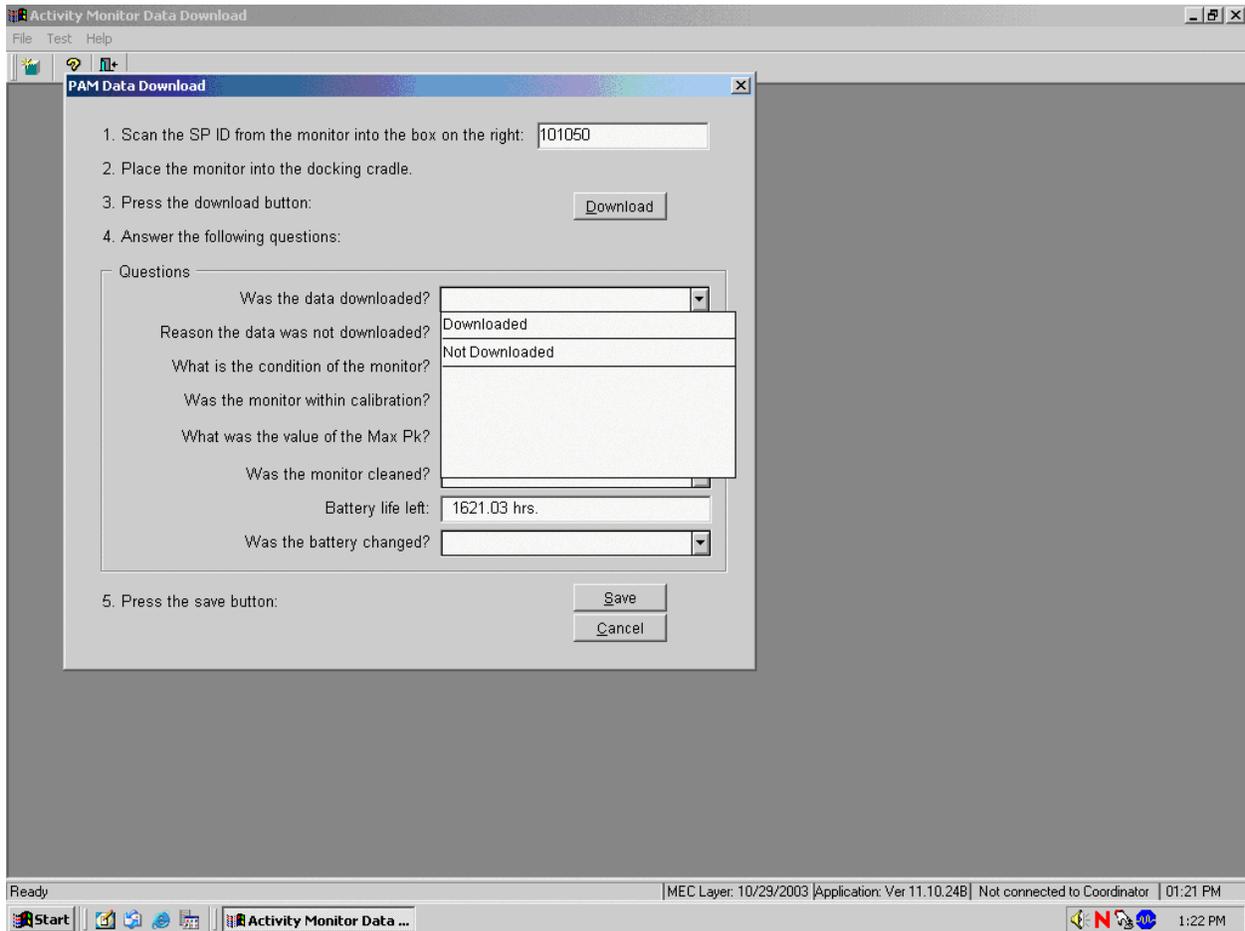
Once the Download button has been selected, a brown status line displays the various download process steps. Watch these process steps as the download progresses.

If the Download button is selected and data has already been downloaded for a SP or if the Download button is selected while the data is downloading, then an Activity Monitor Download message box displays.



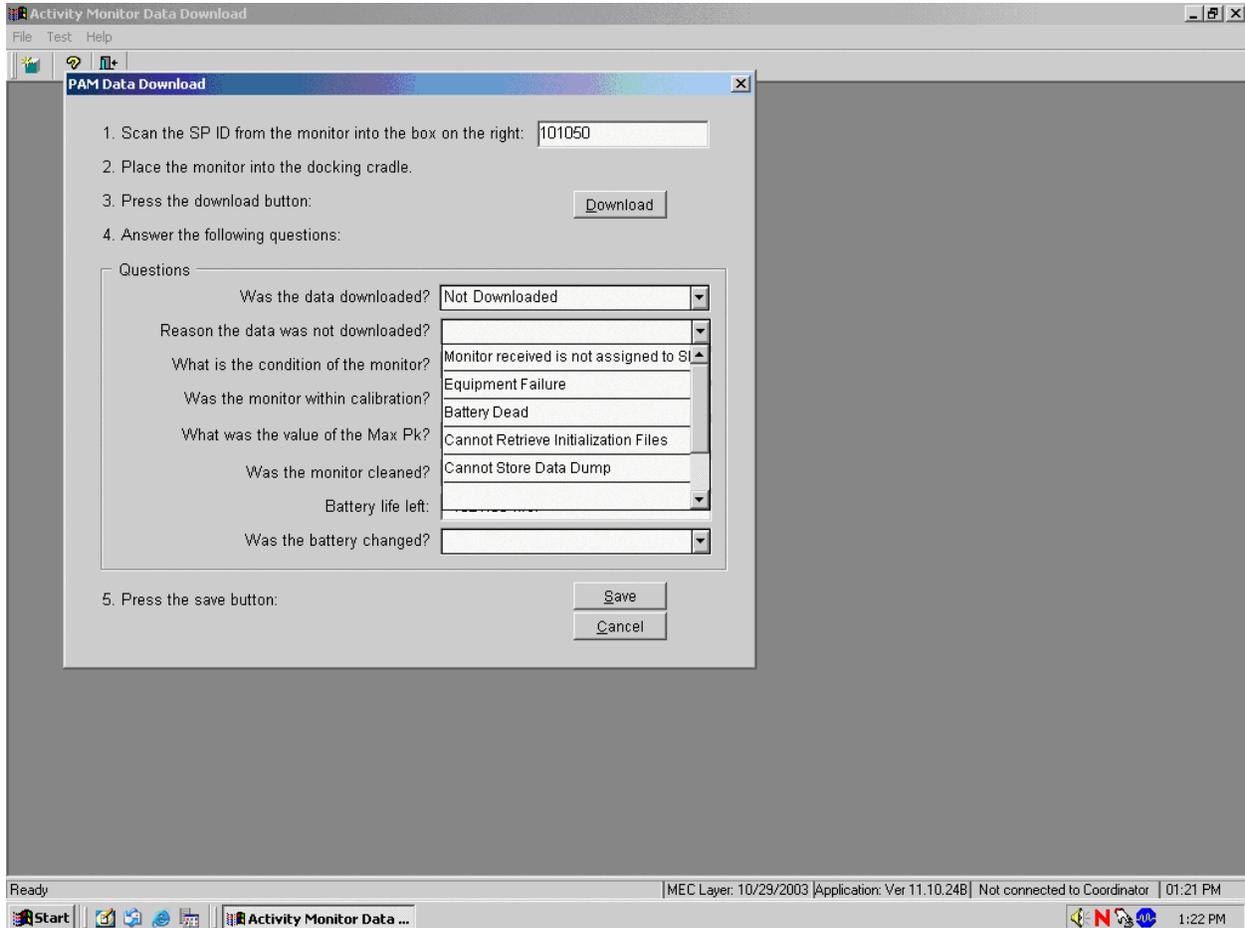
Downloading data more than once does not cause any damage to the monitor or the data in the database. To remove the message window and to download data a second time, use the mouse to direct the mouse arrow to the Yes button and left click. To cancel the additional download request, use the mouse to direct the mouse arrow to the No button and left click or select [Enter].

Once the data download is complete, the Questions in the highlighted box are activated. Remove the monitor from the RIU when the data download is complete and answer the first question, “Was the data downloaded?”



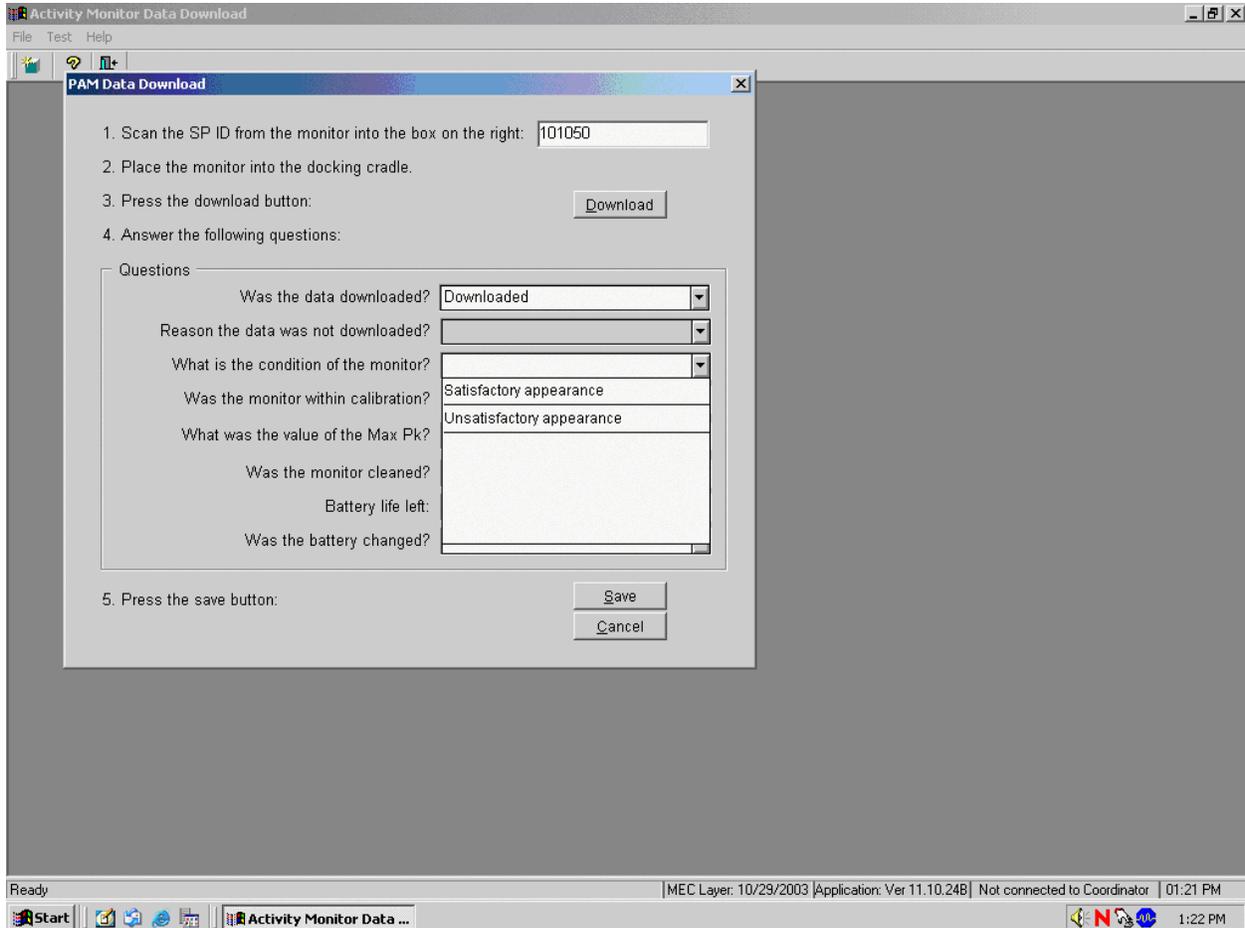
There are two possible responses to this question: Downloaded or Not Downloaded. Record the response by typing [D/d] for “Downloaded” or [N/n] for “Not Downloaded.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Downloaded” or “Not Downloaded” and left click.

If the response to the first question is “Not Downloaded” then the second question text box is activated. Answer the second question; “Reason the data was not downloaded?”



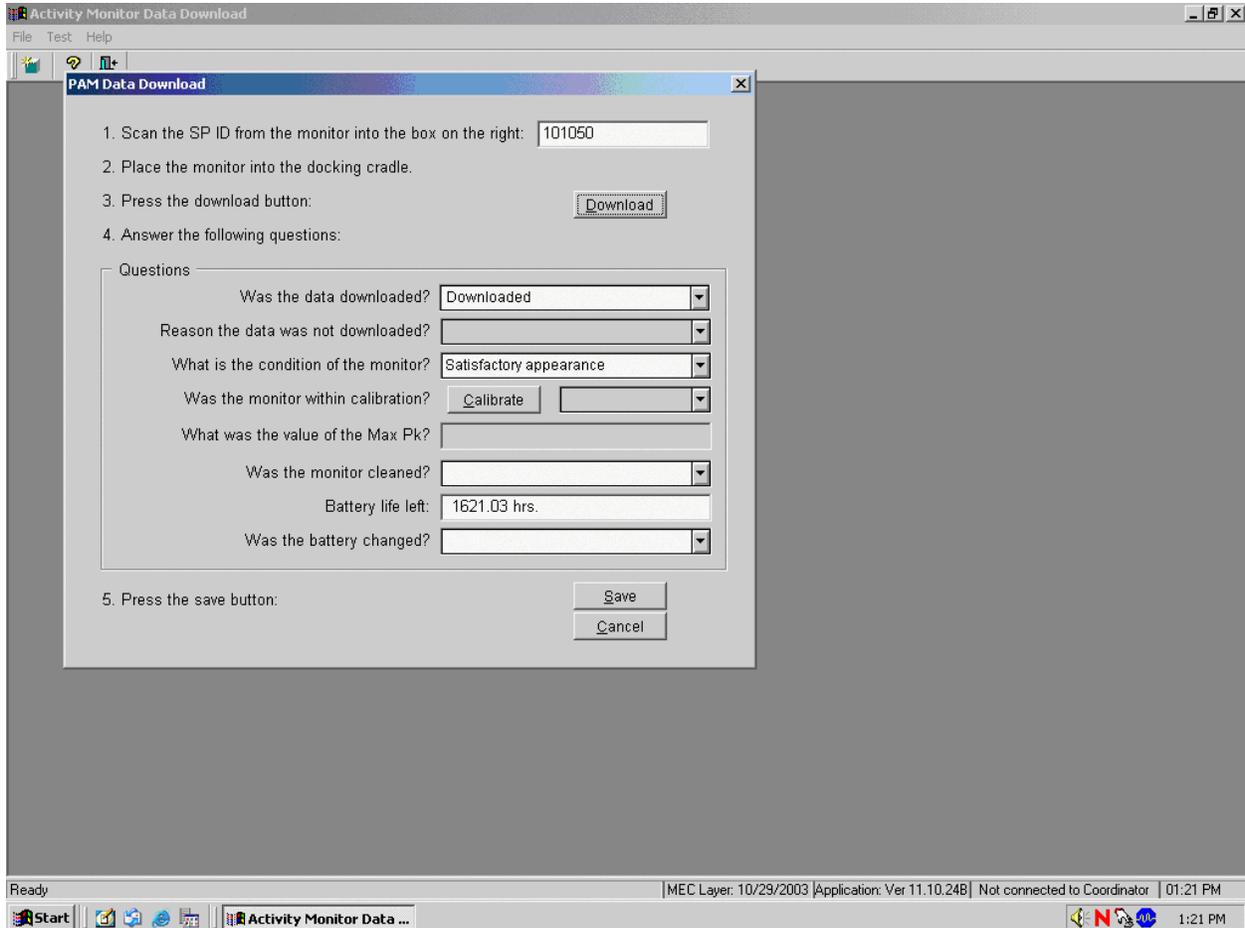
There are several reasons for a data download failure: Monitor received not assigned to SP, Equipment Failure, Battery Dead, Cannot Retrieve Initialization Files, and Cannot Store Data Dump. If the monitor fails because the RIU is broken, or the monitor is damaged beyond repair, record equipment failure. If the battery is dead, then replace the battery and repeat the data download process. If the RIU is broken, then obtain (from the warehouse), install the backup RIU, and repeat the process. If there is no backup available, then save the monitor until a replacement can be obtained. If the monitor is damaged beyond repair, then record “Equipment Failure” in the text box. Record this response by typing the first letter of the comment in the text box. Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the response, and drag the mouse arrow to the desired choice and left click.

Answer the third question, “What is the condition of the monitor?”



There are two possible responses to this question: Satisfactory appearance or Unsatisfactory appearance. Inspect the monitor case carefully for cracks. If the monitor case is not cracked, record “Satisfactory appearance.” If the monitor case is cracked, record “Unsatisfactory appearance” and send the monitor to MTI for repair. Record the response by typing [S/s] for “Satisfactory appearance,” or [U/u] for “Unsatisfactory appearance.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Satisfactory appearance” or “Unsatisfactory appearance” and left click.

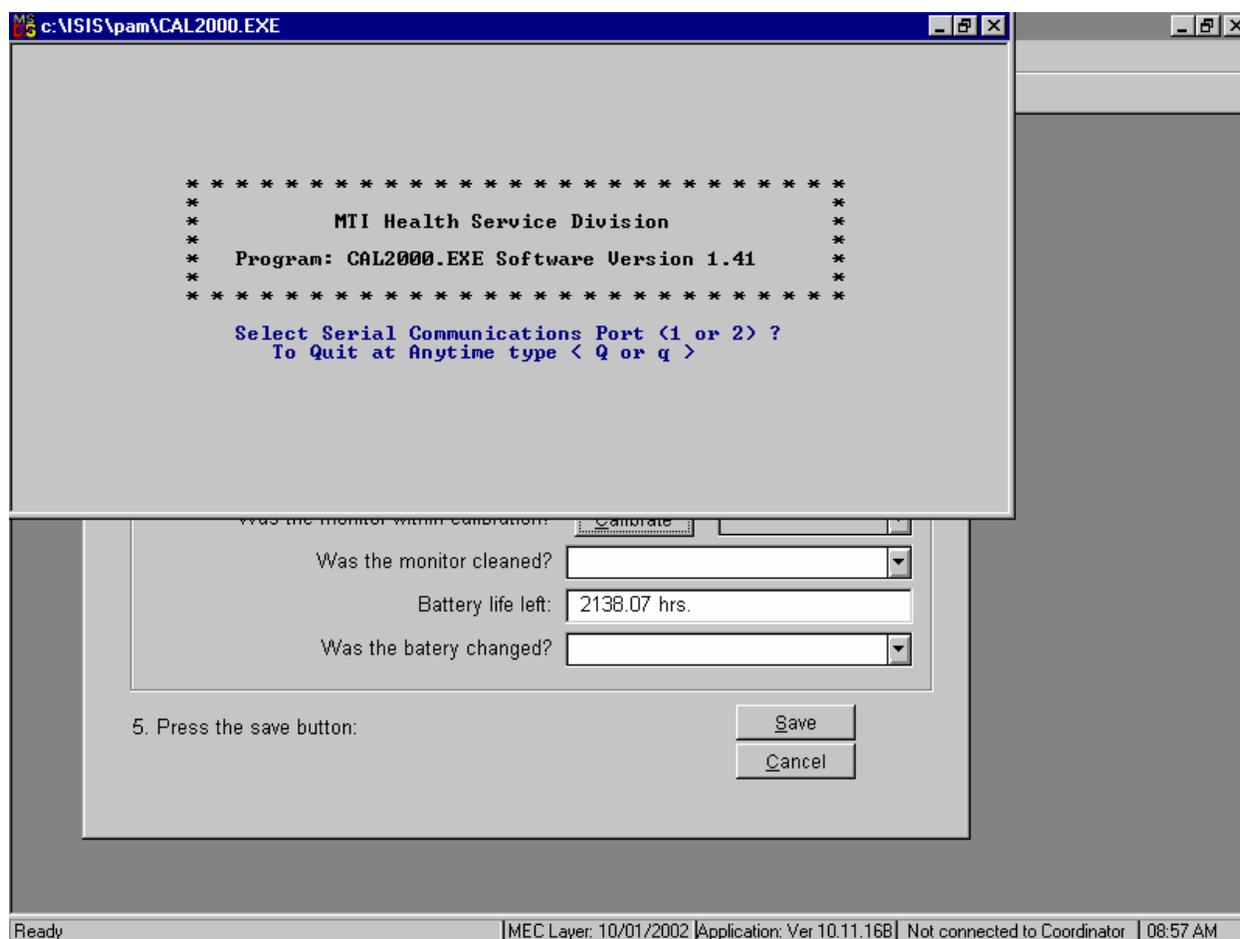
Calibrate every monitor after the data download is complete and after responding to the subsequent questions.



To calibrate a monitor:

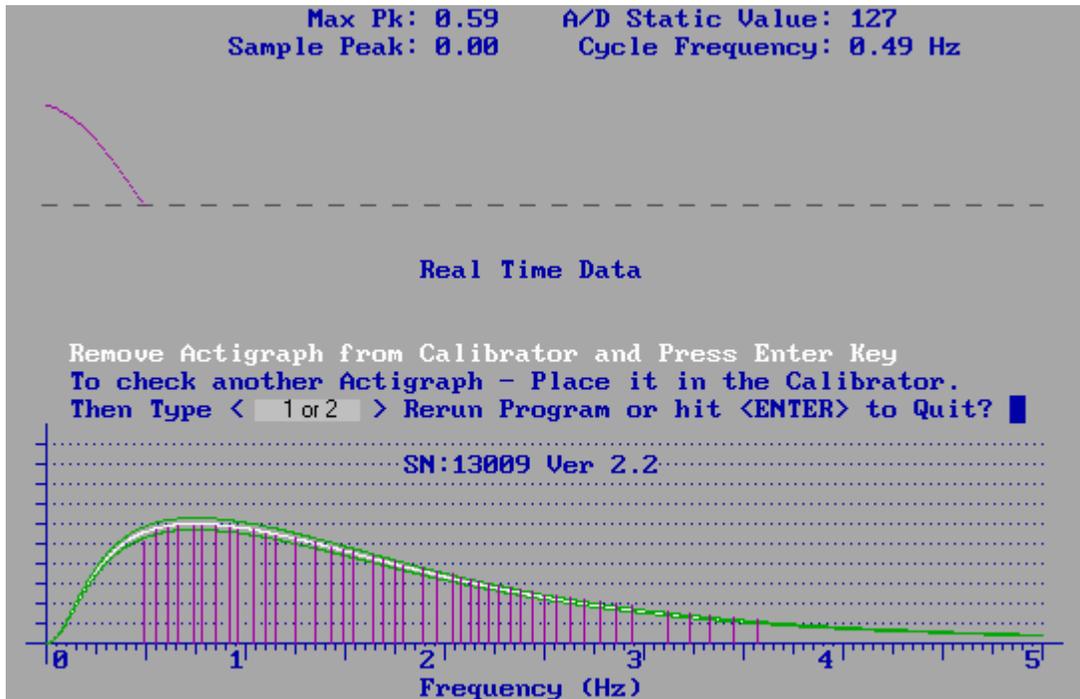
1. Position the calibration unit cradle with the open side facing the up position.
2. Slide the monitor into the calibration cradle with the screws to the back and the smooth side toward the front and the notches down. The LED should flash red.
3. To begin the calibration, use the mouse to direct the mouse arrow to the Calibrate button and left click. This action launches the calibration program.

The calibration application launches when the Calibration button is selected.



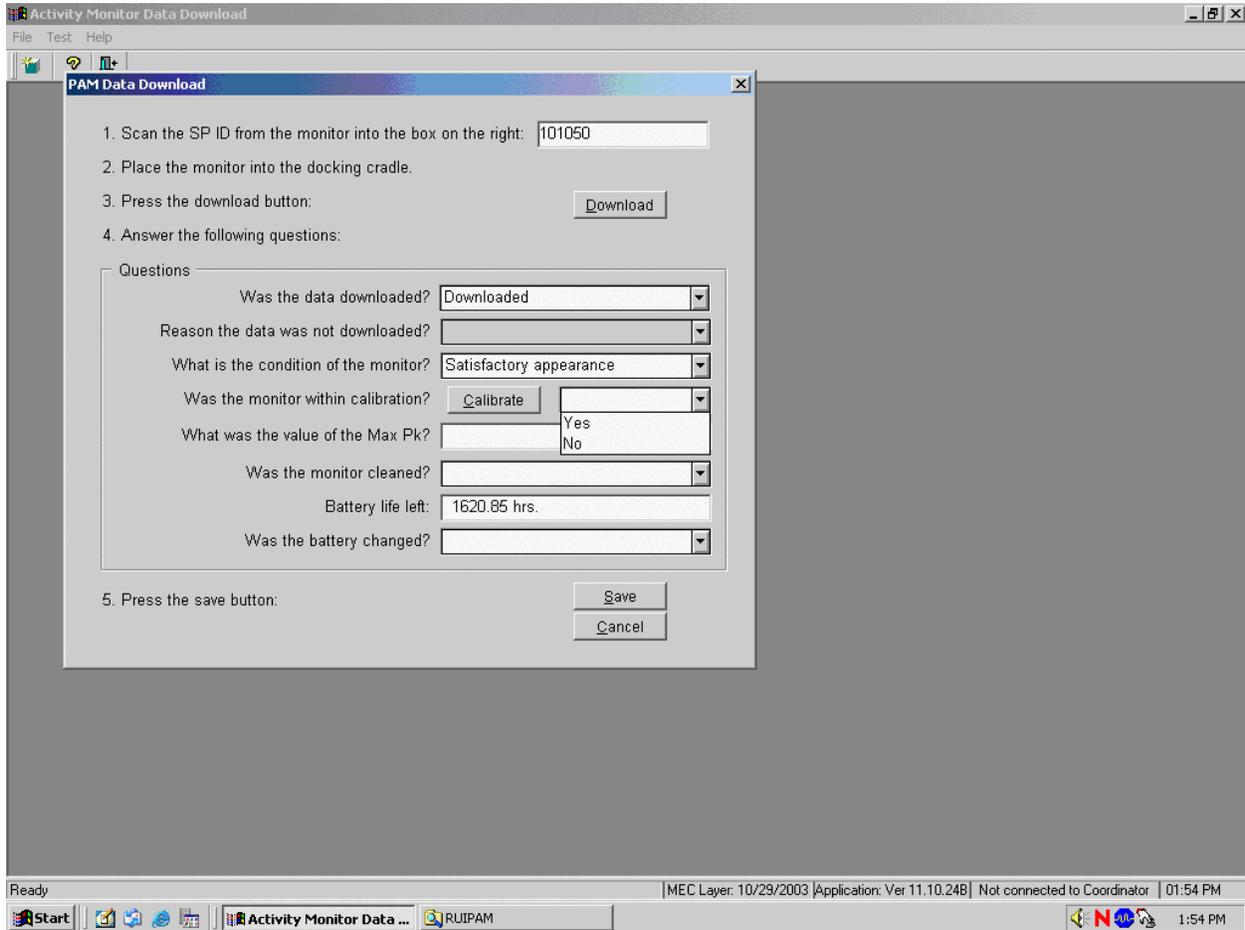
To select the Serial Communication Port number, use the keyboard to select the number “2” when the calibration program asks for the port number.

The calibration unit rotates or spins the monitor during the actual calibration.



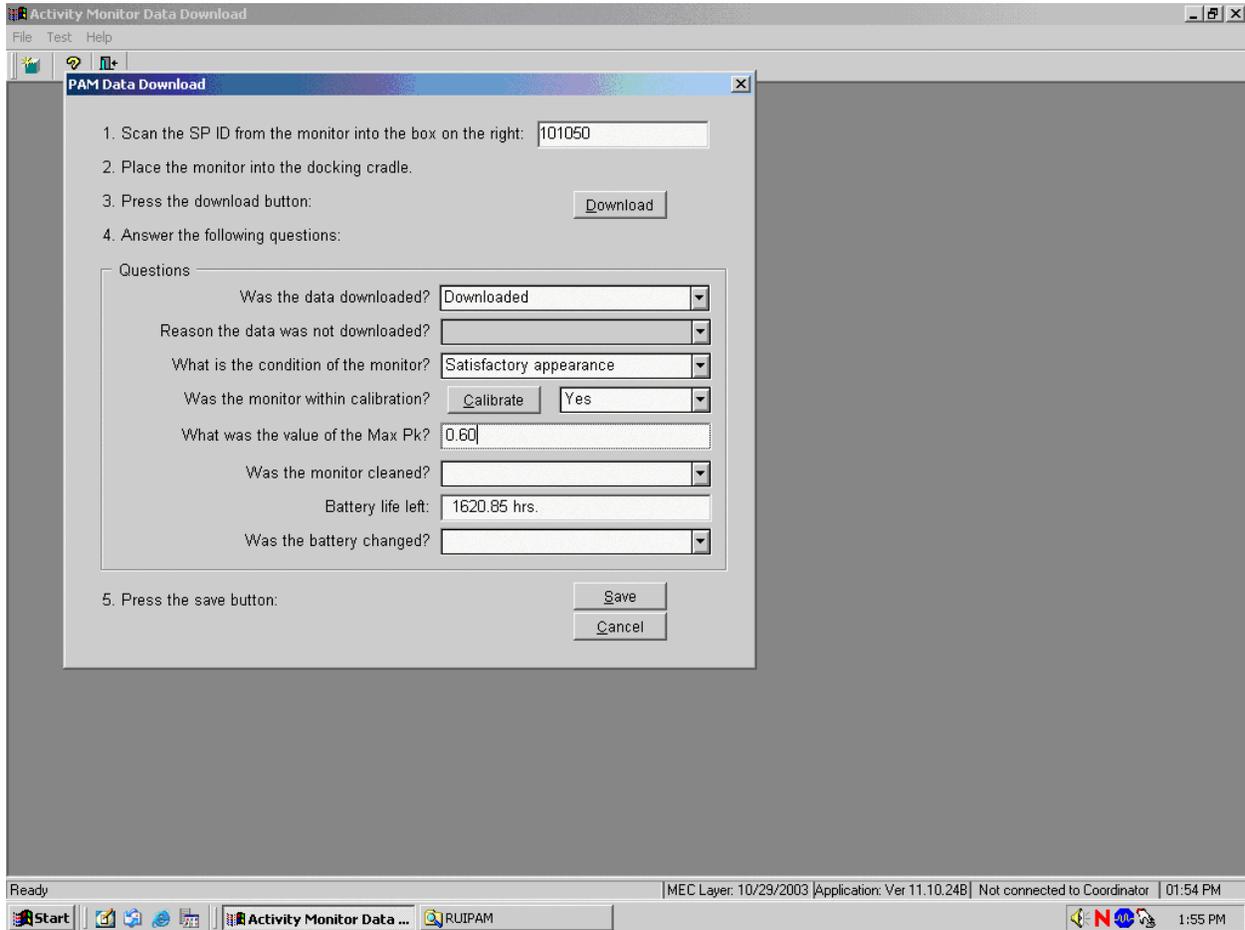
Watch the calibration graph as the monitor is calibrated. The calibration program displays a Max Pk number after the calibration is complete. This number must be between 0.57 and 0.63. If the Max Pk is between 0.57 and 0.63 then no adjustment is necessary and the monitor is calibrated. If the Max Pk is <0.57 or >0.63, then the monitor is not in calibration and must be sent to MTI for repair. Press the [Enter] key to exit the calibration program.

Answer the question; “Was the monitor within calibration?”



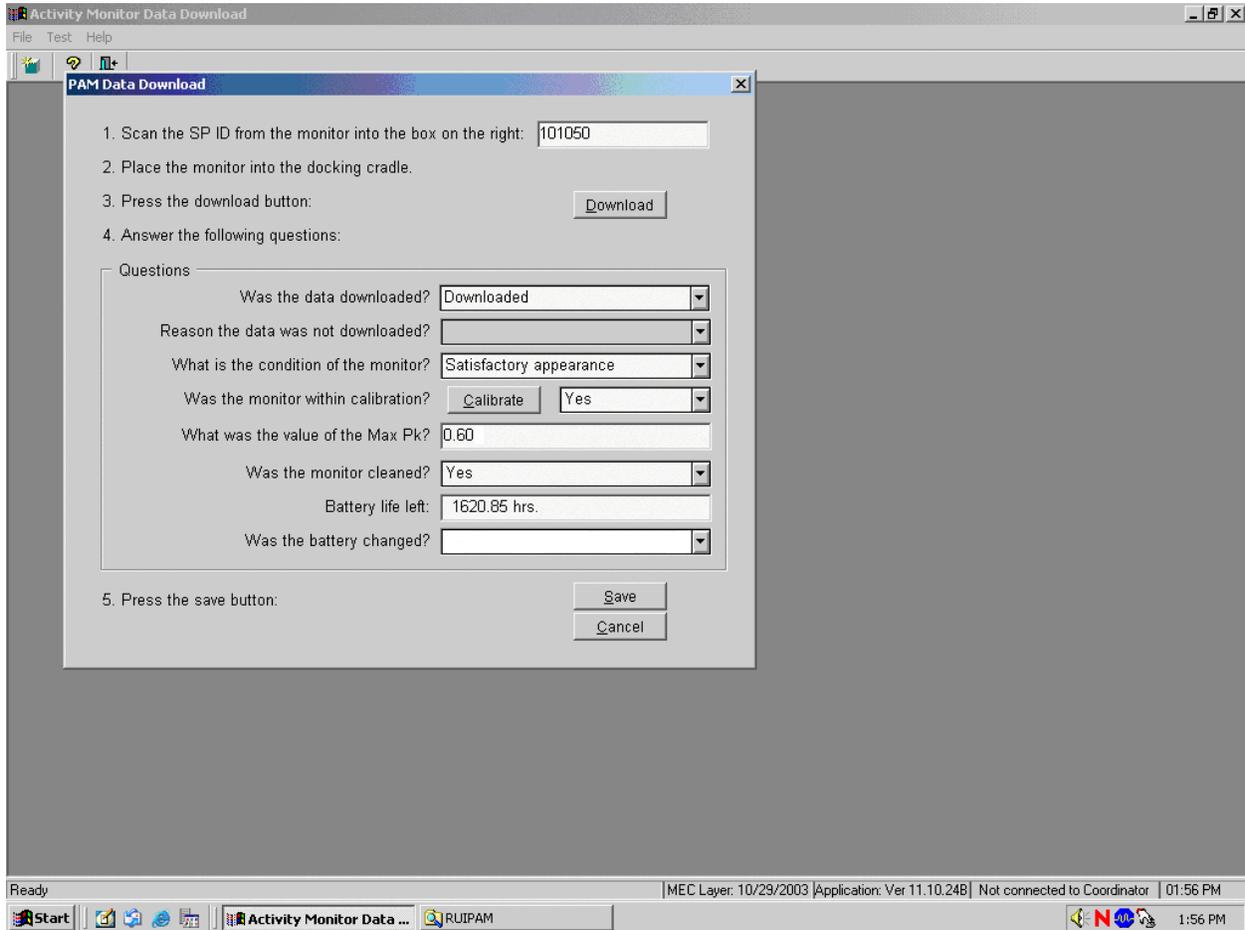
There are two possible responses to this question: Yes or No. If the Max Pk is between 0.57 and 0.63 then record “Yes.” If the Max Pk is  $<0.57$  or  $>0.63$ , then record “No.” Record the responses by typing [Y/y] for “Yes,” or [N/n] for “No.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes” or “No” and left click.

Answer the question, “What is the value of the Max Pk?”



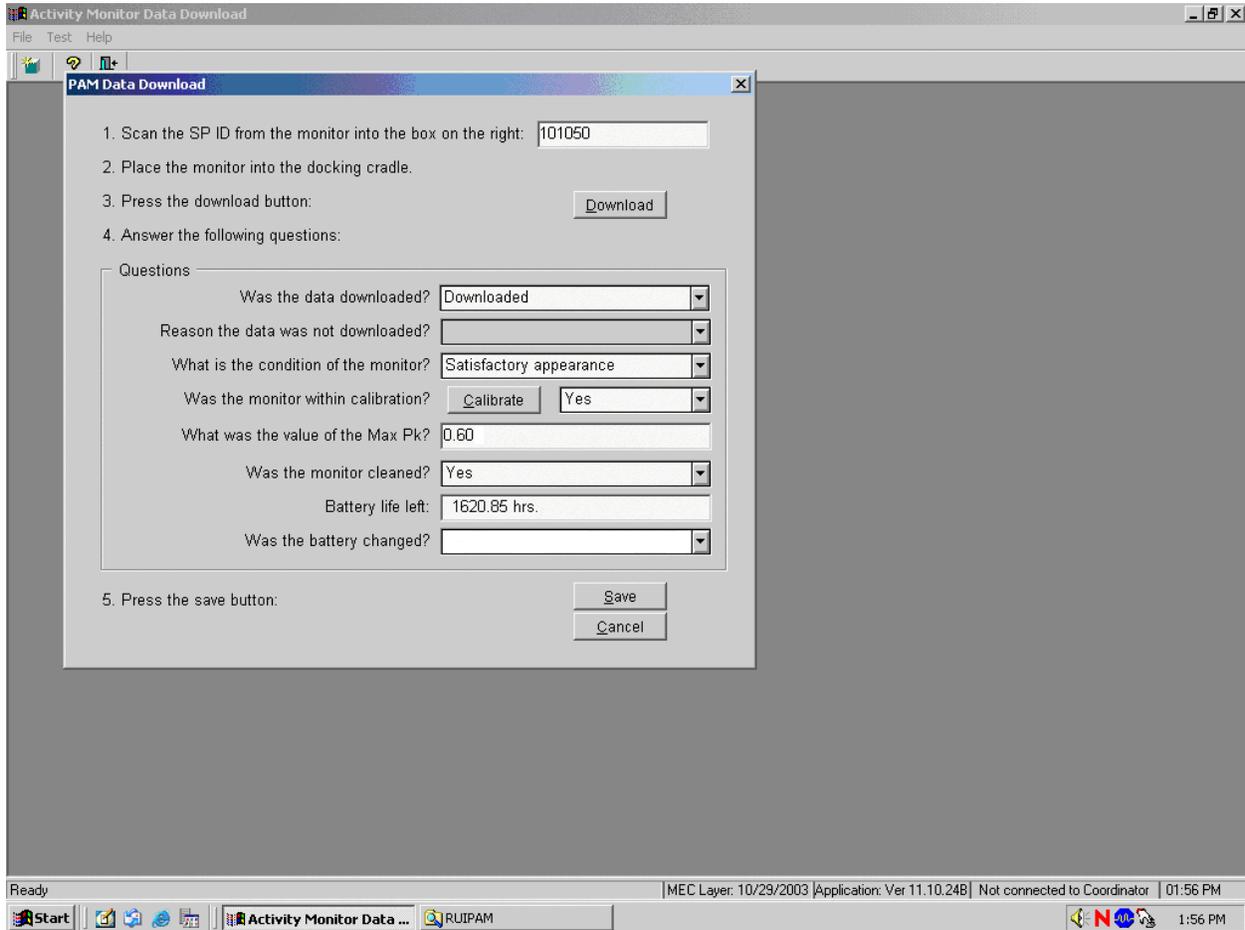
To record the value of the Max Pk in the text box, use the mouse to direct the mouse arrow to the text box and left click. Use the keyboard keys to enter a value using a X.XX format, where there is one number before the decimal and two numbers after the decimal.

Answer the question, “Was the monitor cleaned?”



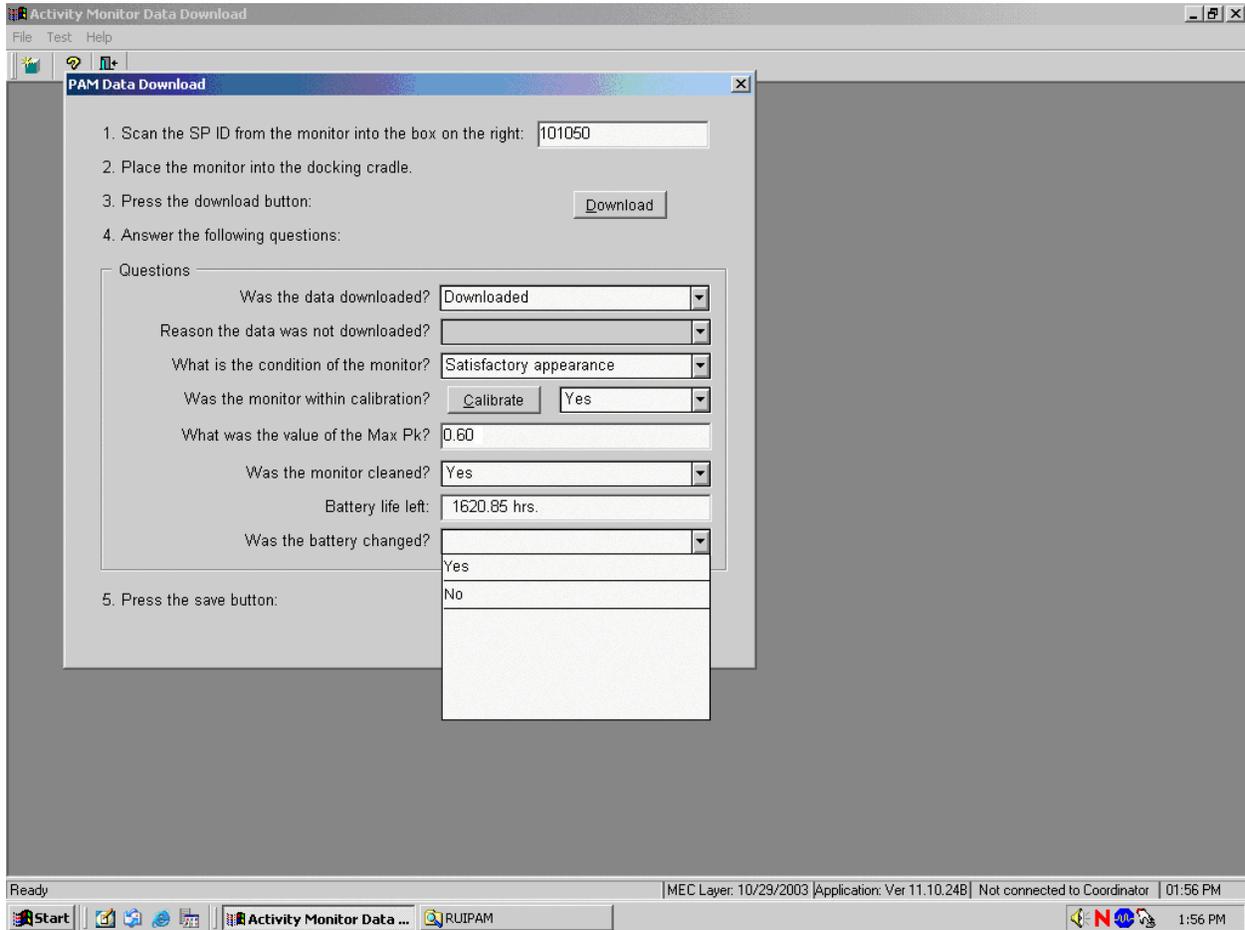
There are two possible responses to this question—Yes or No. Clean every monitor using procedures described in Section 16.14.2. Record the responses by typing [Y/y] for “Yes,” or [N/n] for “No.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes” or “No” and left click.

Review the number of hours displayed in the Battery life left text box.



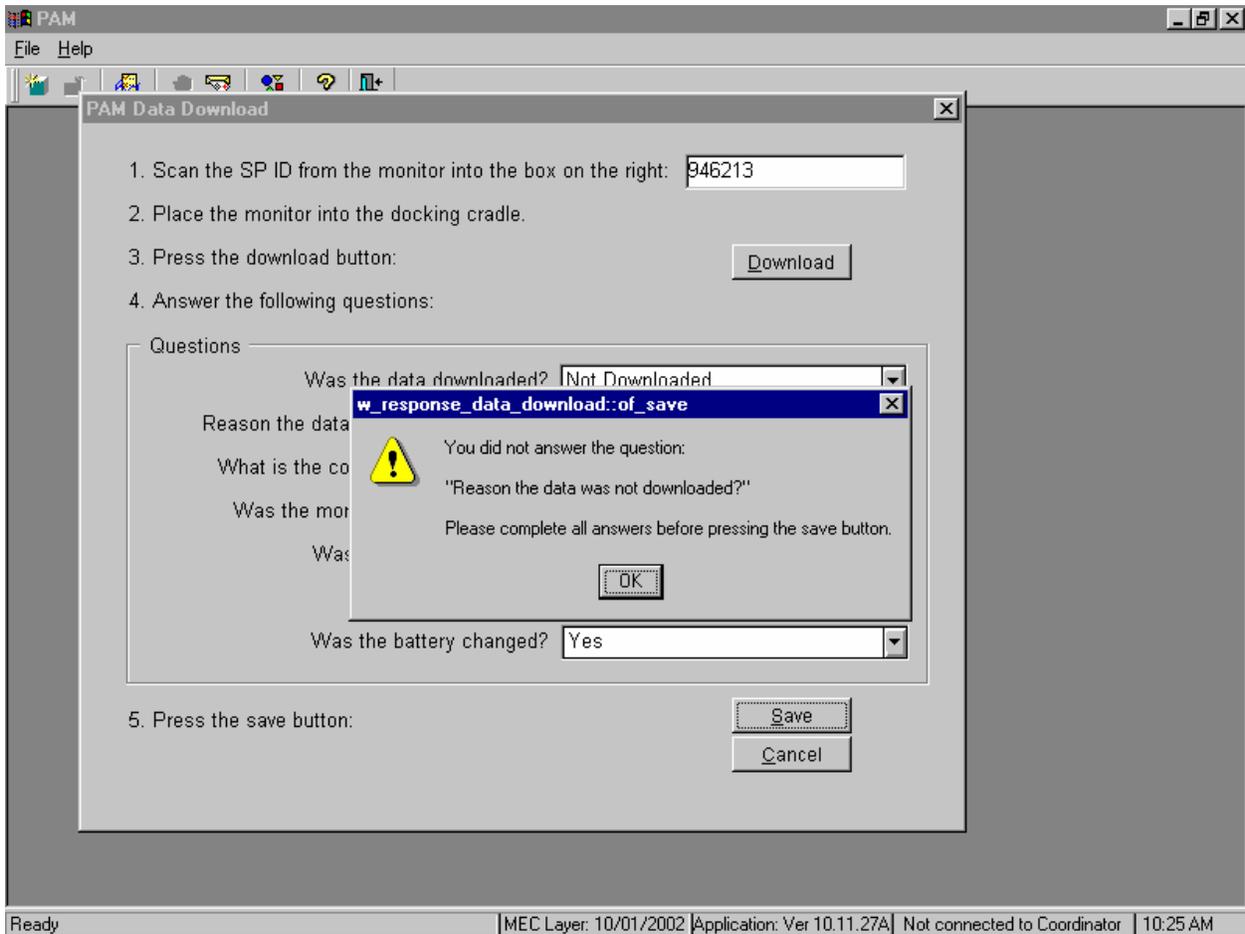
If the number of hours displayed in the Battery life left text box is less than or equal to 1,000, change the battery using procedures described in Section 16.14.1.

Answer the question, “Was the battery changed?”



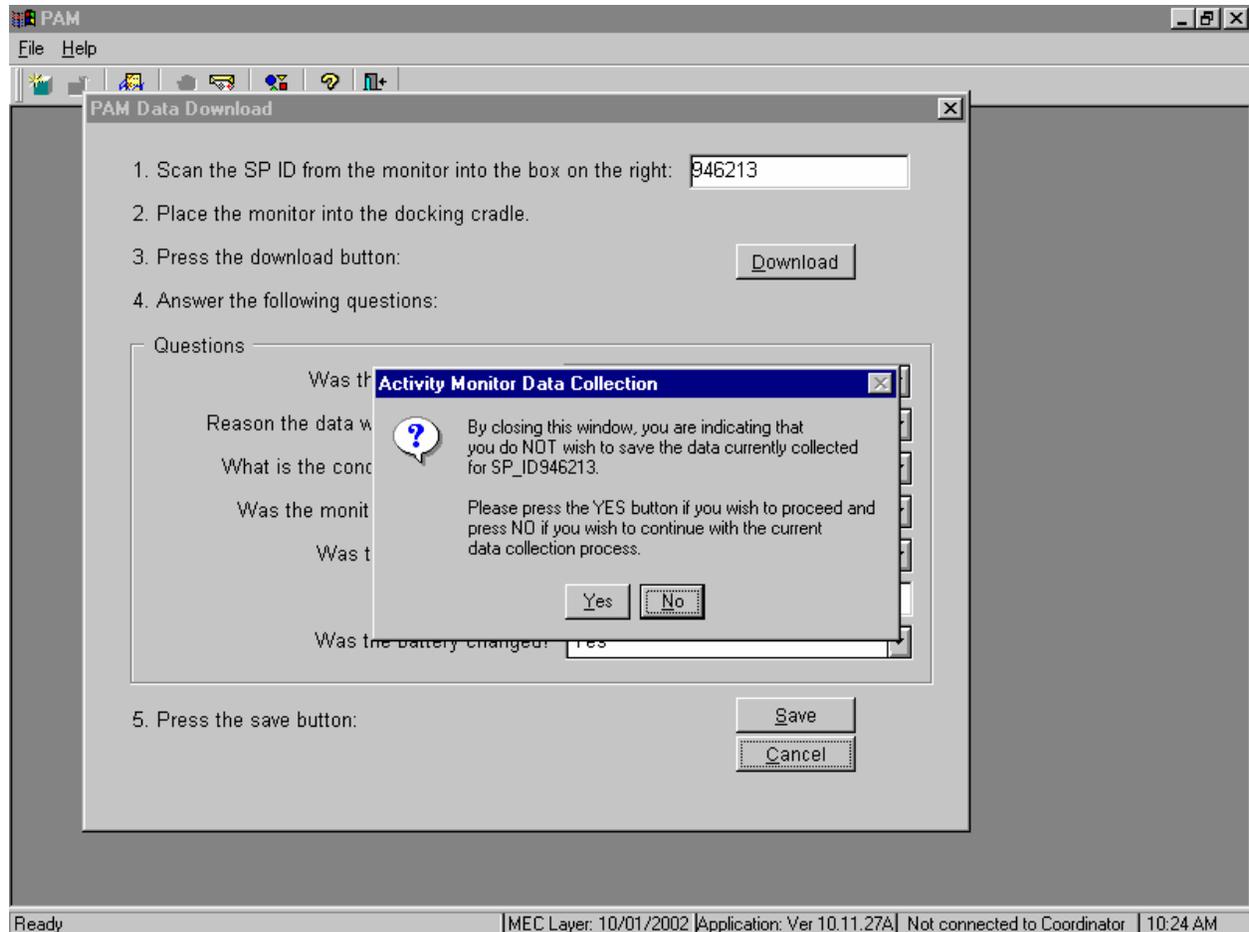
There are two possible responses to this question—Yes or No. Record the responses by typing [Y/y] for “Yes,” or [N/n] for “No.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes” or “No” and left click.

Save the data for this SP.



If the Save button is selected and one or more of the text boxes does not contain a response, then a warning message box displays requesting an answer to each unanswered question. To remove the warning message box, use the mouse to direct the mouse arrow to direct the mouse arrow to the OK button and left click or select [Enter].

Select the Cancel button to exit the data download and calibration process without saving any of the data to the database and to restart the process at the beginning.



To exit the data download and calibration process without saving any of the data to the database and to restart the process at the beginning, use the mouse to direct the mouse arrow to the Yes button and left click. To continue with the data collection (data download and calibration) process, use the mouse to direct the mouse arrow to the No button and left click or select [Enter].

## **16.15      Sending Monitors for Repair or Replacement**

Use the Equipment Tracking System to document the actions taken when sending a monitor to MTI for repair or replacement. Give the serial number of the monitor to the Senior Systems Programmer so that he or she can enter the information into the Equipment ID table.

The shipping address for MTI is:

Actigraph  
709 Anchors Street, NW  
Fort Walton Beach, FL 32548  
850-244-7211

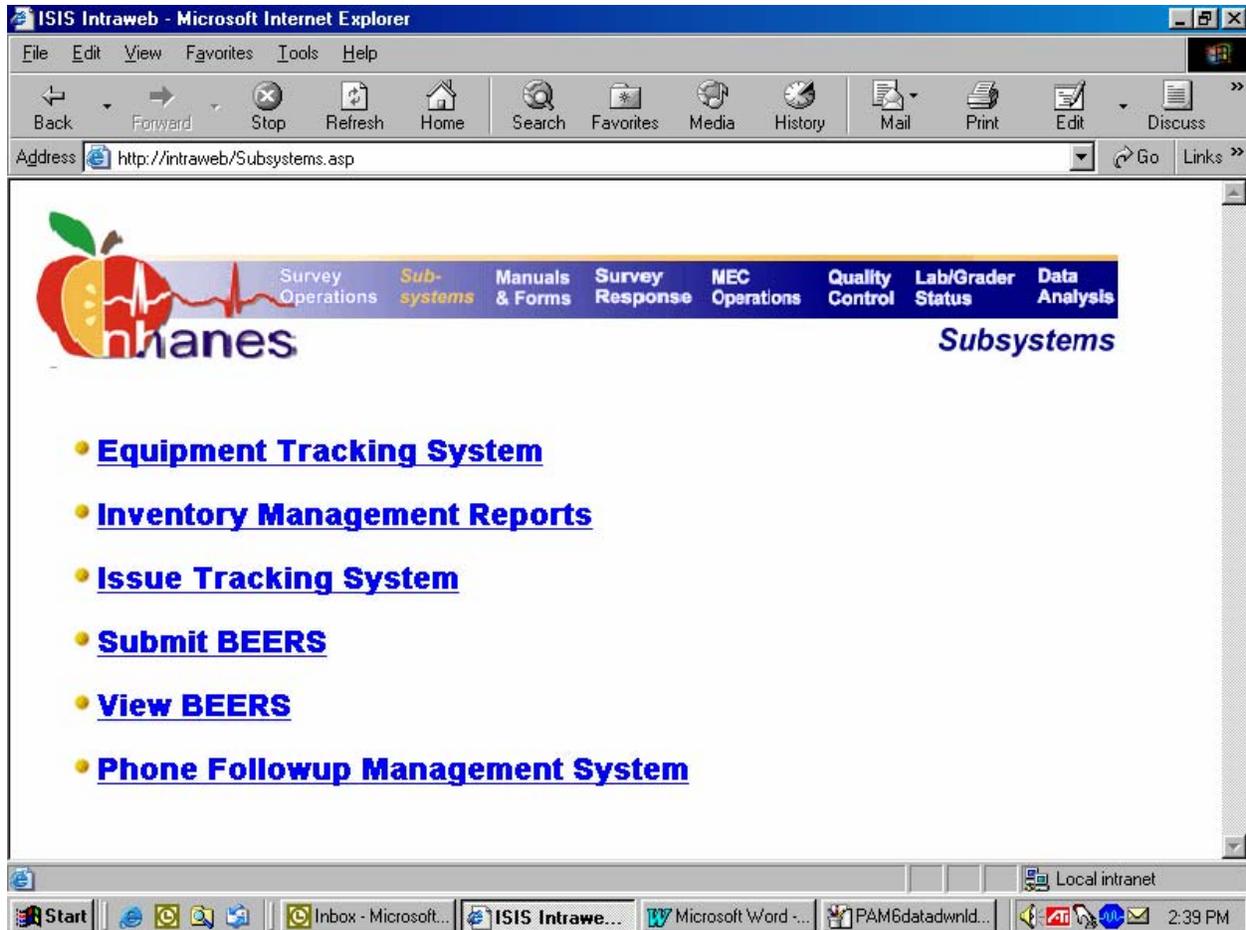
Send the monitor priority overnight to MTI using FedEx. Insure each monitor for \$300.00. Call MTI to inform them that the shipment is coming.

Access the Intraweb and the Equipment Tracking System subsystem.



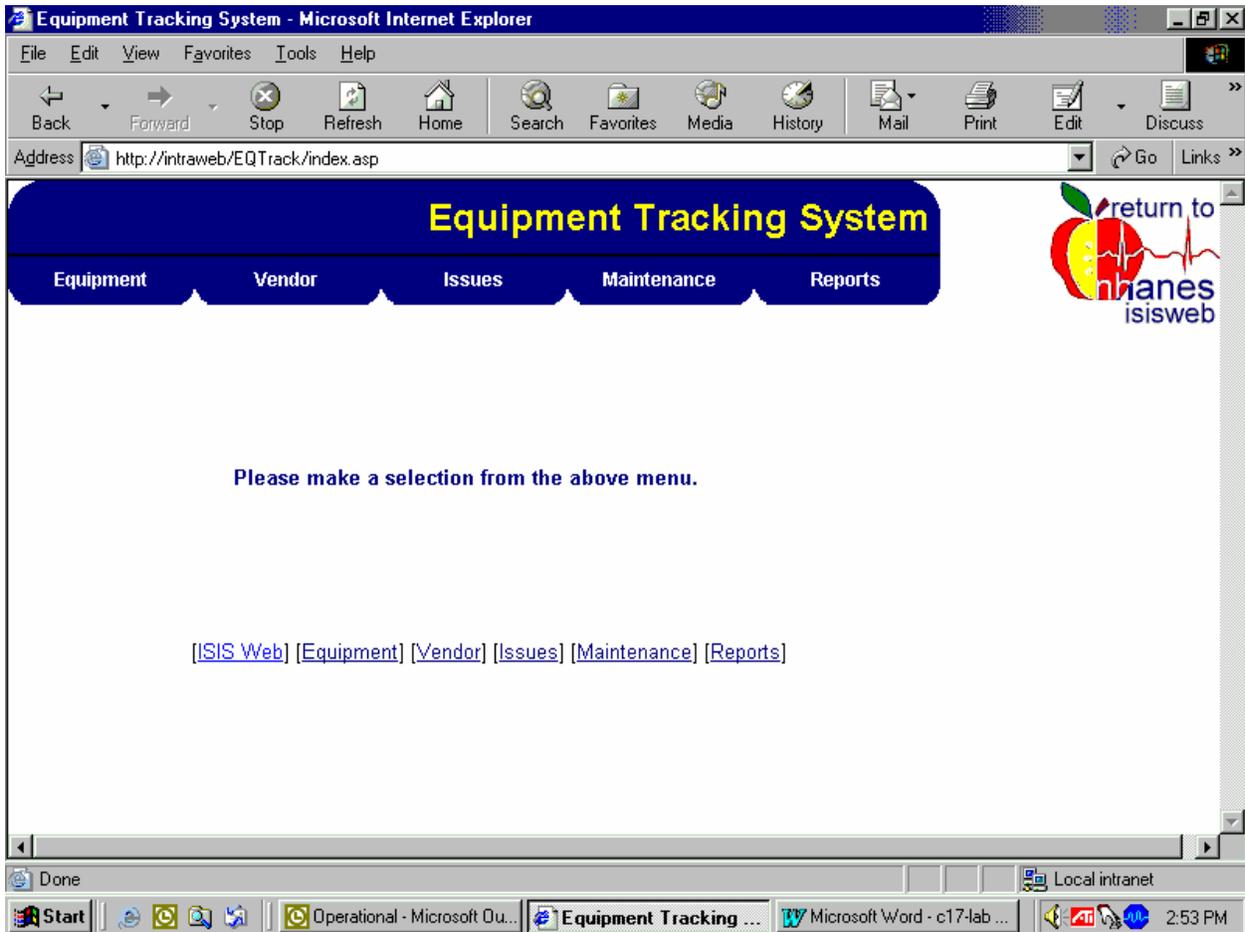
To access the Intraweb, double click on the Internet Explorer icon on the desktop. Type *http://intraweb/* in the address line and select [Enter]. From within the Intraweb main page, select (click on) the subsystems link in the top blue header.

The subsystem options display. From the list of subsystem options, select the Equipment Tracking System link.



To select the Equipment Tracking System option, use the mouse to direct the mouse arrow to the Equipment Tracking System link and left click.

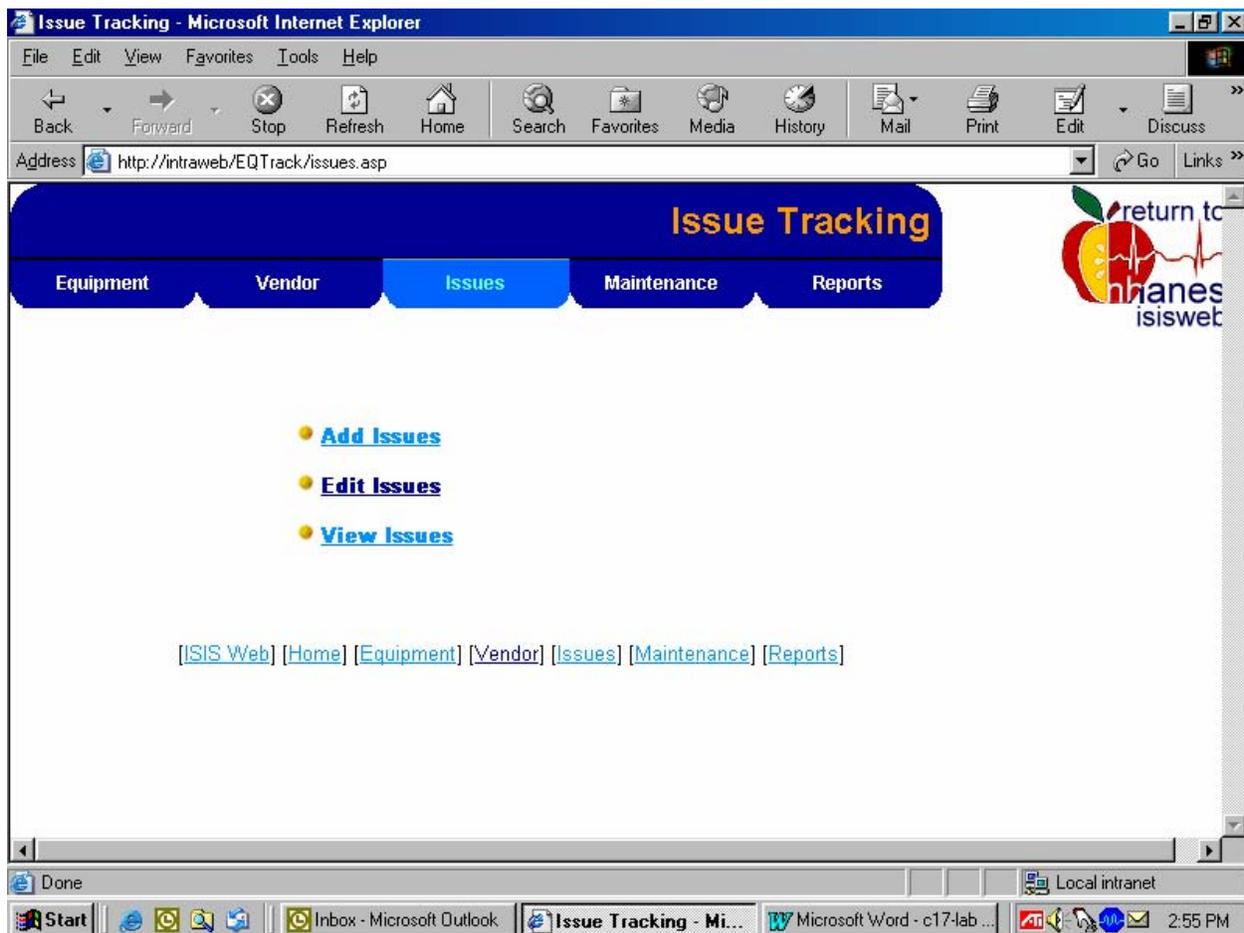
The home page of the Equipment Tracking System will display.



The home page is comprised of a menu bar of links for selecting specific information regarding equipment maintained within the system. Clicking on a link will display the category where additional selections or actions are available. Access the list by clicking on the selection link tab on top of the home screen or the text selection [underlined] link at the bottom of any ETS screen.

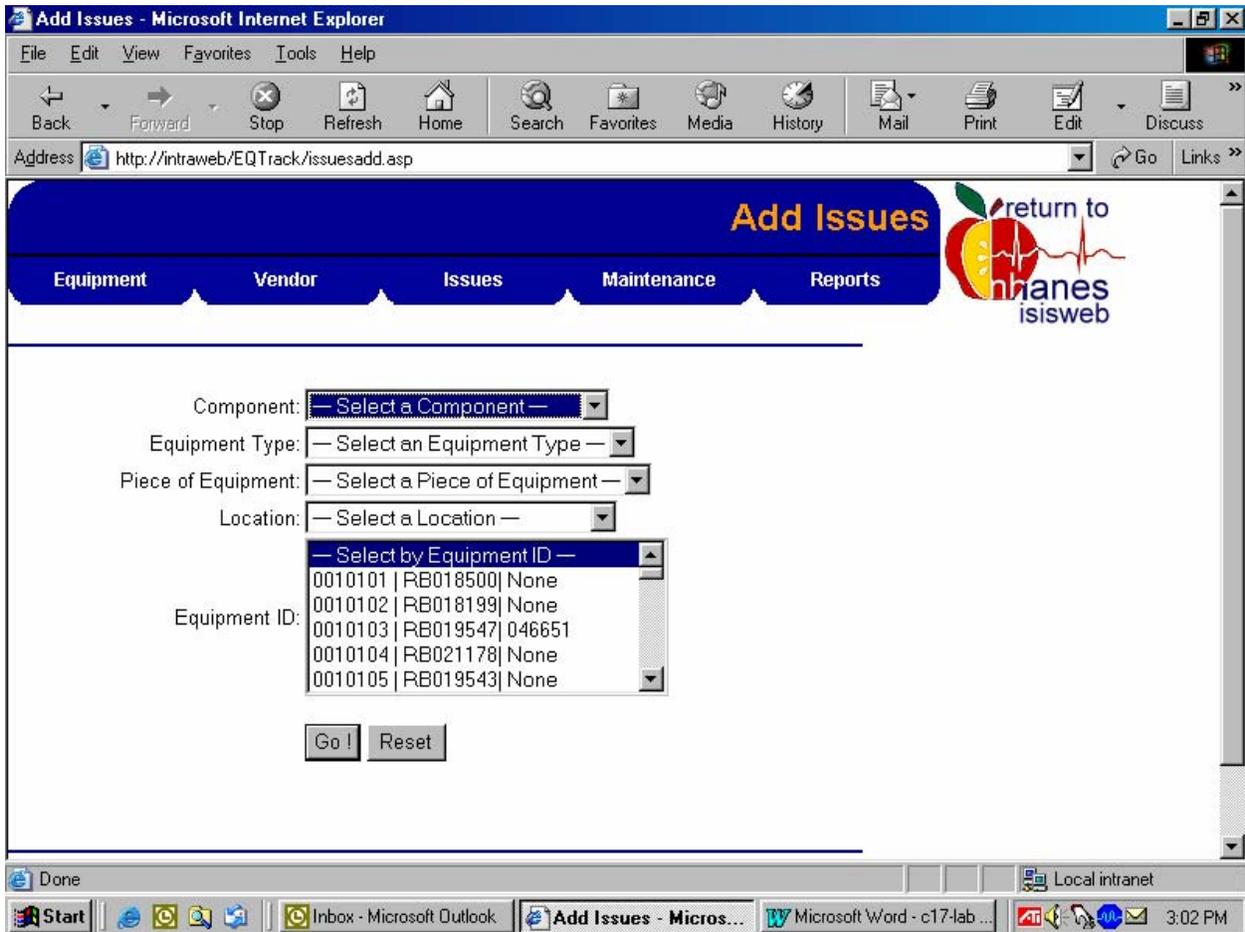
Issues involving equipment and facilities are maintained in the Issues selection link at the top of the home page. There are three submenus: Add issues, Edit Issues, and View Issues. Add a new issue, edit an existing issue, or view the status of and actions associated with resolved or outstanding issues, by selecting the appropriate link on the submenu.

Select the Add Issues submenu to document the initial actions taken when sending a monitor for repair or replacement.



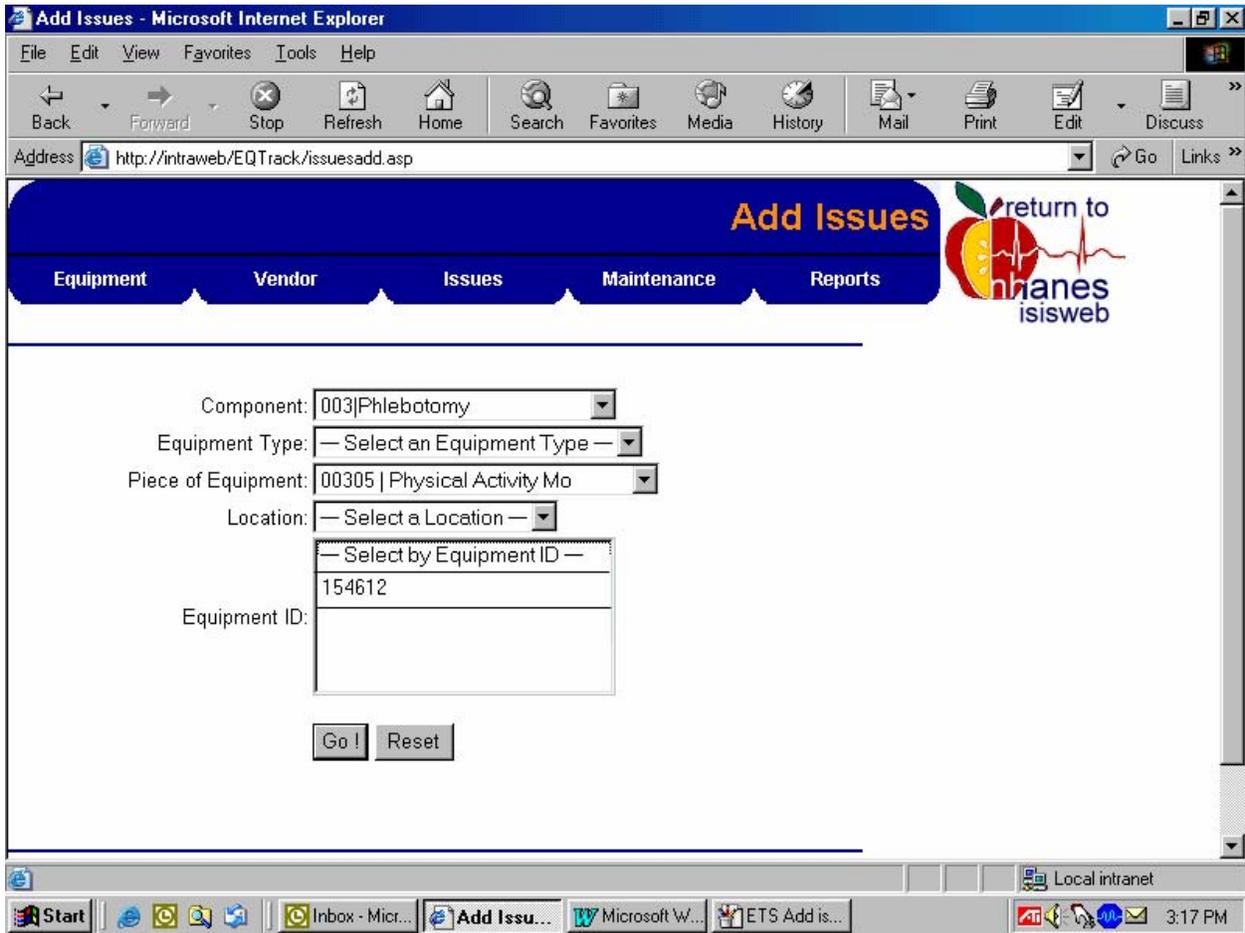
To select the Add Issues submenu, use the mouse to direct the mouse arrow to the Add Issues underlined link and left click.

The initial screen for adding issues displays.



Use drop-down lists to identify the component, the equipment type, a specific piece of equipment, and the location of the equipment or the equipment ID for a specific piece of equipment. To expand the list, use the mouse to direct the mouse arrow to the small down arrow on the right side of each list and left click.

All equipment IDs or serial numbers given to the Senior Systems Programmer are listed in the Equipment ID text box. Once the equipment ID is displayed, select the item from this list and select the Go! Button.



Select Phlebotomy as the component, and the 00305 Physical Activity Monitor as the Piece of Equipment. Finally, select the specific serial number from the list in the Equipment ID text box.

The Add Equipment Issue window appears and displays drop-down lists and text boxes to capture the equipment issue information.

**Add Equipment Issue #379**  
**Component: Phlebotomy**

Issue ID:	379 - pending
Equipment:	Physical Activity Monitor
Equip. ID:	model# AM7164-2.2 Version 2
Issue Date:	4 DEC 2002
Description:	<input type="text"/>
Identified by:	<input type="text"/>
Critical Level:	2   Non-Show Stopper
Issue Status:	1   Outstanding
Action Requested/ Issue Updates:	<input type="text"/>
Requested by:	<input type="text"/>

**Enter the information into each of the text boxes as described below:**

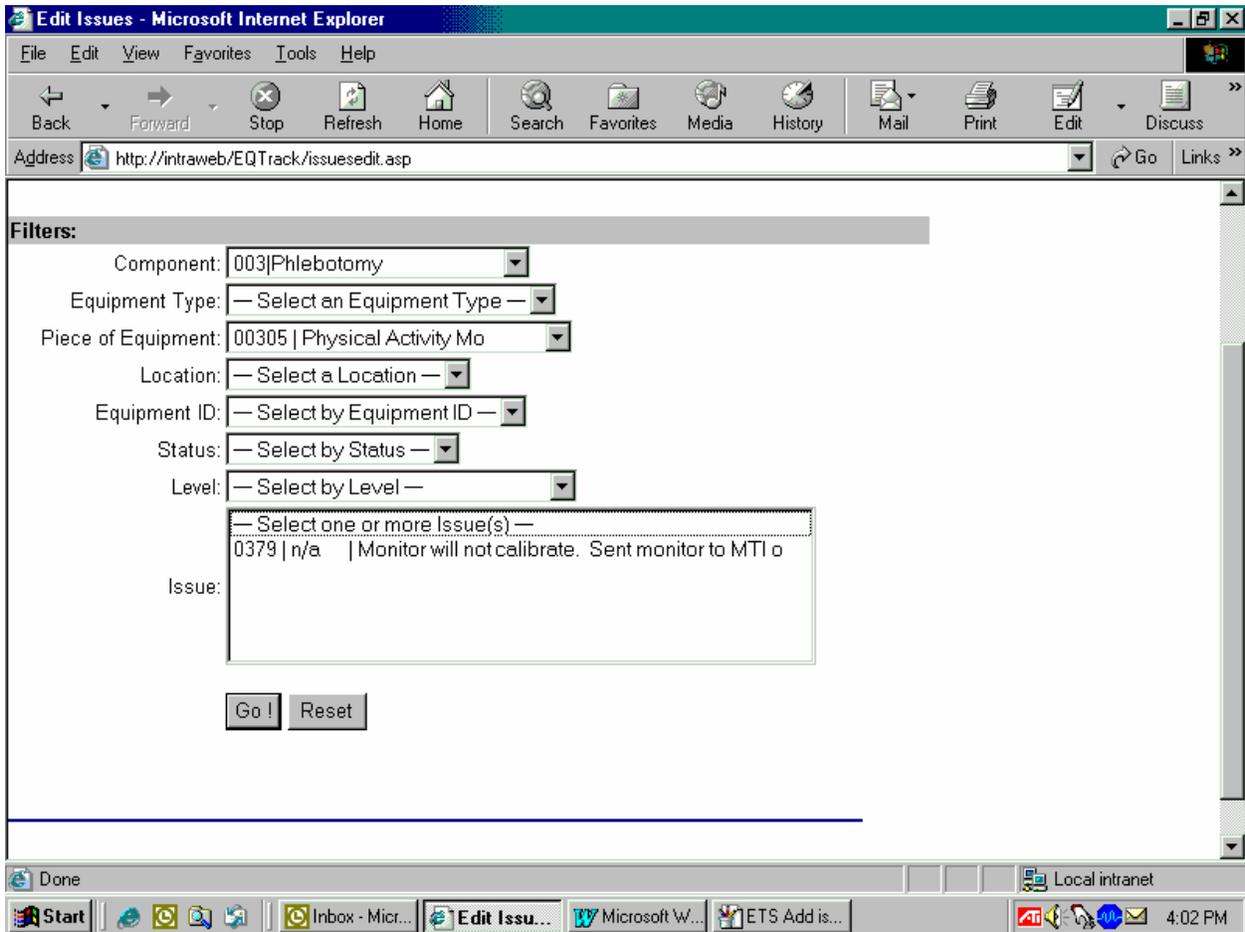
- Issue ID: The database assigns the next available number and designates the status as “pending.”
- Equipment: Information provided in the previous screen is shown as read-only text.
- Equip ID: Information provided in the previous screen is shown as read-only text.
- Issue Date: Issue Date shows the current date by default. To modify the date use the drop-down list on the right side of each of the text boxes to select day, month, and year.

- Description:** Type a description of the issue. Provide sufficient detail to allow someone unfamiliar with the problem to understand the exact location and nature of the problem. Include the date the item was shipped and the FedEx tracking number.
- Identified by:** Type full name.
- Critical Level:** Assess the impact of the equipment issue on the ability of the examiner to perform the exam. Showstopper is indicated when exams can no longer continue because of the issue. Non-Show Stopper is indicated when exams could continue with workarounds despite the issue.
- Issue Status:** Any open issue is considered to be Outstanding. An issue cannot be marked as resolved until the piece of equipment has been restored to working order or has been replaced.

To add this issue to the ETS database, use the mouse to direct the mouse arrow to the **Add** button and left click. To exit this module without saving the information to the database, use the mouse to direct the mouse arrow to the **Close Window** (“X”) in the upper right hand corner of the window and left click.

Update the status of the issue in the ETS after the monitor is returned from MTI. Use the **Edit Issues** submenu option to update the status of or document actions taken to address existing issues. Use filters to narrow the search to all items associated with a component, a particular type of equipment, a specific piece of equipment, or the status of equipment issues.

Select the Edit Issues submenu in the Issues selection link.



Select Phlebotomy as the component and Physical Activity Monitor as the Piece of Equipment. All issues relating to this piece of equipment display in the Issue text box. To access the edit screen, use the mouse to direct the mouse arrow to highlight the specific issue and then select the Go! button.

Once a specific Issue is selected, the Edit window for this issue appears. Only the Priority, Issue Status, Action Requested/Issue Updates, Requested by, Fix by; Resolved on, and Resolved by text boxes can be edited. Enter any action taken to address this issue into the Action Requested/Issue Updates text box. Information provided in the Add Issue screen is shown as read-only text.

Issue ID:	379
Equipment	Physical Activity Monitor - model# AM7164-2.2 Version 2
Equip. ID:	n/a - SN: - NCHS Barcode #
Issue Date:	Wed Dec 4 00:12:00 EST 2002
Description:	Monitor will not calibrate. Sent monitor to MTI on 12/4/02 FedEx tracking number 79855541452214.
Identified by:	Barbara Lindstrom
Priority:	2   Non-Show Stopper
Issue Status:	1   Outstanding
Action Requested/Issue Updates:	Monitor received back from MTI on 1/2/02.
Requested by:	
Fix by:	4   DEC   2002
Resolved On:	4   JAN   2003
Resolved by:	Barbara Lindstrom

Update

**Enter the information into each of the text boxes as described below:**

**Issue Status:** Review and update the status of this issue. Leave the status as outstanding if the issues remain unresolved or mark the status as resolved if the piece of equipment has been restored to working order or has been replaced.

**Action Requested/Issue Updates:** Enter the current date and your initials. Document all steps taken to resolve this issue. Include any requests made for action by someone else. Provide sufficient detail to allow someone unfamiliar with the problem to understand the exact actions taken and any pending requests for action. If this issue is resolved, document the exact steps taken to resolve the issue.

- Requested by: If you made specific requests of someone else, type your full name.
- Fix by: These fields will default to the current date. Correct this information if necessary.
- Resolved on: This date will default to 1 month after the current date unless the issue is marked as resolved. If the issue is marked as resolved, the field will default to the current date.
- Resolved by: Type your full name or the name of the person who resolved the issue.

To update this issue in the ETS database use the mouse to direct the mouse to the Update button and left click. To exit this module without updating the information in the database, select the Close Window "X" in the upper right hand corner of the window.

## **16.16      References**

- Berlin, J.A. and Colditz, G.A. (1990). A meta-analysis of physical activity in the prevention of coronary heart disease. *American Journal of Epidemiology*, 132, 612-628.
- Blair, S.N. and Morrow, Jr. J.R. (1998). Introduction: Cooper Institute/American College of Sports Medicine 1997 Physical Activity Intervention Conference. *American Journal of Preventative Medicine*, 15, 255-256.
- Janz, K.F. (1994). Validation of the CSA accelerometer for assessing children's physical activity. *Medicine and Science in Sports and Exercise*, 26, 369-75.
- Trost, S.G., Ward, D.S., Moorehead, S.M., Watson, P.D., Riner, W., and Burke, J. (1998). Validity of the computer science and application (CSA) activity monitor in children. *Medicine and Science in Sports and Exercise*, 30, 629-33.
- U.S. Department of Health and Human Services (1996). *The U.S. Surgeon General's Report on Physical Activity and Health*. SN 017-023-00196-5).

## Appendix A

International Air Transport Association (IATA)  
Dangerous Goods Regulations  
Revised December 2003

**APPENDIX A**  
**INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) DANGEROUS GOODS**  
**REGULATIONS**

**A.1 General Provisions**

The International Air Transport Association (IATA) publishes dangerous goods regulations. NHANES shipments fall under these regulations because specimens are packed in dry ice, which is classified as dangerous goods, and shipped via Federal Express, which uses air transport.

Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety, or to property, when transported by air and which are classified as to the type of hazard. The IATA Dangerous Goods Regulations are applicable to all shippers and agents that offer consignments of dangerous goods to airlines. A shipper must comply fully with these regulations when offering a consignment of dangerous goods to IATA member airlines, and to airlines participating in IATA interline agreements for cargo. Before offering any package for air transport, the shipper must comply with the following responsibilities (1.3.2).\*

- A shipper must provide such information to his employees as will enable them to carry out their responsibilities with regard to the transport of dangerous goods by air.
- The shipper must ensure that the articles or substances are not prohibited for transport by air.
- The articles or substances must be properly identified, classified, packed, marked, labeled, and documented in accordance with IATA regulations.
- Before a consignment of dangerous goods is offered for air transport, all relevant persons involved in its preparation must have received training to enable them to carry out their responsibilities.

The successful application of regulations concerning the transport of dangerous goods and the achievement of their objectives are greatly dependent on the appreciation of all individuals concerning the tasks involved and on a detailed understanding of the regulations. Initial and recurrent training programs achieve this for all persons concerned in the transport of dangerous goods. Training must be

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\* Notations in parentheses throughout this appendix represent the appropriate section in the *IATA Dangerous Goods Regulations*.

provided or verified upon the employment of a person in a position involving the transport of dangerous goods by air (1.5.0.2). Recurrent training must take place within 24 months of previous training to ensure knowledge is current (1.5.0.3). A test must be undertaken following dangerous goods training to verify understanding of the regulation. A certificate must be issued confirming successful completion of the test (1.5.0.4).

Training requirements (1.5) include:

- General familiarization aimed at providing familiarity with IATA general provisions (1.5.2.2);
- Function specific training in the requirements applicable to the function for which that person is responsible; and
- Safety training to cover the hazards presented by dangerous goods, safe handling, and emergency response procedures.

A record of training must be maintained, which must include the following (1.5.4):

- The individual's name;
- The most recent training completion date;
- A description, copy, or reference to training materials used to meet the training requirement;
- The name and address of the organization providing the training; and
- A copy of the certification issued when the individual was trained, which shows a test has been completed satisfactorily.

#### **Training Curricula (table 1.5A)**

Aspects of transport of dangerous goods by air which packers should be familiar, as a minimum include:

- General philosophy
- Classifications
- List of dangerous goods
- General packing requirements

- Packing instructions
- Labeling and marking
- Provisions for passengers and crew
- Emergency procedures

## **A.2 Limitations**

Some dangerous goods are too dangerous to be carried by aircraft, others may be carried on cargo aircraft only, and some are acceptable on both cargo and passenger aircraft. A number of limitations are placed in dangerous goods, which are permitted to be transported by air. These limitations are established by these Regulations (2.0).

The following goods are permitted on aircraft as checked baggage only and with the approval of the operator(s) (2.3.2).

- Dry Ice – Carbon Dioxide, solid (dry ice) in quantities not exceeding 2 kg (4.4 lb) per person when used to pack perishables not subject to these Regulations, provided the checked baggage (package) permits release of carbon dioxide gas (2.3.2.1).

## **A.3 Classifications**

Dangerous goods are defined as those goods which meet the criteria of one or more of the nine UN hazard classes and, where applicable, to one of the three UN packing groups according to provisions of IATA regulations. The nine classes relate to the *type of hazard*, whereas the packing groups relate to the *degree of danger* within the class (3.0.1). The nine classes are: Class 1 Explosives; Class 2 Gases; Class 3 Flammable Liquids; Class 4 Flammable Solids, Substances Liable to Spontaneous Combustion, Substances Which, in Contact with Water, Emit Flammable Gases; Class 5 Oxidizing Substances and Organic Peroxide; Class 6 Toxic and Infectious Substances; Class 7 Radioactive Material; Class 8 Corrosives; and Class 9 Miscellaneous Dangerous Goods.

Dangerous goods are assigned to the relevant packing group according to the degree of hazard that they present (3.0.3). The three packing groups are: Packing Group 1 – high danger, Packing Group 2 – medium danger, and Packing Group 3 – low danger.

### **A.3.1 Class 6.2 – Infectious Substances (3.6.2)**

Division 6.2 includes substances which are infectious to humans, and/or animals, genetically modified micro-organisms and organisms, biological products, diagnostic specimens, and clinical and medical waste (3.6.2.1).

Diagnostic specimens are defined as any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live infected animals. Diagnostic specimens must be assigned to UN 3373 unless the source patient or animal has or may have a serious human or animal disease, which can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventive measures are not usually available, in which case they must be assigned to UN 2814 or UN 2900 (3.6.2.1.4). Diagnostic specimens are regulated by packing instruction 650.

### **A.3.2 Class 9 – Miscellaneous Dangerous Goods**

Class 9 defines miscellaneous dangerous goods as substances and articles, which, during air transport, present a danger not covered by other classes (3.9.1). Included in this class is solid carbon dioxide, or dry ice. Dry ice is regulated by packing instruction 904.

### **A.3.3 List of Dangerous Goods**

Dry ice is classified as UN number 1845 and is classified as Class 9 dangerous goods. Shipping packaging must be labeled with a Miscellaneous Class 9 label (pg. 139).

Dry ice is included within Packing Group III, which is classified as a minor danger. A maximum net quantity per package is 200 kg or 441 lb. A special provision directs that packing tests are not considered necessary (4.4 A48 Pg 281).

#### **A.4 General Packing Provisions**

For packing purposes, Packing Group numbers I, II, or III are assigned to dangerous goods in Classes 3, 4, 5, 6, 8 and 9 according to the relative degree of danger presented by the article or substance.

- Packing Group I – Substances presenting high danger
- Packing Group II – Substances presenting medium danger
- Packing Group III – Substances presenting low danger

Packing group III indicates a substance presenting a low danger (5.0.2.1). Dry ice (solid carbon dioxide) is produced by expanding liquid carbon dioxide to vapor and “snow” in presses that compact the product into blocks. Dry ice is used primarily for cooling and can cause severe burns (its temperature is about  $-79^{\circ}\text{C}$ ) to skin in case of direct contact. When dry ice (solid carbon dioxide converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent buildup of pressure due to release of carbon dioxide gas.

Dangerous goods must be packed in good quality packaging, which must be strong enough to withstand the shocks and loadings normally encountered in transport. Packages must be constructed, and closed as to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration or by changes in temperature, humidity, or pressure (resulting from altitude, for example) (5.0.2.4).

New, remanufactured, reused, or reconditioned packaging must be manufactured and tested under a program of quality assurance to ensure that such packaging meets requirement (5.0.2.5).

Packaging for which retention of liquid is a basic function, must be capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95 kPa for liquids in packing group III, Class 3 or Division 6.1 (5.0.2.9).

Packaging used for solids, which may become liquid at temperatures likely to be encountered during air transport, must also be capable of containing that substance in the liquid state (5.0.2.10).

Inner packaging – cushioning material: Inner packaging must be packed, secured, or cushioned in an outer packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into outer packaging and so as to control their movement (5.0.2.12.1).

#### **A.4.1 Packing Instruction 904 - Dry Ice (page 487)**

Dry ice (solid carbon dioxide), when offered for transport by air, must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.

The net weight of dry ice must be marked on the outside of the package.

Arrangements between the shipper and operator(s) must be made for each shipment to ensure that ventilation and safety procedures are followed. When a Shipper's Declaration is not required, the information as required by 8.2.3 for dry ice (solid carbon dioxide) must be contained in the "Nature and Quantity of Dangerous Goods" box on the air waybill, excluding the packing instruction number and packing group. The "Nature and Quantity of Dangerous Goods" box of the Air Waybill must show in sequence:

- Proper shipping name (**Dry Ice**)
- Class or division number (**9**)
- UN number (**UN 1845**)
- *Packing Group (III)*

- Subsidiary risk, if any (**none**)
- Number of packages
- Net quantity per package (**kg**)

*For dry ice (solid carbon dioxide), it is not necessary to show the packing group and packing instruction number on the air waybill.*

#### **A.4.2 Packing Instruction 650 - Diagnostic Specimens (page 438-9)**

Diagnostic specimens must be packed in good quality packaging, which must be strong enough to withstand the shocks and loading normally encountered during transport, including transshipment between transport units and warehouses as well as removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging must be constructed and closed to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity, or pressure.

Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into secondary packaging. Secondary packagings must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not substantially impair the protection properties of the cushioning material or of the outer packaging.

Packages must be prepared as follows:

##### **650(a) For Liquids**

- The primary receptacle(s) must be leak proof and must not contain more than 500 mL.
- There must be absorbent material placed between the primary and secondary packagings. If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them. The absorbent material must be in sufficient quantity to absorb the entire contents of the primary receptacles and there must be a secondary packaging, which must be leak proof.

- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40°C to +55°C (-40°F to 130°F).
- The outer packaging must not contain more than 4 L.

**650(b) for Solids**

- The primary receptacles must be slitproof and must not contain more than 500 g.
- If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them and there must be a secondary packaging, which must be leakproof.
- The outer packaging must not contain more than 4 kg.

**For Liquids and Solids**

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
- Each completed package must be capable of successfully passing the following drop tests: (6.6.1.1)
  - Samples must be subjected to free-fall drops onto a ridged, nonresilient, flat, horizontal surface from a height of not less than 1.2 m.
  - Where the samples are in the shape of a box, five must be dropped in sequence:
    1. Flat onto the base;
    2. Flat into the top;
    3. Flat into the longest side;
    4. Flat onto the shortest side; and
    5. Onto a corner.
  - Following the appropriate drop sequence, there must be no leakage from the primary receptacles(s), which must remain protected by absorbent material in the secondary packaging.
- The samples must be subjected to a water spray that simulated exposure to rainfall of approximately 5 cm per hour for at least 1 hour. It must then be subjected to the drop test.

- The samples must be conditioned in an atmosphere of -18°C (0°F) or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the drop test (6.6.1.3).
- Where packaging is intended to contain dry ice (solid carbon dioxide), an additional test must be carried out. One sample must be stored so that all the dry ice dissipates and then it is subjected to the drop test.
- Packages must have one side with dimensions of not less than 100 mm x 100 mm (4 in x 4 in) or packages must be in an overpack that has one side with dimensions of not less than 100 mm x 100 mm (4 in x 4 in).
- Each package and the “Nature and Quantity of Goods” box of the air waybill must show the text “DIAGNOSTIC SPECIMENS.” Each package must also be marked to indicate that the shipper has determined that the packaging meets the applicable air transport requirements. The marking must be durable, legible, and of such a size relative to the package as to be readily visible. The marking must include the symbol consisting of an aircraft within a circle and may include the words “Air Eligible.” The marking must be applied adjacent to the words “DIAGNOSTIC SPECIMENS” (7.1.5.8).
- A Shipper’s Declaration for Dangerous Goods is not required.
- An operator must report dangerous goods accidents or incidents to the appropriate authorities of the state of the operator and the state in which the accident or incident occurred, in accordance with the reporting requirements of those appropriate authorities.

The majority of diagnostic specimens can and must be packaged according to the Packing Instruction.

### **Specific Requirements**

*Substances shipped at ambient temperatures or higher:* Primary receptacles include those of glass, metal or plastic. Positive means of ensuring a leakproof seal, such as heat seal, skirted stopper or metal crimp seal must be provided. If screw caps are used, these must be reinforced with adhesive tape.

*Substances shipped refrigerated or frozen [wet ice, prefrozen packs, dry ice (solid carbon dioxide)]:* Ice, dry ice, or other refrigerant must be placed outside the secondary packaging(s) or alternatively in an overpack with one or more completed packages. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after ice or dry ice (solid carbon dioxide) has been dissipated. If ice is used, the packaging must be leak-proof. If dry ice (solid carbon

dioxide) is used, the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

## **A.5 Packing Specifications and Performance Tests**

Performance tests are designed to ensure that there will be no loss of contents under normal transport conditions. The severity of the tests on a packaging is dependent on the intended contents, taking account of the degree of danger; that is, packing group, relative density (specific gravity), and vapor pressure (for liquids) (6.3.0.2).

The design type of each packaging must be tested in accordance with procedures established by IATA regulation (6.3.1). Tests must be successfully performed on each packaging type before such packaging is used (6.3.1.1.1).

## **A.6 Marking and Labeling**

All markings must be so placed on packages or overpacks that they are not covered or obscured by any part of or attachment to the packaging or any other label or marking (7.1.3.1).

All markings must be:

- Durable and printed or otherwise marked on, or affixed to, the external surface of the package or overpack;
- Readily visible and legible;
- Able to withstand open weather exposure without a substantial reduction in effectiveness; and
- Displayed on a background of contrasting color (7.1.3.2).

Each package must be marked durably and legible on the outside with each of the following:

- The proper shipping name of the contents and the corresponding UN numbers (7.1.5.1a) (dry ice is UN 1845);
- The full name and address of the shipper and the consignee (7.1.5.1b);
- The NET Quantity of dry ice contained in each package or overpack must be shown. The quantity must be marked on each package or overpack adjacent to the UN number and Proper Shipping Name (7.1.5.1d); and
- Packages containing “Diagnostic Specimens”: “DIAGNOSTIC SPECIMENS” (7.1.5.1g).
- Each package must also be marked to indicate that the shipper has determined that the packaging meets the applicable air transport requirements. The marking must be durable, legible, and of such a size relative to the package as to be readily visible. The marking must include the symbol consisting of an aircraft within a circle and may include the words “Air Eligible.” The marking must be applied adjacent to the words “DIAGNOSTIC SPECIMENS” (7.1.5.8).

The hazard label is specified for each substance. All packages must bear the appropriate hazard label (7.2.3.1). The label identifying the primary hazard of the dangerous goods must bear the class number in the bottom corner of the label (7.2.3.2). For Class 9 goods (dry ice), the package is required to bear the Class 9 “Miscellaneous” dangerous goods label (7.2.3.9).

There are two types of labels: hazard labels (in the shape of a square set at 45°) which are required for most dangerous goods in all classes and handling labels (in various rectangular shapes), which are required, wither alone or in addition to hazard labels for some dangerous goods (7.2.2.2).

A primary hazard label is specified for each listed article and substance and a secondary hazard label or labels for each article and substance having subsidiary risks (7.2.3.1). For Class 9 materials, the package must bear the class 9, “Miscellaneous Dangerous Goods” label as required for all dry ice shipments (7.2.3.10).

All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label (7.2.6.1a). Each label must be affixed on a background of contrasting color or must have a dotted or solid line outer border (7.2.6.1b). The label must not be folded or affixed in such a manner that different parts of the label

appear on different faces of the package (7.2.6.1c). The package must be of such a size that there is adequate space to affix all required labels (7.2.6.1e).

Labels must be located on the same surface of the package near the proper shipping name marking if the package dimensions are adequate (7.2.6.2.1).

## **A.7 Documentation**

An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). A “Shipper’s Declaration for Dangerous Goods” is not required for shipments containing dry ice. (FedEx, page 79 F.). For each shipment containing dangerous goods, the shipper must (8.0.2):

- Use only the correct form in the correct manner (8.0.2a).
- Ensure that the information on the form is accurate, easy to identify, legible, and durable (8.0.2b).
- Ensure that the shipment has been prepared in accordance with IATA regulations (8.0.2d).

Each air waybill must include the following (8.2):

- Full name, address, telephone number, and ZIP code of the shipper;
- Full name, address, telephone number, and ZIP code of the recipient;
- The dry ice box must be checked and the dry ice information must be entered under the Special Handling section on the airbill; and
- Net quantity per package (kg) of dry ice.

## **A.8 References**

1. *IATA Dangerous Goods Regulations*, 45th Edition, effective January 1, 2004, ISBN 92—9195-116-1
2. *FedEx Service Guide Vol. 1*, effective June 1, 2000.

**A.9 IATA Regulations Examination**

Name \_\_\_\_\_

Date \_\_\_\_\_

1. IATA is the acronym for \_\_\_\_\_
2. Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety or to property, when transported by air and which are classified as to the type of hazard. (T or F)
3. What are the four responsibilities the shipper must comply with before offering any package for air transport?
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
4. List the three training requirements:
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
5. How many UN hazard classes are there? \_\_\_\_\_
6. To what UN hazard class does dry ice belong? \_\_\_\_\_
7. What is the dry ice UN number? \_\_\_\_\_
8. To what packing group does dry ice belong? \_\_\_\_\_
9. Solid carbon dioxide or dry ice is produced by expanding liquid carbon dioxide to vapor and “snow” in presses that compact the product into blocks. Dry ice is used primarily for cooling and can cause severe burns (its temperature is about -79° C) to skin in case of direct contact. When dry ice (solid carbon dioxide) converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent buildup of pressure due to release of carbon dioxide gas. (T or F)

10. List the four types of packaging that must be tested to ensure that packaging meets requirements:
- \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
11. What is the internal pressure that a package designed for liquid retention must be capable of withstanding?  
\_\_\_\_\_
12. The weight of dry ice is required on the outside of the packaging.  
(T or F)
13. Diagnostic specimens must be packed in good quality packaging, which must be strong enough to withstand the shocks and loading normally encountered during transport, including transshipment between transport units and warehouses as well as removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging must be constructed and closed to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity, or pressure. What packing instruction regulates diagnostic specimens? \_\_\_\_\_
14. List the four packaging requirements for liquids.
- \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
15. What special requirement does the absorbing material have?  
\_\_\_\_\_
16. Each package and the “Nature and Quantity of Goods” box of the air waybill must show the text “DIAGNOSTIC SPECIMENS.” Each package must also be marked to indicate that the shipper has determined that the packaging meets the applicable air transport requirements. The marking must be durable, legible and of such a size relative to the package as to be readily visible. The marking must include the symbol consisting of an aircraft within a circle and may include the words “Air Eligible.” (T or F)
17. Where is an itemized list of contents placed?  
\_\_\_\_\_

18. What three primary receptacles are included in the guidelines for substances shipped at ambient temperature?

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

19. Ice, dry ice (solid carbon dioxide), or other refrigerant must be placed outside the secondary packaging(s) or alternatively in an overpack with one or more completed packages. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after ice or dry ice has been dissipated. If ice is used, the packaging must be leakproof. If dry ice (solid carbon dioxide), is used, the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost. (T or F)

20. The performance tests are designed to ensure that there will be \_\_\_\_\_ under normal transport conditions.

21. All markings must be:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

22. For Class 9 goods (dry ice), the package is required to bear the \_\_\_\_\_ dangerous goods label.

23. All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label. (T or F)

24. An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). Dry ice shipments prepared in accordance with IATA regulations do not require a Shipper’s Declaration (FedEx, page 79 F.). List the three requirements that the shipper must meet for each shipment containing dangerous goods:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

25. Each airbill must include:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

**A.10 IATA Regulations Examination (Answer Key)**

Name \_\_\_\_\_

Date \_\_\_\_\_

1. IATA is the acronym for the International Air Transport Association
2. Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety or to property, when transported by air and which are classified as to the type of hazard. (T or F) True
3. What are the four responsibilities the shipper must comply with before offering any package for air transport?
  - Information to employees as will enable them to carry out their responsibilities.
  - Ensure that articles or substances are not prohibited for transport by air.
  - Articles must be properly identified, classified, packed, marked, labeled, and documented.
  - All persons involved in preparing consignment must have received training.
4. List the three training requirements:
  - General familiarization aimed at providing familiarity with IATA general provisions;
  - Function specific training in the requirements applicable to the function for which that person is responsible; and
  - Safety training to cover the hazards presented by dangerous goods, safe handling, and emergency response procedures.
5. How many UN hazard classes are there? 9 (nine)
6. To what UN hazard class does dry ice belong? Class 9
7. What is the dry ice UN number? UN 1845
8. To what packing group does dry ice belong? Packing group 3
9. Solid carbon dioxide or dry ice is produced by expanding liquid carbon dioxide to vapor and “snow” in presses that compact the product into blocks. Dry ice is used primarily for cooling and

can cause severe burns (its temperature is about  $-79^{\circ}\text{C}$ ) to skin in case of direct contact. When dry ice (solid carbon dioxide) converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent buildup of pressure due to release of carbon dioxide gas.

(T or F) True

10. List the four types of packaging that must be tested to ensure that packaging meets requirements:
  - New
  - Remanufactured
  - Reused
  - Reconditioned
11. What is the internal pressure that a package designed for liquid retention must be capable of withstanding? 95 kPa
12. The weight of dry ice is required on the outside of the packaging.  
(T or F) True
13. Diagnostic specimens must be packed in good quality packaging, which must be strong enough to withstand the shocks and loading normally encountered during transport, including transshipment between transport units and warehouses as well as removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging must be constructed and closed to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity, or pressure.  
What packing instruction regulates diagnostic specimens? Packing instruction 650
14. List the four inner packaging requirements.
  - A leak proof primary receptacle(s) - for diagnostic specimens, the maximum quantity must not exceed 500-mL.
  - An absorbent material - must be placed between the primary and the secondary packaging.
  - Secondary leakproof packaging.
  - The primary or the secondary receptacles must be capable of withstanding , without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.
15. What special requirement does the absorbing material have?  
The absorbing material must be sufficient to absorb the entire contents of all primary receptacles.

16. Each package and the “Nature and Quantity of Goods” box of the air waybill must show the text “DIAGNOSTIC SPECIMENS.” Each package must also be marked to indicate that the shipper has determined that the packaging meets the applicable air transport requirements. The marking must be durable, legible and of such a size relative to the package as to be readily visible. The marking must include the symbol consisting of an aircraft within a circle and may include the words “Air Eligible.” (T or F) True
17. Where is an itemized list of contents placed?  
An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
18. What three primary receptacles are included in the guidelines for substances shipped at ambient temperature?
- Glass
  - Metal
  - Plastic
19. Ice, dry ice (solid carbon dioxide), or other refrigerant must be placed outside the secondary packaging(s) or alternatively in an overpack with one or more completed packages. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after ice or dry ice has been dissipated. If ice is used, the packaging must be leakproof. If dry ice (solid carbon dioxide), is used, the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost. (T or F) True
20. The performance tests are designed to ensure that there will be no loss of contents under normal transport conditions.
21. All markings must be:
- Durable and printed or otherwise marked on, or affixed to, the external surface of the package or overpack
  - Readily visible and legible
  - Able to withstand open weather exposure without a substantial reduction in effectiveness
  - Displayed on a background of contrasting color
22. For Class 9 goods (dry ice), the package is required to bear the Class 9 “Miscellaneous” dangerous goods label.
23. All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label. (T or F) True

24. An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). Dry ice shipments prepared in accordance with IATA regulations do not require a Shipper’s Declaration (FedEx page 79 F.). List the three requirements that the shipper must meet for each shipment containing dangerous goods:
- Use only the correct form in the correct manner.
  - Complete the form accurately and legibly.
  - Ensure that the shipment has been prepared in accordance with IATA regulations.
25. Each airbill must include:
- Full name, address, telephone number, and ZIP code of the shipper.
  - Full name, address, telephone number, and ZIP code of the recipient.
  - The dry ice box must be checked and the dry ice information must be entered under the Special Handling section on the airbill.
  - Net quantity per package (kg) of dry ice.

45<sup>th</sup> Edition International Air Transport Association.

WESTAT

# Certificate of Test Completion

International Air Transport Association (IATA) Dangerous Goods Regulations

Name \_\_\_\_\_

Date of Successful Exam \_\_\_\_\_

Examiner \_\_\_\_\_

# Appendix B

## Biosafety

## **APPENDIX B**

### **BIOSAFETY**

#### **B. POLICY FOR MANAGEMENT OF EXPOSURE TO BLOODBORNE PATHOGENS**

##### **Exposure Control Plan for NHANES Training and Examinations**

#### **B.1 Introduction**

The policy presented in this section is intended to serve as the written policy for the NHANES Mobile Examination Center staff training and main study period. It is based on the OSHA Regulations for exposure to bloodborne pathogens as published in the *Federal Register* (29CFR 1910.1030); the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis* (MMWR, June 29, 2001); the CDC recommendations, *Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC)* (December 1997); and the revised Occupational Exposure to Bloodborne Pathogens: Needlestick and Other Sharps injuries; Final Rule.

The Infection Control manual describes the procedures required to treat and document blood-exposure injuries to MEC staff. Universal precautions are the foundation of standard operating procedures and emergency procedures throughout the exam center. MEC staff, the home office staff, and NCHS monitor compliance with these precautions and the pertinent OSHA regulations.

OSHA's rule applies to all persons occupationally exposed to blood or other potentially infectious materials. Blood means human blood, blood products, or blood components. On NHANES, the only body fluids that are collected are blood, vaginal swabs, and urine. Urine is not considered infectious unless the specimens are visibly contaminated with blood or are known to contain an infectious agent.

The Occupational Safety and Health Administration revised the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act. This Act directs OSHA to (1) revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; (2) require that Exposure Control Plans reflect

how employers implement new developments in control technology; (3) require employers to solicit input from employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and to (4) require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps.

## **B.2 Exposure Determination**

### **B.2.1 MEC Employees by Group**

Exposure determination is based on the definition of occupational exposure without regard to personal protective clothing and equipment. Job classifications within the work environment are reviewed for exposure and two groups of exposures are identified: Category I job classifications in which all the employees have occupational exposure, and Category II classifications in which some of the employees have occupational exposure. Where all employees have occupational exposure, it is not necessary to list specific work tasks. Where only some employees have occupational exposure, procedures causing occupational exposure must be listed.

Occupational exposure for NHANES staff is categorized as follows:

#### **Category I Exposures**

- Dentist
- Phlebotomist
- Medical Technologist

#### **Category II Exposures**

- Physician
- MEC Manager

The physician may risk exposure in the event of an emergency in the MEC. The physician is expected to respond to any emergency and perform appropriate procedures, but this does not include the

initiation of IV fluids. The MEC manager is responsible for insuring that biohazardous waste is removed and thus may occasionally handle bagged biohazardous waste. The MEC manager is also expected to respond to emergencies and thus may risk exposure if the emergency involves a laceration.

### **B.3 Methods of Compliance**

#### **B.3.1 Control for Category I and II Exposures**

Risks posed by bloodborne pathogens may be reduced through vaccination, engineering controls, employee work practices, personal protective equipment, and housekeeping procedures. Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Because some infectious diseases can be communicable through contact with SPs and blood, all category I and category II staff members are advised to:

- Obtain the hepatitis B vaccine if recommended by Westat for their category of exposure; and
- Use universal precautions (see Section B.3.2) when there is a potential for exposure to blood or body fluids.

#### **B.3.2 General - Universal Precautions**

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. Universal precautions are observed to prevent contact with blood or other potentially infectious materials. Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a

human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. Universal precautions are applied to procedures involving all sample persons.

### **B.3.3 Engineering and Work Practice Controls**

Engineering and work practice controls are the primary methods used to prevent occupational transmission of HBV, HIV, and other bloodborne pathogens. Sharps disposal containers, self-sheathing needles, autoclaves, and biological safety cabinets are examples of engineering controls used in the NHANES.

Autoclaves are apparatus used to sterilize materials by steam under pressure. Autoclaving is one of the most effective methods for destruction of all types of microorganisms. Autoclaves are used in the dental component to sterilize the probes and mirrors used in the dental exam.

Biological safety cabinets are similar in appearance to laboratory fume hoods and protect employees from exposure to airborne biohazards by providing an enclosed, mechanically ventilated space for them to work. A laminar flow biological safety cabinet is located in the laboratory in every MEC.

Sharps containers are liquid-tight, puncture-resistant vessels used to minimize the hazards posed by discarded needles, broken glass, scalpels, and other contaminated sharp objects. Light plastic bottles such as those that hold consumer products are unacceptable because the walls are easily penetrated by sharps. Metal, heavy-gauge plastic or laminated multi-ply cardboard containers are a much better choice.

These controls isolate or remove the bloodborne pathogen hazard from the workplace. Work Practice Controls are controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

Work practices are specific procedures that employees follow to reduce their exposure to pathogens. These include procedures for processing and handling blood and blood products, waste disposal, and personal hygiene.

## Category I

Specific procedures for preventing exposures in Category I staff are as follows:

- All materials intended for reuse are inspected and decontaminated on a regular basis and are cleaned and decontaminated immediately upon visible contamination.
- Sinks that can be used for hand washing are provided in the bathrooms in trailers 1 and 4 and in the hallways in trailers 1 and 2; in the laboratory, phlebotomy room, and staff lounge in trailer 3; and in the dental exam room in trailer 4. The laboratory and dental sinks include an electronic eye on/off mechanism.
- All MEC exam staff are instructed to wash hands with soap and water after removing gloves or upon accidental skin contact with blood or body fluids, and between each SP exam.
- Employees are instructed to wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.
- Sharps should be handled with extreme care and discarded into the needle disposal containers provided in the MEC. Staff members are instructed that contaminated needles and other contaminated sharps shall not be bent, recapped, or removed. Shearing or breaking of contaminated needles is prohibited. They are required to use the shielding mechanism. Contaminated sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires. Use of the safety shielding mechanism is mandatory.
- Discarded needles and other waste sharps must be placed in an “approved” sharps container. Care must also be taken when mounting a sharps container on the walls and cabinets to make sure the container is accessible to everyone. Immediately or as soon as possible after use, contaminated reusable sharps are placed in puncture resistant and leak proof containers until properly reprocessed. These containers are identified as containing potentially infectious materials and are not allowed to overfill.
- Employees are instructed to not eat, drink, smoke, handle contact lenses, or apply cosmetics or lip balm in the exam rooms.
- No food or drinks are kept in refrigerators, freezers, shelves, cabinets, or work surfaces in the examination rooms. An employee lounge with a refrigerator is provided for personal food storage.
- Procedures involving blood or other potentially infectious materials are performed in such a manner as to minimize splashing, spraying, spattering, or aerosolizing. For

example, the splattering of blood or serum that occurs when rubber stoppers are pulled out of specimen tubes is minimized by covering the stopper with gauze before removing it and performing this procedure under the biosafety hood.

- Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.
- Equipment should be checked and decontaminated before servicing and shipping. Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
- Work surfaces and or equipment contaminated with blood or body fluids are washed with detergent and disinfected with a 1:10 or 1:100 dilution of bleach at the end of every examination session, as described in the examiner manuals.
- Protective coverings used to cover equipment and environmental surfaces are removed and replaced as soon as feasible when overtly contaminated with blood or body fluids during the exam session.
- Broken glassware is never picked up by hand, but swept up with a brush and dustpan. To minimize aerosol formation, broken glass is not dropped into a disposal container but gently placed in the container.

## **Category II**

Although the MEC is not set up to treat or manage medical problems, medical emergencies may occur. If the staff must administer CPR, it is recommended that all staff observe the following procedures to prevent exposures:

- Wear gloves and a lab coat when performing emergency procedures. Disposable impervious lab jackets are available in the lab if needed.
- Use the disposable resuscitation masks found in designated areas.
- Follow the instructions of the MEC physician, who will direct the emergency response.
- Decontaminate and/or dispose of all emergency medical supplies.
- Change any protective equipment contaminated with blood or body fluids.
- Wash hands after removing gloves and before working with the next SP.

### **B.3.4 Personal Protective Equipment**

Personal Protective Equipment is used when occupational exposure remains after instituting these engineering and work practice controls. Personal protective equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered personal protective equipment. Personal protective clothing and equipment also are necessary when occupational exposure to bloodborne pathogens remains even after instituting these controls.

The selection of protective equipment depends on the nature of the potential exposure but generally includes gloves, lab coats, and gowns. If there is a chance for potentially infectious material to splash into the eyes or mouth, staff members are instructed to wear face protection in the form of a mask and/or safety glasses with side shields. The employer provides all protective equipment in appropriate sizes and sufficient quantities for staff use. Hypoallergenic gloves or other alternatives are available to employees with allergic sensitivity to standard gloves.

Staff members other than those in Category I or II are not expected to perform work procedures that carry risk for exposure to blood or body fluids but the following precautions are communicated to the staff in training and monitored:

- Staff should not perform any procedure or task for which they have not been trained.
- Gloves, disposable impervious lab jackets, and/or safety glasses with side shields are worn when performing dental, venipuncture, and laboratory procedures. Personal protective equipment is provided to the staff. Disposable impervious lab jackets are provided to the medical technologists, phlebotomists, and dentists. Reusable cloth lab coats are provided to the physician and MEC manager and are laundered by the employer if contaminated with blood or body fluids. Safety glasses are optional for the phlebotomist but safety glasses with side shields are required for the dentist and are available onsite. Disposable, powder-free hypoallergenic latex and non-latex powder-free gloves are provided to the medical technologists, phlebotomist, and dental examiner. Wear appropriate gloves if contact with blood or other potentially infective materials is anticipated. Never wash or decontaminate disposable gloves for reuse.
- Gloves are changed after each sample person exam or when visibly soiled with blood and/or body fluids. Disposable impervious lab jackets worn by the laboratory and phlebotomy staff are discarded when soiled and at the end of each workweek. Disposable impervious lab jackets worn by dentists are changed when visibly soiled with blood and body fluids. All disposable impervious lab jackets are removed before

leaving the work area and after a garment becomes contaminated. Place used protective equipment in appropriately designated areas or containers when being stored or discarded.

### **B.3.5 Housekeeping**

Under the OSHA standard, all areas must be kept clean and sanitary. A cleaning schedule that includes appropriate methods of decontamination procedures has been developed for every component and is included in the component specific procedure manuals. These procedures are included in component training programs and are part of daily component procedures. Cleaning procedures are based on the type of surfaces, the type of contamination present, the tasks or procedures, and their location in the facility. Housekeeping staff also receive a written set of instructions for cleaning designated areas of the MEC.

The following housekeeping procedures must be observed and will be monitored by project staff:

- Clean and decontaminate all equipment and environmental and work surfaces contaminated with blood or other potentially infectious materials.
- Decontaminate work surfaces with an appropriate disinfectant after completion of procedures, immediately when overtly contaminated, after any spill of blood or other potentially infectious material, and at the end of the work shift when surfaces have become contaminated since the last cleaning.
- Remove and replace protective coverings such as plastic wrap.
- Inspect and decontaminate, on a regular basis, reusable receptacles such as bins, pails, and cans that have the likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as possible.
- Place other regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that prevent leakage.
- When discarding contaminated sharps, place them in containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leak proof on the sides and bottom.

- Ensure that sharps containers are easily accessible to personnel and located as close as feasible to the use area. Keep sharps containers upright throughout use, replace routinely, close when moved, and do not allow to overflow.
- Never manually open, empty, or clean contaminated sharps disposable containers.
- Discard regulated waste into appropriate containers, labeled as biohazardous waste, and seal to prevent leakage during handling storage and transport. Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials. A hazardous waste company is responsible for the disposal of biohazardous waste from the MEC.

Specific methods and regular schedules for cleaning bench tops, equipment, and other environmental surfaces contaminated with potentially infectious materials are documented in the Infection Control Manual and in the respective component procedure manuals. The time required for cleanup may be reduced if surfaces are covered before work with an impermeable, disposable covering such as plastic sheeting or absorbent bench pads.

Good housekeeping procedures are not limited to areas in which infectious materials are handled. Prudent safety practice dictates that halls and passageways are kept clear of obstructions such as carts, obsolete equipment, and shipping containers. Fire doors, other than those interconnected to smoke-detection systems, are kept closed. Stairs are not obstructed and exits are clearly marked.

Contaminated laundry is handled as little as possible and placed in labeled bags at locations where it is used. Leak proof bags are used to transport wet laundry. In addition, all employees who work with contaminated laundry wear gloves.

#### **B.4 Hepatitis B Vaccine**

The hepatitis B vaccine is made available to Category I and II MEC staff at no cost and at a reasonable time and place within 10 working days of initial assignment, and to any MEC staff following an exposure incident. Employees who refuse the hepatitis vaccine must sign the Declination Form, which is kept with the employee's medical records. Employees who have previously received the vaccine should provide evidence of antibody testing or completion of the vaccine series.

If an exposure incident occurs, the MEC manager and MEC physician must be notified immediately. The MEC physician must complete a Medical Incident Form, and the employee must receive an immediate medical evaluation to assess their level of vaccine protection, their level of exposure, and to recommend an appropriate treatment regimen per the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis* (MMWR, June 29, 2001).

#### **B.4.1 Procedures for Evaluating Exposure Incidents**

The OSHA standard requires that following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up. Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties. The exposure report must include at least the following elements:

1. Date and time of exposure;
2. Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;
3. Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;
  - a. The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV, HCV, and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.
  - b. Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
4. Collection and testing of blood for HBV, HCV, and HIV serological status;
  - a. The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.
  - b. If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90

days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

5. Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;
6. Counseling; and
7. Evaluation of reported illnesses.

It is important that the employee have access to treatment for possible HBV, HCV, or HIV exposure as soon as possible after the incident because HBIG, hepatitis B vaccine, and HIV PEP are most likely to be effective if administered as soon after the exposure as possible. During training, the training supervisor, the Director of MEC Operations, Catherine Novak, and/or the Director of Examinations, Carla Maffeo, Ph.D., will oversee the response to a needlestick or other exposure. During the examination period, the MEC physician is responsible for initiating the response, referring the employee to the nearest emergency department, notifying home office staff, and documenting the incident.

At a minimum, the evaluation and follow-up must include the following elements:

- Treatment of exposure site
  - Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen transmission; however, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.
- Exposure Report
  - Document the routes of exposure and how the exposure occurred on a Medical Incident Form and OSHA 300 Log (see Section 5.6). The Medical Incident Form can be accessed from any exam room by clicking on the ambulance icon on the toolbar.
- Evaluation of the Employee and the Exposure
  - The employee should proceed immediately to the closest emergency department where they can be evaluated and counseled. Hospitals are available during all working hours, including nights and weekends. HBIG, hepatitis B vaccine, and antiretroviral agents for HIV PEP should be available for timely administration (i.e., either by providing access on-site or by creating linkages with other facilities or providers to make them available off-site). The

evaluating emergency physician is responsible for providing postexposure management and counseling. They are familiar with evaluation and treatment protocols and the hospital has access to HBIG, hepatitis B vaccine, and antiretroviral drugs for HIV PEP.

- The exposure will be evaluated by the hospital physician for the potential to transmit HBV, HCV, and HIV based on the type of body substance involved and the route and severity of the exposure. Blood, fluid containing visible blood or other potentially infectious fluid can be infectious for bloodborne viruses. Exposures to these fluids through a percutaneous injury (i.e., needlestick or other penetrating sharps-related event) or through contact with a mucous membrane are situations that pose a risk for bloodborne virus transmission and require further evaluation. For HCV and HIV, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher risk exposure than exposure to a needle that was most likely used for giving an injection.
  - The physician evaluating the employee must be provided with a copy of the OSHA bloodborne pathogen regulations, a description of the employee's duties relevant to the exposure incident, and documentation of the route and circumstances of exposure. Within 15 days after the evaluation of the exposed employee, the employer must obtain a copy of the report from the healthcare professional responsible for the postexposure evaluation and insure that the employee receives a copy of the written opinion. The evaluating physician must provide a written opinion regarding vaccination status and postexposure evaluation and follow-up. The written opinion to the employer is limited to whether the vaccine is necessary, documentation of administration, and whether the employee was informed of the results of the evaluation, including any medical conditions resulting from exposure, which require further evaluation or treatment. However, all diagnoses not related to the exposure incident are protected by patient/physician confidentiality and should not be included in the written report to the employer.
  - For skin exposure, follow-up is indicated only if it involves exposure to a body fluid previously listed and evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).
- Evaluation of the Exposure Source
- The person whose blood or body fluid is the source of an occupational exposure should be evaluated for HBV, HCV, and HIV infection.
  - The HBV, HCV, and/or HIV infection status of the source is unknown. The source person should be informed of the incident and asked to undergo testing at the emergency department or to consent to have their blood tested by an independent reference laboratory. It will be explained to the SP that a blood test is needed to determine treatment options for the exposed person. Offer to use serum that has already been collected for testing so that a second venipuncture will not be necessary. The SP may also choose to go to their physician to obtain the test at NHANES project expense. The SP will be asked to consent to release

the results of the tests to the exposed staff person by sending the results to the staff person's physician. The SP should sign the consent form (Exhibit 5-3) and a copy of the consent should be provided to the SP. If the SP refuses to be tested, the MEC physician or other supervisor named above should document the refusal in writing.

- Procedures should be followed for testing source persons, including obtaining informed consent, in accordance with applicable state and local laws. Any persons determined to be infected with HBV, HCV, or HIV should be referred for appropriate counseling and treatment. Confidentiality of the source person should be maintained at all times.
  - Testing to determine the HBV, HCV, and HIV infection status of an exposure source should be performed as soon as possible. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by EIA cannot be completed within 24--48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorescent antibody is not necessary to make initial decisions about postexposure management but should be done to complete the testing process and before informing the source person. Repeatedly reactive results by EIA for anti-HCV should be confirmed by a supplemental test (i.e., recombinant immunoblot assay [RIBA™] or HCV PCR). Direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV RNA or HCV RNA) for routine HIV or HCV screening of source persons are not recommended.
  - If the exposure source cannot be tested or refuses to provide consent, information about where and under what circumstances the exposure occurred should be assessed epidemiologically for the likelihood of transmission of HBV, HCV, or HIV. Certain situations as well as the type of exposure might suggest an increased or decreased risk; an important consideration is the prevalence of HBV, HCV, or HIV in the population group (i.e., institution or community) from which the contaminated source material is derived.
  - Testing of needles or other sharp instruments implicated in an exposure, regardless of whether the source is known or unknown, is not recommended. The reliability and interpretation of findings in such circumstances are unknown, and testing might be hazardous to persons handling the sharp instrument.
- The exposed employee's physician is provided with the source individual's test result and information about the applicable disclosure laws and regulations concerning the source identity and infectious status. (This will be accomplished through the evaluating physician and not through the employer.)

A copy of all documentation related to the incident, including the Medical Incident Form and OSHA Log 300, should be sent to the Director of Mobile Examination Center Operations, Catherine Novak, as soon as possible.

A more detailed description of these recommendations are in the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis* (MMWR, June 29, 2001). Copies of these guidelines are available in Appendix C of the Infection Control Manual.

## **B.5 Labeling**

The OSHA standard requires that fluorescent orange and orange-red warning labels be attached to containers of regulated waste, to refrigerators and freezers containing blood and other potentially infectious materials, and to other containers used to store, transport, or ship blood or other potentially infectious materials. These labels are not necessary when (1) using red bags or red containers; (2) labels designate the contents of containers of blood, blood components, or blood products; and (3) individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, or disposal. The warning label must be fluorescent orange or orange-red, contain the biohazard symbol and the word BIOHAZARD, in a contrasting color, and be attached to each object by string, wire, adhesive, or other method to prevent loss or unintentional removal of the label.

In the MEC, labels are affixed to containers of infectious waste, centrifuges, refrigerators and freezers containing blood or body fluids and containers used to store, transport, or ship blood or body fluids.

## **B.6 Communication of Hazards to Employees - Training**

All MEC employees, including those designated as Category I and II, will receive information and training during their working hours regarding the OSHA regulation and their exposure category at the time of initial assignment and at no cost to the employee. The training program will be provided at least once a year thereafter. Additional training will be provided as necessary when existing tasks are modified or tasks are added that affect the employee's exposure risk. Persons conducting the

training will be knowledgeable about the subject matter, and the information will be appropriate in context and vocabulary to the education level, literacy, and language of the audience. All training programs for MEC staff will include instruction in the OSHA regulations, general infection control practices, and specific infection control procedures relevant to each examination component. The training must include the following elements:

- How to obtain a copy of the regulatory text and an explanation of its contents;
- Information on the epidemiology and symptoms of bloodborne diseases;
- Ways in which bloodborne pathogens are transmitted;
- Explanation of the exposure control plan and how to obtain a copy;
- Information on how to recognize tasks that might result in occupational exposure (categories of exposure);
- Explanation of the use and limitations of work practice and engineering controls, and personal protective equipment;
- Information on the types, selection, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment;
- Information on hepatitis B vaccination such as safety, benefits, efficacy, methods of administration, and availability;
- Information on who to contact and what to do in an emergency;
- Information on how to report an exposure incident and on postexposure evaluation and follow-up;
- Information on warning labels, and signs, where applicable, and color-coding;
- Information on other infectious disease concerns in the MEC; and
- Question and answer session on any aspect of the training.

## **B.7 Recordkeeping**

The exposure control plan is reviewed and updated at least annually or whenever new tasks and procedures affect occupational exposure. A copy of the Exposure Plan is kept in every copy of the Infection Control Manual. Copies of the Infection Control Manual are kept in the staff lounge and in the physician exam room, and in each field office. The plan must be made available to the Assistant Secretary for OSHA and to the Director of the National Institute for Occupational Safety and Health for examination and copying if required.

Employers also must preserve and maintain for each employee an accurate record of occupational exposure. Under the OSHA bloodborne pathogens standard, medical records must include the following information:

- Employee's name and Social Security number;
- Employee's hepatitis B vaccination status including vaccination dates and any medical records relating to the employee's ability to receive vaccinations;
- Results of examinations, medical testing, and postexposure evaluation and follow-up procedures;
- Health care professional's written opinion; and
- A copy of the information provided to the health care professional.

Medical records must be kept confidential and maintained for at least the duration of employment plus 30 years.

Training records must also be maintained and kept accurate by the employer for 3 years and must include the following:

- Training dates;
- Content or a summary of the training;
- Names and qualifications of trainer(s); and
- Names and job titles of trainees.

Upon request, both medical and training records must be available to the Director of the National Institute for Occupational Safety and Health and to the Assistant Secretary of Labor for Occupational Safety and Health. Training records must be available to employees or employee representatives upon request. The employee or anyone having the employee's written consent can obtain an employee's medical records. In addition, if the employer ceases to do business, medical and training records must be transferred to the successor employer. If there is no successor employer, the employer must notify the Director, NIOSH, U.S. Department of Health and Human Services, for specific directions regarding disposition of the records at least 3 months before intended disposal.

#### **B.8 Schedule and Methods for Implementing Sections of the Standard Covering the Methods of Compliance**

Procedures for compliance with OSHA bloodborne pathogen recommendations are included in initial NHANES training programs and incorporated into all specific component procedures and operations procedures in the MEC. All procedures should be operational at the time of training and during the main study.

#### **B.9 Sharps Injury Log**

29 CFR Part 1904 – Recording and Reporting Occupational Injuries and Illnesses requires establishment and maintenance of a sharps injury log. All work-related needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material must be entered on the OSHA 300 Log as an injury. The OSHA 300 Log serves as the sharps injury log. Do not enter the employee's name to maintain confidentiality. The sharps injury log must contain, at a minimum:

1. The type and brand of device involved in the incident;
2. The department or work area where the exposure incident occurred; and
3. An explanation of how the incident occurred

The sharps injury log is maintained for the period required by 29 CFR 1904.03; the OSHA 300 Log is maintained for five (5) years following the end of the calendar year that these records cover.

## **B.10 Needlestick and other Sharps Injuries**

In January 2001, the Occupational Safety and Health Administration revised the Bloodborne Pathogens (BBP) standard in conformance with the requirements of the Needlestick Safety and Prevention Act. The revisions to OSHA's BBP standard required under the Needlestick Safety and Prevention Act can be broadly categorized into four areas: modification of definitions relating to engineering controls, revision and updating of the Exposure Control Plan, solicitation of employee input, and record keeping.

The standard has been revised to add new requirements to the annual review and update of the Exposure Control Plan. Consideration and implementation of safer medical devices must be documented in the Exposure Control Plan by describing the safer devices identified as candidates for adoption, the method or methods used to evaluate devices and the results of evaluations, and justification for selection decisions. The revised standard requires that solicitation of input from employees be documented in the Exposure Control Plan. This information must be updated at least annually. The recordkeeping requirements of the standard have been amended by adding a paragraph to require that employers maintain a sharps injury log to serve as a tool for identifying high-risk areas and evaluating devices.

In November 1999, NIOSH published ALERT, Preventing Needlestick Injuries in Health Care Settings. A comprehensive plan and program to prevent transmission of bloodborne pathogens and to meet (and exceed, whenever possible) regulations was implemented to identify and evaluate various new safer needle technologies and devices. The intent was to replace the existing nonshielded blood collection needles.

The first part of this plan required the phlebotomist and home examiners to use and evaluate BD's shielded-needle butterfly blood collection set in all three sizes during the last 2 weeks at stands 114 and 115. Each of the four staff members viewed a training video that demonstrated the features and use of the new shielded-needle blood collection set and BD's Eclipse multisample needle. They used the new BD shielded-needle blood collection sets and completed evaluation forms (Exhibit B.1)

Exhibit B.1 Evaluation form  
**Safety Syringes**  
**Safety Feature Evaluation Form**

Date: \_\_\_\_\_ Tech ID: \_\_\_\_\_ Position: \_\_\_\_\_

Product evaluating include needle size \_\_\_\_\_ Number of times used: \_\_\_\_\_

Please circle the most appropriate answer for each question.  
 Not applicable (N/A) may be used if the question does not apply to this product.

<b>DURING USE:</b>	agree					disagree	
1. The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A	
2. The safety feature <u>does not</u> interfere with normal use of this product	1	2	3	4	5	N/A	
3. Use of this product requires you to use the safety feature	1	2	3	4	5	N/A	
4. This product does not require more time to use than a nonsafety device	1	2	3	4	5	N/A	
5. The safety feature works well with a variety of hand sizes	1	2	3	4	5	N/A	
<b>AFTER USE:</b>	agree					disagree	
6. There is a clear and unmistakable change (either audible or visible) that occurs when the safety feature is activated	1	2	3	4	5	N/A	
7. The safety feature operates reliably	1	2	3	4	5	N/A	
8. The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A	
<b>TRAINING:</b>	agree					disagree	
9. The product <u>does not</u> need extensive training to be operated correctly	1	2	3	4	5	N/A	

Did this needle interfere with your ability to complete the venipuncture protocol?      Yes or No

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions that you feel should be asked regarding the safety/utility of this product?

Based on the evaluation forms, the new BD shielded-needle blood collection set was deemed unacceptable. The multisample Eclipse needle was evaluated and proved acceptable.

As a second alternative, the Sherwood Kendall Monoject Angel Wing™ System blood collection set was identified and evaluated. This needle uses the same winged technology as BD but the safety shielding apparatus operates differently. Based on the evaluation forms and discussion with staff, the existing BD blood collection sets were eliminated and replaced by the Sherwood Kendall sets. This change took effect at the start of stands 117 and 118.

The cost for the previous BD blood collection set was ~\$1.08 per set and the cost for the new Sherwood Angle Wing set is ~\$.93 per set.

All previous blood collection sets were replaced with these newer safer technologies effective August 8, 2000.

The OSHA's Form 300 (Log of Work-Related Injuries and Illness) and the OSHA's Form 301 (Injury and Illness Incident Report) served as the sharps injury log. The type and brand of the device was included on the form. This form is used exclusively to record sharps injuries.

In September 2000, the MEC staff reported quality control problems with the 21 G Sherwood Kendall blood collection sets; the tubing was leaking at the junction of the tubing and the back end of the metal needle. A formal complaint was immediately filed with the company. All products were pulled from the field and replaced with BD's Safety-Loc blood collection sets. In December 2000, the 19 G Sherwood Kendall blood collection sets exhibited the same defects and this product was pulled from the field. All defective lots were returned to the manufacturer for credit. Because of the complaint, Kendall Sherwood altered the manufacturing process to:

- Perform a gravity test at the beginning of each production lot;
- Increase the needle to wing insertion depth;
- Designate a permanent tutor for critical operations and training;
- Require weekly cleaning of the fixtures; and
- Design a new fixture for the adhesive application by immersion.

Product manufactured under the new manufacturing requirements was obtained and sent to the field in June 2001. The vendor inadvertently pulled old 19 G stock from their warehouse to fill some of the replacement order and this defective product had to be pulled from stand 133 on June 8 and stand 134 on June 24.

In July 2001, the phlebotomists reported further problems with the Sherwood Kendall blood collection sets. The metal needle protector at the tip of the needle assembly was not attached when the sealed packages were opened. A formal complaint was filed with Sherwood Kendall and all 19, 21, and 23 G product was pulled from the field and returned to the manufacturer for credit. The survey will no longer use Sherwood Kendall products.

In July 2001, the phlebotomists and home examiners evaluated the BD 19 G Saf-T E-Z set (#367290) and the 21 G (#367281) and 23 G (#367283) BD Safety-Lok Blood Collection sets. Based on the evaluation forms, the BD shielded-needle blood collection sets were deemed acceptable. Effective July 19, 2001 (start of stands 137 and 138) all Sherwood Kendall blood collection sets were replaced with the BD sets.

The latest evaluation memo describes the annual review process that was conducted in 2002. This memo is shown in Exhibit B-2.

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## MEMORANDUM

### Previous Evaluations

As of January 2002, the NHANES survey maintained four shielded blood collection needles for use during venipuncture:

- Becton Dickinson™ (BD) Vacutainer Eclipse Multi-sample needle (21G x 1 1/4")
- Becton Dickinson™ Butterfly Needle 19G Saf-T EZ Set and Luer Adapter
- Becton Dickinson™ Butterfly Needle 21G Safety-Lok Blood Collection Set
- Becton Dickinson™ Butterfly Needle 23G Safety-Lok Blood Collection Set

These were evaluated during the annual evaluation process that began in February 2000. They were selected and put into use in August 2000. They were evaluated for a second time in July 2001 and were again determined to be acceptable.

### New Technology

Recent research of vendors, supply representatives, and the Internet has yielded a newer shielding needle technology. Bio-plexus® manufactures a Puncture-Guard® internal blunt technology that activates the safety mechanism while the needle point is still in the arm eliminating almost any possibility of a needlestick injury. The winged blood collection sets (available in 21 and 23 G only) have an ergonomically designed center wing that helps guide the needle during the insertion process and allows one-handed activation of the safety mechanism.

### Evaluation Plan

The MEC phlebotomists and home examiners evaluated the Bio-Plexus multi-sample and winged blood collection sets in both sizes from July 13 through July 26 at stand 150 and from August 3 through August 19 at stand 151. Three products were evaluated:

- Bio-Plexus® Puncture-Guard® Multi-sample blood collection needle #4212 21G x 1.0" and the Puncture-Guard Revolution™ Quick Release Safety Needle Holder #4750
- Bio-Plexus® Puncture-Guard® Winged Set for Blood Collection with Multiple Sample Luer Adapter #5114 21G x 3/4" - 10" tubing
- Bio-Plexus® Puncture-Guard® Winged Set for Blood Collection with Multiple Sample Luer Adapter #5314 23G x 3/4" - 10" tubing

Bio-Plexus has produced an excellent training video that the phlebotomists and home examiners viewed before beginning the evaluation. They viewed the sections of the training video that address the multi-sample needle and quick release holder and the winged blood collection sets.

The phlebotomists and home examiners conducted the evaluation at stand 150 beginning on July 13 and at stand 151 beginning on August 3. They took the following actions:

1. Reviewed the package insert for the Puncture-Guard needle holder.
2. Reviewed the instructions for using the Bio-Plexus winged blood collection set.
3. Signed and dated the training statement that was included with the instruction packet.
4. Reviewed the Bio-Plexus Training Program video.

## Exhibit B-2. Venipuncture evaluations, 2002 (continued)

5. Replaced the existing BD Eclipse 21 G multi-sample needle with the Bio-Plexus 21 G multi-sample needle and holder.
6. Replaced the existing BD 21 G, and 23 G butterfly blood collection sets with the new 21 G, and 23 G Bio-Plexus winged sets.
7. Selected the appropriate gauge needle for each SP (used the 21 gauge shielded blood collection set for most SPs), performed the venipuncture, and completed an evaluation form. It was not necessary to complete an evaluation form for each SP. They completed at least 10 evaluation forms in the MEC and as many as possible in the home. They evaluated at least 1 SP in each age group, 1-2, 3-5, 6-11 and 12+.
8. Sent the training video from stand 150 to stand 151.
9. Sent the evaluation forms and all unused Bio-Plexus needles back to the home office at the end of the stands.
10. Sent the training video back to the home office at the end of stand 151.

### Sharps Container Evaluation

The phlebotomists, home examiners, and medical technologists used the Sharps Disposal evaluation form to evaluate the 8-gallon biohazard sharps container used in the lab and phlebotomy and the 1-quart red biohazard sharps container used in the home. Each medical technologist and phlebotomist completed at least one evaluation form for the 8-gallon container and the home examiner completed at least one evaluation form for the 1-quart container. The evaluation forms were sent back to the home office at the end of the stand.

### Results

The Bio-Plexus® Puncture-Guard® Multi-sample blood collection needle functioned as designed and no problems were noted by the evaluating staff. However, since the staff uses less than five per year and a new account would need to be established, the change does not seem justified. The decision is to continue to use the Becton Dickinson™ Vacutainer Eclipse Multi-sample needle (21G x 1 1/4”).

The phlebotomists use the 19 G needle on the majority of SPs. Bio-Plexus® does not manufacture a 19 G needle so the staff was unable to evaluate this needle. Bio-Plexus® does manufacture 21 and 23 G blood collection sets and the staff did complete this evaluation as directed. The Bio-Plexus® Puncture-Guard® Winged Set for Blood Collection with Multiple Sample Luer Adapter #5114 21G x 3/4” - 10” tubing and the Bio-Plexus® Puncture-Guard® Winged Set for Blood Collection with Multiple Sample Luer Adapter #5314 23G x 3/4” - 10” tubing performed as described by the manufacturer. The evaluation revealed:

- The tubing is 2 inches shorter and the staff noted that there is less flexibility when changing the tubes.
- The tubing is narrower than the tubing used by BD. The staff noted that the flow rate is slower and that they were unable to complete the protocol in many cases.
- While the shielding technology provides more protection when it is used as described, the staff noted that once the shielding mechanism is engaged, they were unable to manipulate or adjust the needle in the arm. This objection can be overcome by engaging the mechanism just before removing the needle from the arm.

Since the existing BD blood collection sets offer shielding needle technology and the Bio-Plexus needle does not allow the staff to complete the protocol, the decision is to continue to use the BD Safety-Lok needle.

Exhibit B-2. Venipuncture evaluations, 2002 (continued)

The phlebotomists, home examiners, and medical technologists evaluated the 8-gallon biohazard sharps container used in the lab and phlebotomy and the 1-quart red biohazard sharps container used in the home. The evaluation forms revealed no problem with these items. The decision is to continue to use the existing sharps containers.

The phlebotomy protocol for year 5 includes fewer tubes so it may be possible in the near future to reevaluate the decision to continue using the BD blood collection sets. This reevaluation will wait until Bio-Plexus® has the production capacity to manufacture a 19 G Puncture-Guard® Winged Set for Blood Collection with Multiple Sample Luer.

All evaluation forms will be kept in a notebook at the home office and are available for inspection at any time.

Exhibit B-2. Venipuncture evaluations, 2002 (continued)

**Safety Blood Collection Set  
Evaluation Form – Stand 150**

Date: \_\_\_\_\_ Tech ID: \_\_\_\_\_ Position: \_\_\_\_\_  
 Manufacturer: \_\_\_\_\_ Number of  
 Needle size: \_\_\_\_\_ times used: \_\_\_\_\_

- ✓ Indicate the degree to which you agree or disagree with each statement by circling the most appropriate number for each statement.  
 ✓ Not applicable (N/A) may be used if the question does not apply to this product.

<b>DURING USE:</b>	agree					disagree	
1. The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A	
2. The safety feature <u>does not</u> interfere with normal use of this product	1	2	3	4	5	N/A	
3. Use of this product requires you to use the safety feature	1	2	3	4	5	N/A	
4. This product does not require more time to use than a non-safety device	1	2	3	4	5	N/A	
5. The safety feature works well with a variety of hand sizes	1	2	3	4	5	N/A	
<b>AFTER USE:</b>	agree					disagree	
6. There is a clear and unmistakable change (either audible or visible) that occurs when the safety feature is activated	1	2	3	4	5	N/A	
7. The safety feature operates reliably	1	2	3	4	5	N/A	
8. The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A	
<b>TRAINING:</b>	agree					disagree	
9. The product <u>does not</u> need extensive training to be operated correctly	1	2	3	4	5	N/A	

Did this needle interfere with your ability to complete the venipuncture protocol? Yes or No

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions that you feel should be asked regarding the safety/utility of this product?

Exhibit B-2. Venipuncture evaluations, 2002 (continued)

**Safety Blood Collection Set  
Evaluation Form – Stand 151**

Date: \_\_\_\_\_ Tech ID: \_\_\_\_\_ Position: \_\_\_\_\_  
 Manufacturer: \_\_\_\_\_ Number of  
 Needle size: \_\_\_\_\_ times used: \_\_\_\_\_

- ✓ Indicate the degree to which you agree or disagree with each statement by circling the most appropriate number for each statement.
- ✓ Not applicable (N/A) may be used if the question does not apply to this product.

<b>DURING USE:</b>	agree					disagree	
1. The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A	
2. The safety feature <u>does not</u> interfere with normal use of this product	1	2	3	4	5	N/A	
3. Use of this product requires you to use the safety feature	1	2	3	4	5	N/A	
4. This product does not require more time to use than a non-safety device	1	2	3	4	5	N/A	
5. The safety feature works well with a variety of hand sizes	1	2	3	4	5	N/A	
<b>AFTER USE:</b>	agree					disagree	
6. There is a clear and unmistakable change (either audible or visible) that occurs when the safety feature is activated	1	2	3	4	5	N/A	
7. The safety feature operates reliably	1	2	3	4	5	N/A	
8. The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A	
<b>TRAINING:</b>	agree					disagree	
9. The product <u>does not</u> need extensive training to be operated correctly	1	2	3	4	5	N/A	

Did this needle interfere with your ability to complete the venipuncture protocol? Yes or No

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions that you feel should be asked regarding the safety/utility of this product?

Exhibit B-2. Venipuncture evaluations, 2002 (continued)

**Sharps Disposal  
Evaluation Form**

Date: \_\_\_\_\_ Name: \_\_\_\_\_  
 Position: \_\_\_\_\_ Stand: \_\_\_\_\_  
 Manufacturer: \_\_\_\_\_ Capacity: \_\_\_\_\_

Indicate the degree to which you agree or disagree with each statement by circling the most appropriate number for each statement.

Not applicable (N/A) may be used if the question does not apply to this product.

<b>Please Rate:</b>	agree	disagree
1. The container is puncture resistant	1 2 3 4 5	N/A
2. The container does not leak	1 2 3 4 5	N/A
3. The container is stable	1 2 3 4 5	N/A
4. The container is accessible from any direction	1 2 3 4 5	N/A
5. The container is located where the needles are used	1 2 3 4 5	N/A
6. The container allows single handed use	1 2 3 4 5	N/A
7. It is possible to drop sharps or tubes into the container vertically	1 2 3 4 5	N/A
8. No force is required to put sharps or tubes into the container	1 2 3 4 5	N/A
9. Needles/tubing do not get caught on the opening or interior shape	1 2 3 4 5	N/A
10. The container opens and closes easily	1 2 3 4 5	N/A
11. The container has a solid tight-fitting cover	1 2 3 4 5	N/A
12. The box accommodates a range of sharp sizes or tubes	1 2 3 4 5	N/A
13. The size of the container is appropriate for its use	1 2 3 4 5	N/A
14. No one (including a child) can access the contents	1 2 3 4 5	N/A
15. There is a permanent lock for final disposal that is not reversible	1 2 3 4 5	N/A
16. The user can determine the fill level visually	1 2 3 4 5	N/A
17. The container is appropriately labeled	1 2 3 4 5	N/A
18. The box is not threatening to participants	1 2 3 4 5	N/A
19. Use of this container does not compromise infection control practices	1 2 3 4 5	N/A

Did this sharps container interfere with your ability to complete the venipuncture or blood processing protocol? Yes or No

Are there other questions that you feel should be asked regarding the safety/utility of this product?

## **B.11 Laboratory and Phlebotomy Infection Control**

This section contains a summary of all procedures used for infection control in the MEC laboratory and phlebotomy components. For detailed information regarding these procedures, refer to the component's manual of operation.

### **B.11.1 Glossary**

Decontamination:	The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
Detergent:	A cleansing agent used to facilitate the removal of gross debris from an object.
Disinfect:	To inactivate virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial endospores) on inanimate objects.
Engineering Controls:	Controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.
Mucous membrane exposure:	Occurs from droplet contamination (splashes, spatters) of the eyes, nose, or mouth.
Parenteral exposure:	Piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.
Personal Protective Equipment:	Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered personal protective equipment.
Regulated Waste:	Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Sharps with engineered sharps injury protections:	Non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
Sterilize:	The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.
Universal precautions:	An approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.
Work Practice Controls:	Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

In order to comply with Federal regulations, minimize the spread of infectious diseases, and provide a safe working environment, follow defined safety procedures at all times.

### **B.11.2 Laboratory Access**

- Unauthorized people should not enter the MEC laboratory.
- All authorized persons must wear gloves when working with equipment, and when handling biological specimens such as blood, blood products, or urine in the laboratory. Examples are lab staff, biomedical engineers, Coulter technical representatives, NCHS or observers, coordinator, assistant coordinator, health techs, and MEC manager. People who visit the lab to observe should not touch countertops, equipment, or supplies if they are not wearing gloves.

### **B.11.3 Laboratory/Phlebotomy - Universal Precautions**

A complete description of Universal Precautions is described in Section B.3.2. “Laboratory staff, including the phlebotomist, observe Universal Precautions at all times.

#### **B.11.4 Laboratory/Phlebotomy - Specific Engineering and Work Practice Controls**

Engineering and work practice controls are described in Section B.3.3. Engineering controls eliminate hazards at their source. The biological safety cabinet and waste containers for sharps are examples of engineering controls used in the NHANES. A laminar flow biological safety cabinet is located in the laboratory in every MEC.

All health care workers take precautions to prevent injuries caused by needles and other sharp instruments or devices during procedures, when cleaning used instruments, during disposal of used needles, and when handling sharp instruments after procedures. It is mandatory and essential to use the shielded mechanism of the needle.

Specific measures of protection for the laboratory staff (including the phlebotomist) are described below.

Hang outside street clothing in a designated separate clean area.

##### **Engineering Controls**

- Do not eat, drink, smoke, handle contact lenses, or apply cosmetics or lip balm in the MEC laboratory or in the examination rooms.
- Do not keep food or drinks in refrigerators, freezers, shelves, cabinets, or work surfaces in the examination rooms. An employee lounge with a refrigerator is provided for personal food storage.
- Do not mouth pipette.
- Procedures involving blood or other potentially infectious materials are performed in such a manner as to minimize splashing, spraying, or aerosolizing. For example, the splattering of blood or serum that occurs when rubber stoppers are pulled out of specimen tubes is minimized by covering the stopper with gauze before removing it and performing this procedure under the biosafety hood.
- Perform all blood processing tasks in the LSBSC.
- Use Aerosolve containers when centrifuging blood tubes.
- Used needles must never be sheared, bent, clipped, broken, or recapped by hand. Discarded needles and other waste sharps must be placed in an “approved” sharps container. Either use a one-handed “scoop” technique or a mechanical device designed for holding the needle sheath.

- Use of the safety shielding mechanism on the blood collection needle is mandatory.
- Never point (direct) or move the unsheathed tip of a needle toward anyone.
- Always be alert and extremely cautious when handling unsheathed needles.
- Immediately after use, dispose of sharps in sharps containers.
- When discarding contaminated sharps, place them in containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom.
- Ensure that sharps containers are easily accessible to personnel and located as close as feasible to the use area.
- Keep sharps containers upright throughout use, replace routinely, close when moved, and do not overfill. Do not overstuff the biohazard waste containers by poking the trash down with another object. Shaking the container back and forth is acceptable.
- Never manually open, empty, or clean contaminated sharps disposable containers.
- Never discard needles directly into a container used for ordinary (“noninfectious”) waste.

#### **B.11.5 Laboratory/Phlebotomy - Personal Protective Equipment**

A complete description of personal protective equipment is contained in Section B.3.4.

- Wear impervious lab jackets when performing venipuncture and laboratory procedures. Disposable impervious lab jackets are provided to the medical technologists and phlebotomists.
- Remove protective equipment before leaving the work area and after a garment becomes contaminated.
- Place used protective equipment in appropriately designated areas inside the laboratory and place in designated biohazardous containers when being discarded.
- Discard lab jackets when soiled and at the end of each workweek.
- If the LFBSC is nonfunctional, then wear safety glasses when processing blood. Safety glasses are optional for the phlebotomist but safety glasses are available onsite.
- Wear appropriate face and eye protection such as a mask with glasses with solid side shields or a chin-length face shield when splashes, sprays, spatters, or droplets of

blood or other potentially infectious materials pose a hazard to the eye, nose, or mouth.

- It is mandatory to wear gloves when performing venipuncture, collecting a nasal swab, processing blood specimens, processing urine, processing vaginal swabs, and performing hematology testing. Disposable, powder-free hypoallergenic latex and nonlatex powder-free gloves are provided to the medical technologists and phlebotomist.
- Change gloves after each sample person's exam or when visibly soiled with blood and/or body fluids.
- Never wash or decontaminate disposable gloves for reuse.
- Discard utility gloves at the first sign of deterioration.
- Remove gloves before leaving the laboratory or phlebotomy room.

#### Personal Hygiene – Infection Control

- Wash hands with soap and water after removing gloves or upon accidental skin contact with blood or body fluids, and before working with the next SP.
- Hand washing sinks are located in the bathrooms in trailers 1 and 4, in the hallways in trailers 1 and 2, in the laboratory, phlebotomy room, and staff lounge in trailer 3, and in the dental exam room in trailer 4. The laboratory and dental sinks include an electronic eye on/off mechanism.
- If using liquid soap for hand washing, replace with fresh product when empty. Do not add liquids to a partially full dispenser.

#### **B.11.6 Laboratory/Phlebotomy - Waste Management**

A complete description of the waste management procedures is described in Section B.3.5.

- Discard hazardous waste into appropriate containers. Biohazardous waste containers are labeled and sealed to prevent leakage during handling storage and transport. A hazardous waste company is responsible for the disposal of biohazardous waste from the MEC. Do not overstuff the biohazard waste containers by poking the trash down with another object. Shaking the container back and forth is acceptable.
- Dispose of all potentially infectious materials in a biohazard waste container.

- When discarding glass blood tubes, place them in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leak proof on the sides and bottom.
- Place solid waste from the laboratory in biohazard bags and transport to an area designated to hold these bags. A single bag is adequate if the bag is sturdy (not easily penetrated) and if the waste can be put in the bag without contaminating the outside of the bag; otherwise, double bagging is indicated.
- To minimize the potential risk for accidental transmission of disease or injury, store infective waste waiting terminal processing in a pre-incineration storage area in the MEC accessible only to personnel involved in the disposal process.
- Place regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that prevent leakage.
- Transport closed sharps containers and biohazard bags destined for incineration or steam sterilization to the designated pre-incineration storage.
- Discard all regulated waste according to Federal, state, and local regulations.
- Refer to “infectious waste” in the glossary for any questions about identifying wastes for which special precautions appear prudent.
- Liquid Wastes
  - Pour urine down the sink connected to the sewer before discarding the cup into biohazard container.
  - Pour Coulter waste down the sink connected to a sewer. Add 1 3/4 cups (3.75-mL) undiluted bleach to the 10-gallon waste container and reattach to the instrument.

### **B.11.7 Laboratory/Phlebotomy - Labeling**

In the MEC, labels are affixed to containers of infectious waste, centrifuges, refrigerators, and freezers containing blood or body fluids and containers used to store, transport, or ship blood or body fluids.

A complete description of the OSHA label requirements is described in Section B.5.

### **B.11.8 Laboratory/Phlebotomy - Housekeeping**

A complete description of OSHA's housekeeping requirements is described in Section B.3.5.

All housekeeping procedures must be observed and will be monitored by project staff:

- Wash work surfaces and or equipment contaminated with blood or body fluids with detergent and disinfected with a 1:10 dilution of bleach.
- At the end of every examination session, disinfect work surfaces with a 1:10 dilution of bleach.
- Check and decontaminate equipment before servicing and shipping.
- Remove protective coverings used to cover equipment and environmental surface and replace as soon as feasible when overtly contaminated with blood or body fluids during the exam session.
- Inspect and decontaminate all materials intended for reuse on a regular basis and clean and decontaminate immediately upon visible contamination.
- Inspect and decontaminate, on a regular basis, reusable receptacles such as bins, pails, and cans that have the likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as possible.
- Place other regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that prevent leakage.
- Clean and decontaminate all equipment and environmental and work surfaces contaminated with blood or other potentially infectious materials.
- Decontaminate work surfaces with an appropriate disinfectant after completion of procedures, immediately when overtly contaminated, after any spill of blood or other potentially infectious material, and at the end of the work shift when surfaces have become contaminated since the last cleaning.
- Remove and replace protective coverings such as plastic wrap and aluminum foil when contaminated.
- Clean and disinfect equipment and working surfaces, including keyboard covers, with a 1:10 bleach solution (5-mL bleach to 50-mL tap water) or 1:100 bleach solution (1-mL bleach to 100-mL water) after completion of procedures, when surfaces are overtly contaminated, immediately after any spill of blood or other potentially infectious materials, and at the end of the work shift.

- Remove and replace nonabsorbent paper used to cover equipment and environmental surfaces at the end of the work shift or when they become overtly contaminated.
- Check equipment routinely and decontaminate as necessary before servicing or shipping.
- Decontaminate reusable items contaminated with blood or other potentially infectious materials before washing and/or reprocessing. Routinely check equipment and decontaminate it before servicing and shipping.
- Clean and decontaminate all equipment and work surfaces contaminated with blood or other potentially infectious materials.
- On a regular basis inspect and decontaminate reusable receptacles such as bins, pails, and cans that have likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as possible.

#### **B.11.9 Laboratory/Phlebotomy – Cleaning a Blood Spill**

If a blood spill occurs, wear gloves, and if needed, a gown and facial protection during the cleanup procedure.

If spill contains broken glass use dustpan and broom to collect glass pieces. Dispose of broken glass and contaminated paper towels in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leak proof on the sides and bottom. Disinfect dustpan and broom with bleach solution. Always use mechanical means such as forceps or a brush and dust pan to pick up contaminated broken glass; never pick up broken glass with hands even if wearing gloves. To minimize aerosol formation, broken glass is not dropped into a disposal container but gently placed in the container.

- To clean a blood spill perform the following procedure:
  - Wear gloves;
  - Cover spill with disposable paper towels;
  - Soak paper towels with 10% bleach solution;
  - Let soak for at least 30 seconds;

- Dispose of blood/bleach soaked paper towels in biohazard container;
- Allow area to dry and then remove gloves; and
- Wash hands.

## **B.12 References**

The following references were used to prepare the Exposure Plan:

1. *Occupational Exposure to Bloodborne Pathogens*, U.S. Department of Labor, Occupational Safety and Health Administration. OSHA 3127, 1996 (Revised). Title 29 Code of Federal Regulations, Part 1910.1030. [56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]
2. *Immunization of Health-Care Workers*, USPHS, CDC,, MMWR 1997;46(No. RR-18).
3. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis* (MMWR, June 29, 2001)
4. *Occupational Exposure to Bloodborne Pathogens, Needlestick and other Sharps injuries: Final Rule*, U.S. Department of Labor, Occupational Safety and Health Administration. OSHA, 2000 (Revised).
5. Title 29 Code of Federal Regulations, Part 1904.
6. CDC. Guideline for Hand Hygiene in Health-Care Settings Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(RR-16).

Copies of these materials are included in the Appendixes of the *Infection Control Manual*.

## Appendix C

### NHANES Specimen Protocol

#### C-1. Historical Master List

#### C-2. Year 6 Protocol by Tube Type

Appendix C-1. Historical Master List

**NHANES SPECIMEN PROTOCOL (Working with year 6 development)**

Underlined = Three week results

**Omega** = Critical ROF analytes

*Italics* = Storage and shipping refrigerated

Courier = Ship at room temperature

**Bold** = Changes

Color key for historical text – Blue = year 1 (stands 101-112), green = year 2 (113-127), red = year 3 (stands 128-142), pink = year 4 (stands 143-157), bright blue = year 5 (stands 158-172), violet = year 6 (stands 173-187)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
			Began stand 101 on 4/2/99	Began stand 101 on 4/2/99	Began stand 101 on 4/2/99	Began stand 107 on 9/8/99 and at stand 108 9/14/99	Began stand 101 on 4/2/99	Began stand 101 on 4/2/99	Began stand 109 on 9/30/99 and at stand 110 on 10/26/99 Delete effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).	Began stand 113 on 1/10/00 and at stand 114 on 1/27/00 Delete effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).						
1 6	<u>Lead/Cad/HG</u> Lead ROF Cad and HG early reporting if abnormal Organic HG	1-5 6-11 12-150	0.3 0.5 0.5	0.5	0.5	0.3 0.5 0.5			0.5	0.5	Whole blood-W	3 mL EDTA 3 mL EDTA 4 mL EDTA	2 mL-01 No	Yes	9 x 9 two inch box	CASPIR NCEH Attn: Robert White 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 <a href="mailto:rnw9@cdc.gov">rnw9@cdc.gov</a> 770-339-5942 Robert Jones

Began stand 101

January 10, 2000 (stand 113) & January 27 (stand 114) The test volume for was changed from 0.2 to 0.3 for primary and VIP Guest person types age 1-5 and from 0.5 to 0.6 for primary and VIP guest person types age 6-11.

August 1, 2002 (stands 151 and 152) began using the spray-dried 6-mL EDTA tube in place of the 5-mL liquid EDTA on age 6+.

Changed test volume for age 6-11 from 0.6 to 0.5 effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Added Organic HG to the vessel effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
2 39	<u>Ery Proto</u> ROF	3-5 12-49 females	0.4 0.4	0.4		0.4 0.4			0.4	0.4	Whole blood- W	3 mL EDTA 4 mL EDTA	2 mL-02 No	Yes	9 x 9 two inch box	NYS DOH/Wadsworth CTR L&R Attn: Patrick Parsons, PhD. ESP P1 South Dock J3 Albany, NY 12237 <a href="mailto:Lead@wadsworth.org">Lead@wadsworth.org</a> 518-474-5475

Began stand 101

January 10, 2000 (stand 113) & January 27 (stand 114) The test volume was changed from 0.4 to 0.3 for primary and VIP Guest person types age 1-11.

Changed labs from NCEH to NYS DOH at the end of year 3. Changed the shipping address on February 18, 2002 (stands 144 and 145); began shipping specimens to NY DOH.

Stand 152 (August 2) and stand 153 (August 27) began using the spray-dried 6-mL EDTA tube in place of the 5-mL liquid EDTA on age 12+.

Changed test eligibility from 1+ (1-11 0.3 and 12+ 0.4) to 3-5 (0.4) and 12-49 females (0.4) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

3 6	<u>RBC Folate</u> ROF	1-2 3-5 6-11 12-150	0.1 0.1 0.1 0.1		0.1	0.1 0.1 0.1 0.1			0.1	0.1	Whole blood- W	3 mL EDTA 3 mL EDTA 4 mL EDTA 4 mL EDTA	2 mL-03 Yes	Yes	9 x 9 two inch box	CASPIR EHLS Christine Pfeiffer
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Began stand 101

Stand 152 (August 2) and stand 153 (August 27) began using the spray-dried 6-mL EDTA tube in place of the 5-mL liquid EDTA on age 12+.

Stand 152 (August 2) and stand 153 (August 27) changed protocol for dry run appointment type, eliminated this test for odd, added test to even.

Changed test eligibility from 3+ (0.1) to 1+ (0.1) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

4 10	<u>Glycohem</u> ROF	12-150	0.4	0.4		0.4			0.4	0.4	Whole blood- W	4 mL EDTA	2-mL-04	Yes	9 x 9 two inch box	Univ of Missouri Attn: Hsiao-Mei Wiedmeyer Child Hlth One Hospital Drive Room M770 Columbia, MO 65212 <a href="mailto:wiedmeyerh@missouri.edu">wiedmeyerh@missouri.edu</a> 573-882-2705
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Began stand 101

Stand 152 (August 2) and stand 153 (August 27) began using the spray-dried 6-mL EDTA tube in place of the 5-mL liquid EDTA on age 12+.

5 6	<u>Mercury</u> ROF if abnormal	1-5 6-150	0.3 0.3		0.3	0.3 0.3					Whole Blood- W	3 mL EDTA 4 mL EDTA	2 mL-05 No	Yes	9 x 9 two inch box	CASPIR NCEH Robert Jones
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Began stand 101

Stand 152 (August 2) and stand 153 (August 27) began using the spray-dried 6-mL EDTA tube in place of the 5-mL liquid EDTA on age 12+.

Stand 152 (August 2) and stand 153 (August 27) changed protocol for dry run appointment type, eliminated this test for odd, added test to even.

Changed test volumes from 1-5 (0.5) and 16-49 (1.0) to (0.3) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Changed the age eligibility from 1-5 both sexes and 16-49 females to 1+ effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

6	CD4	18-49	0.5								Whole blood- W	4 mL EDTA	2 mL-06 Yes	Yes	9 x 9 two inch box	CASPIR NCEH
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Began stand 101

Stand 152 (August 2) and stand 153 (August 27) began using the spray-dried 6-mL EDTA tube in place of the 5-mL liquid EDTA on age 12+.

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
88 6	Acrylamide	3-5 6-150	0.4 1.0								Whole blood- W	3 mL EDTA 4 mL EDTA	2 mL-88	Yes	9 x 9 two inch box	CASPIR NCEH Dr. Vesper
Began at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).																
81 43	Vitamin B6	1-5 6-11 12-150	0.2 0.2 0.5			0.2 0.2 0.5					Plasma-P	3 mL EDTA 4 mL EDTA 4 mL EDTA	2-mL-81	No	9 x 9 two inch box	AC Diag Robert M. Hoffman, Ph.D. 7917 Ostrow Street San Diego, CA 92111 858-654-2555 <a href="mailto:all@anticancer.com">all@anticancer.com</a>
Began at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).																
<b>Changed the test volume for age 12 from 0.2 to 0.5 for all appointment types, effective at the start of stand 160 (February 20, 2003) and stand 161 (March 10, 2003)</b>																
7 6	Homocys/MMA	3-5 6-150	1.0 1.0		1.0 1.0				1.0 1.0	1.0 1.0	Plasma-P	3 mL EDTA 4 mL EDTA	2 mL-07 No	Yes	9 x 9 two inch box	CASPIR NCEH Christine Pfeiffer
Began stand 101																
Stand 152 (August 2) and stand 153 (August 27) began using the spray-dried 4-mL EDTA tube in place of the 5-mL liquid EDTA on age 6+.																
8	Xtra Plasma	6-150	0.5								Plasma-P	4 mL EDTA	2 mL-08	Yes	9 x 9 two inch box	CASPIR NCEH
Began stand 101																
Stand 152 (August 2) and stand 153 (August 27) began using the spray-dried 4-mL EDTA tube in place of the 5-mL liquid EDTA on age 6+.																
9 10	<u>Glucose</u> Morning SPs only ROF	12-150	0.5	0.5	0.5	0.5				0.5	Plasma-P BD 367921	2 mL Grey	2 mL-09 No	Yes	9 x 9 two inch box	Univ of Missouri
Began stand 101																
Stand 152 (August 2) and stand 153 (August 27) began using the 2 mL gray tube (BD 367921) in place of the 3-mL gray tube (BD 367722).																
98 10	<b>OGTT</b> Morning SPs only ROF	12-19	0.5	0.5	0.5	0.5				0.5	Plasma-P BD 367921	2 mL Grey	2 mL-98 No	Yes	9 x 9 two inch box	Univ of Missouri
<b>Pilot began at stand 175 on Feb 16, 2004 and at stand 176 on Mar 15, 2004</b>																
<b>Ended at the end of stand 178 on June 9, 2004 and at stand 179 on Jun 23, 2004.</b>																
70 6	Vitamin D	1-2 3-5 6-150	0.3 0.5 0.5							0.5	Serum	Red top	2 mL-70 No	Yes	9 x 9 two inch box	CASPIR NCEH Christine Pfeiffer
Began January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The new Vitamin D vessel 70 was added for primary SPs age 6+ and dry run even volunteers.																
Changed test eligibility from 6+ (0.5) to 1-2 (0.3) and 3+ (0.5) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).																
12 6	<u>Fol/B12</u> Fol ROF B12 if abnormal	1-2 3-5 6-150	0.7 0.7 1.0			0.7 0.7 1.0			1.0	1.0	Serum-S	Red top	2 mL-12 very little/No	Yes	9 x 9 two inch box	CASPIR NCEH

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
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Began stand 101

September 8, 1999 (stand 107) & September 14 1999 (stand 108) Ferritin was removed from vessel 12 and designated as new vessel #68

Effective January 10, 2002 (stand 143) & January 24, 2002 (stand 144) change the vessel volume from 1.3 to 1.0 for SPs age 6+.

Changed test eligibility from 3+ (3-5 0.8 and 6+1.0) to 1-5 (0.7) and 6+ (1.0) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

13 11	<u>CRP/Hpylori</u>	1-2 3-5 6-11 12-150	0.5 0.5 0.5 0.5	0.5					0.5	0.5	Serum-S	Red top	2 mL-13 No/No	Yes	9 x 9 two inch box	Univ of Washington Attn: Phyllis Daum Immunology 1959 NE Pacific Avenue Room NW 176 Seattle, WA 98195 (206) 598-6149 daum@mail.labmed.washington.edu
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Began stand 101 – Eliminate Hpylori at end of stand 142

Eliminate Hpylori at end of stand 142

Stand 152 (August 2) and stand 153 (August 27) changed protocol for dry run appointment type, eliminated this test for even, added test to odd.

Changed test eligibility from 3+ (0.5) to 1+ (0.5) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

14 2	<u>Hep Profile</u> ROF B and C if abnormal	6-150	1.5		1.5				1.5		Serum-S	Red top	2 mL-14 No	Yes	9 x 9 two inch box	CDC NCID Hepatitis Ref Lab Attn: Ed Simard Code NH4 1600 Clifton Road NE Building 1, Room 1389 Atlanta, GA 30329 <a href="mailto:Esimard@cdc.gov">Esimard@cdc.gov</a> 404-371-5451
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Began stand 101

Effective August 7, 2001 (stands 136 & 137) changed volume from 0.2 to 0.4 for age groups 2-5.

Stand 152 (August 2) and stand 153 (August 27) changed protocol for dry run appointment type, eliminated this test for odd, added test to even.

Separated vessel 14 into separate containers for 2-5 and 6+ effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

87 2	<u>Hep ab</u>	2-5	0.4								Serum-S	Red top	2 mL-87 No	Yes	9 x 9 two inch box	CDC NCID Hepatitis Ref Lab
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Created this vessel to create separate containers for 2-5 and 6+ effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

68 6	<u>Ferritin/TfR</u> ROF	1-2 3-5 12-49 females	0.3 0.4 0.4	0.4		0.3 0.4 0.4			0.3	0.3	Serum-S	Red top	2-mL-68 No	Yes	9 x 9 two inch box	CASPIR Christine Pfeiffer
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Began September 8, 1999 (stand 107) & September 14, 1999 (stand 108) Ferritin was removed from vessel 12 and designated as new vessel #68.

Added transferrin receptor to vessel 68 and changed test eligibility from 1+ (0.3) to 1-2 (0.2) to 3-5 (0.4) and 12-59 females (0.4) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

**Effective at the start of Year 6 (stand 173 January 5, 2004), change the test eligibility for vessel 68 to age 1-5 and age 12-49 females only**

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
11 6 40	<u>Iron/TIBC</u> ROF	3-5 12-59 females	1.0 1.0		1.0	1.0 1.0			1.2	1.2	Serum-S	Red top	2 mL-11 No/reduced values	Yes	9 x 9 two inch box	Collaborative Laboratory Services Attn: Sue Vanness 1005 Pennsylvania Suite 102 Ottumwa, Iowa 52501 <a href="mailto:svanness@colabserv.com">svanness@colabserv.com</a> 641 684-4621

Began stand 101

April 13, 2001 (stands 131 & 132) Changed vessel 11 (Iron/TIBC) test volume from 1.2 to 1.3 for age 1-2 and 1.0 to 1.2 for age 3+ for dry run even and VIP Guest volunteers and Primary, Home exam, and second exam SPs.

Changed labs from EHLS to CLS at the end of year 3. Began shipping all specimens to CLS effective April 1, 2002.

Changed test eligibility from 1+ (1-2 1.3 and 3+ 1.2) to 3-5 (1.0) and 12-59 females (1.0) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

17 6	Cotinine	3-11 12-150	1.3 1.8		1.8					2.0	Serum-S	Red top	2 mL-17 No	Yes	9 x 9 two inch box	CASPIR Tom Bernert
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Began stand 101

Changed test volumes 3-11 (1.5) and 12+ (2.0) to 3-11 (1.3) and 12+ (1.8) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

21 13	<u>Lipids</u> ROF	3-5 6-11 12-150	0.2 1.0 1.0		1.0 1.0	0.2 1.0 1.0			1.0	1.0	Serum-S	Red top	2 mL-21 Yes	Yes	9 x 9 two inch box	Lipoprotein Analytical Lab/JHU Attn: Donna Virgil 600 North Wolfe Street Blaylock 1379 Baltimore, MD 21287 <a href="mailto:dgvirgil@mail.jhmi.edu">dgvirgil@mail.jhmi.edu</a> 410-614-1030
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Began stand 101

Stand 152 (August 2) and stand 153 (August 27) changed the test volumes for age 6-11 from 1.5 to 1.0 and for age 12+ from 2.0 to 1.0 for all appointment types.

94 11	PTH2 (Parathyroid hormone) Early reporting if abnormal	6-150	1.0	1.0		1.0					Serum	Red top	2-mL-85	No	9 x 9 two inch box	Univ of Washington
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Began effective at the start of exams at stands 158 (January 11, 2003) and at the start of stand 159 (January 26, 2003).

77 37	<u>HPV Serum</u>	14-59	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CDC Ruth Ann Tucker 1600 Clifton Road NE MSG41 Atlanta, GA 30329 <a href="mailto:Rat1@cdc.gov">Rat1@cdc.gov</a> 404-639-2183
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Began September 24, 2001 (stand 139) & October 14, 2001 (stand 140)

79 6	Vitamin C	6-150	0.1		0.1	0.1			0.1	0.1	Serum	Red top	2 mL - 69	Yes	9 x 9 two inch box	CASPIR NCEH
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Originally scheduled to begin at stands 143 and 144.

Began effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
16 19	<u>Rub/Mea/Var</u>	6-49	0.1	0.1						0.1	Serum-S	Red top	2 mL-16 No	Yes	9 x 9 two inch box	Calif Dept of Health Services Attn: Cynthia Cossen 850 Marina Bay Parkway Richmond, CA 94804 <a href="mailto:ccossen@dhs.ca.gov">ccossen@dhs.ca.gov</a> 510-307-8590
<p>Began stand 101                      March 1, 2001 (stands 129 and 130) Changed the shipping address for the Viral and Rickettsial Laboratory.                      Changed test volumes from 0.4 to 0.1 effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
19 11	<u>Bn Alk Phos</u>	8-49	0.5	0.5						0.5	Serum-S	Red top	2 mL-19 No	Yes	9 x 9 two inch box	Univ of Washington
<p>Began stand 101                      January 10, 2000 (stand 113)/January 27, 2000 (stand 114) The age range for Bn Alk Phos (vessel 19) was changed from 18 to 8+ for females.                      Changed eligibility requirements from 8+ (0.5) to 8-49 (0.5) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
20 17	<u>Toxo (Crypto)</u>	6-11 12-49	0.2 0.5	0.5							Serum-S	Red top	2 mL-20 No	Yes	9 x 9 two inch box	CDC DPD Attn: Marianna Wilson 4470 Buford Highway Bldg. 109, Rm 1304, MS F36 Atlanta, GA 30341 <a href="mailto:Mwilson@cdc.gov">Mwilson@cdc.gov</a> 770 488-4431
<p>Began stand 101 - Eliminate Crypto at end of stand 142                      Added toxo to the data files                      Eliminate Crypto at end of stand 142                      Stand 143 and 144 Changed the shipping address from CDC/DPD Attn: Dr Partick Lammie, 4770 Buford Highway, F13, Atlanta, GA 30341 to CDC/DPD/Marianna Wilson/Chris Burns, 4470 Buford Highway, Bldg. 109, Rm 1304, MS F36, Atlanta, GA 30341</p>																
18 <del>18</del> 40	<u>Biochem ROF</u>	12-150	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	Serum-S	Red top	2 mL-18	Yes	9 x 9 two inch box	Coulston Collaborative Laboratory Services
<p>Began stand 101                      Stopped sending shipments to Coulston and began shipping all specimens to CLS effective March 4, 2002 (stands 145 and 146).</p>																
23 10	<u>Insul/Cpep Morning SPs only</u>	12-150	1.0	1.0						1.0	Serum-S	Red top	2 mL-23 No/Yes	Yes	9 x 9 two inch box	Univ of Missouri
<p>Began stand 101                      Stand 152 (August 2) and stand 153 (August 27) changed protocol for dry run appointment type, eliminated this test for even, added test to odd.</p>																

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
22 3	<u>HIV</u> <u>STD</u>	18-49	0.5								Serum-S	Red top	2 mL-22 No	Yes	9 x 9 two inch box	CDC NCID AIDS Division Attn: Faye Cowart 1600 Clifton Road NE Building 17, Room 3129 MS D-12 Atlanta, GA 30329 <a href="mailto:mfc1@cdc.gov">mfc1@cdc.gov</a> 404-639-0286
Began stand 101																
24 9	<u>HSV</u> <u>STD</u>	14-49	0.2								Serum-S	Red top	2 mL-24 No	Yes	9 x 9 two inch box	Emory University Attn: Dr. Francis Lee 46 Armstrong Street SE. Room 219 Atlanta, GA 30303 <a href="mailto:Flee@emory.edu">Flee@emory.edu</a> 404-616-4997
Began stand 101 April 20, 1000 Modified the dry run blood processing protocol by deleting vessel 24. Changed test volumes from 0.5 to 0.2 effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).																
74 36	<u>Syphilis</u> <u>STD</u>	18-49	0.5								Serum-S	Red top	2 mL-74 No	Yes	9 x 9 two inch box	CDC DASTLR/NCID Dr. Victoria Pope Bldg 1, Room 3318 1600 Clifton Road NE Atlanta, GA 30329 404-639-3224 Victoria Pope, PhD <a href="mailto:vpope@cdc.gov">vpope@cdc.gov</a> 404-639-3224
Began January 14, 2001 stand (128) & January 29, 2001 (stand 129)																
75 11	<u>PSA</u> <u>ROF</u>	40+ Males	1.0							1.0	Serum-S	Red top	2 mL-75 Yes	Yes	9 x 9 two inch box	Univ of Washington
Began January 14, 2001 stand (128) & January 29, 2001 (stand 129)																
15 45	<u>Vit A/E/Car</u> <u>Vit A ROF if</u> <u>abnormal</u>	6-11 12-150	0.4 0.5		0.5	0.4 0.5			0.5	0.5	Serum-S	Red top	2 mL-15 Carotinoids some, A/E No	Yes	9 x 9 two inch box	Brian Grawburg Craft Technologies, Inc. 4344 Frank Price Church Road Wilson, NC 27893-0923 <a href="mailto:bgrawburg@crafttechnologies.com">bgrawburg@crafttechnologies.com</a> (252) 206-7071

Began stand 101

Effective April 1, 2002 (stands 146 and 147) Changed (increased) the test volumes from 0.3 (age 3-11) to 0.6 and from 0.4 (age 12+) to 0.7

Changed the age eligibility from 3+ to 6+ effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Changed the test volume for age 3-11 from 0.6 and 12+ 0.7 to 0.4 for age 6-11 and 0.5 for 12+ effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Changed the lab from lab 6 to Craft Technologies effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
26 6 39	Selenium	40+	0.5								Serum-S	Red top	2 mL-26 No	Yes	9 x 9 two inch box	NYS DOH/Wadsworth CTR L&R

Began stand 101 – age 3-11 primary appointment type only, test volume 0.3, sent to lab 6.

Eliminated at end of stand 142.

Began again at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

New age criteria is 40+, test volume 0.5.

Began shipping to NYS DOH/Wadsworth CTR L&R on January 20, 2003.

29 28	Persis Pest (NP) Dioxins (Previously 63) 1/3 subsample 12+ 4, 6, 8, 9	12-150	4.0								Serum-S	10 mL Red top BD 366441	5 mL-29	Yes	9 x 9 three inch box	CASPIR/Dr. Wayman Turner Attn: Cheryl McClure 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 <a href="mailto:Pcm4@cdc.gov">Pcm4@cdc.gov</a> 770-488-7883
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Began stand 101

Original age eligibility 12-19, subsample fraction 1/3, remainder 4, 6, 8, 9.

September 8, 1999 (stand 107) & September 14, 1999 (stand 108) Changed the age eligibility from 12-19 to 12+.

April 6, 2001 (stands 131 & 132) Eliminated vessel 63 Serum Dioxin analysis is being done on serum from vessel 29.

October 4, 2001 (stands 138 & 139) Modified phlebotomy application to display the 10-mL red top tube only if the SP is eligible for the vessel.

89 28	Persis Pest2 (NP) 1/3 subsample 12+ 4, 6, 8, 9	12-150	4.0								Serum-S	10 mL Red top BD 366441	5 mL-89	Yes	9 x 9 three inch box	CASPIR/Dr. Wayman Turner
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Added one additional 10-mL red top tube to the venipuncture protocol and added this new vessel to the protocol effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Vessels 29 and 86 are assigned sequentially to the same container.

90	Future Res1 1/3 subsample 12+ 1, 2, 5, 11	12-150	4.0								Serum-S	10 mL Red top BD 366441	5 mL-90	Yes	9 x 9 three inch box	CASPIR
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Began stand 158

Use second dedicated 10-mL red top tube for this vessel.

New non-overlapping (with vessel 29/89 and 92/93) subsample with remainder 1, 2, 5, 11.

Added this new vessel to the protocol effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).

Vessels 90 and 91 are assigned sequentially to the same container.

91	Future Res2 1/3 subsample 12+ 1, 2, 5, 11	12-150	4.0								Serum-S	10 mL Red top BD 366441	5 mL-91	Yes	9 x 9 three inch box	CASPIR
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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
<p>Began stand 158 Use dedicated 10-mL red top tube for this vessel. New non-overlapping (with vessel 29/89 and 92/93) subsample with remainder 1, 2, 5,11. Added this new vessel to the protocol effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003). Vessels 90 and 91 are assigned sequentially to the same container.</p>																
92	Future Res3 1/3 subsample 12+ 0, 3, 7, 10	12-150	4.0								Serum-S	10 mL Red top BD 366441	5 mL-92	Yes	9 x 9 three inch box	CASPIR
<p>Began stand 158 Use second dedicated 10-mL red top tube for this vessel. New non-overlapping (with vessel 29/89 and 90/91) subsample with remainder 0, 3, 7, 10. Added this new vessel to the protocol effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003). Vessels 92 and 93 are assigned sequentially to the same container.</p>																
93	Future Res4 1/3 subsample 12+ 0, 3, 7, 10	12-150	4.0								Serum-S	10 mL Red top BD 366441	5 mL-93	Yes	9 x 9 three inch box	CASPIR
<p>Began stand 158 Use second dedicated 10-mL red top tube for this vessel. New non-overlapping (with vessel 29/89 and 90/91) subsample with remainder 0, 3, 7, 10. Added this new vessel to the protocol effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003). Vessels 92 and 93 are assigned sequentially to the same container.</p>																
32	Xtra Sera	3-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
<p>Began stand 101 Changed the age eligibility from 6+ to 3+ effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
33	Xtra Sera	6-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
<p>Began stand 101</p>																
34	Xtra Sera	12-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
<p>Began stand 101</p>																
35	Xtra Sera	12-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
<p>Began stand 101</p>																
36	Xtra Sera	12-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
<p>Began stand 101</p>																
37	Xtra Sera	12-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
Began stand 101																
38	Xtra Sera	12-150	1.0								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
Began stand 101 Changed the vessel volume from 0.5 to 1.0 effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).																
39	Xtra Sera	12-150	1.0								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
Began stand 101 Changed the vessel volume from 0.5 to 1.0 effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).																
40	Xtra Sera	12-150	1.0								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
Began stand 101 Changed the vessel volume from 0.5 to 1.0 effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).																
45 16	<u>Alb/Creat</u>	6-150	3.0		3.0	3.0				3.0	Urine-U		5 mL-45 Yes	Yes	9 x 9 three inch box	Univ of Minnesota Attn: Susan Kupcho Dept of Pediatrics 515 Delaware Street SE Room 13-219 – MOOS Tower Minneapolis, MN 55455 <a href="mailto:kupch001@maroon.tc.umn.edu">kupch001@maroon.tc.umn.edu</a> 612-624-6153
Began stand 101																
46 5	<u>Chlam/GC STD</u>	14-39	10.0								Urine-U		14 mL 17 x 100-46 No if RT <24 hours	Yes	5 x 5 three inch box	CDC NCID NCHSTD Attn: Carol Farshy 1600 Clifton Road NE MS D13 Atlanta, GA 30329 <a href="mailto:cfarshy@cdc.gov">cfarshy@cdc.gov</a> 404-639-2870
Began stand 101 April 20, 2000 Modified the dry run urine processing protocol by deleting vessel 46. Effective on October 23, 2002 at stands 154 and 155, change the vessel volume for primary appointment type from 3.0 to 10.0, the vessel type from 5-mL to 14-mL 17 x 100 Falcon snap cap tube and the container type from 9 x 9 two inch box to 5 x 5 three inch box.																
69 6	Urn Iodine (UI) 1/3 Subsample 4, 6, 8, 9	6-150	3.0								Urine-U		5-mL-69 No	Yes	9 x 9 three inch box	CASPIR Robert Jones
Began January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The new urinary iodine 1/3 (vessel 69) subsample was added (remainder 4, 6, 8, 9) on SPs age 6+.																
<b>Began shipping weekly at the start of stand 173, January 5, 2004.</b>																

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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
86 6	Speciated Arsenic 1/3 subsample 1, 2, 5, 11	6-150	3.0								Urine-U		5-mL-69 No	Yes	9 x 9 three inch box	CASPIR Robert Jones
<p>Began effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).  <b>Began shipping weekly at the start of stand 173, January 5, 2004.</b></p>																
48 26	Prior Pest (PP) Subsample 1/3 age 6+ 4, 6, 8, 9	6-150	10.0								Urine-U		14 mL 17 x 100-48 No	Yes	5 x 5 three inch box	CDC Dr. Dana Barr Attn: Dr. Dana Barr 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341-3724 <a href="mailto:dlb1@cdc.gov">dlb1@cdc.gov</a> 770-488-4598
<p>Began stand 101            Original age eligibility 6-11, subsample fraction 1/2, remainder 0, 1, 3, 4, 8, 11 and age 12-59, subsample fraction 1/4, remainder 4, 6, 8.            January 10, 2000 (stand 113) &amp; January 27, 2000 (stand 114) Change the age eligibility for 12-59 to 12+ and changed the subsample fraction from 1/4 to 1/3 and remainder to 4, 6, 8, and 9.            Changed the subsample requirements from 1/2 age 6-11 (0, 1, 3, 4, 8, 11) and 1/3 12+ (4, 6, 8, 9) to 1/3 age 6+ (4, 6, 8, 9) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
49 26	Organophos (OP) Subsample 1/3 age 6+ 4, 6, 8, 9	6-150	10.0								Urine-U		14 mL 17 x 100-49 No	Yes	5 x 5 three inch box	CDC/Dr. Dana Barr
<p>Began stand 101            Original age eligibility 6-11 subsample fraction 1/2, remainder 0, 1, 3, 4, 8, 11 and for age 12-59 subsample fraction 1/4 remainder 4, 6, 8.            January 10, 2000 (stand 113) &amp; January 27, 2000 (stand 114) Changed the age eligibility from 12-59 to 12+ and the subsample fraction from 1/4 to 1/3, remainder 4, 6, 8, 9.            Changed the subsample requirements from 1/2 age 6-11 (0, 1, 3, 4, 8, 11) and 1/3 12+ (4, 6, 8, 9) to 1/3 age 6+ (4, 6, 8, 9) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
62 6	Urn Merc 1/3 subsample 1, 2, 5, 11	6-150	5.0								Urine-U		14 mL 17 x 100-62 No	Yes	5 x 5 three inch box	CASPIR Robert Jones
<p>Began stand 101            Changed the age eligibility from 16-49 females to age 6+ effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).            Added the subsample requirement 1/3 overlapping with vessel 50 (1, 2, 5, 11) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
50 6	Heavy Metal (HM) 1/3 subsample 1, 2, 5, 11 (13 metals)	6-150	10.0								Urine-U		14 mL 17 x 100-50 No	Yes	5 x 5 three inch box	CASPIR Robert Jones
<p>Began September 8, 1999 (stand 107) &amp; September 14, 1999 (stand 108)            A new 1/3 subsample urine heavy metal, (vessel 50) was added (reminder 1, 2, 5, 11) on SPs age 6+.</p>																

Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
65 <del>26</del> 24 6	Urn Phytoes (UY) 1/3 subsample 0, 3, 7, 10 (8 chemicals)	6-150	3.0								Urine		5 mL-65 No	Yes	9 x 9 three inch box	<b>CASPIR NCEH Christine Pfeiffer</b>
<p>Began September 8, 1999 (stand 107) &amp; September 14, 1999 (stand 108)                      A new 1/3 subsample urine phytoestrogens, (vessel 65) was added (reminder 0, 3, 7, 10) on SPs age 6+.                      Began shipping this vessel to lab 24 instead of lab 26 (Dr. Barr) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).                      Changed on January 11, 2003 - Began shipping this vessel to lab 6 Dr. Antonia Calafat instead of lab 26 (Dr. Barr) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).                      Changed on January 29, 2003 - Began shipping this vessel to the lab 6 CASPIR address instead of CDC Dr. Antonia Calafat, 4770 Buford Highway, Building 17, Loading Dock, Atlanta, GA 30341-3724, 770-488-7891.</p>																
66 31	PAH (UA) 1/3 subsample 0, 3, 7, 10 (16 chemicals)	6-150	3.0								Urine		5 mL-66 Unknown	Yes	9 x 9 three inch box	CASPIR/Dr. Courtney D. Sandau Attn: Dr. Courtney D. Sandau 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 <a href="mailto:csandau@cdc.gov">csandau@cdc.gov</a> 770-488-4299 Dr. James Grainger
<p>Began September 8, 1999 (stand 107) &amp; September 14, 1999 (stand 108)                      A new 1/3 subsample urine polyaromatic hydrocarbons, (vessel 66) was added (reminder 0, 3, 7, 10) on SPs age 6+.                      Began shipping this vessel to Dr. Sandau (instead of Dr. Grainger) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
67 24	Phthalates (UT) 1/3 subsample 0, 3, 7, 10 (7 chemicals)	6-150	3.0								Urine		5-mL-67 No	Yes	9 x 9 three inch box	CDC/Dr. Antonia Calafat Attn: Dr. Antonia Calafat 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341-3724 <a href="mailto:Aic7@cdc.gov">Aic7@cdc.gov</a> 770-488-7891
<p>Began September 8, 1999 (stand 107) &amp; September 14, 1999 (stand 108)                      A new 1/3 subsample urine phthalates, (vessel 67) was added (reminder 0, 3, 7, 10) on SPs age 6+.                      Began shipping this vessel to lab 24 instead of lab 26 (Dr. Barr) effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
51	Xtra Urine	6-150	5.0								Urine-U		5 mL-51	Yes	9 x 9 three inch box	CASPIR
Began stand 101																
52	Xtra Urine	6-150	5.0								Urine-U		5 mL-52	Yes	9 x 9 three inch box	CASPIR
Began stand 101																

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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
53 3	<u>HIV Urine STD</u>	18-49	3.0								Urine-U		5 mL-53	Yes	9 x 9 three inch box	CDC AIDS Laboratory Division

Began stand 101

54 4	VOC Blood (VT) 1/2 Subsample 4, 5, 6, 7, 8, 9	20-59	10.0							10.0	Whole blood Phlebotomy- PW	10 mL Gray top	10 mL Gray top-54	Yes	5 x 5 five inch box with foam insert	CDC/Air Toxicant Branch Attn: Ben Blount 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341 <a href="mailto:bblount@cdc.gov">bblount@cdc.gov</a> 770-488-7962
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Began stand 101

Original age requirements 20-59, subsample fraction ¼, remainder 4, 6, 8.

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The VOC subsample fraction was changed from ¼ to 1/3 and the remainder changed from 4, 6, 7 to 4, 6, 8, 9.

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) Revisions to the VOC protocols; two 7-mL gray top VOC blood tubes were included in the venipuncture protocol and new English and Spanish second exam VOC questionnaire was required for all SE SPs age 20-59.

February 29, 2000 (stands 114 & 115) Began shipping VOC blood and water vessels to Dr. Blount and not Dr. Ashley.

January 29, 2001 (stand 129) & February 22, 2001 (stand 130) Began using the home examiners to conduct VOC exams in SP's homes on days when the MEC is closed.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Eliminate second exam convenient sample, move water collection responsibility to field office staff and home examiner, revise the questionnaire.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Change subsample fraction from 1/3 to ½ and change remainder from 4, 6, 8, 9 to 4, 5, 6, 7, 8, 9.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Replace two 7-mL gray top tubes with one 10-mL gray top tube.

**February 19, 2003 (stand 160) & March 9, 2003 (stand 161) Changed the blood collection tube from one 10-mL gray top tube to one 5-mL gray top tube and reactivated vessel 55. Assign to separate container.**

**Did not deploy this change because the lab could not identify an acceptable 5-mL tube. This change is on hold until further notice.**

56 4	VOC Water (VT) 1/2 Subsample 4, 5, 6, 7, 8, 9	20-59	10.0								Tap Water- H2O		10 mL glass vial-56	Yes	5 x 5 five inch box with foam insert	C D C/ Ai r T ox ic a nt B ra nc h
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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
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Began stand 101

Original age requirements 20-59, subsample fraction ¼, remainder 4, 6, 8.

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The VOC subsample fraction was changed from ¼ to 1/3 and the remainder changed from 4, 6, 7 to 4, 6, 8, 9.

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) Revisions to the VOC protocols; two 7-mL gray top VOC blood tubes were included in the venipuncture protocol and new English and Spanish second exam VOC questionnaire was required for all SE SPs age 20-59.

February 29, 2000 (stands 114 & 115) Began shipping VOC blood and water vessels to Dr. Blount and not Dr. Ashley.

January 29, 2001 (stand 129) & February 22, 2001 (stand 130) Began using the home examiners to conduct VOC exams in SP's homes on days when the MEC is closed.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Eliminate second exam convenient sample, move water collection responsibility to field office staff and home examiner, revise the questionnaire.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Change subsample fraction from 1/3 to ½ and change remainder from 4, 6, 8, 9 to 4, 5, 6, 7, 8, 9.

60 20	<u>F Lead Dust</u>	1-5 house- holds	Wipe								Dust	Wipe	50-mL conical- 60	No	4 x 4 five inch box	Univ of Cincinnati Attn: Sandy Rhoda Dept of Environmental  3223 Eden Avenue Cincinnati, OH 45267- 0056 <a href="mailto:rodasm@ucmail.uc.edu">rodasm@ucmail.uc.edu</a> 513-558-1705
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Began stand 101

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) Lead dust quality control was implemented; this QC criteria included processing two spiked positive blinded controls at each stand during weeks one and week 3 or after approximately 25 routine lead dust samples.

August 14, 2001 (stand 137) & August 30, 2001 (stand 138) The Lead Dust QC Labels module has been modified to include a "control#" text box. This field is linked to a list of control numbers provided by the analysis laboratory.

61 20	<u>W Lead Dust</u>	1-5 house- holds	Wipe								Dust	Wipe	50-mL conical- 61	No	4 x 4 five inch box	Univ of Cincinnati
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Began stand 101

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) Lead dust quality control was implemented; this QC criteria included processing two spiked positive blinded controls at each stand during weeks one and week 3 or after approximately 25 routine lead dust samples.

August 14, 2001 (stand 137) & August 30, 2001 (stand 138). The Lead Dust QC Labels module has been modified to include a "control#" text box. This field is linked to a list of control numbers provided by the analysis laboratory.

78 37	<u>HPV STD</u>	<i>Women 14-59</i>	<i>Swab</i>								<i>Genital Swab #3 (Dacron)</i>	<i>Swab</i>	<i>Swab - 78 Yes</i>	No	<i>9 x 9 three inch box</i>	<i>CDC Ruth Ann Tucker</i>
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Began September 24, 2001 (stand 139) & October 14, 2001 (stand 140).

72 34	<u>Vaginitis STD</u>	<i>Women 14-49</i>	<i>Swab</i>								<i>Genital Swab #1 (cotton)</i>	<i>Swab</i>	<i>Glass Slide- 72 (Store at room temp)</i>	No	<i>1 x 25 box ship refrigera ted with</i>	<i>Magee-Womens Hosp Attn: Dr. Jeanne Jordan Clin Micro Lab Room 4680 300 Halket Street Pittsburgh, PA 15213</i>
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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
															vessel 73	<a href="mailto:jordanja+@pitt.edu">jordanja+@pitt.edu</a> 412-641-4104
Began October 15, 2000 (stand 125) & November 10, 2000 (stand 126) Began processing VS specimens.																
73 34	<u>T vaginalis</u> STD	Women 14-49	Swab								Genital Swab #2 (Dacron)	Swab	Swab – 73 Yes	No	9 x 9 three inch box	Magee-Womens Hosp
Began October 15, 2000 (stand 125) & November 10, 2000 (stand 126) Began processing VS specimens.																
76 35	<u>MRSA</u>	1-150	Swab						Swab	Swab	Nasal Swab	Swab	Swab -76	No	9 x 9 three inch box	CDC Data and Specimen Handling Attn: Sigrid McAllister 1600 Clifton Road NE, MS G12 CLFT 4 B35 Atlanta, GA 30329 <a href="mailto:smcallister@cdc.gov">smcallister@cdc.gov</a> 404-639-1171
Began January 14, 2001 stand (128) & January 29, 2001 (stand 129). September 4, 2001 Changed the shipping address. January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Moved to Phlebotomy component (became a section).																
95 46	DNA Blood	20+	6.0								Whole blood-W	6 mL EDTA	3" x 5" 384 well plate-95	No	2 x 5 box	GenVault Corporation 2101 Faraday Ave. Carlsbad, CA 92008 (760) 268-5200 <a href="mailto:david.wellis@genvault.com">david.wellis@genvault.com</a>
Pilot at stands 170 (effective Oct 21, 2003), 171 (November 10, 2003), 172 and 173																
96 47	RNA Blood	40+	2.5								Whole blood-W	10 mL PAXgene tube	10-mL-96	No	5 x 5 five inch box with foam insert	Laboratory of Molecular Technology 915 TollHouse Road, Suite 211 Frederick, MD 21701 301-435-2891 Dr. David Munroe
Pilot at stands 170 (effective Oct 21, 2003), 171 (November 10, 2003), 172 and 173																
97 47	RNA Buccal	40+	Swab								Buccal cells	Swab	2-mL-97	No	9 x 9 two inch box	Laboratory of Molecular Technology 915 TollHouse Road, Suite 211 Frederick, MD 21701 301-435-2891 Dr. David Munroe
Pilot at stands 170 (effective Oct 21, 2003), 171 (November 10, 2003), 172 and 173																
58	Dental saliva	40+	5.0								Saliva		5-mL – 58	Yes	9 x 9	CASPIR

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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
															three inch box	
<p>Began stand 101 May 25, 2000 (stands 118 &amp; 119) Eliminated this vessel from the protocol.</p>																
59 22	<u>Methylmerc</u>	1-5 (both sexes) 16-49 (femal es)	100 mg								Hair-H		Plastic bag-59	Yes	10 x 10 bag	Research Triangle Institute Attn: Dr. Edo Pellizzari 3040 Cornwallis Road Dreyfus Bldg Research Triangle Park, NC 27709-2194 919-541-6000 edp@rti.org
<p>Began stand 101 – Eliminated at end of stand 142 Eliminated at the end of stand 142</p>																
31	Xtra Sera	6-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
<p>Began stand 101 – Eliminated at end of stand 112 January 10, 2000 (stand 113) &amp; January 27 (stand 114) The extra serum vessel #31 was deleted.</p>																
63 28	Dioxins (SD) 1/3 subsample 12+ 4, 6, 8, 9	12-150	4.0								Serum-S	10 mL Red top BD 366441	5 mL-29	Yes	9 x 9 three inch box	CASPIR/Dr. Wayman Turner Attn:Dr. Wayman Turner 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 pcm5@cdc.gov 770-488-7974
<p>Began stands 107/108 – Eliminated at start of stands 131/132 September 8, 1999 (stand 107) &amp; September 14, 1999 (stand 108) A new 1/3 subsample, serum dioxins, (vessel 63) was added (remainder 1, 2, 5, 11) on SPs age 12+. April 6, 2001 (stands 131 &amp; 132) Changed the subsample remainder to 4, 6, 8, and 9 (to match vessel 29) and Eliminated the vessel. Serum Dioxin analysis is being done on serum from vessel 29.</p>																
64 Lab never report results	Phytoestro (SP) 1/3 subsample 0, 3, 7, 10	12-150	4.0								Serum	10 mL Red top BD 366441	5 mL-64	Yes	9 x 9 three inch box	CASPIR/Dr. Charles Dodson Attn: Dr. Charles Dodson 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 wcd1@cdc.gov 770-788-4504
<p>Began stands 107/108 – Eliminate at end of stand 142 Began September 8, 1999 (stand 107) &amp; September 14, 1999 (stand 108) A new 1/3 subsample serum phytoestrogens, (vessel 64) was added (reminder 0, 3, 7, 10) on SPs age 12+. Eliminated at end of stand 142 October 4, 2001 (stands 138 &amp; 139) Modified phlebotomy application to display the 10-mL red top tube only if the SP is eligible for the vessel.</p>																
55 4	<i>VOC Blood (VT)</i> 1/2 Subsample	20-59	7.0							7.0	Whole blood Phlebotomy-	7 mL Gray top	7 mL Gray top-54	Yes	5 x 5 five inch box	CDC/Air Toxicant Branch Attn: Ben Blount

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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
	4, 5, 6, 7, 8, 9										PW				with foam insert	4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341 770-488-7962 bkb3@cdc.gov

Began stand 101

Original age requirements 20-59, subsample fraction ¼, remainder 4, 6, 8.

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The VOC subsample fraction was changed from ¼ to 1/3 and the remainder changed from 4, 6, 7 to 4, 6, 8, 9.

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) Revisions to the VOC protocols; two 7-mL gray top VOC blood tubes were included in the venipuncture protocol and new English and Spanish second exam VOC questionnaire was required for all SE SPs age 20-59.

February 29, 2000 (stands 114 & 115) Began shipping VOC blood and water vessels to Dr. Blount and not Dr. Ashley.

January 29, 2001 (stand 129) & February 22, 2001 (stand 130) Began using the home examiners to conduct VOC exams in SP's homes on days when the MEC is closed.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Eliminate second exam convenient sample, move water collection responsibility to field office staff and home examiner, revise the questionnaire.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Change subsample fraction from 1/3 to ½ and change remainder from 4, 6, 8, 9 to 4, 5, 6, 7, 8, 9.

January 7, 2002 (stand 143) & January 24, 2002 (stand 144) Replace two 7-mL gray top tubes with one 10-mL gray top tube. This effectively eliminates this vessel.

**February 19, 2003 (stand 160) & March 9, 2003 (stand 161) Change the blood collection tube from one 10-mL gray top tube to one 5-mL gray top tube and reactivated vessel 55. Assign to separate container.**

**Did not deploy this change because the lab could not identify an acceptable 5-mL tube. This change is on hold until further notice.**

57 21	VOC Badge (VT) ¼ 101-112 1/3 subsample 4, 6, 8, 9	20-59	48 hour sample								Badge-EB 3M 3520 Organic Vapor Monitor		Badge-57	Yes	2 x 2 five inch box 2 high = 8	Dr. Clifford Weisel/Mr. Kris Mohan RWJMS/UMDNJ EOHSI Room #309 170 Frelinghuysen Road Piscataway, NJ 08855-1179 732-445-0154 732-445-0799 <a href="mailto:weisel@eohsi.rutgers.edu">weisel@eohsi.rutgers.edu</a> Dr. Robert Hague <a href="mailto:Haguero@umdnj.edu">Haguero@umdnj.edu</a>
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Began stand 101 – Eliminated at end of stand 142

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The VOC subsample fraction was changed from ¼ to 1/3.

July 15, 2000 Changed the number of repeat participants from 1 to 2.

August 3, 2000 Suspended all shipments to Clayton Laboratories.

December 4, 2000 (stand 127) & December 5, 2000 (stand 126) Began shipping badges directly to EOHSI.

January 29, 2001 (stand 129) & February 22, 2001 (stand 130) Began using the home examiners to conduct VOC exams in SP's homes on days when the MEC is closed.

Eliminated at the end of stand 142.

27 7	Latex	12-59	0.5		0.5					0.5	Serum-S	Red top	2 mL-27 One cycle no	Yes	9 x 9 two inch box	CDC/Data And Specimen Handling Attn: Dr. Matthew J. Arduino 1600 Clifton Road, NE MS G12, CLFT 4 B35 Atlanta GA 30329 <a href="mailto:Bej7@cdc.gov">Bej7@cdc.gov</a> 404-639-2318
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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
<p>Began stand 101 – Eliminated at end of stand 142                      September 4, 2001 Changed the shipping address.                      Eliminated at the end of stand 142</p>																
10 11	<u>Fibrin</u>	40-150	1.0	1.0					1.0	1.0	Plasma-P BD 366395	3 mL Light blue	2 mL-10 Yes	Yes	9 x 9 two inch box	Univ of Washington Attn: Phyllis Daum Immunology 1959 NE Pacific Avenue Room NW 176 Seattle, WA 98195 <a href="mailto:Immuno@u.washington.edu">Immuno@u.washington.edu</a> (206) 598-6149
<p>Began stand 101                      Stand 152 (August 2) and stand 153 (August 27) changed protocol for dry run appointment type, eliminated this test for even, added test to odd.                      Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
25 18	<u>FSH/LH</u> <u>ROF</u>	35-60 Females	0.8	0.8		0.8				0.8	Serum-S	Red top	2 mL-25 Yes	Yes	9 x 9 two inch box	Coulston Foundation Collaborative Laboratory Services LLC
<p>Began stand 101                      Began sending the samples to CASPIR for storage on March 4, 2002.                      Stands 150 and 151 Began sending the samples to CLS on July 16, 2002                      Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).</p>																
28 18	<u>TSH/Thyrox</u> <u>ROF (T4)</u> 1/3 subsample 12+ 4, 6, 8, 9	12-150	1.0								Serum-S	Red top	2 mL-28 Yes	Yes	9 x 9 two inch box	Collaborative Laboratory Services LLC Coulston Foundation
<p>Began stand 101                      Original age eligibility 12+, subsample fraction 1/3, remainder 4, 6, 8, 9 for age 12-19 and 1, 2, 3, 6 for 20+.                      Originally matched PP remainder 4, 6, 8, 9 for age 12-19 and 1, 2, 3, 6 for 20+.                      September 8, 1999 (stand 107) &amp; September 14, 1999 (stand 108) Changed the subsample remainder for 20+ from 1, 2, 3, 6 to 4, 6, 8, and 9.                      Began sending the samples to CASPIR for storage on March 4, 2002.                      Stands 150 and 151 Began sending the samples to CLS on July 16, 2002                      Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)</p>																
44	WBC/DNA - PC	20-150	10.0								Packed Cells -PC	10 mL EDTA BD 366457	14 mL 17 x 100-44	Yes	5 x 5 three inch box	CDC/Molecular Biology Branch Attn: Jennifer Rapeir 4770 Buford Highway Building 32, Room 1505 MS F24 Atlanta, GA 30341-3724 <a href="mailto:Jlm2@dc.gov">Jlm2@dc.gov</a> 770-488-4313

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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
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Began stand 101

January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The existing CPT genetic tube was replaced by two ACD tubes, creating a new WBC/DNA vessel #71.

July 25, 2001, begin storing and shipping the ACT tubes (vessels 44 and 71) at refrigerated temperatures.

September 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week.

January 10, 2002 (stand 143) & January 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube.

Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)

We did not process the packed cells and plasma for MBB from Jan 2000 through Sept 22, 2001. We collected two ACD tubes from Jan 10, 2000 to Sept 22, 2001 but we did not begin processing (separating) the packed cells from the plasma until Sept 22, 2001.

From Jan 10, 2000 through Sept 22, 2001 vessels 044 & 071 were collected with two 8.5ml ACD yellow top tube (#364606). On Sept 22, 2001 vessel 080 was created for the plasma from the ACD tubes. On Jan 10, 2002 the two ACD tubes were replaced with two 10-mL EDTA Lavender top tube (#366457) for vessels 44, 71 and 80.

Vessel 44 - packed cells

Began stand 101 (4/2/99)

Apr 2, 1999 through Jan 10, 2000 one 8-mL CPT tube #632761 Sodium Citrate Jan 10, 2000 (stand 113) & Jan 27, 2000 (stand 114) The existing CPT genetic tube was replaced by two ACD tubes, creating a new WBC/DNA vessel #71. July 25, 2001, begin storing and shipping the ACT tubes (vessels 44 and 71) at refrigerated temperatures. Sept 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week. Jan 10, 2002 (stand 143) & Jan 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube. Deleted effective at the start of stands 158 (Jan 6, 2003) and 159 (Jan 26, 2003)

71	WBC/DNA - PC	20-150	10.0								Packed Cells - PC	10 mL EDTA BD 366457	14 mL 17 x 100-71	Yes	5 x 5 three inch box	CDC/Molecular Biology Branch
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Began January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The existing CPT genetic tube was replaced by two ACD tubes, creating a new WBC/DNA vessel #71.

July 25, 2001, begin storing and shipping the ACT tubes (vessels 44 and 71) at refrigerated temperatures.

September 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week.

January 10, 2002 (stand 143) & January 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube.

Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)

Vessel 71 - packed cells

Began Jan 10, 2000 (stand 113) & Jan 27, 2000 (stand 114) The existing CPT genetic tube was replaced by two ACD tubes, creating a new WBC/DNA vessel #71. July 25, 2001, begin storing and shipping the ACT tubes (vessels 44 and 71) at refrigerated temperatures. Sept 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week. Jan 10, 2002 (stand 143) & Jan 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube. Deleted effective at the start of stands 158 (Jan 6, 2003) and 159 (Jan 26, 2003)

80	WBC/DNA - P	20-150	10.0								Plasma - P	10 mL EDTA BD 366457	14 mL 17 x 100-80	Yes	5 x 5 three inch box	CDC Attn: Wayman Turner 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341 <a href="mailto:Wet1@cdc.gov">Wet1@cdc.gov</a> 770-488-7974
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Began September 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week.

January 10, 2002 (stand 143) & January 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube and the shipping address from MBB to CDC/Dr. Turner.

Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)

Vessel 80 - Plasma

Began Sept 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week. Jan 10, 2002 (stand 143) & Jan 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube and the shipping address from MBB to CDC/Dr. Turner. Deleted effective at the start of stands 158 (Jan 6, 2003) and 159 (Jan 26, 2003)

41	Xtra Sera	12-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two	CASPIR
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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
															inch box	
Began stand 101																
Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)																
42	Xtra Sera	12-150	0.5								Serum-S	Red top	2 mL-32	Yes	9 x 9 two inch box	CASPIR
Began stand 101																
Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)																
43	DNA	20-150	17.0								Clot-C	Red top	17 x 100 vial- 43	Yes	5 x 5 three inch box	CASPIR
Began stand 101																
Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)																
47 11	<u>NTX</u>	8-150	1.0		1.0					1.0	Urine-U		2 mL-47 No	Yes	9 x 9 two inch box	University of Washington
Began stand 101																
January 10, 2000 (stand 113) & January 27, 2000 (stand 114) The age range for urine NTX (vessel 47) was changed from 18 to 8+ for females.																
Deleted effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003)																
82 6	<u>TfR</u> <u>ROF</u>	12-49 females	0.3	0.3		0.3					Serum-S	Red top	2-mL-82 No	Yes	9 x 9 two inch box	CASPIR Christine Pfeiffer
Began at the start of stand 160 (February 20, 2003) and stand 161 (March 10, 2003)																
TfR being done from vessel 68 on SPs age 1-5.																
Effective at the start of Year 6 (stand 173 January 5, 2004) deactivate vessel #82.																
TfR and Ferritin are being done on serum from vessel 68 for ages 1-5 and 12-49 (felames) effective at the start of stand 173 on January 5, 2004.																
85 11	PTH (Parathyroid hormone) Early reporting if abnormal	6-150	1.0	1.0		1.0					Serum	Red top	2-mL-85	No	9 x 9 two inch box	Univ of Washington

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Appendix C-1. Historical Master List (continued)

Vessel ID/ Lab #	Test Name	Primary Ages Gender	Primary 1+	Odd SS 12+	Even SS 12+	VIP Guest 1+	Guests 1+	Surplus 1+	Home Exam 50+	Second Exam 12-69	Sample Type	Collection Type (from VP)	Vessel Type - ID Affected by freezer/thaw	ASTRO ID	Container	Shipping Address
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Began effective at the start of stands 158 (January 6, 2003) and 159 (January 26, 2003).  
 January 11, 2003 changed the vessel volume from 2.0 to 1.0 and created a corresponding new vessel 94 with the same requirements.  
 Inactivated September 1, 2003 (the start of stand 168) but reactivated September 17, 2003.  
 Deactivate it at the start of stand 173, making the effective date December 18, 2003 at stand 171 and January 25 at stand 172.

September 8, 1999 (stand 107) & September 14, 1999 (stand 108)  
 The new Datamax label printer and new thermal transfer labels and ribbons were introduced. These labels replaced the sheet-fed laser labels. The label size was increased from 1 1/8 x 2/ 1/8 to 1 1/8 x 2 5/8.  
 On October 26, 1999 (stand 110) & October 27 (stand 109) The VOC application was added to the MEC interviewer desktop. The MEC interviewers were trained to collect the VOC badge and water, administer the VOC questionnaire, and perform the field blank and office air monitor QC  
 September 30, 1999 (stand 109) & October 26, 1999 (stand 110) The home examination component pilot began.  
 January 10, 2000 (stand 113) & January 27 (stand 114) The ICON II hCG urine test kit was replaced with the Biomerica serum/urine hCG test kit and new serum hCG controls were added to the pregnancy quality control module. Pregnancy testing is performed on females of all person types except home exam, ages 12-59, and primary female SPs age 8+ who reported that they are menstruating when asked in the home interview. If a urine pregnancy test is positive on any female SP age 8-17, then a serum pregnancy test is performed. Results of the serum pregnancy test, a repeat urine pregnancy test, or the inability to perform either a serum test or repeat urine test are sent to the physician using the observation function.  
 February 22, 2001 (stand 130) & March 15, 2001 (stand 131) Changed pregnancy test kits from the Biomerica hCG to the Beckman Coulter ICON 25 hCG kit and changed serum and urine controls from ICON to Sure-Vue.

Summary – ACD plasma processing summary

We did not process the packed cells and plasma for MBB from Jan 2000 through Sept 22, 2001. We collected two ACD tubes from Jan 10, 2000 to Sept 22, 2001 but we did not begin processing (separating) the packed cells from the plasma until Sept 22, 2001.

From Jan 10, 2000 through Sept 22, 2001 vessels 044 & 071 were collected with two 8.5ml ACD yellow top tube (#364606). On Sept 22, 2001 vessel 080 was created for the plasma from the ACD tubes. On Jan 10, 2002 the two ACD tubes were replaced with two 10-mL EDTA Lavender top tube (#366457) for vessels 44, 71 and 80. >  
 Tube 364606  
 Solution A = 22.0 g/L trisodium citrate, 8.0 g/L citric acid, 24.5 g/L dextrose

Vessel 44 - packed cells

Began stand 101 (4/2/99)

Apr 2, 1999 through Jan 10, 2000 one 8-mL CPT tube #632761 Sodium Citrate Jan 10, 2000 (stand 113) & Jan 27, 2000 (stand 114) The existing CPT genetic tube was replaced by two ACD tubes, creating a new WBC/DNA vessel #71. July 25, 2001, begin storing and shipping the ACT tubes (vessels 44 and 71) at refrigerated temperatures. Sept 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week. Jan 10, 2002 (stand 143) & Jan 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube. Deleted effective at the start of stands 158 (Jan 6, 2003) and 159 (Jan 26, 2003)

Vessel 71 - packed cells

Began Jan 10, 2000 (stand 113) & Jan 27, 2000 (stand 114) The existing CPT genetic tube was replaced by two ACD tubes, creating a new WBC/DNA vessel #71. July 25, 2001, begin storing and shipping the ACT tubes (vessels 44 and 71) at refrigerated temperatures. Sept 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week. Jan 10, 2002 (stand 143) & Jan 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube. Deleted effective at the start of stands 158 (Jan 6, 2003) and 159 (Jan 26, 2003)

Vessel 80 - Plasma

Began Sept 22, 2001 (stands 138 & 139) Began processing the ACD tubes, separating and pooling the plasma, transferring the packed cells to 14-mL vessel, freezing the three vessels and shipping once per week. Jan 10, 2002 (stand 143) & Jan 24, 2002 (stand 144) Change the 8-mL ACD tube to a 10-mL EDTA tube and the shipping address from MBB to CDC/Dr. Turner. Deleted effective at the start of stands 158 (Jan 6, 2003) and 159 (Jan 26, 2003)



Appendix C-2. Year 6 Protocol by Tube Type

11/19/2003	P 1-2	P 3-5	P 6-11	P 12+		DR odd		DR even		VIP 1-2	VIP 3-5	VIP 6-11	VIP 12+		G 1-11	G 12+	Surplus
<b>Whole Blood</b>																	
CBC	1.5	1.5	1.5	1.5		1.5		1.5		1.5	1.5	1.5	1.5		1.5	1.5	1.5
1 Lead/Cad/HG	0.3	0.3	0.5	0.5		0.5		0.5		0.3	0.3	0.5	0.5				
2 Ery Proto		0.4		0.4	12 to 49 females	0.4	12 to 49 females				0.4		0.4	12 to 49 females			
3 RBC Folate	0.1	0.1	0.1	0.1				0.1		0.1	0.1	0.1	0.1				
4 Glycohem				0.4		0.4							0.4				
5 Mercury	0.3	0.3	0.3	0.3				0.3		0.3	0.3	0.3	0.3				
6 CD4				0.5	18-49												
88 Acrylamide		0.4	1.0	1.0													
<b>Whole blood total</b>	<b>2.2</b>	<b>3</b>	<b>3.4</b>	<b>4.7</b>		<b>2.8</b>		<b>2.4</b>		<b>2.2</b>	<b>2.6</b>	<b>2.4</b>	<b>3.2</b>		<b>1.5</b>	<b>1.5</b>	<b>1.5</b>
<i>EDTA tube size</i>	3	3	4	4		3		3		3	3	3	4		3	3	3
<i>Number of EDTA</i>	1	1	1	2		2		2		1	1	1	1		1	1	1
<b>EDTA Plasma</b>																	
81 Vitamin B6	0.2	0.2	0.2	0.5				0.5		0.2	0.2	0.2	0.5				
7 Homocys/MMA		1.0	1.0	1.0				1.0									
8 Xtra Plasma			0.5	0.5													
<b>Plasma total</b>	<b>0.2</b>	<b>1.2</b>	<b>1.7</b>	<b>1.7</b>				<b>1.0</b>		<b>0.2</b>	<b>0.2</b>	<b>0.2</b>	<b>0.5</b>		<b>0</b>	<b>0</b>	<b>0</b>
<i>EDTA tube size</i>		3	4	4				3			3	3	3				
<i>Number of EDTA</i>		1	1	1				2			1	1	1				
<b>NaCit Plasma</b>																	
9 Glucose				0.5	morning only	0.5	morning only	0.5	morning only				0.5	morning only			
<i>2-mL Gray</i>				2		2		2					2				
<i>Number of gray</i>				1		2		2					1				
<b>Serum</b>																	
70 Vitamin D	0.3	0.5	0.5	0.5				0.5									
12 Fol/B12	0.7	0.7	1.0	1.0		1.0				0.7	0.7	1.0	1.0				
13 CRP	0.5	0.5	0.5	0.5		0.5											
14 Hep profile			1.5	1.5				1.5									
87 Hepatitis ab	0.4	0.4			2-5												
68 Ferritin/TfR	0.3	0.4		0.4	12 to 49 females	0.4	12 to 49 females			0.3	0.4		0.4	12 to 49 females			
11 Iron/TIBC		1.0		1.0	12 to 59 females			1.0	12 to 59 females		1.0		1.0	12 to 59 females			
17 Cotinine		1.3	1.3	1.8				1.8									
21 Lipids		0.2	1.0	1.0		1.0		1.0			0.2	1.0	1.0				
94 PTH2			1.0	1.0		1.0											
77 HPV Serum				0.5	14 to 59												
79 Vitamin C			0.1	0.1				0.1				0.1	0.1				
16 Rub/Mea/Var			0.1	0.1	6 to 49	0.1	12 to 49										
19 Bn Alk Phos			0.5	0.5	8 to 49	0.5	8 to 49										
20 Toxo			0.2	0.5	12 to 49	0.5	12 to 49										
18 Biochem				0.8		0.8		0.8					0.8				
23 Insul/Cpep				1.0	morning only	1.0										0.8	0.8
22 HIV				0.5	18 to 49												
24 HSV				0.2	14 to 49												
74 Syphilis				0.5	18 to 49												

Appendix C-2. Year 6 Protocol by Tube Type (continued)

11/19/2003	P 1-2	P 3-5	P 6-11	P 12+		DR odd		DR even		VIP 1-2	VIP 3-5	VIP 6-11	VIP 12+		G 1-11	G 12+	Surplus	
75 PSA				1.0	40+ males													
16 Vit A/E/Car			0.4	0.5				0.5				0.4	0.5					
26 Selenium				0.5	40+ years													
32 Xtra serum		0.5	0.5	0.5														
33 Xtra serum			0.5	0.5														
34 Xtra serum				0.5														
35 Xtra serum				0.5														
36 Xtra serum				0.5														
37 Xtra serum				0.5														
38 Xtra serum				1.0														
39 Xtra serum				1.0														
40 Xtra serum				1.0														
Serum total	2.2	5.5	9.1	21.4		6.8		7.2		1	2.3	2.5	4.8			0.8	0.8	
Serum yield	2.4	5.6	10.8	24.0		16		16		1.2	2.4	5.6	8.0			1.2	1.2	
Red tube size	3	7	10	15						3	3	7	10			3	3	
Number of Red	2	2	2	4						1	2	2	2			1	1	
Red tube size				7		10		10										
Number of Red				1		4		4										
29 Persis Pest (NP)				4	1/3 subsample 4, 6, 8, 9													
89 Persis Pest2 (NP)				4	1/3 subsample 4, 6, 8, 9													
90 Future Res1				4	1/3 subsample 1, 2, 5, 11													
91 Future Res2				4	1/3 subsample 1, 2, 5, 11													
92 Future Res3				4	1/3 subsample 0, 3, 7, 10													
93 Future Res4				4	1/3 subsample 0, 3, 7, 10													
10-mL Red tube				10														
Number				2														
54 VOC Blood				10	1/2 subsample 4, 5, 6, 7, 8, 9													
CDC 10-mL Gray				10														
Number of Grey				1														
Total blood draw	9	20	35	104		50		56		6	12	20	29		3	6	6	
<b>Urine</b>																		
45 Alb/Creat			3	3				3				3	3					
46 Chlam/GC				10	14 to 39													
69 Urn Iodine (UI)			3	3	1/3 subsample 4, 6, 8, 9													
86 Speciated Arsenic (SA)			3	3	1/3 subsample 1, 2, 5, 11													
48 Prior Pest (PP)			10	10	1/3 subsample 4, 6, 8, 9													
49 Organophos (OP)			10	10	1/3 subsample 4, 6, 8, 9													
62 Urn Merc			5	5	1/3 subsample 1, 2, 5, 11													
50 Heavy Metal (HM)			10	10	1/3 subsample 1, 2, 5, 11													
65 Urn Phytoes (UY)			3	3	1/3 subsample 0, 3, 7, 10													
66 PAH (UA)			3	3	1/3 subsample 0, 3, 7, 10													
67 Phthalates (UT)			3	3	1/3 subsample 0, 3, 7, 10													
51 Xtra Urine			5	5														
52 Xtra Urine			5	5														

Appendix C-2. Year 6 Protocol by Tube Type (continued)

11/19/2003	P 1-2	P 3-5	P 6-11	P 12+		DR odd		DR even		VIP 1-2	VIP 3-5	VIP 6-11	VIP 12+		G 1-11	G 12+	Surplus	
53 HIV Urine				3	18 to 49													
Total urine mL			63	76				3										
56 VOC Water				10	1/2 subsample 4, 5, 6, 7, 8, 9													
60 F Lead Dust	Wipe	Wipe																
61 W Lead Dust	Wipe	Wipe																
78 HPV				Swab	14-59 females													
72 Vaginitis				Slide	14-49 females													
73 T vaginalis				Swab	14-49 females													
76 MRSA	Swab	Swab	Swab	Swab														

## Appendix D

### Laboratory and Phlebotomy Inventory

Appendix D. Laboratory and Phlebotomy Inventory

**Laboratory Inventory**

**Consumable Items:**

**Exam Supplies**

<u>Part Number</u>	<u>Description</u>	<u>Unit</u> <u>Distribution</u>	<u>Par Level</u>	<u>Price</u>
56616-032	Absorbent Bench Pad	each	12 each	\$0.26 / each
FA201-10	Absorbent Sheets ( 2" x 2" )	pack	5 packs	\$15.00 / pack
SO-AA	Absorbic Acid Vial	each	10 each	No Charge / CDC
24-54	Cotton Tip Applicator Sticks	bag	1 bag	\$0.60 / bag
19-086333	Wooden Applicator Sticks	box	1 box	\$5.73 / box
SO-ZB	Quart Zip Lock Bag	box	1 box	\$2.59 / box
12-007-187	Bench Kote Paper	case	2 cases	\$67.05 / case
9A-7793	Bio-Hazard Bag (19" x 23")	box	1 box	\$115.00 / box
108M	Bio-Hazard Bag (25" x 35")	box	1 box	\$31.20 / box
14-830-132	8 Gallon Bio-Hazard Container	each	20 each	\$14.12 / each
SO-Bleach	Regular Bleach	gallon	3 gallons	\$0.88 / gallon
1441266	Bleach Rite Disinfectant Spray	bottle	2 bottles	\$9.27 / bottle
107-7756	Gloves, Latex Powderfree (Lg.)	box	20 boxes	\$7.25 / box
107-7594	Gloves, Latex Powderfree (Med.)	box	10 boxes	\$7.25 / box
681-5874-L1	Gloves, Latex Powderfree (Sm.)	box	3 boxes	\$7.25 / box
18999442C	Gloves, Maxxim Latexfree (Lg.)	box	10 boxes	\$7.92 / box
18999442B	Gloves, Maxxim Latexfree (Med.)	box	10 boxes	\$7.92 / box
18999442A	Gloves, Maxxim Latexfree (Sm.)	box	12 boxes	\$7.92 / box
34155	Kimwipes (4 1/2" x 8 1/2")	box	3 boxes	\$1.68 / box
SO-MA	Metaphosphoric Acid Vial 6%	vial	10 vials	No Charge / CDC
M95823	Ph Paper, EM ColorpHast	pack	1 pack	\$8.88 / pack
05-403-11	Pipette Tips 1000uL	box	3 boxes	\$55.37 / box
05-403-09	Pipette Tips 200uL	box	1 box	\$51.52 / box
05-403-62	Pipette Tips 5mL (Bulk Pack)	case	1 case	\$62.29 / case
12-518-103	Microscope Slides	pack	2 packs	\$19.59 / pack
RDR024	Temperature Chart Pens	pack	1 pack	\$66.00 / pack
RDR020	Temperature Charts	pack	1 pack	\$26.00 / pack
86.1171	3.5mL Transfer Pipette	box	3 boxes	\$34.00 / box
15-235-61	Terri Wipes (13" x 18")	box	1 box	\$14.86 / box

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**Office Supplies**

<u>Part Number</u>	<u>Description</u>	<u>Unit Distribution</u>	<u>Par Level</u>	<u>Price</u>
DUR PC1604	Durcell 9-Volt Battery	each	10 each	\$2.43 / each
AVE 5160	Copier Labels (1" x 2 5/8")	box	1 box	\$40.78 / box
UVF 1x2625	DataMax Labels	roll	4 rolls	\$24.50 / roll
LBL-Cust	Sheet Labels (8 1/2" x 11")	pack	1 pack	\$146.25 / pack
SAN 30001	Sharpie Magic Marker	each	3 each	\$1.09 / each
95.954	Felt Tip Waterproof Marker	each	3 each	\$2.11 / each
MMM 670-5AU	Post-It Page Markers	pack	6 packs	\$5.40 / pack
48SRB-4PPL	DataMax Printer Ribbon	roll	2 rolls	\$46.37 / roll
FJI2374C104	Fujitsu Printer Ribbon	each	1 each	\$10.65 / each
ALL 28335	Rubber Bands # 33	box	1 box	\$3.19 / box
HEW C4127X	HP 4000 Toner Cartridge	each	1 each	\$210.00 / each

**Hematology Supplies**

23-293371	Coulter 5C Cell Control	pack	2 packs	\$204.50 / pack
23-257520	Coulter Clenz	box	2 boxes	\$46.13 / box
23-165951	Coulter Isoton III	box	6 boxes	\$26.27 / box
23-273856	Coulter Latron Control	pack	1 pack	\$122.22 / pack
23-273857	Coulter Latron Primer	pack	1 pack	\$50.30 / pack
23-287835	Coulter Lyse-S	bottle	3 bottles	\$86.30 / bottle
23-212076	Coulter S-Cal Calibrator	pack	1 pack	\$159.88 / pack
23-275278	Coulter Scatter Pak	box	2 boxes	\$100.85 / box

**Specialized Stickers**

8A-17697	Bio-Hazard Sticker	roll	1 roll	\$37.10 / roll
8A-674	Keep Frozen Sticker	pack	2 packs	\$7.50 / pack
8A-675	Refrigerate-Do Not Freeze Sticker	pack	1 pack	\$7.50 / pack

**Pregnancy Test  
Supplies**

22247114	ICON 25 Pregnancy Test Kit	box	9 boxes	\$33.31 / box
SA087712	Sure-Vue hCG Serum Control	pack	1 pack	\$28.14 / pack
SA087413	Sure-Vue hCG Urine Control	pack	1 pack	\$21.68 / pack

**Lab Jackets**

1A-32187	Disposable Lab Jacket, Lite Blue	box	1 box	\$22.50 / box
1721L	Lab Jacket, Large	each	20 each	\$3.32 / each
1721P	Lab Jacket, Petite	each	20 each	\$3.32 / each
1721XL	Lab Jacket, X-Large	each	20 each	\$3.32 / each

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**Tubes, Vials, & Filters**

<u>Part Number</u>	<u>Description</u>	<u>Unit Distribution</u>	<u>Par Level</u>	<u>Price</u>
62.559.001	50mL Red Top Conical Tube	bag	16 bags	\$11.25 / bag
SO-14mL	Mercury Additive 14mL Tube	each	250 each	\$0.24 / each
14-959-11B	14mL Falcon Culture Test Tube	bag	25 bags	\$6.26 / bag
LDQC-Tube	Lead Dust QC Tube	each	4 each	\$6.00 each
679800-5840	2.0mL Non-Sterile Cryovial	case	15 cases	\$126.00 / case
5000-0020	2.0mL Sterile Cryovial	case	2 cases	\$148.69 / case
03-337-7H	5.0mL Sterile Cryovial	case	12 cases	\$56.10 / case
02-681-50	Serum Filter (13mm x 4")	pack	3 packs	\$11.59 / pack
02-681-52	Serum Filter (16mm x 6")	pack	17 packs	\$11.92 / pack

**Shipping Supplies**

1A-55968	Ziplock Bag (9" x 12")	case	1 case	\$55.30 / case
BX-2-D	2" Cardboard Box w/ 9 x 9 Grid	each	300 each	\$1.35 / each
36-6434-22	3" Cardboard Box w/ 9 x 9 Grid	each	80 each	\$3.21 / each
36-6434-52	3" Cardboard Box w/o Grid	each	50 each	\$1.90 / each
95.064.916	5.25" Cardboard Box w/ 4 x 4 Grid	each	10 each	\$3.16 / each
95.064.925	5.25" Cardboard Box w/ Foam Insert	each	15 each	\$4.75 / each
SO-CD	3" Cell Dividers (5 x 5)	each	50 each	\$1.00 / each
STP 730	Combo. Bag Envelope System	case	6 cases	\$160.78 / case
STP 710	Combo. Bag Envelope System	case	2 cases	\$102.70 / case
STP 740	Combo. Bag Envelope System	case	1 case	\$227.07 / case
DSL	Diagnostic Specimen Label	sheet	10 sheets	\$0.30 per sheet
SEL 01115	Envelopes, Large Padded	each	each	\$0.80 / each
(no part number)	FEDEX Airbill Pouch	pack	3 packs	No Charge
(no part number)	FEDEX Blank Airbills	pack	1 pack	No Charge
(no part number)	FEDEX Class 9 Dry Ice Label	roll	1 roll	No Charge
(no part number)	FEDEX Large Shipping Box	each	2 each	No Charge
(no part number)	FEDEX Pre-printed FO Airbill	each	300 each	No Charge
(no part number)	FEDEX Pre-printed WHSE Airbill	each	300 each	No Charge
03-448-6	Micro Slide Box	each	10 each	\$2.75 / each
240-20	News-Pak (Newsprint on roll)	each	1 roll	\$34.20 / roll
49-4886-36	Medium Shipper 16" x 16"	each	30 each	\$14.00 / each
49-4886-15	Small Shipper 14" x 14"	each	75 each	\$7.27 / each
MMM 3710-2-TT	2" Packing Tape	roll	24 rolls	\$1.57 / roll
03-528C	U-Tek Refrigerant Pack	case	9 cases	\$12.47 / case

**Component Tools**

G31-500	Glycerin - 500mL Bottle	bottle	1 bottle	\$23.84 / bottle
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Appendix D. Laboratory and Phlebotomy Inventory (continued)

**Non-Consumable  
Items:**

**Spare Parts & Tools**

<u>Part Number</u>	<u>Description</u>	<u>Unit Distribution</u>	<u>Par Level</u>	<u>Price</u>
22-46-139-7	Eppendorf Pipettor 100-5000uL	each	1 each	\$394.00 / each
22-46-138-9	Eppendorf Pipettor 50-1000uL	each	2 each	\$369.00 / each
22-46-138-9	Eppendorf Pipettor 5-100uL	each	1 each	\$369.00 / each
99833	16 oz. Claw Hammer	each	2 each	\$7.92 / each
NC9818625	Pipettor Battery (Spare)	each	1 each	\$45.88 / each
22-46-155-9	Pipettor Charging Stand	each	1 each	\$442.00 / each
40822	Screwdriver (4 in 1 Driver)	each	1 each	\$2.96 / each
66-039-6	Screwdriver Set - 6 Piece Precision	each	1 each	\$6.00 / each

**Shipping Supplies**

14-241B	Aluminum Ice Scoop	each	2 each	\$15.22 / each
8A-18116	Full Face Sheild	each	1 each	\$15.40 / each
11-394-200	Cryo Gloves - Large	pair	1 pair	\$77.14 / pair
11-394-305	Cryo Gloves - Medium	pair	1 pair	\$77.14 / pair
1E-24039	Leather Utility Gloves	pair	1 pair	\$5.20 / pair
SPR 01750	Tape Gun 2"	each	2 each	\$9.95 / each

**Component Tools**

B100	100 Place Styrofoam Rack Blood Processing Template Age	each	100 each	\$3.80 / each
BPT-12+	12+ Blood Processing Template Age 1-	each	100 each	\$2.50 / each
BPT-1-11	11	each	25 each	\$2.50 / each
21-102-52	Cube Rack - 4 Way Flipper Rack	each	2 each	\$10.49 / each
OA-9188	Flashlight	each	1 each	\$13.45 / each
08-572-7C	Graduated Cylinder 50mL Multicolor 4 Way Flipper Rack	each	1 each	\$4.51 / each
60985-444	(4/set)	set	1 each	\$38.00 / set
14-809-101	Nalge 13mm Half Rack	each	3 each	\$6.80 / each
14-809-134	Nalge 16mm Full Rack	each	4 each	\$9.37 / each
14-809-117	Nalge 16mm Half rack	each	5 each	\$7.62 / each
03-409-11E	Distilled Water Bottle	each	2 each	\$3.00 / each
415S0023BY	NOTRAX Floor Mat	each	1 each	\$21.00 / each
9A-33810	Protective Eyewear	each	3 each	\$3.70 / each
15-078J	Thermometer, Calibration	each	1 each	\$19.58 / each
15-077-19	Thermometer, Solar	each	2 each	\$18.44 / each
06-662-51	Timer	each	1 each	\$8.80 / each
06-662-3	Timer, Triple Display	each	2 each	\$18.20 / each

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**Phlebotomy Inventory**

**Consumable Items**

**Exam Supplies**

<u>Part Number</u>	<u>Description</u>	<u>Unit</u> <u>Distribution</u>	<u>Par Level</u>	<u>Price</u>
7000HP	Air Sickness Bags	each	5 each	\$1.26 / each
58-104	Alcohol Wipes	box	6 boxes	\$1.85 / box
17-98797E	Ammonia Ampules	box	1 box	\$1.36 / box
AB95	Band-aids - Cartoon Characters	box	6 boxes	\$8.95 / box
4434	Band-aids 3/4" x 3"	box	3 boxes	\$4.27 / box
B4320099	BBL Nasal Culture Swabs	each	500 each	\$0.56 / each
SEL 01110	Bubble Mailer 6" x 10"	each	5 each	\$0.35 / each
387359	Butterfly Needle 19g EZ-Set	box	6 boxes	\$54.05 / box
02-6641	Butterfly Needle 21g Safety-Lock	box	6 boxes	\$57.20 / box
06-664	Butterfly Needle 23g Safety-Lock	box	1 box	\$56.86 / box
19-003-428D	Co-Flex NL Cohesive Bandage	case	1 case	\$27.37 / case
7632	Gauze Pads (2" x 2")	pack	6 packs	\$3.20 / pack
209269	Heel Warmers	each	5 each	\$1.04 / each
367290	Luer Adapters	box	3 boxes	\$29.49 / box
120-4240	Opsite Dressing	box	2 boxes	\$41.00 / box
18-917	Pillow Covers	each	15 each	\$0.23 / each
P1723-20	Pillow	each	1 each	\$3.12 / each
530212	Squeeze Ball	each	4 each	\$1.75 / each
Cartoon Sticker	Kids Cartoon Stickers	roll	4 rolls	\$3.75 / roll
TB-1-18	Latex Tourniquets	each	10 each	\$0.11 / each
02-6576	Stretch Tourniquets (non-latex)	box	20 boxes	\$9.50 / box
1530-0	Transpore Paper Tape	roll	1 roll	\$0.34 / roll
1527-0	Transpore Tape	roll	1 roll	\$0.69 / roll

**Forms**

(no part number)	List of Reported Tests	each	50 each	\$0.03 / each
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**Specialized Stickers & Labels**

E20842	Intermec Polypropylene Label	roll	2 rolls	\$28.96 / roll
FID051SP	PPS Ribbon - Black Resin	roll	2 rolls	\$12.72 / roll
1-110501-00	Printhead Cleaning Cards	box	1 box	\$19.55 / box

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**VOC Supplies**

<u>Part Number</u>	<u>Description</u>	<u>Unit</u> <u>Distribution</u>	<u>Par Level</u>	<u>Price</u>
(no part number)	VOC 10mL Blood Draw Tube	each	100 each	No Charge / CDC

**Fasting Snacks**

Austin Cracker	Animal Crackers (kosher)	bag	400 bags	\$0.19 / bag
132-745	Apple Juice Box	box	250 boxes	\$0.38 / box
Minute Maid	Orange Juice Box	box	300 boxes	\$0.35 / box

**Tubes, Vials, & Filters**

367921	BD Hemogard 2mL Gray Top Tube	tray	2 trays	\$30.43 / tray
367856	BD Hemogard 3mL EDTA Tube	tray	2 trays	\$27.32 / tray
369612	BD Hemogard 3mL Red Top Tube	tray	1 tray	\$17.33 / tray
367861	BD Hemogard 4mL EDTA Tube	tray	10 trays	\$27.32 / tray
369615	BD Hemogard 7mL Red Top Tube	tray	2 trays	\$ 17.82 / tray
366430	BD Vacutainer 10mL Red Top Tube	tray	6 trays	\$18.72 / tray
366432	BD Vacutainer 15mL Red Top Tube	tray	10 trays	\$19.78 / tray
368607	BD Vacutainer Eclipse 21g Needle	box	1 box	\$19.53 / box
02-658-210	BD Vacutainer Yellow Tube Holder	each	500 each	\$0.11 / each

**Non-Consumable Items**

**Emergency Supplies**

1A-16896	CPR Mask - Adult	each	1 each	\$20.00 / each
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**Component Tools**

20-373030-3	2 Step White Step Stool	each	1 each	\$15.99 / each
14-809-130	Nalge 13mm Full Rack	each	1 each	\$6.80 / each
14-809-101	Nalge 13mm Half Rack	each	2 each	\$6.80 / each
14-809-117	Nalge 16mm Half Rack	each	7 each	\$7.62 / each
415S0023BY	NOTRAX Floor Mat	each	1 each	\$21.00 / each
30-1310-05	Lister Bandage Scissors	each	1 each	\$13.50 / each
15-077-19	Thermometer, Solar	each	1 each	\$18.44 / each

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**PAM Inventory**

**Exam Supplies** ( Items Placed Into Kits )

<u>Part Number</u>	<u>Description</u>	<u>Unit Distribution</u>	<u>Par Level</u>	<u>Price</u>
SEL 01110	Bubble Mailer 6" x 10"	each	1 each	\$0.35 / each
(no part number)	Direction Sheet - Light Green	each	1 each	\$0.01 / each
(no part number)	PAM Color Letter	each	2 each	\$0.03 / each
Monitor	PAM Monitor	each	1 each	\$300.00 / each
12979	Black 80" Velcro Belt	each	1 each	\$1.20 / each

**\*\*\*\* NOTE\*\*\*\***

Physical Activity Monitor Kits are part of the Phlebotomy Component. The items listed above are what is included in each kit prepared by the warehouse.

The current par level for each site is 300 kits.

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**VOC Inventory**

**Exam Supplies (Items Placed Into Kits)**

<u>Part Number</u>	<u>Description</u>	<u>Unit Distribution</u>	<u>Par Level</u>	<u>Price</u>
(no part number)	VOC Water Tube	each	1 each	No Charge / CDC
63-4-05W	Write On Ziplock Bag	each	1 each	\$0.03 / each
(no part number)	VOC Water Collection Instruction Sheet	each	1 each	\$0.02 / each

\*\*\*\* **NOTE** \*\*\*\*

VOC Water Collection Kits are part of the Field Office Inventory and the Phlebotomy Component Inventory. The items listed above are what is included in each kit prepared by the warehouse.

The current par level for each Field Office is 250 kits and the par level for each Phlebotomy Component is 25 kits per site.

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**Lead Dust Inventory**

**Exam Supplies**

<u>Part Number</u>	<u>Description</u>	<u>Unit</u> <u>Distribution</u>	<u>Par Level</u>	<u>Price</u>
(no part number)	NCHS Lead Dust Consent Form	each	1 each	No Charge / CDC
(no part number)	Lead Dust Sampling Form	each	1 each	\$0.03 / each
(no part number)	EPA/HUD Disclosure Rule (Eng)	each	1 each	\$0.10 / each
(no part number)	EPA/HUD Disclosure Rule (Span)	each	1 each	\$0.10 / each
(no part number)	Cardboard Floor Template	each	1 each	\$1.60 / each
1A-28803	3/4" Masking Tape	roll	1 roll	\$1.85 / roll
56105	12" x 12" Ziplock Bag	each	1 each	\$0.22 / each
795	Paper Measuring Tape	each	1 each	\$0.05 / each
12-31	Plastic Handle Bag	each	1 each	\$0.02 / each
107-7756	Latex Powderfree Gloves (Lg)	pair	4 pair	\$0.15 / pair
90085	Oil Free Lead Dust Wipes	each	6 each	\$0.30 / each
62.559.001	50mL Red Top Conical Tube	each	4 each	\$0.45 / each
(no part number)	Lead Dust Tube Labels	each	6 each	\$0.04 / each
SO-ZB	Quart Ziplock Bag	each	1 each	\$0.05 / each

**\*\*\*\* NOTE \*\*\*\***

Lead Dust Kits are part of the Field Office Inventory. The items listed above are what is included in each kit prepared by the warehouse.

The current par level for each Field Office is 50 kits per site.

Appendix D. Laboratory and Phlebotomy Inventory (continued)

**BV Inventory**

**Exam Supplies**

<u>Part Number</u>	<u>Description</u>	<u>Unit Distribution</u>	<u>Par Level</u>	<u>Price</u>
OA-56084	Mini-Grip Bag 4" x 8"	each	1 each	\$0.05 / each
BVIS1449	BV Instruction Sheet Age 14-49	each	1 each	\$0.02 / each
BVIS5059	BV Instruction Sheet Age 50-59	each	1 each	\$0.02 / each
14-959-70B	Cotton Tipped Swaube	each	1 each	\$0.86 / each
NC9955395	Dacron Tipped Swaube	each	1 each	\$0.36 / each
QEC 091H	Catch-All Collection Swaube	each	1 each	\$1.28 / each

**\*\*\*\* NOTE \*\*\*\***

BV Kits are made up into two different age groups, 14-49 & 50-59. For the younger age group one of each swaube is included in the kit along with a mini-grip bag and instruction sheet. For the older age group the kit will include a mini-grip bag, and instruction sheet, and only one Catch-All Collection swaube. Both kits are prepared by the warehouse.

The current par levels are 100 kits for the 14-49 age group and 50 kits for the 50-59 age group.