



# National Health and Nutrition Examination Survey (NHANES)

## Laboratory Procedures Manual



March 2011

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

This chapter provides a general history and description of the National Health and Nutrition Examination Survey (NHANES), and an overview of the tasks that staff perform during the survey.

## 1.1 History

The National Health Survey Act, passed in 1956, provided the legislation authorizing for a survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. NHANES was created to fulfill the purpose of this act. The NHANES 99 for 2004 was the eighth in a series of national examination studies conducted in the United States since 1960, but effective in 2005, NHANES has become a continuous field survey with year-round data collection.

To fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) direct interviews with Americans of all ages; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) facilities where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, 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 of these 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); and
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 gained importance 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 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); and

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 and 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. HHANES, conducted from 1982 to 1984, aimed at

producing 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 and characteristics of minority groups can be very different from that of nonminority groups. Thus, black Americans and Mexican Americans were selected in large proportions in NHANES III. Each of these groups comprised separately 30 percent of the sample. It was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. For the first time a home examination was developed for those persons who were unable or unwilling to come into the examination center but would agree to an abbreviated examination in their homes. To obtain reliable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure the levels of pesticide exposure, the presence of certain trace elements in the blood, and the amounts of carbon monoxide present in the blood.

NHANES 99, conducted between 1999 and 2005, was the first of the series of surveys designed with the goal of becoming 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 is 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.

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

Epidemiological Follow-up Survey, a multiphase project that has been conducting follow-up interviews with the NHANES I survey population in order to provide a longitudinal picture of the health of the U.S. population.

## 1.2 Goals of the Survey

NHANES 2009, the current version of the survey, was designed to continue the collection of information about the health and diet of people in the United States. These data are used to fulfill specific goals. The overall goals of NHANES 2009 are to:

- Estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposures;
- Analyze risk factors for selected diseases;
- Study the relationship between diet, nutrition, and health;
- Explore emerging public health issues and new technologies; and
- Establish a national probability sample of genetic material for future genetic testing.

## 1.3 NHANES Data Accomplishments

NHANES data have been used to influence policy and improve the health of the U.S. population in many ways since the survey series was established. For the past 40 years, the U.S. Public Health Service has been interviewing and examining tens of thousands of Americans. Currently, teams of doctors, nutritionists, and health technologists are conducting the National Health and Nutrition Examination Survey (NHANES) in communities across the United States. Information from the survey will be updated annually.

Some of the contributions of the NHANES data include:

- **Pediatric growth charts.** Developed by the National Health and Nutrition Examination Survey, the NHANES growth charts are found on the walls of pediatricians' offices and clinics not only across the United States, but also around the world. With new information on younger babies, the current charts have been expanded and improved.
- **Vitamins and minerals.** The earlier NHANES showed that low iron levels were a serious problem for many people, including women of childbearing age, preschool children, and the elderly. As a result, the government decided to fortify grain and cereal with iron to correct this deficiency. The surveys also showed the need for folate to eliminate another deficiency and prevent birth defects. Today, we have a wealth of information at our fingertips and, indeed, on our food labels to help us make better choices about our diets. Much of that information comes directly from the National Health and Nutrition Examination Survey.
- **Cholesterol levels.** The first survey in the 1960s led public health officials to sound the alarm about the link between high cholesterol levels and the risk of heart disease. When NHANES started testing, one-third of adults had high cholesterol. Today fewer than 1 in 5 adults have high cholesterol. Changes in diet and lifestyle, all built on information from the national survey, have sharply reduced our risk of dying from a heart attack. These strategies have also helped doctors find ways to better treat heart attack patients and speed their recovery.
- **Lead-free gasoline.** It was NHANES that gave the first clear-cut evidence that Americans had too much lead in their blood. This led Congress, the Environmental Protection Agency, and others to phase out the use of lead as an additive in gasoline, and the results have been remarkable. By the 1990s, NHANES found that only 4 percent of Americans had elevated lead in their blood, but it remains a problem for certain groups, especially poor children living in old houses, in cities where lead paint was once common. The survey helps public health agencies pinpoint where lead still remains a problem.

As the NHANES survey continues to collect and update health information, there are other ways in which the information will be of use, including:

- **Osteoporosis.** This condition, in which bones get weaker as people grow old, is blamed for many of the fractures among the elderly. The National Health and Nutrition Examination Survey measures bone density of participants.
- **Environmental smoke.** Recent NHANES data found that nearly 9 out of 10 nonsmoking Americans were exposed to smoke either at home or on the job.
- **Obesity.** Despite the public health gains in recent years, more Americans are overweight than ever before. Today, more than half of the adults in the U.S. are overweight, and the number of overweight children and teens has doubled in the past

decade. This has led public health experts to look for ways to improve both diet and fitness.

- **Changes in Food/Diet.** Today consumers can find a wide range of low fat and light foods in their grocery stores, from dinner entrees to snacks. As the food we eat changes, NHANES helps monitor whether these new foods and dietary changes actually are in the best interest of our health.
- **Immunizations.** The National Health and Nutrition Examination Survey has turned up important information about the extent of hepatitis B infections, and led to the recommendation that all infants and children be vaccinated against it. Though babies and children are the primary targets for immunizations, the survey also has alerted doctors to the importance of tetanus shots for older people.

#### **1.4 National Center for Health Statistics**

The Division of Health and Nutrition Examination Surveys (DHANES) is one of the survey divisions at the CDC's National Center for Health Statistics (NCHS).

DHANES is responsible for planning, operations, informatics, analysis, and reporting activities related to the family of health and nutrition examination surveys. These surveys range from the capstone cross-sectional National Health and Nutrition Examination Survey, to longitudinal studies, and more recent efforts with community-based studies. DHANES is comprised of more than 60 Federal employees who have training and expertise in diverse areas including public health, informatics, survey methodology, and statistics. The Federal staff are augmented by contractor staff working on- and off-site.

The Division consists of four branches and the Office of the Division Director. The DHANES Office of the Director coordinates the major activities in the Division. Each of the four branches consists of a multidisciplinary team with specific duties and responsibilities.

#### **1.5 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 United States 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) with 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 Mobile Examination Center (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 and genetics testing 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 and to collect a sample for genetics 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.

## **1.6 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. She or 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. She or 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.
- **Facilities Specialist (FES)** – One Facilities and Equipment Specialist will travel with each field office team and caravan to oversee the maintenance and operation of the trailers.
- **Household Interviewers** – These staff members are 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** – These health professionals conduct 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, 3 medical technologists, 4 health technologists, 2 registered dental hygienists, 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.

The following section describes the steps that are always completed before the opening of a stand and provides an overview of the tasks that interviewers are expected to perform.

Steps completed prior to interviewing include:

1. 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.
2. Segments are listed by NHANES staff. 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.
3. 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.
4. 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 informs the household that an interviewer will contact them in the near future.

Steps followed by the interviewers at a stand include:

1. Obtain assignment of sampled dwelling units to contact from the field manager.
2. Locate dwelling units using addresses on the Household Folders and listing/mapping materials in the Segment Folder.
3. Contact an adult who lives in the selected household (occupied residential dwelling unit) 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.
4. If all persons in a household are ineligible, no further work is done with the case. If eligible household members are identified, interviewers continue to conduct all the necessary tasks associated with the case.
5. In eligible households, obtain a signed interview consent form prior to completing the medical history and/or the family questionnaire.

6. Administer the appropriate medical history CAPI interview to eligible respondents. The questions asked depend on the age of the SP.
7. Administer the Family questionnaire to one adult family member from each eligible family in the household.
8. Schedule a MEC appointment for each SP, coordinating the MEC schedule and the SP schedule.
9. Obtain signed consent form(s) for each SP for the examination, confirm the examination appointment(s) with the field office, and give each SP an appointment slip.
10. If there is more than one eligible family in a household, repeat this process with each additional family.
11. Record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.

Interviewers also support the survey by conducting field reminders prior to MEC appointments and reschedule broken, cancelled, or no-show MEC appointments. When an interview has been completed, interviewers edit their work, carefully reviewing all forms for completeness and legibility. Interviewers report in person to the field manager 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.

To ensure 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.

## **1.7 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.

### 1.7.1 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, workweeks 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

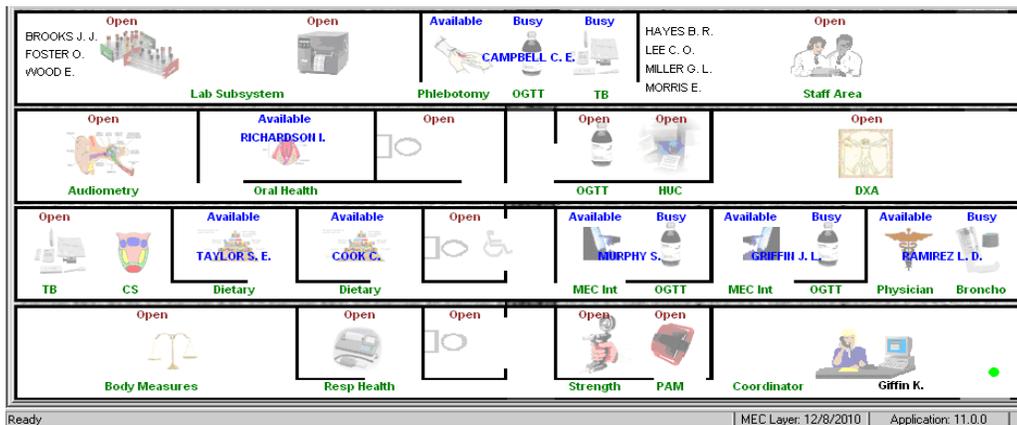


Exhibit 1-2. MEC exams and rooms

Trailer	Room	Room Use
Trailer 1	Coordinator	Welcoming and waiting area for SPs
	Muscle Strength	Muscle Strength, Physical Activity Monitor, Proxy
	Respiratory Health	Exhaled Nitric Oxide Spirometry
	Anthropometry	Body measurements
Trailer 2	Physician	Physician examination
	MEC Interview 1	Health interview, OGTT Trutol administration, Proxy exam
	MEC Interview 2	Health interview, OGTT Trutol administration, Proxy exam
	Dietary Interview 1	Dietary interview
	Dietary Interview 2	Dietary interview
	Tuberculosis Testing	Tuberculosis testing, Chemosenses
Trailer 3	Bone Density (DXA)	Bone Density scans
	Home Urine Collection	Home urine collection, Tuberculosis testing
	Oral Health	Dental examination
	Audiometry	Hearing tests
Trailer 4	Phlebotomy/OGTT	Drawing of blood samples Oral glucose tolerance Trutol administration Tuberculosis testing
	Laboratory	Processing of biological samples
	Label/shipping area	Lab area for labeling and shipping specimens
	Staff area	Staff area that houses main computer system

### 1.7.2 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. The duties of the exam team members are summarized below:

- One MEC manager supervises the exam staff, oversees exam flow, 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 oral health exam and obtains the HPV specimen.
- Two health (MEC) interviewers administer questionnaires for physical and mental health information. The interviewers are also trained to administer the proxy exam, the OGTT exam, and the home urine collection exam.
- 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. They are also trained to administer the OGTT and home urine collection exam.
- Four health technologists (some with radiologic technology and/or other health training) take and record body measurements, conduct respiratory health exams and bone density (DXA) scans, administer hearing tests, record for the oral health exam, conduct the home urine collection exam, and administer the Trutol solution for the glucose tolerance test.
- 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 conducts the phlebotomy interview, administers the fasting questionnaire, and draws blood for laboratory tests and special studies like the volatile organic compound special study. The phlebotomist is also responsible for administering the Trutol and drawing a second blood sample for the GTT test. They are trained as a backup examiner for other MEC components like body measures and the home urine collection.

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.

### **1.7.3 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.

Exhibit 1-3. MEC exam components by age

Examination	Age group
Audiometry	20-69
Body Composition (DXA)	8-59
Body Measures	All ages
Chemosenses (Taste & Smell)	40+
Dietary Interview	All ages
Glucose Tolerance	12+
Laboratory	1+
Urine Sample	6+
MEC (Health) Interview	8 +
Pubertal Maturation	8-19
Muscle Strength	6+
Oral Health	2+
Phlebotomy	1+
Physical Activity Monitor	6+
Physician	All ages
Blood Pressure	8+
Respiratory Health	6-79
Spirometry	
Exhaled Nitric Oxide	
Bronchodilation with spirometry	Limited subsample
Tuberculin Skin Testing	6+
Urine Collection	6+

The specific tests an SP will receive depend on his or her age and gender and selection into various subsamples. Exhibit 1-3, shown earlier, lists all of the MEC exam components and indicates which components are given to each age group. The major exam modules are described briefly here.

- **Audiometry**—The goals of the hearing exam are to obtain normative data on the hearing status of the adolescent U.S. population and to evaluate certain covariates that may be related to hearing loss, such as noise exposure. The hearing component tests adults aged 20-69 years by performing pure tone air conduction audiometry and tympanometry. Because air conduction thresholds alone cannot detect middle ear disease, tympanometry is conducted to identify potentially medically-correctible conditions which may be contributing to hearing impairment.
- **Body Composition**—The DXA component will use dual energy x-ray absorptiometry to evaluate body composition for SPs aged 8-59 years. A whole body scan will be used to assess body composition changes that occur with age by measuring fat mass, lean mass, and percent body fat. Body composition by DXA is a more accurate representation of a person's body fat than scale weight or body mass index (BMI), because it does not rely on height and weight alone to measure fat mass and lean mass. Excess body fat or body composition with a high fat-to-lean ratio can increase the risk of cardiovascular disease, Type II diabetes, metabolic syndrome and certain cancers. Excess body fat, especially at levels considered obese, can also put stress on the joints and interfere with mobility and the ability to perform everyday activities.
- **Body Measures or Anthropometry**—All SPs will have body measurements taken. The exam will include height, weight, and other body measurements such as arm girth, waist circumference, and sagittal abdominal diameter. These measurements will be used to assess growth, obesity, and body fat distribution, and will provide information that can be used as a reference for later studies. Measurements of height and weight will allow for a revision of the child growth charts now in widespread use. Measuring body fat is important because it is associated with hypertension, adult diabetes, cardiovascular disease, gallstones, arthritis, and some forms of cancer. Furthermore, obesity and overweight can have an effect on the mental, physical, and social well-being of individuals.
- **Chemosenses**—The goals of the chemosenses exam is to obtain normative data on the ability to taste and smell for U.S. adults ages 40 years and older. Smell testing is performed by standardized scratch and sniff tests including the ability to smell the odor of smoke and natural gas. These are important safety hazards for older adults. Taste testing is performed for the ability to taste samples of salty and bitter solutions. The smell and taste data will be linked to the nutritional data that is collected to see whether differences in the ability to smell and taste are related to diet and nutrition.
- **Dietary Interview**—Dietary information has been collected in NHANES since the 1970s. Researchers and policymakers rely on NHANES data for detailed information about the foods and beverages that are consumed by the U.S. population. In addition to providing important national reference data on food and nutrient intakes that are obtained on all survey participants, the data help us to learn about food patterns of

ethnic subgroups, the adequacy of diets consumed by young children and older persons, and the contribution of food to total nutrient intakes. Total nutrient intakes from food and dietary supplements can be computed by combining NHANES Dietary Recall data with the dietary interview supplement and antacid recall information. Many Federal agencies use NHANES data to evaluate Federal regulations in the areas of food fortification and human risk assessment analyses that are used to measure human exposure to contaminants that are found in food.

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 are obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system.

Two dietary interviews will be administered to all SPs. The primary dietary interview is administered in person in the MEC (the MEC In-person interview). At the end of the MEC dietary interview, the interviewers will schedule the SPs for a Phone Follow-up (PFU) 4-11 days later. The PFU is a follow-up dietary interview conducted by telephone by dietary interviewers from the home office.

- **Oral Glucose Tolerance Test (OGTT or GTT)**—The purpose of this test is to reassess the prevalence of diabetes and impaired glucose tolerance (IGT) in the U.S. population. Persons with impaired glucose tolerance (IGT) – 15.6 percent of the U.S. population – are at high risk for developing diabetes. Also, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined on the basis of an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hr value of 140-199 mg/dl are considered to have IGT. Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT.
  - The GTT will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts.
  - A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast. After the venipuncture, participants are asked to drink 75 milligrams of Trutol® and to have a second venipuncture 2 hours (plus or minus 15 minutes) after consuming the Trutol. The blood glucose level from the second venipuncture will be used to determine if an SP has IGT.
- **MEC (Health) Interview**—Participants aged 8 and older will have a private health interview in the MEC. Generally, the questions asked in the MEC are considered to be more sensitive than the questions asked in the household. The MEC environment is

believed to be a more appropriate setting for the administration of these questions. Depending upon the age of the survey participant, the interview may consist of questions about reproductive health (birth control practices, pregnancy and reproductive history), sexual activity, pubertal maturation, health behaviors (physical activity, weight history, tobacco, drug, and alcohol use), current health status, urinary conditions and mental health, as well as recent exposure to certain environmental chemicals. Adults 60 and older are also given a short series of tests to assess their cognitive functioning. Children 8-11 years are asked questions only about weight history and pubertal maturation. Participants who are 8-69 years old answer the most sensitive questions of their questions when the interviewer steps out of the room. In complete privacy, they use earphones which enable them to both hear and see the written questions on the screen. They enter responses by touching the responses on the computer screen.

- **Muscle Strength**—The goals of this component are to provide: (1) nationally representative data on muscle strength; (2) prevalence estimates of persons with poor muscle strength; and (3) data to study the association between muscle strength and other health conditions and risk factors, such as obesity, cardiovascular disease, diabetes, hypertension, and activity and dietary patterns. One of the most common methods of measuring muscle strength is the isometric grip strength test. We will measure isometric grip strength using a handgrip dynamometer for all participants 6 years and older. The participant will be asked to squeeze the dynamometer as hard as possible with each of his or her hands in a standing position.
- **Oral Health**—SPs aged 1 years and older will receive an oral health exam. Depending upon the age of the SP, persons will be checked for tooth loss, cavities, restorations, dental sealants, and dental fluorosis. Examinees 30 years and older will receive a periodontal examination.
  - Oral and dental diseases affect many in the United States. Dental caries and tooth loss remain significant problems affecting the Nation’s oral health. Although average dental caries rates for school-aged children have declined, nearly a half of all children still have caries. Additionally, more than 90 percent of adults in the United States have experienced caries. Dental sealants, an effective caries prevention measure, have been underutilized in the United States, with less than one-quarter of children aged 5-17 having them. This oral health examination will meet a critical need to continue monitoring trends in dental health status and will produce oral health data to monitor key oral health objectives for the *Healthy People* national health promotion initiative.
- **Phlebotomy**—SPs aged 1 and older will have blood drawn. The amount drawn will depend on the person's age. It is important to draw blood from study participants for a number of reasons:
  - Knowledge can be gained about how healthy a person is by measuring for various substances in his or her blood.
  - Blood tests can provide early warnings of potential health problems, perhaps before physical signs appear. For example, a blood test for lead might indicate

exposure to unsafe lead levels before an individual shows any physical signs of lead poisoning. Also, diabetes mellitus will be assessed by measures of plasma glucose, insulin, and glycohemoglobin in examinees ages 12 years and older. Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and more than 1 million new cases of diabetes are diagnosed each year. Alarming, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.

- Blood tests will also indicate the presence of STDs such as hepatitis, herpes, and HIV infection.
  - Blood tests help in monitoring nutritional status, one of the key goals of NHANES. What researchers discover from this data can lead to health policy recommendations—the need for more vitamin fortification, for example.
  - The blood testing also provides information about the levels of cholesterol and other blood lipids, another important study goal.
- **Physician**—All SPs see the physician. The physician measures blood pressure and pulse of all participants over 8 years of age, explains to female SPs how the HPV examination will be completed and explains the meaning of the STD/HIV test results to eligible SPs. The physician explains how SPs receive the results of STD/HIV tests so that the results remain totally confidential to the SP. Beginning in 2007, the physician will screen participants who qualify for the bronchodilator with spirometry exam, obtain consent for, and administer the bronchodilator. The physician must be present on the MEC before any exams can be conducted, and the physician is in charge of any medical emergency that occurs on the MEC.
  - **Respiratory Health**—Beginning in 2007, the Respiratory Health (RH) was incorporated in the NHANES study. RH will be collected by means of an assessment of lung function testing, or spirometry, and a measurement of exhaled nitric oxide (ENO). The objective of collecting this data is to assess the prevalence of asthma and adult chronic obstructive pulmonary disease in the U.S. population. All SPs aged 6-79 years will be eligible to participate in the component. SP's will be excluded from the RH exam if they answer positively to any pre-exam safety exclusion questions.

RH has three subcomponents: (1) spirometry, (2) ENO measurements, and (3) repeat spirometry measurements after the administration of a bronchodilator. For the third subcomponent, a subset of SPs whose baseline spirometry results show lung function values below a certain threshold, and will be provided with an opportunity to repeat spirometry after inhaling a bronchodilator medication. The MEC physician will first evaluate the participant to determine if the participant meets the requirements for safe bronchodilator administration. The physician will then obtain written informed consent, and then instruct the SP in the administration of the bronchodilator, and then administer the medication. Results from repeat spirometry testing following the bronchodilator could potentially provide a more detailed picture of each individual's

breathing problem, i.e., and indication of whether the person is likely to have asthma or chronic obstructive pulmonary disease.

ENO provides a noninvasive marker measure of airway inflammation, a factor in asthma and possibly other lung diseases. Evaluation of airway inflammation, a precursor of asthma symptoms, is important in the investigation of underlying disease. Currently, there are no U.S. population-based estimates of ENO baseline levels for normal subjects, or for those persons with asthma and chronic obstructive pulmonary disease.

- **Tuberculosis**—To support public health programs in the control, prevention, and eventual elimination of tuberculosis (TB) in the United States, accurate and comprehensive data are needed about the extent of the TB burden. National prevalence was last measured in NHANES 1999–2000. At that time 4.2 percent of the civilian, noninstitutionalized population had latent TB infection (LTBI). Foreign-born participants had a higher LTBI prevalence (18.7%) than US born (1.8%), with 63 percent of TB infections among people who were foreign-born. In addition, only 19.5 percent of foreign-born persons had been previously diagnosed and only 11.6 percent were prescribed treatment.

To determine the current prevalence of TB infection, NHANES participants 6 years of age and older will receive two tests for *M. tuberculosis* infection: a skin test and a blood test. Those who DON'T have the venipuncture will not be eligible for the TB skin test. It is hoped that in future years tuberculosis infection will be able to be monitored with just the blood test.

- **Urine Collection**—All participants ages 6 and older will be asked to provide a urine specimen. It is important that NHANES know how long since the participant last voided so we will be asking that question when they come to the MEC.
  - Urine tests for women of child bearing age will be used to test for pregnancy.
  - Urine tests can also indicate the presence of STDs such as chlamydia infection.
  - Dozens of chemical exposures are measured in the urine samples collected by NHANES.
  - Characteristics of the urine indicate whether participants may have early signs of chronic kidney disease.
  - A second home urine collection will be obtained after the examination specifically to look for early signs of chronic kidney disease.

#### **1.7.4 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 may include an extra fasting incentive if the SP is eligible. SPs who complete the dietary phone interview and the Consumer Behavior Questionnaire also receive an incentive.

#### **1.7.5 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 on the day of the SP's examination and includes results that are immediately available and require no further evaluation or interpretation. Before the examinee's departure from the MEC, the coordinator prints a report that can include height, weight, complete blood count, blood pressure and heart rate, and results from the oral health and audiometry examinations. The MEC physician reviews the blood pressure and complete blood count test results for abnormalities and discusses any problems with the SP (or his or her parent.) 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. This Final Report of Findings will include all the results from the Preliminary Report of Findings and may include laboratory tests like liver and kidney function tests and lipids, bone density scan results, retinal image scan reports, and spirometry results. 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, herpes simplex, and human papillomavirus) 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 that 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.

#### **1.7.6 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 before the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. All procedures in the dry run are completed as though the actual exam session was being conducted. The only difference is that the e

Examinees are 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.

#### **1.8 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 Dual

Energy X-Ray Absorptiometry (DXA) scanner for body composition is directly downloaded to the ISIS system where it is displayed on the computer screen and stored in the system database.

## **1.9 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 from SPs selected for the VOC (volatile organic compounds) special study and two EDTA tubes for genetic testing on consenting SPs aged 20+. They may administer a dextrose solution (Trutol) to and will collect an additional 2-mL gray top tube from SPs selected for the glucose tolerance (GT) component.

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) perform a test for osmolality; (3) allocate urine into vessels for storage and transport to multiple government and contract laboratories for analysis; and (4) calculate a urine flow rate, and (5) allocate urine into a vessel for future studies.

The purpose of blood processing is to (1) perform a complete blood count; (2) allocate blood (whole blood, plasma, and serum) into vessels for transport to multiple government and contract laboratories for analysis; (3) allocate serum into vessels for future studies and process tubes for genetic testing; and (4) process serum for environmental testing.

The purpose of collecting and processing one vaginal swab is to be able to store and transport the samples to a laboratory for HPV (human papilloma virus) analysis.

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) section of the body composition component of the MEC exam.

The purpose of the osmolality test is to measure the concentration of urine which can help both EPA and NCEH determine if data should be ignored because it's too dilute or too concentrated.

The purpose of conducting the special volatile organic compounds (VOCs) study is to collect blood to determine the prevalence of exposures to certain chemicals.

The purpose of collecting and processing an oral rinse for HPV is to be able to store and transport the samples to a laboratory for HPV (human papilloma virus) analysis. This sample is used to determine the prevalence and type of distribution of infection and to investigate the demographic and behavioral factors associated with infection.

## **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 primary tasks include conducting the venipuncture, administering the Trutol solution, administering TB antigen, conducting a second venipuncture 2 hours after the Trutol solution has been consumed, assisting the medical technologists as needed, managing the phlebotomy, GTT and TB component inventories, performing MEC equipment QC activities and recording the results,

printing laboratory labels, labeling blood processing racks, and assisting with the shipping process at the end of each stand. In addition, the phlebotomist acts as a backup examiner and recorder for the body measures exam and oral health recorder for the oral health exam.

The medical technologist's tasks include printing labels and labeling vessels; performing complete blood counts (CBCs); conducting pregnancy tests; performing the osmolality test; processing blood, genetic tubes, urine, vaginal swabs and oral rinse samples; performing MEC equipment QC activities and recording the results; 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 two areas—the phlebotomy room and the laboratory (label/ship and environmental sample processing area, biological sample processing and hematology/pregnancy and osmolality testing) area. The phlebotomy room and laboratory area are located in trailer 4. Figures 2-1 and 2-2 illustrate the laboratory layout and phlebotomy room layout.

The phlebotomist performs the following activities in the phlebotomy room: collects blood, administers the Trutol solution, administers the TB antigen and collects a second blood sample from SPs who consumed the Trutol.

The medical technologist processes, stores, and ships biological and environmental samples, analyzes blood for a complete blood count, and performs pregnancy testing and they print labels, label blood processing racks, and prepare shipping documents.

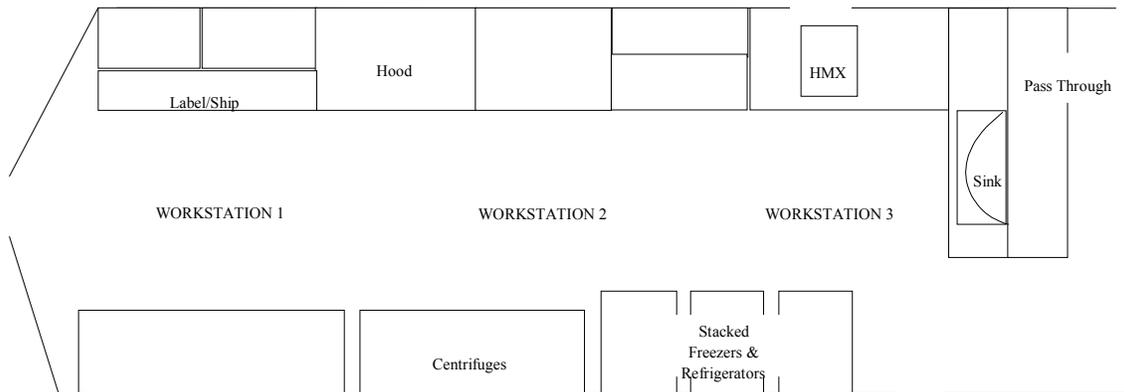


Figure 2-1. Laboratory layout

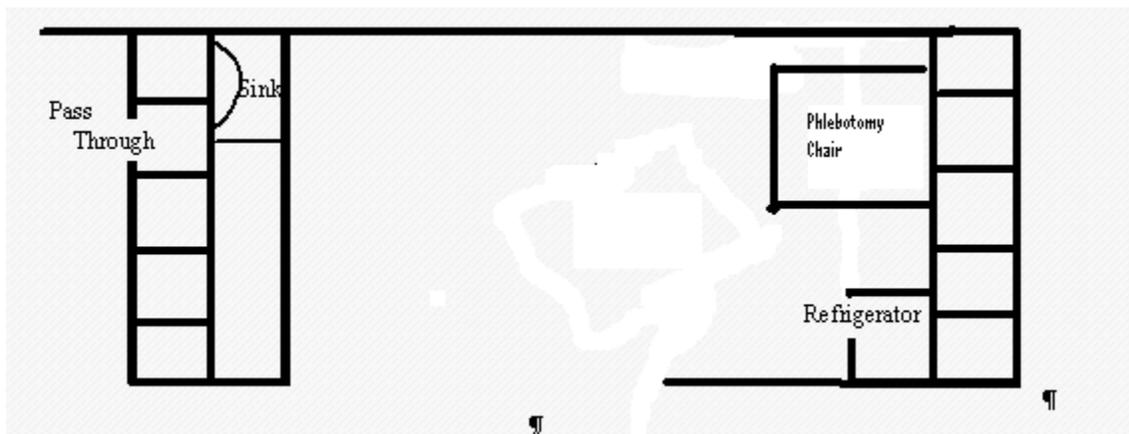


Figure 2-2. Phlebotomy room layout

### Laboratory Area Floor Plan

The laboratory area contains three workstations designated workstation 1, 2, and 3. TB blood tube processing, printing labels, labeling vials for each SP's blood-processing rack, and shipping activities occur at workstation 1. Blood processing and storage occurs at workstation 2. Urine collection, urine processing and storage, pregnancy testing, osmolality testing, running CBCs, vaginal swab specimen processing, oral rinse specimen processing, and routine quality control activities occur at workstation 3.

## **2.5 Tasks – Phlebotomy Room**

- Set up supplies and check expiration dates of all items with lot numbers, such as the Vacutainer® tubes.
- Enter lot numbers and expiration dates into the automated Supply Use Control Log.
- Complete the phlebotomy examination, including conducting the venipuncture interview, administering the fasting questionnaire, and performing the venipuncture.
- Complete the OGTT examination including administering the Trutol solution to eligible SPs and performing a second blood draw on all GTT SPs who consumed the Trutol.
- Administer TB skin tests according to CDC approved protocol and monitoring TB inventory.
- Label and transfer all blood tubes to the laboratory area.
- Disinfect all the counters and blood draw chair at the end of each session.
- Take and 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, including the equipment, at the start and end of each stand.
- Assist in printing laboratory labels and label and assemble blood-processing racks.
- Assist the lab staff when they pack the shippers.
- Serve as the backup examiner and recorder in body measures and recorder in oral health.

## **2.6 Tasks – Workstation 2**

- Stock blood processing and storage supplies.
- Receive blood specimens.

- Select the correct pre-labeled rack and age appropriate template.
- Set the red and royal top blood tubes aside to clot.
- Pipette whole blood into separate 2-mL cryovials from the 3-mL or 4-mL lavender tube for vessels 1 (Lead/Cad/HG) vessels 3 (RBC Folate), vessel 4 (Glycohem) and vessel 5 (Mercury).
- Make the dilution for RBC Folate vessels and serum Folate vessels.
- Transfer the 3-mL or 4-mL lavender tube to the workstation 3 technologists for hematology.
- 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 7-mL lavender tube.
- Pipette the plasma from the 7-mL lavender tube into a 5-mL cryovial for vessel 91 (SRM Pesticide).
- Centrifuge the red top tubes and royal blue top tube.
- Aliquot serum from the 6 mL royal blue top tube into a 2 mL cryovial for vessel 136 (Selenium/Copper/Zinc).
- Pool the serum from the 3-mL, 7-mL, 15-mL and 10-mL red top tubes, plus the remaining serum from the 6 mL royal blue top tube for each SP and mix well.
- Aliquot serum into separate 2-mL cryovials for the serum vessels according to the age-specific protocols.
- Pour serum from each of the 5 to 10-mL red tubes into 5 - 5-mL cryovials for vessels 29, 90, 92, 89 and 93.
- Enter all blood processing results.
- Centrifuge the second 2-mL gray tube.
- Pipette the plasma from the second 2-mL gray tube into a 2-mL cryovial for vessel 98 (OGTT).
- Enter the blood processing results.
- Refrigerate or freeze the processed vessels.

- Check contents of blood storage boxes (containers) using the container 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 3**

- Perform start of stand, start of session, end of session, weekly, and end of stand quality control checks on laboratory equipment and record results.
- Prepare the 1% and 7% ascorbic acid solutions daily.
- Enter the ascorbic preparation into Daily QC.
- Stock supplies for urine processing, hematology, and pregnancy and osmolality testing.
- Verify and accept the urine volume and record the urine collection results.
- Run the pregnancy test controls.
- Run the osmolality test controls.
- Perform startup procedures and run quality control materials on the Coulter® HMX.
- Run specimens on the Coulter® HMX and enter results.
- Refrigerate vessels 119 and 120 (Genetics).
- Refrigerate VOC blood (vessel 54) tube.
- Conduct the pregnancy test and enter results.
- Conduct the osmolality test and enter results.

- Label urine vessels and aliquot into 2 or 5-mL cyrovials, 14-mL Falcon snap cap, or 10-mL VWR screwcap tubes according to the processing protocol.
- Enter the urine processing results.
- Store the urine vessels.
- Process vaginal swab (vessel 78).
- Process oral health rinse (vessel 129).
- Check contents of urine, vaginal swab, vaginal swab, and oral rinse boxes and bags using the container maps module at the end of each session.
- Disinfect all counters at the beginning of the stand and end of each session.
- Maintain the appearance of the urine processing/hematology 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.

## **2.8 Tasks – Workstation 1**

- Complete blood processing tasks for the first 45 minutes of each session.
- Print blood, urine, pregnancy, and oral rinse testing labels.
- Prelabel the vials for each SP's blood-processing rack.
- Assist the phlebotomist with venipuncture.
- Generate container IDs at the start of stand.
- Assign a container ID label to one container for each vessel.
- When shipping, close all open containers, create air bills, and assign containers to shippers.
- Print shipping manifests.
- Prepare blood (whole blood, serum, and plasma), urine, vaginal swab, and oral rinse samples for shipping.

- Pack, label, and ship shippers.
- Open all new containers after shipping.
- Maintain appearance of the label/ship area and the equipment.
- Monitor inventory and restock supplies.
- Assist phlebotomist with venipuncture.
- Complete the Trutol section in the GTT examination as assigned.
- Conduct start and end of stand inventory counts.
- Clean the laboratory at the start and end of each stand.

## 2.9 Cross Training

Cross training the medical technologists and the phlebotomist increases individual's skills and provides scheduling flexibility and a safety net during staff absences. The primary phlebotomist helps the lab team setup and teardown. Medical technologists trained in phlebotomy (backup phlebotomists) work in phlebotomy on a routine basis to ensure competency and proficiency. The basic underlying assumption is that the blood draw must **never** be compromised. The primary phlebotomists must be available to step in and complete the blood draw even when backups are working in phlebotomy.

- When the backup phlebotomist is assigned to workstation 1 (label/ship):
  - The primary phlebotomist works at workstation 1, except on Monday when the lab team ships. The backup phlebotomist always works their scheduled workstation 1 assignment on shipping Mondays.
  - The backup phlebotomist works in phlebotomy when the primary phlebotomist works at workstation 1.
- The primary phlebotomist **always** performs the pediatric blood draws while the backup phlebotomist observes and holds the child.
- If the backup phlebotomist encounters a difficult blood, then the primary phlebotomist comes into the room and they work together so that the blood draw is successful. This is intended as a learning experience; the backup phlebotomist can continue to learn from the primary phlebotomist.

- There are no rules for how many days the backup phlebotomist works in phlebotomy during each stand. The objective is at least 2-3 days per stand with emphasis on sessions with 8-10 adult SPs.
- On setup day the phlebotomist completes his or her room setup and assigned tasks before helping lab. On setup day the phlebotomist should, at a minimum, make the racks for dry run day. On teardown day he or she helps pack the shippers and assists the lab staff in other ways as directed by the chief medical technologist.

### **3. LABORATORY ISIS FUNCTIONALITY**

#### **3.1 Laboratory-Specific Functionality**

While MEC applications are custom built for each specific component, they share a common design. This commonality provides all component applications the same “look and feel” which minimizes reorienting technologists who rotate from component to component. A complete ISIS overview and these features and characteristics are described in the *ISIS User Guide*. The laboratory application has additional functionality that has been developed to accommodate and facilitate processing specimens and reporting results. This chapter describes the laboratory-specific functionality.

#### **3.2 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.

Use the heads-up display to access modules.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status									
							UC	U	P	OZ	CB	B	GTT	PC	HPV	OR
136701	136701	SC	P	M	49	OBENDORFER, ED	○	○	·	○	○	○	○	·	·	○
224123	224123	SC	P	M	14	HESELS, JOEL	○	○	·	○	○	○	○	·	·	○
333280	333280	SC	P	M	49	HESELS, MARK	○	○	·	○	○	○	○	·	·	○
343133	343133	SC	P	F	17	OBENDORFER, KELLEY	○	○	○	○	○	○	○	○	○	○
489335	489335	EX	P	M	13	OBENDORFER, CORY	⊙	○	·	○	○	○	○	·	·	○
588451	588451	SC	P	F	16	OBENDORFER, ANNMARIE	○	○	○	○	○	○	○	·	·	○
635859	635859	SC	P	M	19	HESELS, BENJAMIN	○	○	·	○	○	○	○	·	·	○
737421	737421	BE	P	F	21	OBENDORFER, JAMIE	⊙	○	○	○	○	○	○	·	·	○
743644	743644	BE	P	F	46	OBENDORFER, KIM	⊙	○	○	○	○	○	○	·	·	⊙
840098	840098	SC	P	F	48	HESELS, JULIE	○	○	○	○	○	○	○	·	·	○
876427	876427	SC	P	M	19	OBENDORFER, EDDIE	○	○	·	○	○	○	○	·	·	○
932761	932761	SC	P	M	15	HESELS, JONAH	○	○	·	○	○	○	○	·	·	○

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), Appointment Type (P=primary, G=guest, VIP=VIP guest, D=dry run), Gender (M=male, F=female), Age, and Name (last, first.)

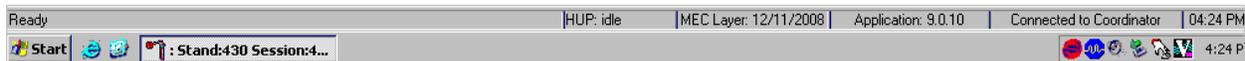
The heads-up display provides the Process Status for the following modules: UC (urine collection), U (urine processing), P (pregnancy testing), OZ (Osmolality), CB (complete blood count), B (blood processing), gtt (glucose tolerance test or vessel 98 processing), PC (washed packed cell processing), HPV (HPV swab processing), and OR (oral rinse processing). 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 ◯. 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 (O) but the process status for blood processing (B), the complete blood count (CB), and packed cell processing (PC), will not enable until at least one blood tube has been recorded as collected in the phlebotomy component. Only SPs who have checked in are eligible for HPV processing. The process status is O for urine processing (U), pregnancy testing (P), and osmolality testing (OZ), 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 O. The gtt and OR modules will enable as soon as one SP has the OGTT blood tube drawn in phlebotomy and one SP has the oral rinse collected in the oral health examination. 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 the active SP is not the SP of choice.

### 3.3 Laboratory Task Bar

Monitor the activity in the laboratory task bar which is located on the bottom of the screen.



The laboratory task bar displays the following information:

- The status of the refresh routine such as when the labels are printing or the data are updating;
- The status of the heads-up display (HUP) 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.

### 3.4 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.

#### 3.4.1 File Menu Options

The screenshot shows a window titled "Lab Subsystem: Stand:614 Session:614630 05/12/2010 08:30 am - 12:30 pm". The menu bar includes: File, View, Utilities, Quality Control, Reports, Modules, Shipping, Window, Help. The File menu is open, showing options: Open (Ctrl+O), Close, Print..., Delete, and Exit. The main area contains a table with columns: ID, Status, Type, Gender, Age, Name, and Process Status (UC, U, P, OZ, CB, B, GTT, PC, HPV, OR). The table lists several individuals with their respective IDs and statuses.

ID	Status	Type	Gender	Age	Name	UC	U	P	OZ	CB	B	GTT	PC	HPV	OR
01	SC	P	M	49	OBENDORFER, ED	○	○	-	○	○	○	-	-	-	○
03	SC	P	M	14	HESELS, JOEL	○	○	-	○	○	○	-	-	-	○
333280	333280	SC	P	M	49	HESELS, MARK	○	○	-	○	○	○	-	-	○
343133	343133	SC	P	F	17	OBENDORFER, KELLEY	○	○	○	○	○	○	○	○	○
489335	489335	EX	P	M	13	OBENDORFER, CORY	●	○	-	○	○	○	○	-	-
588451	588451	SC	P	F	16	OBENDORFER, ANNMARIE	○	○	○	○	○	○	-	○	○
635859	635859	SC	P	M	19	HESELS, BENJAMIN	○	○	-	○	○	○	-	-	○
737421	737421	BE	P	F	21	OBENDORFER, JAMIE	●	○	○	○	○	○	-	○	○
743644	743644	BE	P	F	46	OBENDORFER, KIM	●	○	○	○	○	○	-	○	●
840098	840098	SC	P	F	48	HESELS, JULIE	○	○	○	○	○	○	○	○	○
876427	876427	SC	P	M	19	OBENDORFER, EDDIE	○	○	-	○	○	○	-	-	○
932761	932761	SC	P	M	15	HESELS, JONAH	○	○	-	○	○	○	○	-	○

System tray information: Ready | HUP: idle | MEC Layer: 6/14/2010 | Application: 10.0.0 | Connected to Coordinator | 09:07 AM

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 the coordinator if the application is not in standalone mode.
* <u>C</u> lose	This option is grayed out and not applicable.
* <u>P</u> rint	Prints the current examination screen or report.
* <u>D</u> elete	This option is grayed out and not applicable.
* <u>E</u> xit	Exits the application.

### 3.4.2 Utilities Menu Options

The screenshot displays the 'Lab Subsystem' application window. The title bar reads 'Lab Subsystem: Stand:614 Session:614630 05/12/2010 08:30 am - 12:30 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Quality Control', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. The 'Utilities' menu is open, showing options: 'Exam Pause', 'Observations', 'IC Exclusions', 'Send Message' (with keyboard shortcut 'Ctrl+M'), 'UFO Sighting', and 'Set Session'. The main window contains a table with the following columns: 'SP ID', 'Gender', 'Age', 'Name', and 'Process Status'. The 'Process Status' column is further divided into sub-columns: 'UC', 'U', 'P', 'OZ', 'CB', 'B', 'GTT', 'PC', 'HPV', and 'OR'. The table lists 13 examination records with various statuses, some indicated by filled or empty circles.

SP ID	Gender	Age	Name	Process Status									
				UC	U	P	OZ	CB	B	GTT	PC	HPV	OR
136701	M	49	OBENDORFER, ED	○	○	-	○	○	○	○	-	-	○
224123	M	14	HESELS, JOEL	○	○	-	○	○	○	○	-	-	○
333280	M	49	HESELS, MARK	○	○	-	○	○	○	○	-	-	○
343133	F	17	OBENDORFER, KELLEY	○	○	○	○	○	○	○	○	○	○
489335	M	13	OBENDORFER, CORY	●	○	-	○	○	○	○	○	-	-
588451	F	16	OBENDORFER, ANNMARIE	○	○	○	○	○	○	○	-	-	○
635859	M	19	HESELS, BENJAMIN	○	○	-	○	○	○	○	-	-	○
737421	F	21	OBENDORFER, JAMIE	●	○	○	○	○	○	○	-	-	○
743644	F	46	OBENDORFER, KIM	●	○	○	○	○	○	○	-	-	○
840098	F	48	HESELS, JULIE	○	○	○	○	○	○	○	○	○	○
876427	M	19	OBENDORFER, EDDIE	○	○	-	○	○	○	○	-	-	○
932761	M	15	HESELS, JONAH	○	○	-	○	○	○	○	-	-	○

The status bar at the bottom shows 'Utilities', 'HUP: idle', 'MEC Layer: 6/14/2010', 'Application: 10.0.0', 'Connected to Coordinator', and '09:08 AM'. The taskbar includes 'Start', 'SQL Server Versions', and 'Lab Subsystem: Stan...'.

<b>*Utilities</b>	
*Exam <u>P</u> ause	This option is grayed out and not applicable.
* <u>O</u> bservation	Submits an observation to the physician for possible referral.
IC <u>E</u> xclusions	This option is grayed out in the Laboratory application and is not applicable. Posts an exclusion record for those SPs who do not want HIV, STD, PSA, or HPV tests performed, genetic tubes processed, or samples stored for future research; this utility is available only for coordinator, physician, and phlebotomy. A complete description of this functionality is described in Section 3.5.
*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 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. A complete description of this functionality is described in Section 3.6.
<u>E</u> nglish <i>Ctrl+E</i>	This option is grayed out in the Laboratory application and is not applicable. Toggle option to set exam language to English.
<u>S</u> panish <i>Ctrl+S</i>	This option is grayed out in the Laboratory application and is not applicable. Toggle option to set exam language to Spanish.
* <u>T</u> oolbars	Configures placement of toolbars.

### 3.4.3 Quality Control Menu

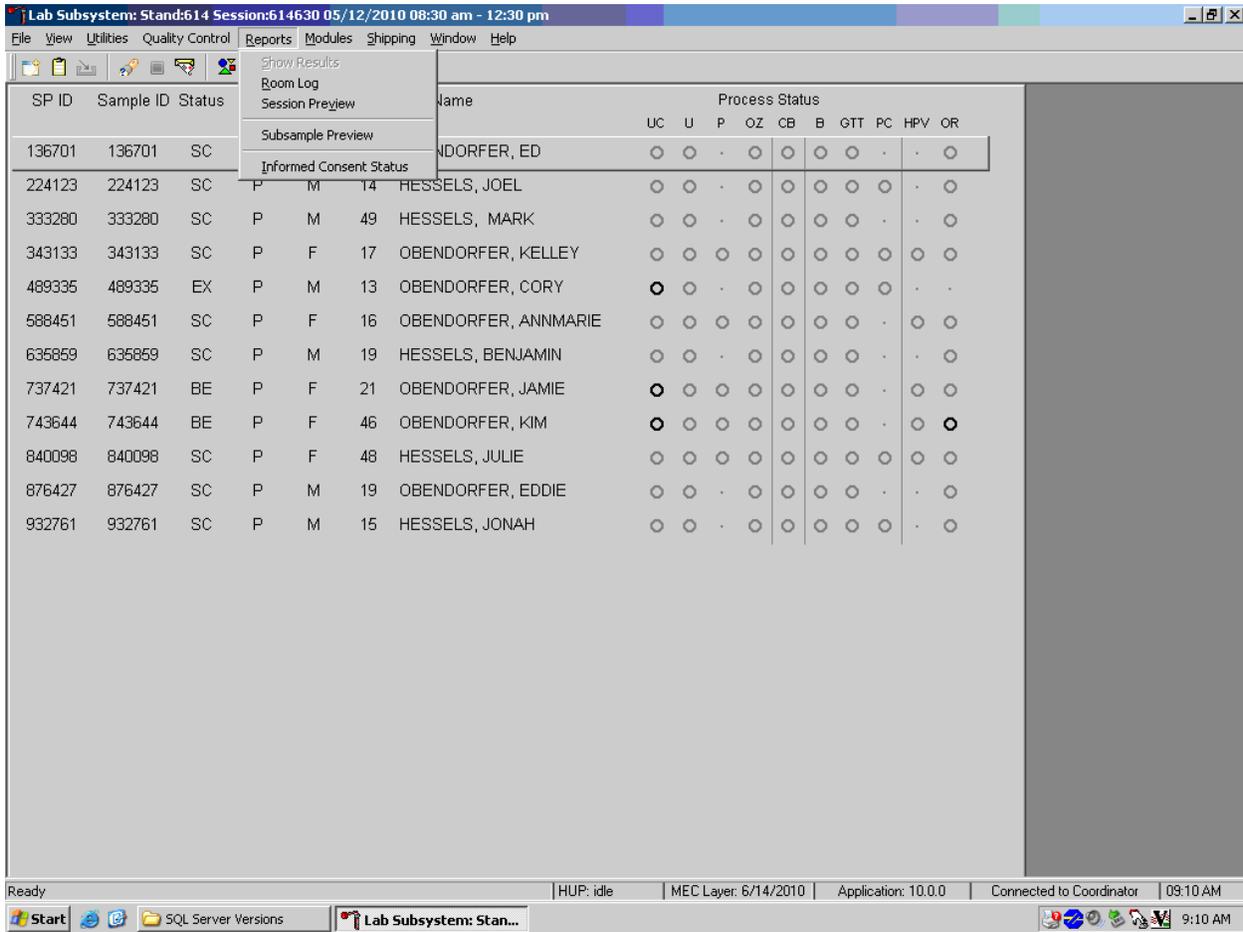
The screenshot shows the 'Lab Subsystem' application window. The title bar reads 'Lab Subsystem: Stand:614 Session:614630 05/12/2010 08:30 am - 12:30 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Quality Control', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. The 'Quality Control' menu is open, showing options: 'Quality Control (Ctrl+Q)', 'Pregnancy QC', 'Coulter QC Lot Info', and 'Osmolality QC'. The main window displays a table with columns for 'SP ID', 'Samp', 'Age', 'Name', and 'Process Status'. The 'Process Status' column contains a grid of radio buttons for various tests: UC, U, P, OZ, CB, B, GTT, PC, HPV, and OR. The status bar at the bottom shows 'Ready', 'HUP: idle', 'MEC Layer: 6/14/2010', 'Application: 10.0.0', 'Connected to Coordinator', and '09:05 AM'.

SP ID	Samp			Age	Name	Process Status												
						UC	U	P	OZ	CB	B	GTT	PC	HPV	OR			
136701	136701	SC	P	M	49	OBENDORFER, ED	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
224123	224123	SC	P	M	14	HESELS, JOEL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
333280	333280	SC	P	M	49	HESELS, MARK	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
343133	343133	SC	P	F	17	OBENDORFER, KELLEY	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
489335	489335	EX	P	M	13	OBENDORFER, CORY	<input checked="" type="radio"/>	<input type="radio"/>										
588451	588451	SC	P	F	16	OBENDORFER, ANNMARIE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
635859	635859	SC	P	M	19	HESELS, BENJAMIN	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
737421	737421	BE	P	F	21	OBENDORFER, JAMIE	<input checked="" type="radio"/>	<input type="radio"/>										
743644	743644	BE	P	F	46	OBENDORFER, KIM	<input checked="" type="radio"/>	<input checked="" type="radio"/>										
840098	840098	SC	P	F	48	HESELS, JULIE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
876427	876427	SC	P	M	19	OBENDORFER, EDDIE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
932761	932761	SC	P	M	15	HESELS, JONAH	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### \*Quality Control

Quality Control	Opens Quality Control for Start of Stand, End of Stand, Daily, Weekly, and NCHS QC
Pregnancy QC	Opens pregnancy quality control window
Coulter QC Lot Info	Opens Coulter quality control window for new lot information
Osmolality QC	Opens Osmolality quality control to input lot information at the start of each stand.

### 3.4.4 Report Menu Options



#### \*Reports

##### Show Results

This option is grayed out and not applicable.

##### \*Room Log

Lists the SPs who have completed the component, including appt/exam and component status.

##### \*Session Preview\*

Lists all SPs in current session.

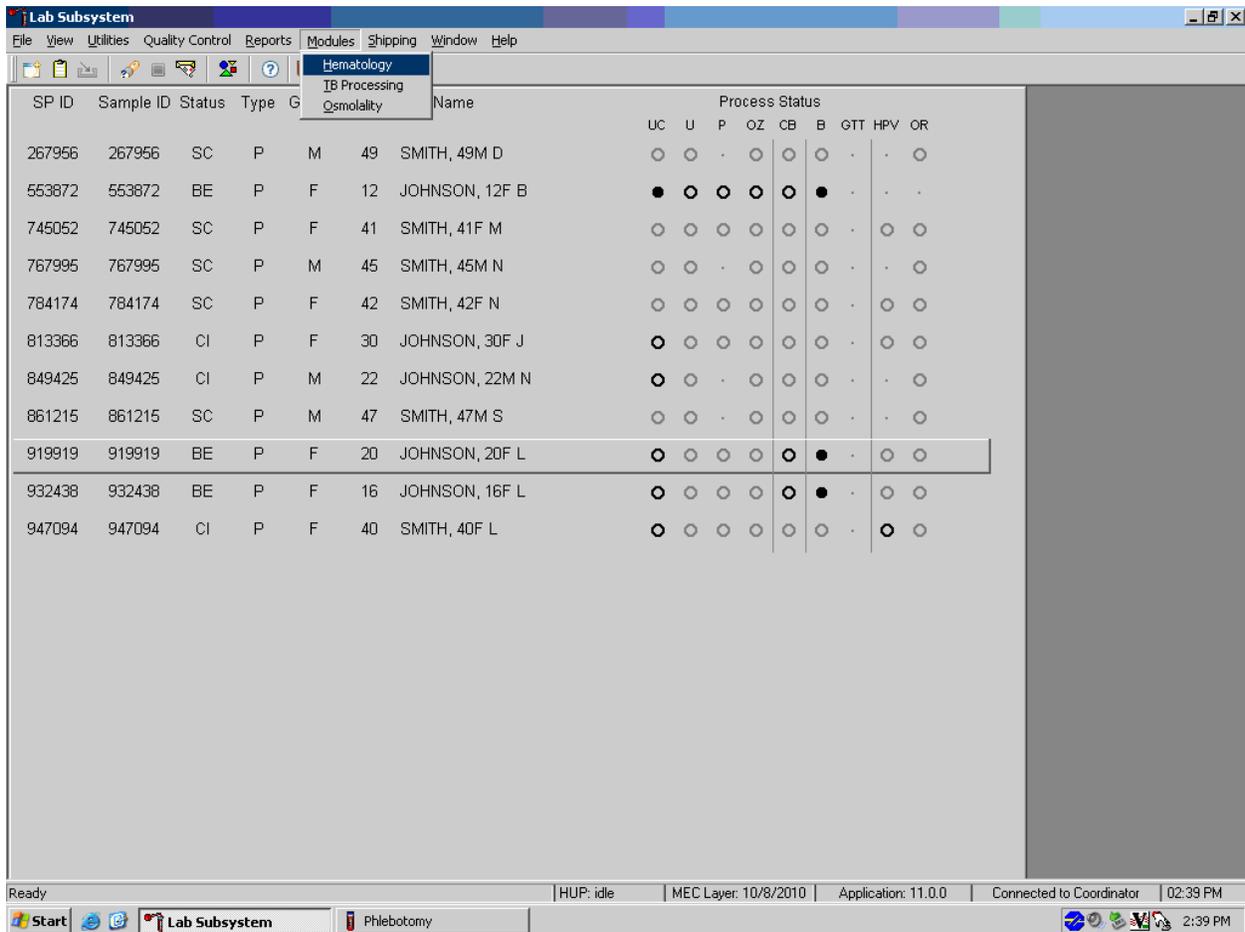
##### Subsample Preview

List the SPs who are eligible for the various subsamples. A complete description of this functionality is described in Section 3.8.

##### Informed Consent Status

Lists the various modules that require consent and displays the result of the consent – excluded or not excluded. A complete description of this functionality is described in Section 3.9.

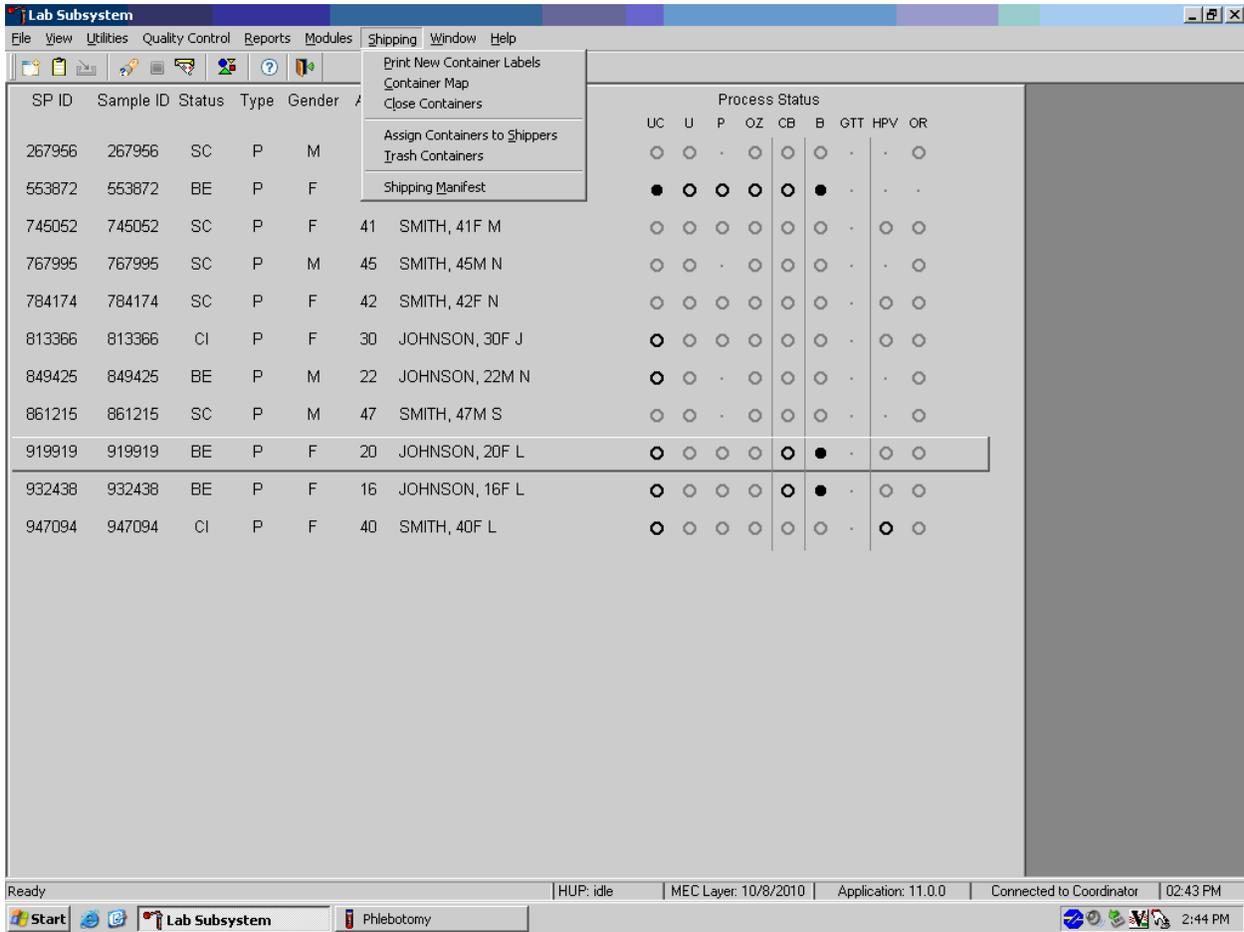
### 3.4.5 Modules



#### Modules

Hematology	Opens the laboratory hematology module. A complete description of this functionality is described in Section 7.XI.
TB Processing	Opens the TB Processing module.
Osmolality	Open the osmolality module. A complete description of this functionality is described in Chapter 12.

### 3.4.6 Shipping



#### Shipping

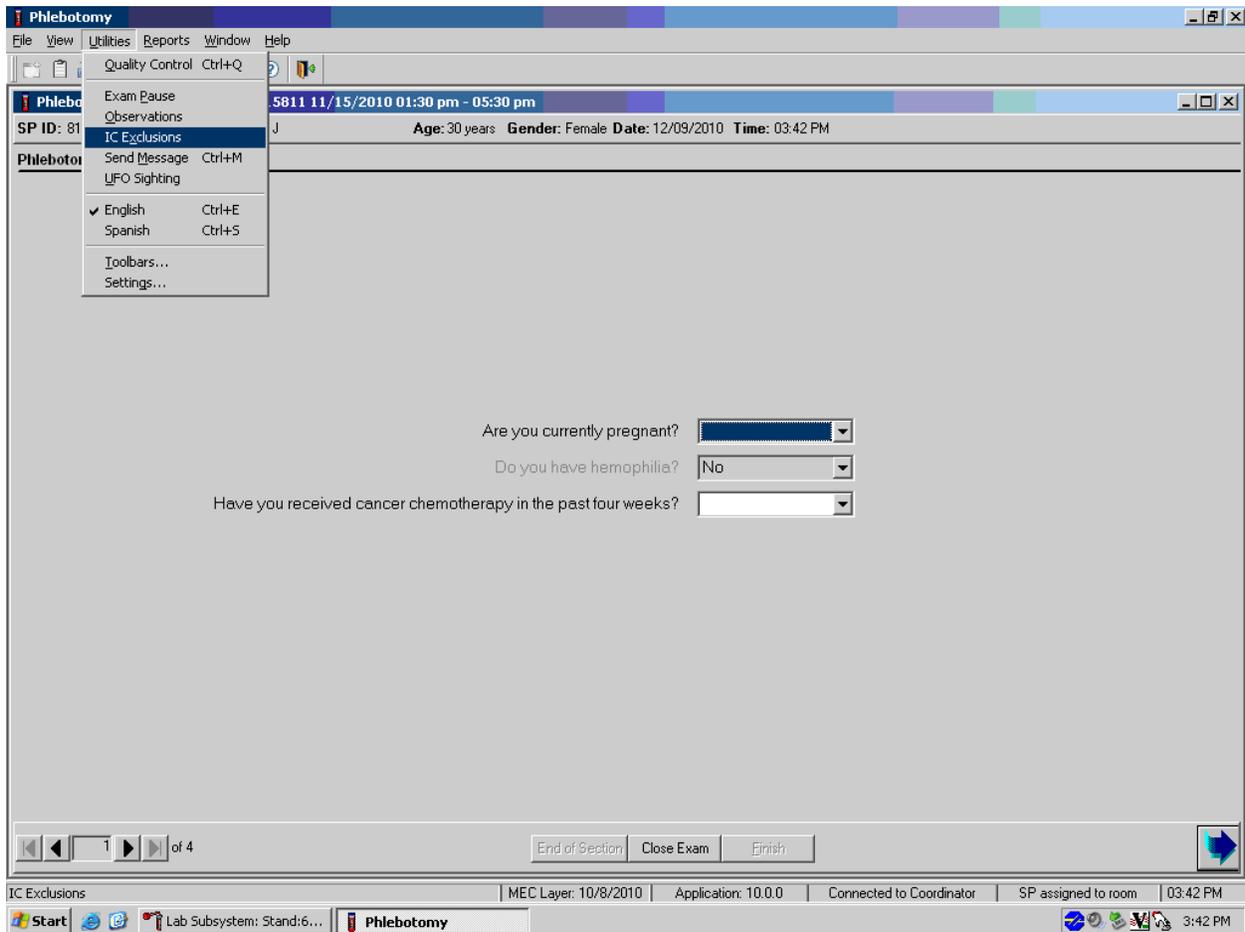
Print <u>N</u> ew Container Labels	Allows the medical technologist to print labels for containers such as a 5-inch box with 9 x 9 grid. A complete description of this functionality is described in Section 9.5.
<u>C</u> ontainer Map	Allows the medical technologist to view a list of all containers with a graphic representation of the samples assigned to that container. A complete description of this functionality is described in Section 3.7.
<u>C</u> lose Containers	Allows the medical technologist to “close” active containers that have been previously opened. A complete description of this functionality is described in Section 9.9.
Assign Containers to <u>S</u> hippers	Allows the medical technologist to assign or associate a closed container with a FedEx airbill number. A complete description of this functionality is described in Section 9.10.

<u>Trash Containers</u>	Allows the medical technologist to delete container label numbers in the database for labels that are damaged. A complete description of this functionality is described in Section 9.6.
Shipping Manifest	Allows the medical technologist to print hard copy manifests and electronically send email files to the contract laboratories. A complete description of this functionality is described in Section 9.11.

### **3.5 Informed Consent Exclusions**

If at any time during the phlebotomy or physician exam, the SP indicates that he or she does not want his or her biological specimens tested for HIV (AIDS), STD (sexually transmitted diseases include chlamydia), PSA, HPV, genetics, or future studies, then the staff 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.

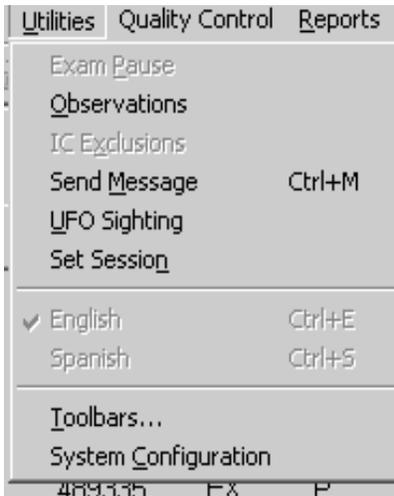
IC Item	Exclude SP from Test	
HIV	<input type="radio"/> Yes	<input checked="" type="radio"/> No
STD	<input type="radio"/> Yes	<input checked="" type="radio"/> No
Genetic Testing	<input type="radio"/> Yes	<input checked="" type="radio"/> No
Future Studies	<input type="radio"/> Yes	<input checked="" type="radio"/> No

OK Cancel

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.

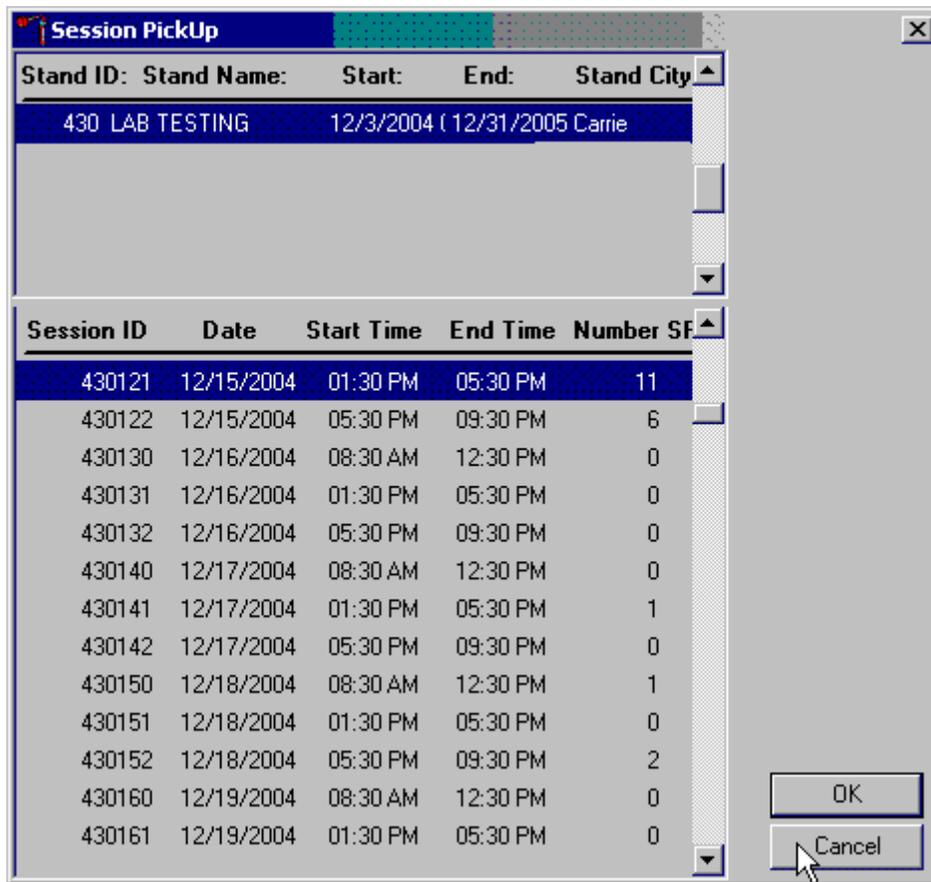
### 3.6 Set Session Utility

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. Use the Set Session utility to access past or future sessions.



To access the Set Session utility, use the mouse to direct the mouse arrow to Utilities and left click. Drag the arrow to Set Session and left click.

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. Use the lower vertical scroll bar to view all sessions. Use the mouse to select the desired session. To proceed, hit the OK button or press [Enter]. To cancel and return to the previous session, click on the Cancel button.

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

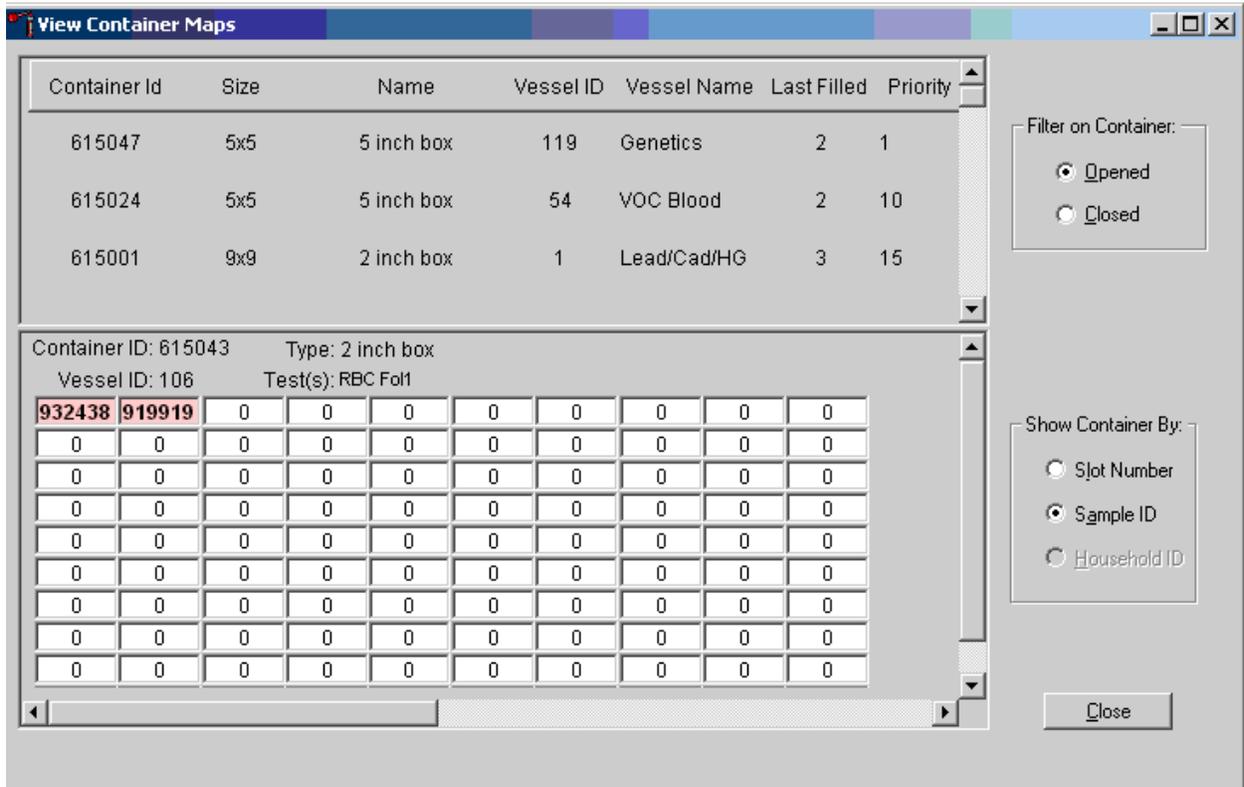
The screenshot shows the 'Lab Subsystem' application window. The 'Shipping' menu is open, showing options like 'Print New Container Labels', 'Container Map', 'Close Containers', 'Assign Containers to Shippers', 'Trash Containers', and 'Shipping Manifest'. The main window displays a table with columns for 'SP ID', 'Sample ID', 'Status', 'Type', 'Gender', and 'Name'. To the right of the table is a 'Process Status' grid with columns for 'UC', 'U', 'P', 'OZ', 'CB', 'B', 'GTT', 'HPV', and 'OR'. Each cell in the grid contains a radio button, with some cells containing a solid black dot indicating a selected state.

SP ID	Sample ID	Status	Type	Gender	Name	UC	U	P	OZ	CB	B	GTT	HPV	OR
267956	267956	SC	P	M		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
553872	553872	BE	P	F		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
745052	745052	SC	P	F	41 SMITH, 41F M	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
767995	767995	SC	P	M	45 SMITH, 45M N	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
784174	784174	SC	P	F	42 SMITH, 42F N	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
813366	813366	CI	P	F	30 JOHNSON, 30F J	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
849425	849425	BE	P	M	22 JOHNSON, 22M N	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
861215	861215	SC	P	M	47 SMITH, 47M S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
919919	919919	BE	P	F	20 JOHNSON, 20F L	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
932438	932438	BE	P	F	16 JOHNSON, 16F L	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
947094	947094	CI	P	F	40 SMITH, 40F L	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Ready | HUP: idle | MEC Layer: 10/8/2010 | Application: 11.0.0 | Connected to Coordinator | 02:45 PM

### 3.7 Container Map

Check the slot assignment of all containers at the end of each session. Access the Container Map report under the Reports or Shipping menu, or type [Alt] [R/r] [C/c] or [Alt] [S/s], [C/c].



Verify the contents of each container against the container map.

- If “Opened” under “Filter on Container” is selected, then all open containers will display.
- If “Sample ID” under “Show Container By:” is selected, then sample IDs will display in the assigned slot in the graphical representation of the container.
- Container IDs may be selected by mouse or by using the up and down keys.
- 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.

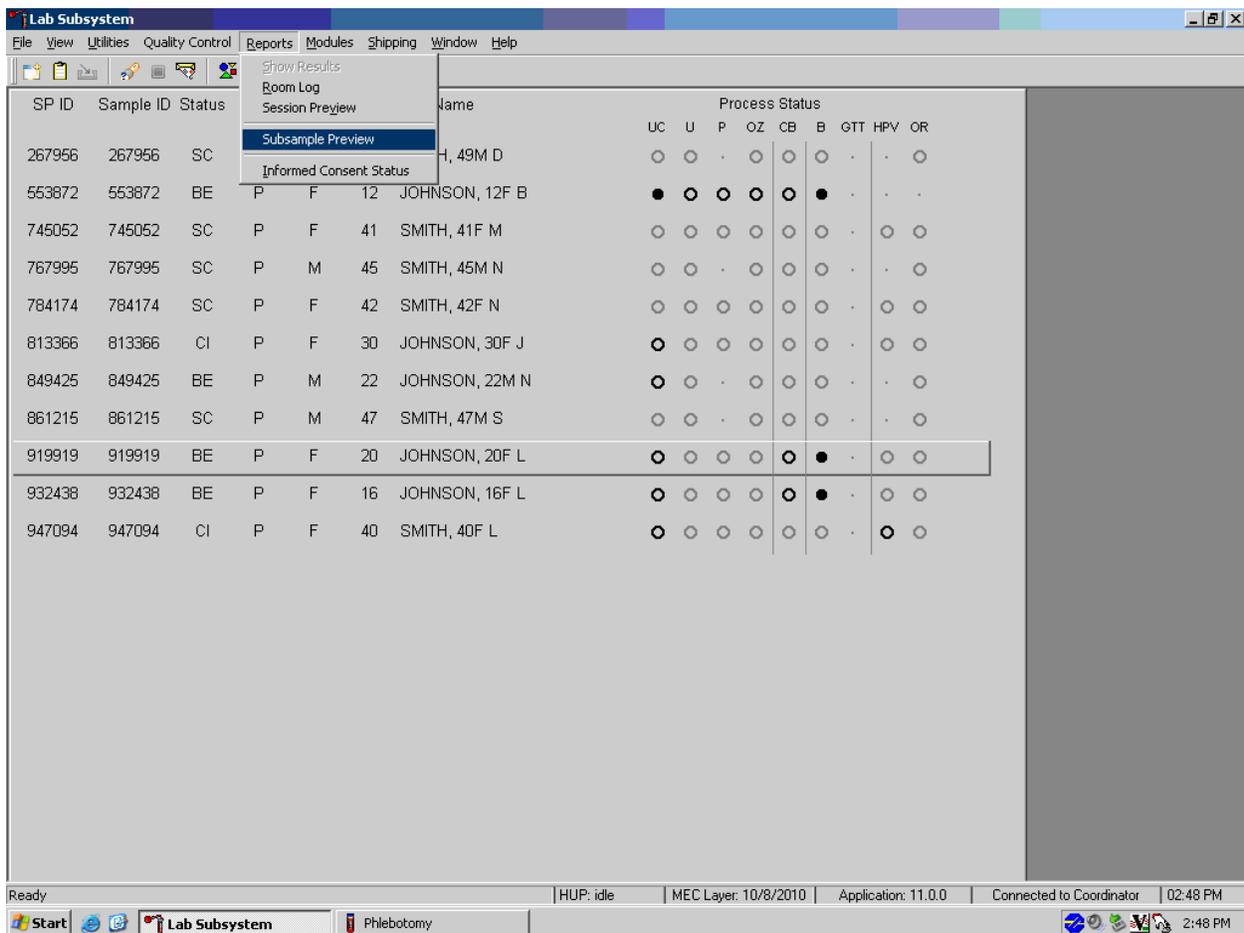
- Mark the specimens that have been checked by placing a black dot in the center of the vial cap. When subsequently checking the Container Map report for this container, begin checking the specimens that are not marked.

Continue checking each Container Map report for the remaining vessels.

To exit the Container Map report, click on the Close button.

### 3.8 Subsample Preview

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



Access the Subsample Preview report under Reports in the menu bar.

Review the Subsample Preview report.

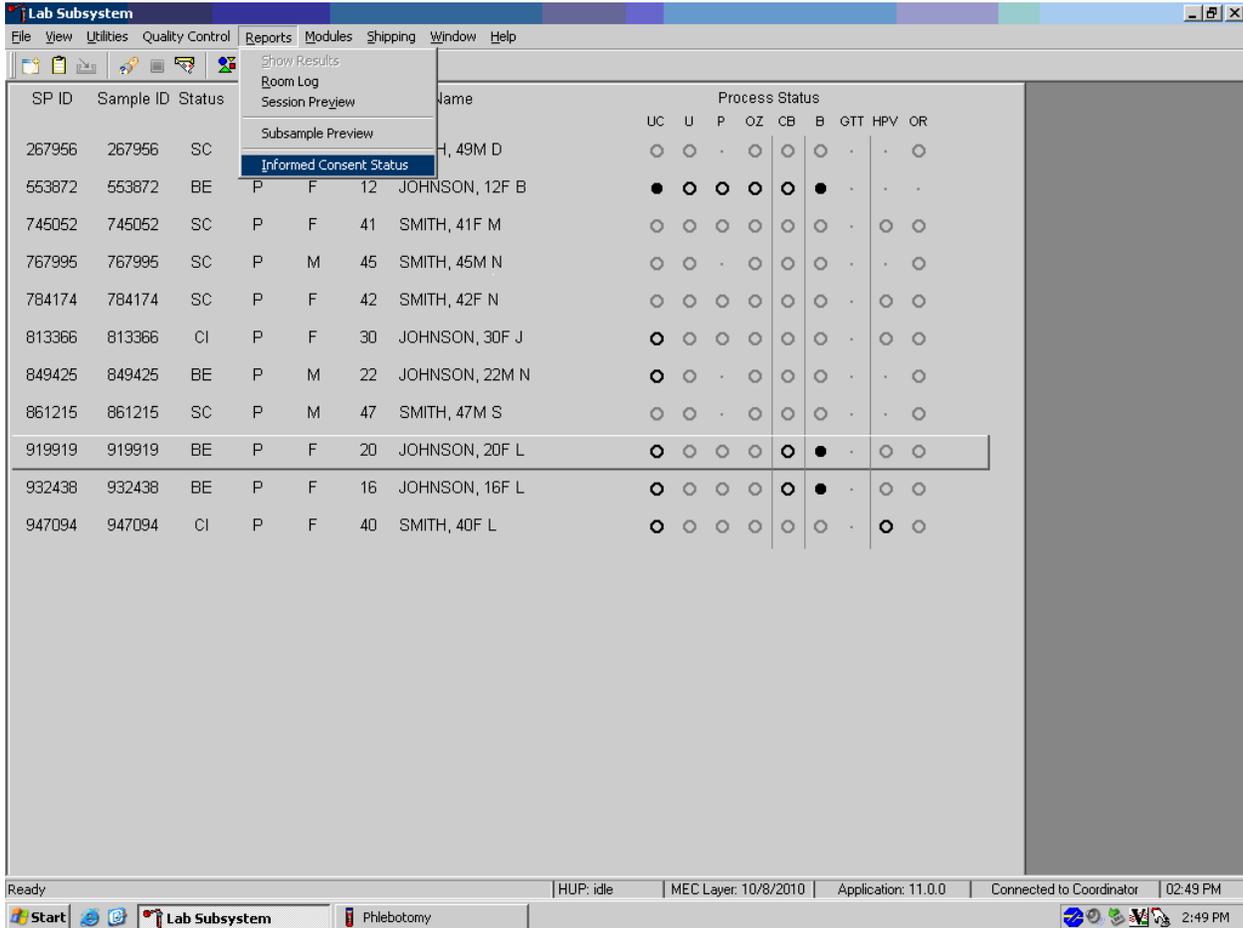
Appt.ID	SP ID	Person Name	Gender	Age	Type	Subsample Description
4109982	229013	FONTANA2, FREDDIE	F	41	1	Volatile Organic Compounds (VC)
					1	Persistent Pesticide and Dioxins
					1	Heavy Metals
					1	Urine Phytoestrogens
					1	Speciated Arsenic
					1	Persistent Pesticides 2
					1	Urine Mercury/Iodine
					1	OMRON / Mercury
					1	Household Water
					1	RBC Folate 1/3
					1	Vitamin B6/Folate 1/3
					1	PAH HB adducts

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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, appointment 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 scroll bar. 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, click on the Close button.

### 3.9 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.



Access the Informed Consent Status report under the Reports menu in the menu bar.

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

Appt Id	Sp Id	Hiv	Std	Genetic Research	Future Research	HPV	PSA
4302791	123442	N	N	Y	Y	N	-
4302792	251401	N	N	Y	Y	-	-
4302793	244445	N	N	Y	Y	N	-
4302796	238763	-	-	Y	Y	-	-
4302798	240491	N	N	Y	Y	N	-
4302799	171098	-	-	Y	Y	-	-
4302821	161002	N	N	Y	Y	-	-
4302827	152141	N	N	-	Y	N	-
4302840	164673	N	N	Y	Y	-	-
4302890	248212	N	N	Y	Y	-	-
4302891	224633	N	N	N	N	-	N
4302927	167942	N	N	Y	Y	N	-

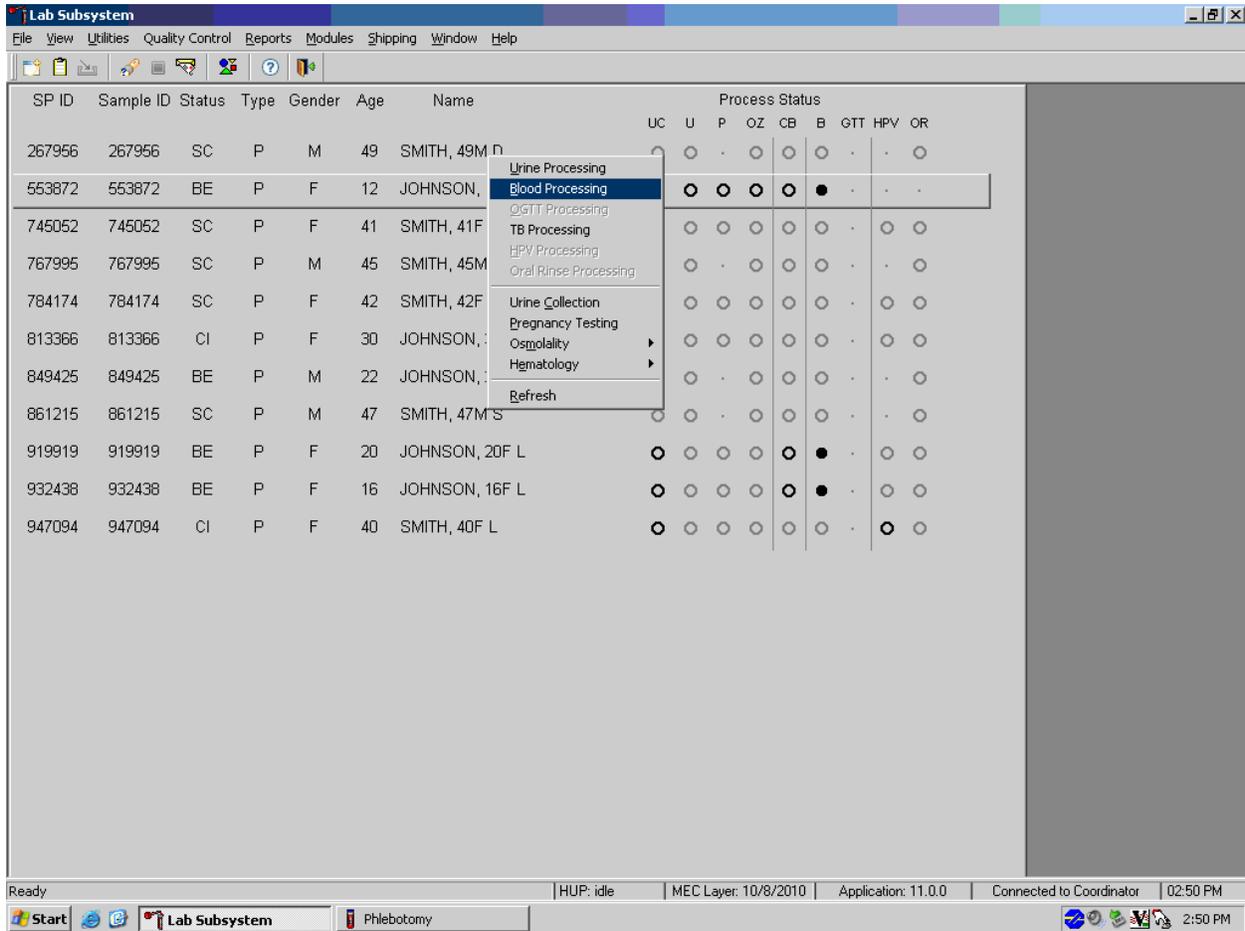
The consent report lists all SPs scheduled in the current session, their appointment and SP IDs, and the exclusion status for the following tests or groups of tests:

- HIV (vessels 22 – serum);
- STD (vessels 24 – HSV);
- Genetic testing (vessels 119 and 120);
- Future research (32-39 – serum, 52 and 139 – urine);
- HPV Swab (vessel 78 – HPV swab)

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

### 3.10 Access a Processing Module

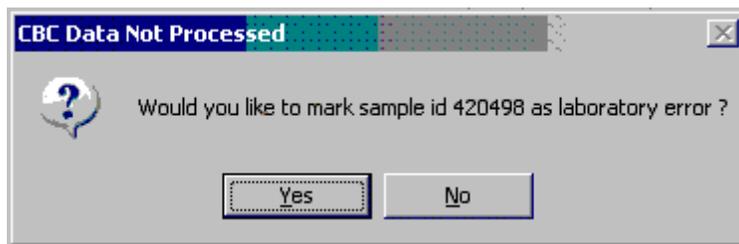
Select the correct SP and access the module of interest. Use the scroll bar to view all SPs scheduled into the session. The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.



To select an SP, use the up and down keys to move up and down the list until the correct SP is highlighted or click on the SP. To access a specific processing module, click on the module on the heads-up screen: UP{Urine Processing}, BP{Blood Processing}, gtt{OGTT Processing}, (PC) Packed Cell Processing, HPV{HPV Processing}, OR {Oral Rinse Processing}, UC{Urine Collection}, P{Pregnancy Testing}, OZ {Osmolality}, or CB{Hematology} and left click. Alternatively, right click on an SP and select the correct module.

### 3.11 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, click on the OK button.

### 3.11.1 Not Filled Require a Comment

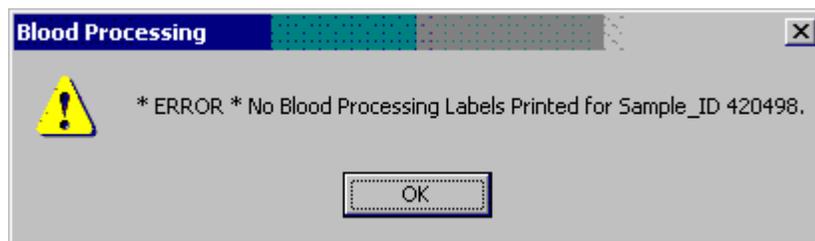
Data cannot be saved until all vessels marked as Filled–”No” are assigned a comment.



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, click on the OK button.

### 3.11.2 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 warning message box, click on the OK button. Reprint the labels for all SPs or an individual SP in a session. See Chapter 9 for detailed instructions on the Lab Print Application.

### 3.12 Coulter, Urine Scale, and Osmolality Icons

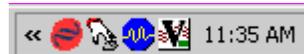
#### Coulter

The Hematology module does not need to be open before running SP samples on the HMX.

This is the NHANES Coulter Monitor. It must be open and running at the start of each session. This icon stores all HMX runs in the ISIS database. Open the icon by double-clicking on the Coulter icon on the desktop. The Coulter icon looks like this:



Note the red icon in the lower left hand corner of the system tray.



#### Urine Scale

Ensure that computer workstation 1 (Urine/Sink) is turned on and a technician is logged into the Laboratory application. Open the Urine Scale application by double clicking on the Urine Scale icon on the desktop. The Urine Scale icon looks like this:



The Urine Scale application icon will appear in the system tray, similar to the Coulter application. This application captures data from the scale and logs it into the database. The Urine Scale

application must be opened and in the system tray in order to capture any urine collection readings from the scale.

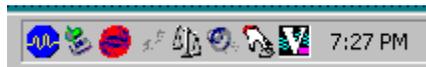


### Osmolality

It is **critical** that the Osmo application must be running on the ISIS computer before running any SP samples. This application captures results from the Osmette II. Any samples run without the Osmo application running will be lost and will need to be rerun. To open the Osmo application, double click on the icon of a pipette on the desktop:



The application icon will display in the system tray when the application is running. It is very faint, but will turn green when data is transmitted from the Osmette to the ISIS computer.



Double check to make sure this icon is visible before running SP samples.

## 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 two additional tubes for genetic testing, one additional blood tube from SPs selected for the VOC (volatile organic compounds) special study, and administers a dextrose solution (Trutol) to and collects an additional 2-mL gray top tube from SPs selected for the Glucose Tolerance (GT) component. The phlebotomist also administers the TB antigen.

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 4-4 illustrate the various venipuncture protocols. 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 or to his or her next component. The phlebotomist may offer juice and crackers to SPs less than 12 years of age and SPs not selected for the GT component.

Exhibit 4-1. Venipuncture protocol – primary

	Age in Years				
	1-2	3-5	6-11	12-19	20+
3-mL Lavender	1	1	1		
4-mL Lavender				1	1
3-1 mL TB IN-Tubes			1	1	1
2-mL Gray (Morning sessions only)				1	1
6 mL Royal Blue			1	1	1
3-mL Red	2	1			
7-mL Red		1	1	1	
15-mL Red				2	3
10-mL Red			1		
10-mL Red <sup>o</sup>				5	5
7-mL EDTA <sup>1</sup>				1	1
10-mL EDTA (20+) <sup>2</sup>					2
10-mL Gray (12+) <sup>3</sup>				1	1
2-mL Gray <sup>4</sup> (GTT morning sessions)				1	1

<sup>o</sup> SPs selected for inclusion in the Persistent Pesticides, Perfluorinated *or* BFR subsamples

<sup>1</sup> SPs selected for inclusion in the Srm Pesticide subsamples

<sup>2</sup> Genetics tubes; must meet IC Exclusion criteria

<sup>3</sup> SPs selected for inclusion in the VOC subsample

<sup>4</sup> Glucose tolerance test

Exhibit 4-2. Venipuncture protocol – VIP guest

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

Exhibit 4-3. Venipuncture protocol – guest

	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 boldface 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+
6 mL Royal Blue		<b>1</b> ( <i>1</i> )	<b>1</b> ( <i>1</i> )
3-mL Red	<b>3</b>	<b>2</b> ( <i>1</i> )	
7-mL Red	<i>(1)</i>	<b>2</b>	<b>4</b>
15-mL Red			<i>(2)</i>
10-mL Red		<i>(1)</i>	<b>5</b> ( <i>5</i> )

**NOTE:** Alternative venipuncture protocol tubes are shown in boldface; regular protocol tubes are shown in parentheses.

## 4.2 Equipment and Supplies

The phlebotomy room contains a phlebotomy chair, drop-down bench, sink, data terminal, Dymo direct thermal label printer, refrigerator, phlebotomy 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 15, Section 15.3.

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® 4-mL EDTA	Trutol
BD Hemogard Vacutainer® 2-mL Gray	Alcohol wipe
BD Hemogard Vacutainer® 3-mL Red	2 x 2 gauze square
BD Hemogard Vacutainer® 7-mL Red	Co-Flex NL cohesive bandage
Kendall Sherwood 15-mL Red	Adhesive bandage - Coverlet
BD Vacutainer® 10-mL Red	Adhesive bandage – children
BD Vacutainer® 10-mL Gray (VOC)	Transpore tape
BD Hemogard Vacutainer® 7-mL EDTA	BD Vacutainer 6 mL Royal Blue
BD Hemogard Vacutainer® 10-mL EDTA	Cellestis TB In-Tube
Nipro19 gauge	Surgical paper tape
BD Luer adapter for use with the 19 gauge Saf- T EZ® set	Cartoon stickers
BD Vacutainer Safety-Lok™ 21 gauge with adapter	Ammonia inhalant packet
BD Vacutainer Safety-Lok™ 23 gauge with adapter	Pillow and disposable pillow cover
	Squeeze ball
BD Vacutainer® needle holder – single use	Juice and crackers
Air sickness bag	List of reportable tests (handout)
Heel warmer	Labels for Dymo printer
Liquid Band-Aid	Sharps container 2 gallon (8 qt.)
Sani-Cloth	Biohazard bags 14 x 19 (5 gallon)
Purell hand soap	Batteries, AA
Medicine cup	
<b>Nonconsumables</b>	
Step stool	Tube racks
Phlebotomy cart	Floor mat
Solar wall thermometer	CPR mask
Emergency blanket	
<b>Obtain From Lab</b>	
Hand cream	
Nonsterile, powder-free, nonlatex gloves -- small, medium, large	Kleenex
	Bleach bottle

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.

It is critical to assign SPs aged 12+ to phlebotomy as soon as possible at the start of a session, especially a morning session. It is also important to assess the fasting status of SPs aged 12+ assigned to a morning session because they are not eligible for the GT examination if they have not met their 9-hour fast requirement. The coordinator gives each SP a hard-copy verification form as part of the check-in process. For SPs aged 12+ who are examined during a morning session, the form includes the question, “Did you eat or drink anything, other than plain water, after 11:30 last night?” The SP records “Yes” or “No” in a checkbox and the coordinator enters this information into the coordinator application. The coordinator application then highlights (hot pink) the names of SPs who responded “Yes” since they have not met the 9-hour fast requirement. The coordinator uses the highlighted names to aid in prioritizing SPs for the phlebotomy component; SPs who are not highlighted are assigned to phlebotomy before SPs whose names are highlighted.

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 and typing the numbers using the keyboard.

The phlebotomist is responsible for completing the venipuncture section of the phlebotomy exam.

- **Phlebotomy seating options**

For the blood draw, the seating options are dependent on the weight of the SP.

The UMF 8678 phlebotomy chair (Figure 4-2) features an electric motor for up and down patient positioning, three positions—upright, recline, and full recline—and fully adjustable padded armrests that recline as the patient reclines. The chair includes both hand-operated and foot-operated controls to recline the chair with a touch of a button. To recline the chair, push the bottom button on the controller. The foot support will rise and the armrests will recline with the chair.

Figure 4-2. UMF 8678 phlebotomy chair



The chair weight restriction is 375 lbs. If the phlebotomist estimates that the weight of the SP is less than 375 pounds, and the SP will fit comfortably in the phlebotomy chair, then ask the SP to sit in the chair. Roll wheelchairs completely into the room. If the SP feels faint, then recline the chair either before or during the blood draw as needed.

- **Blood collection cart**

Set up the appropriate blood collection cart in advance, making sure there are sufficient supplies for all SPs in the session (see Figure 4-3).

Figure 4-3. Blood collection cart



Adjust the height by lifting up on the black lever. Line an empty biohazard waste container with a biohazard bag and use it as a trash receptacle. Discard all Sharps in the 8-quart biohazard container. Lock all needles in the drawer at the end of each day.

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 more than 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, 13-mL (0.4 ounces), 0.8 tablespoons

6-11 years primary SP, 29-mL (1.0 ounces), 2.0 tablespoons

12-19 years primary SP, 121-mL (4.1 ounces), 8.2 tablespoons

20+ years primary SP, 149-mL (5.0 ounces), 10.0 tablespoons

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

3-5 years VIP guest, 6-mL (0.2 ounces), 0.4 tablespoons

6-11 years VIP guest, 10-mL (0.3 ounces), 0.7 tablespoons

12+ years VIP guest, 15-mL (0.5 ounces), 1.0 tablespoons

1+ 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 slightly more than 25 percent (128-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 or 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 phlebotomy component maintains the highest priority among MEC examinations. If an SP comes to the MEC and can complete only one exam, it should be the phlebotomy component.

The Field Office and Interviewing teams use "Special Consideration" codes to describe SPs with reservations about the phlebotomy procedure. The codes are part of the special consideration section of the MEC Appointment Schedule in the coordinator application. The phlebotomist prints the Session Preview Report each session and notes CB/NB codes under the Special Considerations column. The codes entered by the interviewers should be viewed as "warning codes" rather than strict edicts.

- When an SP expressed no reservations or concerns about phlebotomy during the home interview, no code will appear, and no special action is needed from MEC staff.
- **CB**—represents "Convert Blood"—This means that the SP has expressed concern or fear about the blood draw, but did not indicate that he or she intends to refuse having blood drawn. If an SP is coded CB, phlebotomy remains a priority exam.
- **NB**—represents "No Blood"—This means the SP indicated during the home interview that he or she intended to refuse the blood draw. When an SP has a NB code, the coordinator may send the SP to phlebotomy either (1) after all other SPs have completed phlebotomy or (2) after the SP has completed the exams in the profile. The coordinator should use the following script to simply explain that "We need to send you to the exam room; we can scan your ID band barcode into the system.

The MEC manager and coordinator should work in collaboration with the phlebotomist in assigning the NB coded SPs; the phlebotomist is trained in refusal conversion techniques and is responsible for the overall response rate for this component. At all times, the coordinator and MEC manager must use their judgment in assigning SPs with NB to phlebotomy. If the SP is vehemently adamant about giving blood, there is no reason to provoke the SP by sending him or her to the phlebotomy room. In this instance, the coordinator will mark the phlebotomy component as a refusal.

#### **4.5 Performing the Venipuncture on SPs who do not Speak English**

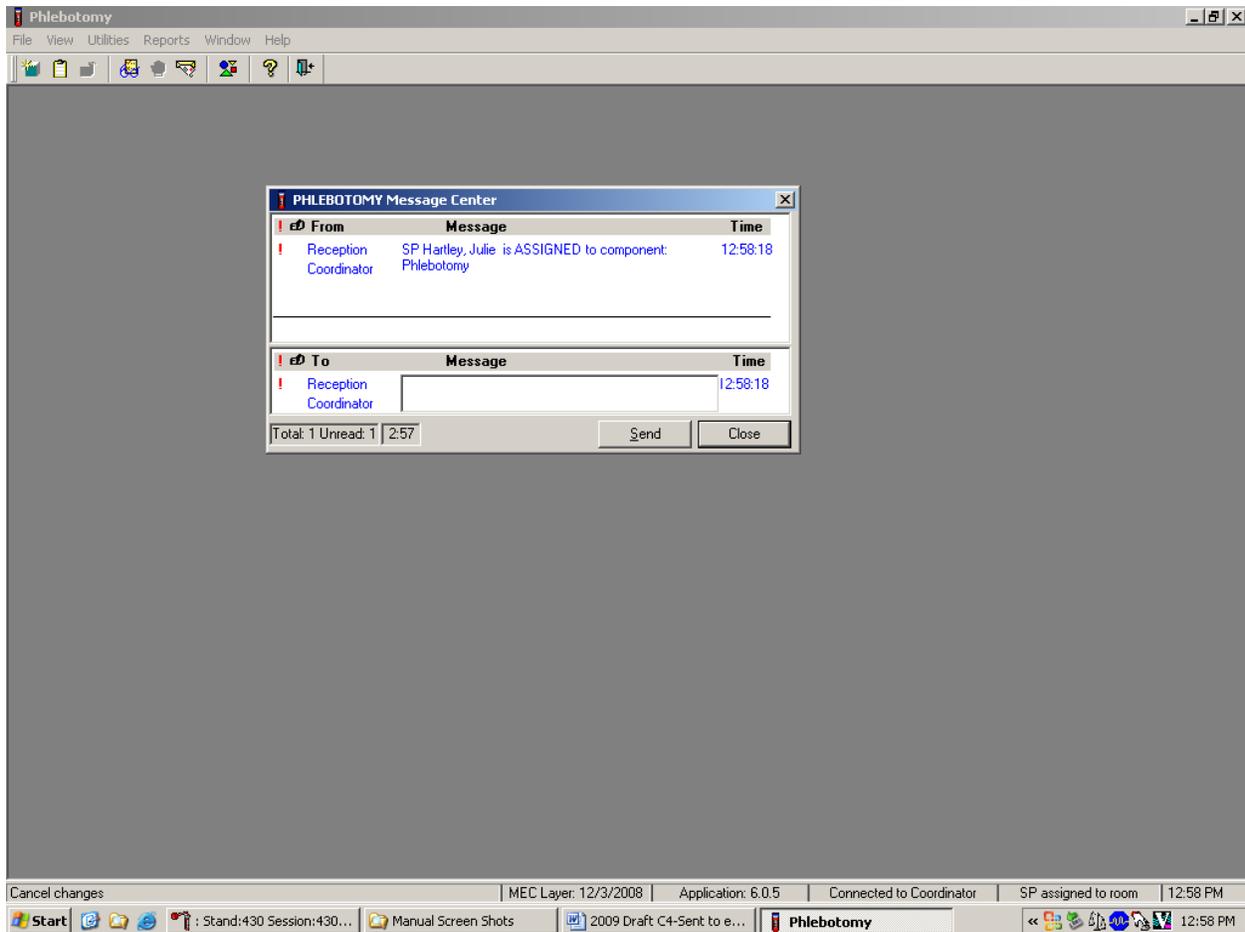
When the phlebotomist must administer the venipuncture procedure to an SP who does not speak English and the phlebotomist does not speak the language of the SP, a translator who does speak the language of the SP assists the phlebotomist.

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. Refer to the MEC Operations manual for detailed instructions on the interpreter module.

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

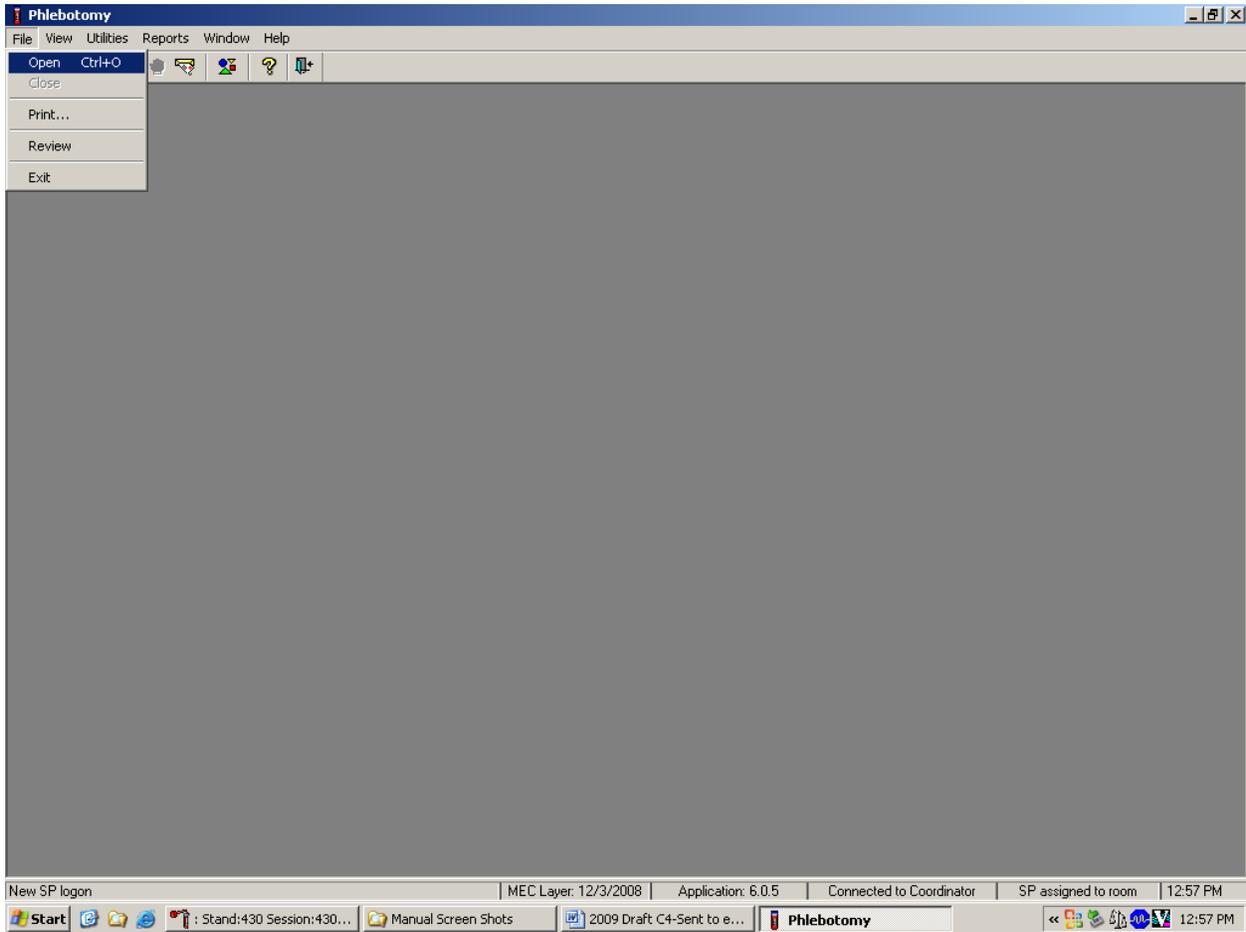
Open and log onto the Phlebotomy application.

The message center window identifies the SP assigned to phlebotomy.



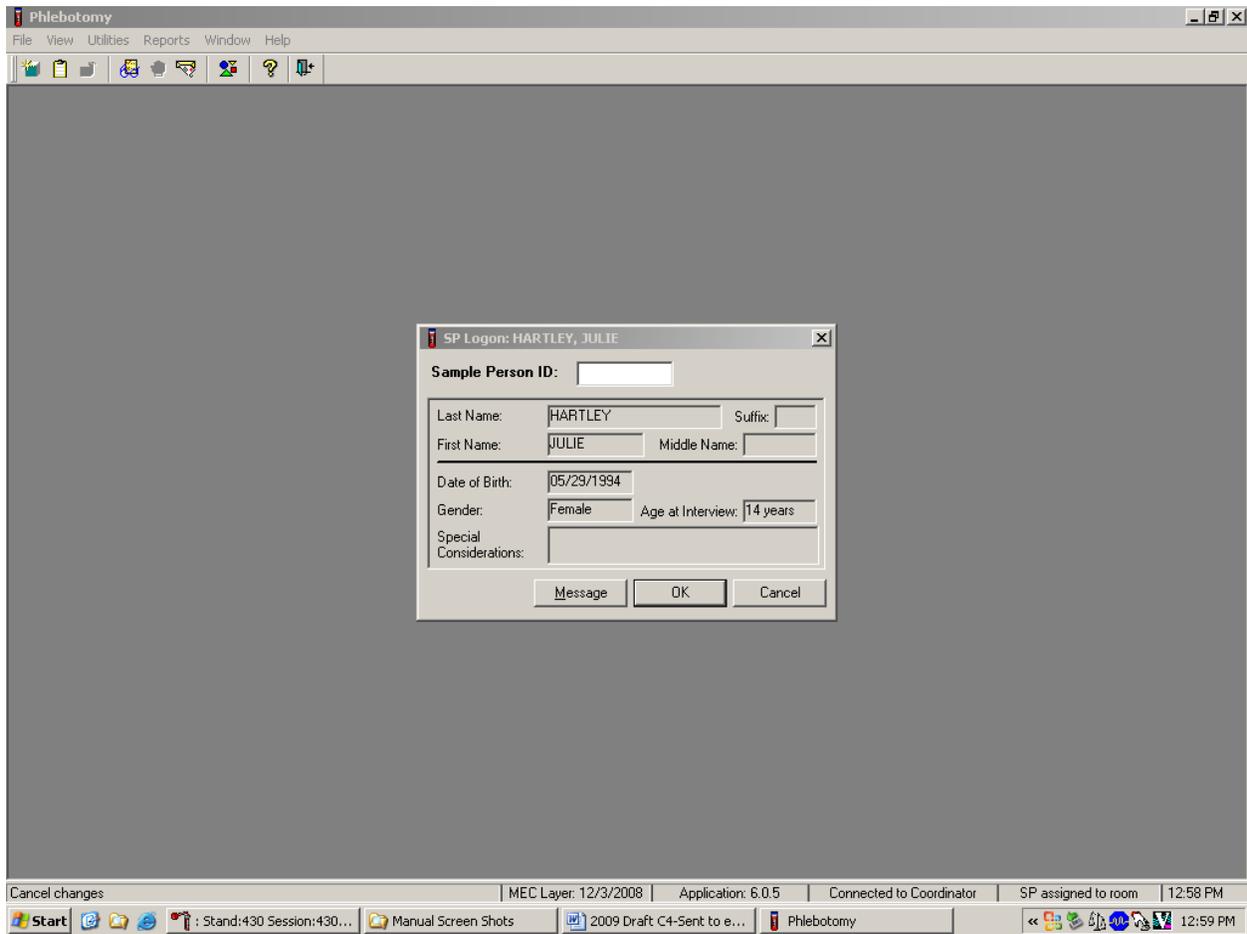
A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the “Send” button and 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.



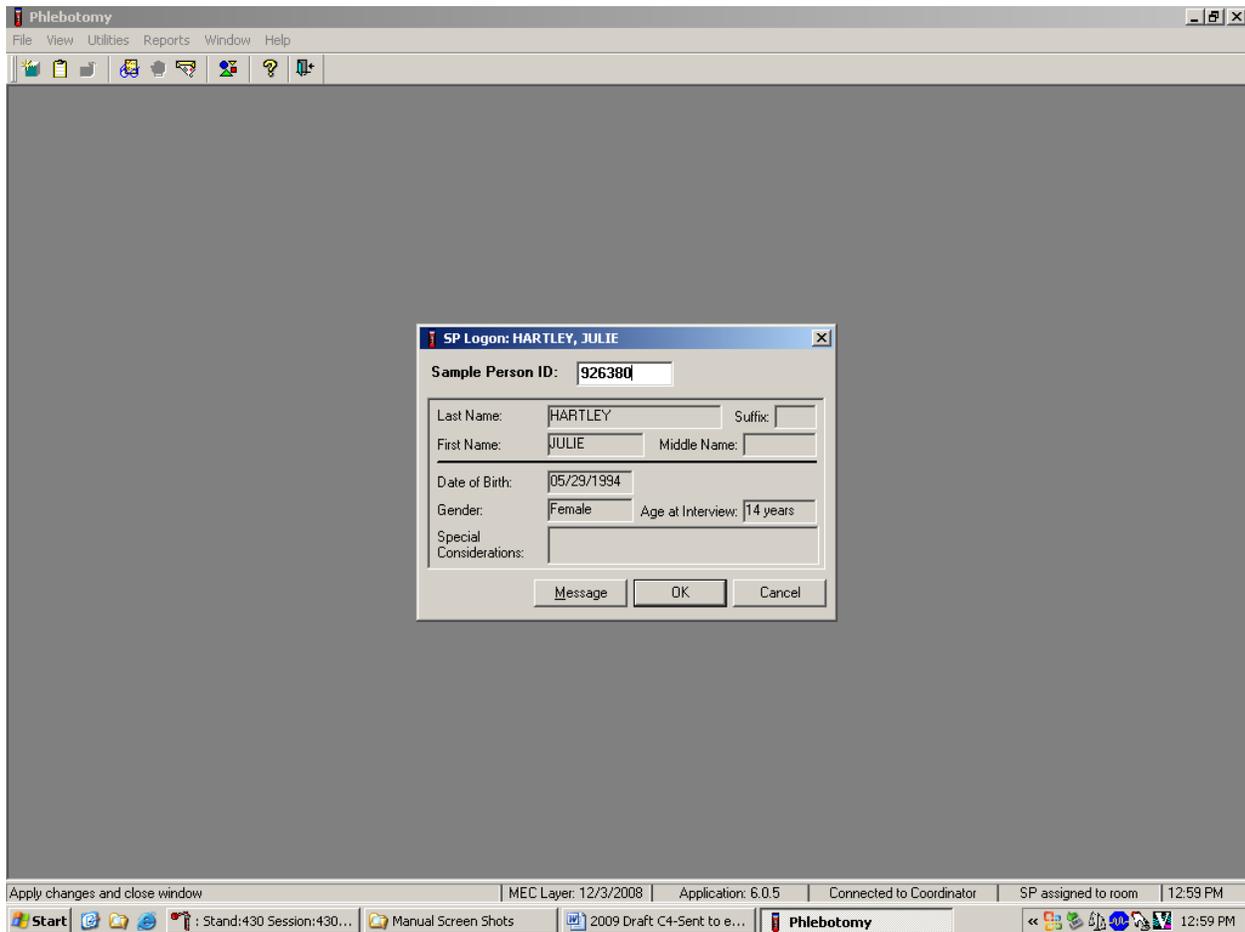
To open an exam, move the mouse to {File} in the menu bar, click on {Open}, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o].

The SP Logon window displays.



The SP Logon window displays for the SP assigned to the component.

Log the SP into 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 in 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 screen includes a shared exclusion pregnancy question for females aged 16-59 and two safety exclusion questions. 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 16, or administer the interview questions (and fasting questionnaire) to the SP’s parent or guardian for SPs under age 16.

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

Phlebotomy Interview

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM

Are you currently pregnant?

Do you have hemophilia?

Have you received cancer chemotherapy in the past four weeks?

End of Section Close Exam Finish

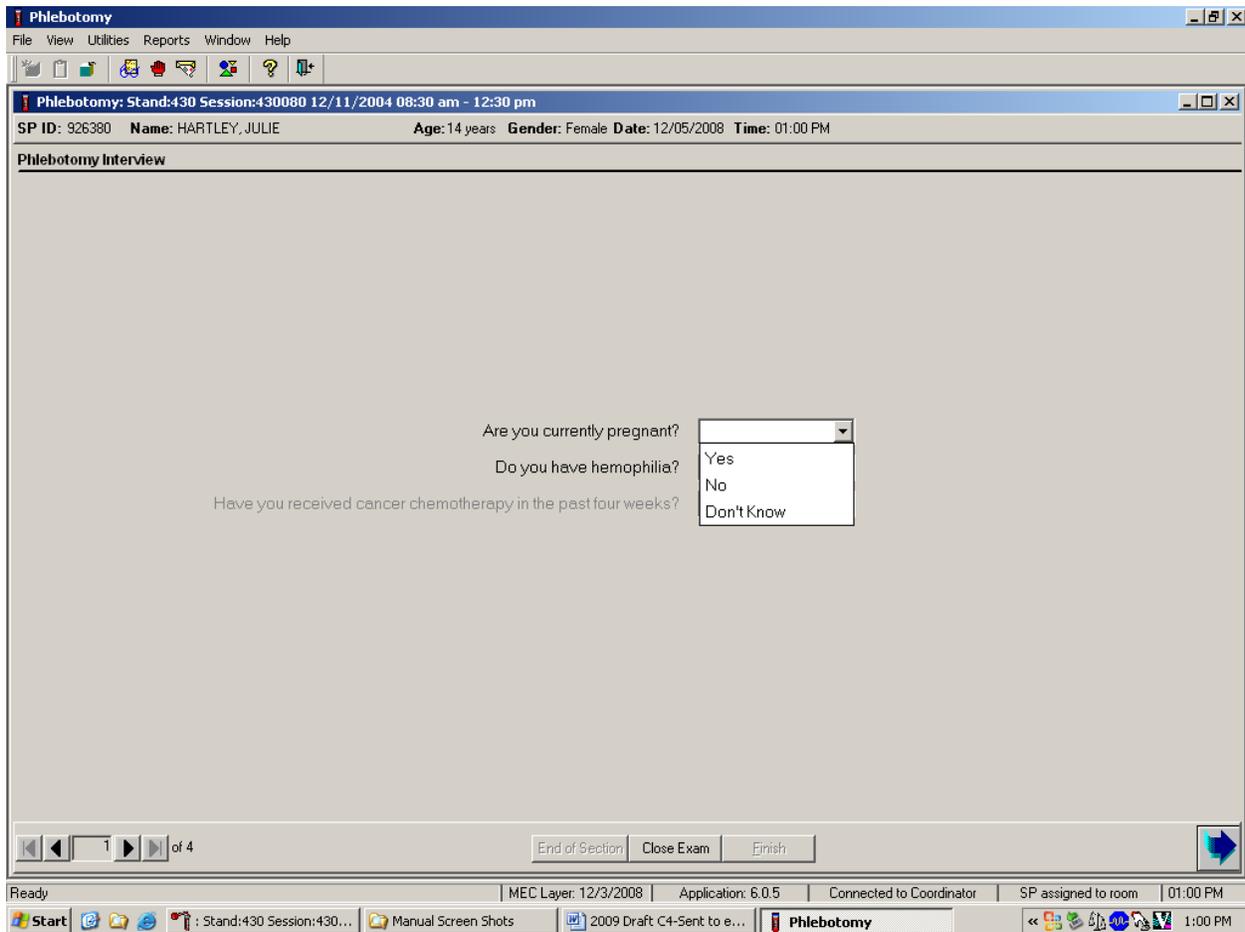
MEC Layer: 12/3/2008 Application: 6.0.5 Connected to Coordinator SP assigned to room 01:00 PM

#### **4.7.1 Pregnancy Shared Exclusion Question**

For female SPs aged 12-59, the shared exclusion pregnancy questions are enabled and are asked during the MEC examination in the first examination where shared exclusions are asked. Each question is asked only once, even when the question is relevant for more than one component. Some examinations, like phlebotomy, do not require all the shared exclusions to be asked. In this situation, there may be some questions answered in one examination and then disabled in the remaining examinations. Shared exclusion questions are component specific. Answers provided during previous components appear on the screen for the next examiner to see, but the text box for data entry is disabled. Only shared exclusion questions relevant to the age and component that have not been answered are enabled. Example: If the SP goes to the physician component before phlebotomy, the questions about “pregnancy” and “how many weeks” would be asked by the physician. The “pregnancy” question would be disabled in the phlebotomy component.

- If the SP is a male, a female less than 12 years, or a female older than 60 years, the shared exclusion pregnancy questions will not be displayed.
- If the SP is a female aged 12-59, the first shared exclusion pregnancy question is displayed and enabled.

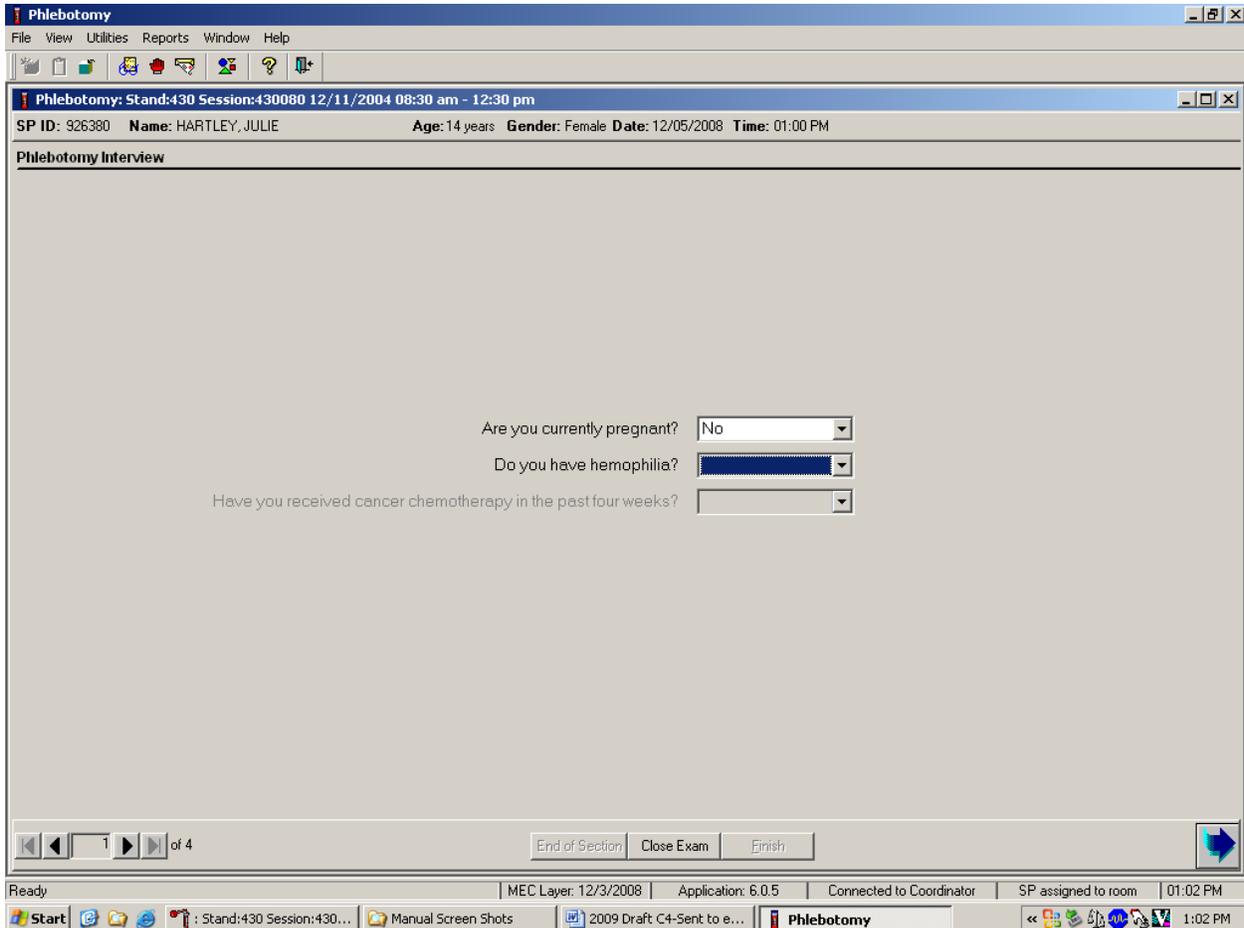
Record the response to the shared exclusion question.



Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” or [D/d] for “Don’t know.” Alternatively, move the mouse to the drop-down arrow on the drop-down list, and drag the mouse arrow to “Yes,” “No,” or “Don’t Know” and left click. Select [TAB] to move to the next text box.

If the response to the question “Are you currently pregnant?” is “Yes,” the SP is excluded from GTT due to pregnancy status. At the coordinator application, the component status for GT defaults to “Not Done” with the comment “Blocked: Not Done [SP pregnant].”

If the response to the question “Are you currently pregnant?” is “No” or “Don’t Know,” the SP is not excluded from the GTT. Ask the next two phlebotomy safety exclusion questions.



If the answer to the shared exclusion pregnancy question is “No” or “Don’t know,” then select [TAB] to proceed to the first safety exclusion question, “Do you have hemophilia?”

#### 4.7.2 Safety Exclusion Questions

Continue to 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.

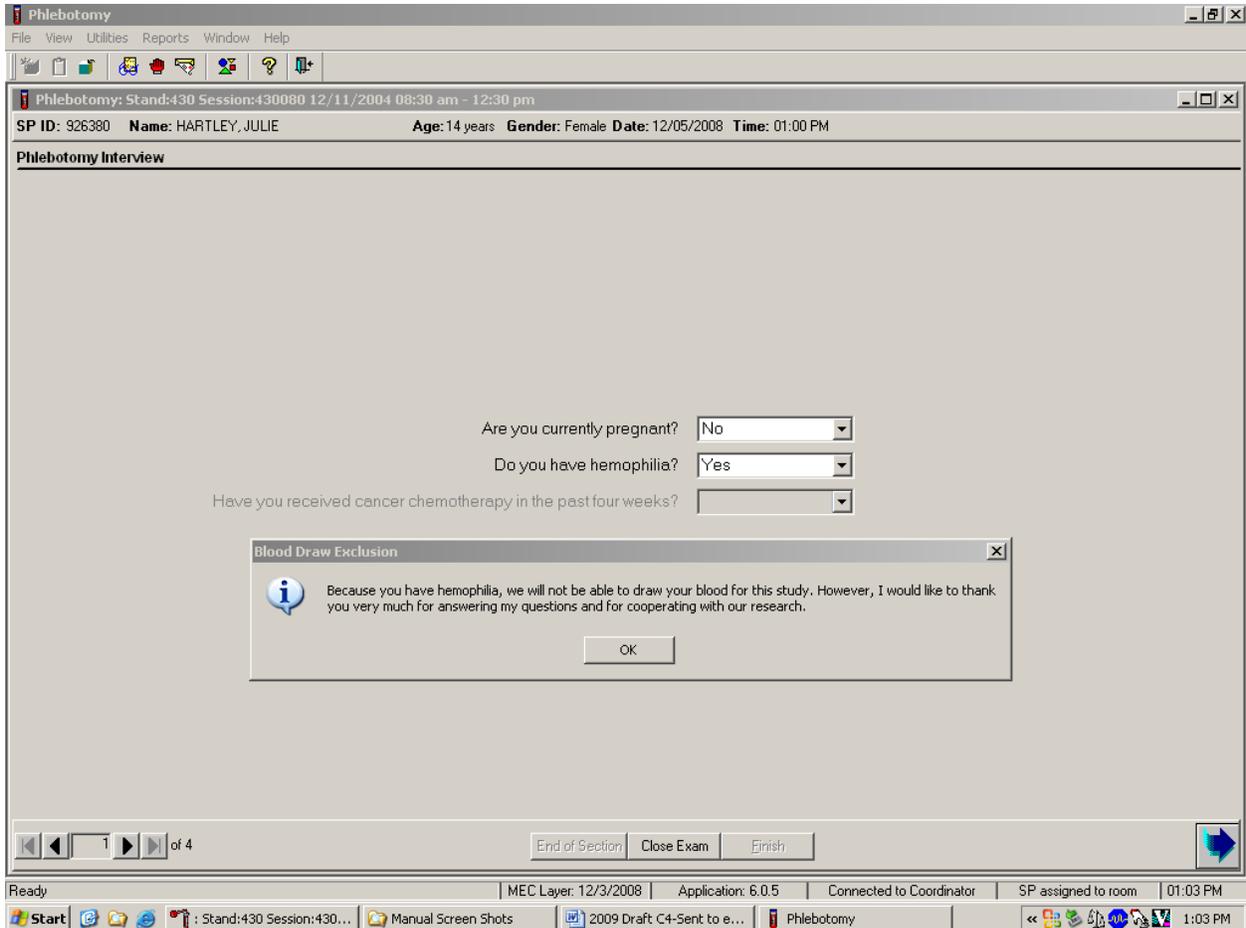
The screenshot displays the Phlebotomy software interface. At the top, the window title is "Phlebotomy". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains various icons for file operations and navigation. The main content area is titled "Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM". The section is labeled "Phlebotomy Interview". The form contains three questions, each with a corresponding drop-down menu:

- Are you currently pregnant? (Dropdown menu showing "No")
- Do you have hemophilia? (Dropdown menu showing "Yes", "No", "Refused", "Don't Know")
- Have you received cancer chemotherapy in the past four weeks? (Dropdown menu showing "Yes", "No", "Refused", "Don't Know")

At the bottom of the form, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "MEC Layer: 12/3/2008", "Application: 6.0.5", "Connected to Coordinator", "SP assigned to room", and "01:01 PM". The Windows taskbar is visible at the bottom, showing the Start button, several open applications, and the system clock at 1:01 PM.

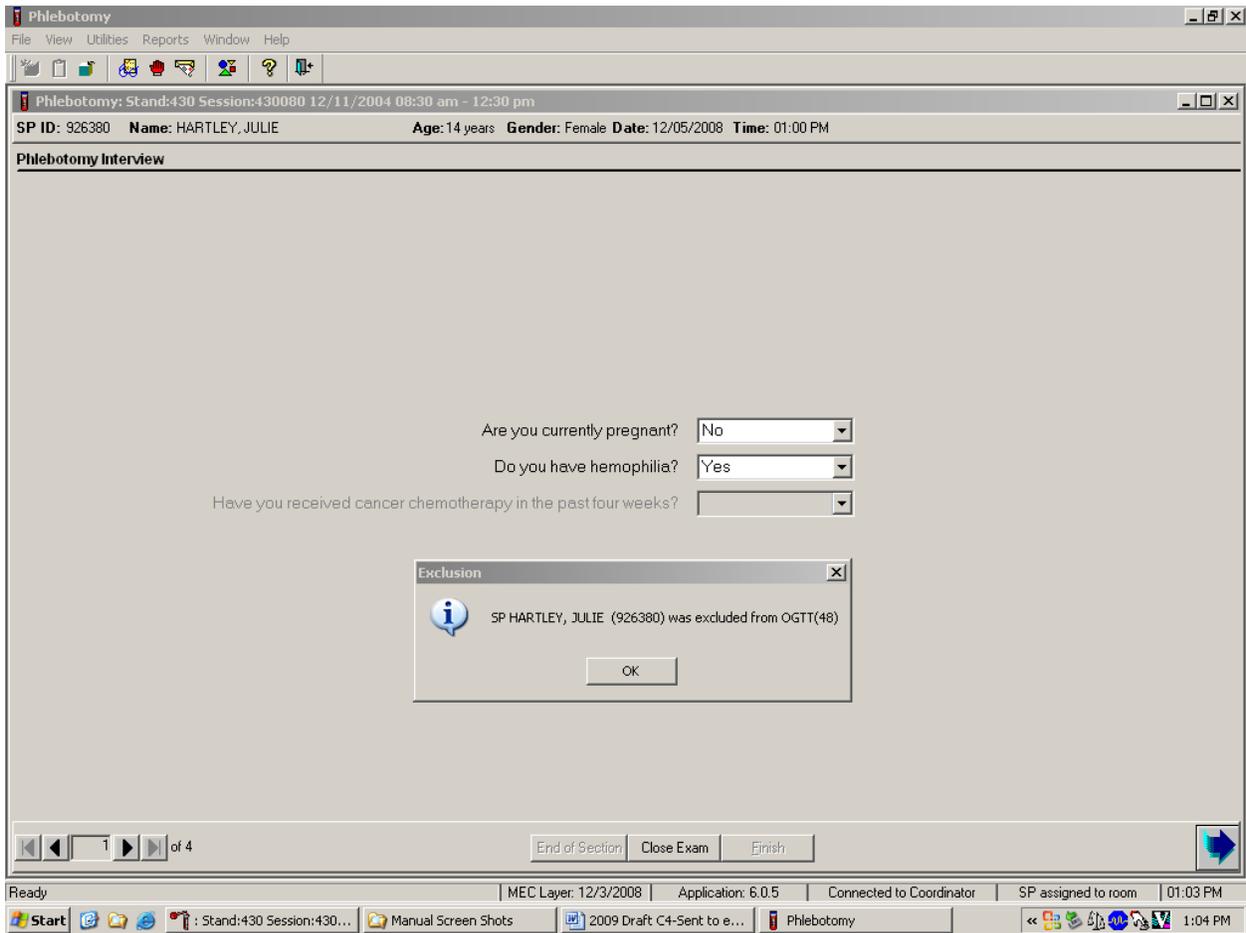
Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, move the mouse to the drop-down arrow on the drop-down list, click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left 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.



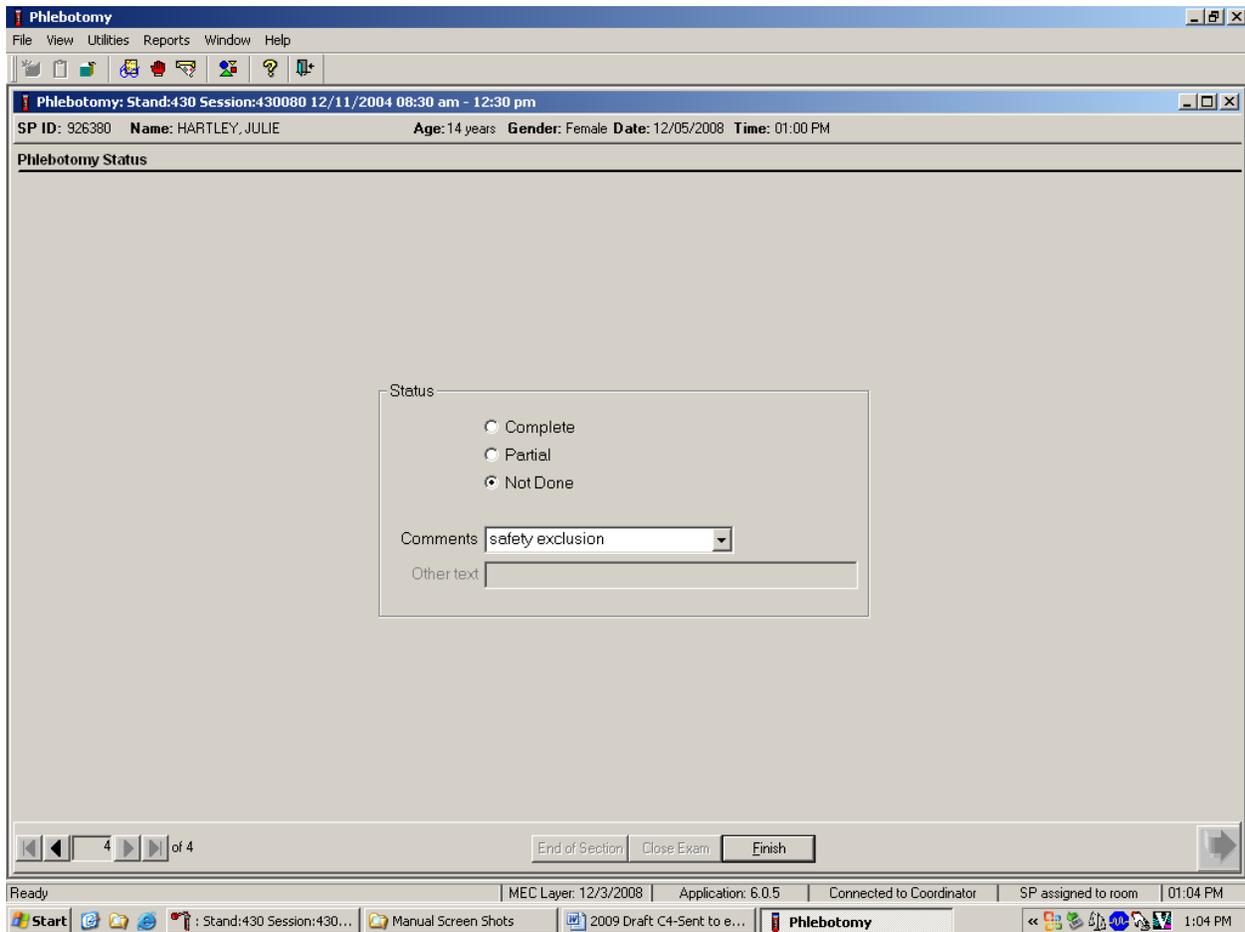
Read the script to the SP. To remove the Blood Draw Exclusion message text box, move the mouse arrow to the “OK” button and left click, or select [Enter].

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



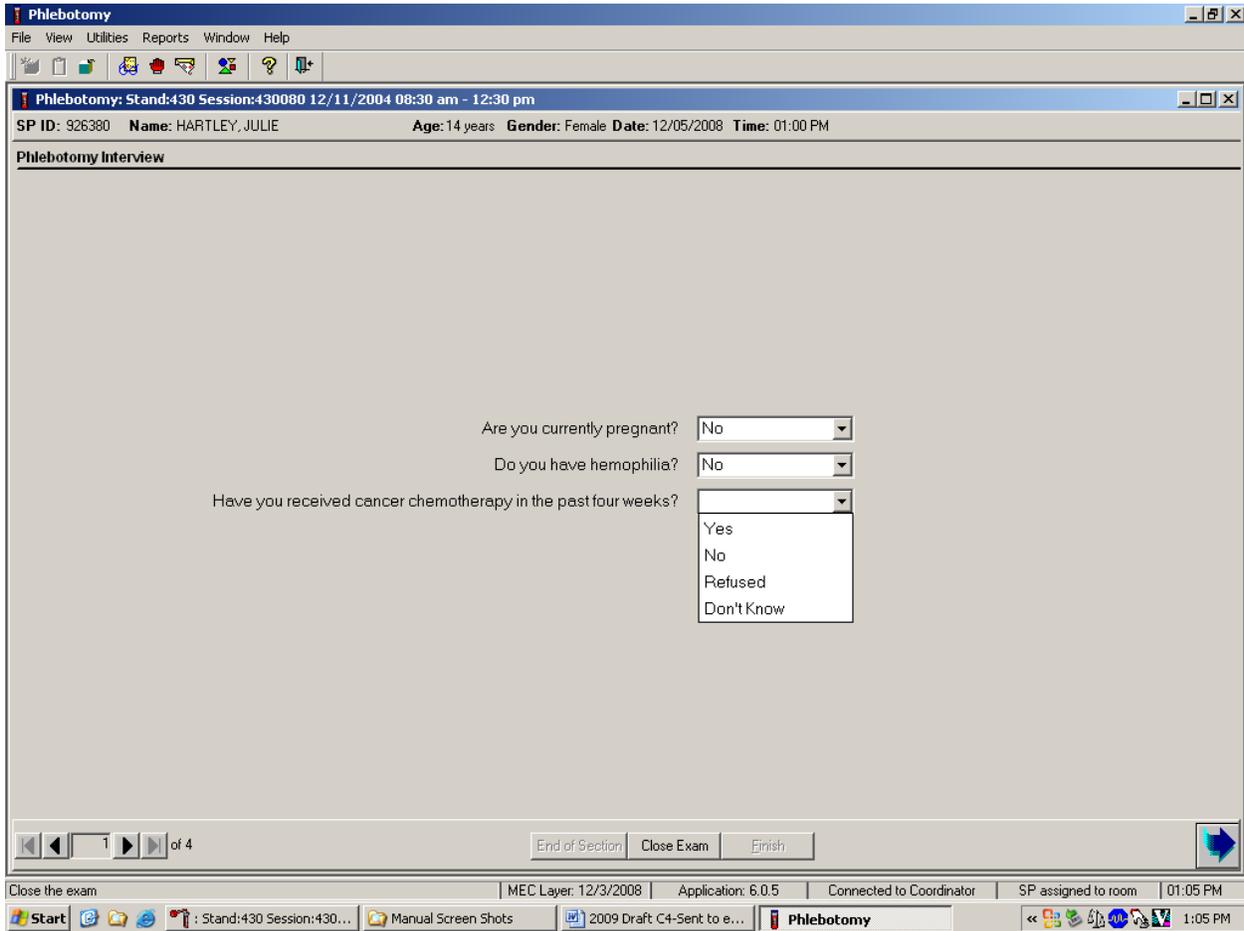
To remove the Exclusion message text box, move the mouse to the “OK” button and left click, or select [Enter].

Verify the status.



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 4 weeks?”

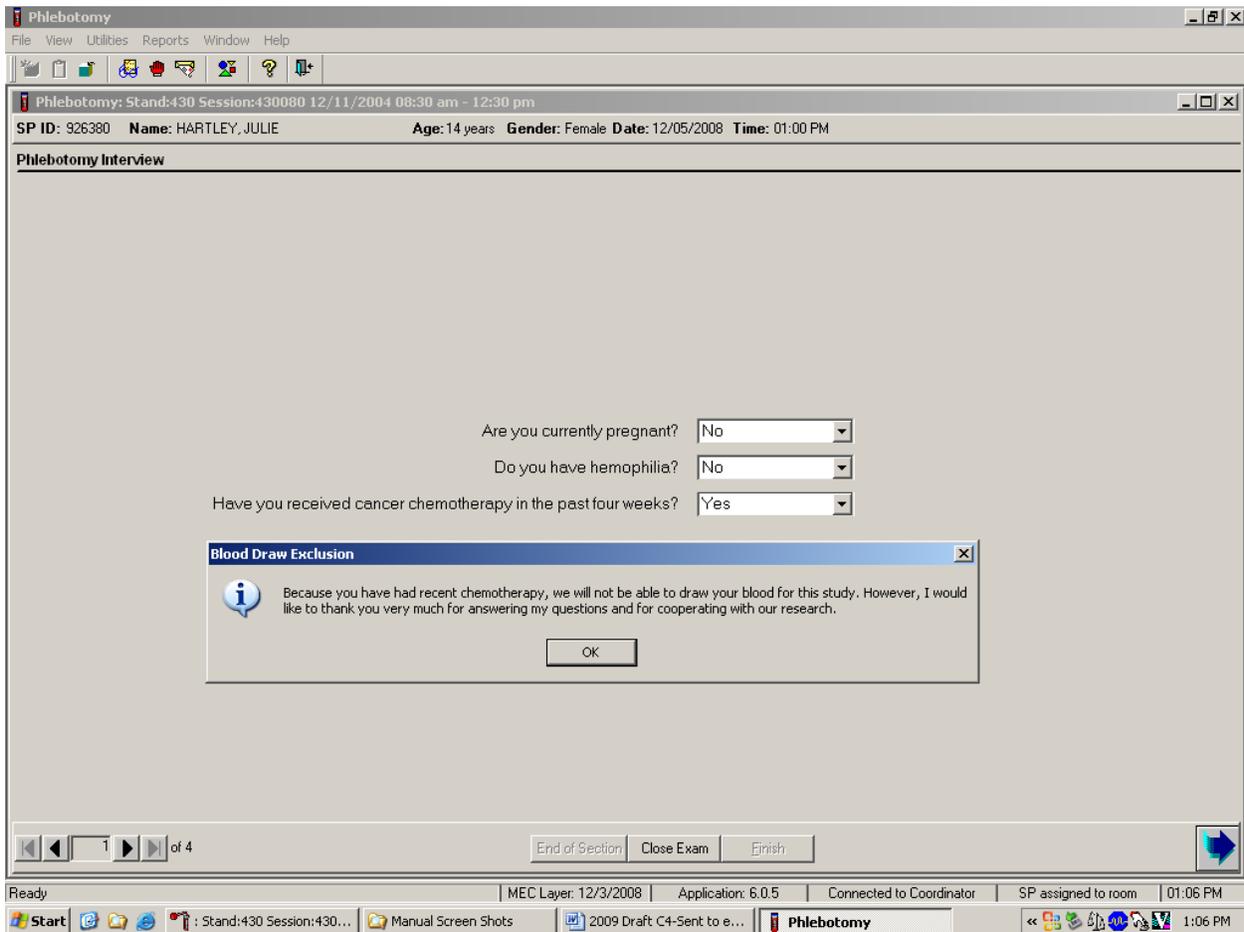


**Q2: Have you received cancer chemotherapy in the past 4 weeks?**

<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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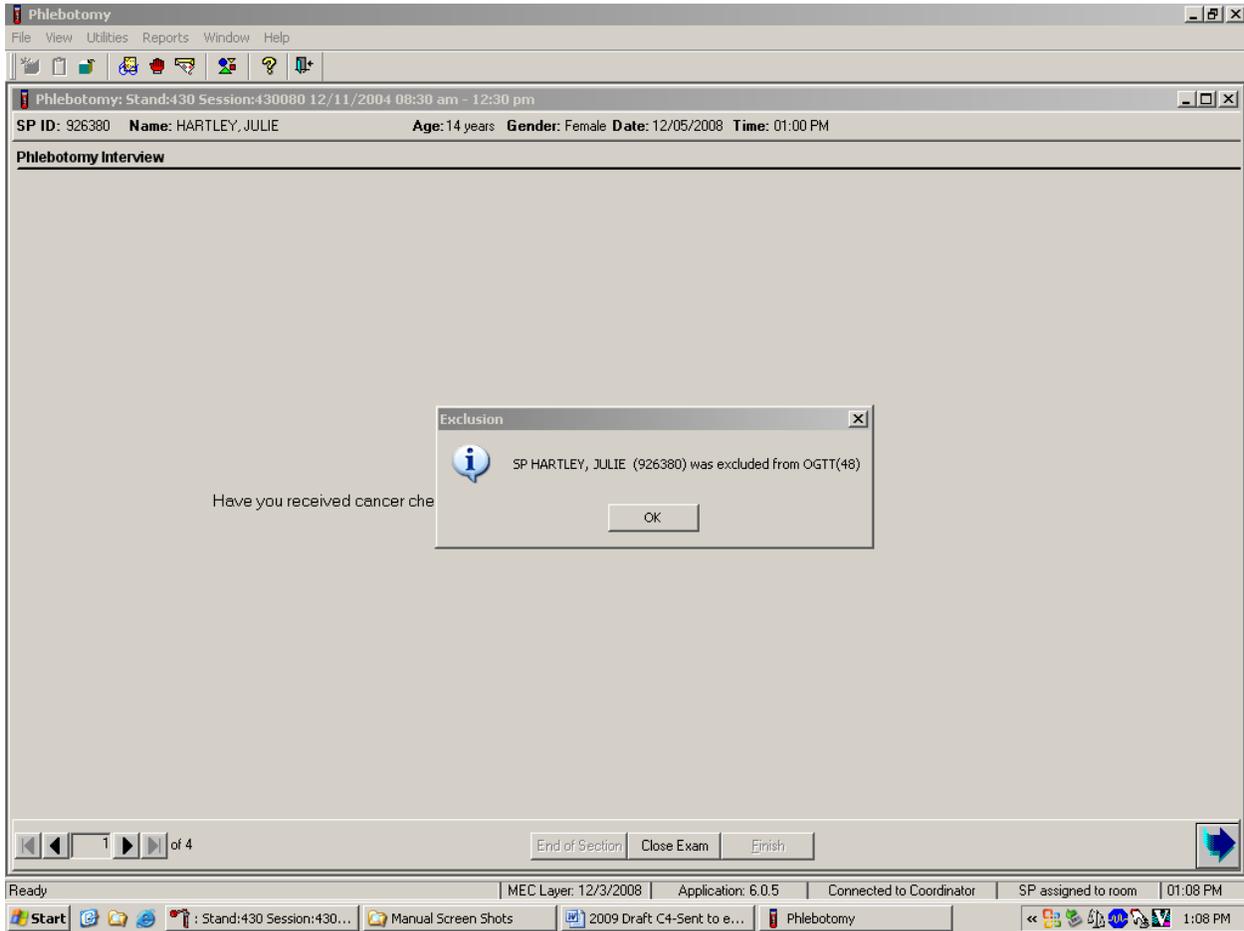
Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, move the mouse to the drop-down arrow on the drop-down list, click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left 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.



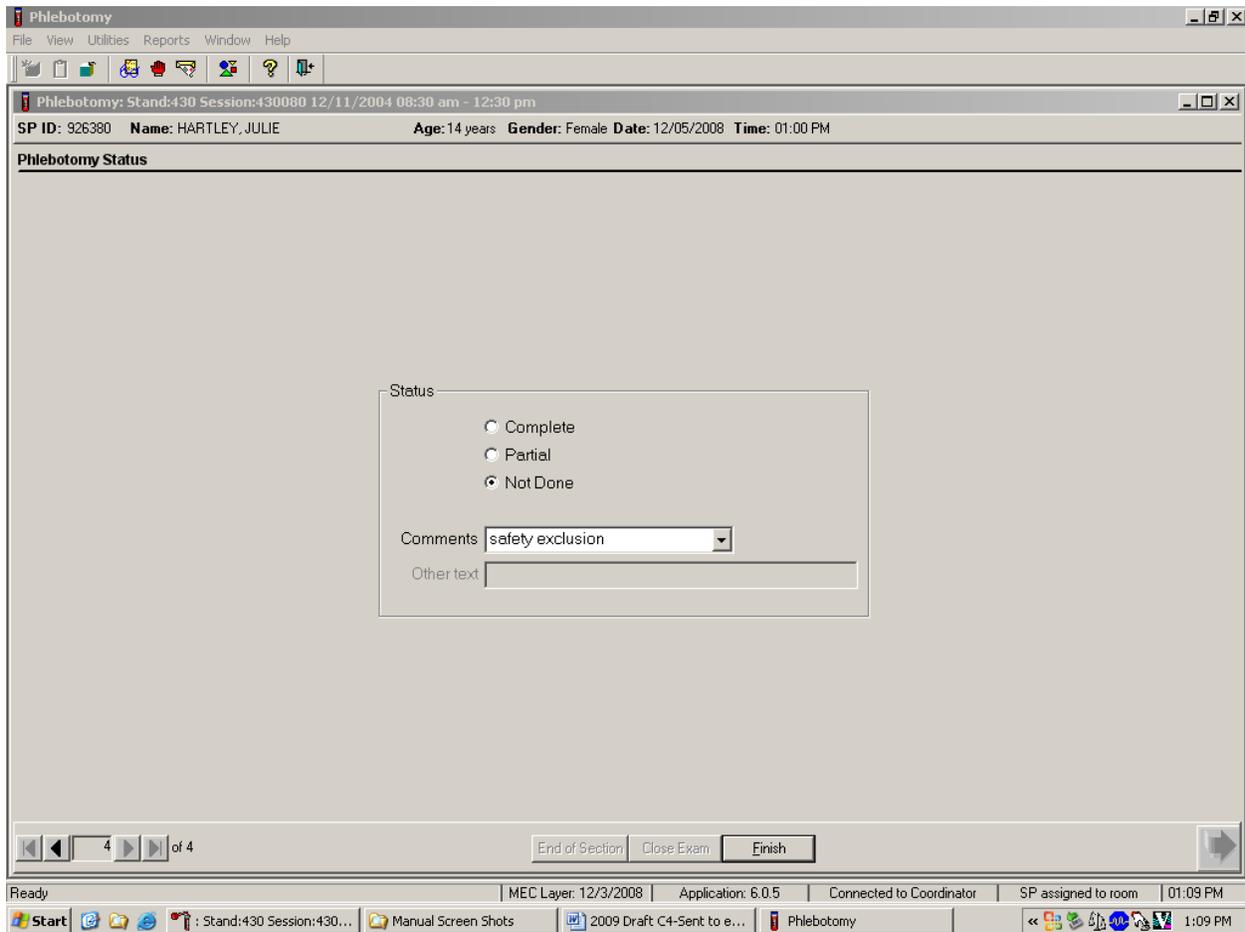
Read the script to the SP. To remove the Blood Draw Exclusion message box, use the mouse to direct the mouse arrow to the “OK” button and left click.

If the SP is excluded from the phlebotomy component due to chemotherapy, an informational 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, move the mouse to the “OK” button and 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.



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 displays the Phlebotomy software interface. At the top, the window title is "Phlebotomy" and the menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm" and contains patient information: "SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM". The section is labeled "Phlebotomy Interview" and contains three questions, each with a dropdown menu set to "No":

- Are you currently pregnant? No
- Do you have hemophilia? No
- Have you received cancer chemotherapy in the past four weeks? No

At the bottom of the main area, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A blue arrow icon is located in the bottom right corner of the main area. The Windows taskbar at the bottom shows the system tray with the time "1:09 PM" and several open applications, including "Stand:430 Session:430...", "Manual Screen Shots", and "2009 Draft C4-Sent to e...".

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 status is critical to many of the laboratory analytes, and fasting data are required for correct interpretation of laboratory results. Fasting is especially critical because only SPs who have met the fast are eligible for the GT component. No primary SPs aged 1-11 or SPs assigned to afternoon or evening sessions are asked to fast. All other primary SPs aged 12+ appointed to a morning session are asked to fast for 9 hours. This includes diabetics taking insulin, although these SPs are always given the highest priority so the venipuncture can be completed as soon as possible after the SP checks into the MEC.

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 then performs the venipuncture.

The overall objective is to perform phlebotomy on all eligible SPs. The coordinator must base the decision to assign 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 before he or she has been assigned to phlebotomy. It is always preferable to get blood from this SP before he or she leaves the MEC. The coordinator and MEC manager are able to provide the best overall assessment of the status of a particular SP.

Guests and VIP guests do not have a fasting requirement, even during morning sessions.

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

Read the text exactly and record the time.

**Phlebotomy**  
 File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda.

Have you had any of the following since

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 Hours Minutes

2 of 4

End of Section Close Exam Finish

Close the exam MEC Layer: 12/3/2008 Application: 6.0.5 Connected to Coordinator SP assigned to room 01:14 PM

Start Stand:430 Session:430... Manual Screen Shots 2009 Draft C4-Sent to e... Phlebotomy 1:14 PM

**Q1: When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet’N Low, NutraSweet, Equal, or Splenda.**

<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 artificial sweeteners like Sweet’N Low, NutraSweet, Equal, or Splenda since these have no effect on study analytes. Do not include flavored waters.</p>
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Enter the response.

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 "Fasting Questionnaire" and contains the following text and form elements:

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. [Time input field]

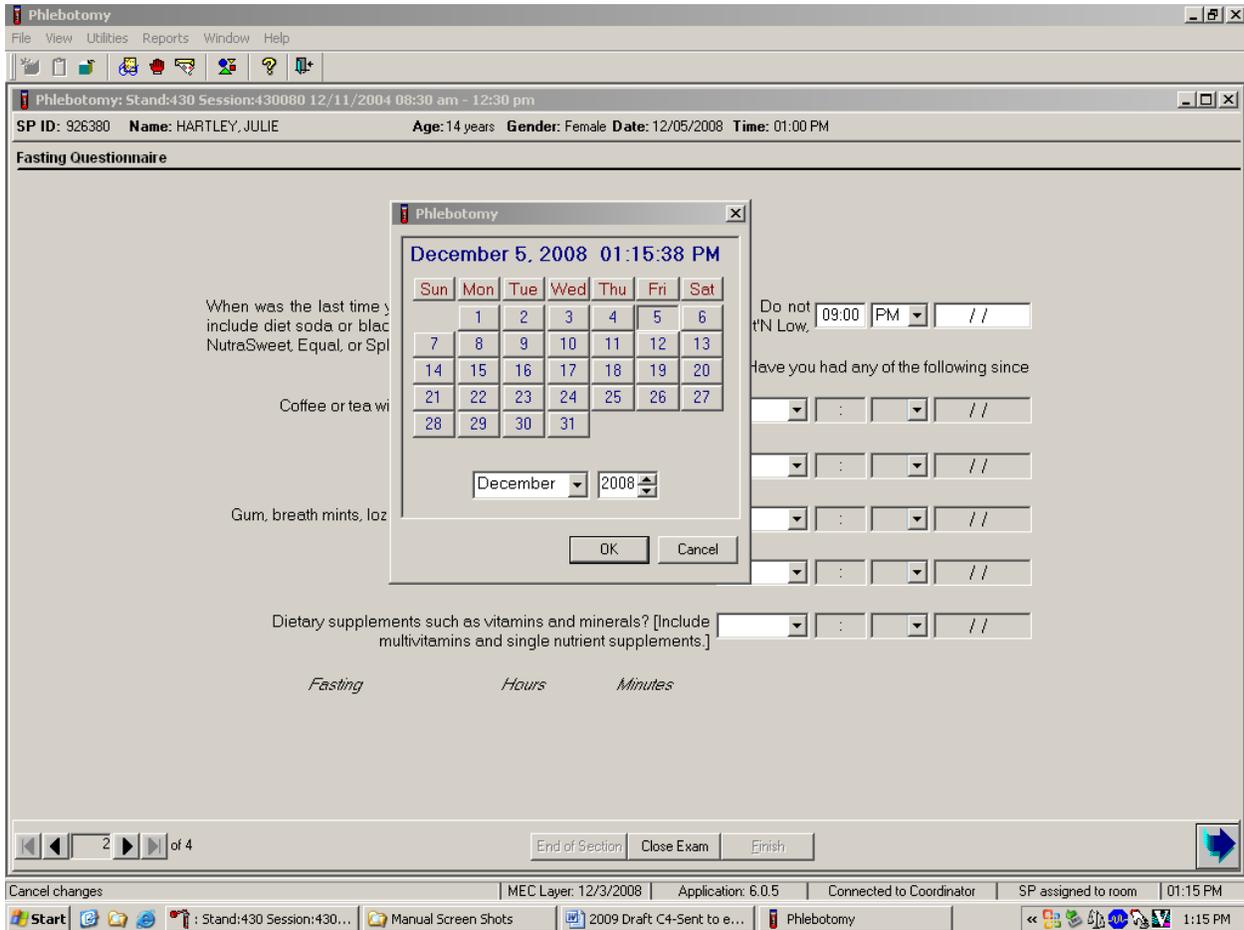
Have you had any of the following since

- Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] [Time input field]
- Alcohol, such as beer, wine, or liquor? [Time input field]
- Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? [Time input field]
- Antacids, laxatives, or anti-diarrheals? [Time input field]
- Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] [Time input field]

Below the questions are labels for "Fasting", "Hours", and "Minutes". At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The Windows taskbar at the bottom shows the system tray with the time 1:15 PM and the application name "Phlebotomy".

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 AM or [P/p] for times between 12:00 noon and 11:59 PM 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.

Enter the date.



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**  
File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 09:00 PM 12/04/2008

Have you had any of the following since yesterday at 9:00 PM?

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 16 Hours 17 Minutes*

2 of 4 End of Section Close Exam Finish

Ready MEC Layer: 12/3/2008 Application: 6.0.5 Connected to Coordinator SP assigned to room 01:16 PM

Start Stand:430 Session:430... Manual Screen Shots 2009 Draft C4-Sent to e... Phlebotomy 1:16 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 artificial sweeteners is unacceptable. Include all milk products such as half-and-half, light cream, non-fat milk, and all other non-dairy creamers like Cremora or Coffee-Mate.</p>
<p>Alcohol, such as beer, wine, or liquor?</p>	<p>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.</p>
<p>Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?</p>	<p>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.</p>
<p>Antacids, laxatives, or anti-diarrheals?</p>	<p>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.</p>
<p>Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]</p>	<p>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.</p>

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

File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 09:00 PM 12/04/2008

Have you had any of the following since yesterday at 9:00 PM?

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 08:00 AM 12/05/2008

*Fasting 16 Hours 17 Minutes*

2 of 4

End of Section Close Exam Finish

Ready MEC Layer: 12/3/2008 Application: 6.0.5 Connected to Coordinator SP assigned to room 01:17 PM

Start : Stand:430 Session:430... Manual Screen Shots 2009 Draft C4-Sent to e... Phlebotomy 1:17 PM

To progress to the next 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].

### SPs Not Meeting 9-Hour Fast – Morning Session Only

A system was implemented to ensure that SPs who would meet their 9-hour fast and still had enough time to complete the OGTT, would wait until they met their fast to have their first venipuncture. The coordinator screen will turn yellow and the phlebotomy application would give a message “I will need to have you wait until approximately (time) before I can collect your blood. I will have the coordinator bring you here at the right time.” When the SP has met the 9-hour fast, the coordinator screen will turn green, which indicates the SP has met the fast and can return to phlebotomy.



Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm

SP ID: 973550 Name: WEAVER\_1, JOE Age: 43 years Gender: Male Date: 11/06/2009 Time: 08:56 AM

**Phlebotomy Status**

Status

Complete

Partial

Not Done

Comments

Other text

If the SP will never meet the 9-hour fast during the session, he or she is excluded from OGTT and is prompted to have his or her blood drawn at that time without waiting. If the SP will meet the 9-hour fast during the session, but doesn't have enough time to complete the OGTT, he or she will be excluded from OGTT and will wait until meeting the 9-hour fast for the first venipuncture.

Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm

SP ID: 991969 Name: BUTLER\_1, REBECCA Age: 59 years Gender: Female Date: 11/06/2009 Time: 09:01 AM

**Fasting Questionnaire**

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 04:00 AM 11/06/2009

Have you had any of the following since today at 4:00 AM?

Coffee or tea with cream or sugar? (Include milk or non-dairy) //

Gum, breath mints, lozenges //

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

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

*Fasting 5 Hours 1 Minutes*

**Exclusion**

SP BUTLER\_1, REBECCA (991969) was excluded from OGTT(48)

OK

#### 4.9 Venipuncture Procedures

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 in 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.

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 them 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 and 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 automated Supply Use Control Log. 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 SP's arm on the armrest or a pillow so that the veins are readily accessible and you are 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.

- 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 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.

#### **4.9.2 Venipuncture Technique for the Nipro (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 or 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 your 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)**

The BD Vacutainer™ Push Button Blood Collection Set provides immediate protection against needle stick injury when properly activated within the vein, and in accordance with package insert directions.

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 or 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 your 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. With thumb and index finger, grasp wings together and access vein using standard needle insertion technique. 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.
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 Safety-Lok set by:
  - Grasping the translucent yellow safety shield grip area with thumb and index finger while at the same time grasping the tubing, OR
  - Grasping either one wing or both wings and withdrawing.
14. Activate the safety shield:
  - One-Hand Technique. Hold tubing in hand and advance translucent yellow safety shield with thumb and index finger until a click is heard indicating that the needle is completely retracted and safety shield is locked in place over needle tip, OR.

- Modified One-Hand Technique. Apply pressure to site using your fingers. Withdraw blood collection set by grasping the translucent yellow safety shield grip area with the thumb and index finger. With opposite hand, grasp tubing between thumb and index finger while pushing the yellow safety shield forward until a click is heard indicating that the needle is completely retracted and the safety shield is locked in place, OR.
- Two-Hand Technique. Grasp either wing with one hand (A) and grip area of the yellow safety shield base with the other hand (B). 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 locked into place over needle tip.

**Do not grasp safety shield by body; this will interfere with safety shield activation.**

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.

#### **4.9.4 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.

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 in 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.

Use judgment when applying any bandage to elderly SPs. The skin of the elderly can be very thin and fragile and the Liquid Band-Aid® may irritate the skin when it is removed.

**If the venipuncture site is in the left arm:**

**For all SPs aged 1-11 and SPs not eligible for GTT** – 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.

**For all SPs aged 12+ who are eligible for the GTT** – Apply CoFlex dressing to the puncture site in place of the regular adhesive bandage.

6. Report any adverse reaction to the venipuncture to the physician immediately and document the event by using the automated Unusual Field Occurrence utility.
7. If the SP has been fasting and is eligible for the GTT, then do not offer him or her a snack and juice. If the SP has not been fasting or is not eligible for the GTT, then offer him or her juice and crackers.
8. Escort the SP back to the coordinator.
9. If blood has spilled on the phlebotomy chair, wash the area with a 10 percent solution of bleach and water, then prepare the workstation for the next SP. Routinely disinfect the phlebotomy chair with Sani-wipes to disinfect. Wash hands and change gloves before approaching the next SP.
10. Wash hands and change gloves before approaching the next SP.

#### **4.10 Pediatric Venipuncture**

Pediatric venipuncture requires special techniques. Because you 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, with a doll for example, 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. You 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 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 him or her that the best technique is being used. It is very important that the adolescent maintain control of the situation; therefore, give him or her 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 adolescent.

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 includes 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 his or her 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 needle stick. Nonetheless, heel sticks, 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 heel stick 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.

### **Children Observing Phlebotomy**

No children who are SPs will be allowed in or near the phlebotomy room until they are assigned for a venipuncture. Children that aren't assigned to phlebotomy should remain in the coordinator area and be supervised by the local or other MEC staff. This will reduce the number of SP refusals in children.

### **REFERENCES**

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2. McCall, R., Tankersley, C. Pediatric venipuncture In: *Phlebotomy Essentials*, 2<sup>nd</sup> Edition. Philadelphia, Lippencott-Raven, 1998.
3. Sommer, S., Warekois, R. Blood collection in special populations In: *Phlebotomy: Worktext and Procedures Manual*. Philadelphia, W.B. Saunders, 2002.
4. Klosinski, D. Collecting specimens from the elderly patient. *Laboratory Medicine*. 1997;28(8): 515-522.

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[http://www.advanceformlp.com/common/editorialsearch/viewer.aspx?FN=03mar10\\_mtp11.html&AD=3/10/2003&FP=mt](http://www.advanceformlp.com/common/editorialsearch/viewer.aspx?FN=03mar10_mtp11.html&AD=3/10/2003&FP=mt)

### **Vol. • Issue • Page LS answers**

#### **Learning Scope Questions**

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) preschool
  - 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) preschool
  - 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 preschool 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) preschool 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

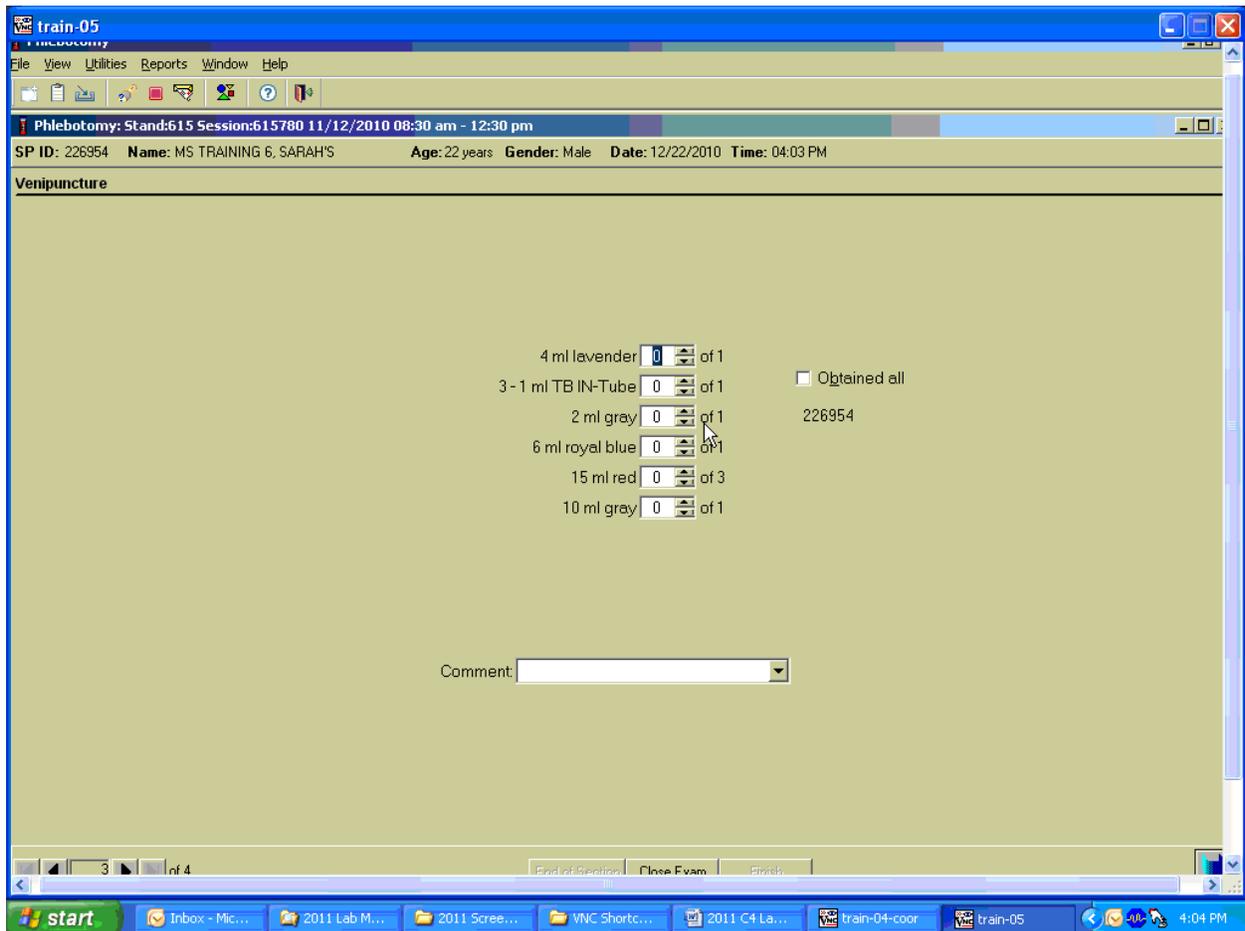
#### **4.11 Hand Venipuncture**

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, 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.

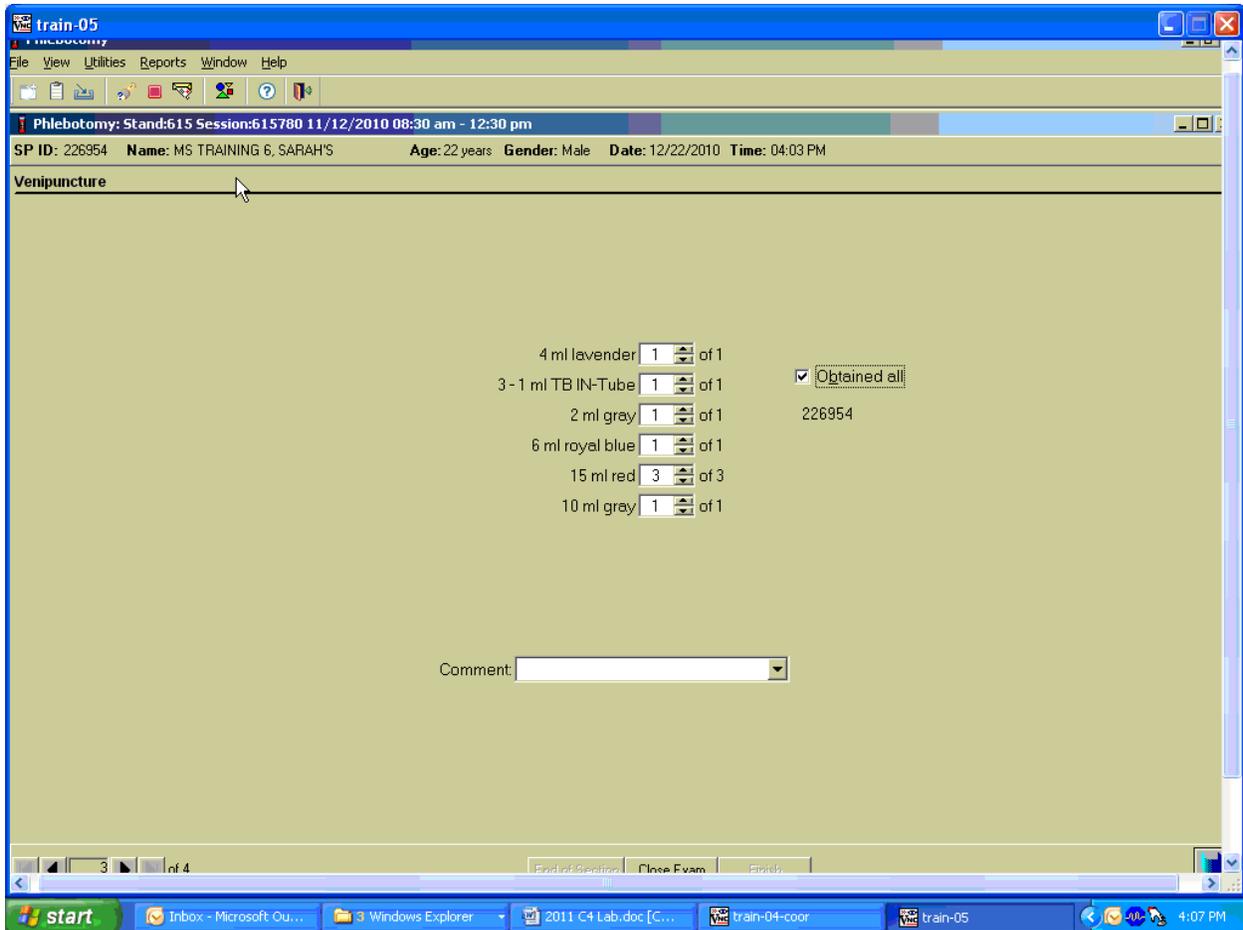
## 4.12 Recording the Results of the Venipuncture Procedure

The Venipuncture screen displays the tube protocol for the SP.



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.



To record all tubes as filled or obtained, move the mouse to the “Obtained all” checkbox and click, or type [Alt] [B/b]. This records a checkmark 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.

**Note: Filling QuantiFERON-TB GOLD In-Tubes (QFT)**

The QFT 1 mL tubes draw relatively slowly, so keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling to ensure that the correct volume is drawn. There is a

black mark on the side of the tubes which indicates the 1 mL fill mark. The QFT blood collection tubes have been validated for volumes ranging from 0.8 to 1.2 mL. If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample.

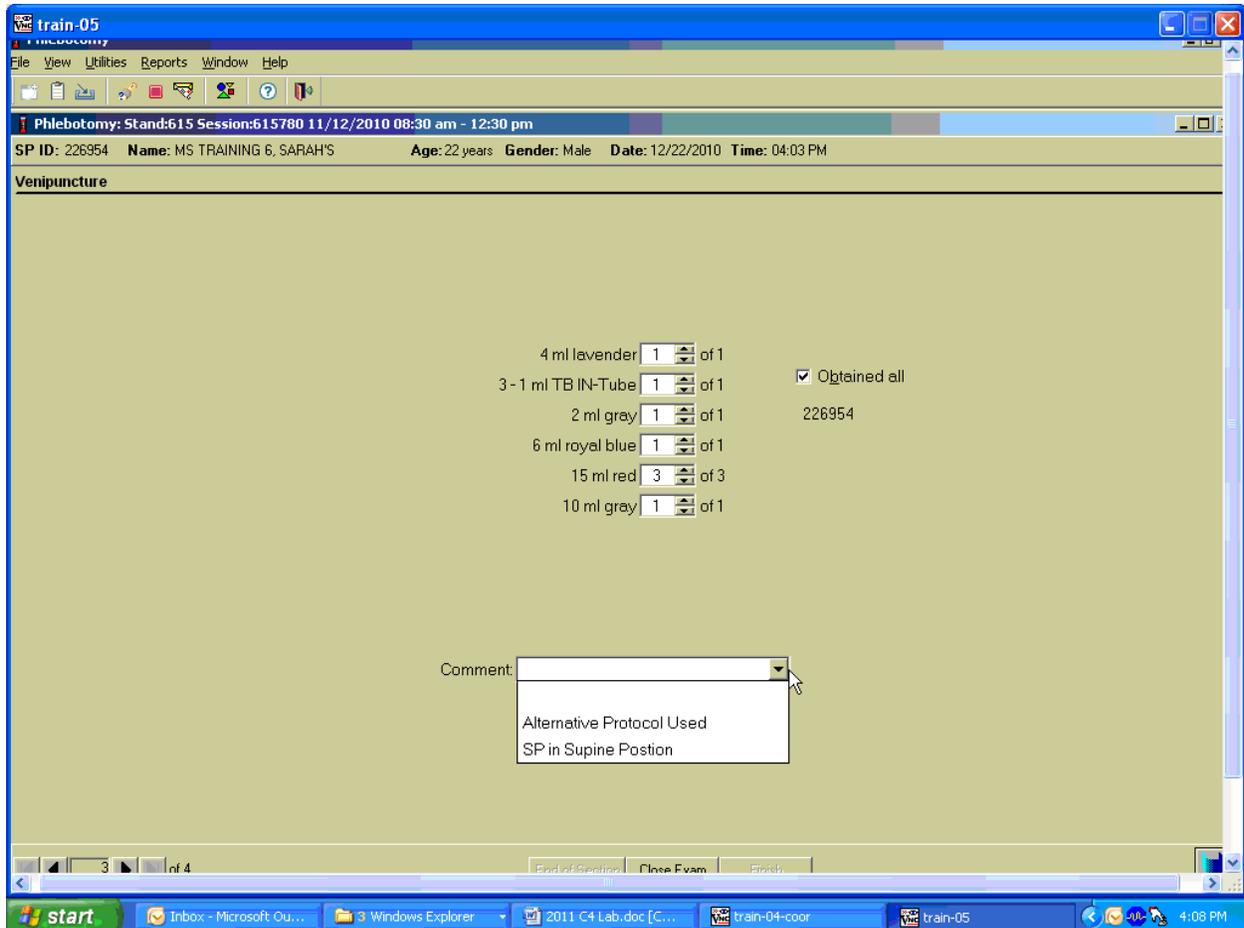
As a guide, the picture below illustrates the approved fill range.



These tubes contain antigens that have been sprayed and dried onto the inner wall of the blood collection tubes so it is essential that the contents of the tubes be thoroughly mixed with the blood. Thorough mixing will dissolve the heparin, preventing clotting, and allow resolubilisation of the stimulating antigen. Mixing is performed by vigorously shaking the tubes up and down for 5 seconds (10 times) to ensure that the entire inner surface of the tube has been coated with blood. Proper shaking will lead to frothing of the blood (see illustration below).



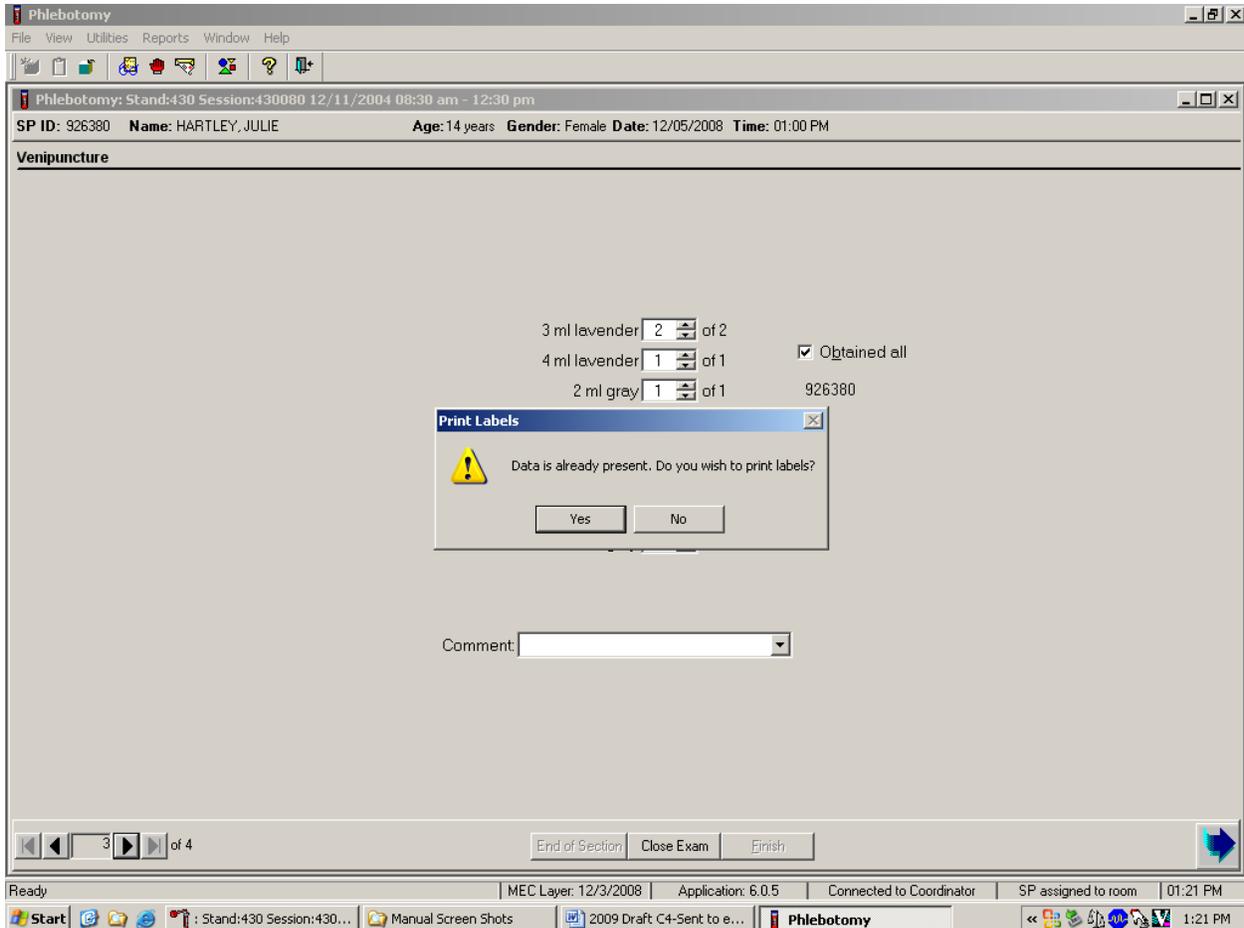
Document circumstances where the alternative protocol was used or the SP was in the supine position.



To record either “Alternative Protocol Used” or “SP in Supine Position” comments in the Comment text box, move the mouse 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 corner and left click, or select [Enter] when this blue arrow is highlighted.

To reprint the Dymo labels, move forward one screen and back using the navigation arrows. A Print Labels informational text box displays. It is also possible to reprint labels in the review mode.



To reprint the labels, use the mouse to direct the mouse arrow to the arrow on the Yes button, and left click. To remove the Print Labels informational text box without reprinting the labels, use the mouse to direct the mouse arrow to the No button and left click.

## 4.13 Venipuncture Status

Verify the venipuncture status.

The screenshot displays the Phlebotomy software interface. The window title is "Phlebotomy". 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 shows the following information:

Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM

**Phlebotomy Status**

Status:

- Complete
- Partial
- Not Done

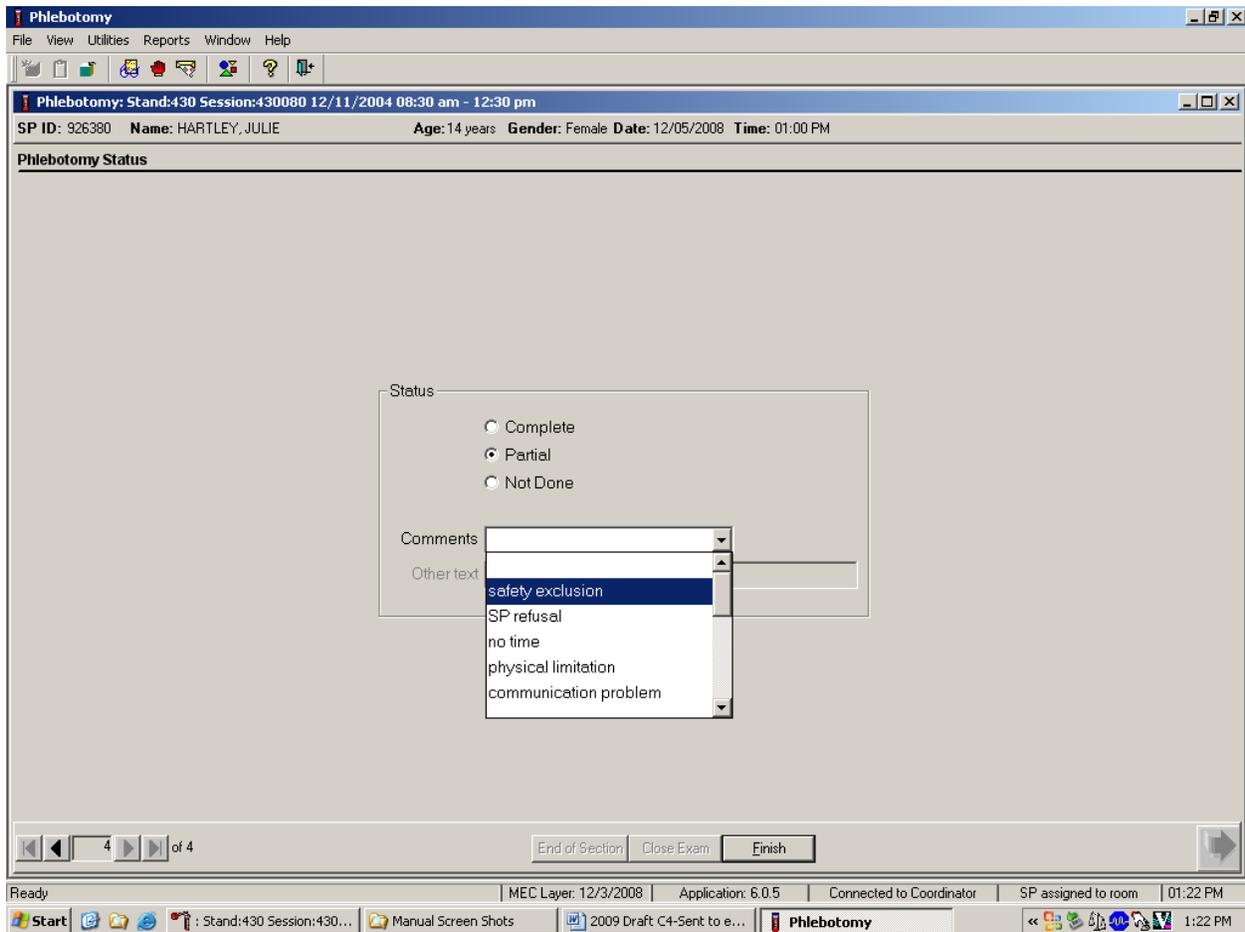
Comments

Other text

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom of the screen shows "Ready", "MEC Layer: 12/3/2008", "Application: 6.0.5", "Connected to Coordinator", "SP assigned to room", and "01:21 PM".

The venipuncture status is complete if all tubes were collected.

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

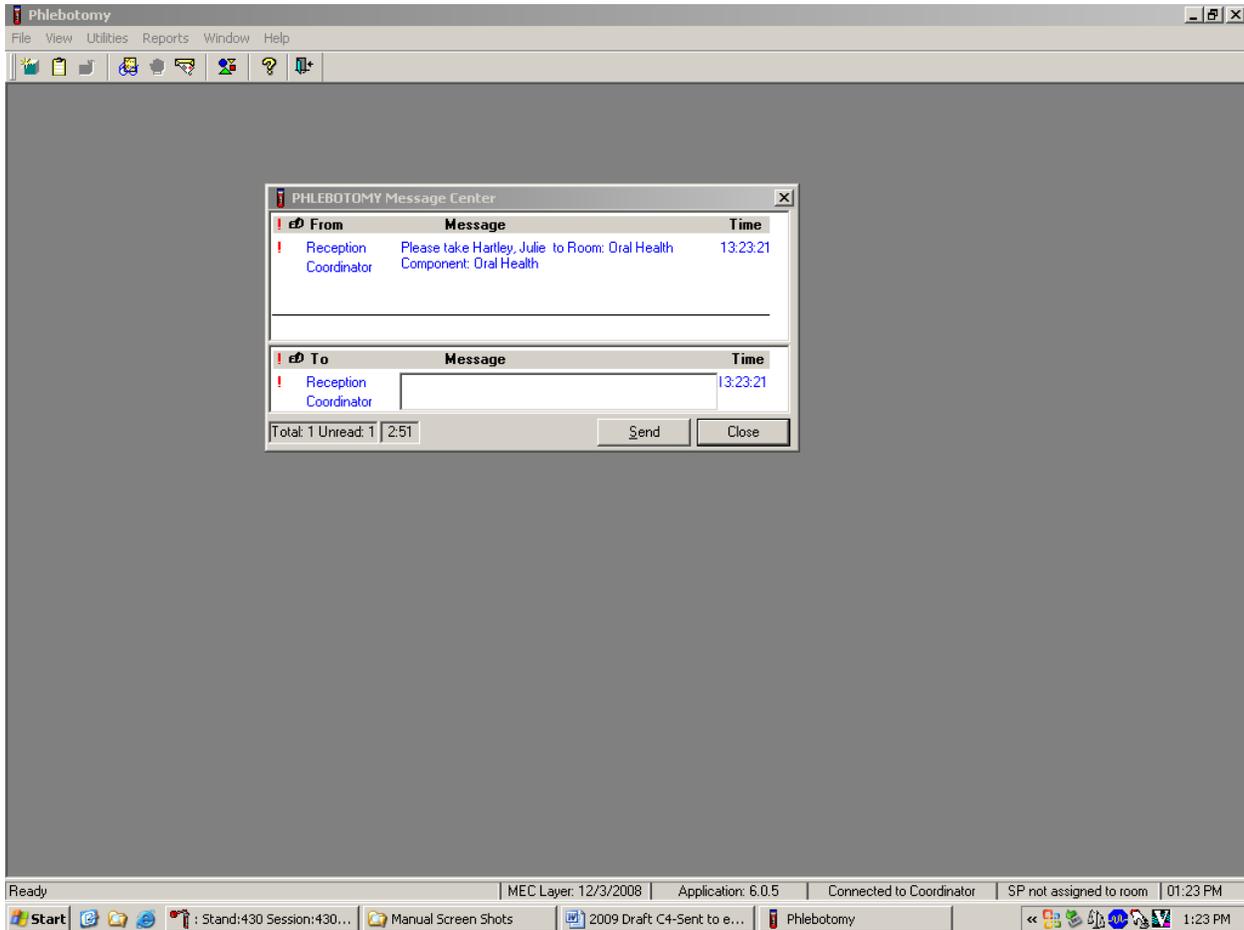


Choose and enter the appropriate comment code when the venipuncture section status is Partial or Not Done. To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. 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.
SP refusal	The SP refuses to have his or 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. All SPs will be sent to the exam room to have their arm band bar code scanned and coded. 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	Not applicable.
Communication problem	Not applicable.
Equipment failure	Not applicable.
SP ill/emergency	Not applicable.
Interrupted	Not applicable.
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.
No suitable vein	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.
Vein collapsed	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 vein collapses.
SP not feeling well	Use this comment to code Not Done or Partial when the SP is about to faint or the SP became ill and the test could not be performed on the SP.
Fainting episode	Use this comment to code Not Done or Partial when the SP faints and the test could not be performed on the SP.
No tubes drawn	Use this comment to code exams as Partial when no tubes are drawn.
Language barrier	Not applicable.

When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click to exit 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 Repeat Blood Draw**

In rare circumstances a result from the complete blood count may be an extreme value that would be considered a “panic” value in clinical practice. An example is severe thrombocytopenia. The physician may repeat the complete blood count if the participant reports no history of nosebleeds or prolonged bleeding and the physician verifies that the site of the first venipuncture clotted normally. The second complete blood count will overwrite the first results in ISIS and will be used for reporting and referrals.

##### **Problem Identification**

Rare occurrences of critical CBC results, particularly low platelet counts, have been observed that resulted in an awkward medical referral for the physicians on the MEC. While the med techs and physician may suspect a laboratory instrument or blood collection effect in the reported results, it is not standard practice to repeat the test with a new blood specimen from a second phlebotomy. There is nothing in the phlebotomy, laboratory, and physician protocols that requires a second blood draw on an SP when critical results are obtained.

False low platelet results (low) are most likely the result of micro clots that cannot be observed. The techs do visually look for clots but they will not see micro clots. Many false low platelet results are caused by cold agglutinins. The techs are able to recognize cold agglutinins because the platelet number will decrease each time the blood is run. In this instance they warm the blood and rerun the sample.

The NHANES protocol is unusual because it requires the techs to run all samples in duplicate (whenever possible), whereas a clinical lab would only rerun a sample if the result was abnormal.

##### **Recommended Action**

If the physician feels a repeat blood count is needed, then he or she has the discretion to discuss this with the SP and have the phlebotomist draw a 3-mL EDTA tube for a repeat CBC if the SP

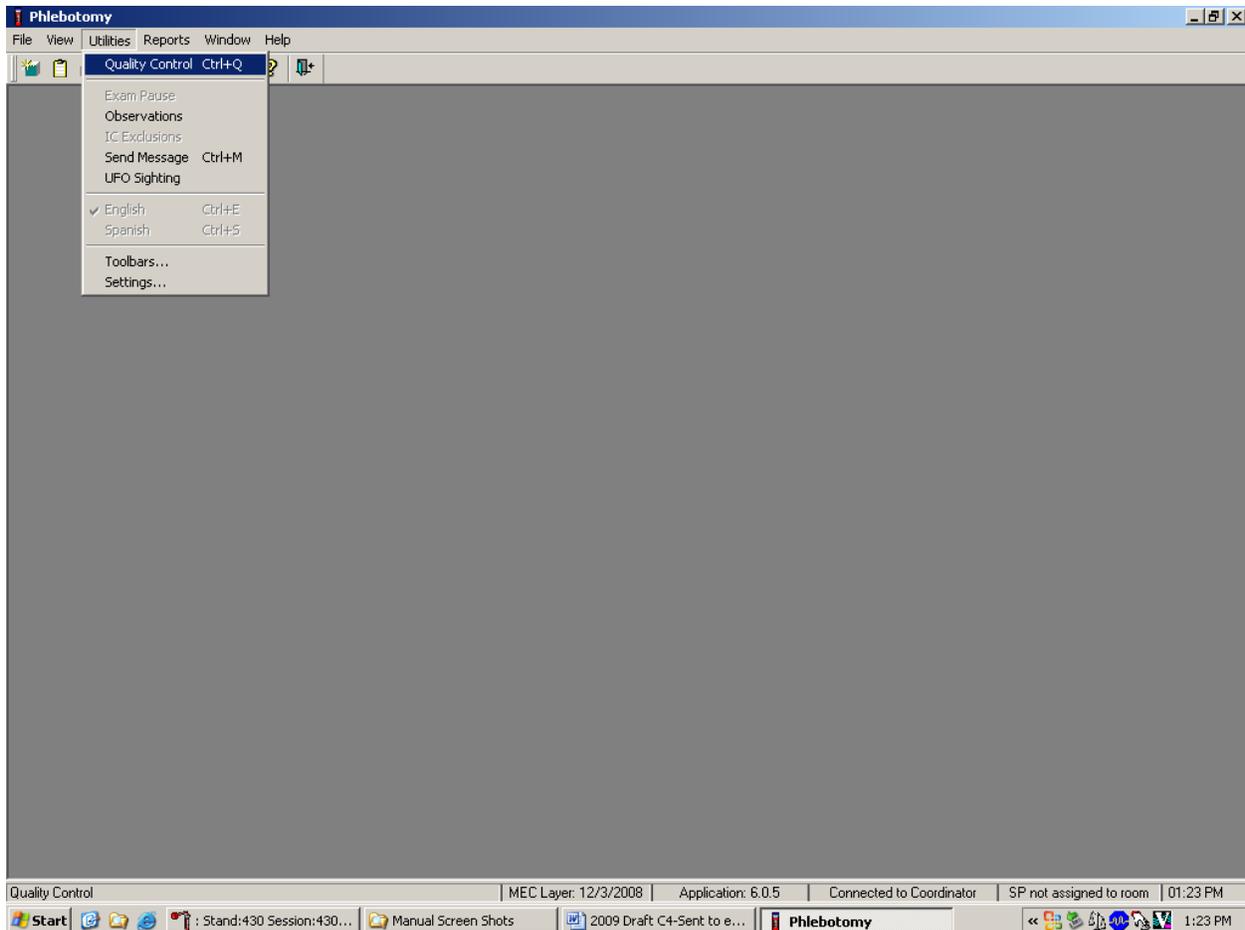
agrees. Prior to a second phlebotomy, the physician should visually inspect the site of the first venipuncture to rule out prolonged bleeding. If the puncture site looks normal, then a second phlebotomy can be requested. The SP always has the right to refuse the blood draw. The need for this action should be rare as evidenced by the four total low platelet counts in the last 2 years.

After the physician reviews the findings with the SP, and the SP agrees to a repeat CBC phlebotomy:

- The physician should consult with the MEC manager and chief med tech to arrange to have the blood drawn at the next earliest opportunity.
- If the SP is eligible for the second GTT blood draw, we currently require the phlebotomist to draw any tubes that might not have been collected during the first blood draw. The second 3-mL EDTA tube could be drawn at that time but the phlebotomist will need to be alerted because the tube will not display on the GTT blood draw protocol screen.
- If the SP is not eligible for the GTT blood draw then he or she will need to be walked to phlebotomy to have the blood drawn.
- This additional blood draw will not be supported by the laboratory and phlebotomy applications.
- As long as the SP has not checked out of the MEC or if the Report of Findings has not been printed, the lab application will allow the med techs to overwrite the existing CBC data with the new data and the new data will become the final result of record.
- The physician will document this event under observations in the physician application.

## 4.15 Phlebotomy Quality Control

Perform phlebotomy quality control at the end of the second session even if there are no SPs scheduled into either session. Record the room temperature reading and the action that the counters were disinfected using the End of Session tab. Record the supply lot numbers and expiration dates by using the Supply Use tab.



To access the phlebotomy Quality Control 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].

## 4.15.1 Daily QC

Record the daily quality control activities at the end of the second session. Mark each Done checkbox with a checkmark.

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

To record a checkmark in the Room Temp. Reading checkbox, use the mouse to direct the mouse arrow to the checkbox 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 chief med tech.
Disinfect Counters	<input type="checkbox"/>		

To record a checkmark in the Disinfect Counters checkbox, use the mouse to direct the mouse arrow to the checkbox 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.

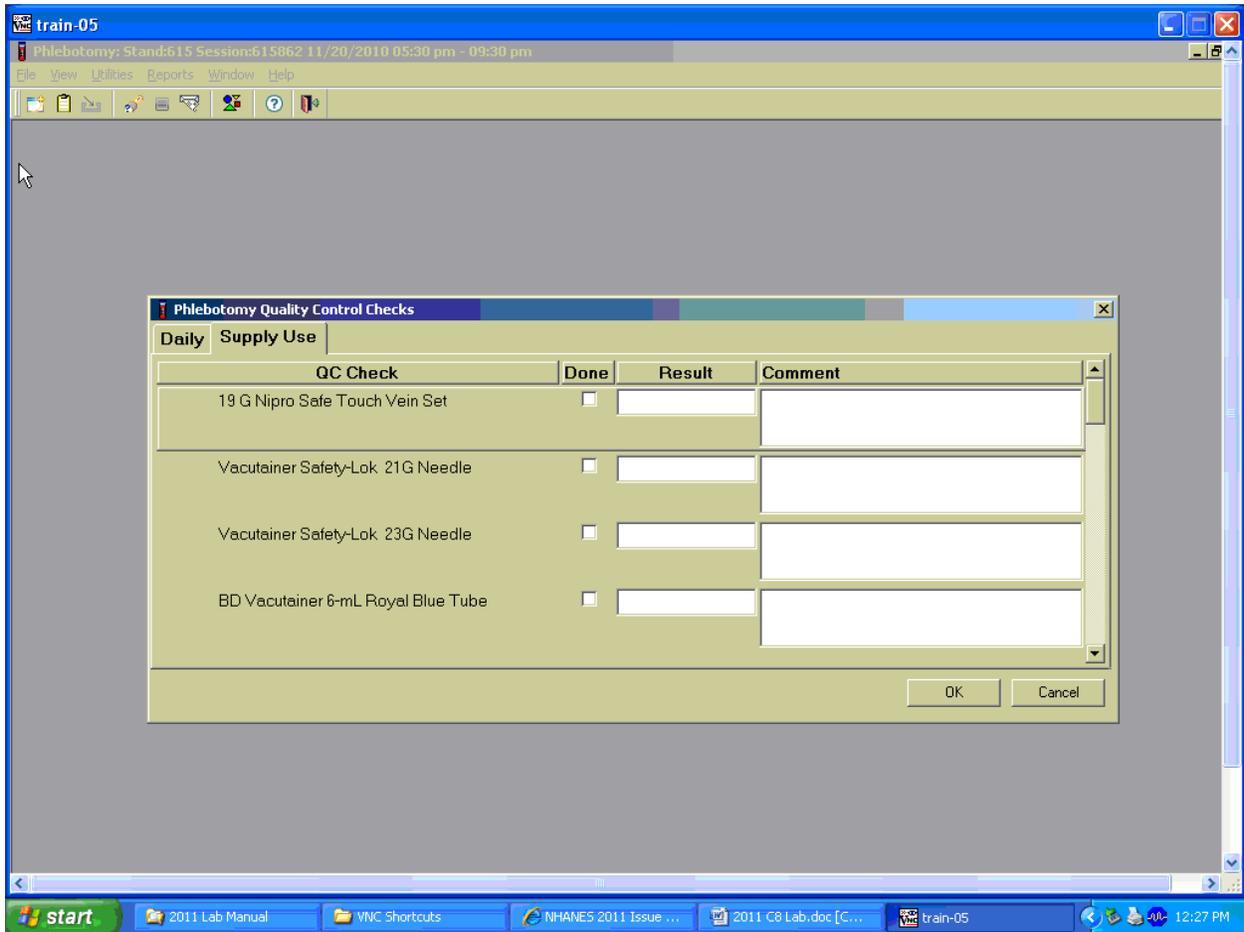
#### 4.15.2 Supply Use Control Log

Many items have specific lot numbers and expiration dates. Enter the lot numbers and expiration dates in the Supply Use module. This module lists every inventory item associated with the phlebotomy component that includes a lot number and expiration date.

<i>Item</i>	<i>Lot Number</i>	<i>Expiration Date</i>
19G Nipro Safe Touch Vein Set	Yes	Yes
Luer Adapter	Yes	No
Vacutainer Safety-Lok 21G Needle	Yes	Yes
Vacutainer Safety-Lok 23G Needle	Yes	Yes
BD Vacutainer 6 mL Royal Blue Tube	Yes	Yes
Quantiferon TB In-Tube	Yes	Yes
BD Vacutainer 3-mL EDTA Blood Tube	Yes	Yes
BD Vacutainer 4-mL EDTA Blood Tube	Yes	Yes
BD Vacutainer 2-mL Gray Blood Tube	Yes	Yes
BD Vacutainer 3-mL Red Blood Tube	Yes	Yes
BD Vacutainer 7-mL Red Blood Tube	Yes	Yes
BD Vacutainer 10-mL Red Blood Tube	Yes	Yes
Sherwood Kendall 15-mL Red Blood Tube	Yes	Yes
BD Vacutainer 7-mL EDTA Blood Tube	Yes	Yes
BD Vacutainer 10-mL EDTA Blood Tube	Yes	Yes
VOC 10-mL Vacutainer Blood Tube	Yes	Yes
Trutol Glucose Drink – Fruit Punch	Yes	Yes
Trutol Glucose Drink – Lemon/Lime	Yes	Yes
Trutol Glucose Drink – Orange	Yes	Yes
Apple Juice	No	Yes
Orange Juice	No	Yes
Solar Thermometer	No	Yes
Ammonia Ampules	Yes	Yes

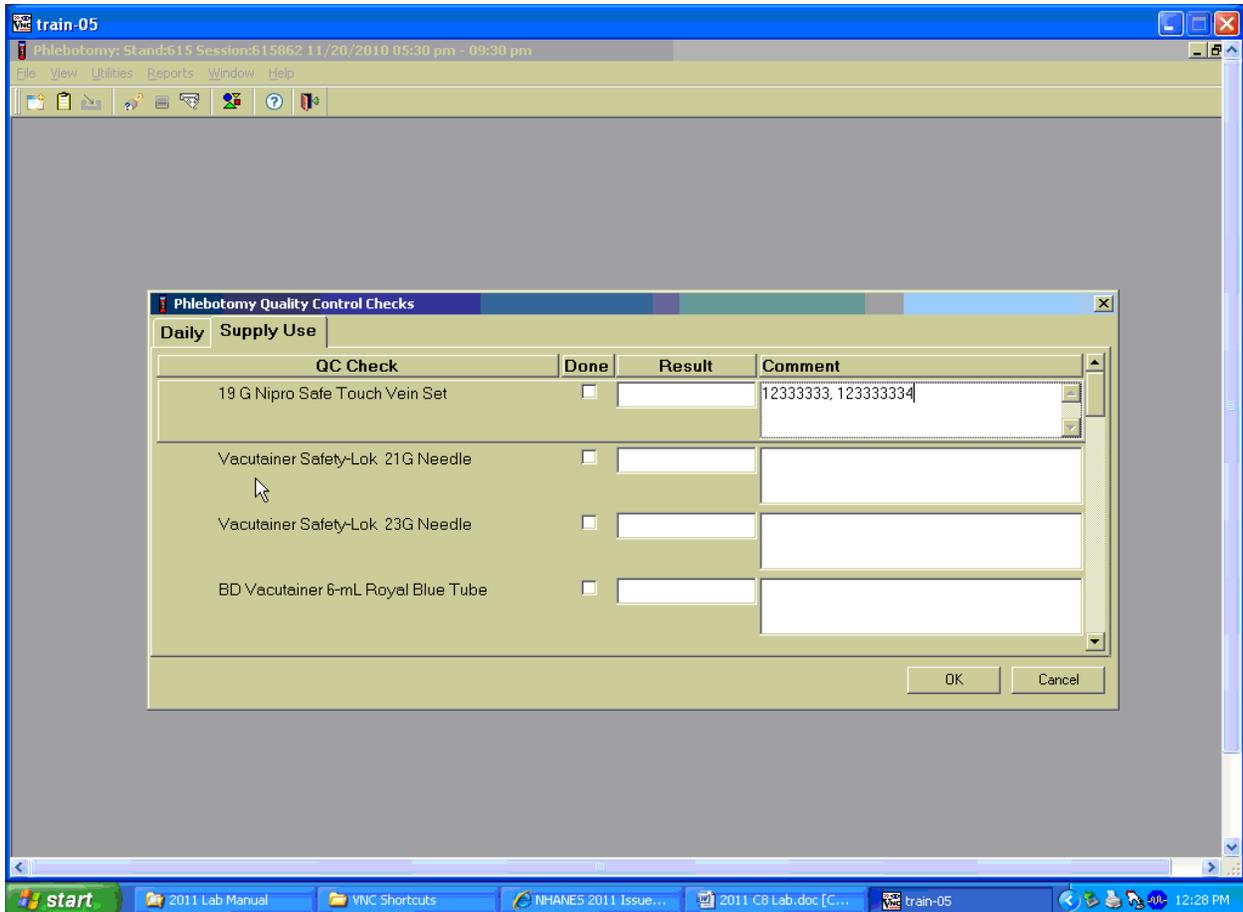
**Note:** TB QFT Blood tubes must be held in a controlled environment between 63-81° F. Send TB QFT blood tubes back to the warehouse at the end of each stand for proper storage.

Use the Supply Use tab to enter lot numbers and expiration dates.



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 checkbox and record the lot and expiration date of each item. Perform this activity 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.

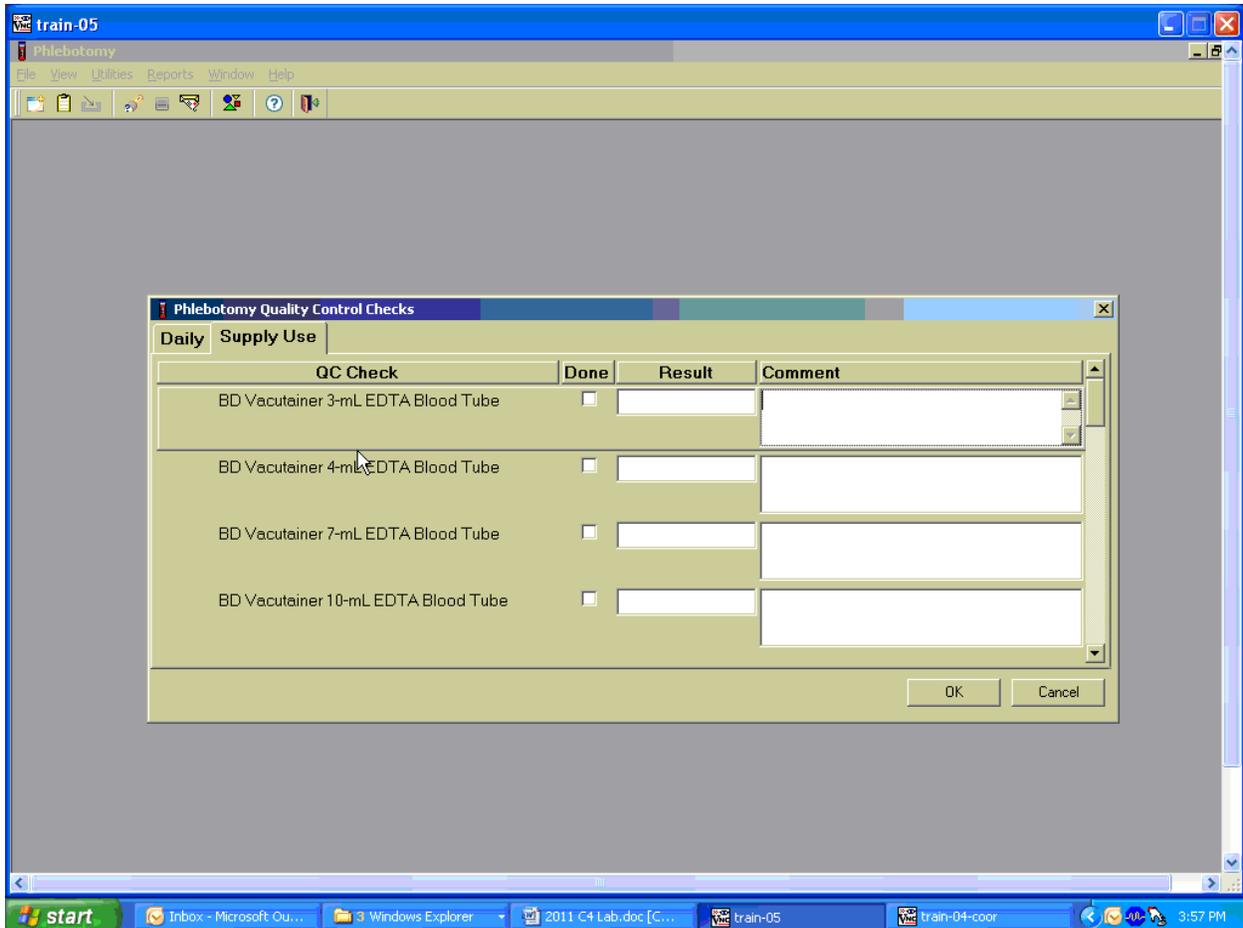


To record an activity as complete or done, use the mouse to direct the mouse arrow to the checkbox in the “Done” column and left click to insert a checkmark. Select [Tab] or [Enter] to move to the Result text box. Do not enter the response or reading in the Result text box. Select [Tab] or [Enter] to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

**For each item:**

- **Record the lot number** (if the item does not have a lot number, then record “no lot”;
- **Add a comma;**
- **Add a space; 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 these results 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.

#### 4.16 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 either roll the SP onto his or her side or turn the SP's 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 or 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>

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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.

#### **4.17      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.

Exhibit 4-6. Phlebotomy worksheet – English Primary  
**PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL**  
**PRIMARY SP**

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

<b>Phlebotomy Interview</b>	Responses <b>Yes, No, Refused, Don't Know</b>	
Do you have hemophilia?		
Have you received cancer chemotherapy in the past 4 weeks?		
<b>Fasting Questionnaire</b>	Record time and date	
Q1. When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda.		
Confirmation Question: Q2. Have you had any of the following since {insert time from Q1 here}?	Responses <u>Yes</u> , <u>No</u>	If Yes, record time and date
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>	# Filled	Not Filled
3 mL lavender (1 age 1-2, 1 age 3-11 and 1 age 6-11)		
4 mL lavender (1 age 12-19 and 1 age 20+)		
2 mL gray (morning only 1 age 12+)		
6 mL royal blue tops (1 age 6+)		
3 mL red (2 age 1-2, 1 age 3-5)		
7 mL red (1 age 3-5, 1 age 6-11 and 1 age 12-19)		
15 mL red (2 age 12-19, 3 age 20+)		
10 mL red (1 age 6-11)		
10 mL red (5 age 12+ if eligible for Persistent Pesticides, Perfluorinated, Srm Pesticide, and BFR subsamples)		
7 mL EDTA (1 age 12+ if eligible for Perfluorinated and Srm Pesticide subsamples)		
10 mL EDTA (2 age 20+ if not IC excluded)		
10 ml gray (1 age 12+ 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>	<b>Responses</b> <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>	<b>Record time and date</b>	
Q1. ¿Cuándo fue la última vez que comió o tomó alguna cosa aparte de agua sola? No incluya soda de dieta o café o té solo endulzado con endulzadores artificiales como Sweet'N Low, NutraSweet, Equal o Splenda.		
Confirmation Question: Q2. ¿Ha tomado o comido algo de lo siguiente desde ayer a las {insert time from Q1 here}?	<b>Responses</b> <u>Yes</u> , <u>No</u>	<b>If Yes, record time and date</b>
¿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>	<b># Filled</b>	<b>Not Filled</b>
3 mL lavender (1 age 1-2, 1 age 3-11 and 1 age 6-11)		
4 mL lavender (1 age 12+)		
2 mL gray (morning only 1 age 12+)		
6 mL royal blue tops (1 age 6+)		
3 mL red (2 age 1-2, 1 age 3-5)		
7 mL red (1 age 3-5, 1 age 6-11 and 1 age 12-19)		
15 mL red (2 age 12-19, 3 age 20+)		
10 mL red (1 age 6-11)		
10 mL red (5 age 12+ if eligible for Persistent Pesticides, Perfluorinated, BFR <i>and</i> Srm Pesticide subsamples)		
7 mL EDTA (1 age 12+ if eligible for Perfluorinated <i>and</i> Srm Pesticide subsamples)		
10 mL EDTA (2 age 20+ if not IC excluded)		
10 ml gray (1 age 12+ if eligible for VOC subsample)		
Comments:		

The following four screenshots document the English text and official Spanish translations for the phlebotomy component:

- Phlebotomy Interview English,
- Phlebotomy Interview Spanish,
- Fasting Questionnaire English, and
- Fasting Questionnaire Spanish.

### Phlebotomy Interview English

: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

SP ID: 312716 Name: HAMILTON, BARBARA Age: 48 years Gender: Female Date: 12/09/2008 Time: 12:58 PM

Phlebotomy Interview

Are you currently pregnant? No

Do you have hemophilia? No

Have you received cancer chemotherapy in the past four weeks? No

of 4 End of Section Close Exam Finish

## Phlebotomy Interview Spanish

: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

SP ID: 312716 Name: HAMILTON, BARBARA Age: 48 years Gender: Female Date: 12/09/2008 Time: 12:58 PM

**Phlebotomy Interview**

¿Está usted actualmente embarazada? No

¿Tiene hemofilia? No

¿Ha recibido tratamiento de quimioterapia para el cáncer en las cuatro semanas pasadas? No

# Fasting Questionnaire English

**Phlebotomy**

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

SP ID: 306325 Name: KAIGA, NEWTON Age: 13 years Gender: Male Date: 12/09/2008 Time: 12:54 PM

### Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 09:30 PM 12/08/2008

Have you had any of the following since yesterday at 9:30 PM?

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.] No : //

*Fasting 15 Hours 26 Minutes*

## Fasting Questionnaire Spanish

**Phlebotomy**  
File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

SP ID: 306325 Name: KAIGA, NEWTON Age: 13 years Gender: Male Date: 12/09/2008 Time: 12:54 PM

### Fasting Questionnaire

¿Cuándo fue la última vez que comió o tomó alguna cosa aparte de agua sola? No incluya soda de dieta o café o té solo endulzado con endulzadores artificiales como Sweet'N Low, NutraSweet, Equal o Splenda. 09:30 PM 12/08/2008

Ha tomado o comido algo de lo siguiente ¿desde ayer a las 9:30 de la tarde?

¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.] No : //

¿Alcohol, tal como cerveza, vino o licor? No : //

¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado? No : //

¿Antiácidos, laxantes, o anti-diarreicos? No : //

¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.] No : //

*Fasting 15 Hours 27 Minutes*

End of Section Close Exam Finish

## 5. URINE SPECIMEN COLLECTION AND PROCESSING

### 5.1 Introduction

The purpose of urine collection and processing is to collect sufficient urine from participants aged 6 years and older to be able to (1) collect a date, time, and volume of urine collection for analysis of urine flow rate; (2) perform a pregnancy test on selected females aged 8 to 11 years and all females aged 12 to 59 years to exclude pregnant participants from other components that could put the participant at risk; (3) perform a test for osmolality; (4) allocate urine into vessels for storage and transport to multiple government and contact laboratories for analysis; and (5) allocate urine into a vessel for future studies.

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. Place the urine container on the Mettler Toledo scale and then scan the label on the barcode. The weight is converted to volume and transferred to the urine collection module. Visually compare the volume in the urine container to the volume displayed in the urine collection screen. Accept or correct the weight. Perform the pregnancy test if indicated, perform the osmolality test, process the urine protocol, and store the vessels. At least 5-mL of urine is required on VIP guest and guest appointment types.

The MEC coordinator instructs each SP aged 6 years and older to provide a urine sample as soon as possible when he or she enters the MEC. Ideally, this sample would be collected at the same time that the SP changes into the exam outfit. If the SP cannot provide a urine sample at that time, the coordinator offers the SP a glass of water and asks the SP to provide a sample as soon as possible. The SP is instructed to collect a complete void by emptying the bladder into the urine collection cup. The coordinator, assistant coordinator, or any MEC staff member is responsible for transporting the urine specimen to the laboratory.

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

- It is important to collect ALL urine by COMPLETELY emptying your bladder into the cup.
- Wash hands with soap and water.
- Take the cap off the cup.

- Urinate directly into the cup until it is full or until you have finished urinating.
- DO NOT OVERFILL THE CUP.
- The inside of the cup and cap should not touch or come into contact with any part of your body, clothing, or external surfaces.
- Recap the collection cup and seal tightly.
- Please remember to wash your hands.

## 5.2 Supplies

The supplies needed for urine collection and urine processing and storage are listed in Exhibits 5-1 and 5-2.

Exhibit 5-1. Urine collection equipment

<b>Blue Scale Carrying Case</b>
Mettler Toledo PL601-S Scale Cone protector Weigh pan One Troemner 100g weight (start of stand QC) Two Troemner 300g weights (start of stand QC)
<b>Care Pac M</b>
Cleaning cloth Two gloves Weight transfer tool for 500g weight Weight transfer forceps for 10g weight Cleaning brush One Ohaus 500g weight (daily QC) One Ohaus 10g weight (daily QC)
<b>Clear Acrylic Scale Cover</b>
<b>Barcode Scanner</b>

Exhibit 5-2. Urine collection supplies – urine processing and storage

5-mL cryovial sterile	14-mL Falcon snap cap test tube
2-mL cryovial	Cube rack – 4 way flipper rack
10-mL VWR screwcap vial with colored dot (Urn Merc)	10-mL VWR screwcap vial
Bench Kote paper	Kimwipes
10x10 three inch box	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
3.5 mL Starstedt Transfer pipette	VWR 15mL narrow stem, large bulb disposable transfer pipette
Nonsterile, powder-free, gloves—small, medium, large	Windex for scale cleaning

### 5.3 Urine Flow Rate Background

The NHANES protocol includes many measures of environmental toxicants or their metabolites in urine. It is difficult to quantify the level of exposure based on measurements in urine because concentrations will vary by the amount of urine produced. Currently, NHANES urine measurements are adjusted by the urinary creatinine concentration to account for variations in urinary dilution. However, creatinine excretion into the urine varies by many factors other than the urinary dilution (e.g., age, gender, muscle mass, and diet). Also, the amount of toxicant excreted in a 24-hour period is often needed to quantify exposures for risk and exposure assessment purposes. Ideally, this requires 24-hour urine collections but this is impractical in NHANES for logistical reasons. However, it is possible to estimate the mass of analyte excreted in the urine in a 24-hour period by estimating the urine flow for the spot urine specimen collection (i.e., equivalent to a single urine specimen as collected in the current NHANES protocol).

The date and time of last urine void, along with the volume of the urine specimen and the date and time of urine collection captured during urine collection will provide NCHS with a measurement of urine flow rate. These items are captured during the SP’s visit to the MEC. All SPs aged 6+ will be eligible for urine flow rate. Urine specimen volume and date and time of collection will be captured only on SPs who submit a urine specimen.

The MEC appointment reminder letter will include the reminder “Before arriving at the exam center, please make a note of the time you last went to the bathroom and urinated (peed). Please

write the time on the appointment card you were given. You will be asked for this time when you get to the exam center,” and will provide a space for the SP to write a response. When the SP arrives at the MEC, the coordinator will prompt the SP to write down the time of his or her last urine void on the verification form. The coordinator will record this time. If there is any discrepancy between the time on the reminder letter and the time reported at the MEC, the coordinator should use the time reported at the MEC.

#### 5.4 Using the Scale for Urine Collection

The Mettler Toledo scale is located in the clean laboratory area near workstation 2. Check to make sure the scale’s weighing pan is free of any objects or debris. Turn on the Mettler Toledo scale by pressing the “On” button. After the display briefly lights up all segments, the LED will display “0.0 g.” This indicates that the scale is ready to weigh samples. The scale should be used only when set to measure in grams. Cover the scale with the clear acrylic scale cover until a sample is available for weighing.

Ensure that computer workstation 2 (Urine/Sink) is turned on and a technician is logged into the Laboratory application. Open the Urine Scale application by double clicking on the Urine Scale icon on the desktop. The Urine Scale icon looks like this:



The Urine Scale application icon will appear in the system tray, similar to the Coulter application. This application captures data from the scale and logs it into the database. The Urine Scale application must be opened and in the system tray in order to capture any urine collection readings from the scale.



Place the urine collection cup on the Mettler Toledo scale. Cover the scale with the clear box cover to protect the scale from draft. Look at the scale's LED display. In the bottom left corner of the display the stability detector "o" will appear briefly. Once the stability indicator goes away, the weight result is valid. Scan the barcode on the cup using the barcode scanner next to the scale.



Look at the scale's LED screen to ensure that the SP ID displays. Checking for the SP ID display on the LED screen is verification that the collection was recorded in the database.

Once the urine cup has been successfully scanned, move it to workstation 2.

## 5.5 Document Urine Collection

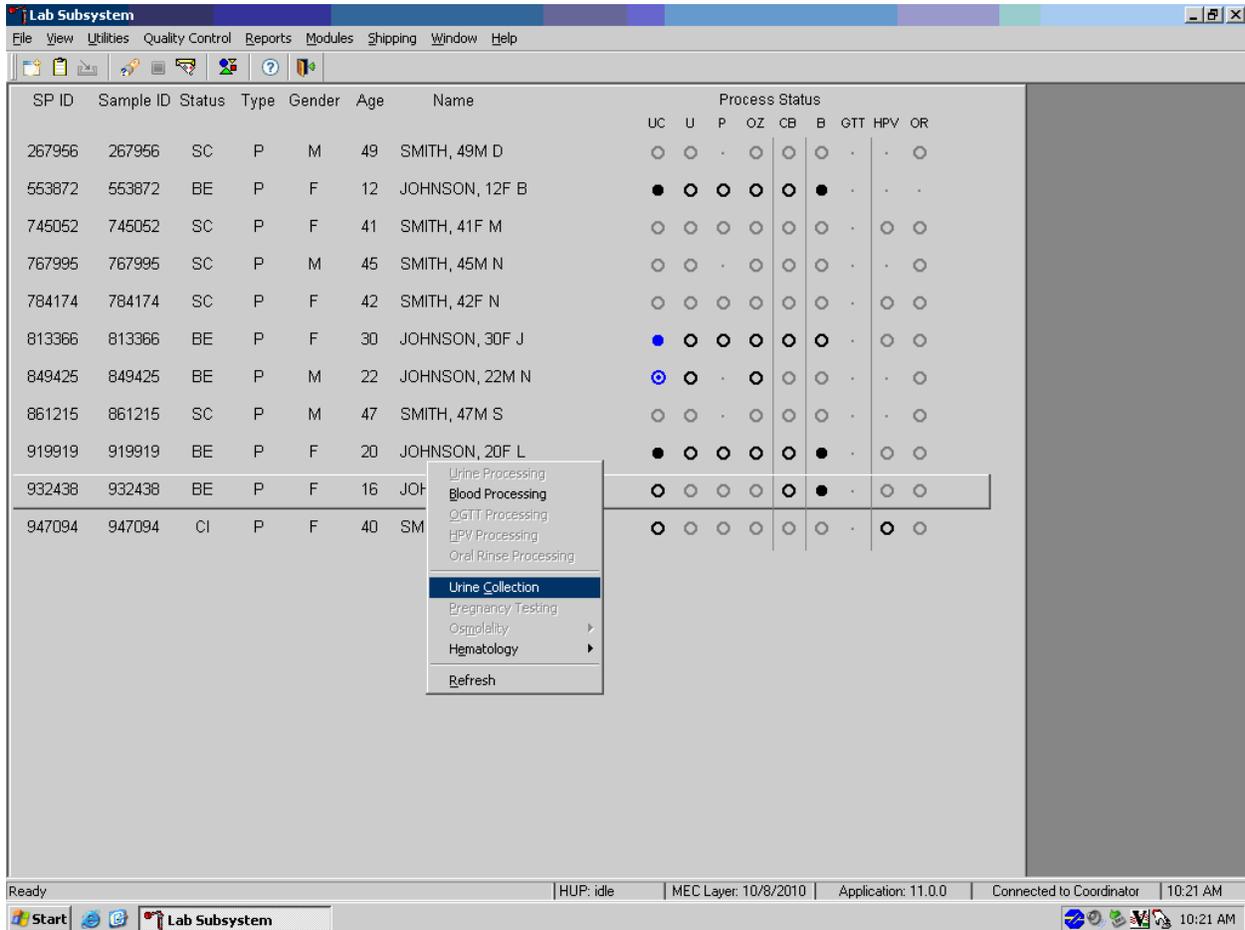
Once a urine sample has been scanned in, the UC circle on the heads-up screen for that SP will turn blue (◉ for QNS or ● for Yes). The blue color indicates that there is a urine sample in the lab ready to be validated by the laboratory technician.

The screenshot shows a software window titled "Lab Subsystem: Stand:615 Session:615811 11/15/2010 01:30 pm - 05:30 pm". The window contains a table with the following columns: SP ID, Sample ID, Status, Type, Gender, Age, Name, and Process Status. The Process Status column includes sub-columns for UC, U, P, OZ, CB, B, GTT, HPV, and OR. The row for SP ID 813366 is highlighted, showing a blue circle in the UC column.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status								
							UC	U	P	OZ	CB	B	GTT	HPV	OR
267956	267956	SC	P	M	49	SMITH, 49M D	○	○	-	○	○	○	-	-	○
553872	553872	BE	P	F	12	JOHNSON, 12F B	●	○	○	○	○	●	-	-	-
745052	745052	SC	P	F	41	SMITH, 41F M	○	○	○	○	○	○	-	○	○
767995	767995	SC	P	M	45	SMITH, 45M N	○	○	-	○	○	○	-	-	○
784174	784174	SC	P	F	42	SMITH, 42F N	○	○	○	○	○	○	-	○	○
813366	813366	BE	P	F	30	JOHNSON, 30F J	●	○	○	○	○	○	-	○	○
849425	849425	BE	P	M	22	JOHNSON, 22M N	◉	○	-	○	○	○	-	-	○
861215	861215	SC	P	M	47	SMITH, 47M S	○	○	-	○	○	○	-	-	○
919919	919919	BE	P	F	20	JOHNSON, 20F L	●	○	○	○	○	●	-	○	○
932438	932438	BE	P	F	16	JOHNSON, 16F L	○	○	○	○	○	●	-	○	○
947094	947094	CI	P	F	40	SMITH, 40F L	○	○	○	○	○	○	-	○	○

At the bottom of the window, a status bar displays: Ready | HUP: idle | MEC Layer: 10/8/2010 | Application: 11.0.0 | Connected to Coordinator | 04:29 PM. The taskbar shows the Start button, a search icon, and the application icon "Lab Subsystem: Stan...". The system tray shows network, volume, and power icons, along with the time "4:30 PM".

Select an SP with a blue UC circle and access the Urine Collection module.



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 Urine Collection module, drag the mouse arrow to {Urine Collection}, and left click or left click and type [C/c].

The urine collection window displays.

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

SP ID: 220901 NAME: RUSSELL\_2, JACK AGE: 25 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	203	12/19/2008 04:16 PM	Yes	(none)	<input type="checkbox"/>

Total Collected: 203  
Total Required: 55

Buttons: Save, New Collection, OK, Cancel

The top of the urine collection window contains columns for the SP ID, Person Name (last, first), Gender, and Age. The row for checked-in SPs is indicated in black, while SPs who have not checked into the MEC session are gray. SPs who have a urine collection ready for verification display in blue. Use the scroll bar to view all SPs scheduled into the session. 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.

The lower portion of the urine collection window displays the selected SP ID, Person Name (last, first), Gender, and Age. Below that are columns for Collection instance, Volume (mL) in whole numbers, Collection date/time, Collection status, Comment code, and a checkbox for Verify. The bottom of the screen displays the Total Collected (sum in mL of all urine collections) and Total Required (total mL required to meet the SP's urine protocol). The total volume includes 2-mL for pregnancy testing and osmolality for eligible female SPs, and 1-mL for osmolality testing only on pregnancy test ineligible female SPs and all male SPs.

**One gram of urine is equal to one mL of urine. The application records the weight of the urine in whole numbers following standard rounding procedures.**

If the SP has submitted a urine collection that has been weighed and scanned into the database, the volume, collection status, and collection date and time will automatically display in the lower portion of the Urine Collection screen. If the collection did not meet the minimum requirement for the protocol, the system will automatically select "QNS" with the comment code "quantity not sufficient." A QNS result immediately notifies the coordinator to prompt for an additional urine collection. A second instance of urine collection for the first QNS sample or third instance of urine collection for the second QNS sample will appear below the current sample. If the quantity of urine collection does meet the requirement of the urine protocol, the system will automatically select "Yes" and no additional collections will appear.

Evaluate the quantity of urine received in the laboratory.

Sp ID	Sample ID	Name	Gender	Age
300780	300780	MARTIN_5, JOE	M	46
304240	304240	BUTLER_5, CATHY	F	22
304755	304755	MARTIN_7, THOMAS	M	22
305504	305504	HOLLAND_6, LISA	F	30
306771	306771	MILLER_3, PATTY	F	50
306998	306998	FULTON_6, JEREMY	M	54
307322	307322	ESTRADA_4, JOSE	M	25

SP ID: 307322 NAME: ESTRADA\_4, JOSE AGE: 25 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	26	11/04/2009 10:46 AM	QNS	quantity not suffic	<input type="checkbox"/>
2			(none)	(none)	<input type="checkbox"/>

Total Collected: 26  
Total Required: 55

Compare the number displayed in the Total Collected column and the actual volume of urine in the cup. If manual adjustment is needed, follow instructions listed in Section 5.6.

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 “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 “QNS” and left click. A “QNS” result automatically turns the lab progress bar yellow on the Coordinator screen. This yellow progress bar alerts the coordinator, who then asks the SP to provide an additional urine specimen.

**Refrigerate all insufficient urine samples. When additional urine is obtained and collected, pool the urine into the most recently collected cup (the cup with the highest urine collection instance number on the cup label), 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. The coordinator also has the ability to mark urine as “No” with a comment code. The Laboratory application will not be able to modify any entries made by the coordinator.

**Urine Collection Verification: 430420**

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

**SP ID: 244445 NAME: NELSON\_2, JENNY AGE: 36 Gender: F**

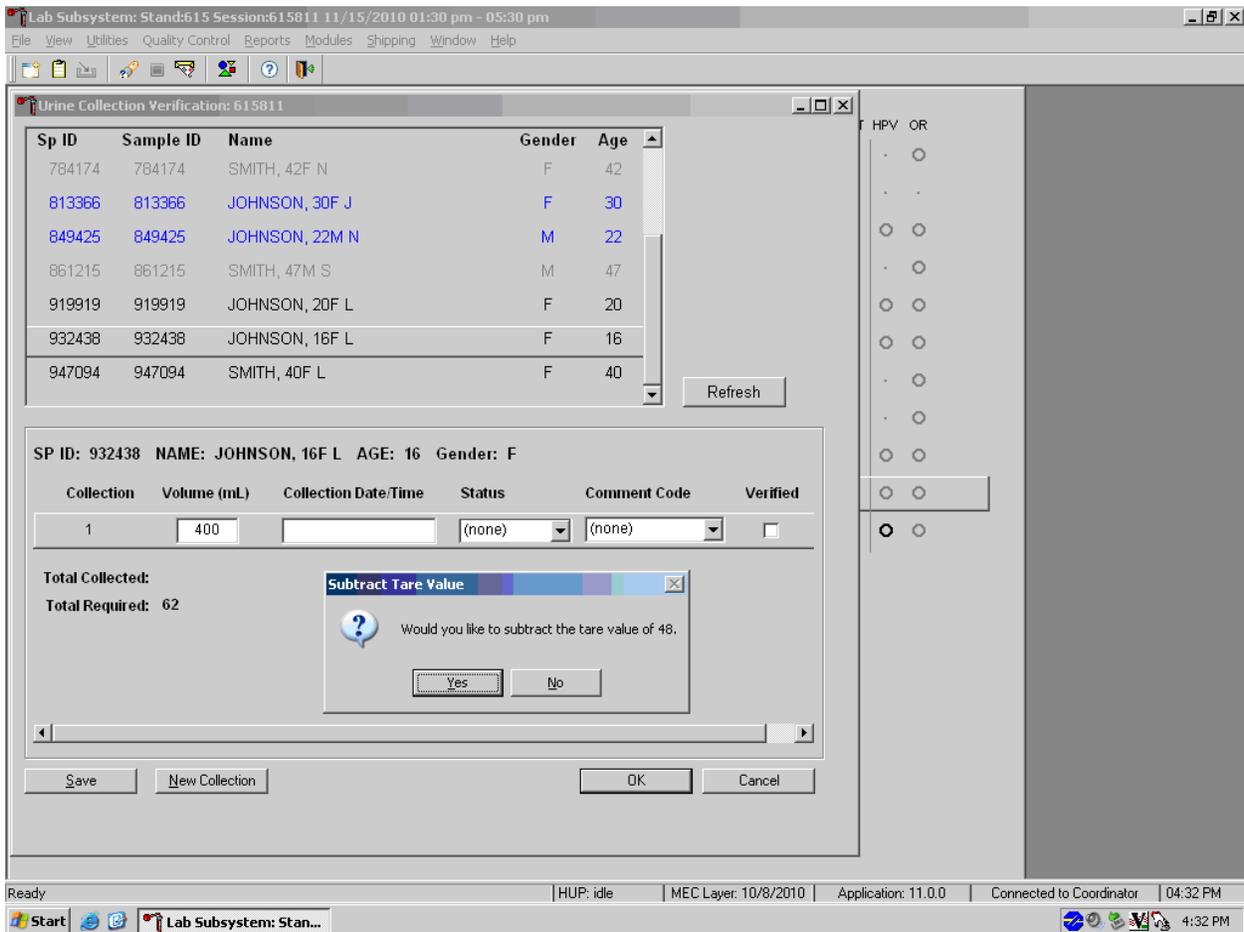
Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	25	12/19/2008 04:13 PM	QNS	quantity not suffic	<input type="checkbox"/>
2			(none)	communications problem SP unable to comply quantity not sufficient SP refusal SP ill/emergency no time	

**Total Collected: 25**  
**Total Required: 56**

Buttons: Save, New Collection, OK, Cancel

The urine collection cup capacity may contain a sample that weighs more than the scale weight capacity of 610 grams. Look at the scale display for full specimens. If the scale displays dashes when it should display a weight, the reading is over the scale limit:  $\Gamma - - - - \Upsilon$ . When the barcode for the sample is scanned in, instead of the barcode number displaying on the LCD screen, the words “over Lnt” display.

When the scale is over limit it does not transmit data to the ISIS application. Manually enter the volume 610 mL in the volume column.



Press “Tab” to move to the Collection Date/Time field. The application will ask “Would you like to subtract the tare value of 48”? Select OK. Enter the date and time of specimen collection. Press tab to continue on to the Status field.

**Urine Collection Verification: 430420**

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

**SP ID: 220901 NAME: RUSSELL\_2, JACK AGE: 25 Gender: M**

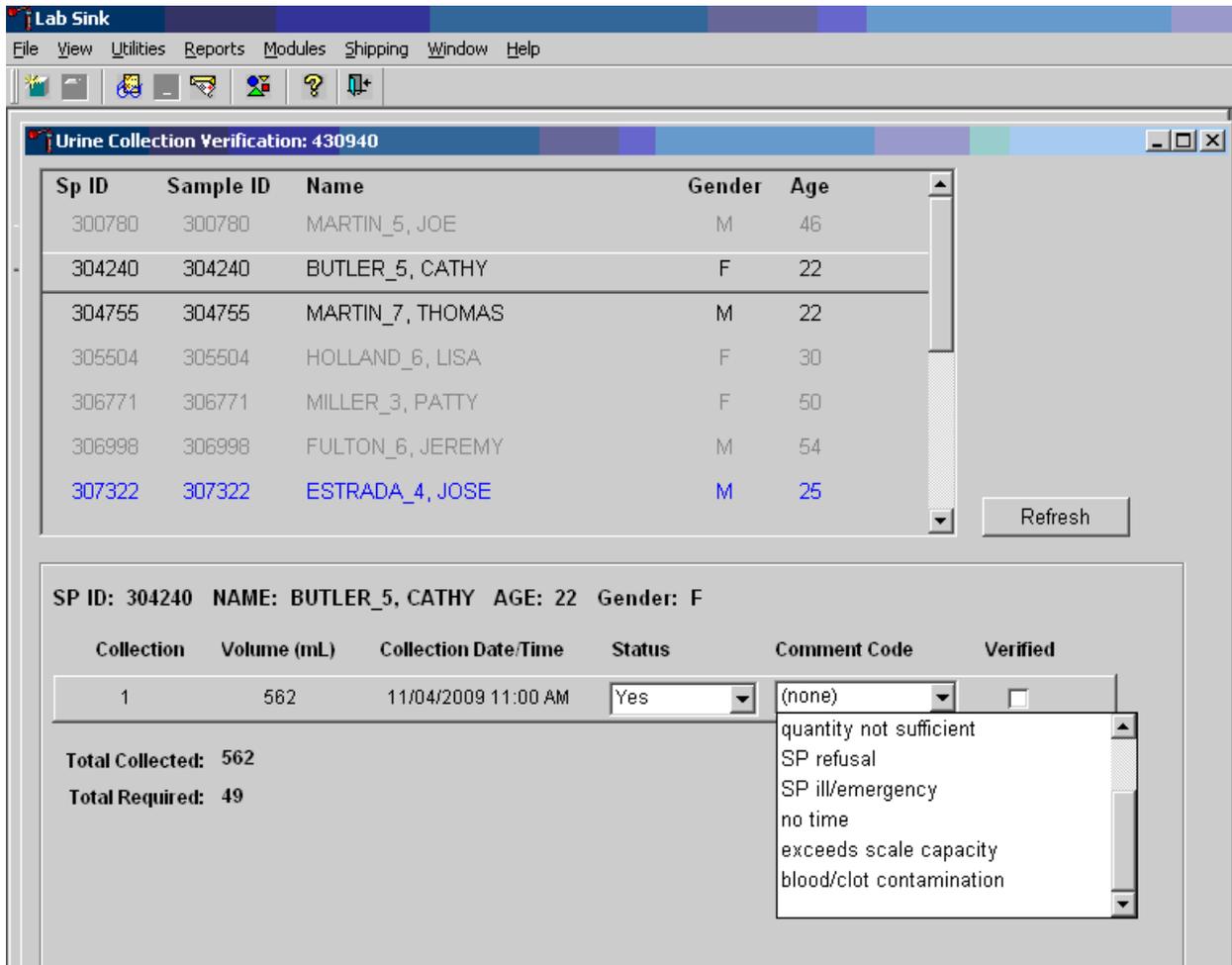
Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	556	12/19/2008 03:30 PM	Yes	(none)	<input type="checkbox"/>

**Total Collected: 556**  
**Total Required: 55**

Save    New Collection    OK    Cancel

Record urine collections that exceed the scale as “Yes.” To mark the urine collection status, direct the mouse arrow to the drop-down list, click to display the different status, and select “Yes” by clicking once on “Yes” with the mouse arrow. Use the Tab key to proceed on to the Comment Code field.

Record a comment for sufficient urine collections if the weight of the urine exceeds the scale weight capacity of 610 grams.



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 “exceeds scale capacity” from the drop-down list. 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.

Visually evaluate the urine sample for blood contamination. Record a comment for sufficient and QNS urine collections if the sample is contaminated with blood.

**Urine Collection Verification: 430420**

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

**SP ID: 244445 NAME: NELSON\_2, JENNY AGE: 36 Gender: F**

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	12	12/19/2008 04:13 PM	QNS	blood/clot contan	<input type="checkbox"/>
2			(none)		

**Total Collected: 12**  
**Total Required: 56**

Comment Code dropdown options:  
 blood/clot contamination  
 quantity not sufficient  
 SP refusal  
 SP ill/emergency  
 no time  
 exceeds scale capacity

Buttons: Save, New Collection, OK, Cancel

The “blood/clot contamination” comment should supersede the “quantity not sufficient” comment code when blood is present in a QNS specimen. 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 “blood/clot contamination” from the drop-down list. 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.

Record a comment for all insufficient urine collections. The laboratory application will automatically assign the comment code “quantity not sufficient” for all urine collections that are calculated as QNS by the scale application. The laboratory technician may also assign this comment code to all samples that are changed to QNS during the verification process.

Urine Collection Verification: 430420

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

SP ID: 244445 NAME: NELSON\_2, JENNY AGE: 36 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	12	12/19/2008 04:13 PM	QNS	quantity not suffic	<input type="checkbox"/>
2			(none)	(none)	<input type="checkbox"/>

**Total Collected: 12**  
**Total Required: 56**

Save    New Collection    OK    Cancel

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 (Exhibit 5-3) and when the correct choice is highlighted, left click.

Exhibit 5-3. Comment codes for insufficient urine collection

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.
SP unable to comply	SP has a physical limitation that prohibits him or her from producing a urine specimen or the SP is unable to produce urine during the session.
quantity not sufficient	The quantity of urine is insufficient to process any or all urine vessel(s).
SP refusal	SP refuses to provide urine during the session.
SP ill/emergency	Not applicable.
no time	Not applicable.
exceeds scale capacity	The weight of the urine exceeds the scale weight capacity of 610 grams.
blood/clot contamination	Blood or clots are present in the urine and may affect the volume capture.

Verify the results of the urine collection. To verify, use the mouse to direct the mouse arrow to the “Verify” checkbox. Left click on the checkbox and a checkmark will appear in the box. Verifying the results will save the results to the database.

Urine Collection Verification: 430420

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

SP ID: 220901 NAME: RUSSELL\_2, JACK AGE: 25 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	556	12/19/2008 03:30 PM	Yes	exceeds scale ca	<input checked="" type="checkbox"/>

Total Collected: 556  
Total Required: 55

Save    New Collection    OK    Cancel

Continue recording and verifying urine collection results as specimens are received in the laboratory. Make sure to use the scroll bar to view all SPs in the top part of the Urine Collection screen. SPs who need their urine verified will appear in blue on the top screen.

An SP will be prompted for additional urine only if (1) the total of his or her urine collection was insufficient to meet the SP's protocol requirement and (2) the SP has submitted less than three collection samples. The Urine Collection screen will display up to three instances of urine collection. Urine collection is complete regardless of the amount of urine collected after three attempts. When urine is collected as QNS, a message is sent to the coordinator to prompt the SP for more urine.

Urine Collection Verification: 430420

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

SP ID: 244445 NAME: NELSON\_2, JENNY AGE: 36 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	12	12/19/2008 04:13 PM	QNS	quantity not suffic	<input type="checkbox"/>
2			(none)	(none)	<input type="checkbox"/>

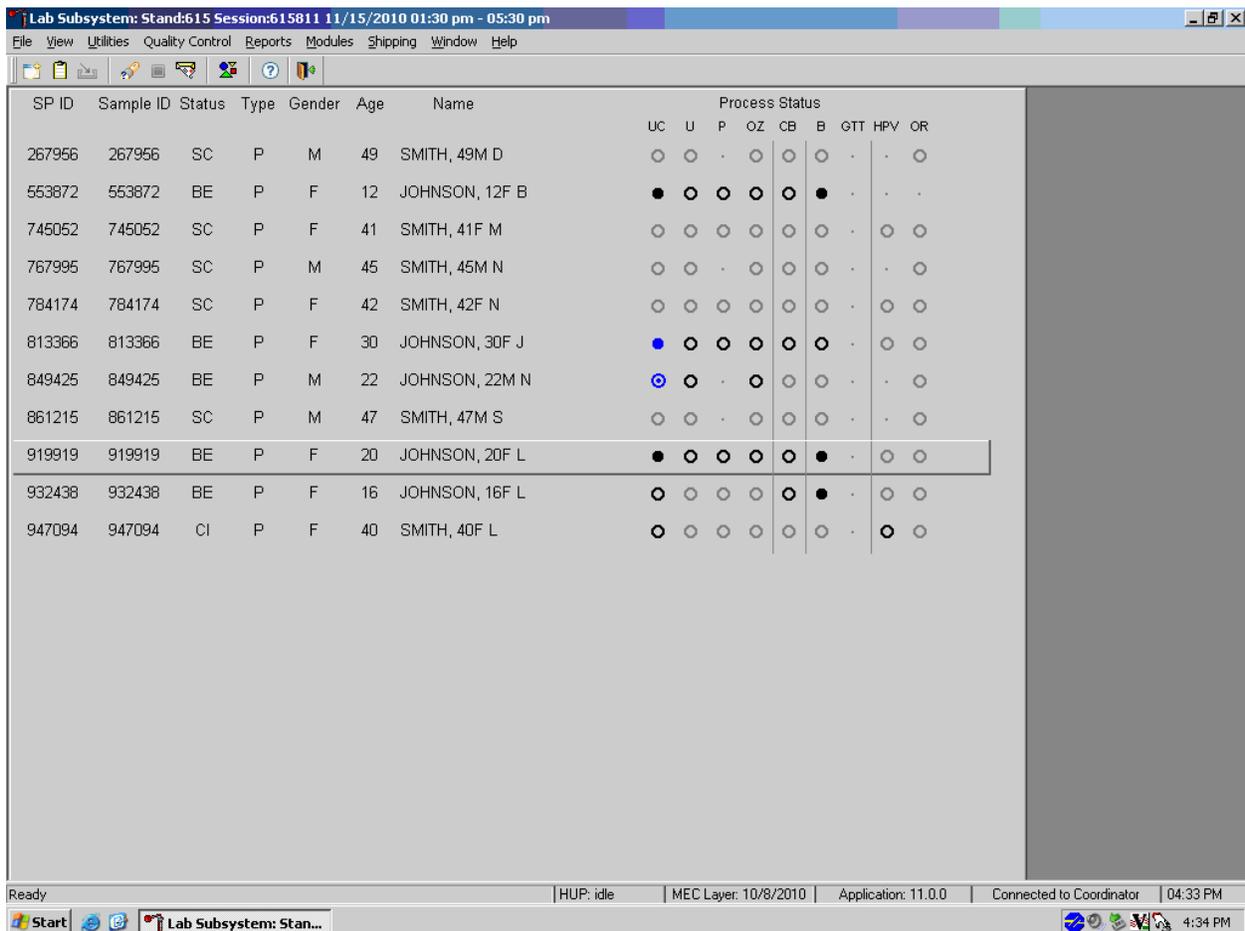
Total Collected: 12  
Total Required: 56

Save    New Collection    OK    Cancel

If the urine collection is the first or second collection and the status is QNS, a record for the second and third instances of urine collection will automatically be added by the Laboratory application. Second and third collections will display as empty rows after the last urine collection. The instance number is displayed under the “Collection” column.

Verify the urine collection by checking the “Verify” box. Use “Save” to save changes or select the  in the upper right corner to exit out of the Urine Collection screen.

Once a urine collection has been recorded for an SP, the circle on the heads-up screen will turn black (⊙ for QNS or ● for Yes). A black urine collection circle indicates that no additional action needs to be taken on that SP for urine collection at that time.



Lab Subsystem: Stand:615 Session:615811 11/15/2010 01:30 pm - 05:30 pm

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status									
							UC	U	P	OZ	CB	B	GTT	HPV	OR	
267956	267956	SC	P	M	49	SMITH, 49M D	○	○	-	○	○	○	-	-	○	
553872	553872	BE	P	F	12	JOHNSON, 12F B	●	○	○	○	○	●	-	-	-	
745052	745052	SC	P	F	41	SMITH, 41F M	○	○	○	○	○	○	-	○	○	
767995	767995	SC	P	M	45	SMITH, 45M N	○	○	-	○	○	○	-	-	○	
784174	784174	SC	P	F	42	SMITH, 42F N	○	○	○	○	○	○	-	○	○	
813366	813366	BE	P	F	30	JOHNSON, 30F J	●	○	○	○	○	○	-	○	○	
849425	849425	BE	P	M	22	JOHNSON, 22M N	⊙	○	-	○	○	○	-	-	○	
861215	861215	SC	P	M	47	SMITH, 47M S	○	○	-	○	○	○	-	-	○	
919919	919919	BE	P	F	20	JOHNSON, 20F L	●	○	○	○	○	●	-	○	○	
932438	932438	BE	P	F	16	JOHNSON, 16F L	○	○	○	○	○	●	-	○	○	
947094	947094	CI	P	F	40	SMITH, 40F L	○	○	○	○	○	○	-	○	○	

Ready | HUP: idle | MEC Layer: 10/8/2010 | Application: 11.0.0 | Connected to Coordinator | 04:33 PM

## **QNS Urines and Enabling HUC**

For QNS urine specimens, HUC will be enabled as soon as the lab verifies the SP has collected greater than or equal to 6 mLs of urine. This verification will turn the HUC box green on the coordinator screen and allow the SP to enter HUC. If UC 1 is QNS, hold until enough urine is available for the entire profile. Pool samples together and proceed filling the vessels.

### **5.6 Manually Documenting Urine Collection**

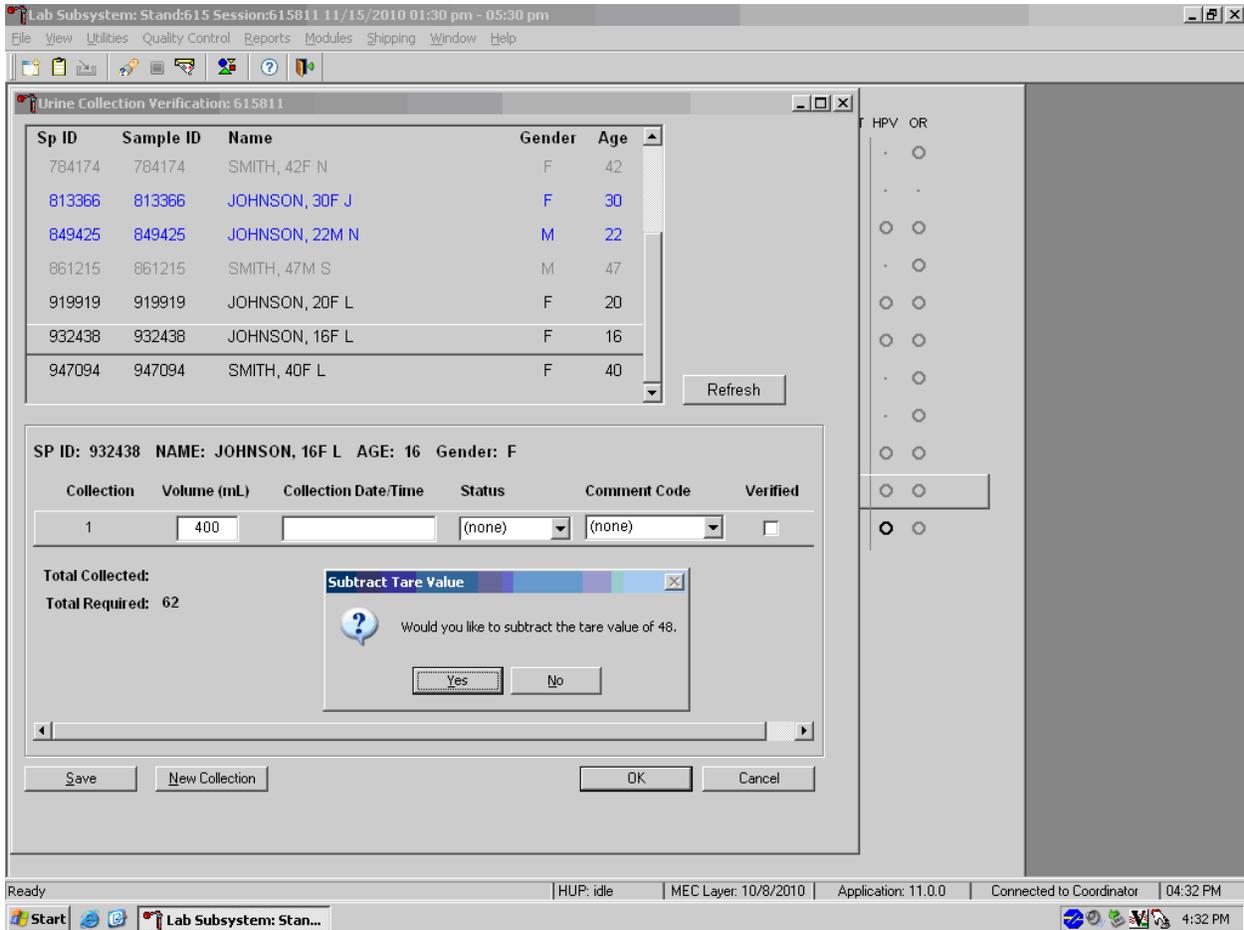
#### **5.6.1 Manually Document Urine Collection With Barcode Scanning**

The technician is able to manually record the volume, status, and collection date and time in the urine collection module within the laboratory application. Place the urine collection cup on the scale and cover with the clear acrylic scale cover. Scan the barcode on the urine cup.

Open the Urine Collection screen from the heads-up as described in Section 3.3. The urine collection window displays. At this point, the technician has the ability to modify the volume of the urine and the collection date/time.

To manually adjust the Volume (mL), use the mouse to direct the mouse arrow to the text box under the Volume (mL) column. Double click to open boxes for modification and then click on the text box to enable the cursor in the box. Make changes using the number pad on the keyboard. Once any necessary adjustments have been made, use the mouse to direct the mouse arrow to the box under the Collection Date/Time column or press the Tab key. A prompt will pop up asking if you would like to subtract the weight of the cup. If the volume of the sample was transmitted from the scale and you have made a manual adjustment to that reading, select “No.”

In the Collection Date/Time box, right click on the text box to enable the cursor inside the box. Adjust the date and time by entering the date in the format “MMDDYYYY ##:##” using the number pad on the keyboard. Adjust “am/pm” by using the up or down arrows. Once any necessary adjustments have been made, use the mouse to direct the mouse arrow to the box under the Status column or press the Tab key.



Continue to enter the collection date/time, selecting the appropriate urine collection status, and a comment code if applicable. Verify the urine collection by checking the “Verify” box.

If the urine collection is the first or second collection and is QNS, second and third instances of urine collection may be added by using the “New Collection” button at the bottom of the screen.



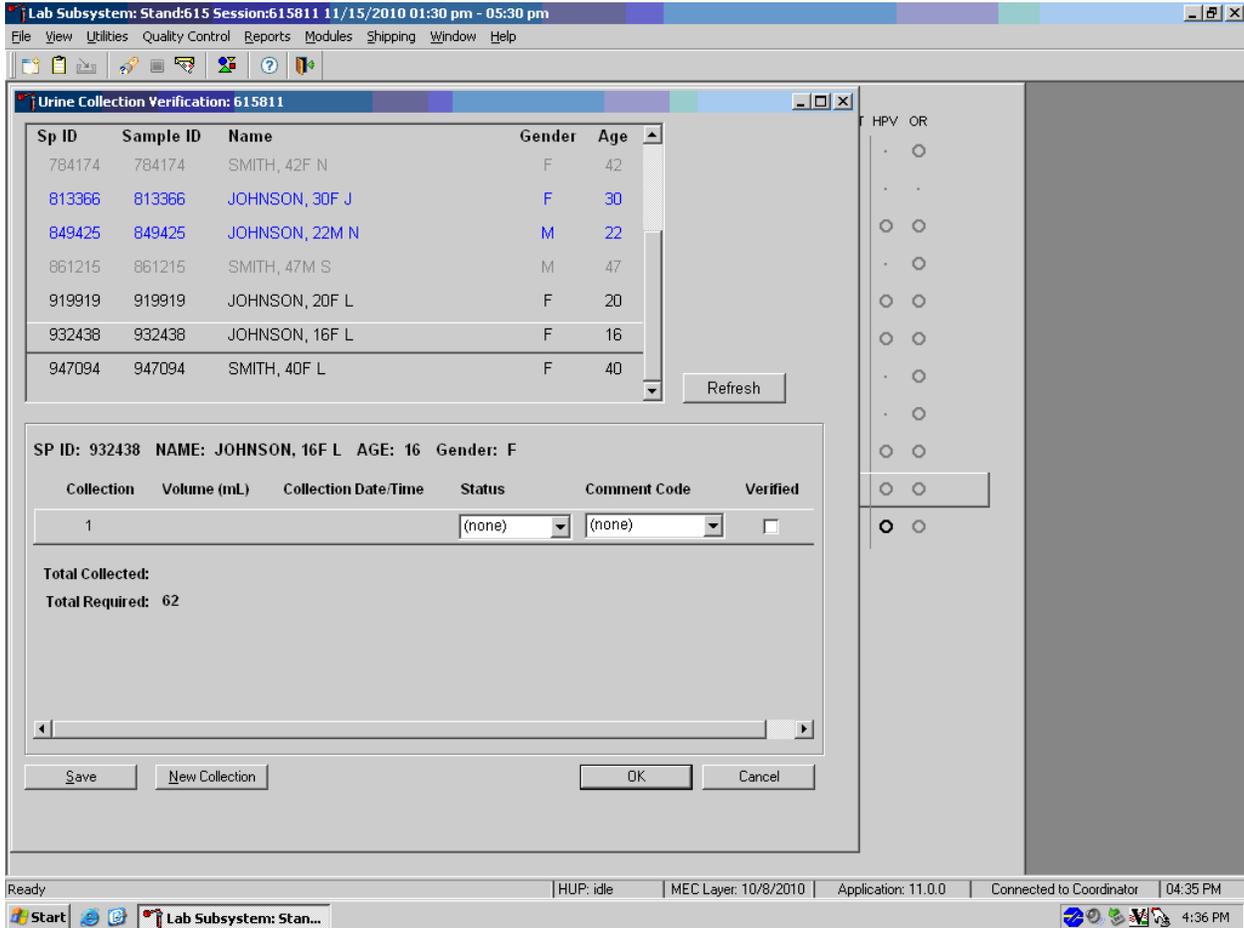
Add a second or third collection only if the previous collection was QNS. Enter the second or third urine collection results when the sample is submitted to the MEC laboratory by typing in the boxes for volume and collection date/time, then selecting the appropriate urine collection status and a comment code if applicable.

Verify the urine collection by checking the “Verify” box. Use “Save” to save changes or select the  in the upper right corner to exit out of the Urine Collection screen.

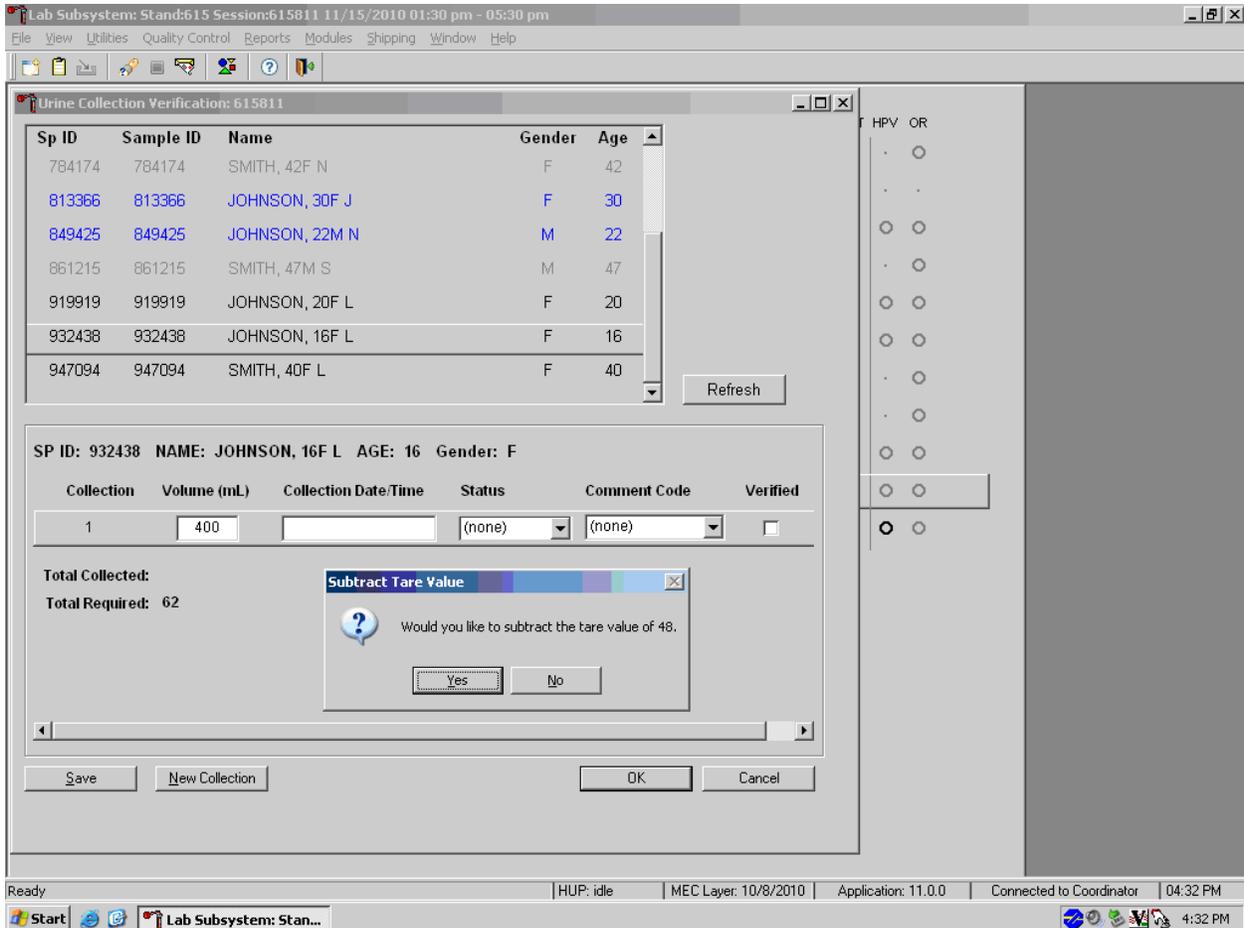
### **5.6.2 Manually Document Urine Collection Without Barcode Scanning**

If the connection between the scale and workstation 2 is down, the technician is able to manually record the volume, status, and collection date and time in the urine collection module within the laboratory application. Place the urine collection cup on the scale and cover with the clear acrylic scale cover. Note the weight reading from the LCD.

Open the Urine Collection screen from the heads-up as described in Section 3.3. The urine collection window displays. Double click in the area underneath Volume or Collection Date/Time to open the boxes where the values can be entered. Enter the urine collection results by typing in the weight reading from the scale's display in the box for volume.



If the next box is selected by pressing the “tab” button or selected by the mouse, a prompt will pop up asking if you would like to subtract the weight of the urine cup from the result entered. Select “Yes.”



Continue to enter the collection date/time, selecting the appropriate urine collection status, and a comment code if applicable. Verify the urine collection by checking the “Verify” box.

If the urine collection is the first or second collection and is QNS, second and third instances of urine collection may be added by using the “New Collection” button at the bottom of the screen.



Add a second or third collection only if the previous collection was QNS. Enter the second or third urine collection results when the sample is submitted to the MEC laboratory by typing in the boxes for volume and collection date/time, then selecting the appropriate urine collection status and a comment code if applicable.

Verify the urine collection by checking the “Verify” box. Use “Save” to save changes or select the  in the upper right corner to exit out of the Urine Collection screen.

## 5.7 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
- Chlamydia (Chlam) on primary SPs 14-39 years old
- Speciated Arsenic (Spc Arsenic) on selected SPs aged 6+ years
- Priority Pesticides (Prior Pest) on selected SPs aged 6+ years
- Organophosphates (Organophos) on selected SPs aged 6+ years
- Urine Mercury/Iodine (Urin Merc) on selected SPs aged 6+ years
- Heavy Metal on selected SPs aged 6+ years
- Polyaeromatic Hydrocarbons (PAH) on selected SPs aged 6+ years
- Phthalates on selected SPs aged 6+ years
- Perchlorate on selected SPs aged 6+ years
- Caffeine on selected SPs aged 6+ years

- NNAL (a tobacco-specific nitrosamine) on SPs aged 6+ years
- Extra urine (Xtra Urine) on SPs aged 6+ years

## 5.8 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	14-39	12	14 mL Falcon
86	Spc Arsenic	6+	3	5 mL cryovial
48	Prior Pest	6+	7	10 mL VWR screwcap
49	Organophos	6+	7	10 mL VWR screwcap
62	Urin Merc	6+	5	10 mL VWR screwcap
50	Heavy Metal	6+	6	14 mL Falcon
66	PAH	6+	3	5 mL cryovial
67	Phthalates	6+	3	5 mL cryovial
102	Perchlorate/VOC/Thiocyante	6+	5	5 mL cryovial
121	NNAL	6+	8	10 mL VWR screwcap
128	Caffeine	6+	1	2 mL cryovial
52	Xtra Urine 1	6+	5	5 mL cryovial
	Xtra Urine 2	6+	5	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

## **5.9 Labeling Urine Processing Vessels**

The appropriate barcode 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.

One hour into the session, if an SP has not checked in, separate the labels for SPs who have checked in from SPs who have not checked in. Set the labels aside for SPs who have not checked in. If the SP does not show up for the session, then discard the labels at the end of the session.

## **5.10 Urine Specimen Processing**

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

Using the large 15-mL plastic transfer pipette for all but vessel 62, allocate the urine sample for each of these tests using the following procedure:

45. Aliquot 3-mL of the specimen for Alb/Creat into a 5-mL vessel.
46. Aliquot 12-mL of the specimen for Chlam into 14-mL vessel.
86. Aliquot 3-mL of the specimen for Spc Arsenic into a 5-mL vessel.
48. Aliquot 8-mL of specimen for Prior Pest into 10-mL vessel.
49. Aliquot 8-mL of specimen for Organophos into 10-mL vessel.

62. Urin Merc - Transfer exactly 5-mL of urine into the 10-mL VWR screwcap vessel, close the cap, and mix gently. Keep vessel 62 upright at all times; do not invert the tube because the preservative could drain into the cap 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 10-mL vessel. Tap the bottom of the capped vessel against a hard surface before opening. 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. Aliquot 8-mL of the specimen for Heavy Metal into a 14 mL Falcon.
66. Aliquot 3-mL of the specimen for PAH into a 5-mL vessel.
67. Aliquot 3-mL of the specimen for Phthalates into a 5-mL vessel.
102. Aliquot 5-mL of the specimen for Perchlorate/VOC/Thiocyanate into a 5-mL vessel.
121. Aliquot 10-mL of the specimen for NNAL into a 10-mL vessel.
128. Aliquot 1-mL of the specimen for caffeine into a 2-mL vessel.
52. Aliquot 5-mL of the specimen for Xtra Urine 1 into a 5-mL vessel.
139. Aliquot 5-mL of the specimen for Xtra Urine 2 into a 5-mL vessel.

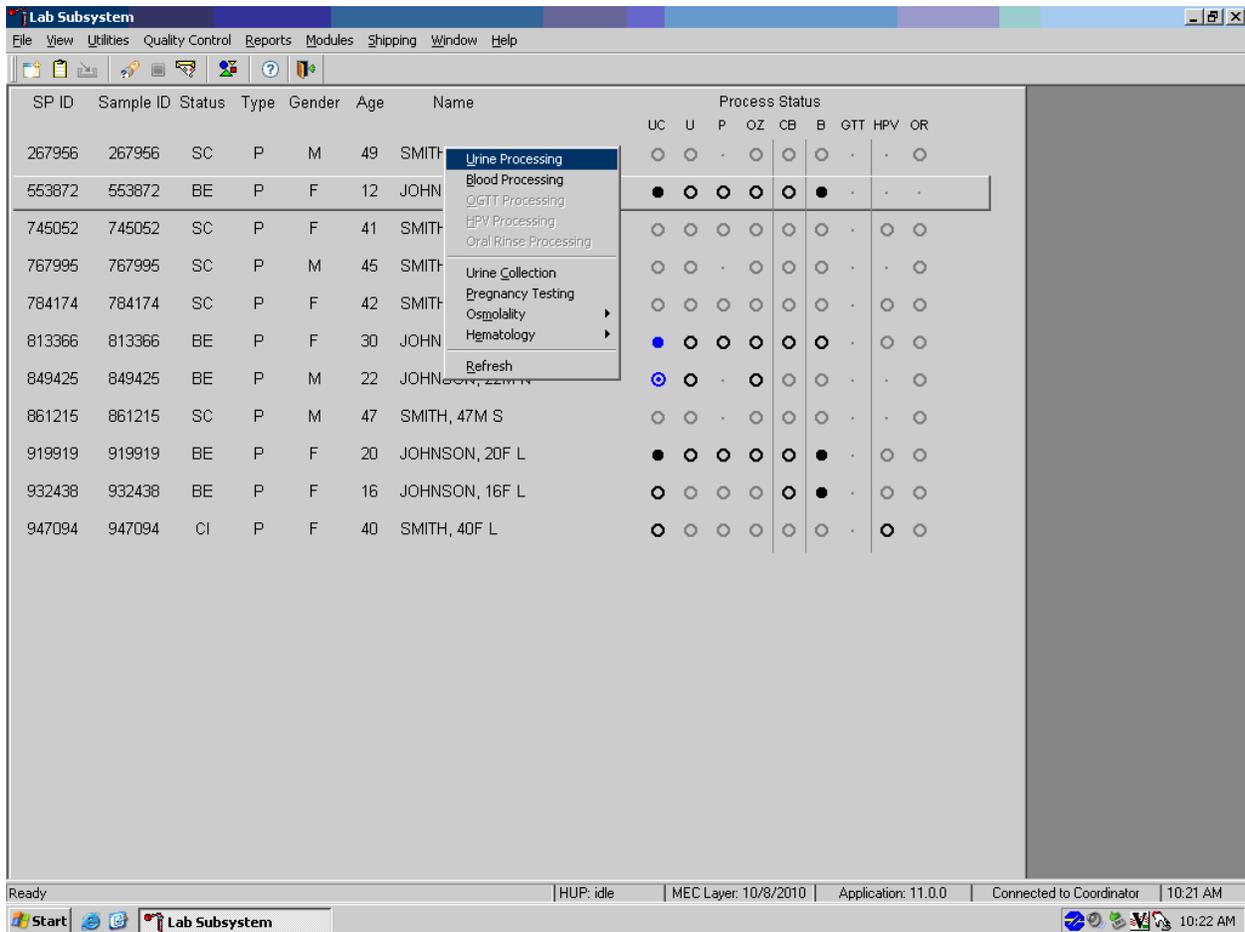
Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink that is connected to the sewer. Flush the sink with water. Discard urine cup in the biohazard trash.

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

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

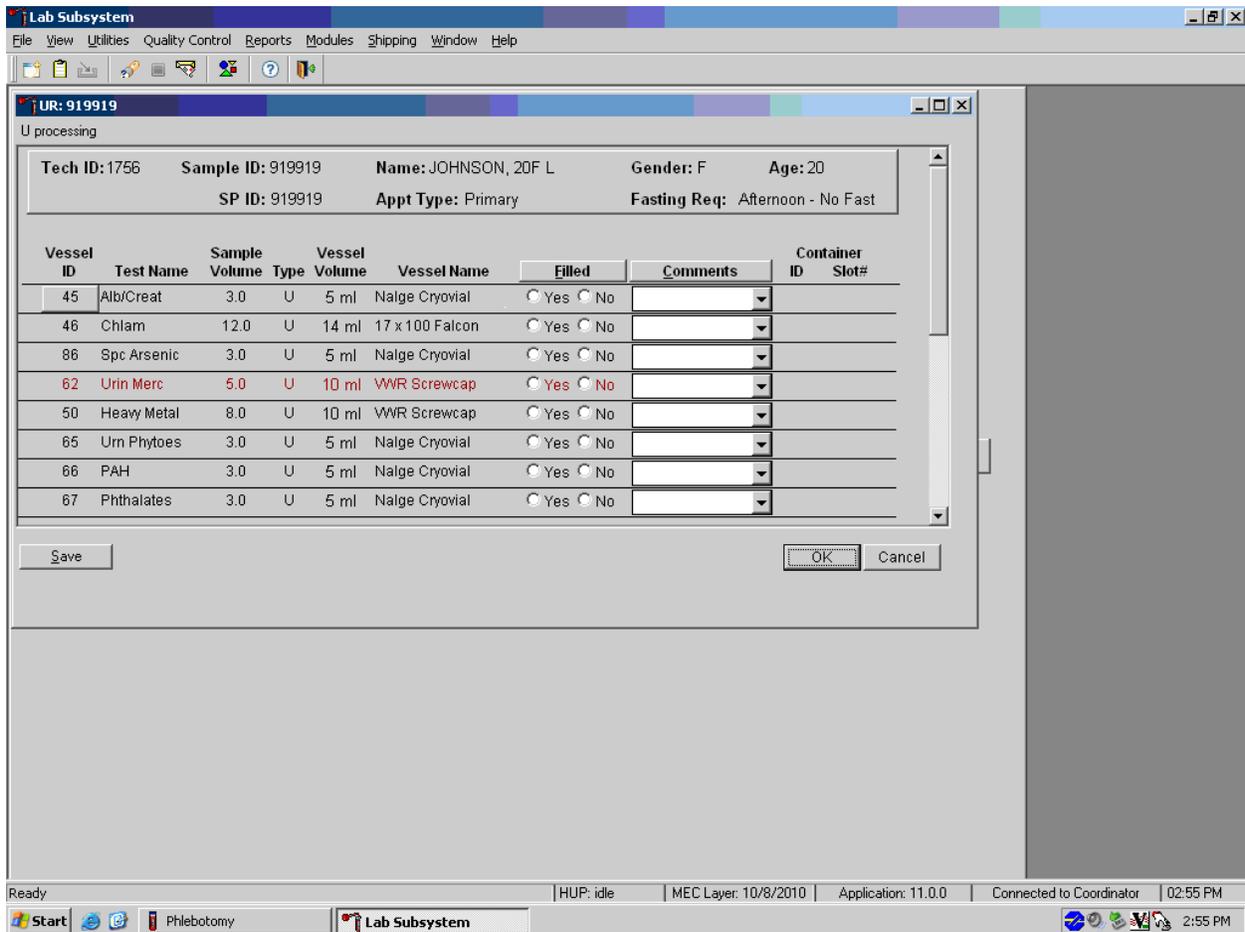
After filling the urine specimen vessels for each SP, use the Urine Processing module to enter the results of urine processing.

Access the Urine Processing module.



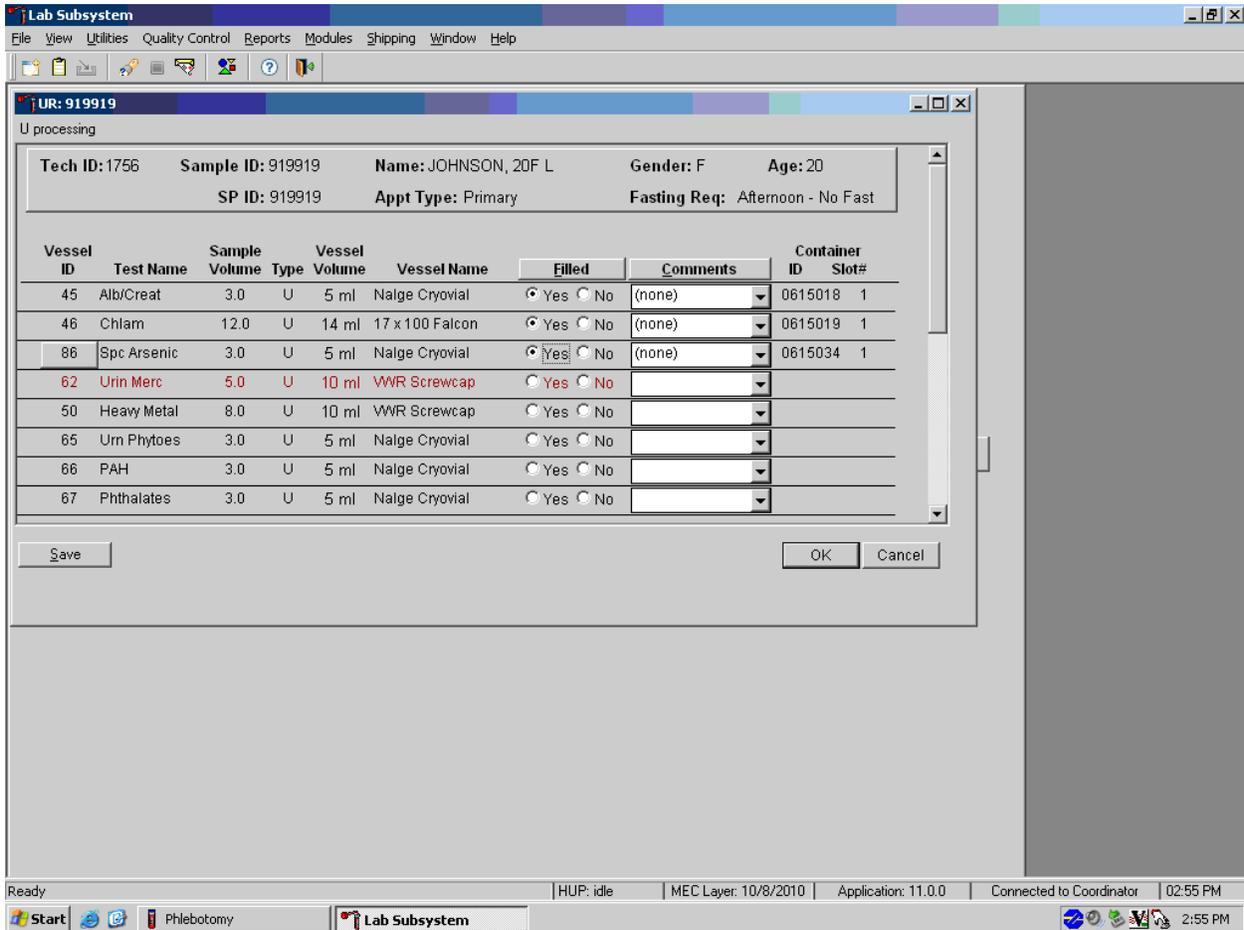
To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Urine Processing}, and right click or right click and type [U/u]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted,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

The SP's urine processing window displays.



The urine processing window contains the following information for SPs: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, and Fasting Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Sample Type (U = urine), Vessel Volume, Vessel Name, Filled (Yes or No) radio buttons, Comment drop-down box, and Container ID and Container Slot# column.

Individually mark each vessel as Filled –“Yes.”



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 and the next open slot number.

Individually mark each vessel as Filled –“No.”

The screenshot shows the 'Lab Subsystem' application window. At the top, there is a menu bar with options: File, View, Utilities, Quality Control, Reports, Modules, Shipping, Window, Help. Below the menu bar is a toolbar with various icons. The main window title is 'UR: 919919' and it contains a sub-window titled 'U processing'.

At the top of the sub-window, there is a summary section with the following information:

- Tech ID: 1756
- Sample ID: 919919
- Name: JOHNSON, 20F L
- Gender: F
- Age: 20
- SP ID: 919919
- Appt Type: Primary
- Fasting Req: Afternoon - No Fast

Below this is a table with the following columns: Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Filled, Comments, Container ID, and Slot#.

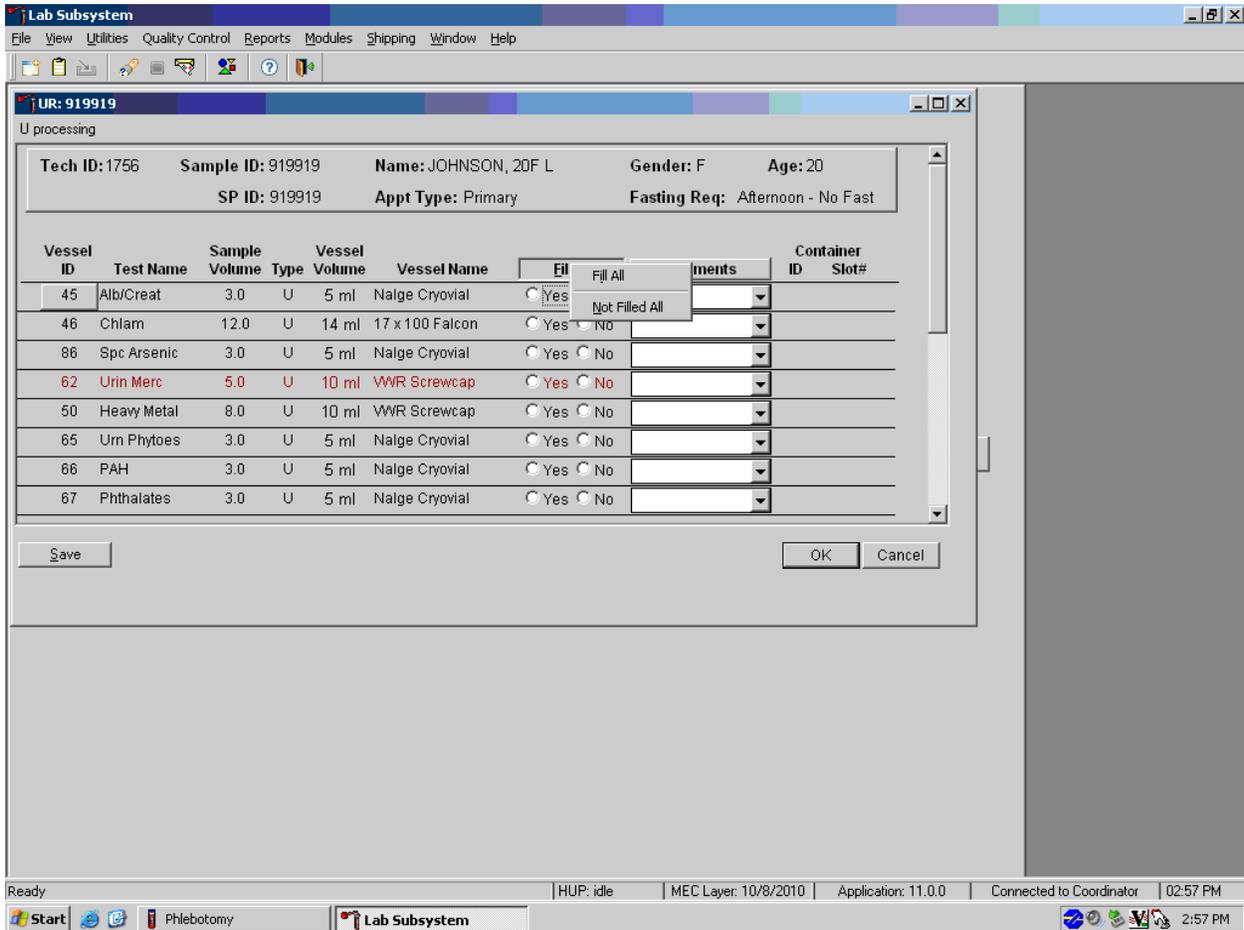
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3.0	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0615018	1
46	Chlam	12.0	U	14 ml	17 x 100 Falcon	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0615019	1
86	Spc Arsenic	3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not suffic		
62	Urin Merc	5.0	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not suffic		
50	Heavy Metal	8.0	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input checked="" type="radio"/> No			
65	Urn Phytoes	3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No			
66	PAH	3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No			
67	Phthalates	3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No			

At the bottom of the sub-window, there are three buttons: 'Save', 'OK', and 'Cancel'.

The bottom status bar of the application shows: 'Apply changes and close window', 'HUP: idle', 'MEC Layer: 10/8/2010', 'Application: 11.0.0', 'Connected to Coordinator', and '02:56 PM'. The Windows taskbar at the very bottom shows the Start button, a search bar, and several open applications including 'Phlebotomy' and 'Lab Subsystem'.

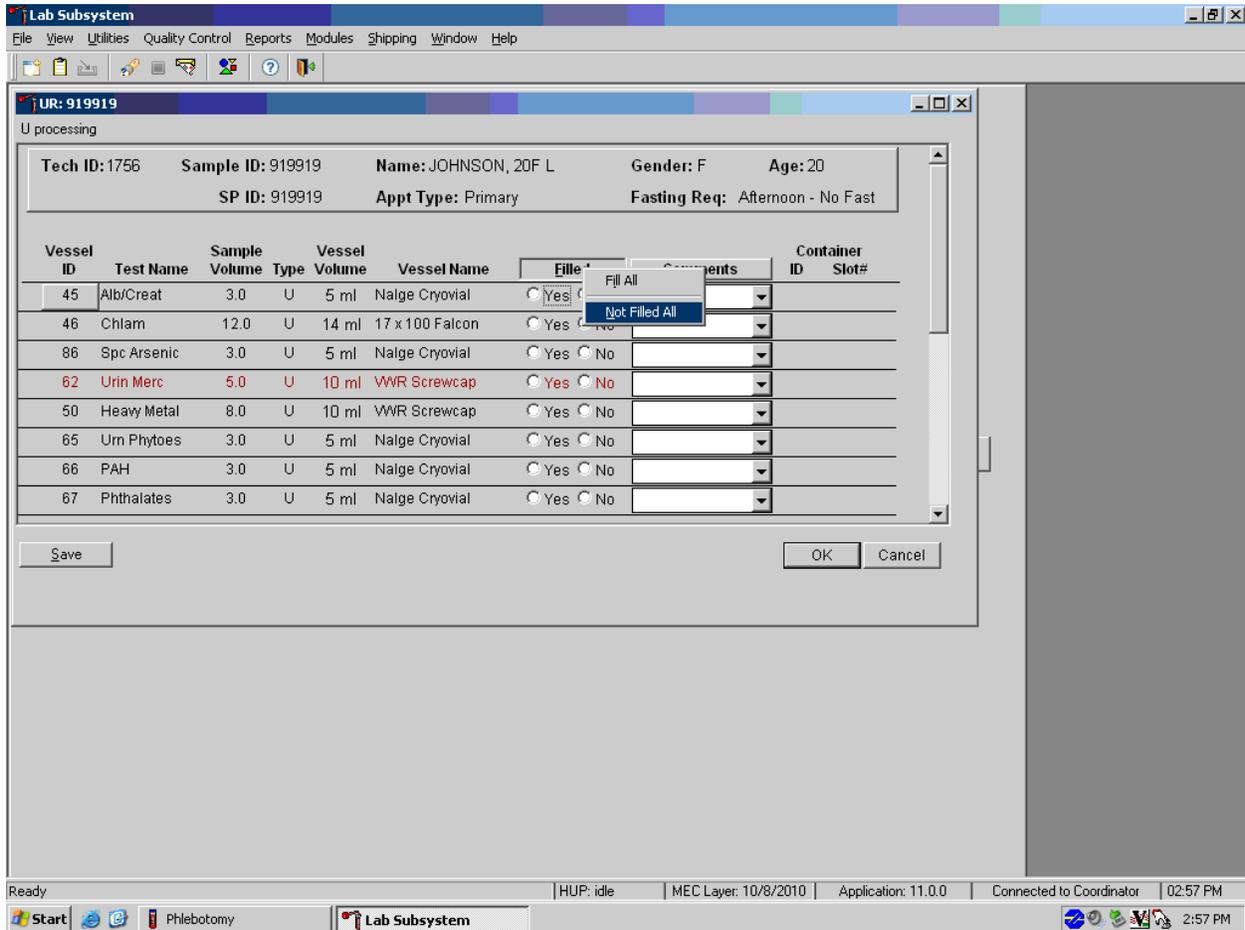
To mark an individual urine vessel as not collected or Filled –“No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. As each vessel is marked as Filled “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column.

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.”

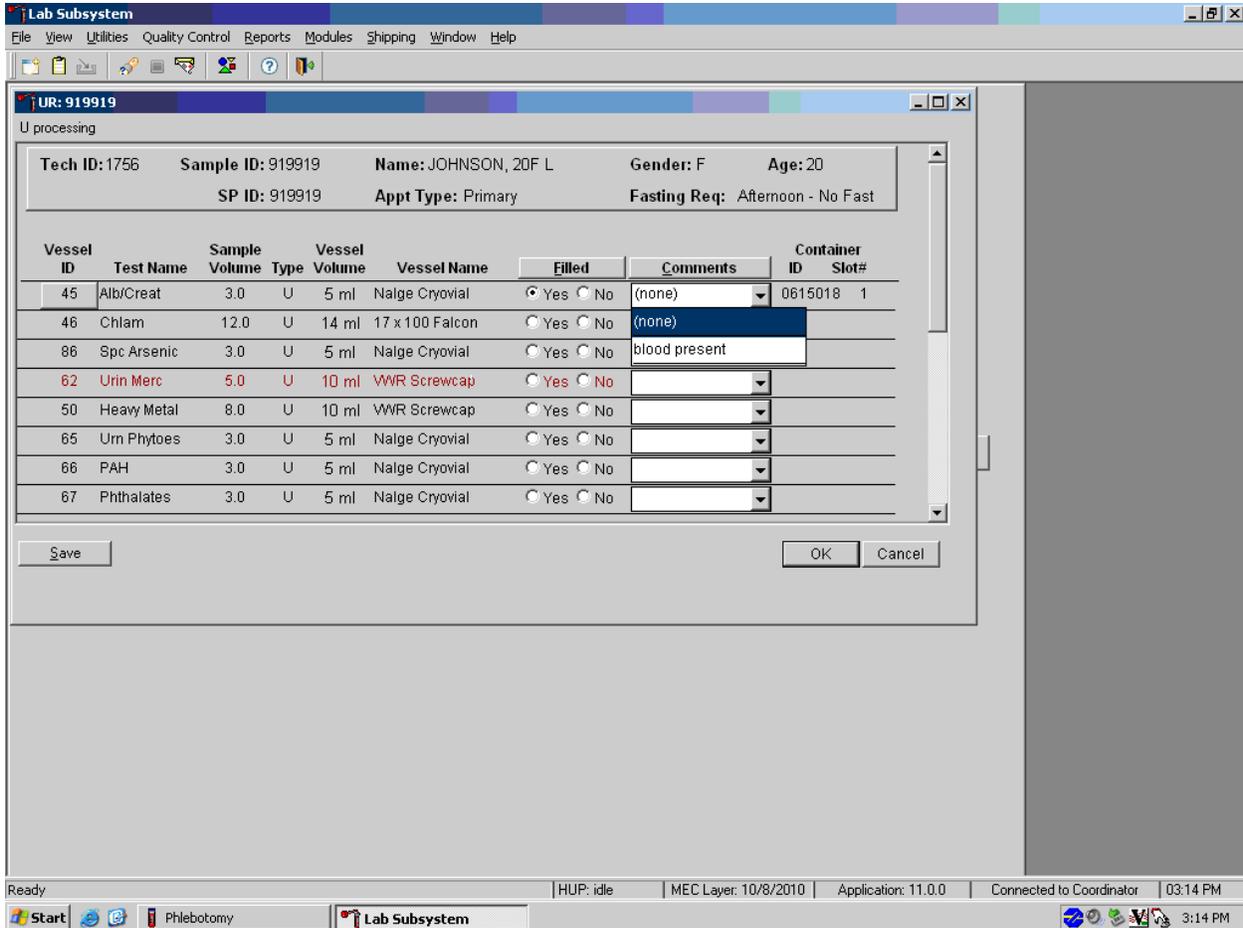


To mark all vessels as Filled –“No,” use the mouse to direct the mouse arrow to the Filled box, left click, drag the mouse arrow to {Not Filled All}, and left click or type [Shift] [F/f], [N/n.]

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

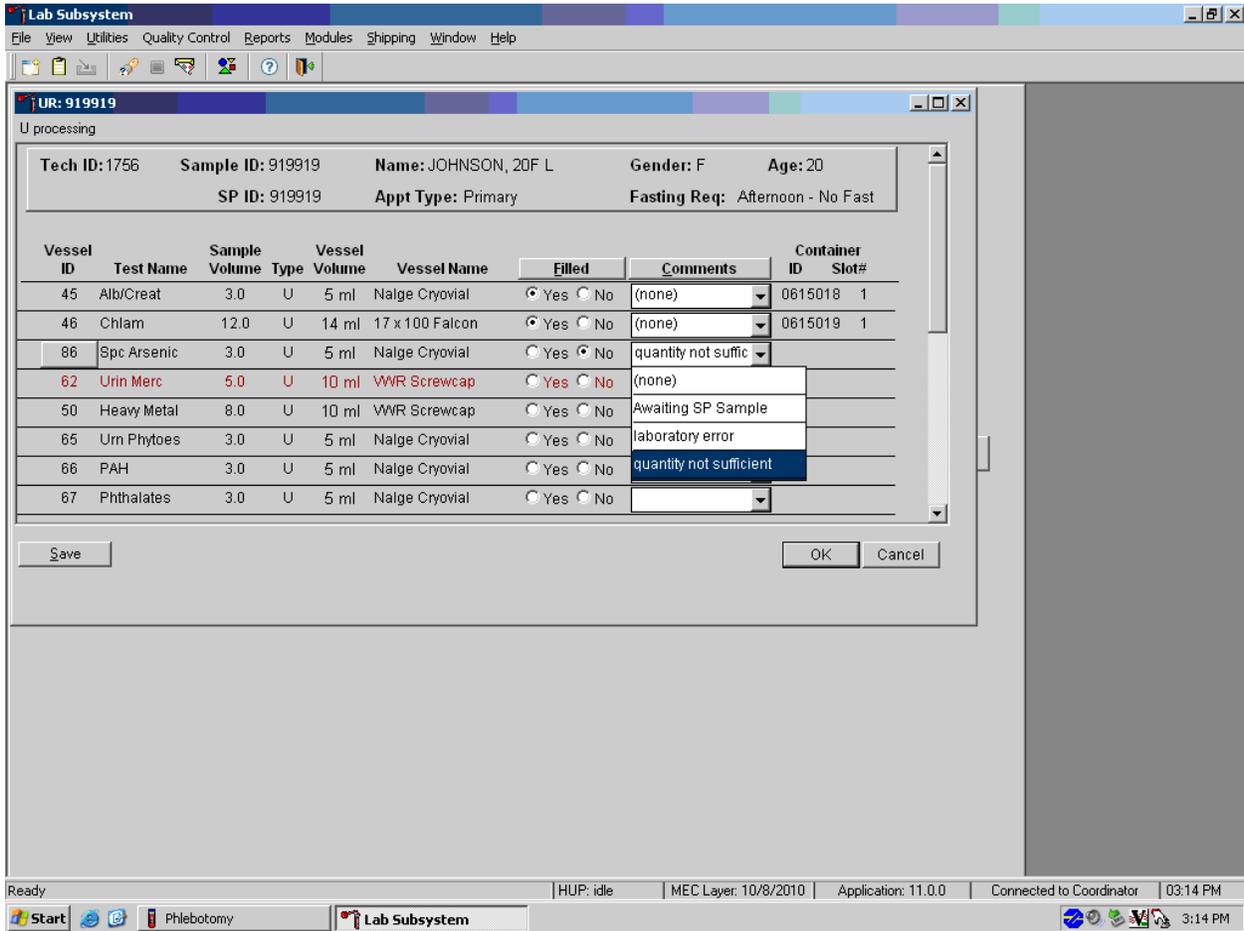
Comment Code	Use when:
Blood present	Blood is visible in the specimen.

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



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 Comments column, left click to display the choices, drag the mouse arrow to {blood present}, and left click.

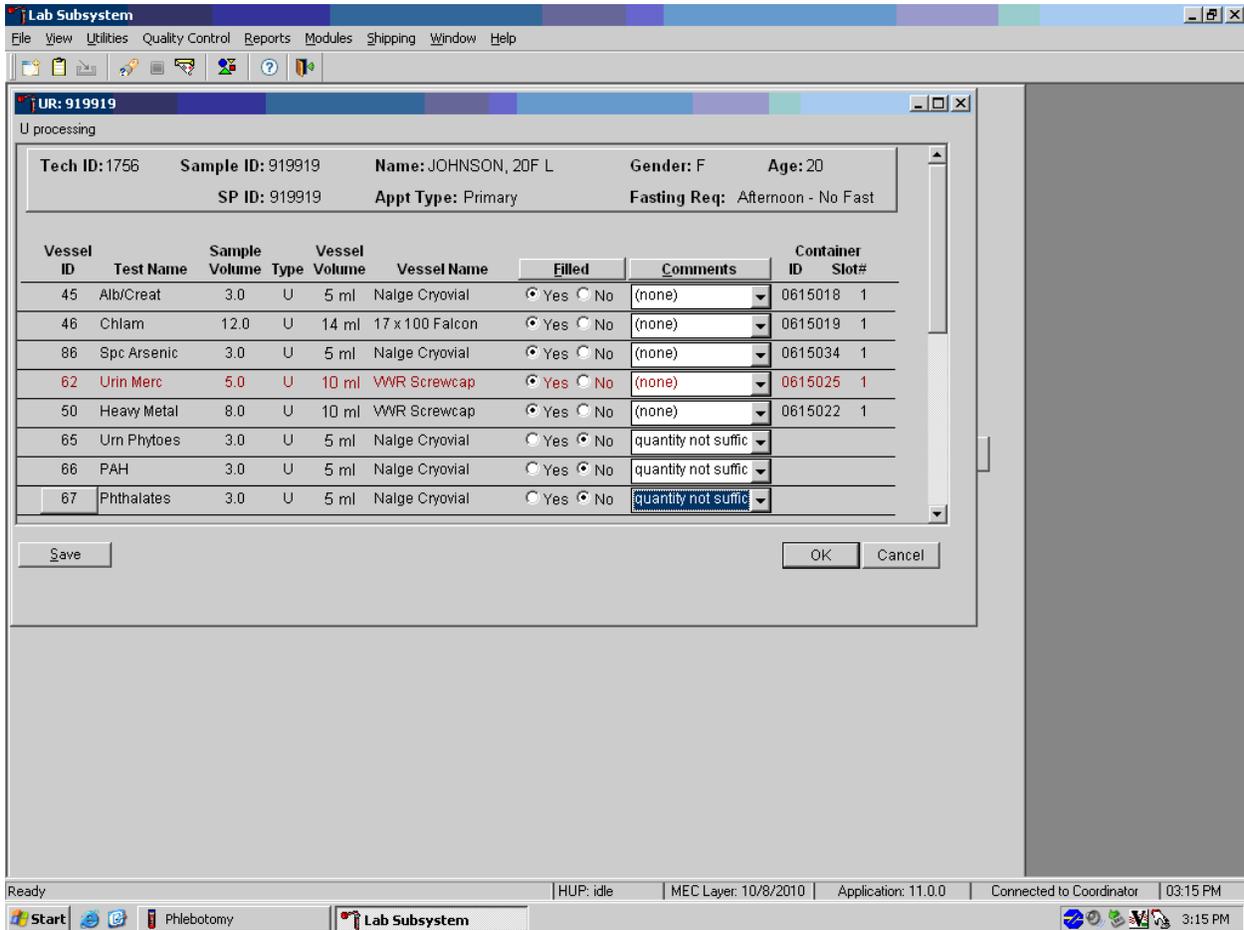
If a vessel is marked as Filled–“No,” the comment “quantity not sufficient” is automatically entered. Review the comment for all insufficient urine collections and correct the comment, when necessary.



Comment Code	Use when:
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.



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 the data to the database and 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.

## **5.12 Second and Third Urine Samples**

If the initial urine sample does not meet the minimum volume requirement, refrigerate the initial urine until enough additional urine is received in the second or third urine collection to meet the minimum requirements to complete the protocol or the session ends. If a subsequent sample collection fulfills the protocol requirement, pool the initial and subsequent urine samples into the most recently collected specimen urine cup, 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,” with the comment code “quantity not sufficient,” and save the results.

## **5.13 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 each urine processing 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 barcoded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a barcode 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 and shipping protocol for urine

Lab #	Shipping location	Vessels	Conditions	Frequency	Vessel storage
16	University of Minnesota	45 Alb/Creat	Frozen	Weekly	9x9 three inch box
5	CDC/NCID NCHSTD	46 Chlam	Frozen	Weekly	5x5 three inch box
61	CASPIR	86 Spc Arsenic	Frozen	Weekly	9x9 three inch box
26	CDC/NCEH Pesticide Laboratory	48 Prior Pest	Frozen	End of stand	5x5 three inch box
26	CDC/NCEH Pesticide Laboratory	49 Organophos	Frozen	End of stand	5x5 three inch box
61	CASPIR	62 Urin Merc	Frozen	Weekly	5x5 three inch box
61	CASPIR	50 Heavy Metal	Frozen	Weekly	5x5 three inch box
31	CASPIR	66 PAH	Frozen	End of stand	9x9 three inch box
24	CDC/NCEH Environmental Health Laboratory	67 Phthalates	Frozen	End of stand	9x9 three inch box
62	CASPIR	102 Perchlorate/VOC/Thiocyanate	Frozen	End of stand	5x5 three inch box
59	CASPIR	121 NNAL	Frozen	End of stand	5x5 three inch box
54	CASPIR	128 Caffeine	Frozen	Weekly	10x10 two inch box
6	CASPIR	52 Xtra Urine 1	Frozen	End of stand	9x9 three inch box
6	CASPIR	139 Xtra Urine 2	Frozen	End of stand	9x9 three inch box

#### 5.14 How to Deal With System Failure

If the computer system fails, record results on a preprinted workstation 2 processing worksheet (Exhibit 5-3). 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 5-4. 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 <u>ill</u> /emergency SP <u>refusal</u> SP <u>unable</u> 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><u>QNS</u></i> <i>Blood Present</i>	Slot #
45	Alb/Creat	6+	3	Urine			
46	Chlam	14-39	10	Urine			
86	Spc Arsenic	6+	3	Urine			
48	Prior Pest	6+	8	Urine			
49	Organophos	6+	7	Urine			
62	Urn Merc	6+	5	Urine			
50	Heavy Metal	6+	8	Urine			
66	PAH	6+	3	Urine			
67	Phthalates	6+	3	Urine			
102	Perchlorate/VOC/Thiocyanate	6+	5	Urine			
121	NNAL	6+	10	Urine			
128	Caffeine	6+	1	Urine			
52	Xtra Urine 1	6+	5	Urine			
139	Xtra Urine 2	6+	5	Urine			

**National Health and Nutrition Examination Survey  
National Center for Health Statistics  
United States Public Health Service  
Procedure: Pregnancy Testing  
January 2011**

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) section 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. The 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)

- This test is 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 percent 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 buildup. 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-View™ hCG Urine and Serum Control Sets

- The Sure-View™ 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 titled “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.

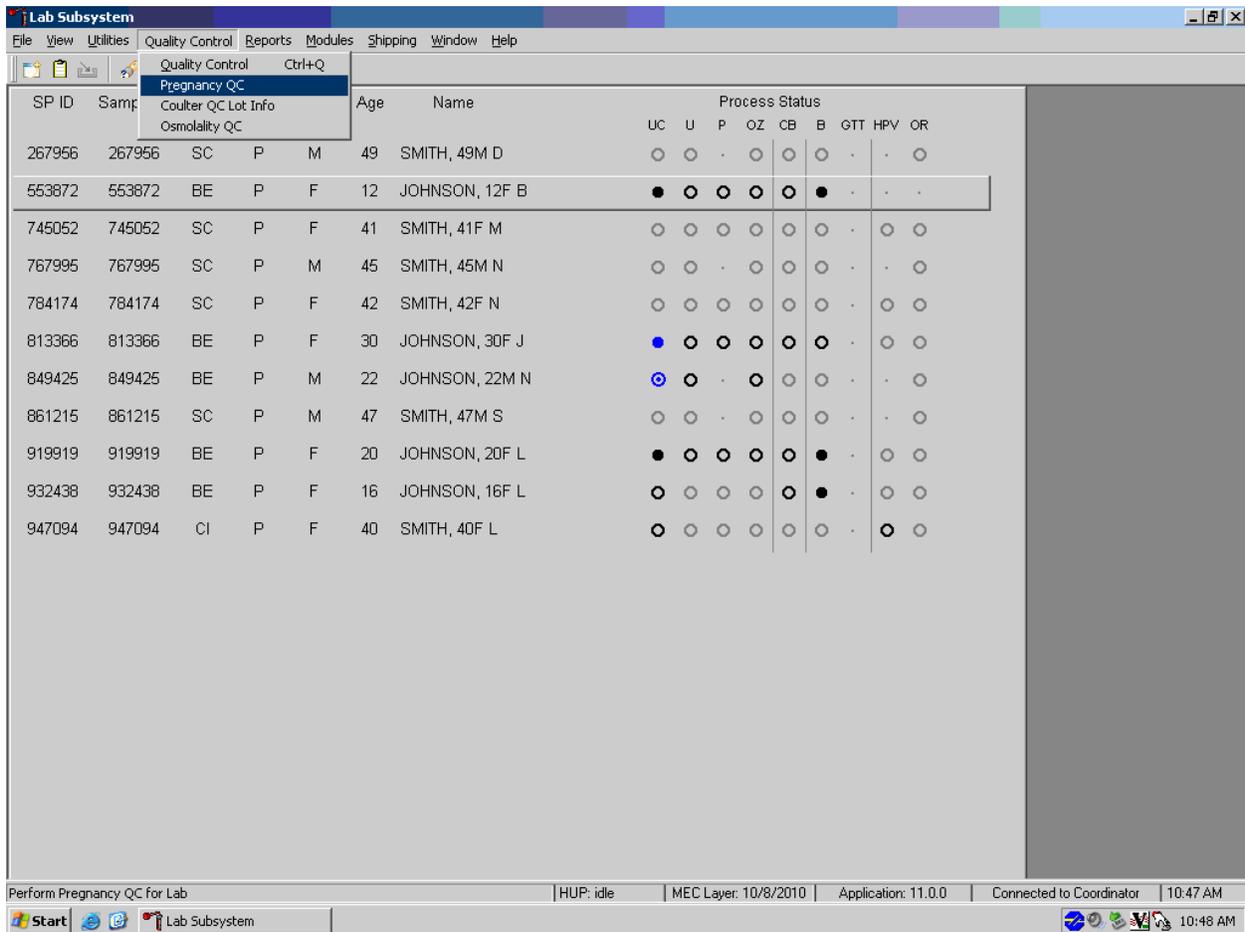
## CAP Proficiency Testing

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.

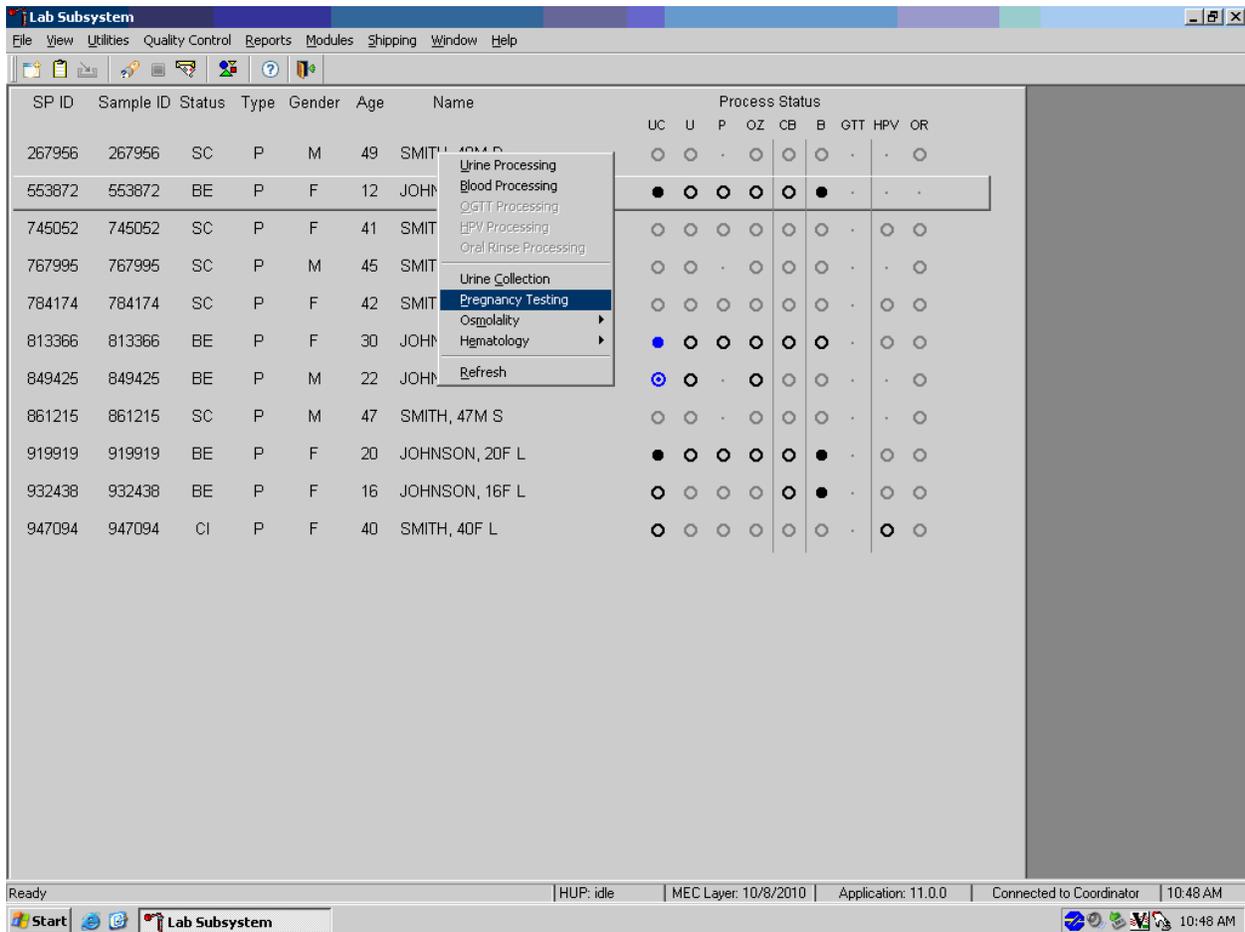
CAP sends samples three times a year for qualitative serum hCG and urine hCG. Each serum survey includes five lyophilized sera specimens and each urine survey includes 5 liquid specimens. Handle and analyze these samples in a manner identical to SP samples. Record results on the CAP forms and send to 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.

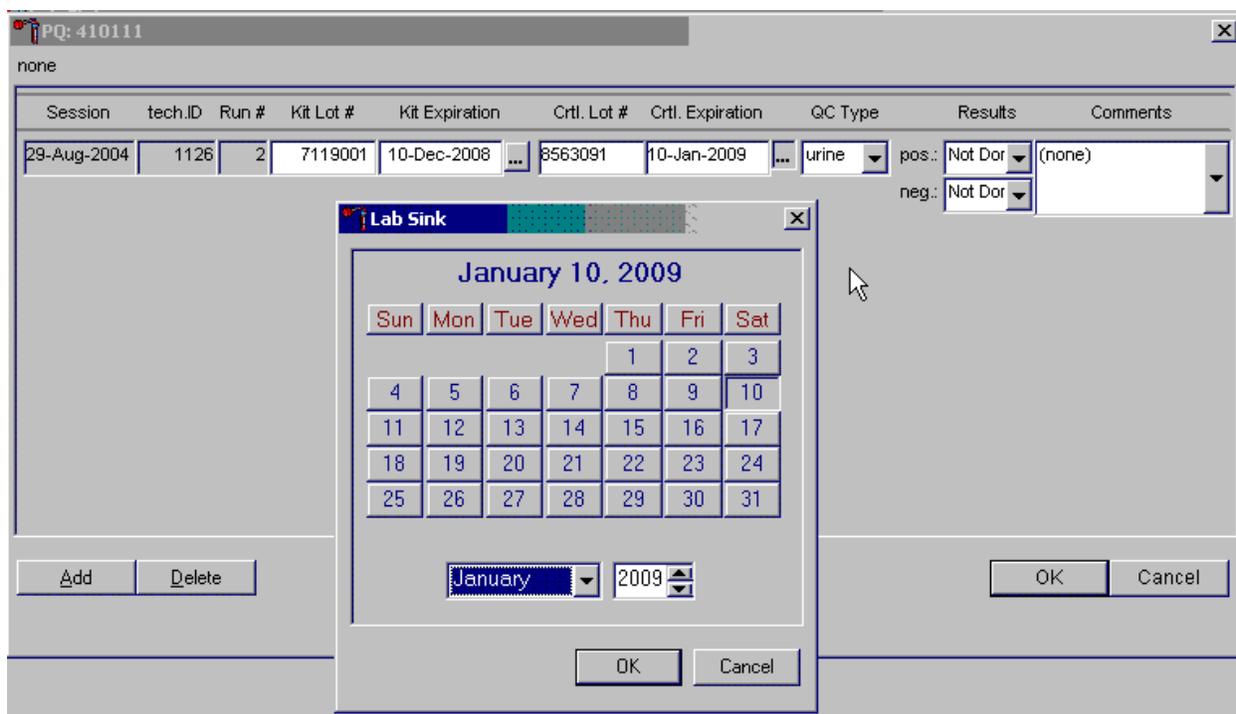
The screenshot shows a software window titled "PQ: 410111" with a close button in the top right corner. Below the title bar, the text "none" is displayed. The main area contains a data entry form with the following fields and values:

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	urine	pos.: Not Dor neg.: Not Dor	(none)

At the bottom of the window, there are four buttons: "Add", "Delete", "OK", and "Cancel".

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
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	urine	pos.: Not Dor neg.: Not Dor	(none)

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
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	urine	pos.: Not Done neg.: Not Done	(none)

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.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	urine	pos.: Positive neg.: Not Done	(none)

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 the drop-down list, drag the mouse arrow to “Positive,” “Negative,” or “Invalid,” and left click.

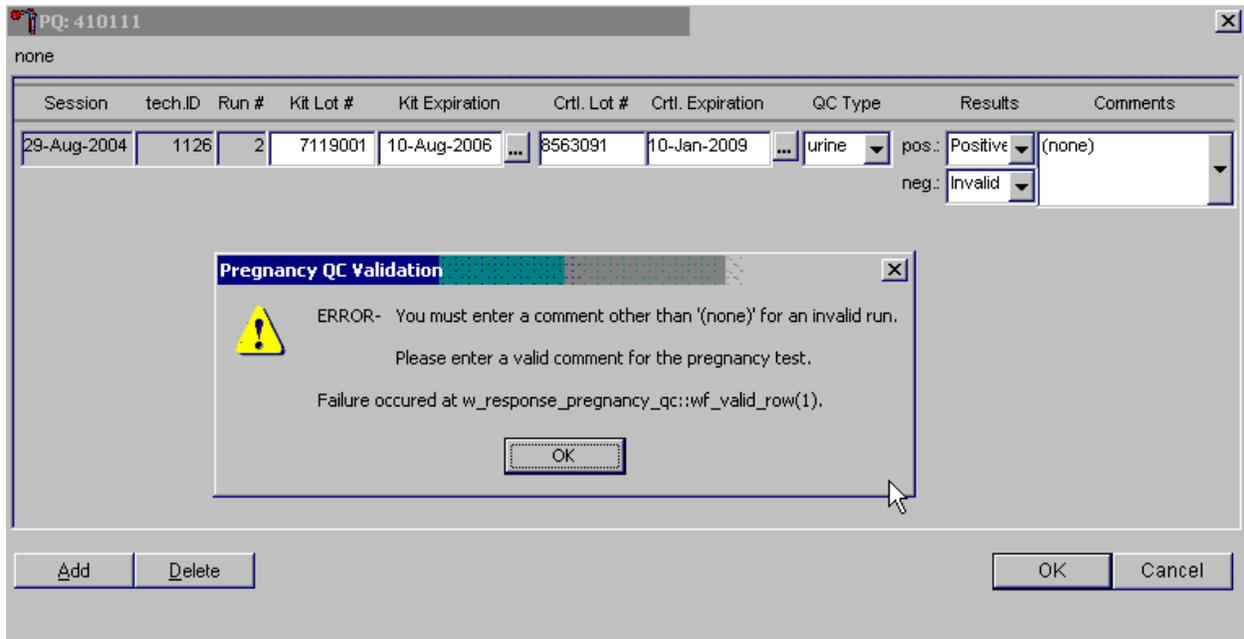
Save results when positive and negative controls demonstrate the expected result.

The screenshot shows a software window titled "PQ: 410111" with a "none" label. It contains a table with the following columns: Session, tech.ID, Run #, Kit Lot #, Kit Expiration, Ctrl. Lot #, Ctrl. Expiration, QC Type, Results, and Comments. The table has one row with the following data: Session: 29-Aug-2004, tech.ID: 1126, Run #: 2, Kit Lot #: 7119001, Kit Expiration: 10-Dec-2008, Ctrl. Lot #: 8563091, Ctrl. Expiration: 10-Jan-2009, QC Type: urine, Results: pos.: Positive, neg.: Negative, Comments: (none). Below the table are buttons for "Add", "Delete", "OK", and "Cancel".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	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.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Aug-2006	8563091	10-Jan-2009	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
29-Aug-2004	1126	2	7119001	10-Aug-2006	8563091	10-Jan-2009	urine	pos.: Positive neg.: Invalid	repeat negative cont

Add Delete OK Cancel

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.

The screenshot shows a software window titled "PQ: 410111" with a "none" label. It contains two tables of QC records. The first table has one row with the following data: Session: 29-Aug-2004, tech.ID: 1126, Run #: 2, Kit Lot #: 7119001, Kit Expiration: 10-Aug-2006, Ctrl. Lot #: 8563091, Ctrl. Expiration: 10-Jan-2009, QC Type: urine, pos.: Positive, neg.: Invalid, Comments: repeat negative conti. The second table has one row with the following data: Session: 29-Aug-2004, tech.ID: 1126, Run #: 3, Kit Lot #: 7119001, Kit Expiration: 10-Aug-2006, Ctrl. Lot #: 8563091, Ctrl. Expiration: 10-Jan-2009, QC Type: urine, pos.: Positive, neg.: Negative, Comments: (none). Below the tables are buttons for "Add", "Delete", "OK", and "Cancel".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Aug-2006	8563091	10-Jan-2009	urine	pos.: Positive neg.: Invalid	repeat negative conti
29-Aug-2004	1126	3	7119001	10-Aug-2006	8563091	10-Jan-2009	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.

none

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	01-Jul-2006	678454	18-Nov-2008	urine	pos.: Positive neg.: Negative	(none)
29-Aug-2004	1126	3	7119001	01-Jul-2006	789612	26-Dec-2008	serum	pos.: Not Done neg.: Not Done	(none)

Add Delete OK Cancel

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: 410111" with a "none" label. It contains a table with two rows of QC data. The first row is for a urine sample, and the second row is for a serum sample. The second row is selected, and its "pos." and "neg." result dropdowns are open, showing "Positive" and "Negative" options respectively. At the bottom of the window are buttons for "Add", "Delete", "OK", and "Cancel".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	01-Jul-2006	678454	18-Nov-2008	urine	pos.: Positive (none) neg.: Negative	
29-Aug-2004	1126	3	7119001	01-Jul-2006	789612	26-Dec-2008	serum	pos.: Positive (none) neg.: Negative	

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

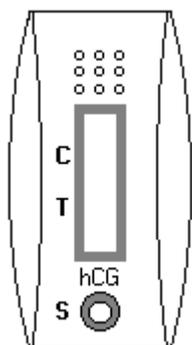


Figure 1.  
ICON 25 test device

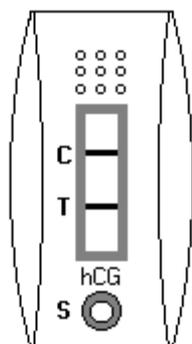


Figure 2.  
Positive Result  
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

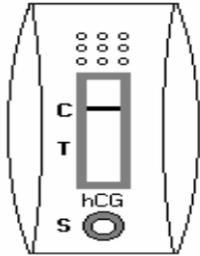


Figure 3.  
Negative Result  
One red line appears in the control region (C). No apparent red or pink line appears in the test region.

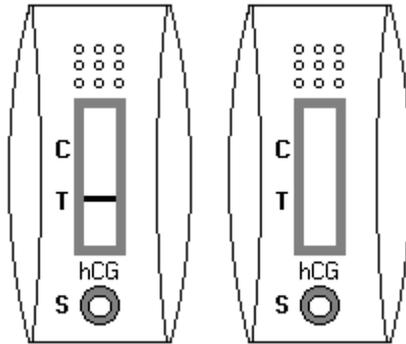


Figure 4.  
Invalid Result  
Control line fails to appear.

**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.

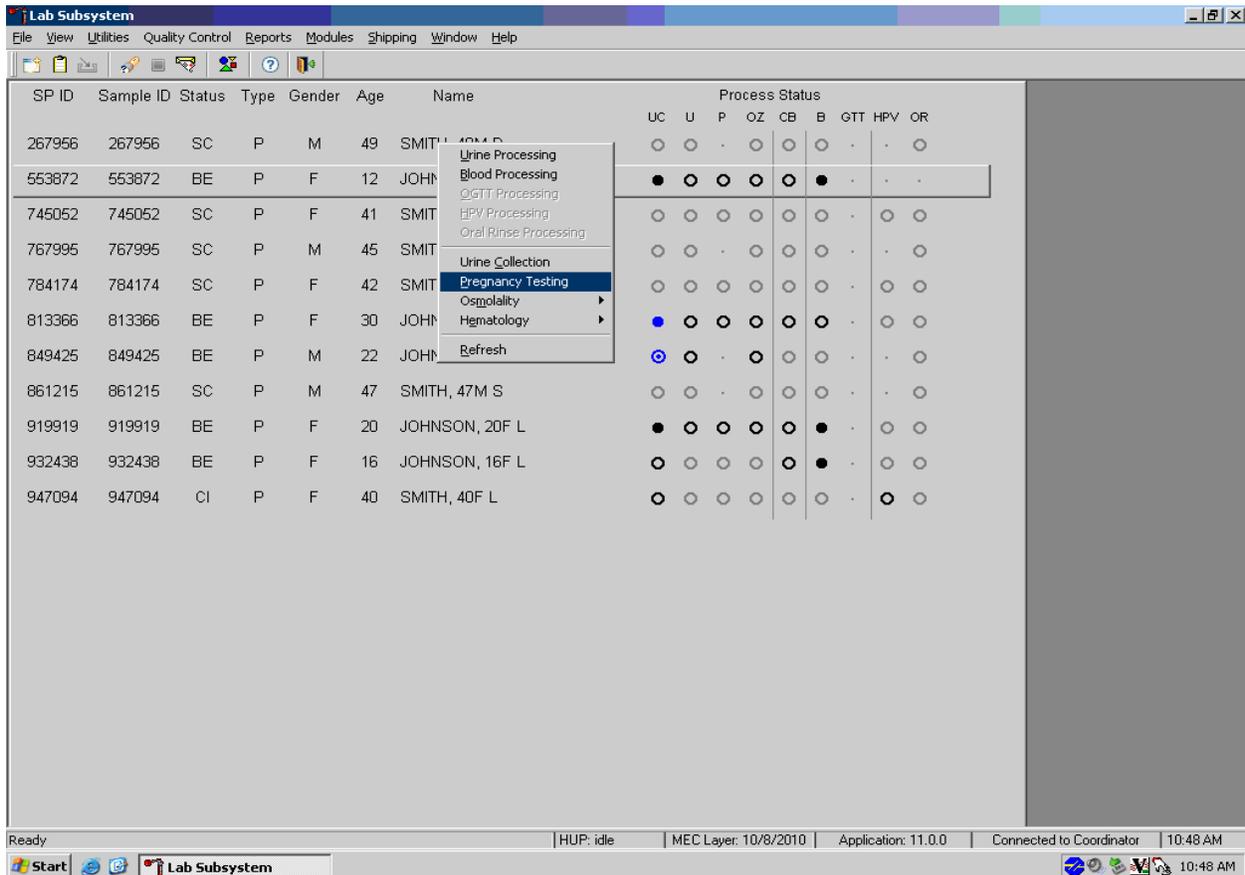
**Negative Result:**

The negative urine and serum control should produce a negative result.

## XII. 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. Note that the first urine collection must be marked as verified for the pregnancy testing module to enable on the heads-up display and on the right click menu.



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.

SP ID	Person Name	Gender	Age	Test Results
215591	PATEL, PAVARTI	F	59	(none)
900081	ABBOTT, HANNAH	F	49	(none)

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, not done, or invalid.

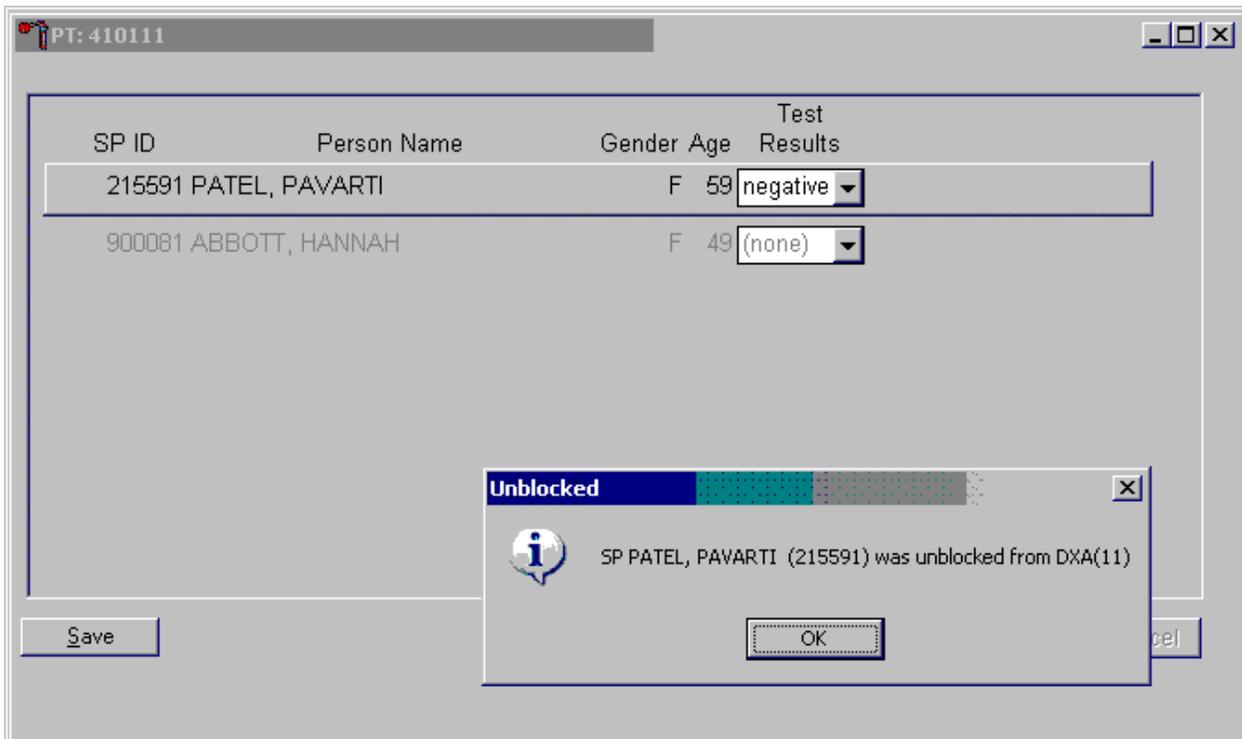
SP ID	Person Name	Gender	Age	Test Results
215591	PATEL, PAVARTI	F	59	(none)
900081	ABBOTT, HANNAH	F	49	(none)

Buttons: Save, OK, Cancel

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. Enter [N/n] not done when the test is not performed. 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.

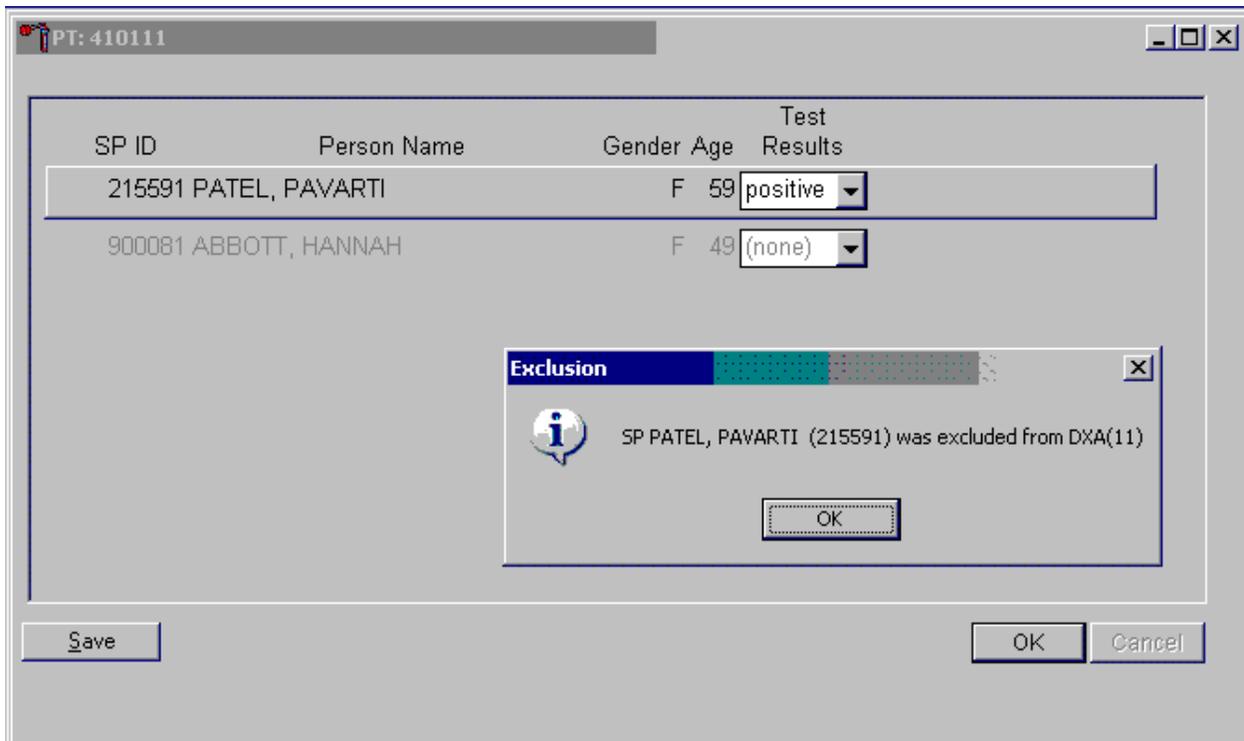
Continue performing pregnancy tests and recording the results. Save the test results after entering each positive, negative, or invalid result. To update the results without exiting the window, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To update 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.

A series of message boxes display to inform that an SP has been excluded (blocked) or is eligible (unblocked.) After each negative result is saved to the database, an unblocking message box displays.



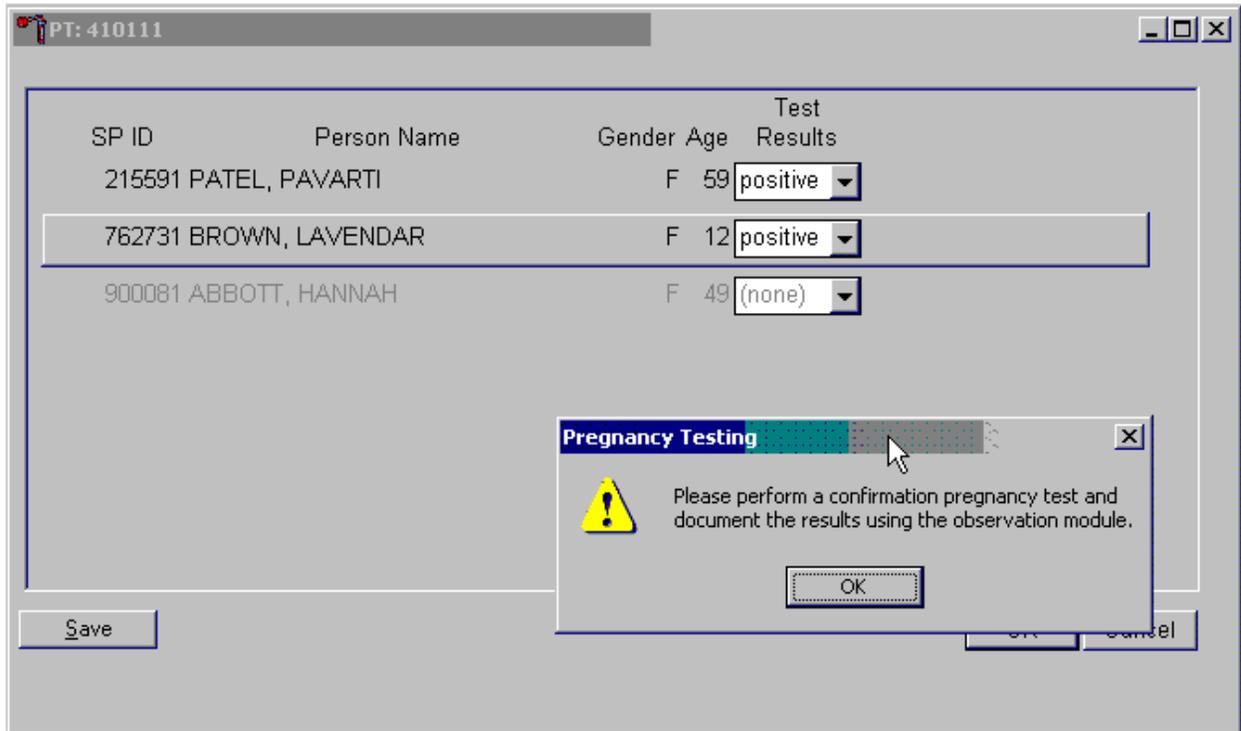
To remove the informational message box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

As each positive result is saved to the database a blocking message 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].

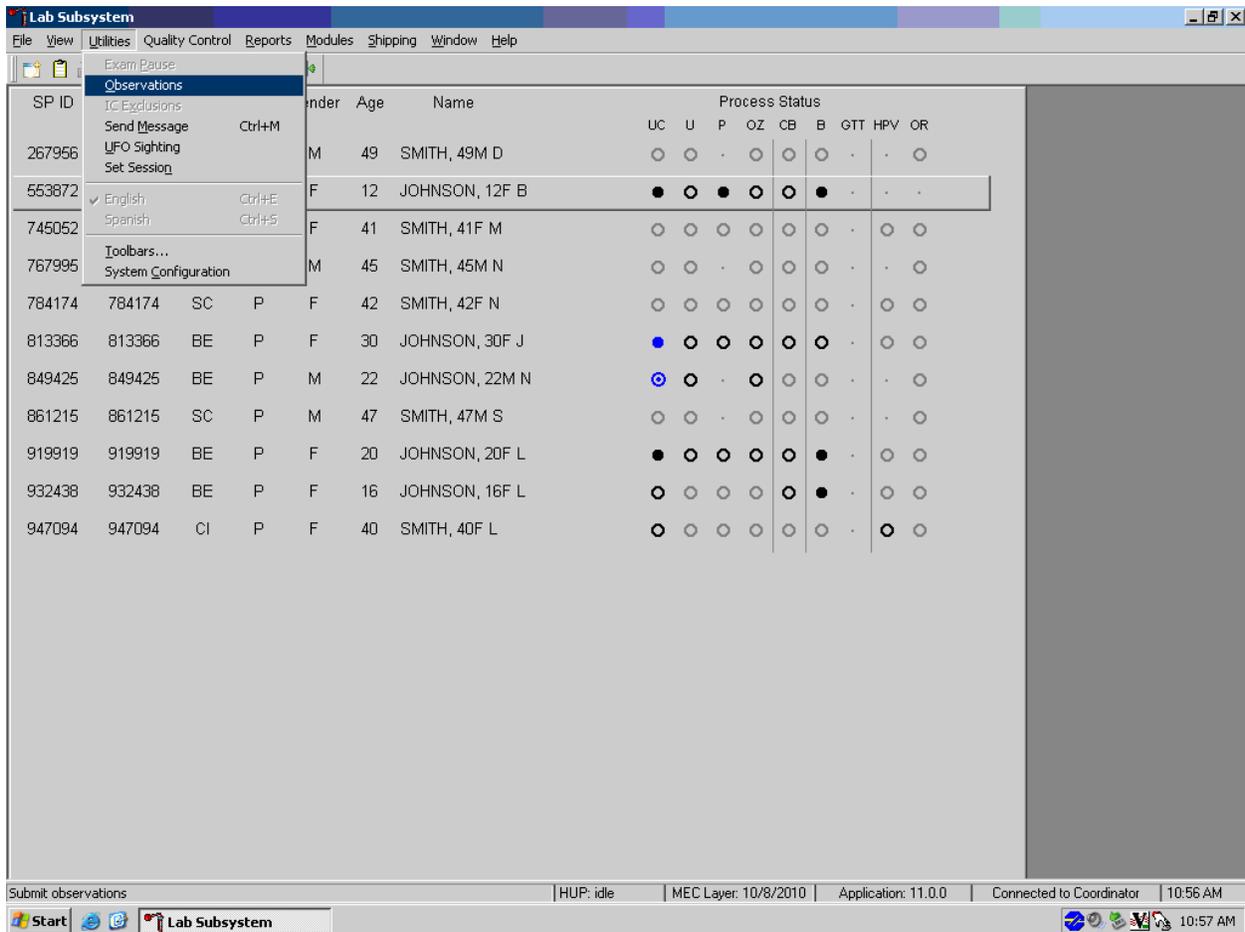
If a urine pregnancy test is positive on any female SPs aged 8-17 years, confirm the result using serum. An informational pop-up box displays as a reminder to perform the confirmation test.



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

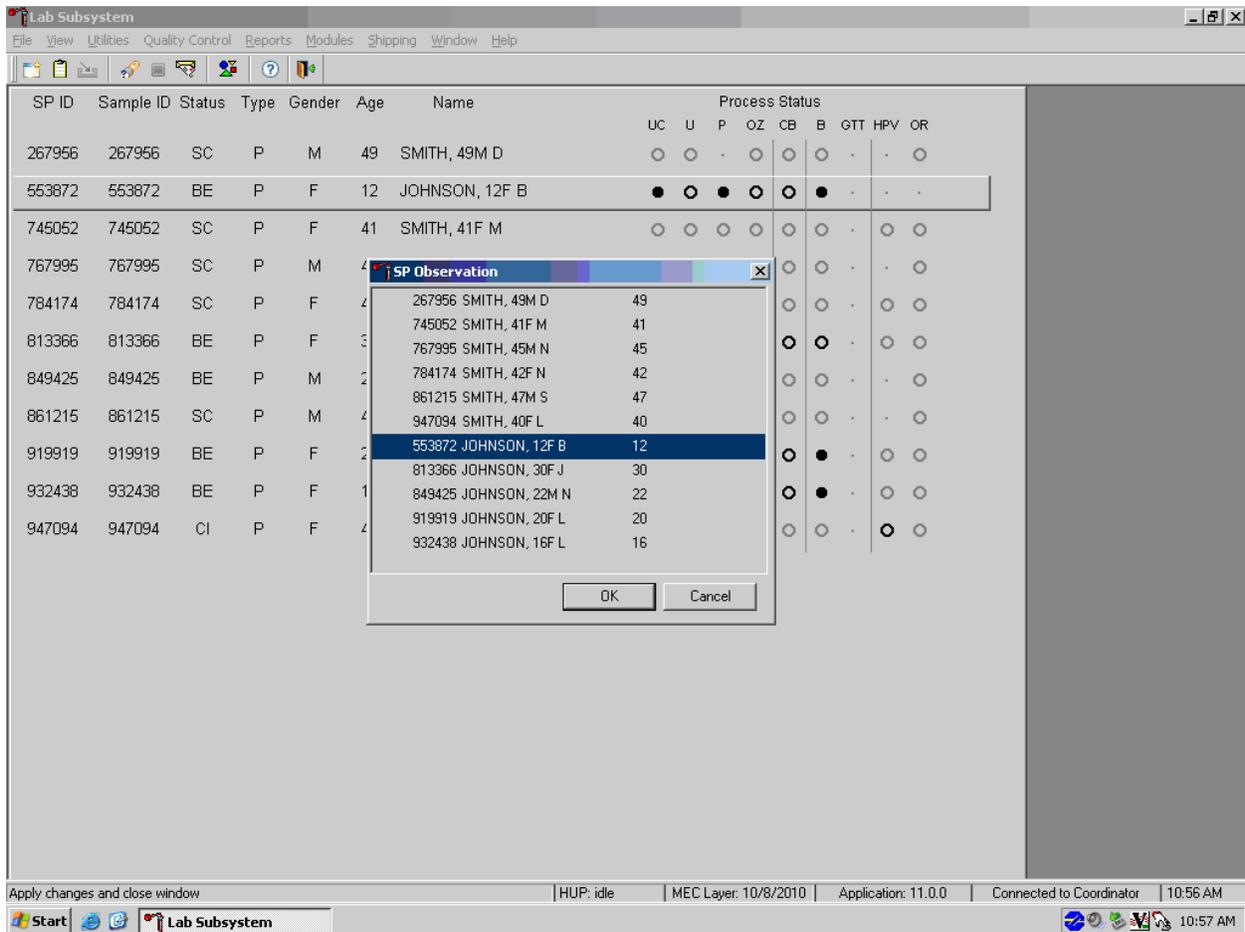
If no blood is drawn, repeat the urine test. **Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.**

Access the observation function to send an observation to the physician.



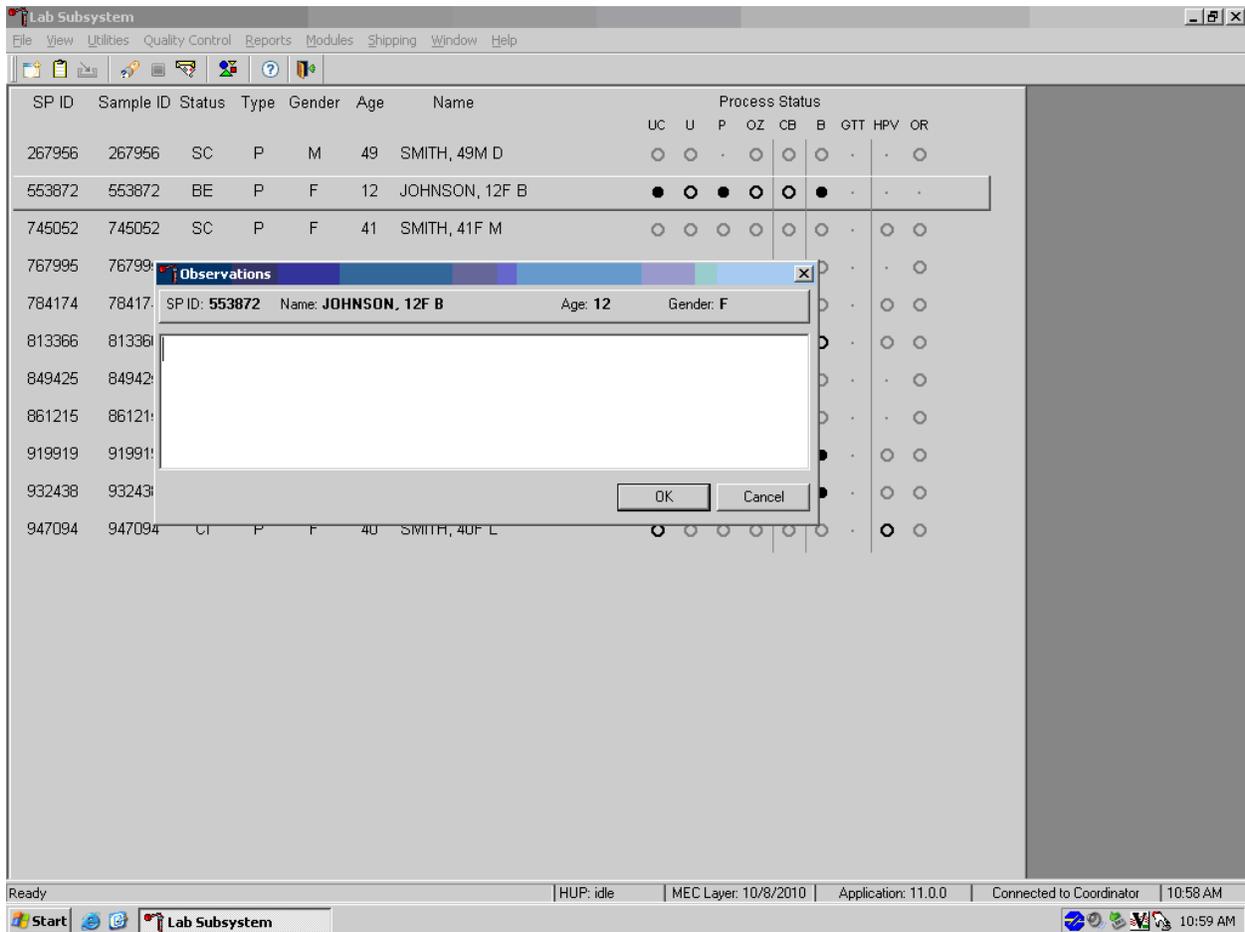
To send an observation to the physician, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the mouse arrow to {Observations} and left click or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



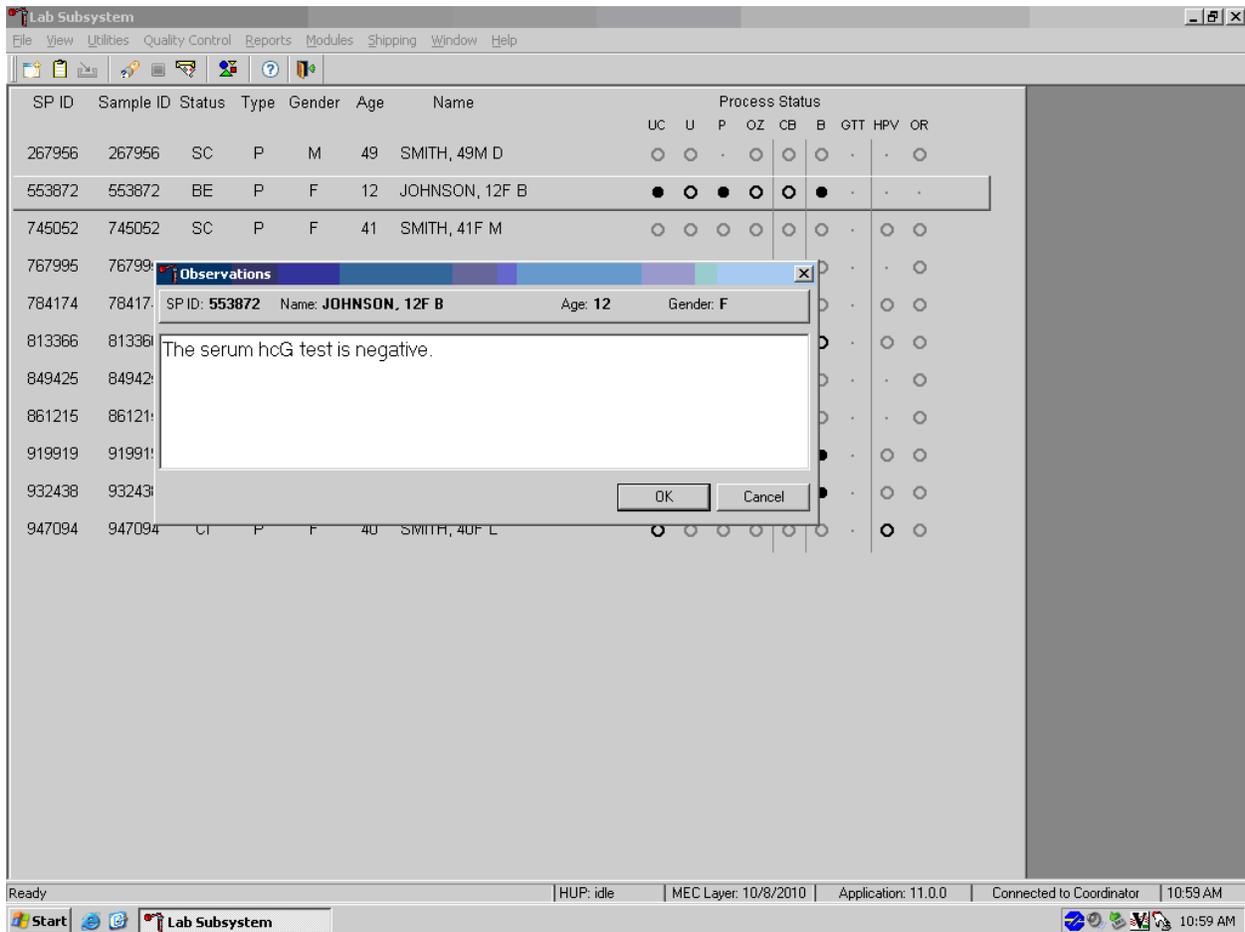
To select or highlight an SP, drag the mouse arrow to the correct SP and left click. Verify that the SP ID, name, and age are correct. Use the vertical scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. 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.



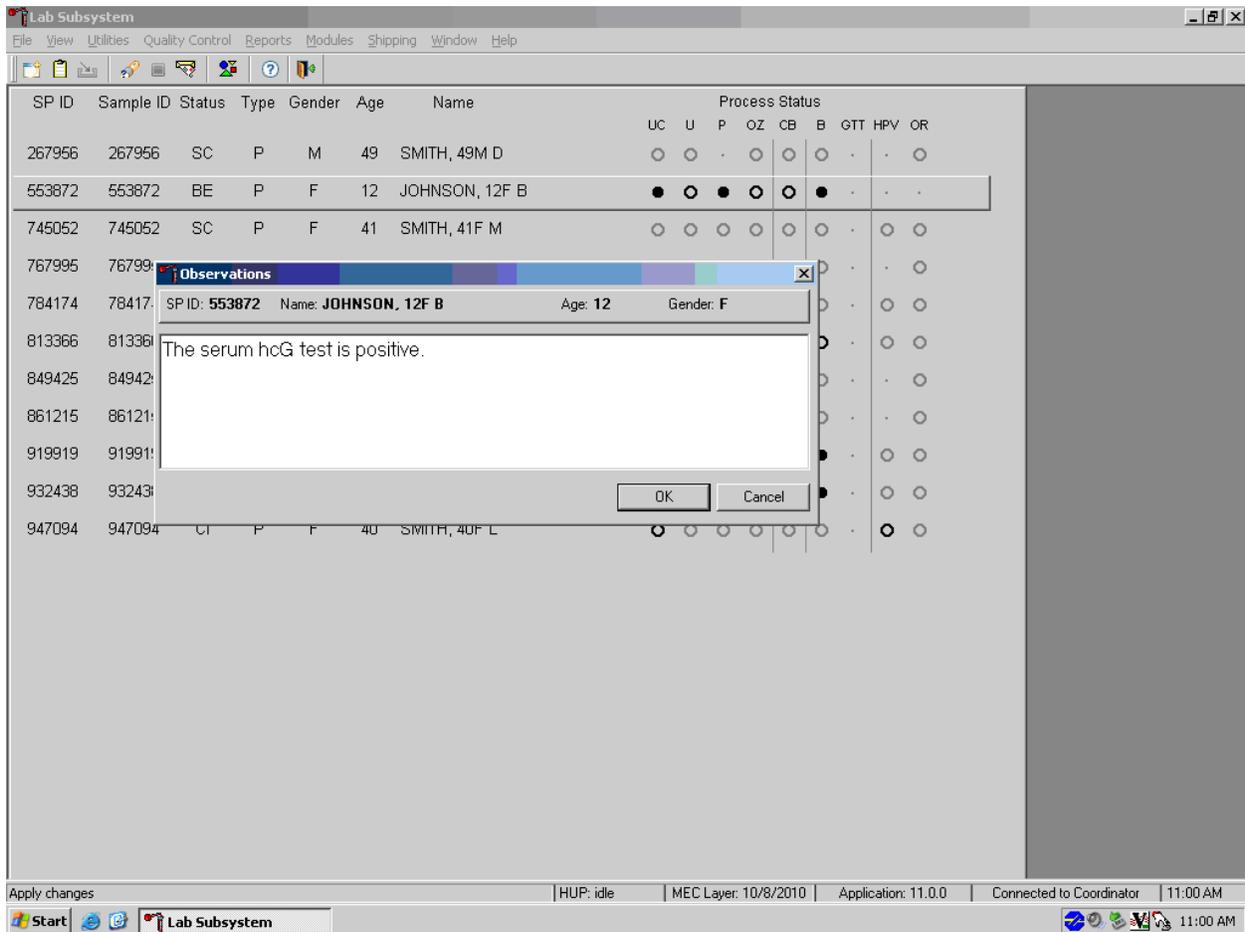
The observation text window contains the SP ID, name, age, and gender. Type the observation using the keyboard's keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation 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.



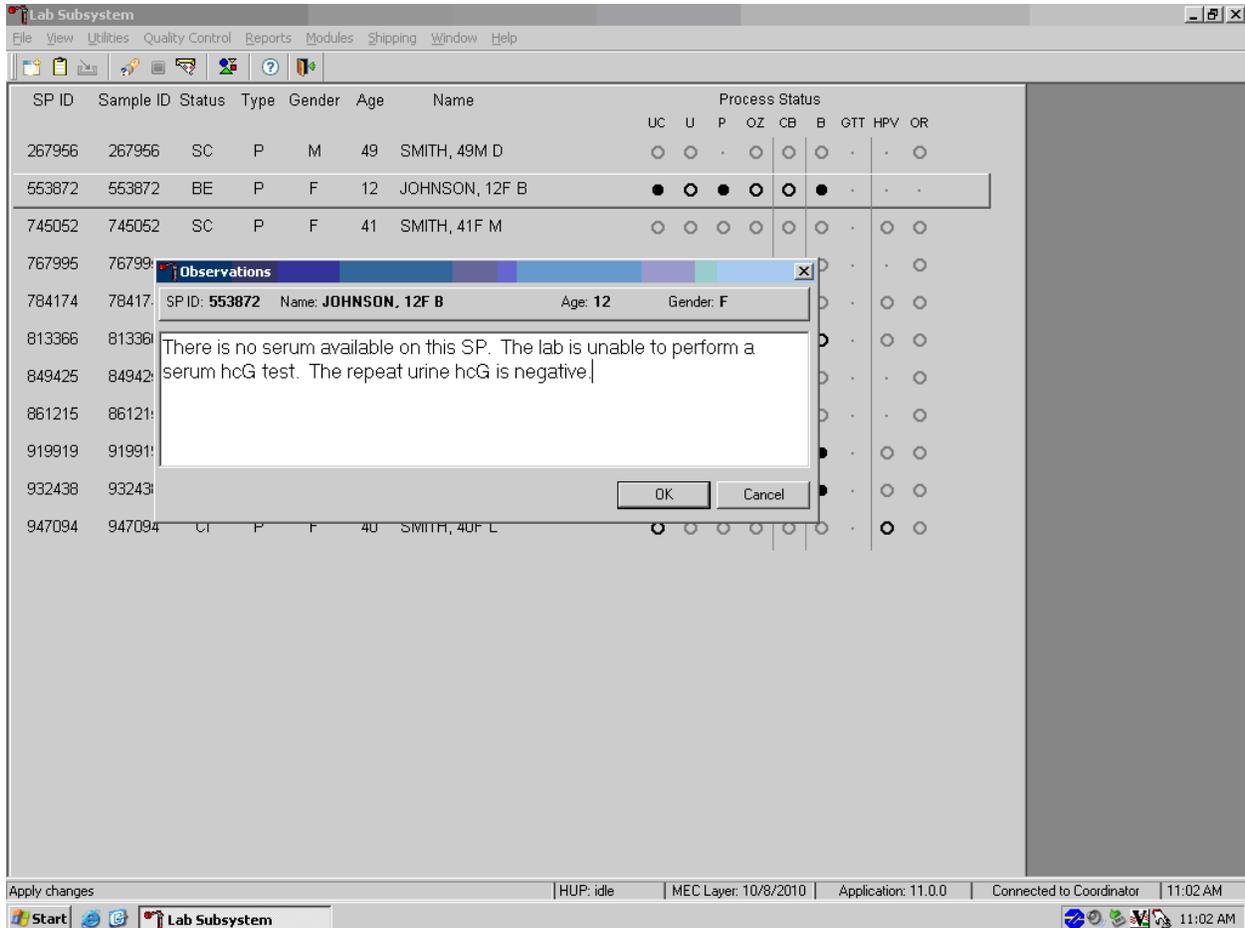
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum hCG test is negative” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions 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.



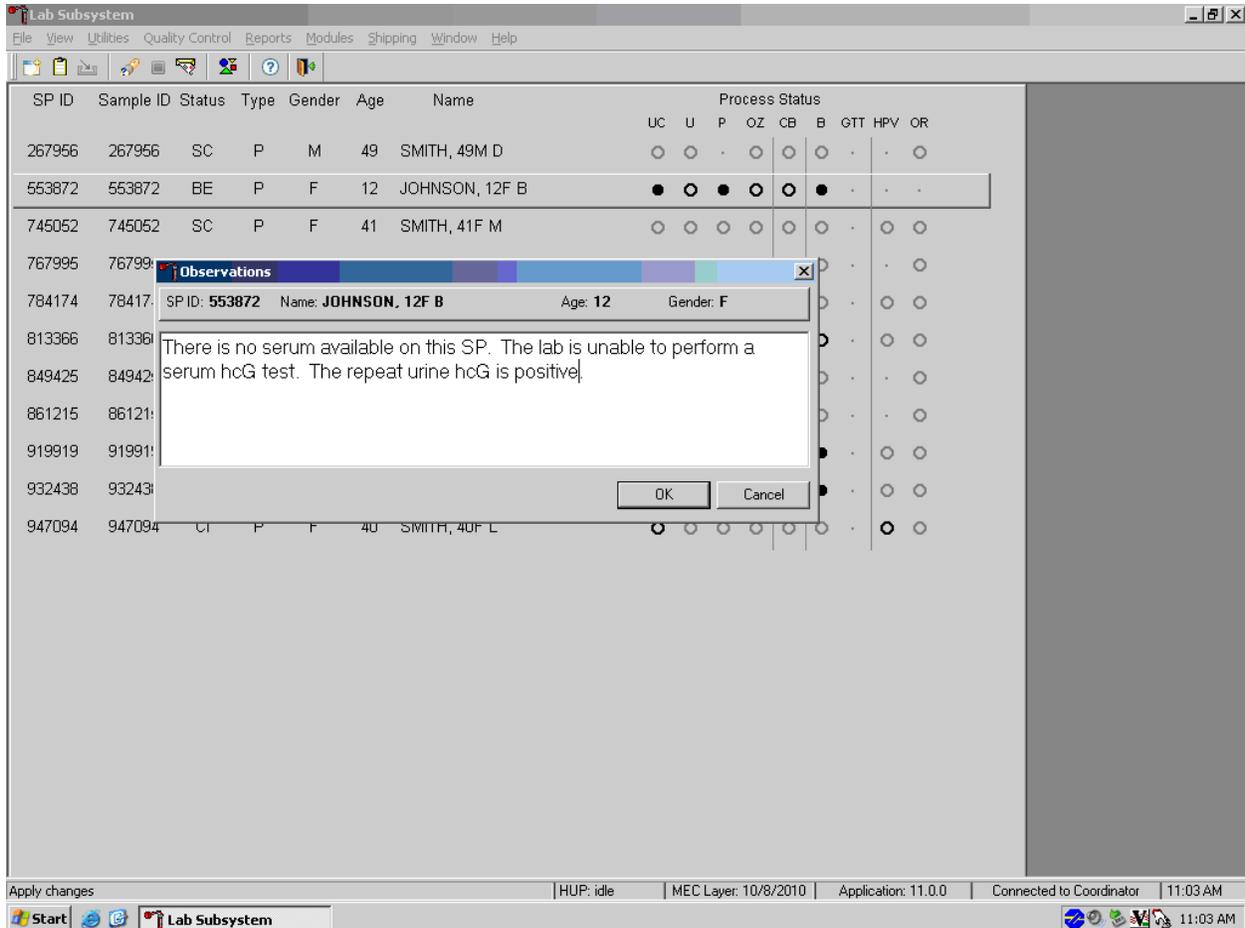
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum hCG test is positive” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions 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.



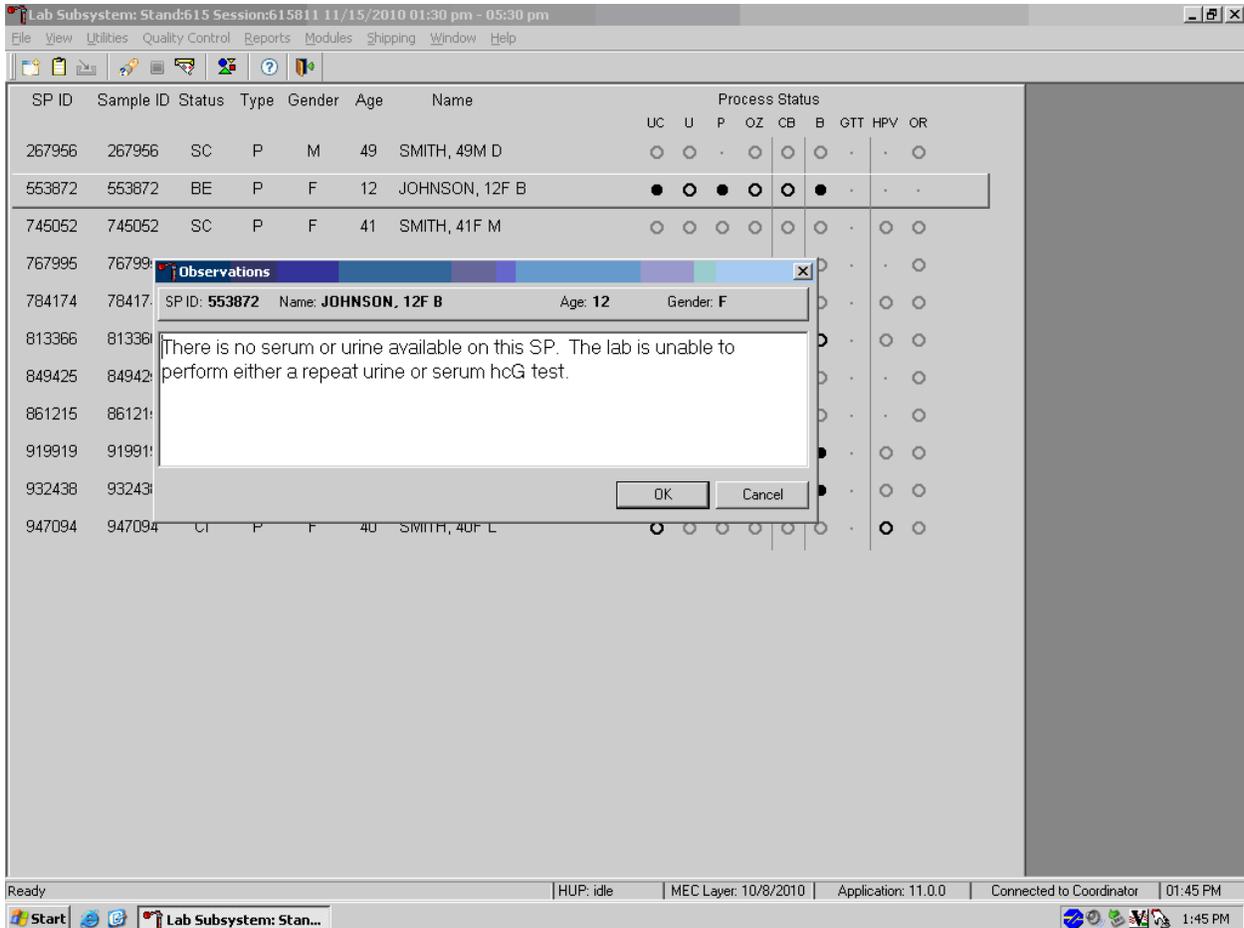
The observation window contains the SP ID, name, age, and gender. Type the observation, "There is no serum available on this SP. The lab is unable to perform a serum hCG test. The repeat urine hCG test is negative," using the keyboard keys. To send the observation to the physician, use the mouse to direct 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.



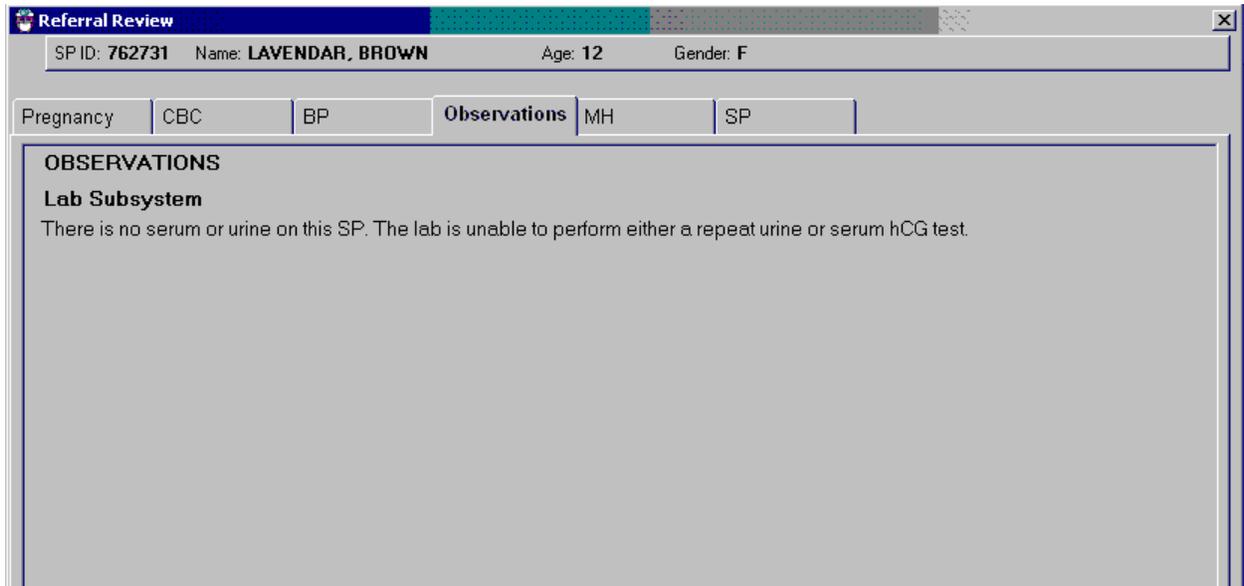
The observation window contains the SP ID, name, age, and gender. Type the observation, “There is no serum available on this SP. The lab is unable to perform a serum hCG test. The repeat urine test is positive.” using the keyboard keys. To send the observation to the physician, use the mouse to direct 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.

XIII. 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 nontrophoblastic 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-Vue™ hCG Urine and Serum Control Sets**

- These controls are formulated for use as quality control specimens in the reagent verification of pregnancy test kits.

**Accuracy, 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 result. 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 nonhemolyzed 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., Bergsjø, 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., Vaitukatitits, 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 2011**

Prepared by \_\_\_\_\_

Date Adopted \_\_\_\_\_

Approved by \_\_\_\_\_

Director

Signed \_\_\_\_\_

Director

Dated \_\_\_\_\_

Director

Reviewed by \_\_\_\_\_

Date Reviewed \_\_\_\_\_

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## 7. COMPLETE BLOOD COUNT (CBC)

### Introduction

Perform a complete blood count (CBC) in duplicate on all Sample Persons (SPs) aged 1 and older. Perform the CBC on the Coulter® HMX. Run a CBC on the SP's EDTA blood tubes.

The three Coulter HMXs serial numbers and system IDs are:

HMX #1	Serial # AK04024	System ID # 495616
HMX #2	Serial # AJ47275	System ID # 495613
HMX #3	Serial #AK04023	System ID # 493955

### I. Purpose and Principle of Test

#### CBC Analysis

The Coulter® method accurately counts and sizes cells by detecting and measuring changes in electrical resistance when a particle (such as a cell) in a conductive liquid passes through a small aperture.

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell goes through the aperture, it momentarily increases the resistance of the electrical path between the submerged electrodes on either side of the aperture. This causes a measurable electronic pulse. For counting, the vacuum used to pull the diluted suspension of cells through the aperture must be at a regulated volume.

The number of pulses correlates to the number of particles. The height of the electrical pulse is proportional to the cell volume.

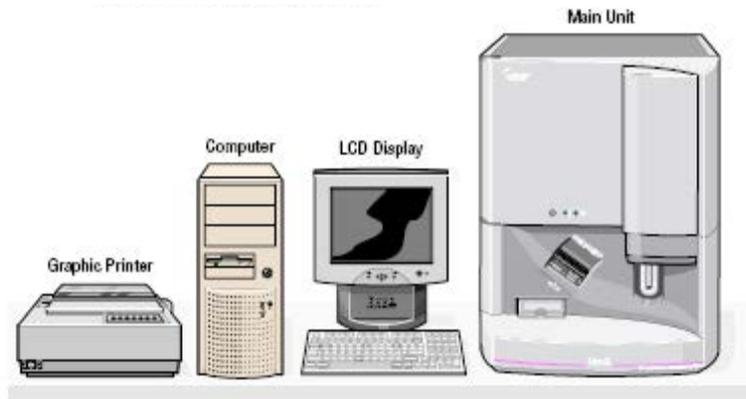
#### Differential Analysis

As the sample, prepared for differential analysis, streams through the flow cell these three measurements occur simultaneously on each individual white cell to classify it:

- Low-frequency current measures volume.
- High-frequency current senses cellular internal content through measuring changes in conductivity.
- Light from the laser bouncing off the individual WBC cells characterizes cellular surface, shape, and reflectivity.

The Coulter HMX Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential cell counter for in vitro diagnostic use in clinical laboratories. The purpose of the HMX Hematology Analyzer is to separate the normal participant, with all normal system-generated parameters, from the participant who needs additional studies. These studies include further measurements of cell size and cell distribution, biochemical investigation, or any other test that helps diagnose the abnormality.

Exhibit 7-1. The HMX hematology analyzer



The HMX measures these parameters in whole blood:

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
WBC	White Blood Cell Count  This is the number of leukocytes measured directly, multiplied by the calibration constant, and expressed as: $n \times 10^3$ cells/ $\mu$ L	WBC bath	$\geq 35$ fL	$n \times 10^3$ cells/ $\mu$ L
RBC	Red Blood Cell Count  This is the number of erythrocytes measured directly, multiplied by the calibration constant, and expressed as: $n \times 10^6$ cells/ $\mu$ L	RBC bath	36 to 360 fL	$n \times 10^6$ cells/ $\mu$ L

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
Hgb	<p>Hemoglobin</p> <p>Concentration Weight (mass) of hemoglobin determined from the degree of absorbance found through photocurrent transmittance is:</p> $\text{Hgb (g/dL)} = \text{Constant} \times \log_{10} \left( \frac{\text{Reference \%T}}{\text{Sample \%T}} \right)$	WBC bath	525 nm	g/dL
Hct	<p>Hematocrit</p> <p>This is the relative volume of packed erythrocytes to whole blood, computed as: Hct (%) = RBC × CV/10</p>	Computed	RBC x MCV/10	% percent

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
MCV	<p>Mean Cell Volume</p> <p>This is the average volume of individual erythrocytes derived from the RBC histogram. The system:</p> <ul style="list-style-type: none"> <li>▪ Multiplies the number of RBCs in each channel by the size of the RBCs in that channel.</li> <li>▪ Adds the products of each channel between 36 fL and 360 fL.</li> <li>▪ Divides that sum by the total number of RBCs between 36 fL and 360 fL.</li> <li>▪ Multiplies by a calibration constant and expresses MCV in femtoliters.</li> </ul>	Derived from RBC histogram	# x size of RBC/ Total RBC	fL
MCH	<p>Mean Cell Hemoglobin</p> <p>This is the weight of hemoglobin in the average erythrocyte count, computed as: Hgb/RBC x 10</p>	Computer	Hgb/RBC x 10	pg

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
MCHC	<p>Mean Cell Hemoglobin Concentration</p> <p>This is the average weight of hemoglobin in a measured dilution, computed as: Hgb/Hct x 100</p>	Computed	Hgb/Hct x 100	g/dL
RDW	<p>Red Cell Distribution Width</p> <p>RDW represents the size distribution spread of the erythrocyte population derived from the RBC histogram. It is the coefficient of variation (CV), expressed in percent, of the RBC size distribution.</p>	Derived from RBC histogram	CV expressed in % of the RBC size distribution	% percent
Plt	<p>Platelet Count</p> <p>This is the number of thrombocytes derived from the Plt histogram and multiplied by a calibration constant. This number is expressed as: n x 10<sup>3</sup> cells/μL</p>	RBC bath	2 to 20 fL	n x 10 <sup>3</sup> cells/μL
MPV	<p>Mean Platelet Volume</p> <p>MPV is the average volume of individual platelets derived from the Plt histogram. It represents the mean volume of the Plt population under the fitted Plt curve multiplied by a calibration constant, and expressed in femtoliters.</p>	Derived from Plt histogram	Mean volume of Plt population under the fitted curve x constant	fL

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
NE%	Neutrophil Percent The percentages of leukocytes from each category are derived from the scatterplot.	Derived from scatterplot	# cells inside NE area/# cells inside total cell area x 100	% percent
NE #	Neutrophil Number The absolute numbers of leukocytes in each category are computed from the WBC count and the differential percentage parameters.	Absolute number	NE%/100 x WBC count	10 <sup>3</sup> cells/μL
LY%	Lymphocyte Percent The percentages of leukocytes from each category are derived from the scatterplot.	Derived from scatterplot	# cells inside LY area/# cells inside total cell area x 100	% percent
LY#	Lymphocyte Number The absolute numbers of leukocytes in each category are computed from the WBC count and the differential percentage parameters.	Absolute number	Ly%/100 x WBC count	10 <sup>3</sup> cells/μL
MO%	Monocyte Percent The percentages of leukocytes from each category are derived from the scatterplot.	Derived from scatterplot	# cells inside MO area/# cells inside total cell area x 100	% percent
MO#	Monocyte Number The absolute numbers of leukocytes in each category are computed from the WBC count and the differential percentage parameters.	Absolute number	MO%/100 x WBC count	10 <sup>3</sup> cells/μL

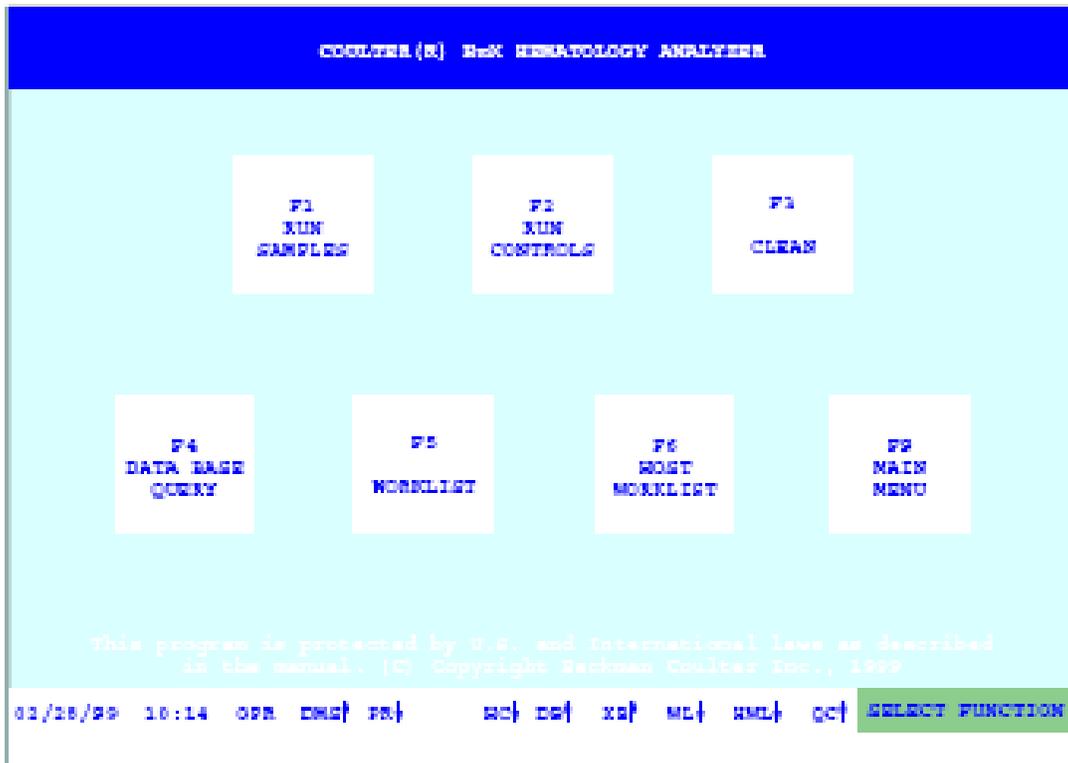
Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
EO%	Eosinophil Percent The percentages of leukocytes from each category are derived from the scatterplot.	Derived from scatterplot	# cells inside EO area/# cells inside total cell area x 100	% percent
EO#	Eosinophil Number The absolute numbers of leukocytes in each category are computed from the WBC count and the differential percentage parameters.	Absolute number	EO%/100 x WBC count	10 <sup>3</sup> cells/ $\mu$ L
BA%	Basophil Percent The percentages of leukocytes from each category are derived from the scatterplot.	Derived from scatterplot	# cells inside BA area/# cells inside total cell area x 100	% percent
BA#	Basophil Number The absolute numbers of leukocytes in each category are computed from the WBC count and the differential percentage parameters.	Absolute number	BA%/100 x WBC count	10 <sup>3</sup> cells/ $\mu$ L

**\*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 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.

## A. Access Screen

The Access screen provides quick access to the most commonly used areas of the software. It is the first screen to appear after a system reset or power up. If you go to any of these areas using the Access screen, you will automatically return to the Access screen upon exit. The Access screen is also available from the Main Menu by using the F1 key.





C. Run Sample Screen Options

**[F5] Opins:**

```

F2 XB:    ON N=2 IN
F3 CAP PIERCER 10mm-13mm
F4 DB:    ON
F5 Print: NONE
F6 Host:  OFF
F7 Display only: OFF
F8 Operator: OPR
F11 B&W screen print
F12 Color screen print
    
```

Description of Run Screen Options

F2 XB: ON N=2 IN	Turns XB ON and OFF. N is the number of samples stored in the current batch. Also displays the status of the last completed batch (IN or OUT).
F3 CAP PIERCER 10mm-13mm	Alternate between this and 16mm. Select the correct carousel slot based on the size of the tube you run.
F4 DB: ON	Turns the data base ON and OFF. Default setting is ON.
F5 Print: NONE	Sets the automatic printing of samples to the graphic printer. Choose between NONE, NORMALS, ABNORMALS, or ALL. Default setting is NONE.
F6 Host: OFF	Turns the automatic host transmission ON and OFF. Default setting is OFF.
F7 Display only: OFF	If ON, then XB, DB, and HOST turn OFF. Default setting is OFF.
F8 Operator: OPR	Enter up to three alphanumeric characters for an Operator ID. Default setting is OPR.
F11 B&W screen print	Initiates a large black and white screen print of the current sample.
F12 Color screen print	Initiates a large color screen print of the current sample if your printer can print in color.

**NOTE:** After a system reset, these options return to their default settings. Be sure to set them up again according to your laboratory's protocol before running patient samples.

**NOTE:** Print, Host, and Operator can also be set up from the Main Menu using **[F5]-Options**.

#### D. Status Line

The status line at the bottom of your screen indicates the current operating status of the HMX Hematology Analyzer.

Symbol	Refers to	↑	↓	Red	Yellow	White
DMS ↑	Data Management System	Connected to Analyzer.	Not connected to Analyzer.	Not communicating with Analyzer.	DMS busy or receiving data.	DMS is OK.
PR ↓	Graphics Printer	Autoprint is set to ALL, ABNORMALS, or NORMALS.	Autoprint is set to NONE.	Printer is off-line, or printer is out of paper.	Printer is printing.	Printer and DMS are connected.
HC ↑	Host Computer	Auto transmission ON.	Auto transmission OFF.	Not connected to host.	Sending data to host computer.	Host and DMS are connected.
DB ↑	Data Base	Store is ON.	Store is OFF.	Data Base is not functional. System stops. Reset the system and rerun last 2 samples.	Data Base is storing data.	Data Base is OK.
XB ↓	X <sub>B</sub> Analysis	XB is ON.	XB is OFF.	Last completed batch was OUT.	N/A	Last completed batch was IN.
WL ↓	Worklist	Preassigned entries pending on Worklist.	No preassigned entries on Worklist.	Three consecutive or 10 total error messages are in the status field.	The Worklist is full. (There are 300 preassigned samples.)	Worklist is OK.
HWL ↓	Host Worklist	Preassigned entries pending on the Host Worklist.	No preassigned entries on Worklist.	Host Worklist is full.	DMS is receiving preassigned samples from the host computer.	Host Worklist is OK.
QC ↑	Quality Control	Auto-Stop is ON.	Auto-Stop is OFF.	Last control run had an error message.	Receiving a control run.	Results of last control run are OK.

\*Changes to MA for manual printing, BA for batch printing, and AU for auto-printing.

## II. Special Safety Precautions

All specimens may be potentially positive for infectious agents including HIV and the hepatitis B and C viruses. Observe universal precautions. It is mandatory to wear gloves and lab coat when handling all human blood products and 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) *Working Safely with Hazardous Chemicals* manual contains all Coulter material safety data sheets (MSDS).

## III. Computerization: Integrated Survey and Information System (ISIS)

The HMX 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 aged 1+ following established venipuncture protocol and procedures. (A 1-2% dilution effect occurs in this liquid EDTA tube.)

2. Sample volume is 185 $\mu$ L of whole blood in the closed-vial mode. The minimum sample volume per tube in the closed-vial mode is 1-mL with the proper proportion of blood to anticoagulant.

#### 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 HMX DMS stores and maintains the lot numbers and expiration dates.

##### A. Reagents, Controls, and Calibrators

1. Isoton III® (diluent) – PN 8546733 (20 L) – an isotonic electrolyte
  - Dilutes the whole-blood samples.
  - Stabilizes cell membranes for accurate counting and sizing.
  - Conducts aperture current.
  - Carries and focuses the sample stream in the flow cell to enable the WBC differential measurements.
  - Rinses the system between samples.
  - Expires on expiration date printed on container.

2. COULTER CLENZ® – PN 8546931 (10L) – a cleaning agent that cleans and rinses the internal surfaces of the Diluter components. Daily use prevents protein buildup and eliminates routine aperture bleaching.
  - Expires 90 days after being opened and installed on the instrument.
  
3. LYSE S® III – PN 8546983 (1L diff lytic reagent is a lytic reagent used for the CBC mode.)
  - Rapidly lyses erythrocytes (RBCs), freeing hemoglobin (Hgb), and reducing the size of cellular debris to a level that does not interfere with the leukocyte (WBC) count.
  - Causes a substantial conversion of the Hgb to a stable pigment, the absorbance of which is directly proportional to the Hgb concentration over the clinical range.
  - **NOTE:** If you use LYSE S III diff lytic reagent you must use ISOTON III diluent.
  - Expires 60 days after being opened and installed on the instrument.
  
4. HMX Pak®-PN 8547166 – The HMX Pak contains the PAK LYSE (Erythrolyse™ II erythrocyte lytic reagent) and the PAK PRESERVE (StabiLyse™ leukocyte preservative) used for the differential measurement.
  - The PAK LYSE (also called the diff lytic reagent), while maintaining leukocytes (WBCs) in near-native state.
  - The PAK PRESERVE preserves the leukocytes (WBCs) in near-native state. It allows the leukocytes to be differentiated into their subpopulations through the volume, conductivity, and light-scatter measurements.
  - Expires 60 days after being opened and installed on the instrument.

5. Latron® Controls – PN 7547116 (5 x 16-mL)
  - LATRON control monitors the performance of the volume, conductivity, and light scatter measurements.
  - Expires 30 days after being opened.
  
6. Latron® Primer – PN 7546915 (5 x 16-mL)
  - LATRON™ primer prepares the tubing and instrument components for the LATRON control.
  - 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)
  - COULTER 5C® cell control monitors the CBC and differential parameters.
  - Expires 13 days or 13 events after being opened.
  
8. Calibration S-CAL® – PN 7546808 (2 x 6-mL)
  - Use at the start of each stand.
  - The S-CAL® calibrator kit calibrates Primary mode CBC parameters and is an acceptable alternative to the whole-blood reference method of calibration.
  - 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.

10. Lin-C – PN 6605374

- LIN-C® linearity control verifies the reportable range of the instrument's CBC parameters.

B. Supplies

1. 3-mL K<sub>2</sub> EDTA Becton Dickinson Hemogard Vacutainer® tube (367856)
2. 4-mL K<sub>2</sub> EDTA Becton Dickinson Hemogard Vacutainer® tube (367861)
3. Tube rocker
4. Bleach, 5.25% Sodium Hypochlorite
5. Bottled distilled water
6. Three 30-mL plastic containers with lid
7. Two 1-liter containers with lid
8. Plastic squirt bottle
9. Cotton gauze pads
10. Three-hole paper punch
11. Notebook
12. Flashlight
13. 10-mL syringe with plastic tubing
14. Precision screwdriver set
15. Distilled water bottle
16. Disposable lab jacket – 48 inches long
17. Diskettes

### C. Notes

1. If reagents become frozen in transit, mix thoroughly by inversion and let bubbles settle before use.
2. To avoid electrical interference, do not place reagents on or near electric cords or lines.

## VII. Calibration

S-CAL® (PN 7546808 - 2 x 6-mL) – The S-CAL® calibrator kit determines the adjustment factors for the calibration of the Coulter® HMX. 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 start of each stand, before you begin analyzing samples;
- After you replace any component dealing with dilution preparation, such as the BSV primary measurement, such as an aperture; and
- If your Beckman Coulter Representative suggests you calibrate.

### B. Verify the Calibration of your Instrument

- 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.

Principle – The HMX 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**, **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.

1. 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.

2. Storage, handling, and stability – Sealed vials are stable through the expiration date when stored at 2-8°C (35-46°F). Open 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-1 and HIV-2) 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.

This product contains <0.1% Sodium Azide. Sodium Azide preservative may form explosive compounds in metal drain lines. Discard this product in biohazardous waste containers.

3. Indications of instability or deterioration – Inability to obtain expected values in the absence of known instrument problems or gross hemolysis (darkly-colored supernatant) is indicative of product deterioration. However, a slight pink color to the supernatant is normal and should not be confused with deterioration of the product.

C. Pre-calibration, Reproducibility, and Carryover Check

Perform a calibration after the instrument has been “cleaned” for at least 30 minutes. From the Access screen, press [F3] **Clean**.

1. Pre-calibration procedure

Bleach the aspiration system using the Clean Needle procedure.

- a) Prepare a fresh bleach solution. Put 1-mL bleach and 1-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 barcode 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 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 barcode 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) 1st diluent sample - 3rd diluent sample x 100 = % carryover  
2nd sample.

D. CBC Calibration with S-CAL® Calibrator

Discard the Calibrator Disks from the S-Cal Calibrator Kit. Locate the hard copy Table of Expected Results that contains 5 gray boxes labeled 1 through 5. Locate box 2 where it lists ISOTON III, Isoton 3E or LH Series Diluent / Lyse S III diff Lytic Reagent----- HMX system. Locate the corresponding gray #2 box in the table.

Take the S-CAL® calibrator from the refrigerator. Remove one vial of S-Cal from the kit. Return the unopened second vial to the refrigerator. Let the vial warm to ambient temperature for 15 minutes. Meanwhile, continue with the following steps:

1. Select **Special Functions → Calibration → CBC Calibration**. Press [F2] **Start Primary**. Delete any data in the table by pressing [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 Expected Results on the package insert on the REF: VALUES line. 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.

- c) Cycle the first cap-pierceable calibrator 11 times. Do not use the barcode 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.
- d) 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 Coulter® representative.
- b) Check the %CV values against these precision %CV limits. If any parameter exceeds the limit, STOP and contact a Coulter® representative.

Parameter	Precision (CV%)
WBC	≤2.5
RBC	≤2.0
Hgb	≤1.5
MCV	≤2.0
Plt	≤5.0
MPV	≤3.0

- c) Determine which calibration factors (if any) should be changed by checking the FAC%DIFF and DELTA DIFF values against these ranges.

**NOTE:** Disregard minus signs. The values are absolute numbers.

Parameter	Calibrate if FAC%DIFF is:	Calibrate if DELTA DIFF is:
WBC	>1.25 and ≤5.00	>0.10 and ≤0.40
RBC	>0.70 and ≤2.00	>0.03 and ≤0.09
Hgb	>0.78 and ≤3.00	>0.10 and ≤0.40
MCV	>1.18 and ≤2.50	>1.00 and ≤2.00
Plt	>2.70 and ≤9.00	>6.00 and ≤20.00
MPV	>5.00 and ≤20.00	>0.50 and ≤2.00

- d) If both the FAC%DIFF and DELTA DIFF values of a parameter fall below their lower limits, that parameter does not need to be calibrated.

**NOTE:** If all parameter values fall below the lower limits of both ranges, you are finished. Resume normal operation. Press [F4] to print the screen for the logbook.

- e) If either the FAC%DIFF or DELTA DIFF value of a parameter exceeds its upper limit, STOP. There could be an instrument problem. Call your Beckman Coulter Representative.

- f) If either the FAC%DIFF or DELTA DIFF value of a parameter falls between its lower and upper limits, that parameter should be calibrated. Continue with step 5 (below).

5. 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) Is *Select Function* displayed? If NO, press [F3] **Run** [F9] **Stop** [Esc]. If YES, Press [F5] **Optns**. Choose **SELECT PARAMETERS**. Use the space bar to select YES for parameters that need adjusting, NO for others. Press [Esc].
- c) Select **TRANSMIT FACTORS**. The following message appears: “WARNING – DATA WILL BE CLEARED AFTER TRANSMISSION. DO YOU WANT TO PRINT DATA? Y/N” If you did not print the Calibration screen press [Y]. Select [N] if the values have already been printed.
- d) Press [F4] Print to print this final calibration screen for the logbook. It reflects the new calibration factors for parameters you adjusted.
- e) Verify calibration by cycling the 5C cell controls in the primary mode. If any of the control level’s results are outside the expected range, run a second sample of the control. If the second sample is also outside of the expected range, call your Beckman Coulter representative.

## 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.
- $$\frac{\text{Reference Value} \times \text{Old Cal Factor}}{\text{S-CAL mean value (n=10)}} = \text{NEW CAL FAC}$$

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 are 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 HMX 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. Are Start Up results already displayed as the result of a Clean cycle?
  - a) If No, go to step 2.
  - b) If Yes, go to step 3.

**NOTE:** The Clean cycle consists of 30 minutes in Shut Down followed by an automatic Start Up.

3. To begin Start Up, select **Diluter Functions, and Start Up**. Press [Enter]. Follow the instructions on the screen.
4. 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 automatically print. Results outside limits turn red. File in the logbook.

5. Review and verify sample analysis set up.

- a) Select **Sample Analysis, Run Samples** [Enter]. Press [F5] for options. Press the corresponding function key to enter specific options.

```

F2  XB:      ON  N=2 IN
F3  CAP PIERCER 10mm-13mm
F4  DB:      ON
F5  Print:   NONE
F6  Host:    OFF
F7  Display only: OFF
F8  Operator: OPR
F11 B&W screen print
F12 Color screen print
  
```

Settings

F2	XB	Off
F3	CAP PIERCER	10mm-13mm
F4	DB	On
F5	Print	None
F6	Host	On
F7	Display only	Off
F8	Operator	Tech initials
F11	B & W screen print	
F12	Color screen print	

Use the corresponding [F] key to change the setting. For example, press [F6] to turn the Diff ON. Press [Esc] to exit.

## B. Run Controls

Run Coulter® LATRON primer and latex control, and all three levels, normal (blue), abnormal I (yellow), and abnormal II (pink), of Coulter® 5C® cell control daily at the beginning of the first session. Run all three levels (normal, abnormal I, and abnormal II) of Coulter® 5C® cell control at the beginning of the second session.

## C. Run Sample Persons

1. Review the placement of the barcode on the sample tube. Place the end of the label flush with the stopper. The bars on the label must be parallel to the stopper. If the label is skewed more than 5°, the scanner may not read it. Do not cover the bottom of the tube with the barcode label. The tube may jam in the carousel.



2. Run all samples in duplicate.
3. Run samples in the Primary mode.

In Primary mode, the system checks each sample aspiration using dual sensors called blood detectors, which monitor the blood before and after it passes through the Blood Sampling Valve (BSV). These blood detectors optically sense air

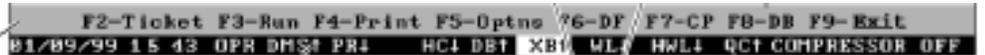
bubbles, diluent, and blood. As an indication of a good aspiration, the system looks for blood in both detectors. If the detectors optically identify bubbles in the sample, the instrument pierces the tube a second time. If the second aspiration contains bubbles, the instrument reports a partial aspiration. Bubbles or air may be present for various reasons, such as short sample aspirations or blockages in the aspiration pathway. Single dots (•••••) and *PART. ASP* are reported instead of numeric results when a partial aspiration occurs. Samples that generate multiple partial aspiration messages should be evaluated for specimen quality according to the laboratory's protocol. Samples with very low hemoglobin results may give partial aspirations when run in the Primary mode because the blood detectors do not recognize the sample as being blood. To obtain results, cycle the sample in the Secondary mode.

Check to make sure the printer is working properly. Operate the Analyzer with the doors and panels closed. Monitor reagent levels.

- a) Does **SELECT FUNCTION** or **S/A 1° MODE ON** appear at the lower right corner of the DMS monitor?

If not, then access the Run Samples screen. At the Access screen, press [F1] **RUN SAMPLES** or at the Main Menu, select **Sample Analysis → Run Samples**.

- b) Press [F3] **Run**.



F2-Ticket F3-Run F4-Print F5-Optns F6-DF F7-CP F8-DB F9-Exit  
01/09/99 15 43 OPR DMS1 PR1 HCl DB1 XBI WLI HWL1 QCT COMPRESSOR OFF

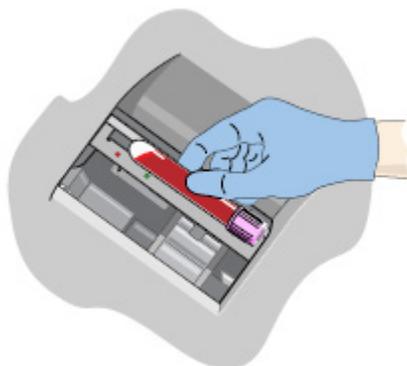
- c) The instrument automatically prepares itself to run in the Primary mode, DIFF ON. Press [F6] **DIFF ON/OFF** to change the DIFF setting. Note, if **SAMPLE MODE** is not displayed, press [F9] **Stop** first.

```
SAMPLE MODE?  
F2 START PRIMARY  
F3 SECONDARY  
F4 PREDILUTE CBC  
F5 RETIC  
F6 DIFF ON/OFF  
F7 PURGE  
F8 RINSE  
F9 STOP  
DIFF: ON  
BLOOD DET: ON  
Select to change/ESC to continue
```

- d) Does the top of the **F3-Run** window display **PRIMARY: SAMPLE ANALYSIS**? If Yes, press [Esc]. If No, press [F2] **START PRIMARY**.

```
PRIMARY:    SAMPLE ANALYSIS  
F2 START PRIMARY  
F3 SECONDARY  
F4 PREDILUTE CBC  
F5 RETIC  
F6 DIFF ON/OFF  
F7 PURGE  
F8 RINSE  
F9 STOP  
DIFF: ON  
BLOOD DET: ON  
Select to change/ESC to continue
```

- e) Identify the sample by holding the barcode 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 barcode label again. Cycle the sample within 10 seconds of reading the barcode. After 10 seconds, the system deletes the identification. If necessary, enter 1 to 16 alphanumeric characters then press [Enter].



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) Access the Run Samples screen. At the Access screen press [F1] **RUN SAMPLES** or at the Main Menu, select **Sample Analysis → Run Samples**.
- b) Press [F3] **Run**.
- c) The instrument automatically prepares itself to run in the Primary mode, DIFF ON. Press [F6] **DIFF ON/OFF** to change the DIFF setting. Note, if **SAMPLE MODE** or **S/A 1°MODE ON** is not displayed, press [F9] **Stop** first.

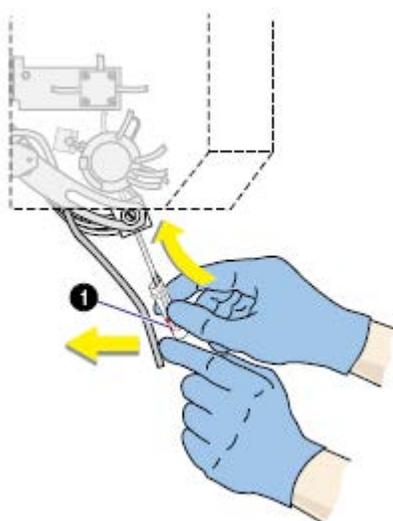
- d) Press [F3] **SECONDARY**.

```
SAMPLE MODE?
F2 START PRIMARY
F3 SECONDARY
F4 PREDILUTE CBC
F5 RETIC
F6 DIFF ON/OFF
F7 PURGE
F8 RINSE
F9 STOP
DIFF: ON
BLOOD DET: ON
Select to change/ESC to continue
```

- e) Identify the sample by holding the barcode label on the tube in front of the reader. Green light will beep. If the red light appears, wait and try reading the barcode label again. Cycle the sample within 10 seconds of reading the barcode. After 10 seconds, the system deletes the identification. If necessary, enter 1 to 16 alphanumeric characters then press [Enter].

- f) 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 tube when the instrument beeps.
5. Review data and transmit
- a) Review the data using the criteria described in Section X.
  - b) Set host computer to ↑. Data from the Coulter DMS is automatically transmitted to the ISIS system.
  - c) Use the Data Base Query to sort, retrieve, transmit, and archive data to diskette. Transmit data from the Coulter DMS to ISIS as necessary. Archive all data at the end of each stand.

Data Base Query							
EXCERPT	S	SELECTED	S	TRANSFER	O	STATUS	O
ID# 1	ID# 2	DATA	TIME	DATE	OFF	FILE	CHARGE
▶▶▶▶▶▶▶▶▶▶			01/18/99	09:34:08	0	OFF	F
▶▶▶▶▶▶▶▶▶▶			01/18/99	09:34:08	0	OFF	F
▶▶▶▶▶▶▶▶▶▶			01/18/99	09:34:08	0	OFF	F
▶▶▶▶▶▶▶▶▶▶			01/18/99	09:34:08	0	OFF	F
▶▶▶▶▶▶▶▶▶▶			01/18/99	09:34:08	0	OFF	F

F1-Down F3-Exit F4-Filter F5-Search F6-Scroll F7-Tag F8-Tag All F10-DB

To access the Data Base Query screen, at the Access screen, press [F4] **DATA BASE QUERY** or at the Main Menu, select **Sample Analysis** → **Data Base Query**.

Use the Sort feature to define the criteria for the data. Sort by date, time, or ID. If you do not choose any sort criteria, the samples in the database are sorted chronologically by date and time.

To transit data from the DMS to ISIS, select **Sample Analysis** → **Data Base Query**, [Enter.] When you access this option, you see what was selected by the last Sort criteria. To review other samples, change the sort criteria. If the last sorting process resulted in no entries displayed here, then when you access this option, the sort window appears.

To access the Sort Criteria window, press [F6] **Sort**. Enter sort criteria by TIME, DATE, ID #1, or ID #2. Select [F8] to execute the sorting process, [F7] **Tag** to tag or untag a highlighted individual sample or [F8] to **Tag All** to tag or untag all samples for batch processing, and [F5] **Batch** to display the Batch Process window.

At the Batch Process window, use the up and down arrows to move through the choices. Use the space bar to toggle between Yes and No. Set Print: to No and Host to Yes. Select [F8] **Execute**.

#### D. Daily Shut Down

1. Shut down the instrument for at least 30 minutes but less than 48 hours each day it is in use.
2. To begin shut down make sure the status line displays *Select Function*. Select **Diluter Functions → Shut Down**. Press [Enter]. Allow the cleaning agent to remain in the instrument for a minimum of 30 minutes.
3. Perform Start Up before running samples or controls. Results must be within tolerance.

#### E. Clean Cycle

1. The Clean Cycle consists of a Shut Down cycle followed 30 minutes later by a Start Up cycle.

- a) To initiate the Clean Cycle: Go to the Access screen [F1] from the Main Menu. Press [F3] **Clean**. Press [Enter] to begin. After the Shut Down portion of the cycle finishes, a window displays. Your options are: (1) Do nothing and allow the Clean Cycle to complete, (2) Press [F4] to abort the Clean Cycle; cleaning agent remains in the system until you perform Start Up, or (3) Press [F5] to begin the Start Up cycle immediately.



#### F. Prolonged Shut Down

1. If the instrument is going to be idle for 48-72 hours, perform the following procedure:
  - a) Go to the Access screen and press [F3] **Clean**.
  - b) Once the cycle is complete, turn OFF the instrument using the On/Off switch on the back of the main unit.
  - c) When it is time to use the instrument:
    - (1) Turn power ON.
    - (2) Prime the HMX PAK.
    - (3) Perform Start Up.
  - d) Perform and verify QC checks according to laboratory protocol.
  - e) 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.

#### G. Autopurge Cycle

1. After 23 hours in Shut Down, with the power ON and the pneumatics OFF, the system automatically:
  - a) Turns ON the pneumatics.
  - b) Purges the flow cell and sample lines with diluent.
  - c) Turns OFF the pneumatics.
  - d) Repeats this cycle every 24 hours until a Start Up is performed.

## H. Beginning and End of Stand Operations

### 1. Beginning of stand:

- a) Obtain one urine collection container or a 50-mL conical tube, one 3 or 4-mL EDTA tubes (1 clean aspiration system), 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. 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 Coulter® representative to perform an instrument verification procedure on setup 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** [Enter]
    - (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** [Enter] - 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** [Enter]

- (a) Enter the “SUPER” password.

- (b) Type in:

		Printed on graphic report
Name	NHANES	Yes
Lab Director	Brenda Lewis	No
Address	NCHS Maryland	No
Phone	301-436-7080	No
Instrument	AJ47275 AK04023 AK04024	No

(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. Press [F10] to save and [Esc] to return to previous screen.

HMX Host Mode	Yes	Retics transmission	No
Timeout (secs)	8	Overall Retics	No
Baud rate	9600	Graphics	No
Parity	none	DF5	No
Stop bits	1	DF6	No
Handshake	Yes		
Block size		Enable Spooler	Yes
		Replace NULL by SP	No
Graphic transmission	No		
DF1	No		
DF2	No		
VCS histograms	No		
RBC histogram	No		
PLT histogram	No		

- (5) Select **IQAP ID#**

Type in the IQAP number.

Enter 32979 1 H1 for instrument AJ47275

32979 1 H2 for instrument AK04023

32979 1 H3 for instrument AK04024

Press [F10] to save and escape.

- (6) 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.

- (7) Select **Supervisor Password**

Do NOT change the password under any circumstances.

- (8) Select **Optimize Hard Disk**

Enter the password "super." Respond to the question, "Do you want to automatically optimize the Hard Disk during Powerup?"

Verify that YES is displayed. Press [F10] to save and escape.

- g) Review sample analysis set up. Select **Special Functions, Set Up, and Sample Analysis Set Up**. Type in the password "super."

- (1) Select **Action limits** [Enter], **XB limits** [Enter].  
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) 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 escape.

- (3) 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.

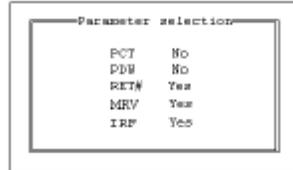
- (4) Select **Action limits** [Enter], **Laboratory Normal Ranges** [Enter].  
Disable High/Low flag limits. Set low limit for all parameter values to zero except for PCT. Set lower limit for PCT to 0.000. Set high limit to 99.9 for all parameters except RBC, PLT, and PCT. Set RBC upper limit to 9.9, PLT to 999 (with no decimal) and PCT to 0.990. Press [F10] and [Enter] to save and exit.

- (5) **Location list** N/A Do not access

- (6) **Physician list** N/A Do not access

(7) **Display formats** [Enter] **Screen Labels** N/A Do not access

(8) Select **Display formats** [Enter] **Parameter Selection**  
Use the space bar to select No for each of these parameters.



Press [F10] to save and escape.

(9) Select **Display formats** [Enter], **Reporting Units**

Use the space bar to select US 1. Press [F10] to save and escape.

(10) Select **Delete database** [Enter]

Delete database at the end of each stand after archiving the data to a diskette. The question, "You have asked to delete the ENTIRE database. Are you sure you want to delete?" Use the space bar to toggle between Yes and No then press [Enter].

(11) Select **Delete host spooler** [Enter]

Use this feature to clear the buffer of results waiting to be transmitted to the host computer. "Do you want to delete the host spooler?" Press the space bar to answer Yes or No to the displayed question. Press [Enter].

(12) **Clear printer spooler queue**

Use this feature to stop a print job and clear the DMS printer spooler of all data not yet sent to the printer. Move the cursor to the appropriate option. Press the space bar to toggle between Yes and No. Press [F10].

**Auto Print:** No  
**Manual:** No  
**Batch:** No

(13) Select **Print options** [Enter]

**Auto Print Format**

Use the space bar to select [**GRAPHIC FORMAT**]. Press [F10] to save and escape.

**Ticket Options**

Verify the following settings.

PRINT UNITS:	Y
PRINT NORMAL RANGES:	N
PRINT PARAMETER LABELS:	Y
S/D FLAGS:	N
DIFF ORDER:	Standard
TICKET FORMAT START OF NEXT FORM	Continuous

**Spooler Priority** [Enter]

Leave [AUTO PRINT] as the default.

**Graphic Options** [Enter]

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	No
Print Units	Yes
Print Diff Box	No
Print Normal Ranges	No

**Optional Printer**

Select "N."

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 printout 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 described on the screen.
- d) Download or archive all stand result data to disk.

The DMS Archive feature lets you copy result data from the DMS onto a diskette and retrieve it on another computer in a spreadsheet format. Use a spreadsheet program that is compatible with the WKS format. Archive data at the end of each stand.

To Archive data, select **Sample Analysis**→**Data Base Query**. Perform a sort that includes all samples run during the stand. Use [F7] or [F8] to tag the samples you want to archive. Press [F5] **Batch** to display the Batch Process window. Move the cursor to the Archive field then press [F2] **Choice List**. Use the space bar to highlight your choice, then press [Enter]. If you select New, all tagged samples that have not yet been archived will be processed. If you select All, all tagged samples will be processed, even if they have already been archived. If you select No, Archive is inactive. Move the cursor to the Filename: field and enter a file name of your choice. Type **A:\** then up to eight characters. An extension is not required. Example: **A:\stand210** could be the file name for sample results archived at the end of stand 210. Insert a formatted diskette into the Data Management System (DMS) diskette drive. Press [F8] Execute. **NOTE:** If a power failure occurs during the archiving process, the samples from this archiving session are incorrectly marked as archived but the data file is empty. Reselect the samples from the session and select **All** to ensure all of the samples in process are correctly archived. Wait until the *Batch is Inactive* message appears, and then remove the diskette from the diskette drive. **NOTE:** If the space on the diskette is insufficient for archiving all of the tagged samples, the DMS displays the error *DISK FULL -ARCHIVING DISCONTINUED*. Remove the full diskette from the DMS diskette drive and insert an empty formatted diskette. Ensure the Archive option selected is **New**, then press [F8] **Execute**. Any samples tagged but not archived yet are copied onto the new diskette.

- e) Perform daily Shut Down. Let cleaning agent remain in the instrument for at least 30 minutes.
- f) Perform Start-up.
- g) 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.”

- h) Bleach the reagent lines.
  - (1) Remove all reagent pick-up 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 Reagents**, select **ALL**. Press [Enter]. Repeat this procedure two more times.
- i) Place all reagent pickup tubes into containers of distilled water.
- j) 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; change the number to 03 or 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.
- k) 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.
- l) 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.

- m) Rinse the reagent lines. Make sure all reagent lines are immersed in containers of distilled water. Select **Diluter Functions, Prime Reagents**, select **ALL**. Press [Enter]. Repeat this procedure two more times.
- n) Perform a Start Up. Make sure containers are full.
- o) 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 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].
- p) Select **Diluter Functions, Start Up**. Press [Enter]. Perform five additional Start-Up procedure with the lines in the distilled water containers.
- q) 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, Diagnostics, Operator options**, 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.
- r) Enable the reagent sensors. Select **Special Functions, Diagnostics, Fluidic Tests**, and **Disable Reagent Sensors**. Toggle through each reagent line using the space bar to change “No” to “Yes.”
  - s) To protect the reagent pickup tubes from contamination, wrap them securely in paper towels. Allow air to continue to dry the tubes.
  - t) Turn off the power.
  - u) 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.
  - v) Wash exterior of instrument with distilled water.

- 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. 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® Primer and 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 HMX. 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. The Latron Primer is supplied as a ready-to-use solution that prepares the sample line by eliminating interfering particles.
2. Reagents – The Latron control consists of latex particles suspended in a buffered bacteriostatic and fungistatic medium containing a surfactant. The Latron primer consists of 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. Do not freeze.
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 Startup has been performed.

- a) Run Latron® primer in the secondary mode. Access the Latex Control Run screen at the Access screen press [F2] Run Controls or at the Main Menu, select **Controls** → **Control Run**. 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 H or L displays, do the following:
- (1) Assigned value or range is incorrect – Be sure the assigned values match the ones on the Latron control package insert. If in error, correct them by selecting **Special Functions** → **Set Up** → **Control Set Up**.
  - (2) Bubbles in the flow cell or improper vial handling – Rerun the primer and control.

- (3) 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.
- (4) “: : : :” 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, either perform a ShutDown or turn the DIFF OFF and run CBCs only. If problem continues, call a Coulter representative for assistance.
- (5) 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. Manually enter the name of the file (Latron), Lot #, expiration date, and operator initials. The system automatically enters the assigned values, expected ranges, and expected %CVs. Check to make sure that the HOST: is set to ON. This means that the control run results are transmitted to the host computer at the time of the run. Use the space bar to toggle between ON and OFF. Check all entries to make sure they are correct. Press [F10] to save and escape.

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 all three levels of control at the beginning of each session. Date and initial the open vials.

1. Principle – The 5C cell control is a reference product prepared from stabilized human blood. 5C cell controls confirms and monitors instrument accuracy and precision performance by providing measurements for counting, sizing, hemoglobin determination, and white blood cell differentiation using CVS technology.
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-1 and HIV-2) 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.

This product contains <0.1% Sodium Azide. Sodium Azide preservative may form explosive compounds in metal drain lines. Discard this product in biohazardous waste containers.

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. Prepare the instrument – Insert the Control Disk when a new lot of 5C cell controls is put into use. Follow the instructions on the Workstation/computer screen.
6. 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. Does *SELECT FUNCTION* appear at the lower right corner of the DMS screen? If No, Access the Run Samples screen: at the Access screen, press [F1] **Run Samples** or at the Main Menu, select **Sample Analysis → Run Samples**. If yes, access the Run Samples screen: at the Access screen, press [F1] **Run Samples** or at the Main Menu, select **Sample Analysis → Run Samples**. Press [F3] **Run**. The instrument automatically prepares itself for Primary mode, DIFF ON. Make sure the DIFF is ON. If it is OFF, press [F6] DIFF ON/OFF. **NOTE:** If SAMPLE MODE? is not displayed, press [F9] **Stop** first. Does the top of the F3-Run window display **PRIMARY: SAMPLE ANALYSIS?** If yes, press [Esc]. If No, press [F2] Start Primary.

- b) Complete the entire procedure and return the controls to the refrigerator within 30 minutes.
- c) Identify the sample by holding the barcode label in front of the reader. Place the control in the carousel. Repeat for other levels of controls.
- d) Check the results of each control. Coulter has established control limits for each parameter for each of the three levels of 5C cell controls. The limits are set at +/- two standard deviations. NCHS does not want QC results that are out of range to be included in the NCHS analytical database. Delete any individual 5C cell control run that includes any results that are flagged out of range. Print the results before deleting and document on the printout what action was taken to correct it. Send all documentation to the home office at the end of each stand.

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. If **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 Coulter® representative to help troubleshoot abnormal operation.

7. 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 barcode wand. Enter information manually if necessary.

Select **Special Functions → Set Up → Control set up → CBC/DIFF file**. Select a file to set up. Insert the 5C cell control diskette into the diskette drive of the computer. Press [F5] **Upload Assay Values**. Press the function key for the desired level of control: [F1] for Normal, [F2] for Abnormal I, [F3] for Abnormal II. Manually enter Shift and Operator ID. Check that HOST: is set according to ↑. ON means that control run results are transmitted to your host computer at the time of the run. Space bar toggles between ON and OFF. Check all entries to make sure they are correct then press [F10] to save and escape. Repeat these steps for the other levels of control. Once you are finished, remove the 5C cell control diskette from the diskette drive of the computer.

a) Manual entry

If the 5C cell control diskette fails to upload, you can enter all data manually. Refer to the package insert for lot specific information and assigned values. The system automatically enters the level and expected ranges based on the first two digits of the lot number. Press [Enter] after each entry. Press [↓] at the end of each row of assigned values unless you are also entering your own expected ranges.

## C. Control Statistics and Graphs

### 1. Use to review and print:

Control results, cumulative statistics, and histograms for LATEX Files;  
Control results, cumulative statistics, and graphs for CBC/DIFF 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. 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:

[F2] File            Displays all available files. Use [↓] and [↑] to select the correct file. Press [Enter].

[F3] Transmit      Transmits the data of the entire control file to a host computer.

[F4] Print           Prints the entire file in a line list format.

[F5] Histo          Displays the volume, conductivity, and scatter (CVS) histograms screen. Use [F4] to print the screen and [F6] Additional Histo to switch between Diff and RETIC histograms.

[F6] Rem/Res       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?*” Press the space bar to select Yes or No then press [Enter] to confirm the choice.
- [F9] Menu Exits to the main menu.
- [←] [→] Press [←] or [→] to go back and forth between the Diff Latex Control Review screen and the Retic Latex Control Review screen.

### 3. CBC/DIFF control review and report

- a) Use this report to review and print control results and cumulative statistics for CBC files. Can also be used to transmit the data of the entire control file to a host computer. 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].   |
| [F3] Transmit    | Transmits the data of the entire control file to a host computer.  |
| [F4] Print       | Prints the entire file in a line list format.  |
| [F6] Rem/Res     | 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 <i>“You have asked to delete ENTIRE control file. Are you sure you want to delete?”</i> Press the space bar to select Yes or No then press [Enter] to confirm the choice. |
| [F9] Menu        | Exits to the main menu.  |
| [F12] Graphics   | Displays scatterplots, histograms, and numeric results.  |
| [←] [→] More     | Press [←] or [→] to see additional parameters not displayed on the screen.   |

D. Record 5C Cell and Latron Lot Numbers in ISIS

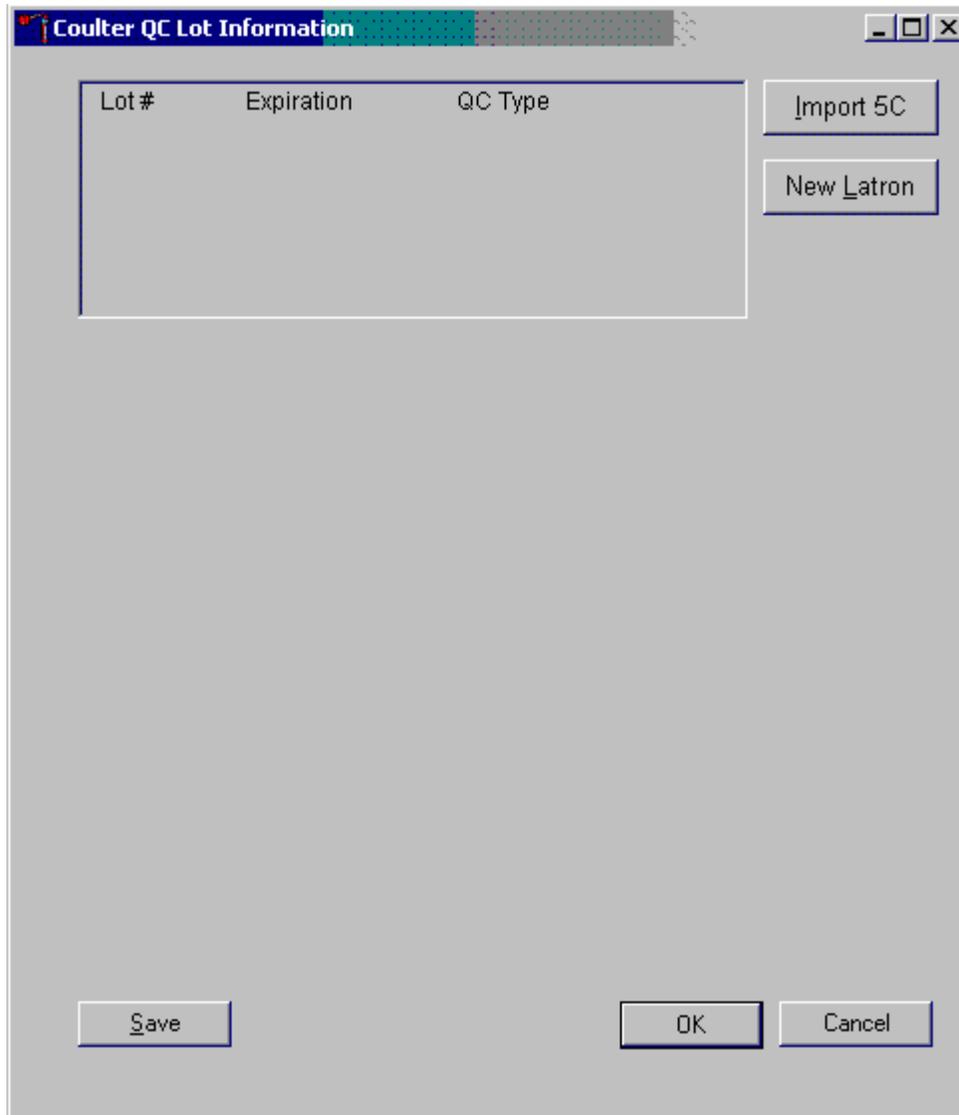
The ISIS maintains the capability to download all 5C cell and Latron control data. The data are used to monitor quality control results. Upload or enter data for each lot number each time a new lot number is put into use. The ISIS uses the same 5C cell control disk as the HmX. Manually enter the Latron data using information contained in the package insert.

Access the Coulter QC Lot Info module.



To open the Coulter QC Lot Info module, use the mouse to direct the mouse arrow to {Quality Control }, in the top menu bar, right click on {Coulter QC Lot Info}.

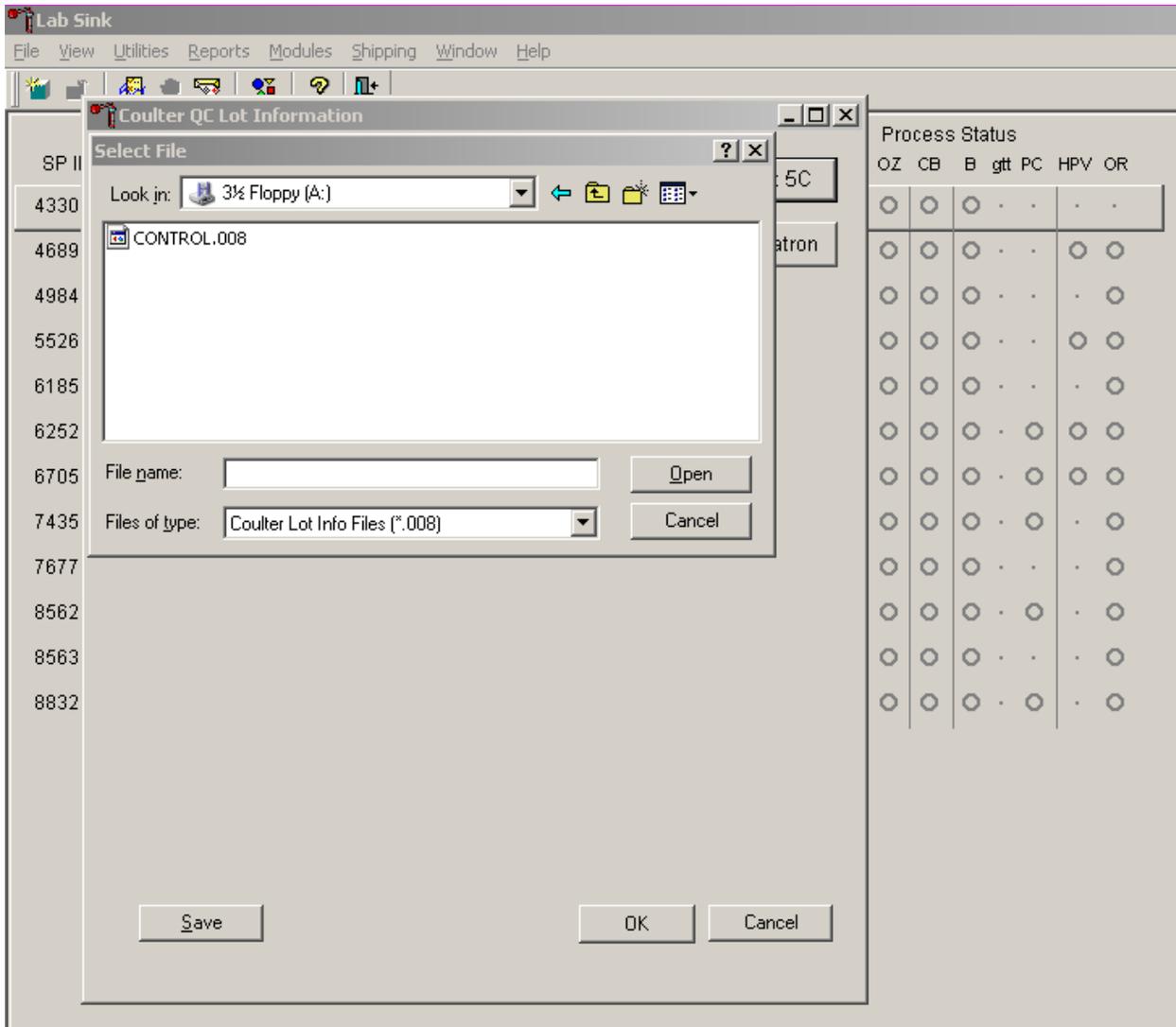
The Lab Hood or data entry window displays.



The data entry window contains **Import 5C** and **New Latron** buttons. The window also contains **Save**, **OK**, and **Cancel** buttons. After the data are entered, there are possible actions: save, save and exit, or exit without saving the data. To save these 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 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. 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.

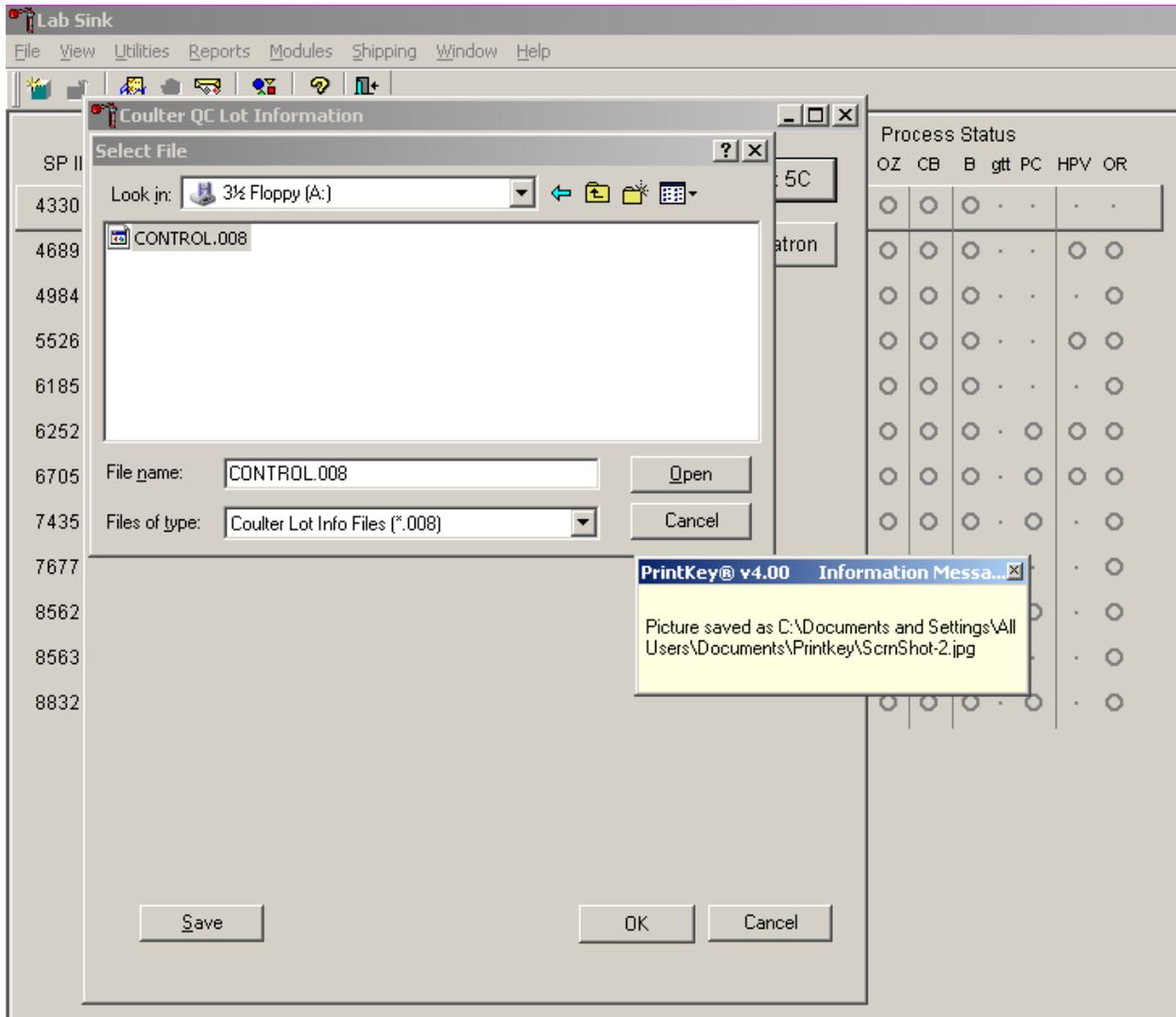
Make sure the separate floppy drive is connected to a USB port on the sink hard dive. Insert the HmX 5C cell control disk into the floppy drive attached to this computer.

Select the **Import 5C** button or type [Alt] [I/i] to begin the process of entering 5C cell lot information.



The Select File window displays.

Identify the location of the disk containing the 5C cell control data.



Highlight the CONTROL.008 file, select the Open button and left click. To close the window without identifying a file, use the mouse to direct the mouse arrow to the Cancel button and left click.

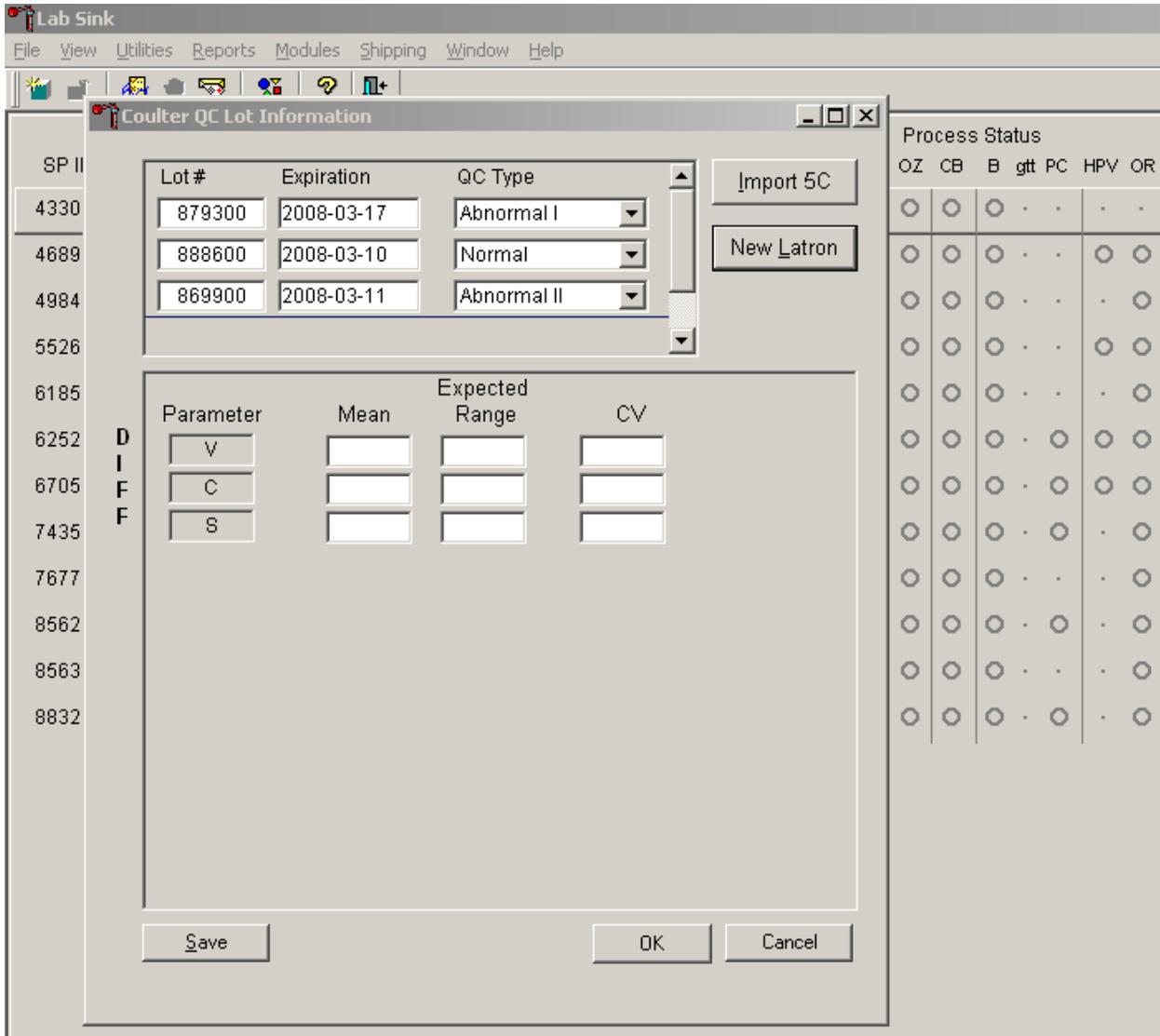






arrow, left click, drag the mouse arrow to the correct choice, and left click. Save the data by selecting the Save button.

Enter the Latron data by hand entering the data from the package insert. To access the Latron data entry fields, select the “New Latron” button.



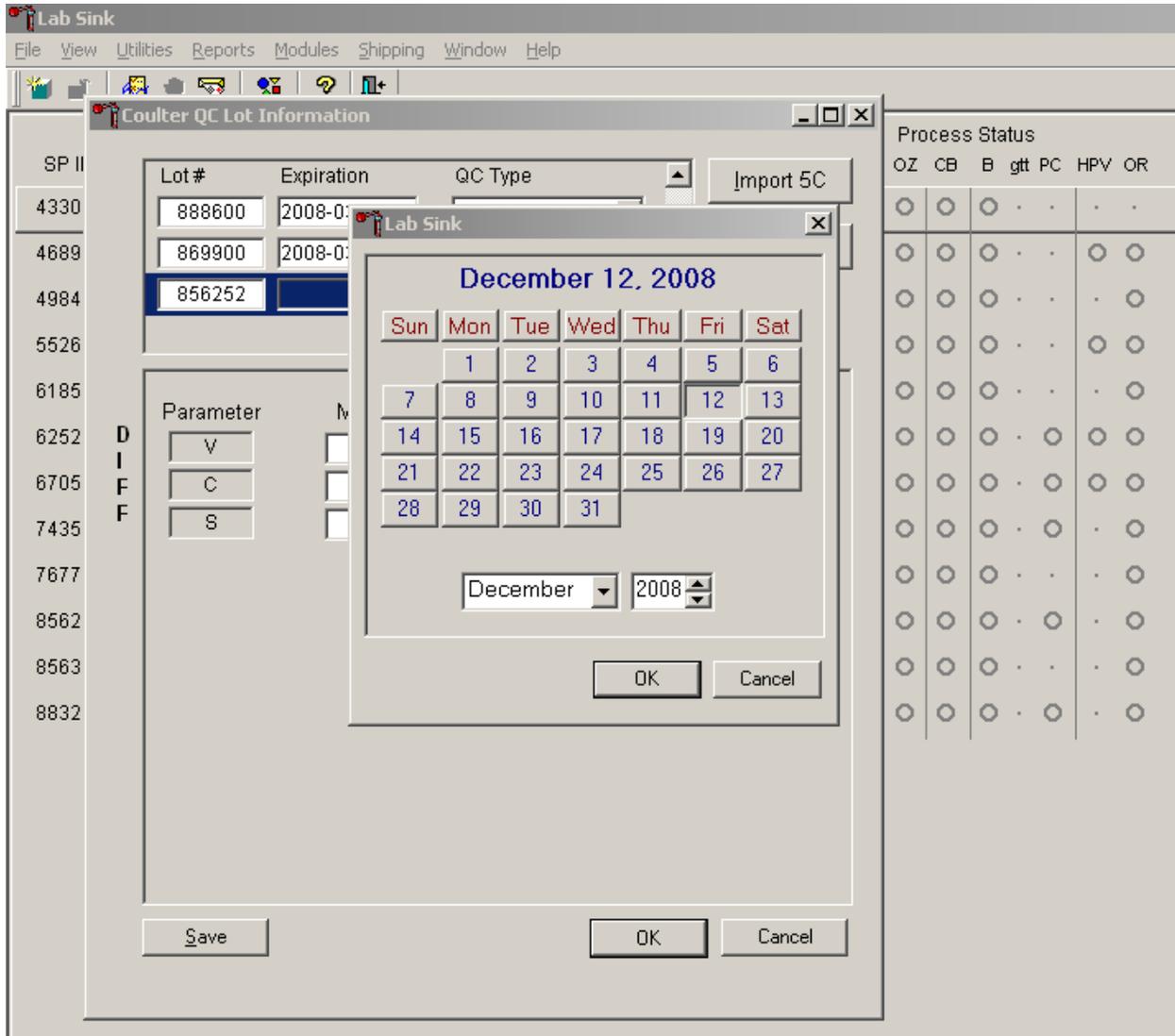
The lower portion of the window contains 9 text boxes, three each for Volume (V), Conductivity (C), and Scatter (S).

Enter the lot number and expiration date.

The screenshot shows the 'Coulter QC Lot Information' dialog box. On the left, a list of lot numbers is displayed: 4330, 4689, 4984, 5526, 6185, 6252, 6705, 7435, 7677, 8562, 8563, and 8832. The '4984' row is selected. The central form contains fields for 'Lot#' (888600), 'Expiration' (2008-03-10), and 'QC Type' (Normal). Below these are buttons for 'Import 5C' and 'New Latron'. A table below the form has columns for 'Parameter', 'Mean', 'Expected Range', and 'CV', with rows for 'V', 'C', and 'S'. The 'Process Status' table on the right has columns for 'OZ', 'CB', 'B', 'ggt', 'PC', 'HPV', and 'OR', with rows of circles representing status indicators.

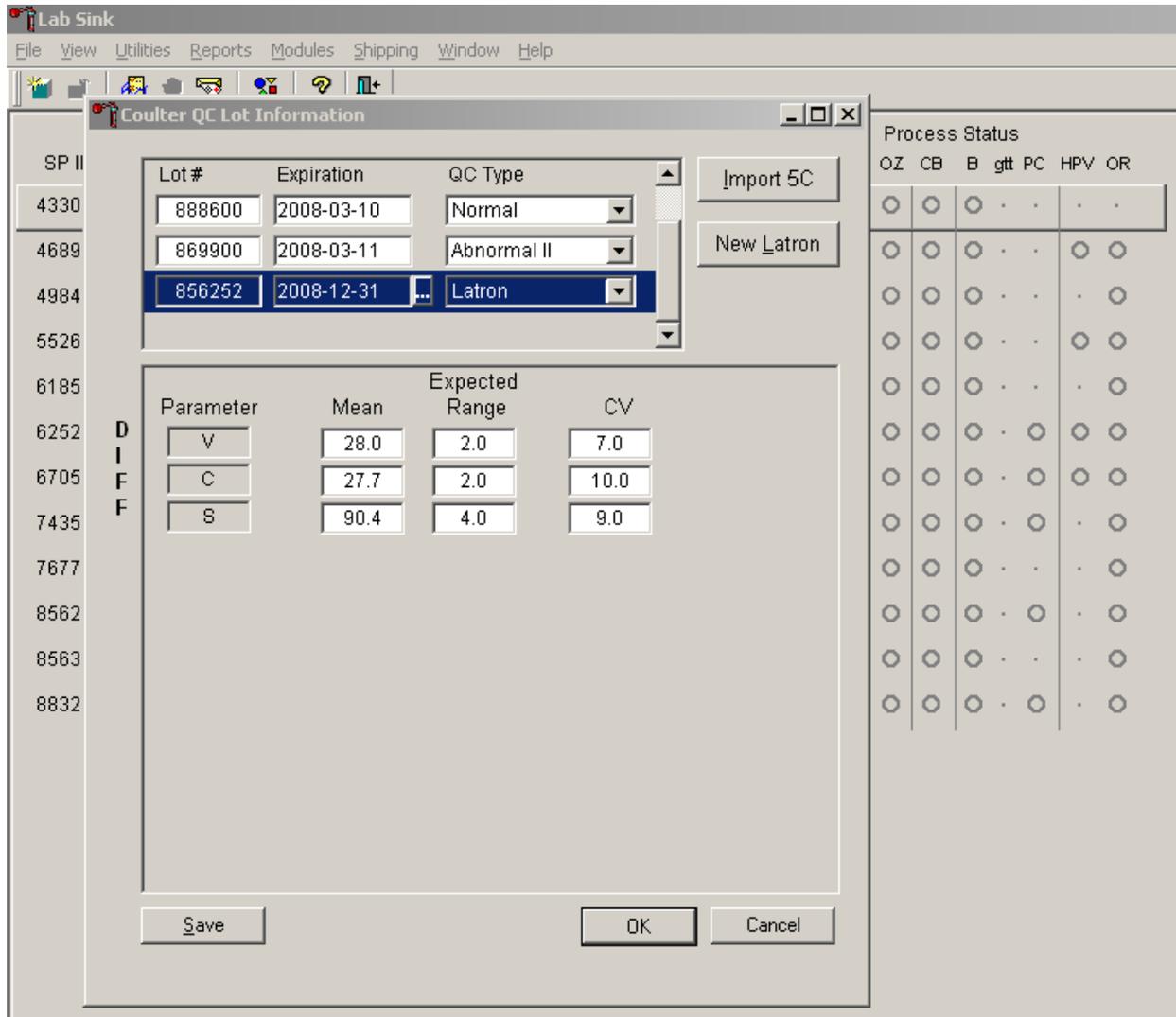
The Lot# and Expiration text boxes are located in the top portion of the window. Use the scroll bar to view the row.

Type in the Lot number using the keyboard numbers and use the calendar to enter the expiration date.



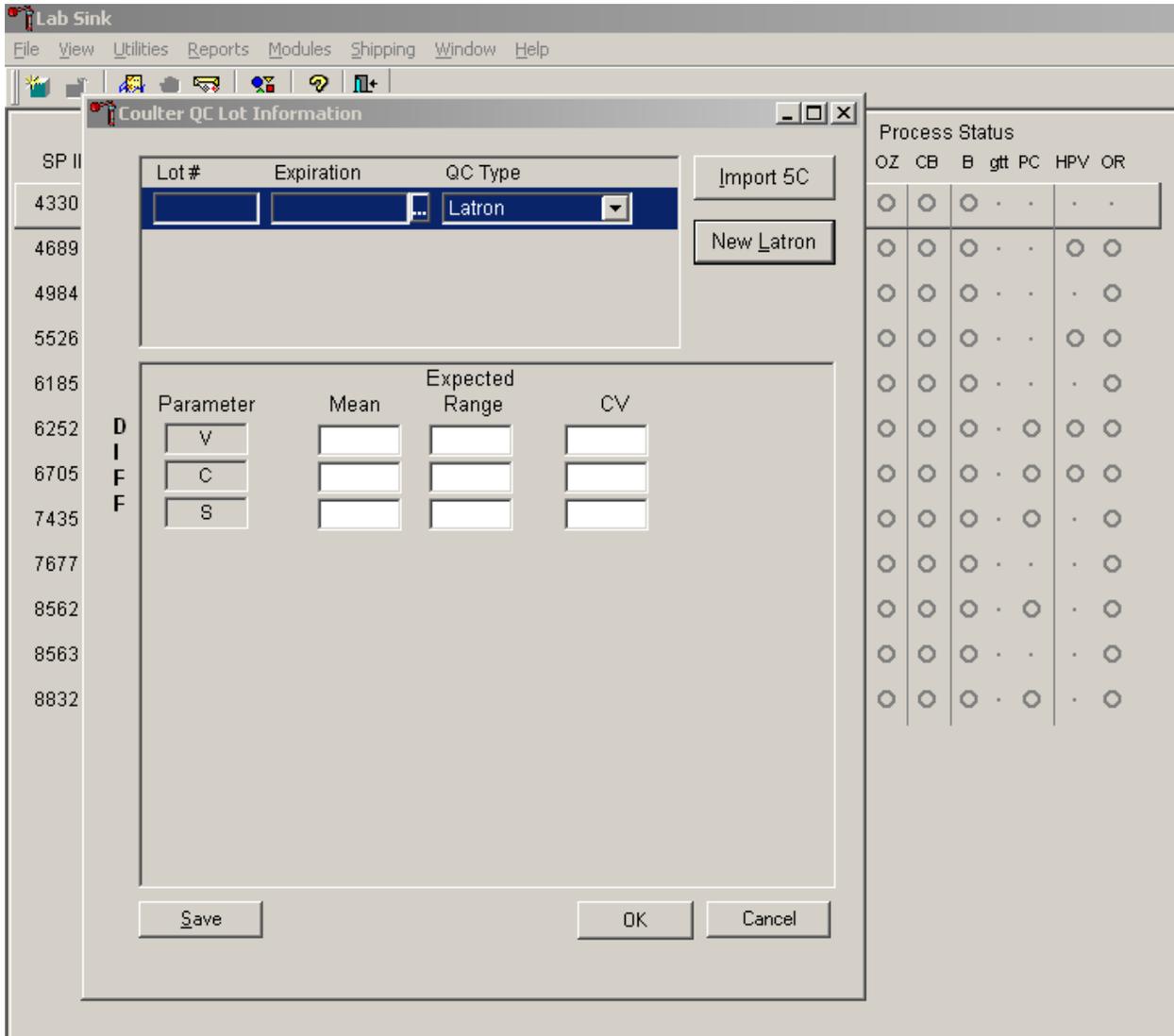
Use the keyboard number keys to enter the lot number then select [Tab] to move to the expiration date field. Use the mouse to direct the mouse arrow to the Ellipsis symbol located on the right side of the text box and left click. The calendar displays. Select the correct expiration date and, when finished, select the “OK” button to insert the date into the field.

Use the keyboard number keys to enter the Latron data. The window is identical to the layout of the data on the package insert.



Use the keyboard number keys to enter each value for Mean, Expected Range, and CV. Select [Tab] to move to the next data field. When finished, select the Save button to save the data to the database.

It is possible to enter Latron data for a new lot without entering 5C cell control data.



Select the “New Latron” button to access the module. The window only contains text boxes for the Latron control. Enter the data and save the information to the database.

E. Interlaboratory Quality Assurance Program (IQAP)

All instruments participate in Coulter’s IQAP program. The IQAP program includes saving results of 5C cell controls, transferring them to a disk, and sending them to

Coulter who compares the results to other laboratories. 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 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 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 Data Management System (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 HMX 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 preaddressed mailer provided and mail. Do not place the label over the drive spindle or high-density hole.

## 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 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 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, 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 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) 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 Coulter Corporation as a guideline.

- g) Plot the instrument background count as a zero value to extend the reportable range. Coulter will prepare tabular summaries and graphic presentations of the data. Submit the top copy of the worksheet to IQAP at the following address:

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.

Open the Hematology module.

The Hematology module does not need to be open before running SP samples on the HMX.

Note the red icon in the lower right corner of the system tray.



This is the NHANES Coulter Monitor icon. It must be open and running at the start of each session. This icon stores all HMX runs in the ISIS database. Open the icon by double-clicking on the Coulter icon on the desktop. The Coulter icon looks like this:

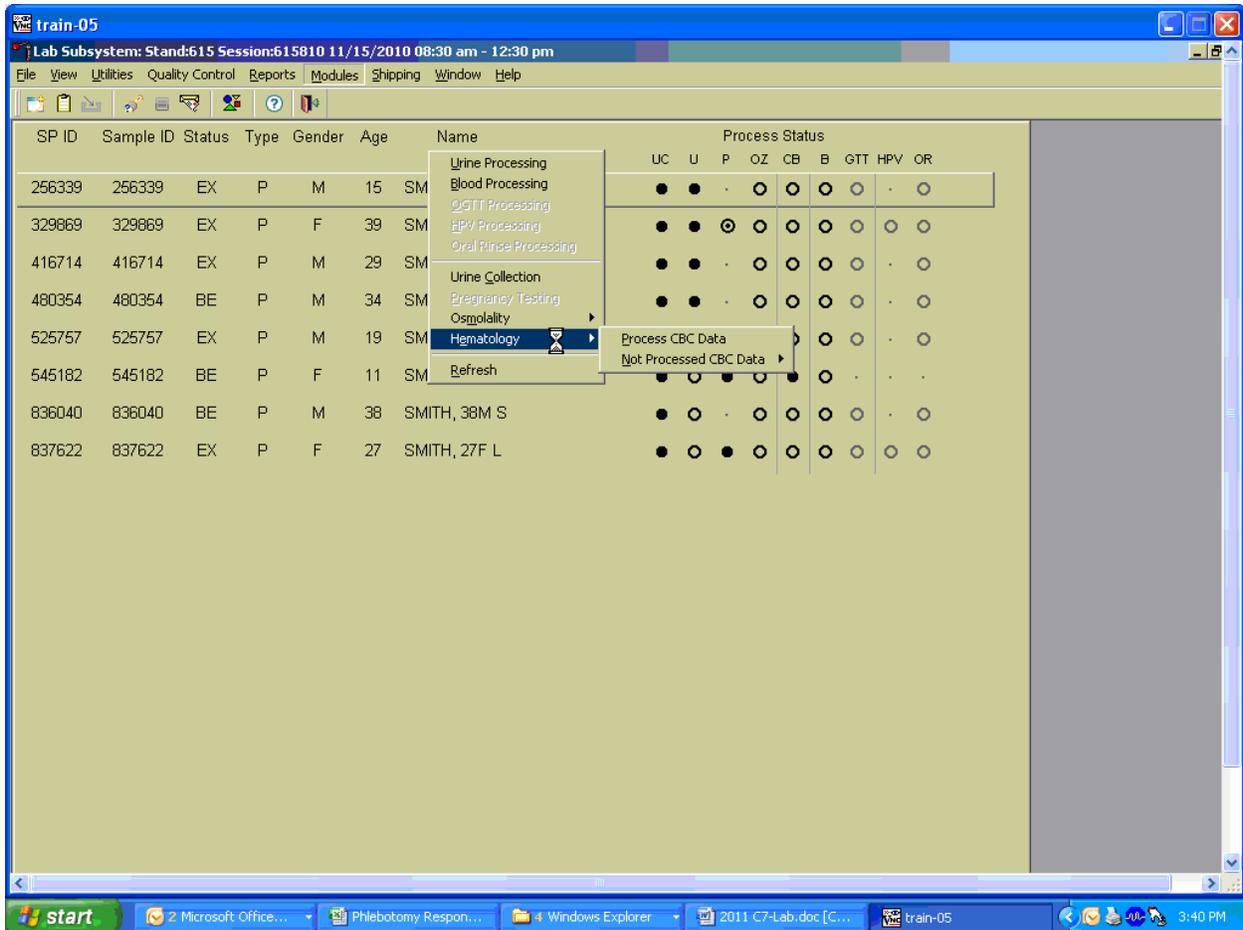


Open the Hematology module.



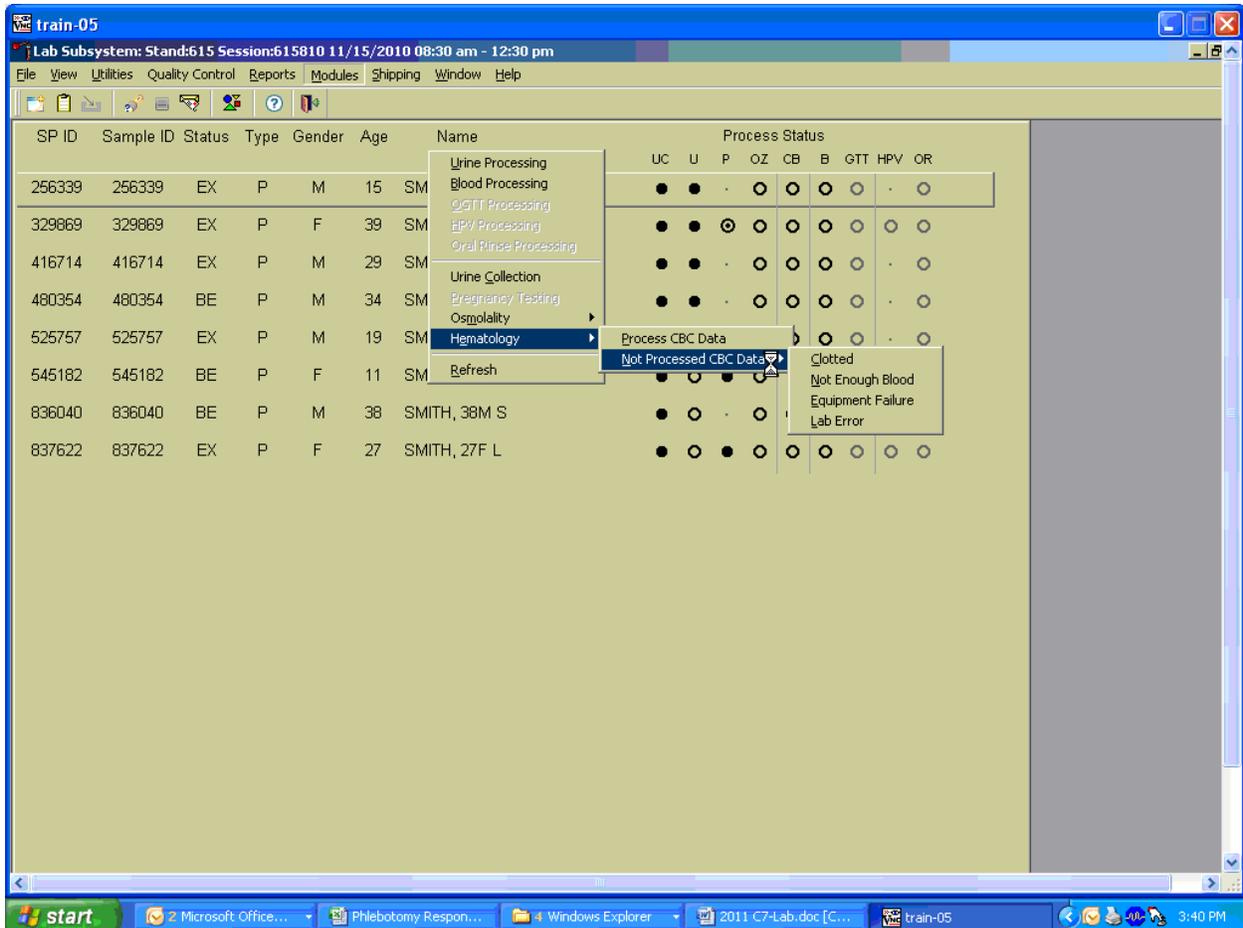
To open the Hematology module, use the mouse to direct the mouse arrow to {Modules}, in the top menu bar, left click, drag the mouse arrow to {Hematology}, and right click, or type [Alt][M/m], [H/h].

Alternatively, open the Hematology module from the heads-up display.



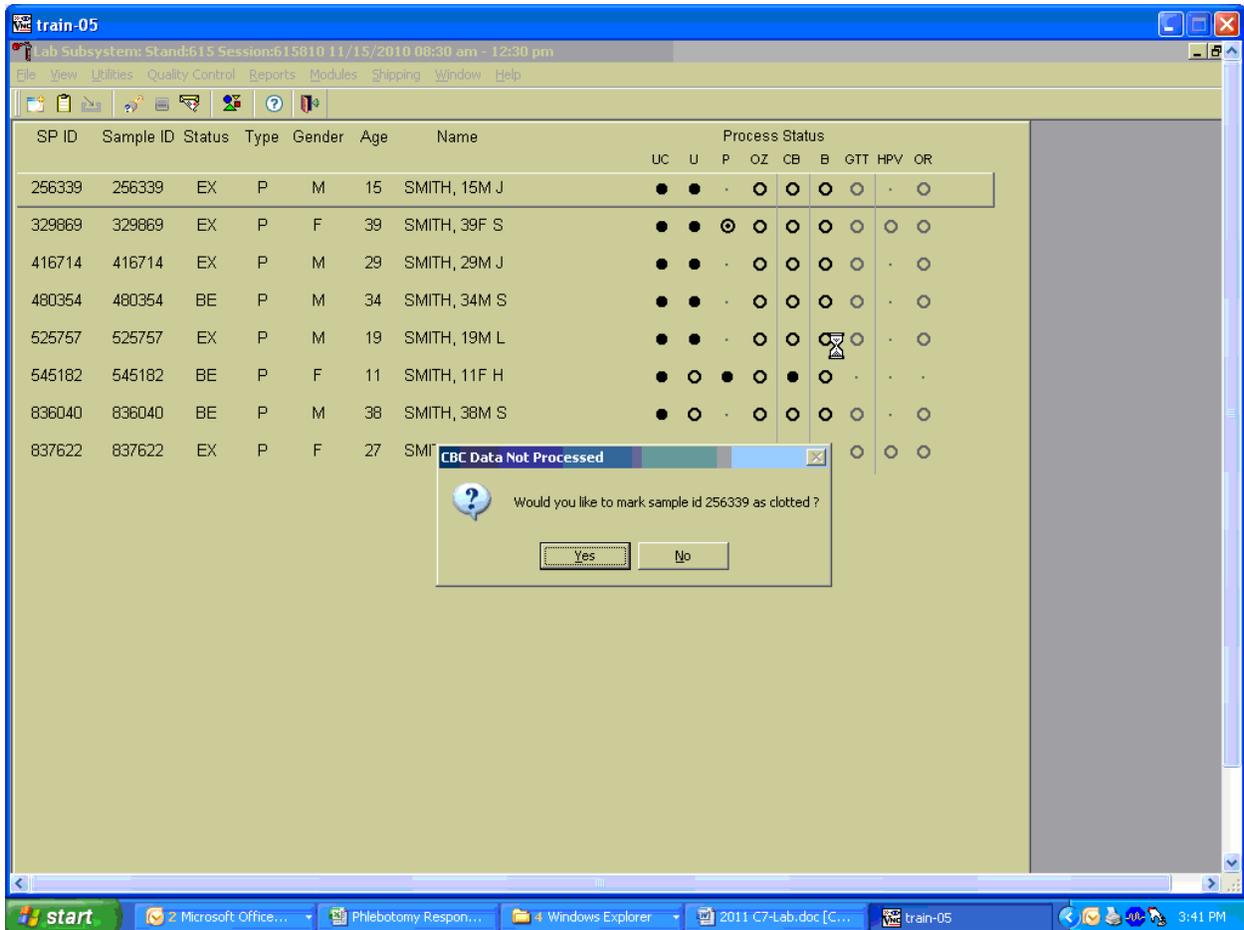
To access the Hematology module, use the mouse to direct the mouse arrow to any SP, right click, drag the mouse arrow to {Hematology} then to {Process CBC Data}, and right click or right click and type [Shift] [E/e] [P/p]. Alternatively, use the up and down keys to move up and down the list until a particular SP is highlighted, right click, drag the mouse arrow to {Hematology} then to {Process CBC Data}, and right click or right click and type [Shift] [E/e] [P/p].

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.



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.

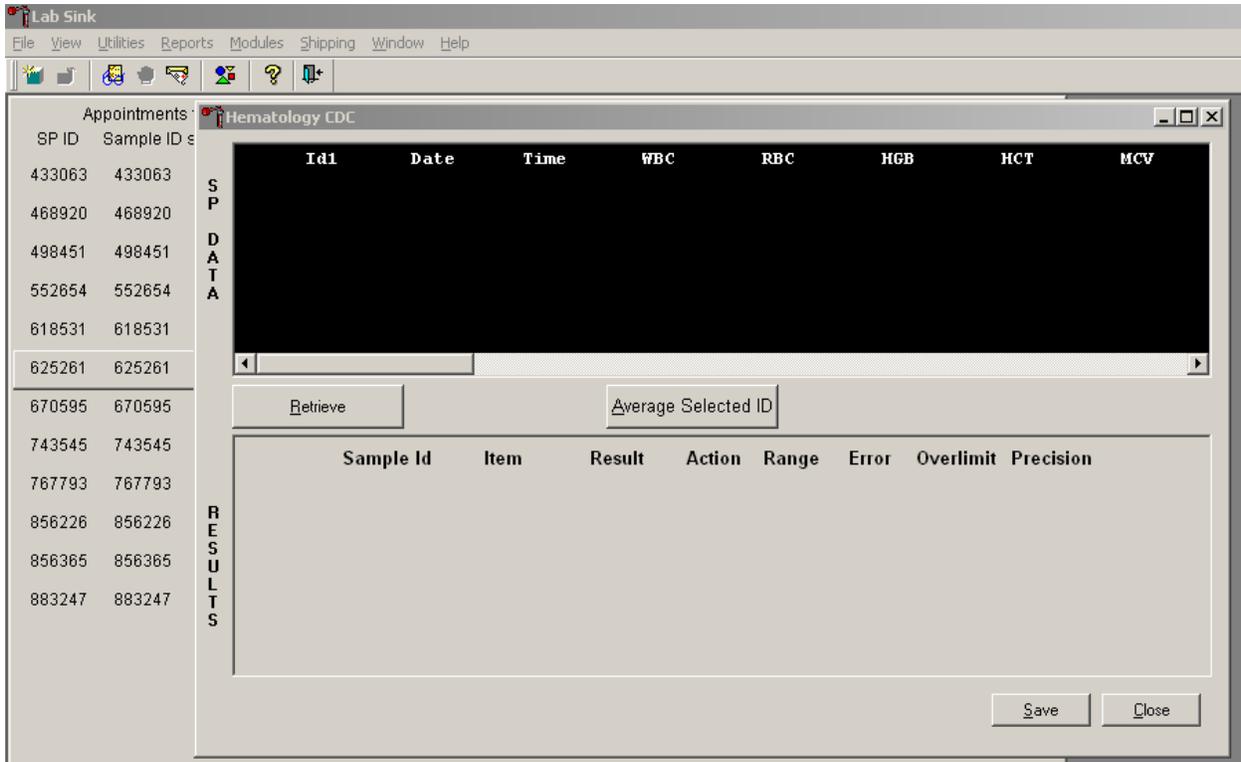
A pop-up window will display. Confirm the selection.



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 black).

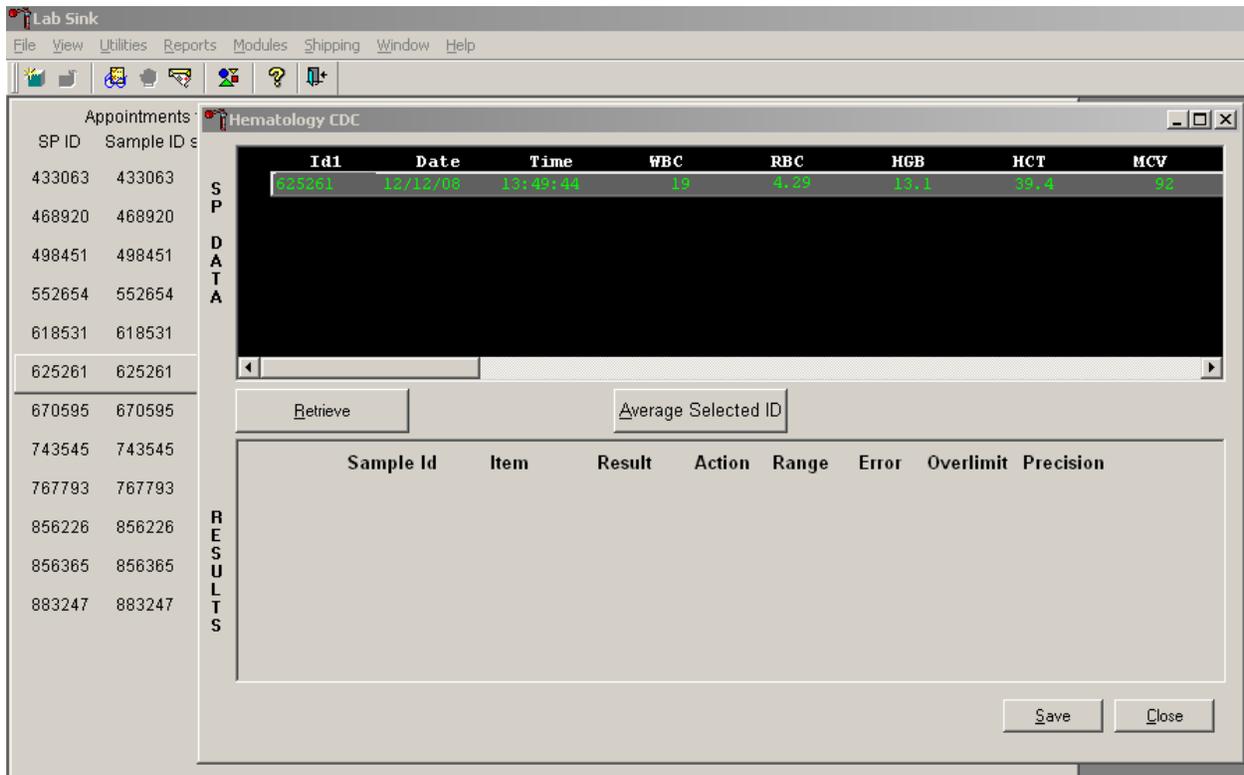
2. Hematology module overview.

Coulter does not automatically transmit results to the Laboratory application. Use the Retrieve button to send the results from the DMS to the Hematology module. Select after each run. Make sure the Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



After data are retrieved, it displays 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 it has been retrieved.



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 Lab Sink Hematology CDC interface. On the left, there is a list of appointments with columns for SP ID and Sample ID. The appointment for Sample ID 625261 is highlighted. The main window displays a 'RESULTS' section with a table of hematology data for Sample ID 625261. The table includes columns for Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The results are as follows:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
625261	CBC_WBC	19.0	H	H			
625261	CBC_RBC	4.29					
625261	CBC_HGB	13.1					
625261	CBC_HCT	39.4					
625261	CBC_MCV	92.0					
625261	CBC_MCH	30.7					

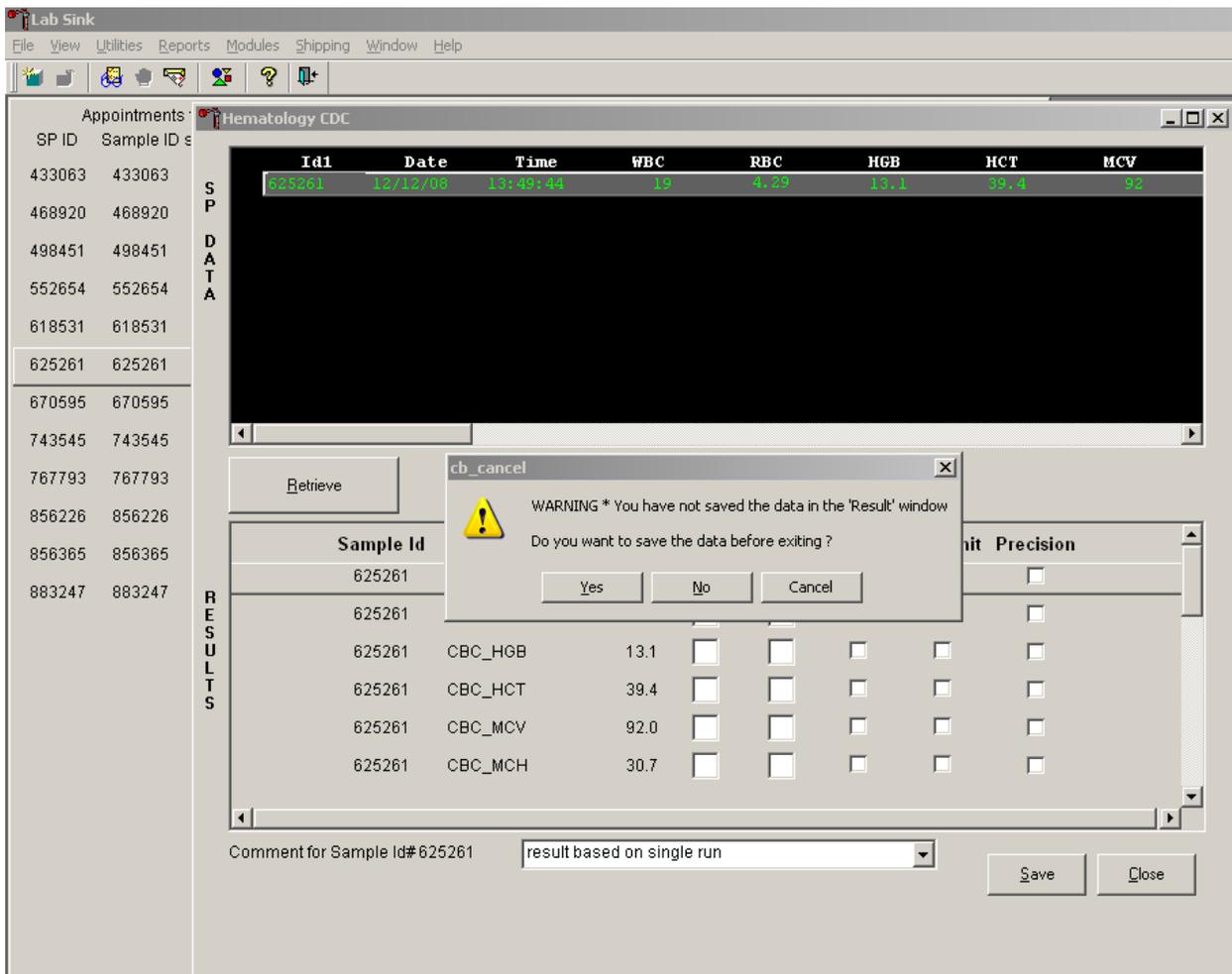
Below the table, there is a comment field for Sample Id#625261 with the text 'result based on single run'. Buttons for 'Retrieve', 'Average ID#625261', 'Save', and 'Close' are also visible.

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].

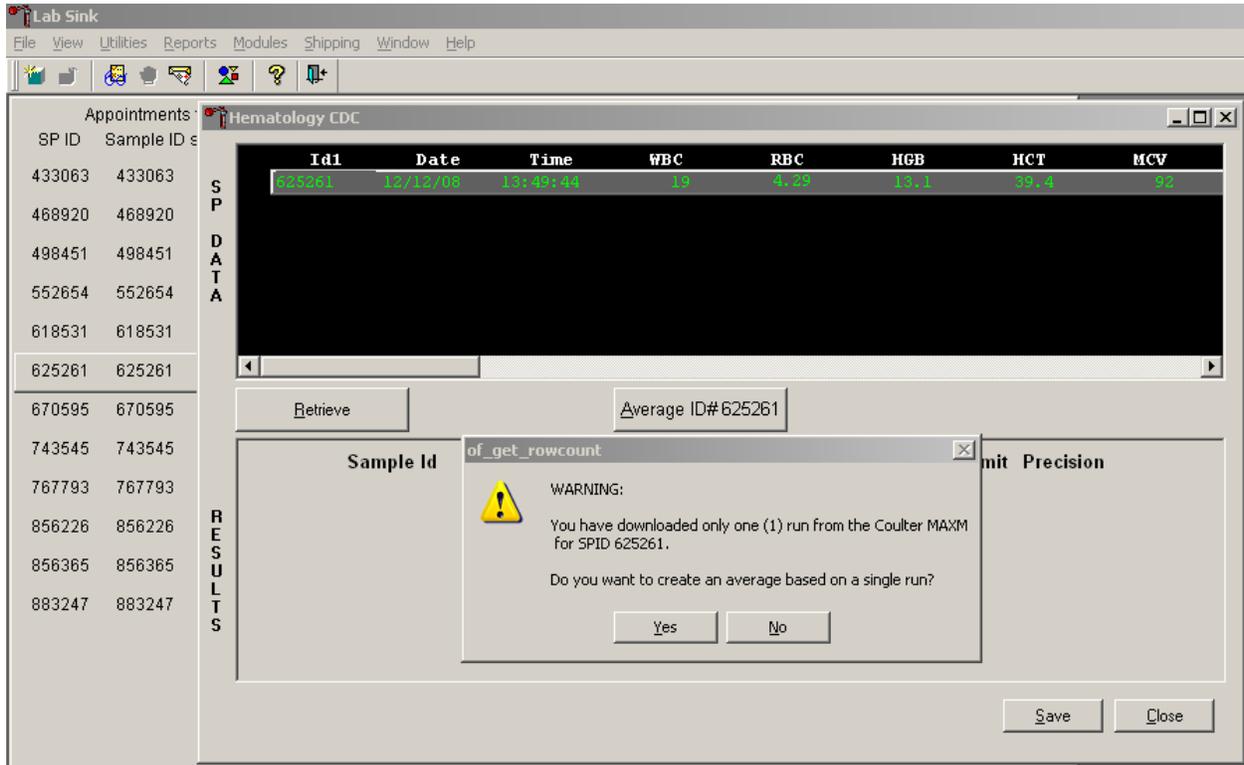
A warning text box displays if the Close button is selected before the results have been saved.



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.

- Running samples when only one run is possible.

Save results where only one run was possible.

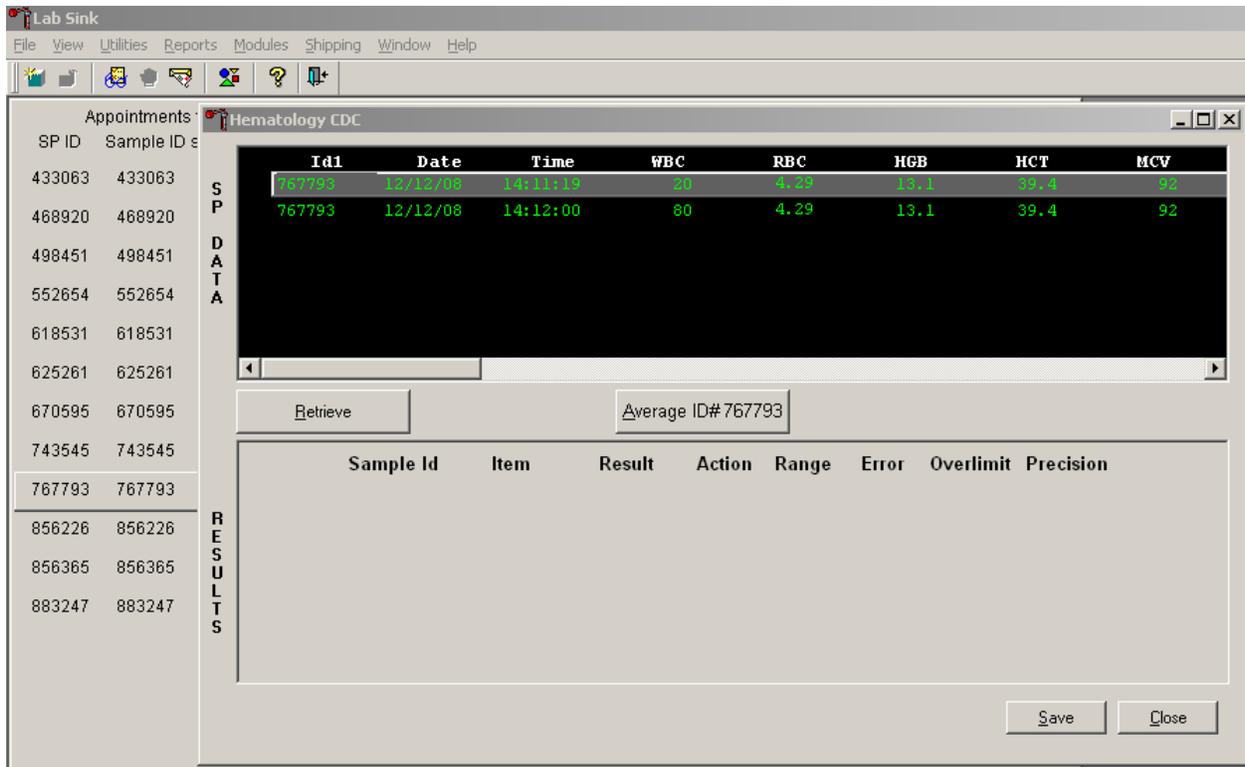


Run samples in duplicate whenever possible. If the whole blood is insufficient, it is acceptable to average and save only one run. To save results where only one run is possible, use the mouse to direct the mouse arrow to the Average Selected ID box and left click. A warning message text box displays that states, “You have downloaded only one (1) run from the Coulter HMX 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 the 'Lab Sink' application window with the 'Hematology CDC' module active. On the left, there is a list of appointments with columns for 'SP ID' and 'Sample ID'. The appointment with Sample ID 767793 is selected. The main window displays a table of sample data with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. Below this, there is a 'Retrieve' button and a text field showing 'Average ID# 767793'. The 'RESULTS' section contains a table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The results for sample 767793 are as follows:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
767793	CBC_WBC	50.0	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
767793	CBC_RBC	4.29	<input type="checkbox"/>				
767793	CBC_HGB	13.1	<input type="checkbox"/>				
767793	CBC_HCT	39.4	<input type="checkbox"/>				
767793	CBC_MCV	92.0	<input type="checkbox"/>				
767793	CBC_MCH	30.7	<input type="checkbox"/>				

At the bottom, there is a 'Comment for Sample Id# 767793' field with '(none)' selected, and 'Save' and 'Close' buttons.

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 the data for 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 'Lab Sink' application window, specifically the 'Hematology CDC' module. On the left, there is a list of 'Appointments' with columns for 'SP ID' and 'Sample ID'. The main area shows a table of data for sample ID 767793, with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. Below this is a 'RESULTS' section with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The 'Action' column contains 'L' or 'H' flags, and the 'Precision' column contains checkmarks. At the bottom, there is a 'Comment for Sample Id# 767793' dropdown menu set to '(none)', and 'Save' and 'Close' buttons.

SP ID	Sample ID
433063	433063
468920	468920
498451	498451
552654	552654
618531	618531
625261	625261
670595	670595
743545	743545
767793	767793
856226	856226
856365	856365
883247	883247

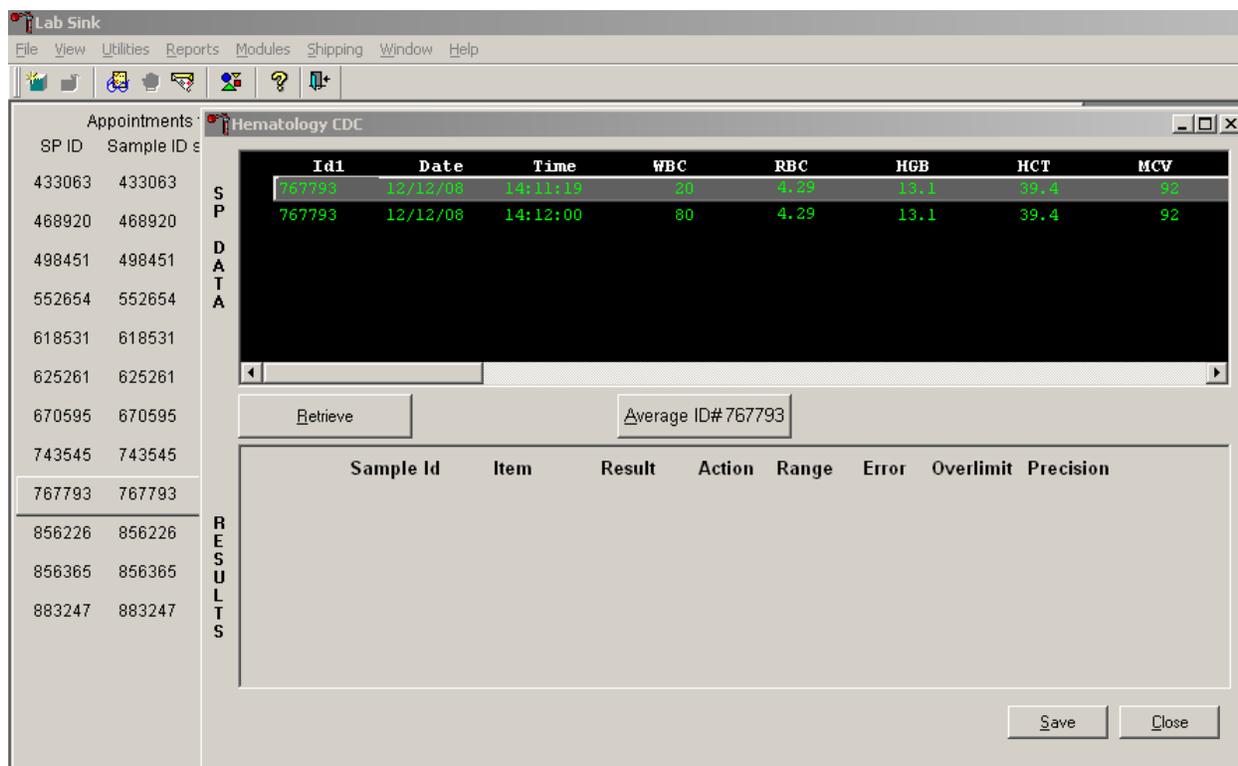
Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
767793	12/12/08	14:12:00	80	4.29	13.1	39.4	92
767793	12/12/08	14:12:00	80	4.29	13.1	39.4	92

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
767793	CBC_MCHC	31.6	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
767793	CBC_RDW	15.1	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
767793	CBC_PLT	427.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
767793	CBC_MPV	11.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
767793	CBC_LYM	14.2	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
767793	CBC_LYC	2.7	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

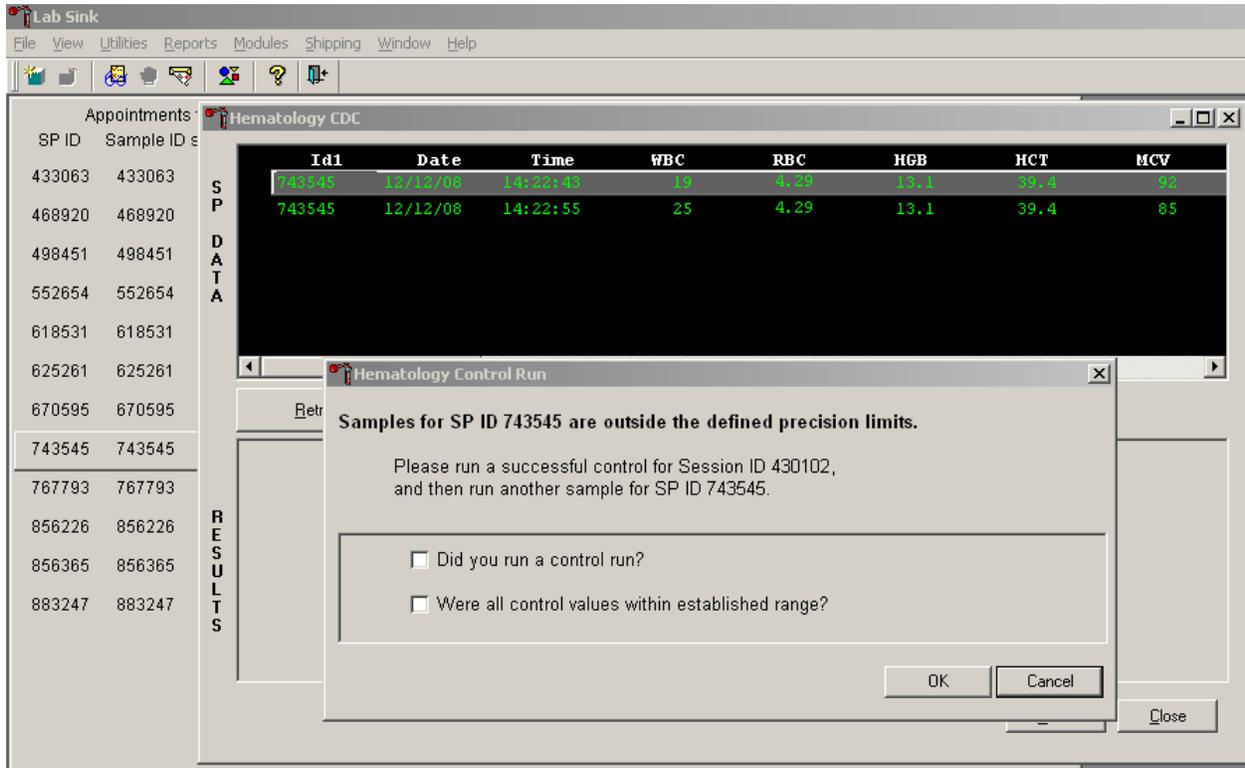
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and “H” or “L” action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results 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.



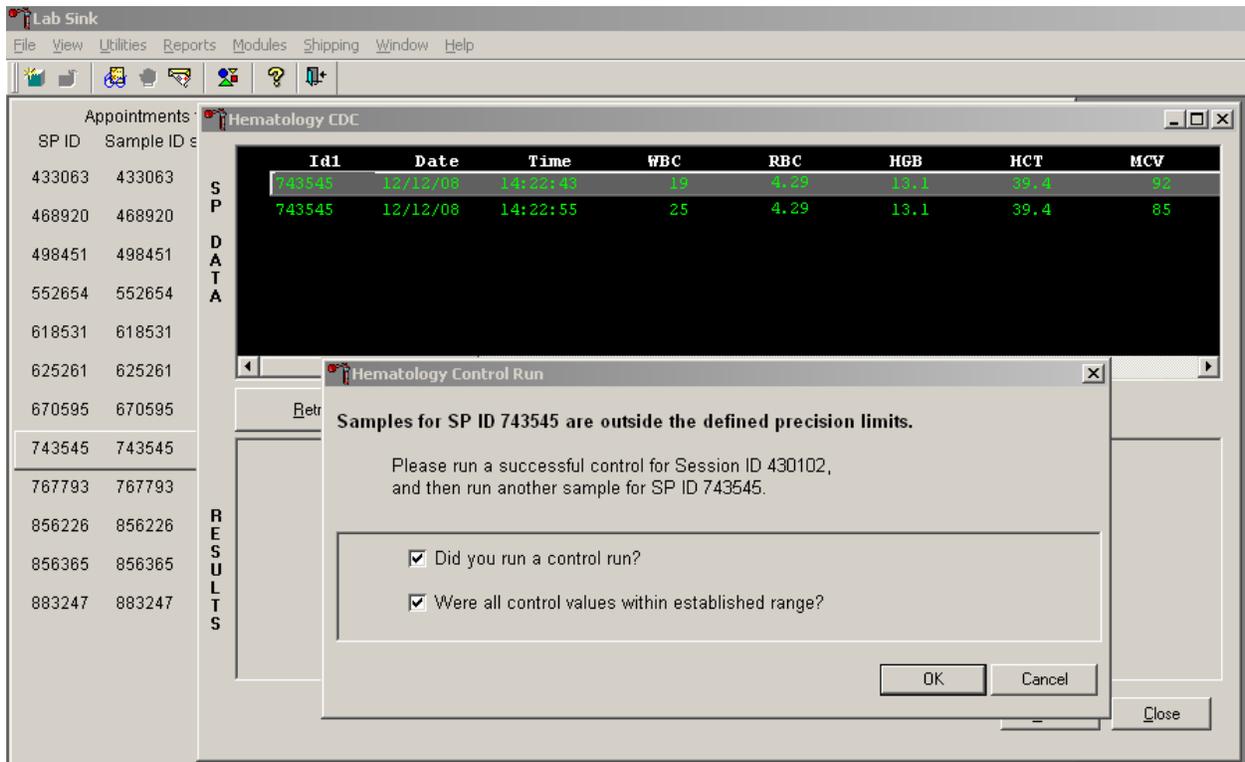
Average the two results by using the mouse to direct the mouse arrow to the Average ID#XXXXXX button and left click. If at this point, precision limits are exceeded for any individual parameter, the technologist is prompted to run a control and evaluate the control to determine if all control values 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 checkboxes and left click to record the checkmarks.

Save the responses to the checkbox 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 'Lab Sink' application window with the 'Hematology CDC' module active. The interface is divided into several sections:

- Appointments:** A list of appointments with columns for SP ID and Sample ID. Sample ID 743545 is highlighted.
- S P D A T A:** A table showing patient data for sample ID 743545, including Date (12/12/08), Time (14:22:55), WBC (25), RBC (4.29), HGB (13.1), HCT (39.4), and MCV (85).
- RESULTS:** A table showing test results for sample ID 743545. The results are as follows:
 

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_WBC	22.0	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
743545	CBC_RBC	4.29	<input type="checkbox"/>				
743545	CBC_HGB	13.1	<input type="checkbox"/>				
743545	CBC_HCT	39.4	<input type="checkbox"/>				
- Comment for Sample Id# 743545:** A dropdown menu showing '(none)'. Buttons for 'Save' and 'Close' are located below this section.

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.

The screenshot shows the Lab Sink Hematology CDC interface. On the left, there is a list of appointments with columns for SP ID and Sample ID. The main window is titled 'Hematology CDC' and contains two primary sections: 'SP DATA' and 'RESULTS'.

**SP DATA Section:**

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
743545	12/12/08	14:22:43	15	4.29	13.1	39.4	85
743545	12/12/08	14:22:55	25	4.29	13.1	39.4	85
743545	12/12/08	14:25:28	80	4.29	13.1	39.4	80

Below the table is a 'Retrieve' button and a text field containing 'Average ID# 743545'.

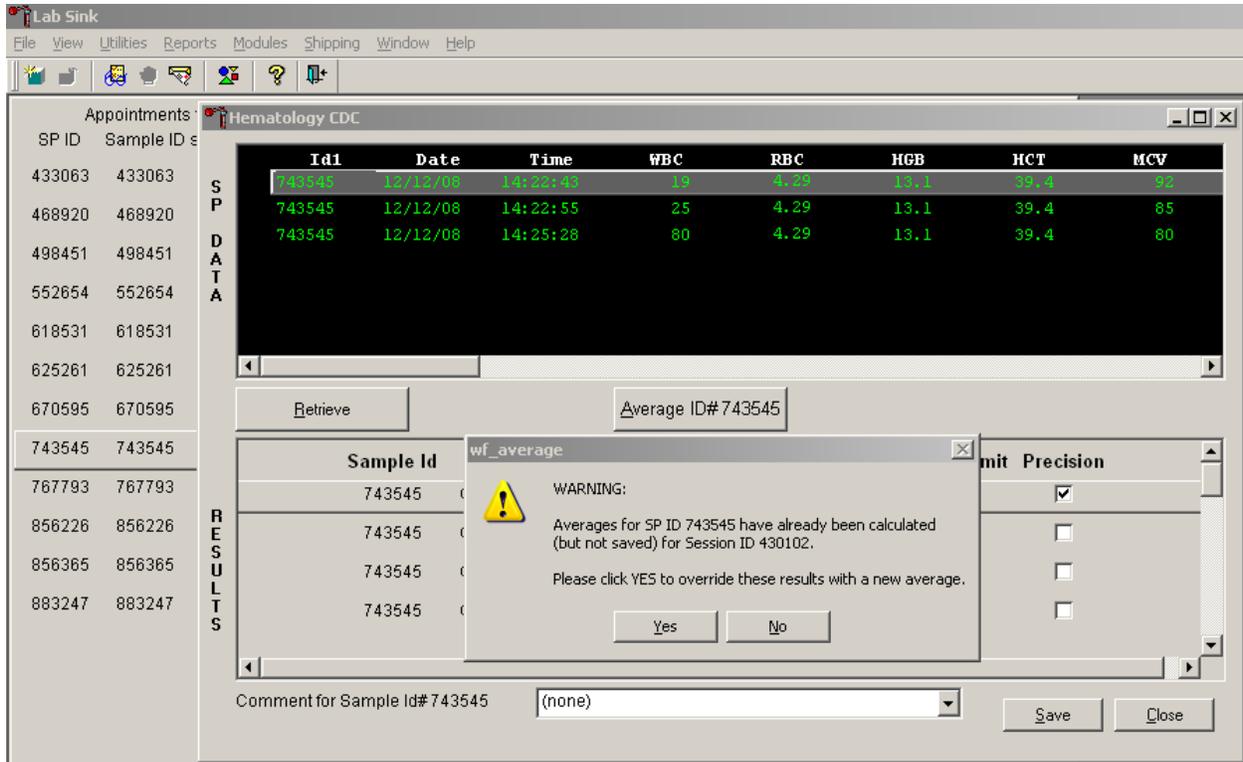
**RESULTS Section:**

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_WBC	22.0	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
743545	CBC_RBC	4.29	<input type="checkbox"/>				
743545	CBC_HGB	13.1	<input type="checkbox"/>				
743545	CBC_HCT	39.4	<input type="checkbox"/>				

At the bottom, there is a 'Comment for Sample Id# 743545' field with '(none)' selected, and 'Save' and 'Close' buttons.

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” and left click. The initial averaged results 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.



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.

The screenshot displays the 'Lab Sink' application window, specifically the 'Hematology CDC' module. On the left, there is a list of appointments with columns for 'SP ID' and 'Sample ID'. The main area shows a table of data for sample ID 743545, including columns for 'Id1', 'Date', 'Time', 'WBC', 'RBC', 'HGB', 'HCT', and 'MCV'. Below this is a 'Retrieve' button and a text field containing 'Average ID# 743545'. The 'RESULTS' section contains a table with the following data:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_BA	0.1	<input type="checkbox"/>				
743545	CBC_BAC	0.0	<input type="checkbox"/>				
743545	CBC_MO	15.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_MOC	2.9	<input type="checkbox"/>				

At the bottom, there is a 'Comment for Sample Id# 743545' field with '(none)' selected, and 'Save' and 'Close' buttons.

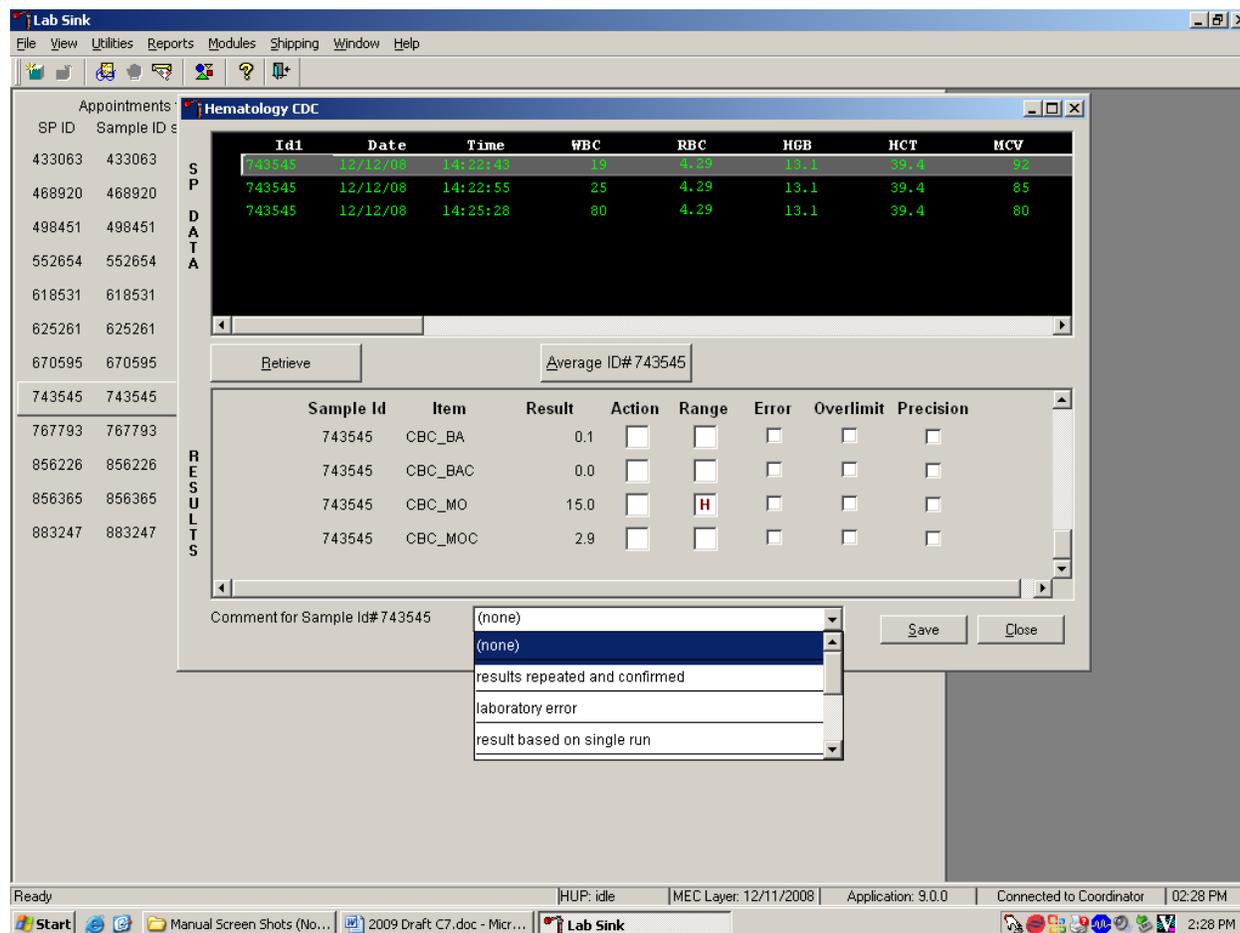
The first three runs are recalculated to find the closest two results for parameters where the difference between any two results exceeded its precision limits. If all parameters now meet precision limits (there are no checkmarks in the Precision column), save the results to the database. To save the 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.
laboratory error	There was a technologist error.
result based on single run	The quantity of specimen is insufficient to run it more than once.
equipment failure	The Coulter malfunctioned.
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.
clotted	The blood is clotted.
not enough blood	There is insufficient blood to perform at least one complete aspiration.

Save the result after attaching a comment.

The screenshot displays the 'Lab Sink' application window, specifically the 'Hematology CDC' module. On the left, a list of appointments is visible, with sample ID 743545 highlighted. The main window contains a table of hematology data for sample ID 743545, showing values for WBC, RBC, HGB, HCT, and MCV. Below this table, a 'Retrieve' button and a dropdown menu for 'Average ID# 743545' are present. A larger table below shows the results for various CBC items, including CBC\_BA, CBC\_BAC, CBC\_MO, and CBC\_MOC. At the bottom, a comment field contains the text 'results repeated and confirmed', and 'Save' and 'Close' buttons are visible.

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
743545	12/12/08	14:22:43	19	4.29	13.1	39.4	85
743545	12/12/08	14:22:55	25	4.29	13.1	39.4	85
743545	12/12/08	14:25:28	80	4.29	13.1	39.4	80

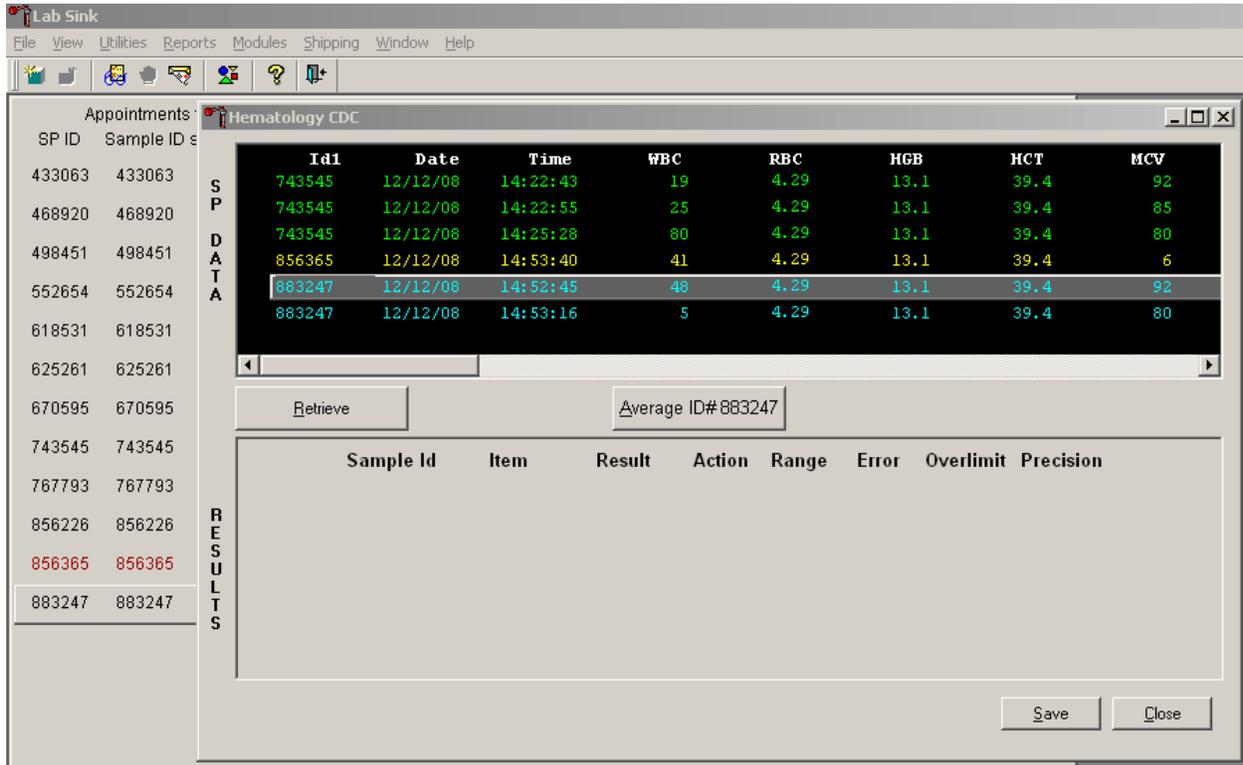
Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_BA	0.1	<input type="checkbox"/>				
743545	CBC_BAC	0.0	<input type="checkbox"/>				
743545	CBC_MO	15.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_MOC	2.9	<input type="checkbox"/>				

Comment for Sample Id# 743545: results repeated and confirmed

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, retrieve the data, 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 the Lab Sink Hematology CDC interface. On the left, there is a list of appointments with columns for SP ID and Sample ID. The main window displays a table of data for sample 743545, including columns for Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. Below this table, there is a 'Retrieve' button and a text field containing 'Average ID# 743545'. A larger table below shows the results for sample 743545, with columns for Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The results table shows four rows of data for CBC\_RDW, CBC\_PLT, CBC\_MPV, and CBC\_LYM. At the bottom, there is a 'Comment for Sample Id# 743545' field with '(none)' selected, and 'Save' and 'Close' buttons.

SP ID	Sample ID
433063	433063
468920	468920
498451	498451
552654	552654
618531	618531
625261	625261
670595	670595
743545	743545
767793	767793
856226	856226
856365	856365
883247	883247

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
743545	12/12/08	14:22:43	19	4.29	13.1	39.4	92
743545	12/12/08	14:23:15	25	4.29	13.1	39.4	81
743545	12/12/08	14:25:28	80	4.29	13.1	39.4	80
856365	12/12/08	14:53:40	41	4.29	13.1	39.4	6
883247	12/12/08	14:52:45	48	4.29	13.1	39.4	92
883247	12/12/08	14:53:16	5	4.29	13.1	39.4	80

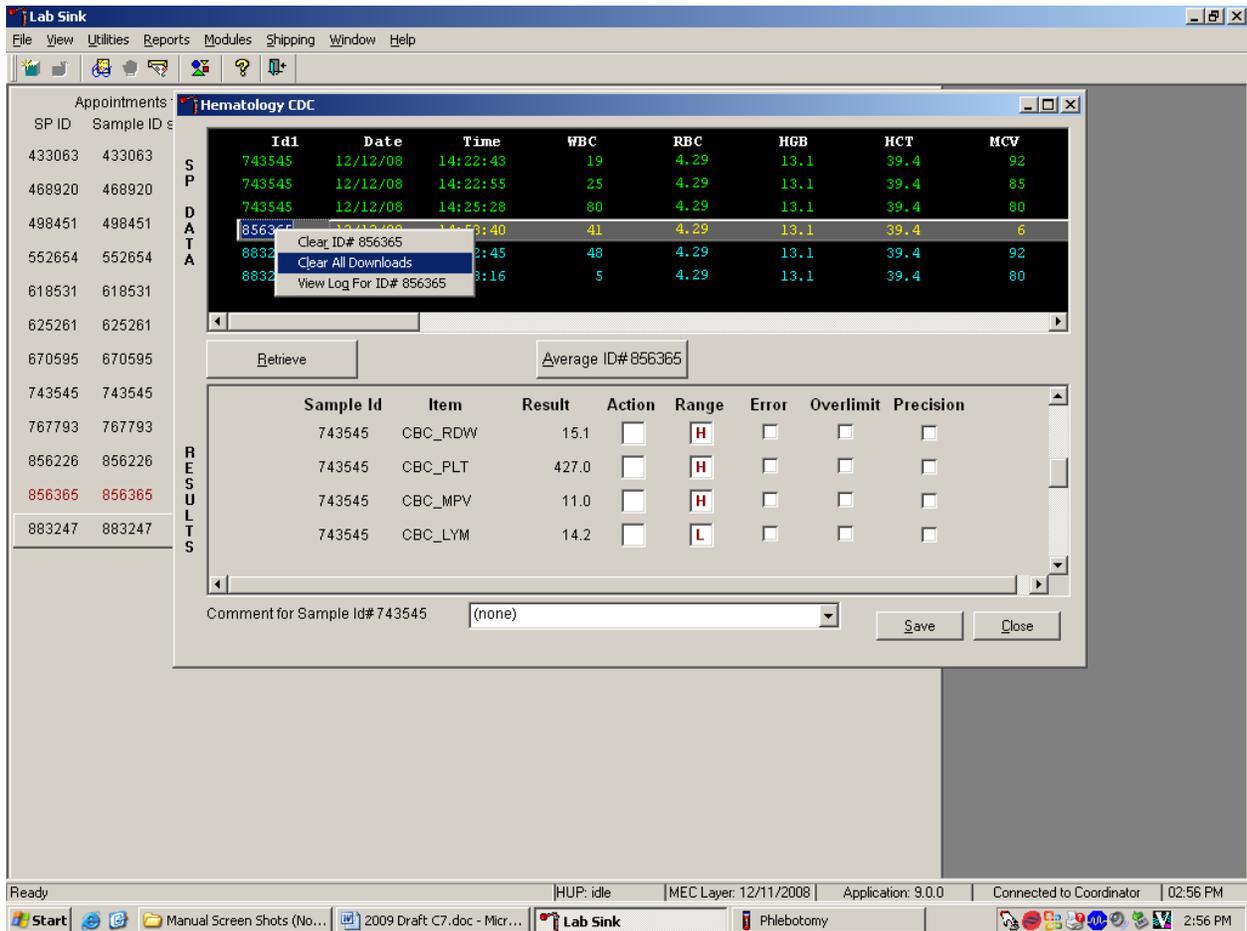
  

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_RDW	15.1	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_PLT	427.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_MPV	11.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_LYM	14.2	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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.

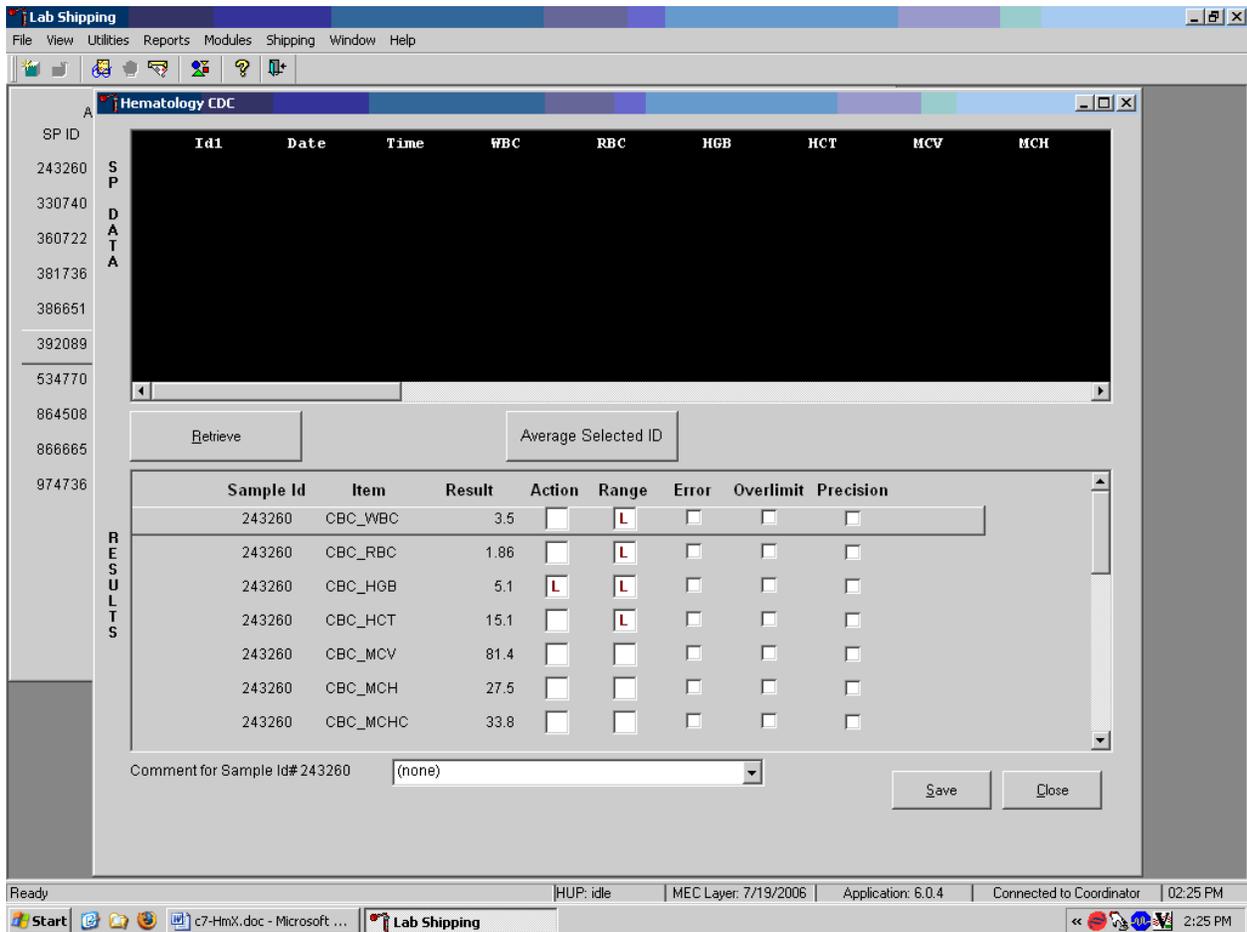
Use alternative data manipulation choices as desired.

Use the “Clear All Downloads” function to delete all data for all SPs in the SP Data section.



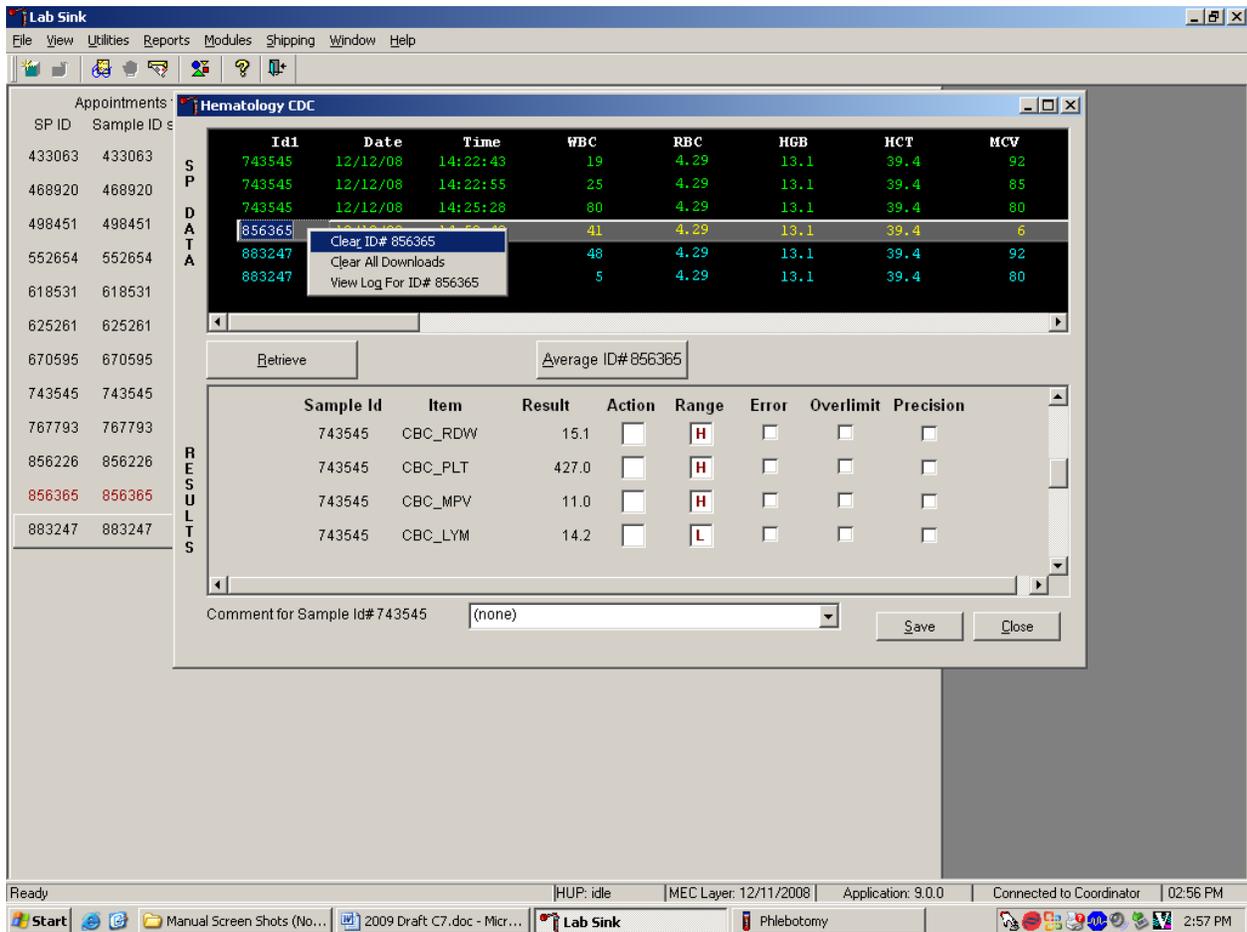
To clear all downloads from the SP Data section, use the mouse to direct the mouse arrow to any individual row in the SP Data section and right click to display the alternative data manipulation choices. To select “Clear All Downloads,” drag the mouse arrow to {Clear All Downloads} and left click or type [Shift] [L/I].

Release the mouse button to clear all downloads.



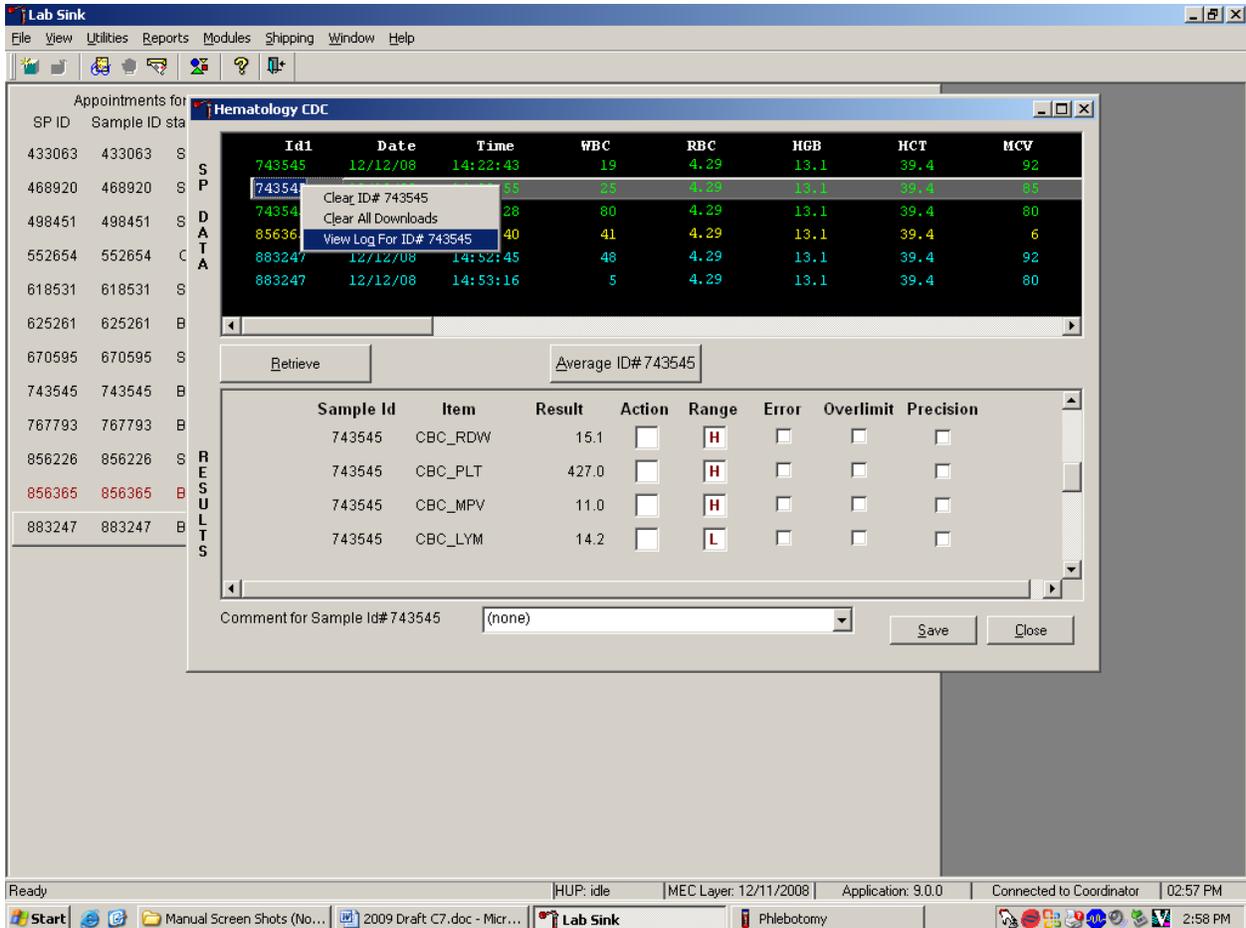
All data in the SP Data section is erased but any averaged result remains in the Results section of the window. To clear the result section, close the Hematology module. To close the hematology module, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

Use the data manipulation functions to erase or delete one SP's data in the SP Data section.



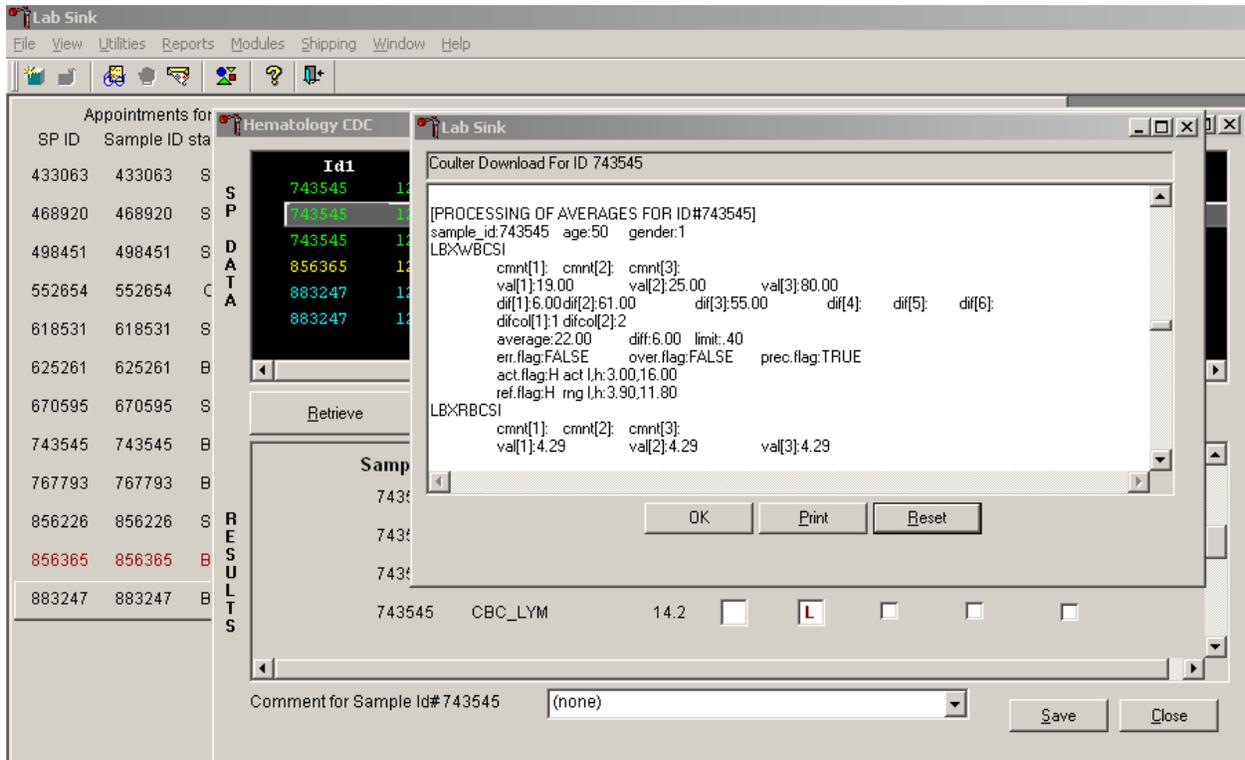
To clear the Coulter downloads for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to {Clear ID#XXXXXX}, and right or left click or type [Shift] [R/r]. Release the mouse button to clear this download. Retransmit, retrieve, 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.



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.

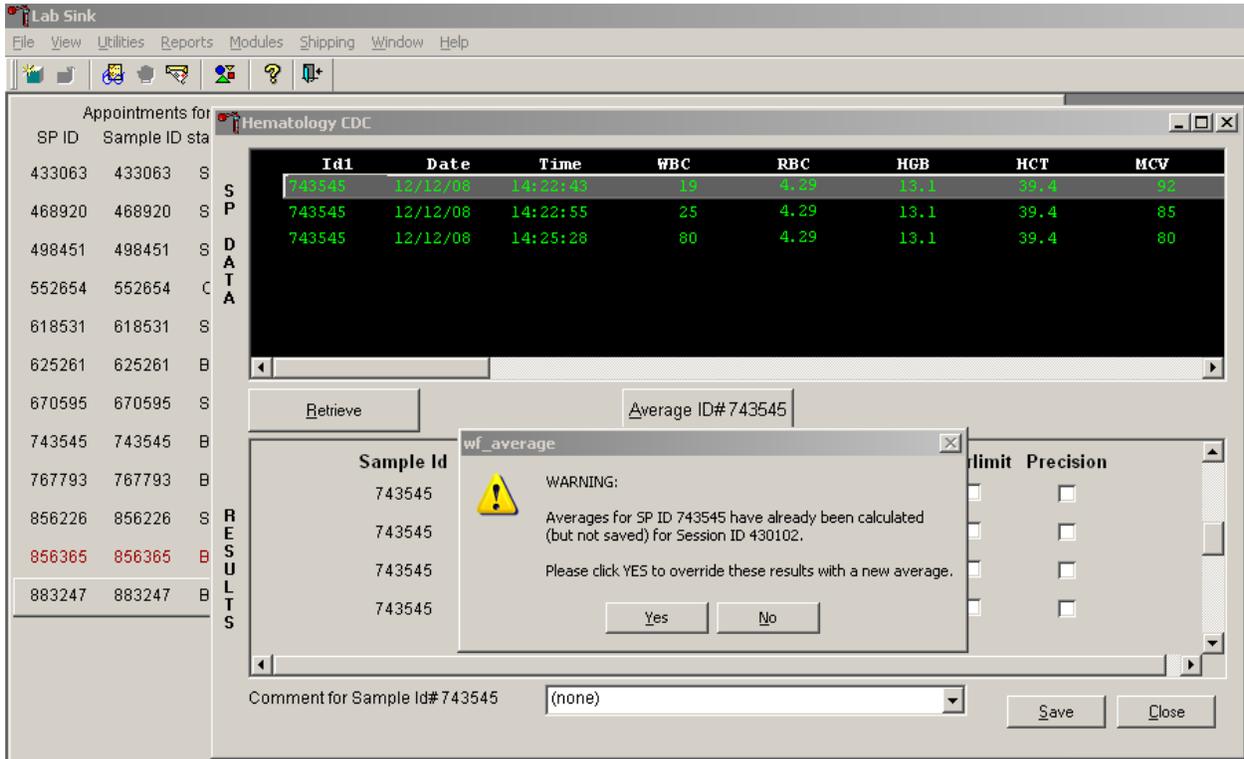
Review the SP's log.



The 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].

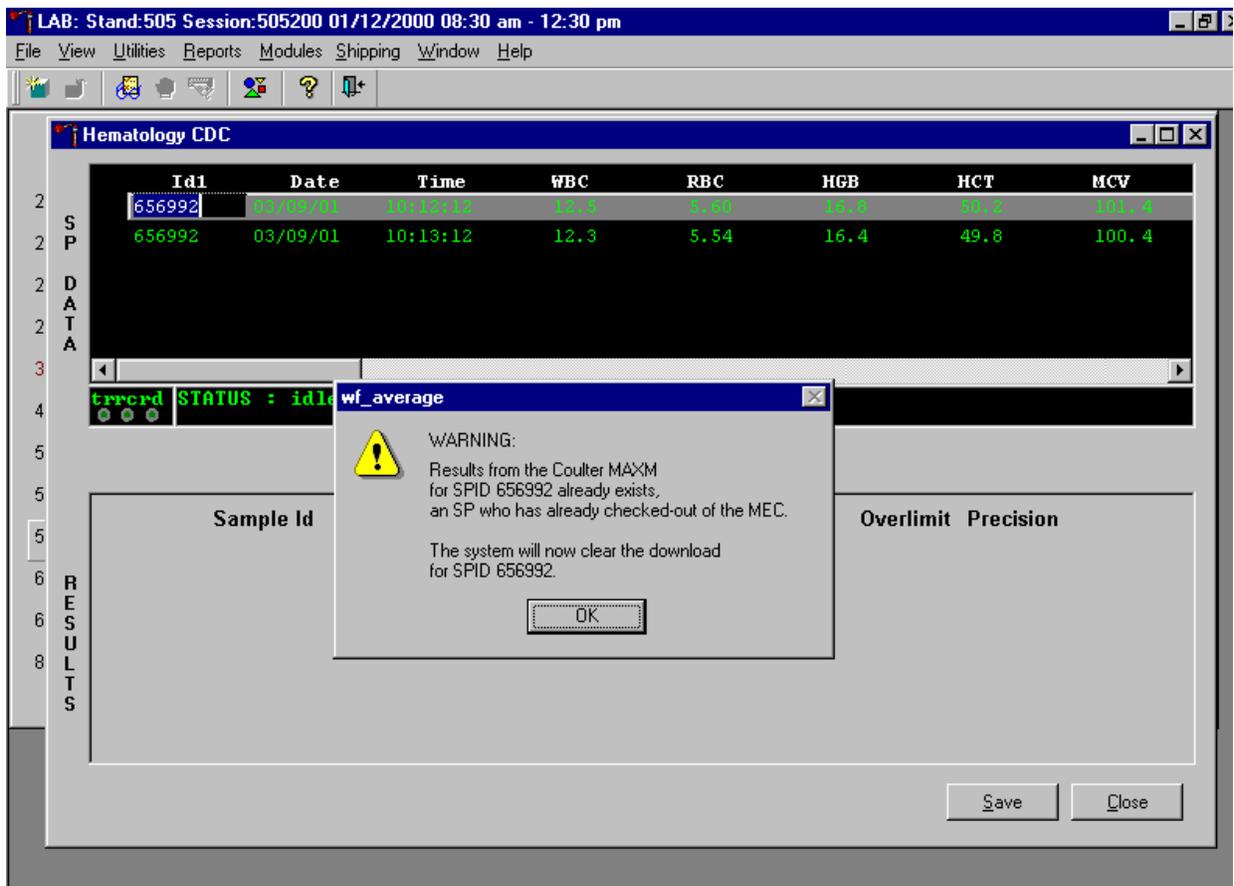
7. Re-averaging results.

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 ID 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 who has exited the MEC or for whom a Report of Findings has been printed. This text states, “Results from the Coulter HMX for SPID XXXXXX already exists, an SP who has already checked-out of the MEC. The system will now clear the download for SPID 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. HMX Parameter Codes

1. Review the message

The Coulter HMX 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 HMX 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 99.9 \times 10^3</math> cells/<math>\mu</math>L</p> <p style="padding-left: 20px;">RBC <math>\geq 9.99 \times 10^6</math> cells/<math>\mu</math>L</p> <p style="padding-left: 20px;">Plt <math>\geq 999 \times 10^3</math> cells/<math>\mu</math>L</p> <p>If WBC is over range</p> <p style="padding-left: 20px;">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 overrange</p> <p style="padding-left: 20px;">an R appears next to Hct, MCH, and MCHC results.</p> <p>If Plt is overrange</p> <p style="padding-left: 20px;">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	DMS has received 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</p> <p>WBC is over range.</p>

<b>RBC Parameters</b>	
“R” next to RDW result	Excessive asymmetry in RBC histogram, or WBC or MCV overrange.
“*R” next to MCV; also “R” next to RBC, Hct, 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	Check of WBC lower threshold failed. Particles are present at the 35 fL threshold (Plt clump, giant Plt, nrbc, lyse resistant RBC, malarial parasites).
“R” next to Diff percentages and numbers	Low differential count statistics. These messages occur also: Population message: ABNORMAL WBC POP Suspect message: REVIEW SLIDE
“:....:” for Diff results	System detects a clog in the flow cell. There are three types of clogs: FC = Full Clog PC1 = Partial Clog 1 PC2 = Partial Clog 2

2. Remedial action

Review the result for the affected parameter. Rerun the specimen if any of the parameter flags occurs.

D. HMX 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

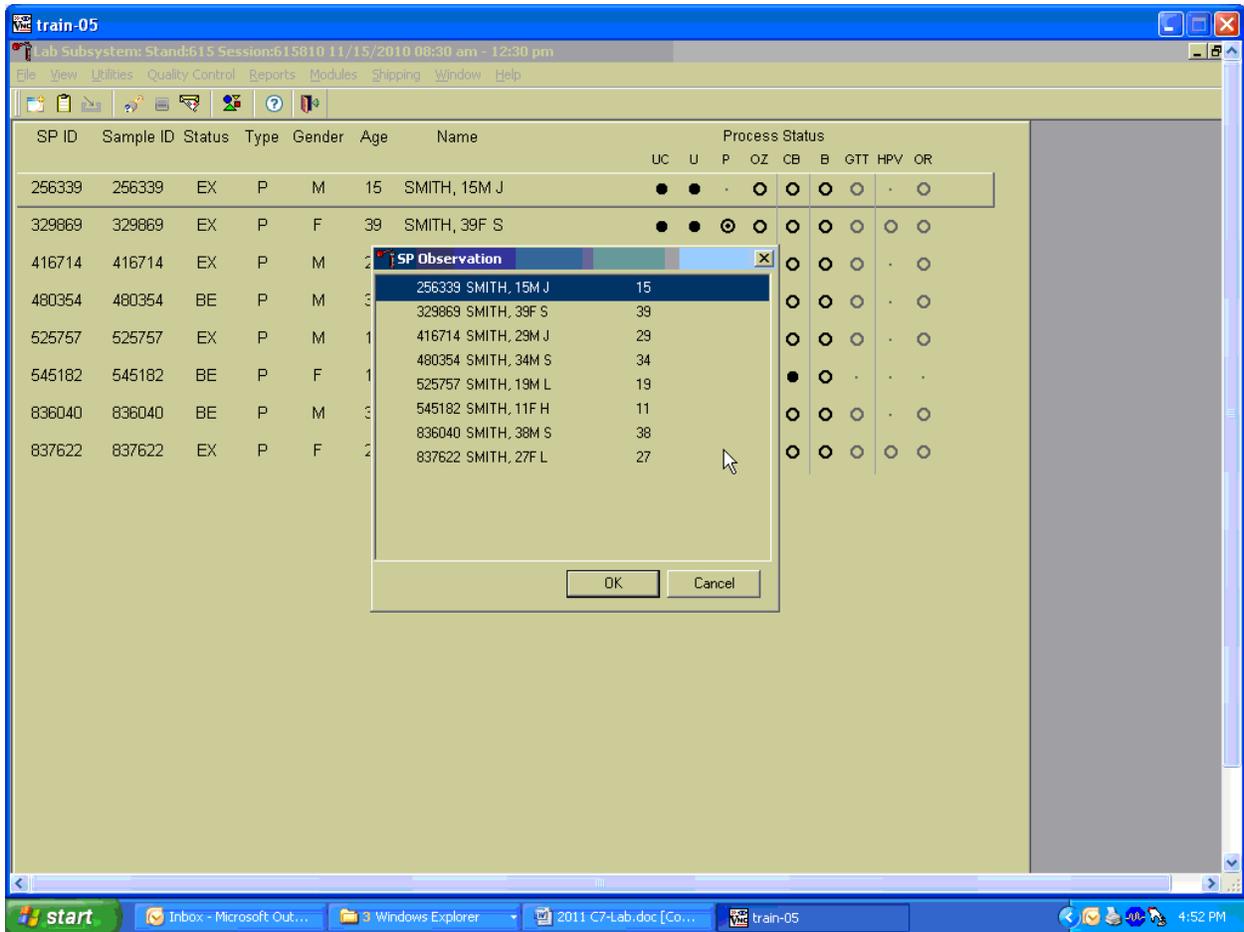
1. The MEC physician reviews and interprets all CBC results. Results outside action limits flash and transmit to the physician immediately. The physician determines if referral for the SP for treatment is necessary.
2. The medical technologist sends an observation to the physician whenever a critical 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.



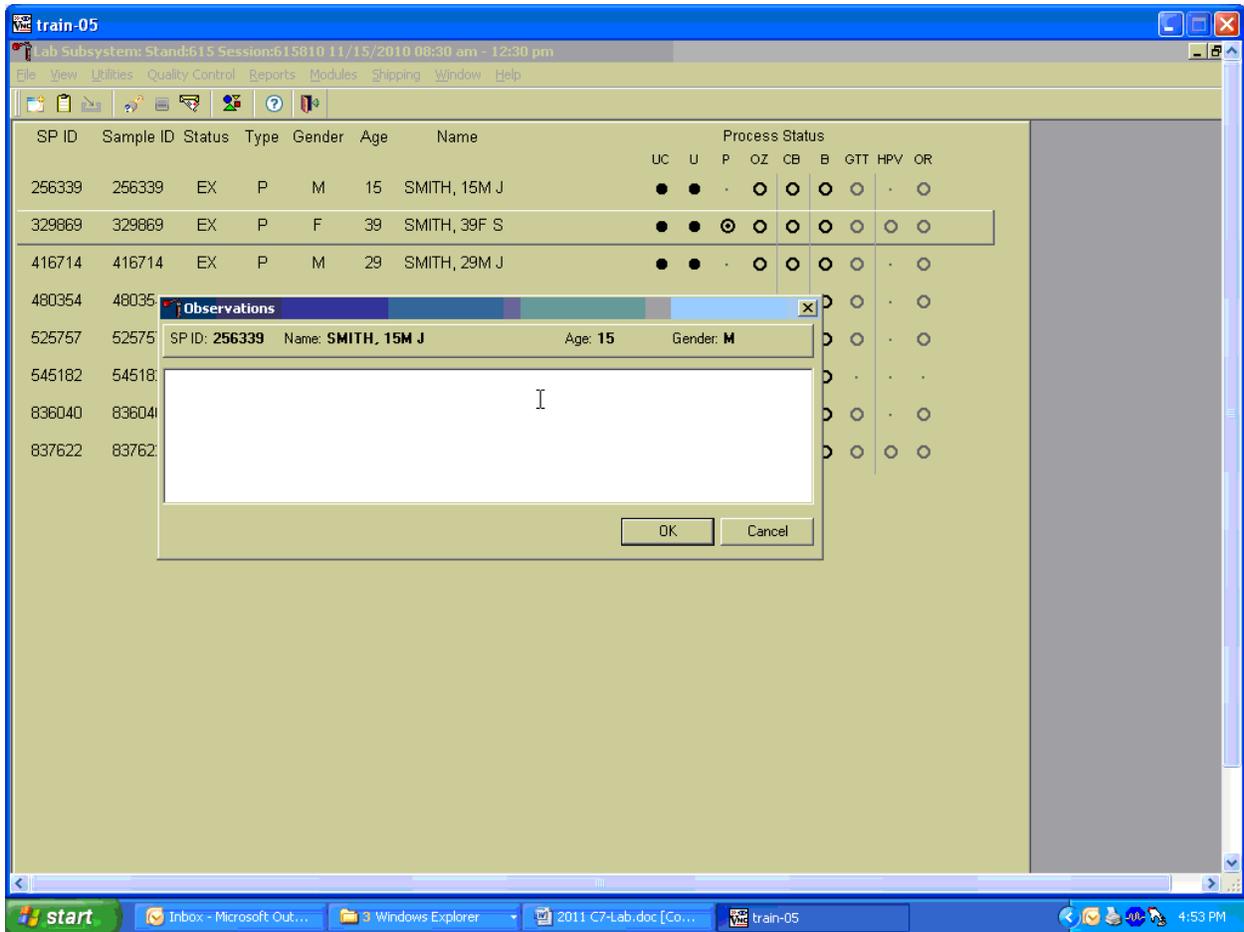
To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations}, and left click, or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



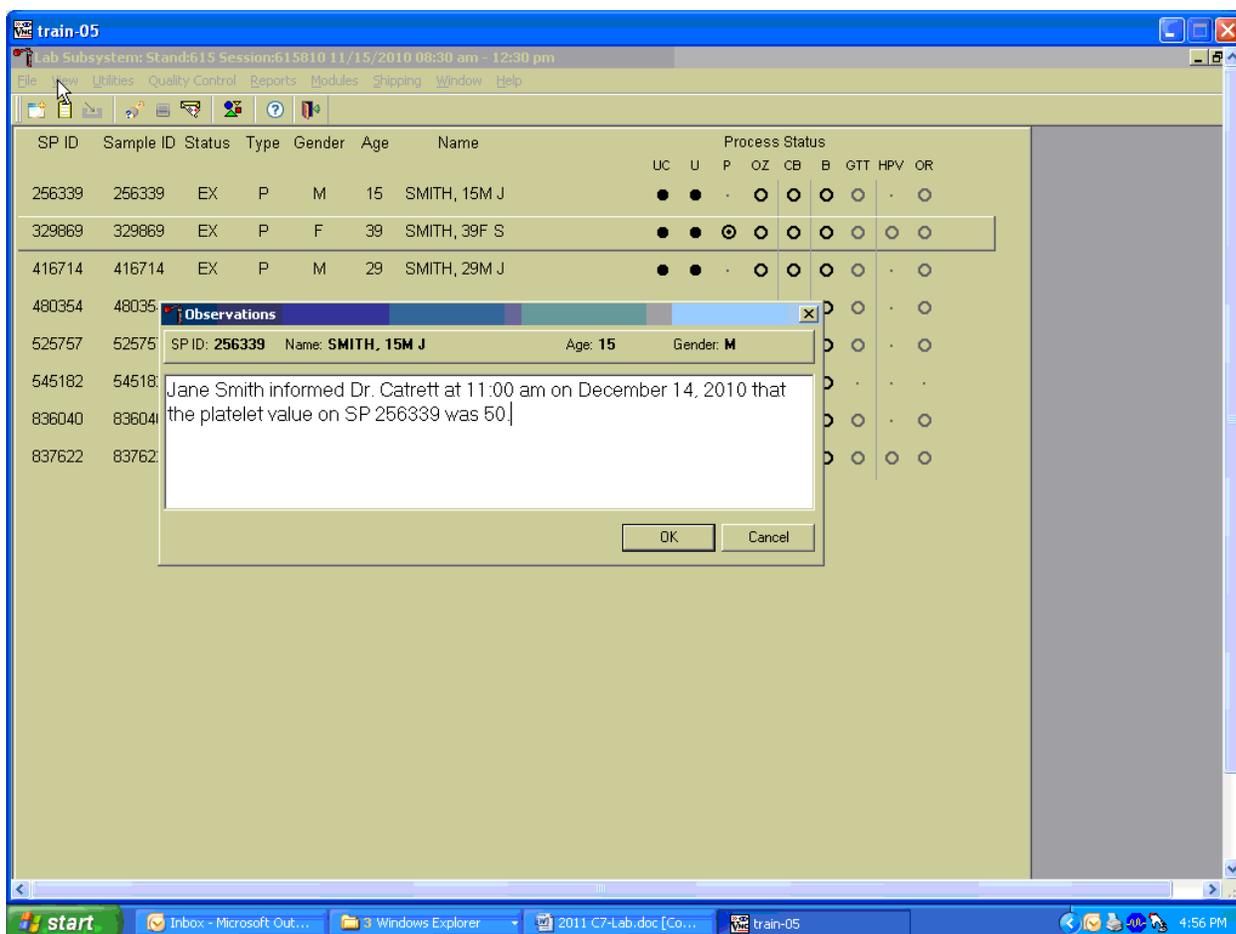
To select or highlight an SP, drag the mouse arrow to the correct SP and left click or use the up and down arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to 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.
- WBC – Certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, agglutinated WBCs, any unlysed particles greater than 35 fL, very large or aggregated platelets as when anticoagulated with oxalate or heparin, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.

- RBC – Very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBCs smaller than 36 fL, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.
- Hgb – Very high WBC count, severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing, or anything that increases the turbidity of the sample such as elevated levels of triglycerides.
- MCV – Very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments that fall below the 36-fL threshold, or rigid RBCs.
- RDW – Very high WBC count, high concentration of very large or clumped platelets as in blood anticoagulated with oxalate or heparin, RBCs below the 36-fL threshold, two distinct populations of RBCs, RBC agglutinates, or rigid RBCs.
- Plt – Very small red blood cells near the upper threshold, cell fragments, clumped platelets as with oxalate or heparin, platelet fragments, or cellular debris near the lower platelet threshold.
- MPV – Known factors that interfere with the Plt count and shape of the histogram or known effects of EDTA.
- Hct – Known factors that interfere with the parameters used for computation: RBC and MCV.
- MCH – Known factors that interfere with the parameters used for computation: Hgb and RBC.
- MCHC – Known factors that interfere with the parameters used for computation: Hgb, RBC, and MCV.
- Diff Parameters – Known factors that affect the WBC count as listed above or high triglycerides that affect lysing.

XIII. Reference Ranges

1. Males

Age in years	1-5		6-18		19-65		66+	
	2.5	97.5	2.5	97.5	2.5	97.5	2.5	97.5
White blood cell count (SI)	4.3	14.6	3.6	11.5	3.9	11.8	3.8	12.1
Red cell count (SI)	3.98	5.3	4.14	5.78	4.18	5.86	3.57	5.67
Hemoglobin (g/dL)	10.7	14.2	11.9	16.9	13.1	17.5	11.4	17.1
Hematocrit (%)	32.1	41.7	35.3	49.9	38.7	51.4	33.9	50.9
Mean cell volume (fL)	68.2	88.8	75.6	94.6	79.8	99.1	81.4	102.7
Mean cell hemoglobin (pg)	22.3	30.6	25.0	32.3	26.3	34.0	26.3	35.0
MCHC (g/dL)	32.3	35.6	32.3	35.3	32.3	35.3	32.1	35.1
Red cell distribution width (%)	11.4	15.8	11.4	14.0	11.4	14.5	11.8	16.2
Platelet count (%) SI	212	546	179	439	152	386	124	384
Mean platelet volume (fL)	6.1	8.9	6.6	10	6.8	10.1	6.6	10.2
Lymphocyte percent (%)	22.8	68.4	17.5	54.3	16.1	47.9	12.3	46.4
Monocyte percent (%)	4.6	15.2	4.8	13.7	4.4	13.5	4.6	14.0
Segmented neutrophils percent (%)	17.6	67.1	30.3	72.8	37.8	74.6	39.5	78.1
Eosinophils percent (%)	0.7	11.3	0.7	11.5	0.7	8.5	0.6	8.8
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.6	0.1	1.6

## 2. Females

Age in years	1-5		6-18		19-65		66+	
	2.5	97.5	2.5	97.5	2.5	97.5	2.5	97.5
White blood cell count (SI)	4.3	14.0	3.9	12.2	4.1	12.9	4.0	11.6
Red cell count (SI)	3.96	5.28	3.84	5.24	3.64	5.2	3.51	5.34
Hemoglobin (g/dL)	11.0	14.2	11.2	15.1	10.6	15.6	10.9	15.9
Hematocrit (%)	32.5	41.9	33.5	44.6	32.0	45.9	32.8	47.0
Mean cell volume (fL)	70.2	89.1	74.7	94.9	74.6	98.2	80.3	100.6
Mean cell hemoglobin (pg)	23.3	30.8	24.5	32.6	24.3	33.8	26.4	34.5
MCHC (g/dL)	32.4	35.5	32.3	35.3	32.1	35.3	32.3	35.1
Red cell distribution width (%)	11.3	15.4	11.3	14.8	11.4	16.3	11.6	16.3
Platelet count (%) SI	215	547	190	446	168	441	155	428
Mean platelet volume (fL)	6.1	8.9	6.6	10.0	6.8	10.2	6.7	10.5
Lymphocyte percent (%)	21.6	68.8	17.2	54.7	14.1	47.6	13.7	46.9
Monocyte percent (%)	4.2	14.4	4.3	12.7	3.8	11.6	4.4	12.8
Segmented neutrophils percent (%)	19.4	69.5	31.9	74.3	39.8	78.1	40.9	78.1
Eosinophils percent (%)	0.6	9.9	0.6	9.9	0.6	7.3	0.6	7.5
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.7	0.1	1.7

3. Reference ranges for normal values were calculated from the NHANES data set (1999-2004) 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  $3 \times 10^3 \mu\text{L}$  or > or = to  $16.0 \times 10^3 \mu\text{L}$
- 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> μL or >800 x 10<sup>3</sup> μL

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."

All records, including QA/QC data will be maintained for 6 years. Use only numerical identifiers for SP results.

## XVIII. Quality Control Summary Statistics and Graphs

Chapter 14 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 using the CAP proficiency results.

## XIX. References

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## 8. BLOOD PROCESSING

### 8.1 Introduction

The purpose of blood processing is to (1) perform a complete blood count; (2) allocate blood into vessels for storage and transport to laboratories across the United States for analysis; (3) allocate serum into vessels for future studies and storage; and (4) ship tubes for genetic analysis. 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 dilutions; and storing the specimens.

### 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 processing supplies in cabinets and/or the trailer compartments. Store the sterile saline in the refrigerator. Exhibits 8-1 and 8-2 list nonconsumable and consumable supplies for blood processing.

Exhibit 8-1. Nonconsumable supplies for blood processing

Blood processing template (6-11/12+ and 1-2/3-5)	Nalge cryovial racks
One Eppendorf pipette 100-5,000 $\mu$ L	Two Eppendorf pipettes 50-1,000 $\mu$ 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
Deionized water bottle	Saline squeeze bottle

Exhibit 8-2. Consumable supplies for blood processing

Cotton swabs	Eight gallon biohazard sharps container
Biohazard bags 25 x 35	
Kimwipes	Bench Kote paper
Pipette tips 1,000 µL	Pipette tips 200 µL
Pipette tips 5-mL	Wooden applicator sticks
Zip closable bags	3.5-mL transfer pipette nonsterile
15.0 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 with 5x5 grid	10x10 three inch box
5.25 x 5.25 x 5.0 inch cardboard box with 5 x 5 foam insert	
10 x 10 two-inch box	5.25 x 5.25 x 3inch box with 7x7 grid
Ascorbic acid 0.3 gm per vessel	Nonsterile, powder-free, nonlatex gloves—small, medium, large
Ascorbic Acid 0.14 gm per vessel	Red cap insert
Sterile saline	Deionized water
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 biased 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
119	Genetics	20+	10.0	Whole blood	EDTA	10-mL	Ship twice per week
120	Genetics	20+	10.0	Whole blood	EDTA	10-mL	Ship twice per week
54	VOC Blood	12+	10.0	Whole blood	10-mL Grey	10-mL	½ subsample 1,2,4,5,10,11
1	Lead/Cad/HG/ Se/Mn	1+	0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	1+	0.1	Whole blood	EDTA	2-mL	Dilute with 1-mL AA 1%
4	Glycohem	12+	0.4	Whole blood	EDTA	2-mL	Refrigerate
5	Mercury, Ethyl & Methyl	1+	0.5	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
9	Glucose	12+	0.5	Plasma	Gray	2-mL	Morning SPs only
98	OGTT	12+	0.5	Plasma	Gray	2-mL	Morning Sps only, if eligible
91	SRM Pesticide	12+	4.0	Plasma	7-mL EDTA	5-mL	1/3 subsample 4, 6, 8, 9

Exhibit 8-5. Primary SP's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
136	Se/Cu/Zn	6+	1.0	Serum	Royal Blue	2 mL	1/3 Subsample 1,2,5,11
138	CMV	1-5	0.4	Serum	Red	2 mL	
70	Vitamin D/PUFA	1-5 6+	0.5 0.7	Serum	Red	2-mL	
14	Hep Profile	20+	1.5	Serum	Red	2-mL	
122	HAV	6+	1.5	Serum	Red	2-mL	
87	Hepatit ab	2 3-5	0.3 0.5	Serum	Red	2-mL	Age 2-5 only
17	Cotinine	3-5 6-11 12+	0.8 1.0 1.8	Serum	Red	2-mL	
21	Lipids	6-11 12+	1.0 1.5	Serum	Red	2-mL	
77	HPV Serum	14-59	0.5	Serum	Red	2-mL	14-59 only
18	Biochem	12+	0.8	Serum	Red	2-mL	
23	Insulin	12+	1.0	Serum	Red	2-mL	Morning SPs only
12	Vit B12/MMA	20+	0.7	Serum	Red	2 mL	
22	HIV	18-59	0.8	Serum	Red	2-mL	18-59 only
24	HSV	14-49	0.2	Serum	Red	2-mL	14-49 only
118	Thyroid	12+	1.0	Serum	Red	2-mL	1/3 subsample 1, 2, 5, 11
127	IgA-TTG/EMA	6+	0.5	Serum	Red	2-mL	
137	Testosterone	6+	0.5	Serum	Red	2 mL	
110	Folate1	1+	0.7	Serum	Red	2-mL	1/3 subsample 1, 2, 5, 11; Add 0.05 mL AA 7%
32	Xtra Sera1	3-11	0.5	Serum	Red	2-mL	
33	Xtra Sera2	3-11	0.5	Serum	Red	2-mL	
34	Xtra Sera3	12+	1.0	Serum	Red	2-mL	
35	Xtra Sera4	12+	1.0	Serum	Red	2-mL	
36	Xtra Sera5	12+	1.0	Serum	Red	2-mL	
37	Xtra Sera6	12+	1.0	Serum	Red	2-mL	
29	Persis Pest1	12+	4.0	Serum	10-mL Red	5-mL	1/3 Subsample 1, 2, 5, 11
89	Persis Pest2	12+	4.0	Serum	10-mL Red	5-mL	1/3 Subsample 1, 2, 5, 11
90	Perfluor	12+	4.0	Serum	10-mL Red	5-mL	1/3 subsample 1, 2, 5, 11
92	BFR1	12+	4.0	Serum	10-mL Red	5-mL	1/3 Subsample 1, 2, 5, 11
93	BFR2	12+	4.0	Serum	10-mL Red	5-mL	1/3 Subsample 1, 2, 5, 11

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 biased 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/Se/Mn	1+	0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	1+	0.1	Whole blood	EDTA	2-mL	Dilute with 1-mL AA
5	Mercury, Ethyl & Methyl	1+	0.5	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
9	Glucose	12+	0.5	Plasma	Grey	2-mL	Morning SPs only

Exhibit 8-8. VIP Guest's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
21	Lipids	6+	1.5	Serum	Red	2-mL	
23	Biochem	12+	0.8	Serum	Red	2-mL	
110	Folate 1	1+	0.7	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 biased results will occur if the exact procedures are not followed.

Exhibit 8-9. Guest 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 8-14 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/Se/Mn	1-2	0.4	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	1-2	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury, Ethyl & Methyl	1-2	0.5	Whole blood	3-mL EDTA	2-mL
138	CMV	1-2	0.4	Serum	3 mL Red	2 mL
70	Vitamin D/PUFA	1-2	0.5	Serum	3-mL Red	2-mL
87	Hepatitis ab	2	0.3	Serum	3-mL Red	2-mL
110	Folate1	1-2	0.7	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/Se/Mn	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, Ethyl & Methyl	3-5	0.5	Whole blood	3-mL EDTA	2-mL
138	CMV	3-5	0.4	Serim	7 mL Red	2 mL
70	Vitamin D/PUFA	3-5	0.5	Serum	7 and 3-mL Red	2-mL
87	Hepatitis ab	3-5	0.5	Serum	7 and 3-mL Red	2-mL
17	Cotinine	3-5	0.8	Serum	7 and 3-mL Red	2-mL
110	Folate1	3-5	0.7	Serum	7 and 3-mL Red	2-mL
32	Extra Sera1	3-5	0.5	Serum	7 and 3 -mL Red	2-mL
33	Extra Sera2	3-5	0.5	Serum	7 and 3-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/Se/Mn	6-11	0.4	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury, Ethyl & Methyl	6-11	0.5	Whole blood	3-mL EDTA	2-mL
136	Se/Cu/Zn	6-11	1.0	Serum	6 mL Royal Blue	2 mL
70	Vitamin D/PUFA	6-11	0.7	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL
122	HAV	6-19	1.5	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL
17	Cotinine	6-11	1.0	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL
21	Lipids	6-11	1.0	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL
127	IGA-TTG/EMA	6-11	0.5	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL
137	Testosterone	6-11	0.5	Serum	10 and 7 mL Red, 6mL Royal blue	2 mL
110	Folate1	6-11	0.7	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL
32	Xtra Sera1	6-11	0.5	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL
33	Xtra Sera2	6-11	0.5	Serum	10 and 7-mL Red, 6mL Royal blue	2-mL

Exhibit 8-13. Blood processing protocol for primary SPs aged 12-19 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
54	VOC Blood	12-19	10.0	Whole blood	10-mL grey	10-mL
1	Lead/Cad/HG/Se/Mn	12-19	0.4	Whole blood	4 -mL EDTA	2-mL
3	RBC Folate	12-19	0.1	Whole blood	4-mL EDTA	2-mL
4	Glycohem	12-19	0.4	Whole blood	4-mL EDTA	2-mL
5	Mercury, Methyl & Ethyl	12-19	0.5	Whole blood	4-mL EDTA	2-mL
9	Glucose	12-19	0.5	Plasma	2-mL Gray	2-mL
91	Srm Pest	12-19	4.0	Plasma	7-mL EDTA	5-mL
98	OGTT	12-19	0.5	Plasma	2-mL Gray	2-mL
136	Se/Cu/Zn	12-19	1.0	Serum	6 mL Royal Blue	2 mL
70	Vitamin D/PUFA	12-19	0.7	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
122	HAV	12-19	1.5	Serum	15 and 7-mL Red	2-mL
17	Cotinine	12-19	1.8	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
21	Lipids	12-19	1.5	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
77	HPV Serum	14-19	0.5	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
18	Biochem	12-19	0.8	Serum	15 and 7-mL Red	2-mL
23	Insulin	12-19	1.0	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
22	HIV	18-19	0.8	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
24	HSV	14-49	0.2	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
118	Thyroid	12-19	1.0	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
127	IgA-TTG/EMA	12-19	0.5	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
137	Testosterone	12-19	0.5	Serum	15 and 7 mL Red, 6mL Royal blue	2 mL
110	Folate1	12-19	0.7	Serum	15 and 10-mL Red	2-mL
34	Xtra Sera3	12-19	1.0	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
35	Xtra Sera4	12-19	1.0	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
36	Xtra Sera5	12-19	1.0	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
37	Xtra Sera6	12-19	1.0	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL

Exhibit 8-13. Blood processing protocol for primary SPs aged 12-19 years (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
29	Persis Pest1	12-19	4.0	Serum	10-mL Red	5-mL
89	Persis Pest2	12-19	4.0	Serum	10-mL Red	5-mL
90	Perflour1	12-19	4.0	Serum	10-mL Red	5-mL
92	BFR1	12-19	4.0	Serum	10-mL Red	5-mL
93	BFR2	12-19	4.0	Serum	10-mL Red	5-mL

Exhibit 8-14. Blood processing protocol for primary SPs aged 20+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
119	Genetics	20+	10.0	Whole Blood	10-mL EDTA	10-mL EDTA
120	Genetics	20+	10.0	Whole Blood	10-mL EDTA	10-mL EDTA
54	VOC Blood	20+	10.0	Whole blood	10-mL gray	10-mL Gray
1	Lead/Cad/HG/Se/Mn	20+	0.4	Whole blood	4-mL EDTA	2-mL
3	RBC Folate	20+	0.1	Whole blood	4-mL EDTA	2-mL
4	Glycohem	20+	0.4	Whole blood	4-mL EDTA	2-mL
5	Mercury, Methyl & Ethyl	20+	0.5	Whole blood	4-mL EDTA	2-mL
9	Glucose	20+	0.5	Plasma	2-mL Gray	2-mL
91	Srm Pest	20+	4.0	Plasma	7-mL EDTA	5-mL
98	OGTT	20+	0.5	Plasma	2-mL Gray	2-mL
136	Se/Cu/Zn	20+	1.0	Serum	6 mL Royal Blue	2 mL
70	Vitamin D/PUFA	20+	0.7	Serum	15 and 10-mL Red, 6mL Royal blue	2-mL
14	Hep Profile	20+	1.5	Serum	15 and 10-mL Red, 6mL Royal blue	2-mL
122	HAV	20+	1.5	Serum	15 and 7-mL Red, 6mL Royal blue	2-mL
17	Cotinine	20+	1.8	Serum	15 Red, 6mL Royal blue	2-mL
21	Lipids	20+	1.5	Serum	15 Red, 6mL Royal blue	2-mL
77	HPV Serum	20-59	0.5	Serum	15 Red, 6mL Royal blue	2-mL
18	Biochem	20+	0.8	Serum	15 Red, 6mL Royal blue	2-mL
23	Insulin	20+	1.0	Serum	15 Red, 6mL Royal blue	2-mL
12	Vit B12/MMA	20+	0.7	Serum	15 mL Red, 6mL Royal blue	
22	HIV	20-59	0.8	Serum	15 Red, 6mL Royal blue	2-mL
24	HSV	20-49	0.2	Serum	15 Red, 6mL Royal blue	2-mL
118	Thyroid	20+	1.0	Serum	15 Red, 6mL Royal blue	2-mL

Exhibit 8-14. Blood processing protocol for primary SPs aged 20+ years (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
127	IgA-TTG/EMA	20+	0.5	Serum	15 Red, 6mL Royal blue	2-mL
137	Testosterone	20+	0.5	Serum	15 mL Red, 6mL Royal blue	2 mL
110	Folate1	20+	0.7	Serum	15 Red, 6mL Royal blue	2-mL
34	Xtra Sera3	20+	1.0	Serum	15 Red, 6mL Royal blue	2-mL
35	Xtra Sera4	20+	1.0	Serum	15 Red, 6mL Royal blue	2-mL
36	Xtra Sera5	20+	1.0	Serum	15 Red, 6mL Royal blue	2-mL
37	Xtra Sera6	20+	1.0	Serum	15 Red, 6mL Royal blue	2-mL
29	Persis Pest	20+	4.0	Serum	10-mL Red	5-mL
89	Persis Pest2	20+	4.0	Serum	10-mL Red	5-mL
90	Perflour1	20+	4.0	Serum	10-mL Red	5-mL
92	BFR1	20+	4.0	Serum	10-mL Red	5-mL
93	BFR2	20+	4.0	Serum	10-mL Red	5-mL

Exhibits 8-15 through 8-18 illustrate the blood processing vessels for each VIP guest.

Exhibit 8-15. 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/Se/Mn	1-2	0.4	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	1-2	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury, Methyl & Ethyl	1-2	0.5	Whole blood	3-mL EDTA	2-mL
110	Folate1	1-2	0.7	Serum	3-mL Red	2-mL

Exhibit 8-16. 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/Se/Mn	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, Methyl & Ethyl	3-5	0.5	Whole blood	3-mL EDTA	2-mL
110	Folate1	3-5	0.7	Serum	3-mL Red	2-mL

Exhibit 8-17. 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, Se/Mn	6-11	0.4	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury, Methyl & Ethyl	6-11	0.5	Whole blood	3-mL EDTA	2-mL
21	Lipids	6-11	1.5	Serum	7-mL Red	2-mL
110	Folate1	6-11	0.7	Serum	7-mL Red	2-mL

Exhibit 8-18. 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/Se/Mn	12+	0.4	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	12+	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury, Methyl & Ethyl	12+	0.5	Whole blood	3-mL EDTA	2-mL
9	Glucose	12+	0.5	Plasma	2-mL Grey	2-mL
21	Lipids	12+	1.5	Serum	10-mL Red	2-mL
18	Biochem	12+	0.8	Serum	10-mL Red	2-mL
110	Folate1	12+	0.7	Serum	10-mL Red	2-mL

Exhibit 8-19 illustrates the blood processing vessel for each guest.

Exhibit 8-19. Blood processing protocol for guest 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:

- Rack
- Age-appropriate processing template
- Storage vessels of the following sizes
  - 2.0-mL vessel
  - 5.0-mL vessel
  - 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 may be unique. When possible, prepare the racks at least 1 day before the SP arrives for the MEC examination.

Before each session, the technologist assigned to workstation 1 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 barcode 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 the MEC exam at the appointed date and time, then it is possible that he or she will reschedule;
- Store the SP's labeled vials in the clear bin or cupboard in workstation 1 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**

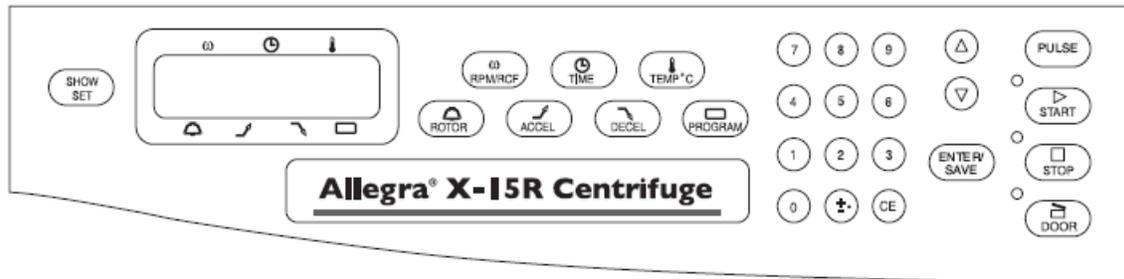
Each laboratory contains two benchtop refrigerated centrifuges.

#### **Allegra X15R**

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.



## Control Panel

The control panel is mounted at an angle on the centrifuge front for easy visibility and access. The control panel has the following features:

## Digital Displays

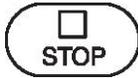
The displays provide run information, user messages, and diagnostics. During a run, they show the actual (real-time) operating conditions.

(SPEED)	Indicates rotor speed in revolutions per minute (rpm)
(TIME)	In a timed run, indicates the remaining run time in hours and minutes.
(TEMPERATURE)	Indicates rotor temperature in degrees C at thermoequilibrium.
(ROTOR)	Displays the name of the selected rotor.
(ACCEL)	When the <b>ACCEL</b> key is pressed, one of ten available acceleration rates can be entered. Displays the selected acceleration rate throughout the run.
(DECEL)	When the <b>DECEL</b> key is pressed, one of eleven available deceleration rates can be entered. Displays the selected deceleration rate throughout the run.
(PROGRAM)	During setup—when the <b>PROGRAM</b> key is pressed, a program number (one of ten possible) can be selected and program parameters entered.

During centrifugation—the number of the program being run is displayed.



Pressing **ENTER/SAVE**, then **START** begins the run. (**START** must be pressed within 5 seconds of pressing **ENTER/SAVE**.) This key combination can also be used to abort a deceleration process and restart the centrifuge.



Can be pressed at any time while the rotor is spinning to terminate a run. The centrifuge decelerates to a complete stop according to the deceleration setting. The green light next to the key flashes while the rotor decelerates.



Unlocks and opens the door. (The instrument will not accept the unlock command if the rotor is spinning.)

### Time

For plasma and serum – set appropriate time and temperature for each tube as follows:

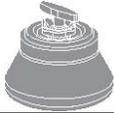
- |   |                                |            |                  |
|---|--------------------------------|------------|------------------|
| - | 3-mL, 4-mL, or 7-mL EDTA       | 10 minutes | 17-25°C or 4-8°C |
| - | 2-mL gray                      | 10 minutes | 17-25°C or 4-8°C |
| - | 3-mL, 7-mL, 10-mL or 15-mL red | 15 minutes | 17-25°C          |
| - | 6 mL royal blue                |            |                  |

### Speed

For plasma and serum – set the speed at 2,900 rpm.

## Run Procedure

### MANUAL RUN

1	POWER	Turn the power switch on (I).
2	<b>DOOR</b>	Press <b>DOOR</b> to open the chamber door; lift the door open.
3		Install the rotor according to the applicable rotor manual, then close the chamber door.
4	<b>ROTOR</b>	Press <b>ROTOR</b> , then press <b>ROTOR</b> again or use the arrow keys to select the rotor.
5	<b>RPM/RCF</b>	Press <b>RPM/RCF</b> , then use the keypad to enter the run speed. Press <b>RPM/RCF</b> a second time to toggle between RPM and RCF modes, RPM/RCF RPM/RCF.
6	<b>TIME</b>	Press <b>TIME</b> , then use the keypad to enter the run time (to 99 hrs, 59 minutes); or press <b>TIME</b> twice to toggle between hold (continuous) run and set time mode.
7	<b>TEMP °C</b>	Press <b>TEMP °C</b> , then use the keypad to enter the required run temperature –10 to +40°C. TEMP °C
8	<b>ACCEL</b>	Press <b>ACCEL</b> , then use the keypad or arrow keys to enter the selected acceleration rate number, 1 (SLOW) through 10 (MAX).
9	<b>DECEL</b>	Press <b>DECEL</b> , then use the keypad or arrow keys to enter the selected deceleration rate number, 0 (OFF) through 10 (MAX).
10	<b>ENTER/SAVE</b> <b>START</b>	Check that all parameters are correct and that the door is closed (door LED will be lit). Press <b>ENTER/SAVE</b> , then press <b>START</b> (within 5 seconds). ENTER/SAVE
11	<b>STOP</b>	Wait for the set time to count down to zero, or end the run by pressing <b>STOP</b> .
12	<b>DOOR</b>	When the rotor stops (a tone sounds and the <b>DOOR</b> LED lights), press <b>DOOR</b> to open the chamber door; lift the door.

## PROGRAMMED RUN

1	POWER	Turn the power switch on (I).
2	(DOOR)	Press (DOOR) to open the chamber door.
3		Install the rotor according to the applicable rotor manual, then close the chamber door.
4	(PROGRAM)	Press (PROGRAM), use the keypad or arrow keys to enter the required program number, then press (ENTER/SAVE).
5	(ENTER/SAVE) (START)	Check that all parameters are correct and that the door is closed (door LED will be lit). Press (ENTER/SAVE), then press (START) (within 5 seconds).
6	(STOP)	Wait for the run to end, or end the run by pressing (STOP).
7	(DOOR)	When the rotor stops (a tone sounds and the (DOOR) LED lights), press (DOOR) to open the chamber door; lift the door.

Maintenance: Use the Beckman Coulter Guide

Instead of using the paint-on graphite which is described in the maintenance section, use the triflow lubricant and use the same maintenance procedure as the old Beckman GS 6R centrifuges.

End of Stand Centrifuge Procedure:

Remove rotors from the Allegra x-15R centrifuges and pack in the black totes with the green foam for safe traveling. The balance detection mechanism is very sensitive during travel and needs to be protected. See photos for proper packing.







### 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 magnehelic 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 disinfectant (Sani-wipe.).
- 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 percent 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 percent 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 50-1,000 $\mu$ L, and one 100-5,000 $\mu$ L. The lab also uses 100  $\mu$ L and 1,000  $\mu$ 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 RBC Folate - vessel 3. Use this pipette to aliquot 50  $\mu$ l the ascorbic acid (7% solution) for Folate 1 (vessel 110)
- Use one of the two 50-1,000  $\mu$ L pipettes in the standard (PIP) mode and set the volume to 1,000 $\mu$ L. Use this dedicated pipette to aliquot the 1% ascorbic acid solution for RBC Folate - vessel 3.
- Use the second 50-1,000  $\mu$ 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 1,000  $\mu$ L. Use this pipette to aliquot all whole blood tests, except RBC Folate - vessel 3 and pooled serum volumes that match the five volume settings.
- Use the second 50-1,000  $\mu$ L pipette and the 100-5,000  $\mu$ L pipette in the DIS mode. Set the DIS volume on the 50-1,000  $\mu$ L to 100  $\mu$ L. Set the DIS volume on the 100-5,000  $\mu$ L to 500  $\mu$ L. Use these pipettes to aliquot pooled serum.
- Use the 100-5,000  $\mu$ L pipette in the FIX mode. Set the five fixed volumes to 1,000  $\mu$ L, 2,000  $\mu$ L, 3,000 $\mu$ L, 4,000  $\mu$ L, and 5,000  $\mu$ L. Use this pipette to aliquot pooled serum volumes that match the five volume settings.
- Use the 100-5,000  $\mu$ L pipette in the ADS mode. Program this mode in slot 2. Set the volume to 500  $\mu$ L and the interval to 1 second. Use this pipette to aliquot pooled serum.
- Use the 100-5,000  $\mu$ L 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 70-24. Set program 3 to match the child's profile ages 1-2. Set program 4 to match the child's profile ages 3-5. Set program 5 to match the child's profile ages 6-11. Use this pipette to aliquot pooled serum.

Pipette	Tip	Mode	Volume	Matrix
<i>*5-100 <math>\mu\text{L}</math></i>	<i>200 <math>\mu\text{L}</math></i>	<i>PIP</i>	<i>100 <math>\mu\text{L}</math></i>	<i>Whole blood &amp; 7% Ascorbic Acid</i>
<i>*50-1,000 <math>\mu\text{L}</math></i>	<i>1,000 <math>\mu\text{L}</math></i>	<i>PIP</i>	<i>1,000 <math>\mu\text{L}</math></i>	<i>1% Ascorbic acid</i>
<i>50-1,000 <math>\mu\text{L}</math></i>	<i>1,000 <math>\mu\text{L}</math></i>	<i>FIX</i>	<i>300 <math>\mu\text{L}</math> 400 <math>\mu\text{L}</math> 500 <math>\mu\text{L}</math> 600 <math>\mu\text{L}</math> 1,000 <math>\mu\text{L}</math></i>	<i>Whole blood Pooled serum</i>
<i>50-1,000 <math>\mu\text{L}</math></i>	<i>1,000 <math>\mu\text{L}</math></i>	<i>DIS</i>	<i>100 <math>\mu\text{L}</math></i>	<i>Whole blood Pooled serum</i>
<i>100-5,000 <math>\mu\text{L}</math></i>	<i>5,000 <math>\mu\text{L}</math></i>	<i>FIX</i>	<i>1,000 <math>\mu\text{L}</math> 2,000 <math>\mu\text{L}</math> 3,000 <math>\mu\text{L}</math> 4,000 <math>\mu\text{L}</math> 5,000 <math>\mu\text{L}</math></i>	<i>Pooled serum</i>
<i>100-5,000 <math>\mu\text{L}</math></i>	<i>5,000 <math>\mu\text{L}</math></i>	<i>DIS</i>	<i>500 <math>\mu\text{L}</math></i>	<i>Pooled serum</i>
<i>100-5,000 <math>\mu\text{L}</math></i>	<i>5,000 <math>\mu\text{L}</math></i>	<i>ADS</i>	<i>500 <math>\mu\text{L}</math> 1 second</i>	<i>Pooled serum</i>
<i>100-5,000 <math>\mu\text{L}</math></i>	<i>5,000 <math>\mu\text{L}</math></i>	<i>SD</i>	<i>Program 1 – 12+ 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 and folate 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 will 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 will 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 percent 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.
- Only authorized service personnel may carry out repairs.
- 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 $\mu\text{L}$	$\pm 0.8$	$\leq 0.2$
50-1,000	1	Blue	1,000 $\mu\text{L}$	1,000 $\mu\text{L}$	$\pm 0.6$	$\leq 0.2$
100-5,000	10	Violet	5-mL	500 $\mu\text{L}$ 5,000 $\mu\text{L}$	$\pm 3.0$ $\pm 0.6$	$\leq 0.6$ $\leq 0.15$

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; and
- 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.

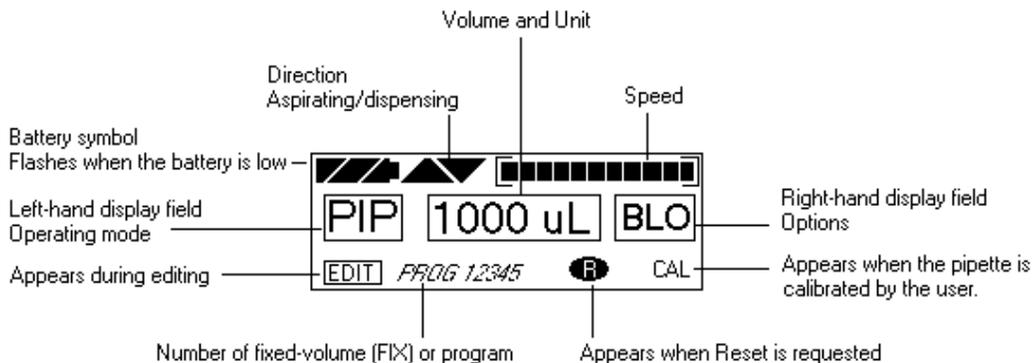
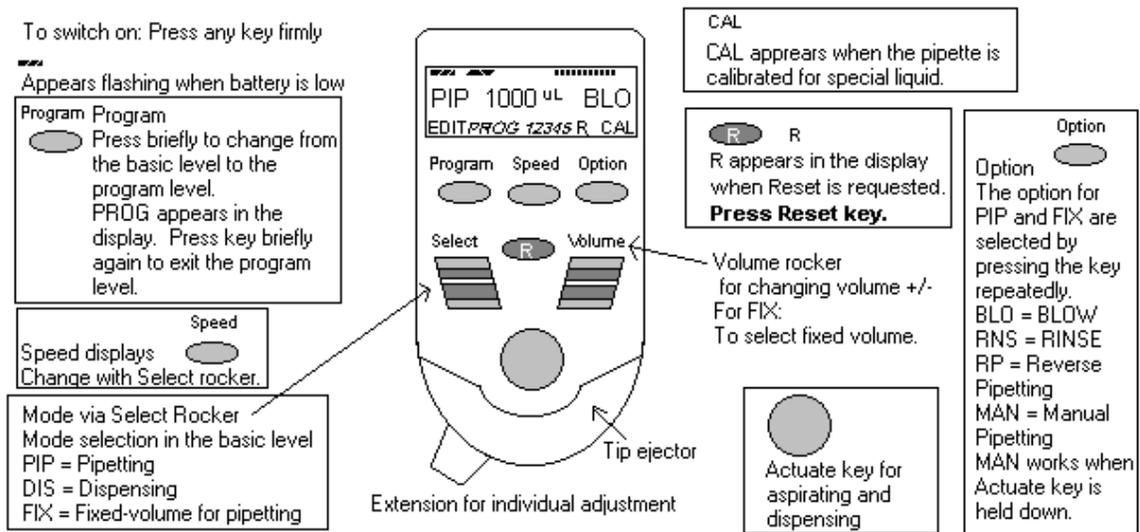
During the start and termination of the charging process, “CON” appears briefly on the left side of the display. The display is switched on during the charging process. The battery symbol appears in a rolling form. During charging, the dispensing function is frozen. When the charging process has finished, 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 remain stored.

### 8.7.1.3 Operating Principle

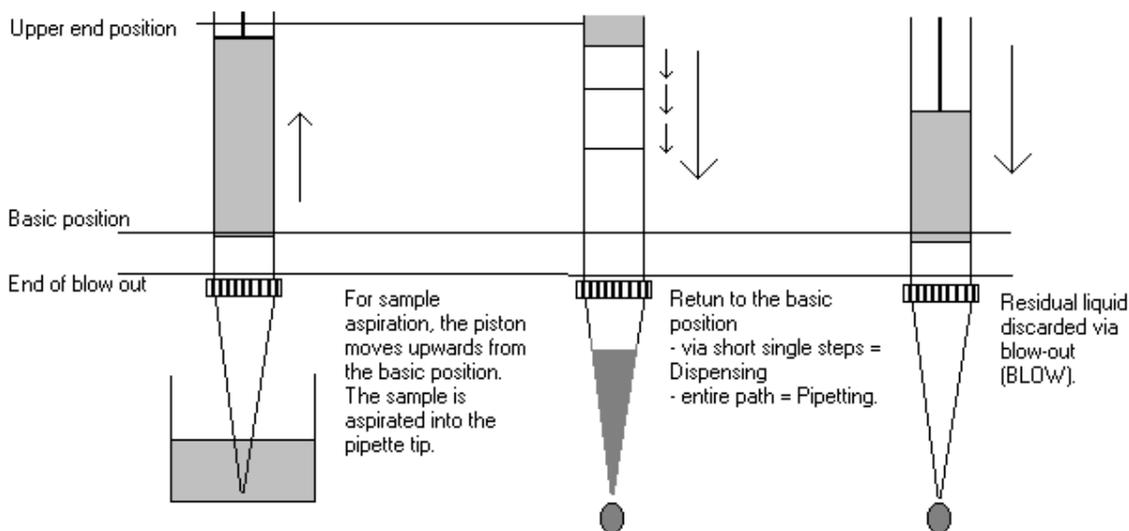
#### Display and Keypad

- 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 Head 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.



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.



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.



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 operation.
- 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 µL pipette] and ascorbic acid [50-1,000 µL 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 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-µL pipette and 1,000 µL for the 50-1,000-µL pipette is reached. If necessary, press the Option key several times until the right 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 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 1,000  $\mu\text{L}$  and for 400  $\mu\text{L}$  MPA – 50-1,000  $\mu\text{L}$  pipette, and for pipetting pooled serum volumes 1,000, 2,000, 3,000, 4000, and 5,000  $\mu\text{L}$  – 100-5,000  $\mu\text{L}$ .)*

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 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 5-1,000- $\mu\text{L}$ pipette or 1,000 $\mu\text{L}$ for the 100-5,000 $\mu\text{L}$ 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 5-1,000- $\mu\text{L}$ pipette or 2,000 $\mu\text{L}$ for the 100-5,000 $\mu\text{L}$ 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 5-1,000- $\mu\text{L}$ pipette or 3,000 $\mu\text{L}$ for the 100-5,000 $\mu\text{L}$ 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 5-1,000- $\mu\text{L}$ pipette or 4000 $\mu\text{L}$ for the 100-5,000 $\mu\text{L}$ 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) 1,000 $\mu\text{L}$ for the 5-1,000- $\mu\text{L}$ pipette or 5,000 $\mu\text{L}$ for the 100-5,000 $\mu\text{L}$ 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 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 – 50-1,000  $\mu$ L pipette and 500  $\mu$ L pooled serum 100-5,000  $\mu$ 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 on the right 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 1,000  $\mu$ L then there are 10 dispensing steps. If the dispensing volume is set at 500  $\mu$ L and the pipette tip is 5,000  $\mu$ 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 50-1,000- $\mu$ L pipette or 500 $\mu$ L for the 100-5,000 $\mu$ 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 into the liquid and press the Actuate key to draw the liquid into the pipette tip. (If <b>R</b> 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 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 on the left 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 are 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 backward and forward 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 – 100-5,000 $\mu$ 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 1,000 is displayed. Press the Actuate key to store the volume for step 1.

Step 7	Continue 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”
Pipetting Procedure	
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 1,000 $\mu$ L.
Step 2	Dispense the serum. Make sure 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 1,000 $\mu$ L aliquot. The dispensing step counter (number) on the right 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 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 – 100-5,000 $\mu$ 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, and 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 on the right 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.
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”

Pipetting Procedure	
Step 1	Aspirate the serum. Make sure the aspirating arrow is pointed upward. Press the Actuate key once. The pipette will aspirate 5,000 $\mu\text{L}$ .
Step 2	Dispense the serum. Make sure 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 $\mu\text{L}$ aliquot, or to automatically pipette sequential 500 $\mu\text{L}$ aliquots, <u>hold the actuate key down</u> . The dispensing step counter (number) on the right 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 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 filter tips 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 a 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 percent 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, 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 *Eppendorf Research Pro Instruction Manual*.

## Ordering Information

Item	Size	Part number
Eppendorf Research pro	5-100 $\mu\text{L}$	2246-136-2
Eppendorf Research pro	50-1,000 $\mu\text{L}$	2246-138-9
Eppendorf Research pro	100-5,000 $\mu\text{L}$	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 $\mu\text{L}$	2249-002-8
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips	1,000 $\mu\text{L}$	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 50-1,000  $\mu\text{L}$  Eppendorf Research pro pipettes and trace metal free pipette tips to aliquot whole blood and perform the dilution for RBC Folate - vessel 3 and RBC Foll - vessel 106 using 1.0- $\mu\text{L}$  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, 4-mL and 7-mL EDTA Tubes**

The EDTA (tripotassium salts of ethylene diamine-tetracetic acid) acts as a chelating agent to combine with calcium in the blood to prevent coagulation. Use the well-mixed lavender 3-mL and 4-mL EDTA tubes for the hematology profile (CBC) and certain whole blood tests. Use the dedicated 7-mL EDTA tube as the source tube for the plasma for vessel 91 - SRM Pesticide. Use the two 10-mL EDTA tubes for genetic testing – vessels 119 and 120.

### **8.7.2.1 Process the 3-mL or 4-mL EDTA Tube for Lead/Cad/HG/Se/Mn, RBC Folate, Glycohem, and Mercury**

The hematology technologist runs the CBC on the room temperature 3-mL (age 1-11) or 4 mL (age 12+) EDTA tube after the blood-processing technologist verifies proper identification and labeling, and processes the tube for the Lead/Cad/HG/Se/Mn, RBC Folate, Glycohem, and Mercury. If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad/HG/Se/Mn), vessel 3 (RBC Folate), vessel 4 (Glycohem), or vessel 5 (Mercury). If the CBC was accidentally run before the whole blood for vessels 1 (Lead/Cad/HG/Se/Mn) and 5 (Mercury) was pipetted, do not process these two vessels and add the comment “laboratory error” to vessel 1 and vessel 5.

Complete the following process for all SPs. Use the following tubes for the CBC and whole blood protocol:

1. Ages 1-2
  - a. Process the 3-mL EDTA tube for CBC and all whole blood tests.
2. Ages 3-5
  - a. Process the first 3-mL EDTA tube for CBC and all whole blood tests.
3. Ages 6-11
  - a. Process the 3-mL EDTA tube for the CBC and all whole blood tests.

4. Ages 12-19
    - a. Process one of the 4-mL EDTA tubes for the CBC and all whole blood tests.
  5. Ages 20+
    - a. Process the first 4-mL EDTA tube for the CBC and all whole blood tests.
- The blood-processing technologist initially processes the 3- or 4-mL EDTA tube for the whole blood tests.
    - Invert the appropriate EDTA tube several times to remix contents thoroughly.
    - Pre-wet pipette tip.
    - Refrigerate L-ascorbic acid diluent when not in use. Discard unused diluent at end of each session.

#### **Vessel 1**

- Use trace metal free pipette tips and the 50-1,000 $\mu$ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 1 (Lead/Cad/HG) on primary SPs and VIP guests aged 1+ 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 SPs and VIP guests aged 1+ into a 2-mL vessel.
- Pre-wet the pipette tips. Dilute the whole blood with ascorbic acid. Use trace metal free pipette tips and the dedicated 50-1,000 $\mu$ L Eppendorf pipette to immediately pipette 1.0-mL of the 1% ascorbic acid into the 2-mL vessel. Mix well.

#### **Vessel 4**

- Use trace metal free pipette tips and the 50-1,000 $\mu$ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 4 (Glycohem) on primary SPs aged 12+ into a 2-mL vessel.

#### **Vessel 5**

- Use trace metal free pipette tips and the 50-1,000 $\mu$ L Eppendorf pipette to aliquot 0.5-mL whole blood for vessel 5 (Mercury) on primary SPs and VIP guests aged 1+ 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 3 or 4-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 7-mL EDTA Tube for SRM Pesticide**

Centrifuge and separate the plasma from the 7-mL EDTA tube as soon as possible. Process the specimen even if the contents of the EDTA 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 7-mL EDTA tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 91 (SRM Pesticide.)

#### **Vessel 91**

- Pre-wet pipette tip.
- Use a calibrated plastic transfer pipette to aliquot all the plasma for vessel 91 (SRM Pesticide) on selected primary SPs aged 12+ into a 5-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.
- 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.

### **8.7.2.3 Process the 10-mL EDTA Tubes for Genetics**

- Mix blood tubes 119 and 120 well.
- Check to ensure that the tubes are securely closed.

- 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 and OGTT**

Centrifuge and separate the plasma from the 2-mL gray top tube within 30 minutes from the time the blood was collected. Process the specimen even if the contents of the gray tube are clotted.

- 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) or vessel 98 (OGTT.)

#### **Vessel 9 or 98**

- Pre-wet pipette tip.
- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 9 (Glucose) or vessel 98 (OGTT) on primary SPs 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 and 6 mL Royal Blue 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 and 6mL Royal Blue 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 and royal blue 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.

- **Vessel 136**
  - Use serum separator to remove serum from the 6 mL royal blue top tube by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard.
  - Use trace metal free pipette tips to aliquot 1.0 mL from the royal blue top tube, into a 2mL sterile cryovial, prior to pooling the serum with the red top tubes. Do not substitute any other tube for this vessel. The 6 mL royal blue top is prescreened by the CDC for these tests.
- **Vessels 138, 70, 14, 122, 87, 17, 21, 77, 18, 23, 12, 22, 24, 118, 127, 137, and 32-37.**
  - 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 the 100-5,000 Eppendorf® pipette and 5-mL pipette tips to aliquot the serum for all vessels.

- 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 138, until the serum is exhausted.

#### **Vessel 110**

- Use trace metal free pipette tips and the dedicated 100-5,000 $\mu$ L Eppendorf pipette to pipette 0.7-mL serum for vessel 110 (Folate 1) on primary SPs and VIP guests aged 1+ into a 2-mL vessel. Pre-wet the pipette tips. Dilute the serum with 50  $\mu$ L of the 7% ascorbic acid, using trace metal free pipette tips and the dedicated 50-1,000 $\mu$ L Eppendorf pipette. Mix well.
- 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 subsamples represent a 1/3 subsample of SPs aged 12+. SPs in the 1, 2, 5, 11 subsample group are eligible for vessels 29, 89,90,92 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, 89, 90, 92 and 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 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 89 (Persis Pest2), vessel 90 (Perfluor1), vessel 92 (BFR1) and vessel 93 (BFR2) on primary SPs aged 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 percent ascorbic acid (AA) for vessel 3 (RBC Folate), and a premeasured 7 percent AA solution for vessel 110 (Folate1). Prepare both reagents 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 of 1% ascorbic acid to 0.1-mL whole blood for vessel 3 (RBC Folate) and 0.05 mL of the 7% AA to vessel 110. Mix by gentle inversion.

- The 1% ascorbic acid powder is in a 50-mL Falcon tube. Dissolve the powder in 30-mL of dionizedwater using a graduated cylinder to measure the water and mix gently. Prepare this reagent **daily**. 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 Daily QC Log each time it is prepared. Record Lot # in the Supply Use Control Log.
- The 7% AA powder is in a 2-mL Nalgene cryovial. Dissolve the powder in 2 mL of dionized water using a graduated cylinder to measure the water and mix gently. Prepare this reagent **daily**. Date and label the Nalgene 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 Daily QC Log each time it is prepared. Record Lot # in the Supply Use Control Log.

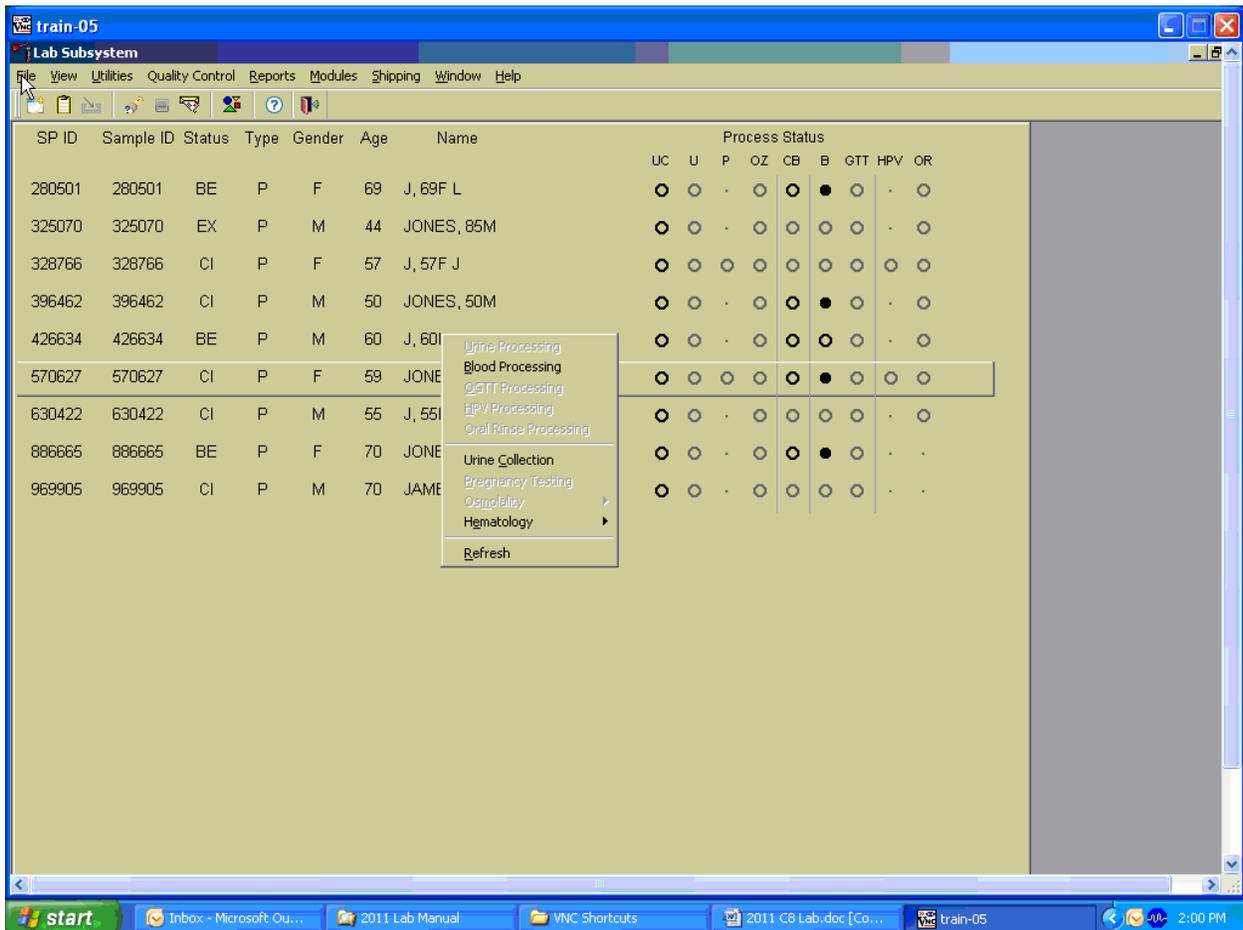
- Discard both the 1% and 7% AA prepared reagents at the end of each day and make fresh vials at the start of the next session.

## 8.8 Record the Results of Specimen Processing

After filling or processing the whole blood, plasma, serum, and/or the EDTA or gray top tubes for each SP, use the Blood Processing module to enter the blood processing results.

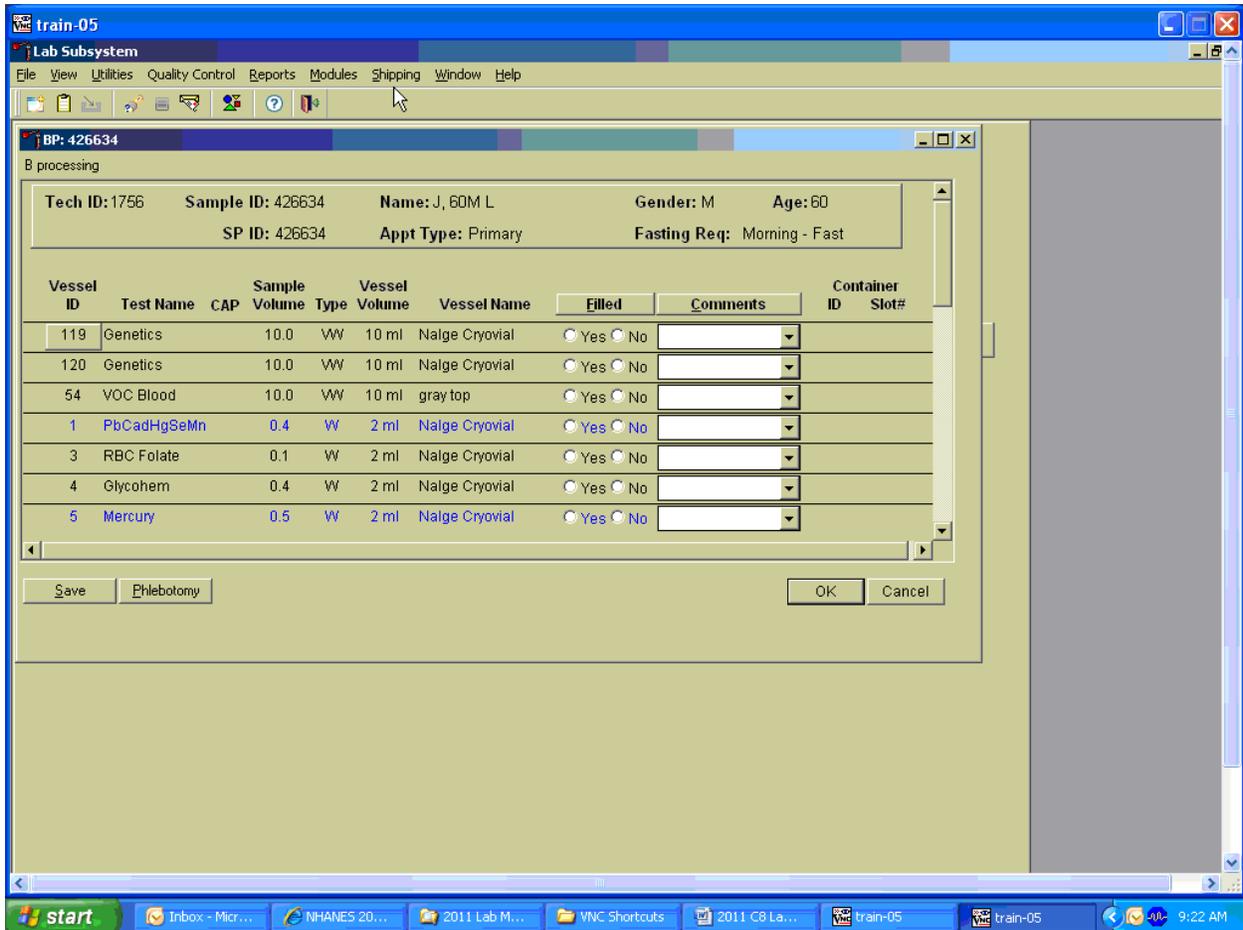
Open and log onto the Laboratory application. Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status.

Select the correct SP and access the Blood Processing module.



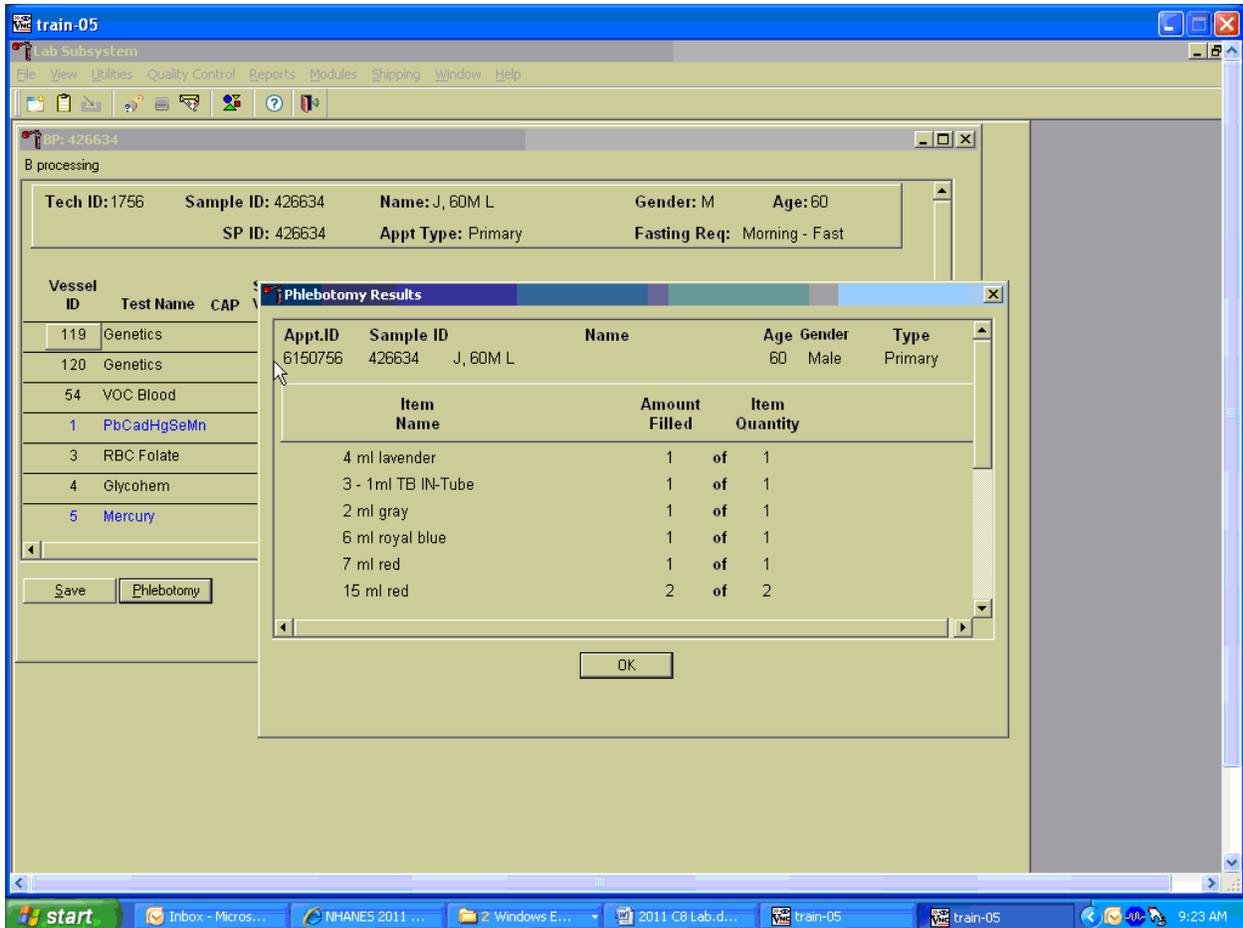
If labels have not been printed in advance the SPs will show up in a red font on the heads up display.. To access the blood processing module, highlight the SP, right click, drag the mouse arrow to {Blood Processing}, and left click or type [Alt] [B/b].

The SP's blood processing screen displays.



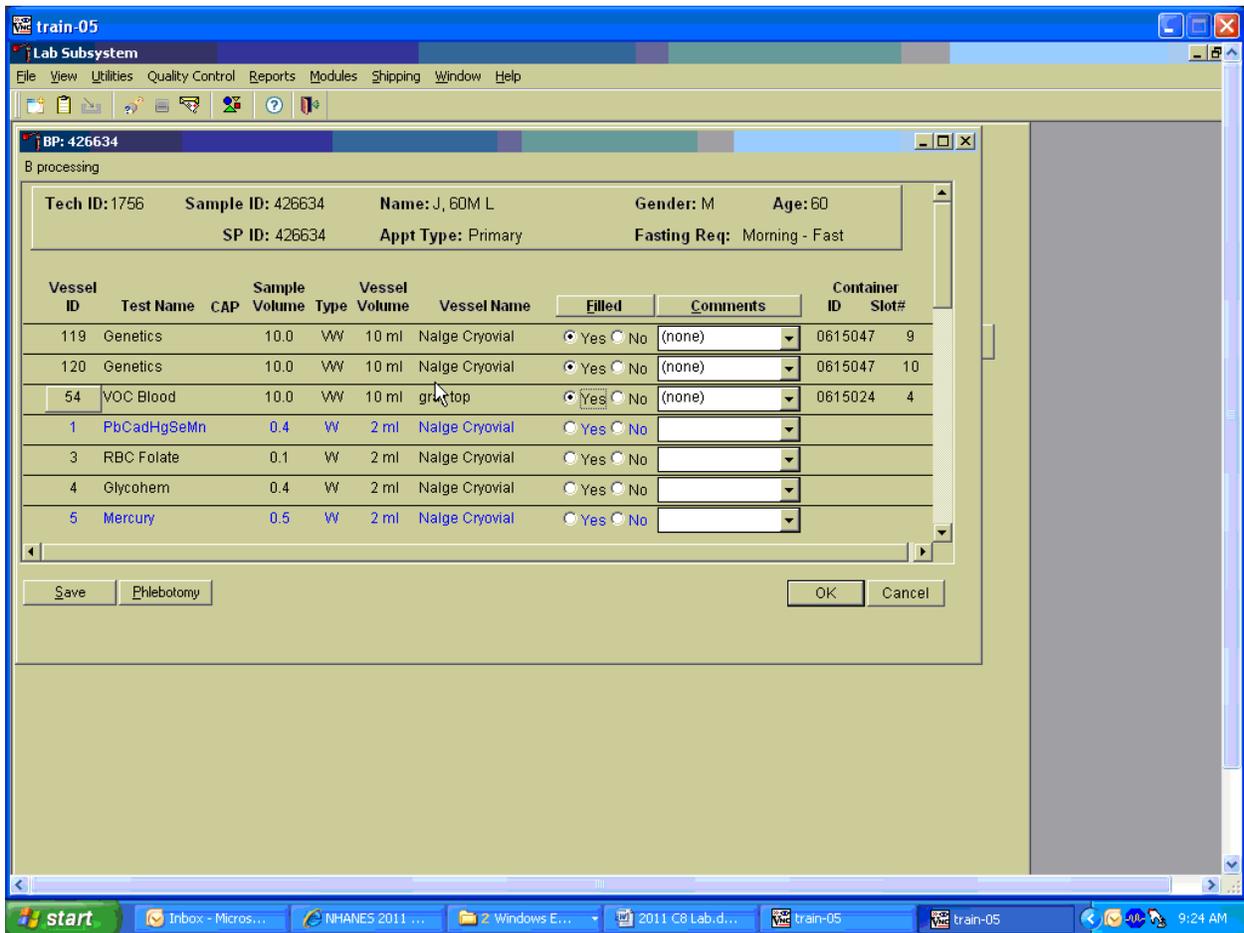
The blood processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, Fasting Req, columns for Vessel ID, Test Name, Sample Volume, Type (whole blood, plasma, serum), Vessel Volume, Vessel Name, Filled radio buttons, Comments text box, and a Container ID/Slot# column. Vessels that require sterile 2-mL cryovials are displayed in blue.

Inspect the SPs Vacutainer® tubes. Compare the Sample ID on the tubes to the barcode label on the vessels. Verify that the number of tubes and the recorded amount of blood collected are correct.



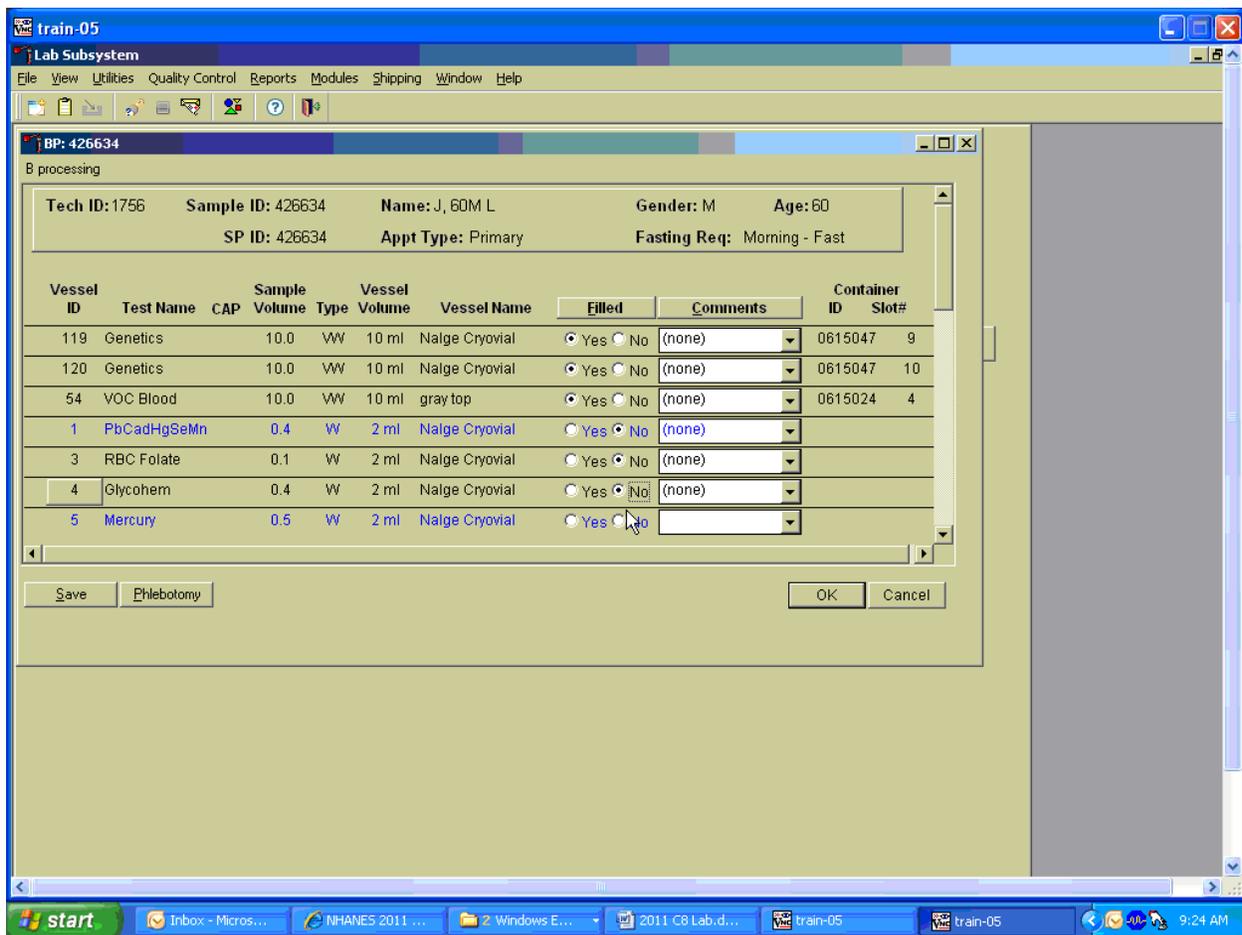
To review the phlebotomy results, use the mouse to direct the mouse arrow to the “Phlebotomy” button on the blood processing screen and left click or type [Shift] [P/p.] The phlebotomy protocol and number of tubes successfully collected displays. To close this screen, use the mouse to direct the mouse arrow to the “OK” button and left click.

Record blood processing results for each SP. Individually mark each vessel as Filled–”Yes.”



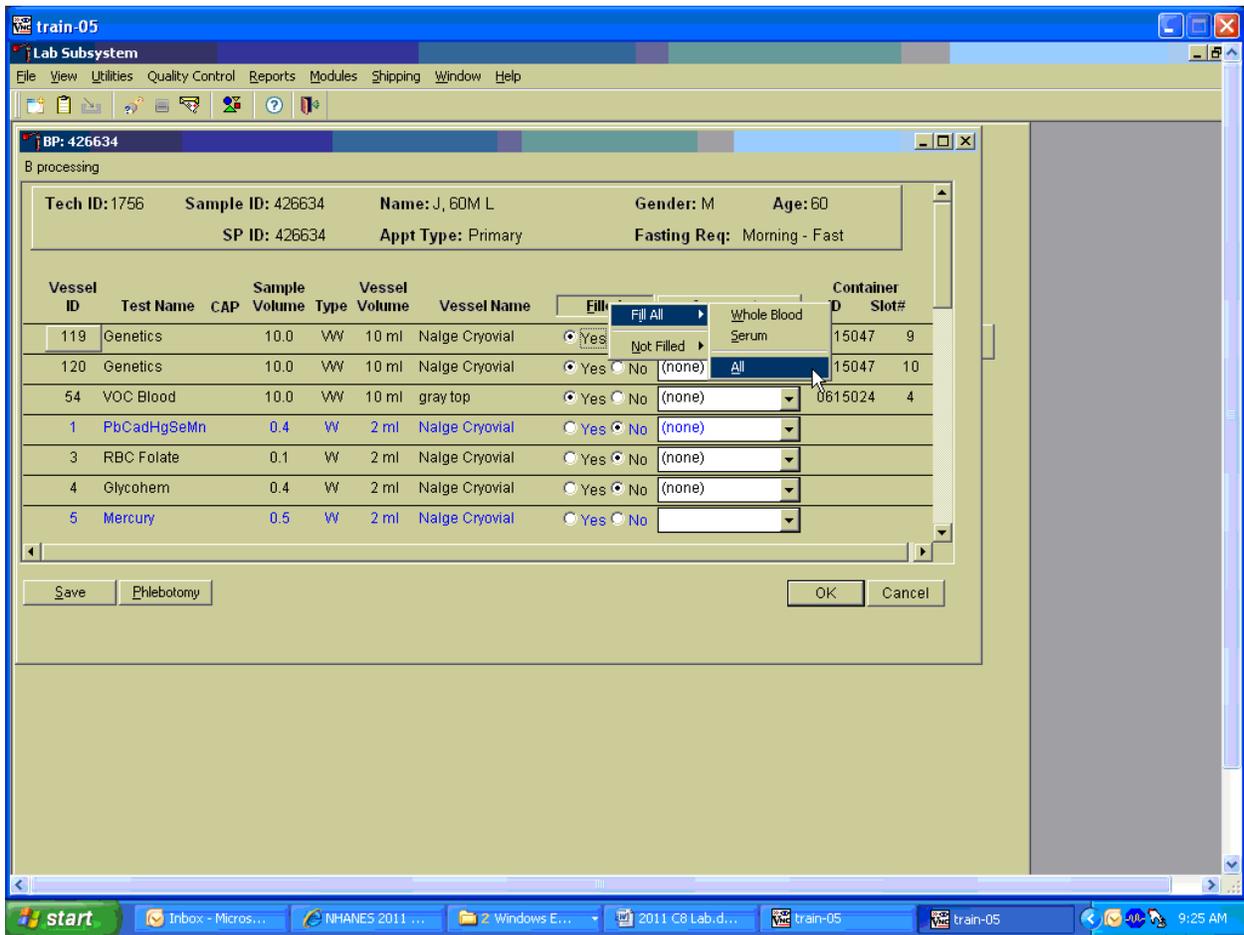
To mark an individual blood vessel as collected or Filled—”Yes” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As each vessel is marked as Filled—”Yes,” it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled—”No.”



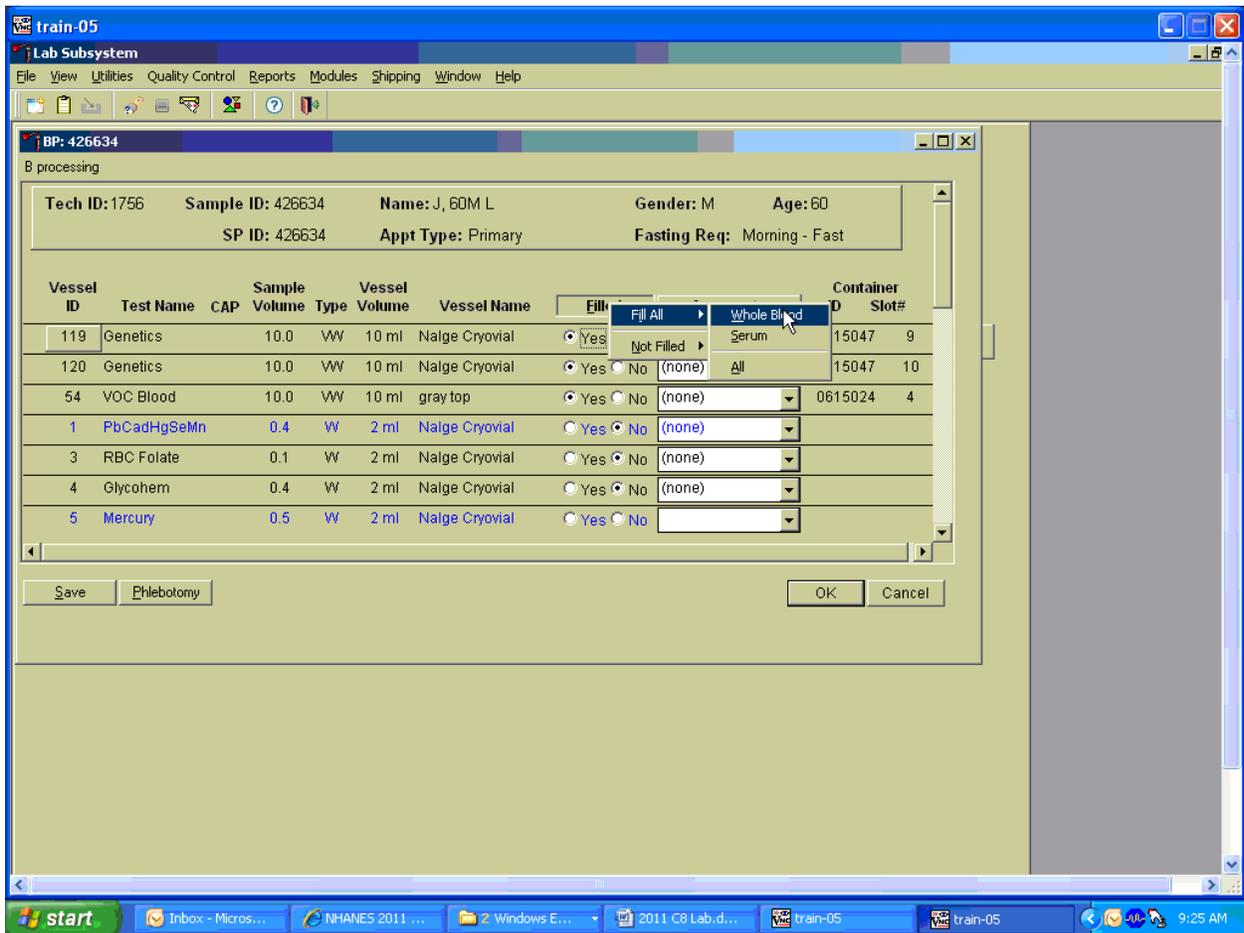
To mark an individual blood vessel as not collected or Filled—"No," use the mouse to direct the mouse arrow to the center of the "No" radio button and left click. Vessels marked as "No" require a comment.

Collectively mark all vessels as Filled—"Yes."



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. Alternatively, to collectively mark all vessels as Filled—"Yes," type [Shift] [F/f], [I/i], and [A/a.]

Selectively mark all whole blood or serum vessels as Filled—"Yes."

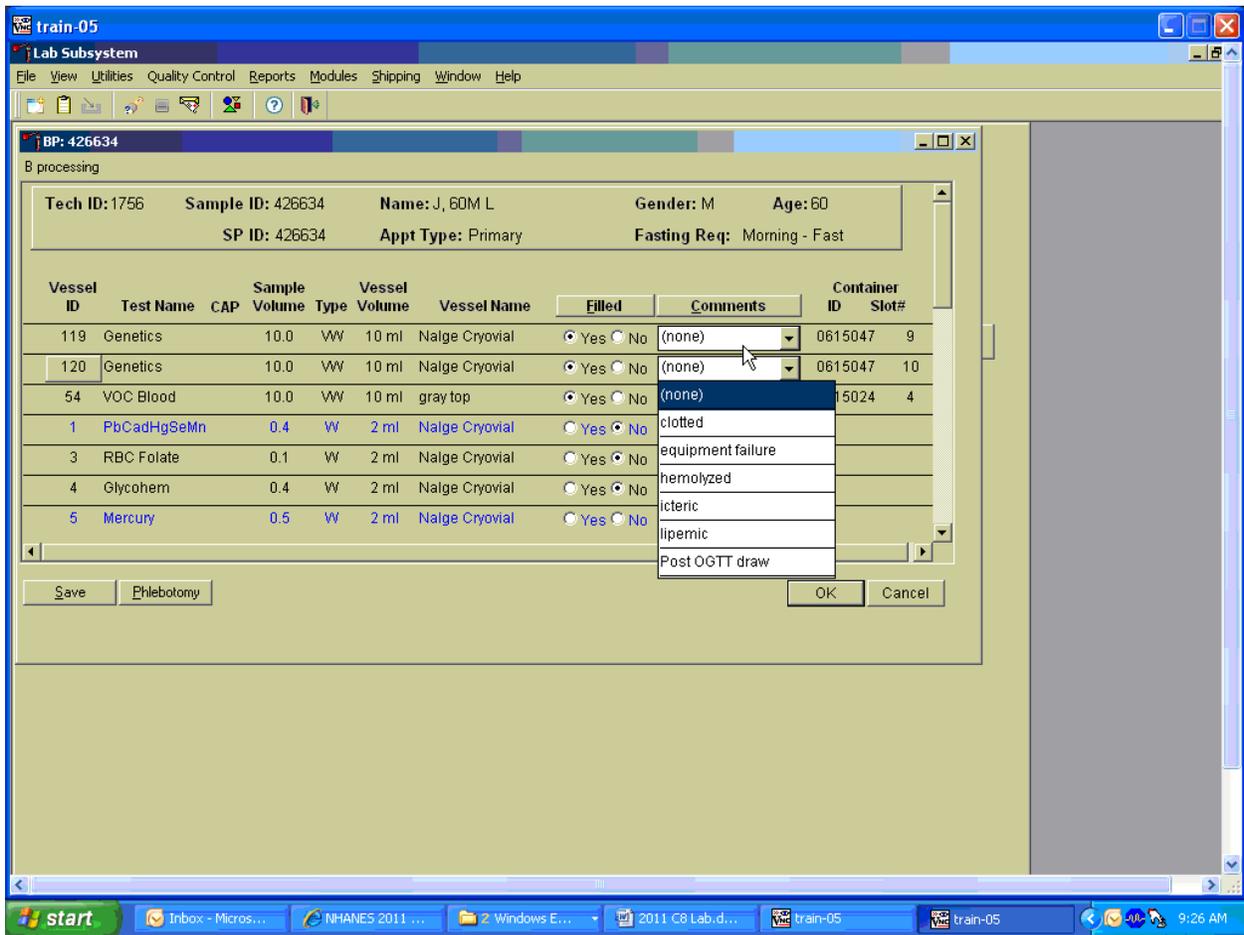


To collectively mark all whole blood vessels as Filled–“Yes,” use the mouse to direct the mouse arrow to the “Filled” button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {Whole Blood}, and left click. To collectively mark all serum vessels as Filled–“Yes,”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

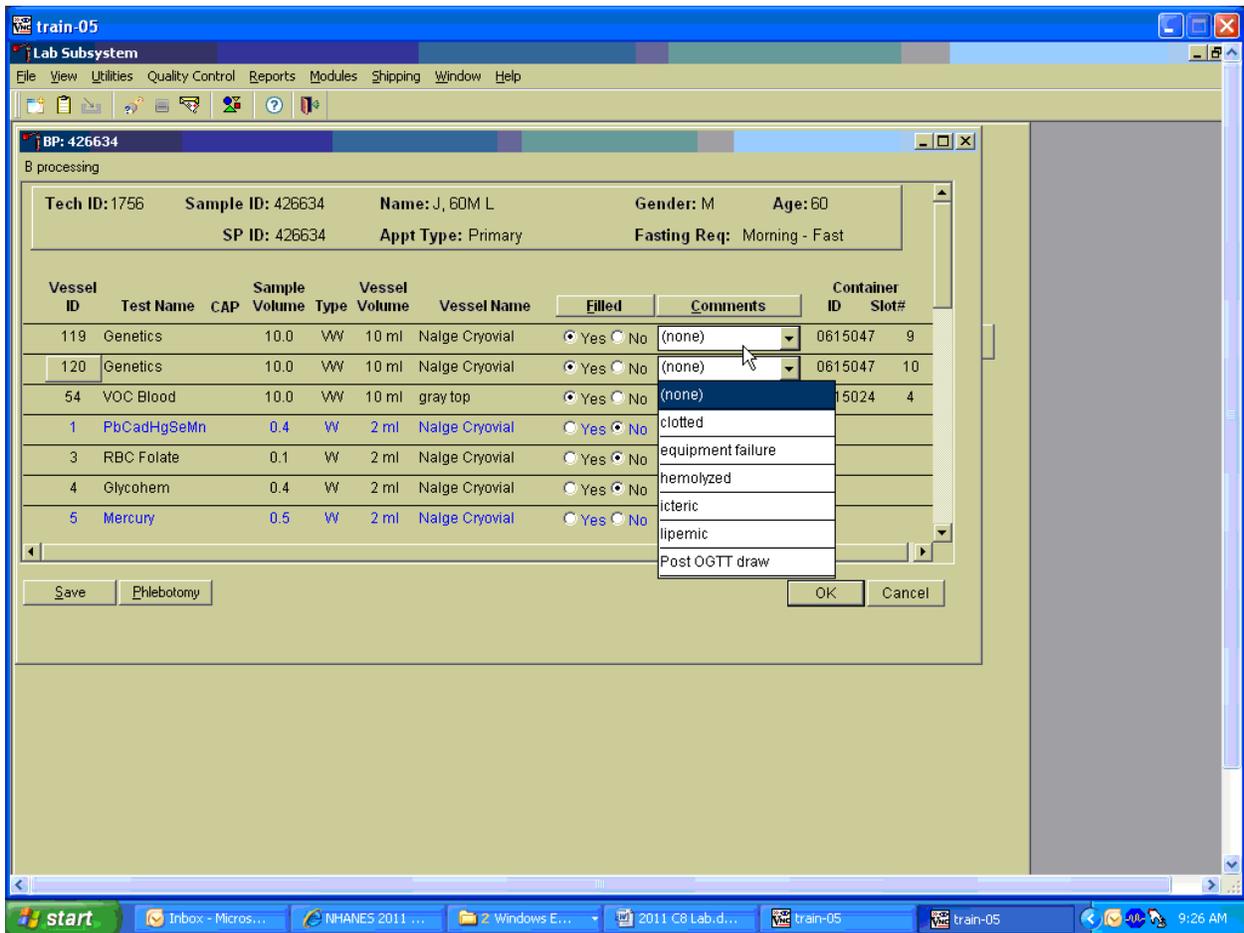
Comment for filled vessels	Use when:
Clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
Equipment failure	Pipettes are malfunctioning.
Hemolyzed	There is red appearance to the serum or plasma. Hemolysis refers to the abnormal lysis of 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 mg/L.
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 umol/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 mmol/L.
Post OGTT draw	During the OGTT blood draw (2 hours after the initial venipuncture and after the SP has consumed the Trutol), the phlebotomist will draw any tubes that were missed during the first venipuncture. If any vessel is filled from one of the tubes drawn during the OGTT blood draw, then add this comment.

Attach a comment to an individual filled vessel.



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 (c, e, h, i, l, p.)

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, p.)

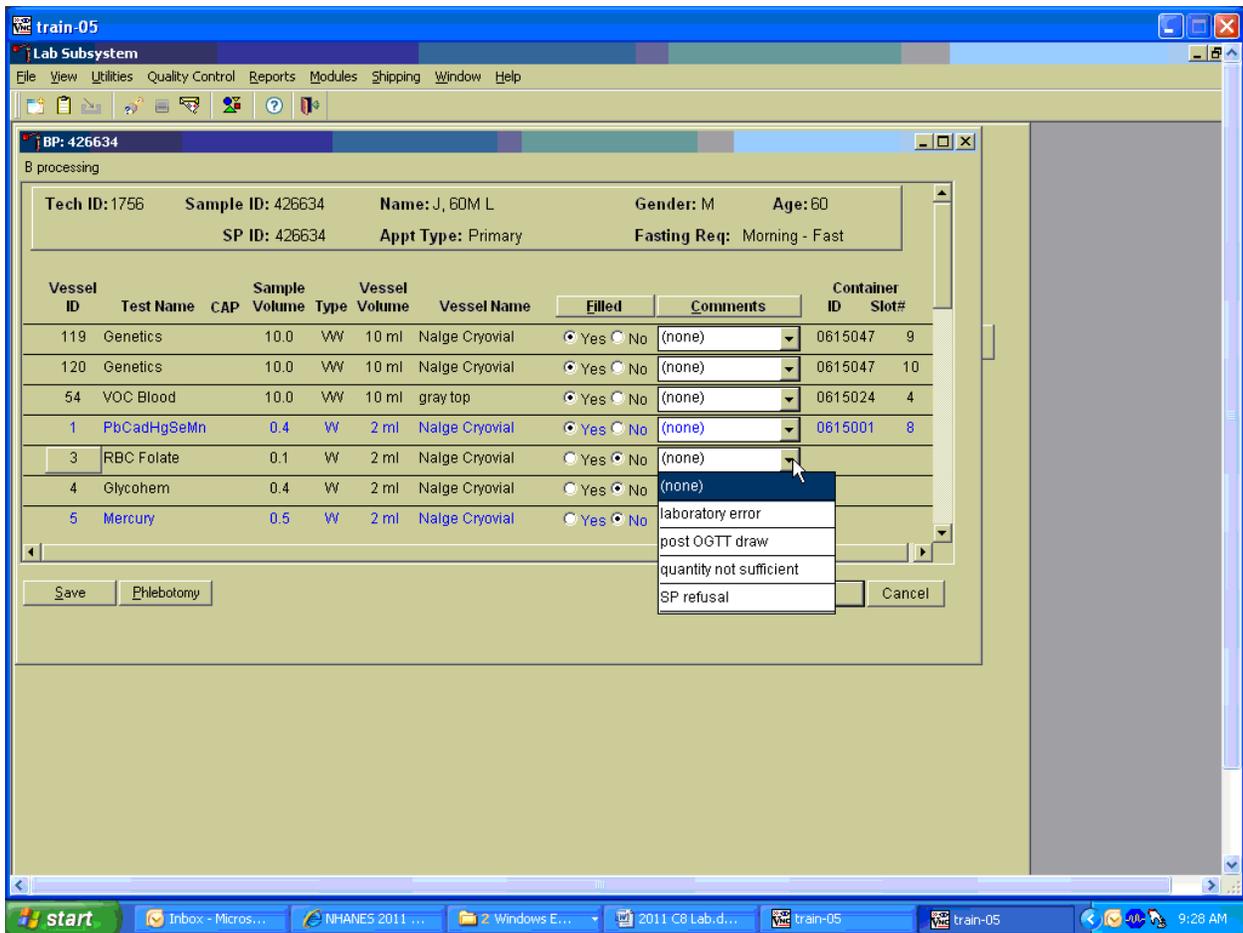
All blood tubes (vessels 119/120/54) must be marked individually.

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.

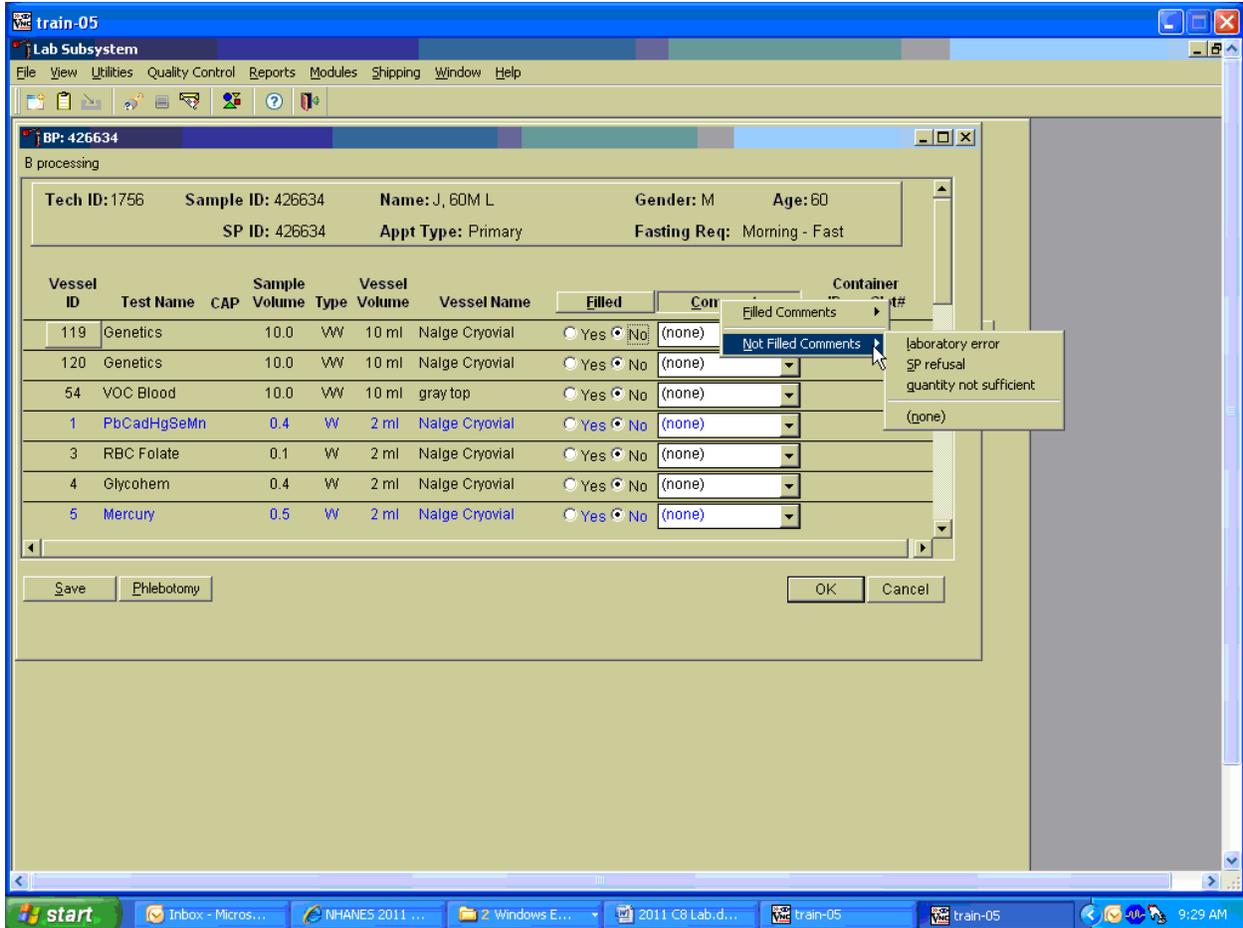
Comment for not filled vessels	Use when:
Laboratory error	A tube breaks in the centrifuge, contents spill, or other technologist error.
Quantity not sufficient	Quantity of blood is not sufficient to complete the protocol.
SP refusal	The SP does not provide consent and consequently, excluded from HIV.

Attach a comment to an individual Filled–“No” vessel.



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.

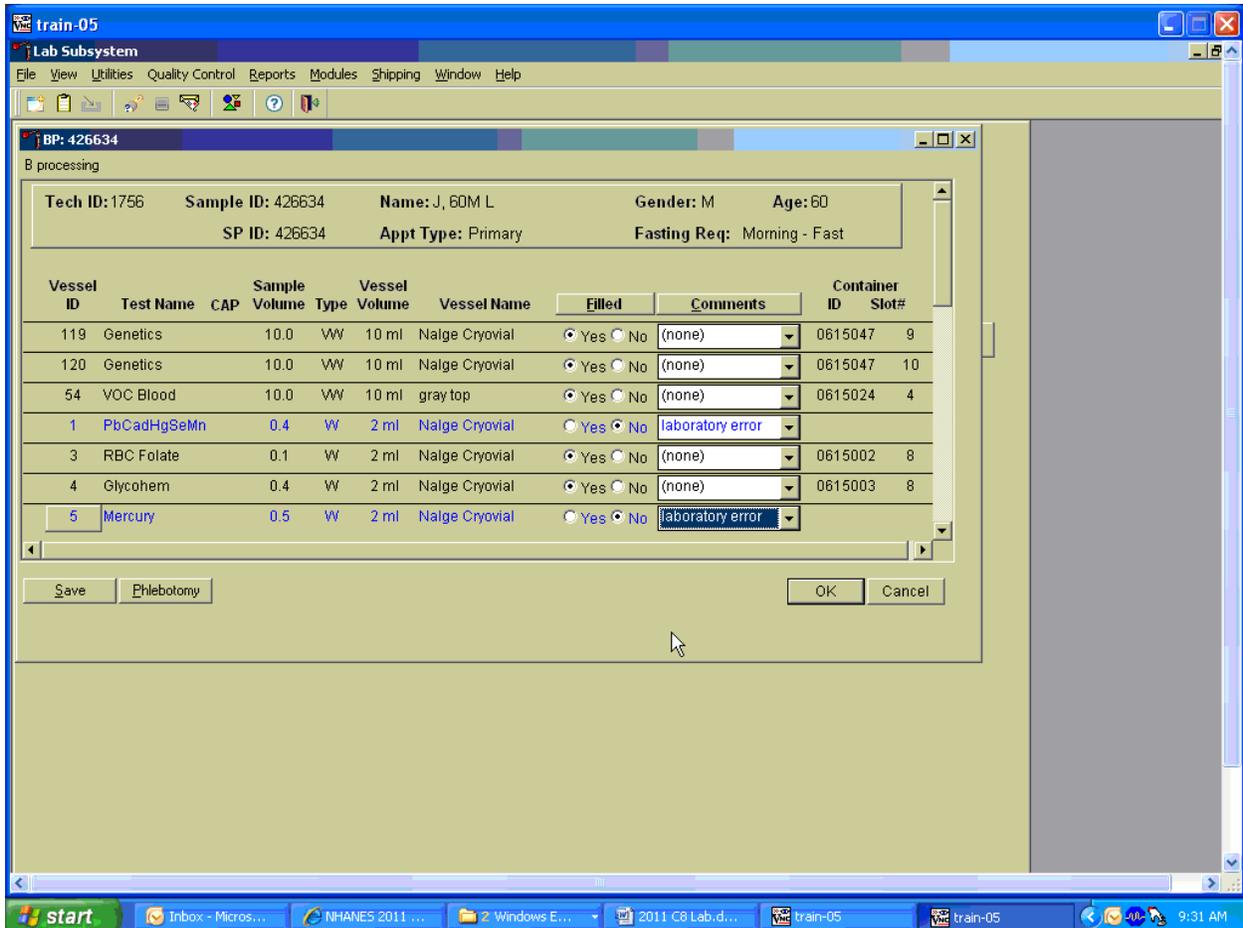
Use the following procedure when all Filled – “No” vessels require the same comment.



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] [L/l], [N/n], and the first letter of the desired choice (l=laboratory error, s= SP refusal, q=quantity not sufficient.).

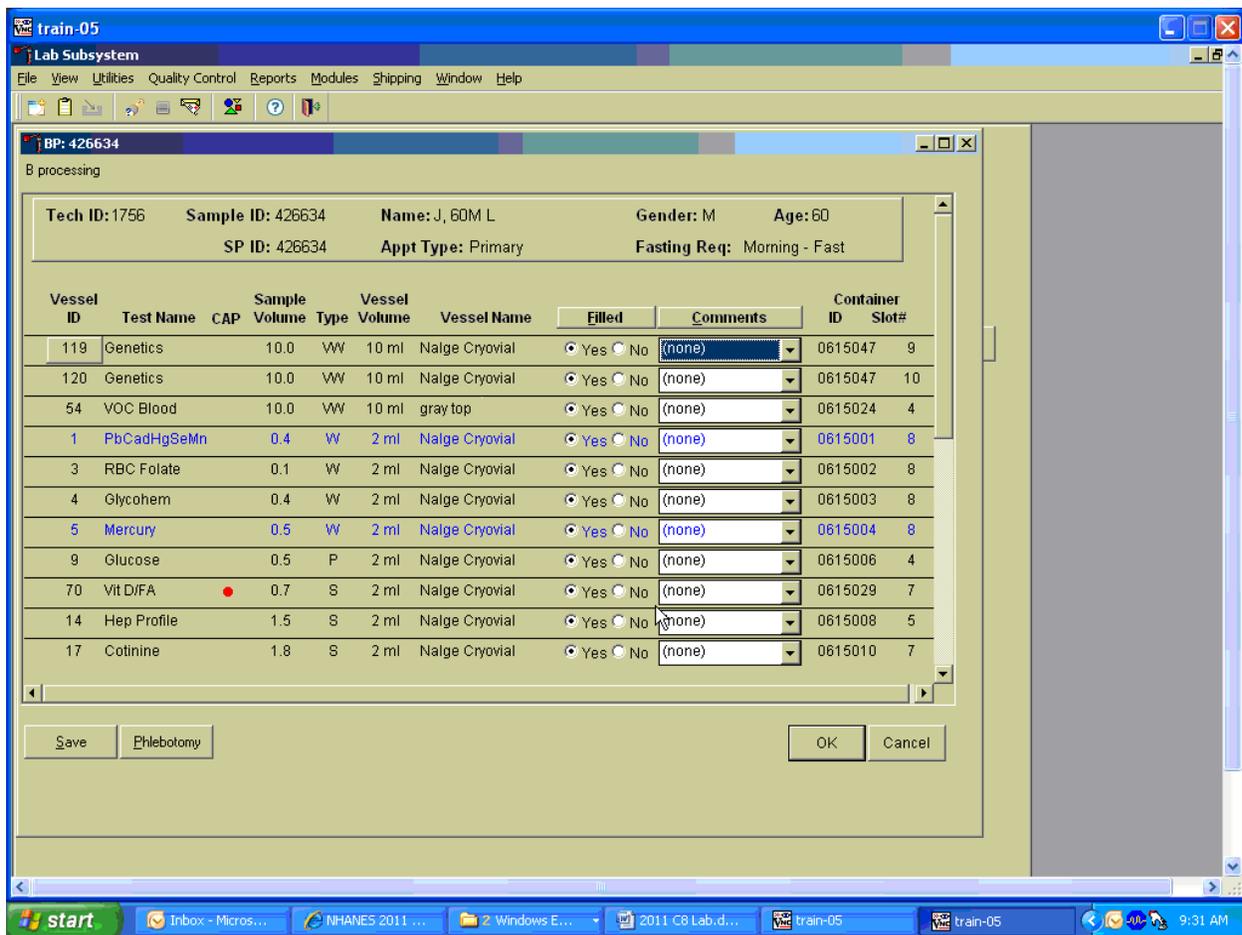
If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad), vessel 3 (RBC Folate), vessel 4 (Glycohem), or vessel 5 (Mercury).

Attach the “Laboratory error” comment to a Filled—No result for vessels 1 and 5, if the CBC was run before the vessels were processed.



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 and 5 as Filled—”No” and attach the comment “laboratory error.” Continue to pipette the whole blood for vessels 3 and 4 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.



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.

## 8.9 TB Blood Processing

### 8.9.1 Introduction

QuantIFERON TB Gold (QFT) is a simple blood test that accurately identifies people infected with *Mycobacterium tuberculosis*, the causative agent of Tuberculosis (TB). QFT is a modern

alternative to the 110-year old Tuberculin Skin Test (TST) and is unaffected by the Bacillus Calmette-Guerin (BCG) vaccination. This method uses Cellestis QFT In-Tube TB blood tubes.

## **8.9.2 QFT Blood Tubes**

Workstation 1 is responsible for incubating and processing the TB blood tubes. After the blood has been collected in phlebotomy, store and batch the TB blood In-Tubes at room temperature until the end of the day. Room temperature must be between 17 and 27° C. The Cellestis portable incubator has a dual temperature setting of 37° C and 4° C. This incubator works with 12V DC power and also AC/DC power with the included adaptor.

### **8.9.2.1 Instructions for Use of Cellestis Portable Incubator**

Connect incubator to power source and push the ON/OFF button to turn the incubator ON. Push the Heat (red)/Cool (blue) button to select heat mode. The unit may take up to 2 hours to equilibrate to 37° C. This unit will be monitored with a certified thermometer and documented each session in the Quality Control record under Daily QC. The acceptable temperature range has been set to 37° C +/- 1° C. A certified 24-hour digital timer will be used with this unit to shut the unit off after the 16-hour incubation period has elapsed.



Record the temperature of the incubator at the start of each session. To record the temperature, access (click) the quality control menu to show the drop-down menu. Select quality control and then the daily tab. Record the temperature for the incubator, for which the acceptable range is 36-38° C.

Lab Shipping						
Start of Stand	Daily	Weekly	End of Stand	Yearly	Supply Use	NCHS QC
QC Check	Done	Result	Comment			
Osmette Dropper Urine Chemistry Control 2	<input type="checkbox"/>	<input type="text"/> (yes/no)	<input type="text"/>			
1% Ascorbic acid	<input type="checkbox"/>	<input type="text"/> (yes/no)	<input type="text"/>			
7% Ascorbic acid	<input type="checkbox"/>	<input type="text"/> (yes/no)	<input type="text"/>			
Incubator temperature reading (36 to 38 °C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>			

### 8.9.2.2 Instruction on Use of Timer

Use digital display to set only one program on 1 day for a 16-hour incubation period.

Turn on the incubator an hour prior to incubation. Remix the TB blood tubes prior to incubation, by vigorously shaking tubes for 5 seconds or approximately ten times prior to placing the tubes in the incubator. This ensures that the entire tube has been coated with blood. Proper shaking will lead to frothing of the blood.

**NOTE:** TB blood tubes must be incubated within 16 hours of collection.

### 8.9.2.3 Incubation of QFT Blood Tubes

Incubate TB blood tubes in the black racks, which are the rack in which the TB blood tubes are stored in, in an upright position for 16 hours at 37 ° C. To allow the air to flow effectively, the tube racks should be placed lengthways (front to back) inside the incubator. Place racks in between the guides in the base of the unit. Prior to incubation, ensure that the incubator lid is secured.

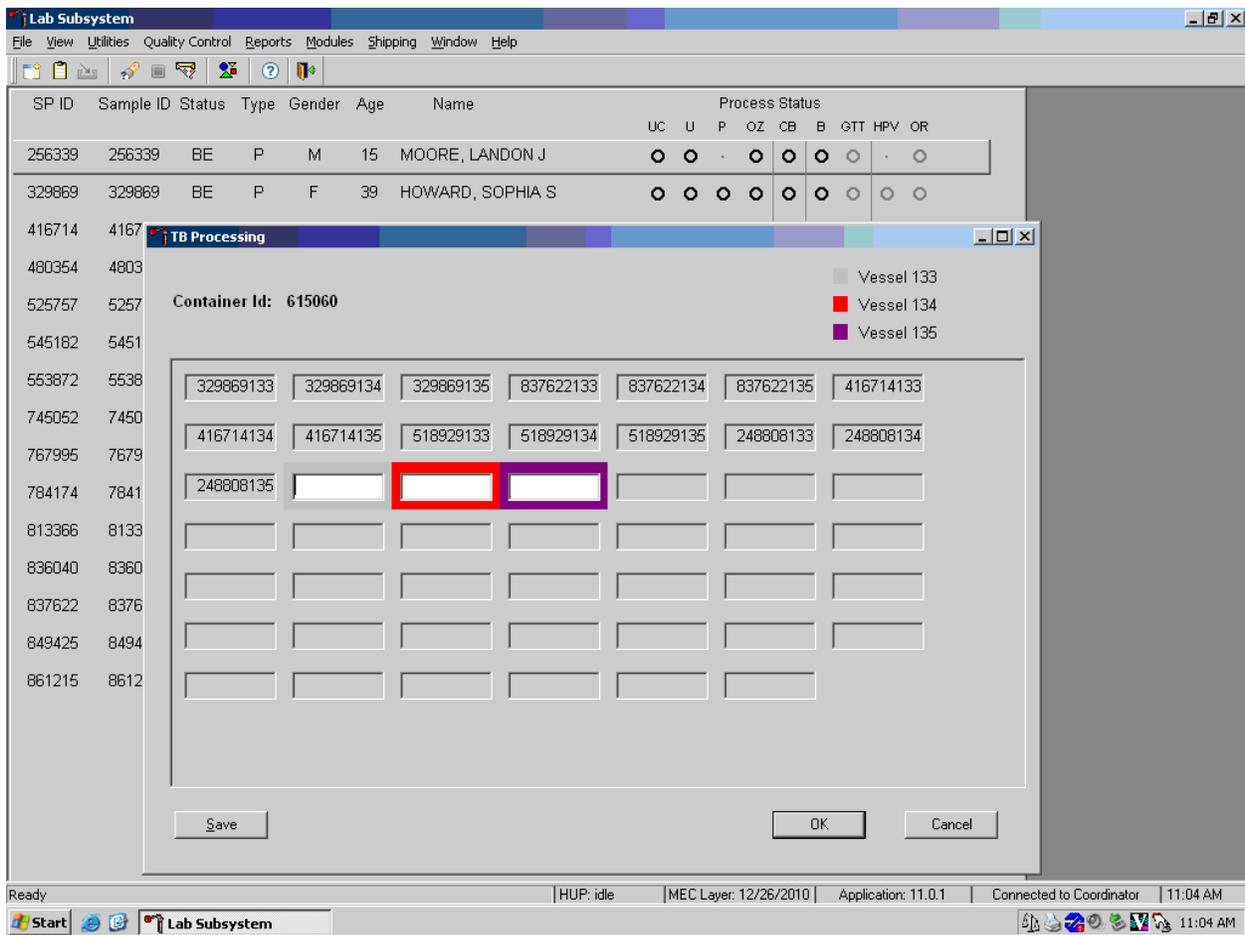
Incubate tubes for 16 hours, while minimizing the shaking of tubes. After the incubation period, centrifuge the tubes for 15 minutes at 2000-3000 RCF (g) at room temperature. The gel plug will separate the cells from the plasma. If separation does not occur, the tubes should be re-centrifuged at a higher speed (3100-3600 RCF).

Immediately after centrifugation, assign the QFT blood tubes to a container by using the TB Processing module located under Modules on the heads-up display. Assign all TB blood tubes container slots and store refrigerated at 2-8° C.

The screenshot shows a software window titled 'train-05' with a menu bar (File, View, Utilities, Quality Control, Reports, Modules, Shipping, Window, Help) and a toolbar. A dropdown menu is open over the 'Modules' menu, showing 'Hematology' and 'TB Processing'. The main area contains a table with the following columns: SP ID, Sample ID, Status, Type, G, Osmolality, Name, and Process Status. The Process Status column includes sub-columns: UC, U, P, OZ, CB, B, GTT, HPV, and OR. The table lists 18 samples, most with 'MS TRAINING' names and 'SARAH'S' as the operator. The status of various process steps is indicated by circles, some of which are filled (black, red, or purple).

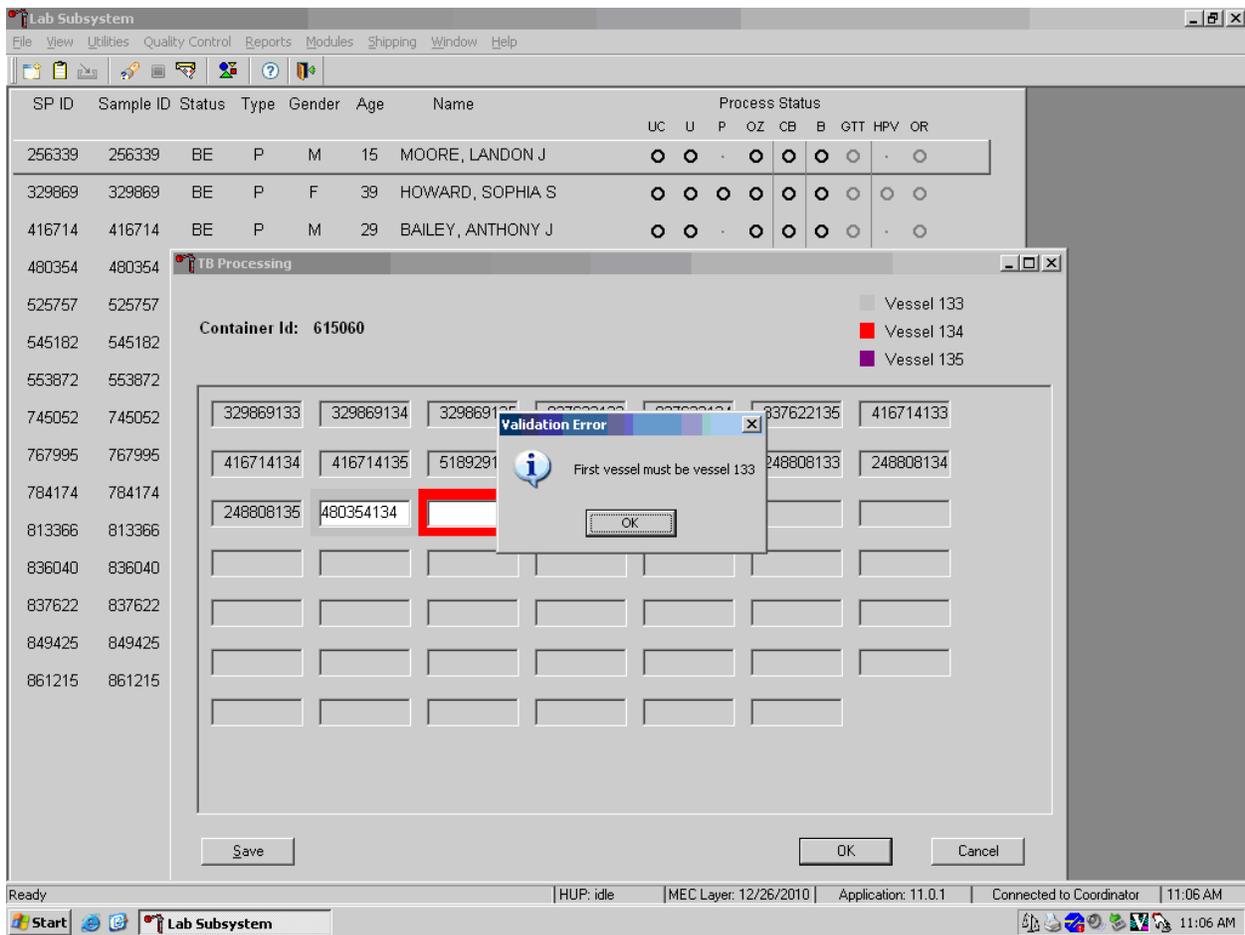
SP ID	Sample ID	Status	Type	G	Osmolality	Name	UC	U	P	OZ	CB	B	GTT	HPV	OR
170843	170843	SC	P	M	48	MS TRAINING 37, SARAH'S	○	○	-	○	○	○	○	-	○
205343	205343	SC	P	M	38	MS TRAINING 15, SARAH'S	○	○	-	○	○	○	○	-	○
210588	210588	SC	P	M	23	MS TRAINING 28, SARAH'S	○	○	-	○	○	○	○	-	○
214617	214617	SC	P	M	45	MS TRAINING 27, SARAH'S	○	○	-	○	○	○	○	-	○
226954	226954	BE	P	M	22	MS TRAINING 6, SARAH'S	●	○	-	○	○	○	○	-	○
243558	243558	SC	P	F	20	MS TRAINING 5, SARAH'S	○	○	○	○	○	○	○	-	○
312237	312237	SC	P	M	14	MS TRAINING 2, SARAH'S	○	○	-	○	○	○	○	-	○
326998	326998	SC	P	M	45	MS TRAINING 20, SARAH'S	○	○	-	○	○	○	○	-	○
328532	328532	SC	P	F	62	MS TRAINING 26, SARAH'S	○	○	-	○	○	○	○	-	○
343778	343778	SC	P	F	12	MS TRAINING 1, SARAH'S	○	○	○	○	○	○	○	-	-
344919	344919	SC	P	M	53	MS TRAINING 34, SARAH'S	○	○	-	○	○	○	○	-	○
388904	388904	SC	P	M	35	MS TRAINING 36, SARAH'S	○	○	-	○	○	○	○	-	○
398527	398527	SC	P	M	26	MS TRAINING 35, SARAH'S	○	○	-	○	○	○	○	-	○
420054	420054	CI	P	M	53	MS TRAINING 30, SARAH'S	○	○	-	○	○	○	○	-	○
429538	429538	BE	P	M	32	MS TRAINING 11, SARAH'S	○	○	-	○	○	○	○	-	○
451058	451058	SC	P	M	65	MS TRAINING 21, SARAH'S	○	○	-	○	○	○	○	-	○
454840	454840	SC	P	M	18	MS TRAINING 40, SARAH'S	○	○	-	○	○	○	○	-	○
466030	466030	SC	P	F	26	MS TRAINING 29, SARAH'S	○	○	○	○	○	○	○	○	○

The TB processing module, which is a container map of the 7x7 box used for TB storage and shipping, displays the container ID and a color code, where gray represents the gray tube or vessel 133, red represents the red tube or vessel 134, and purple represents the purple tube or vessel 135.

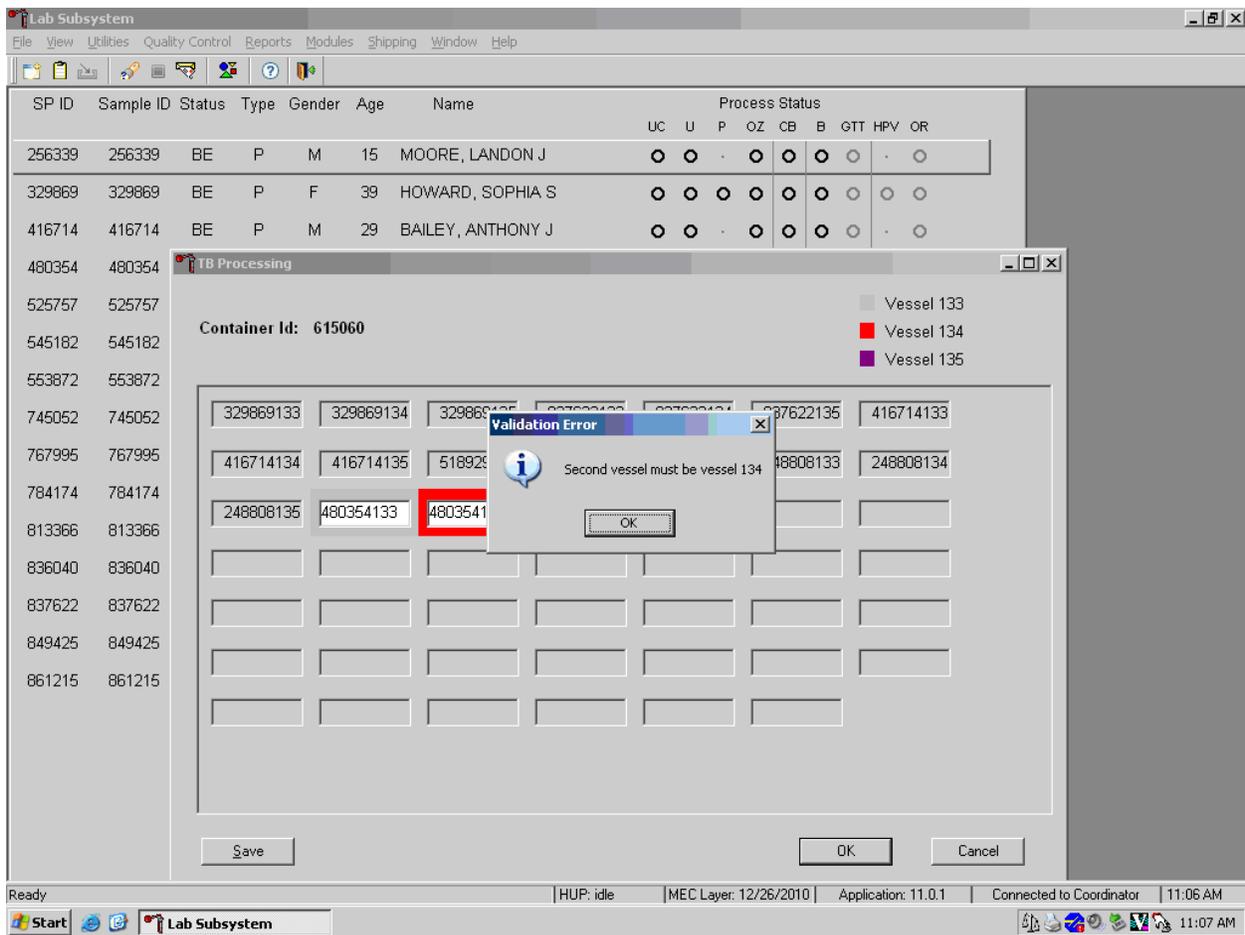


To save currently scanned in tubes, the save button must be clicked before exiting the TB processing module. If you accidentally exit without clicking the save button, your work will be lost and you will need to re-scan. If only one or two tubes are scanned in for an SP and the save button is clicked, a validation error will be displayed.

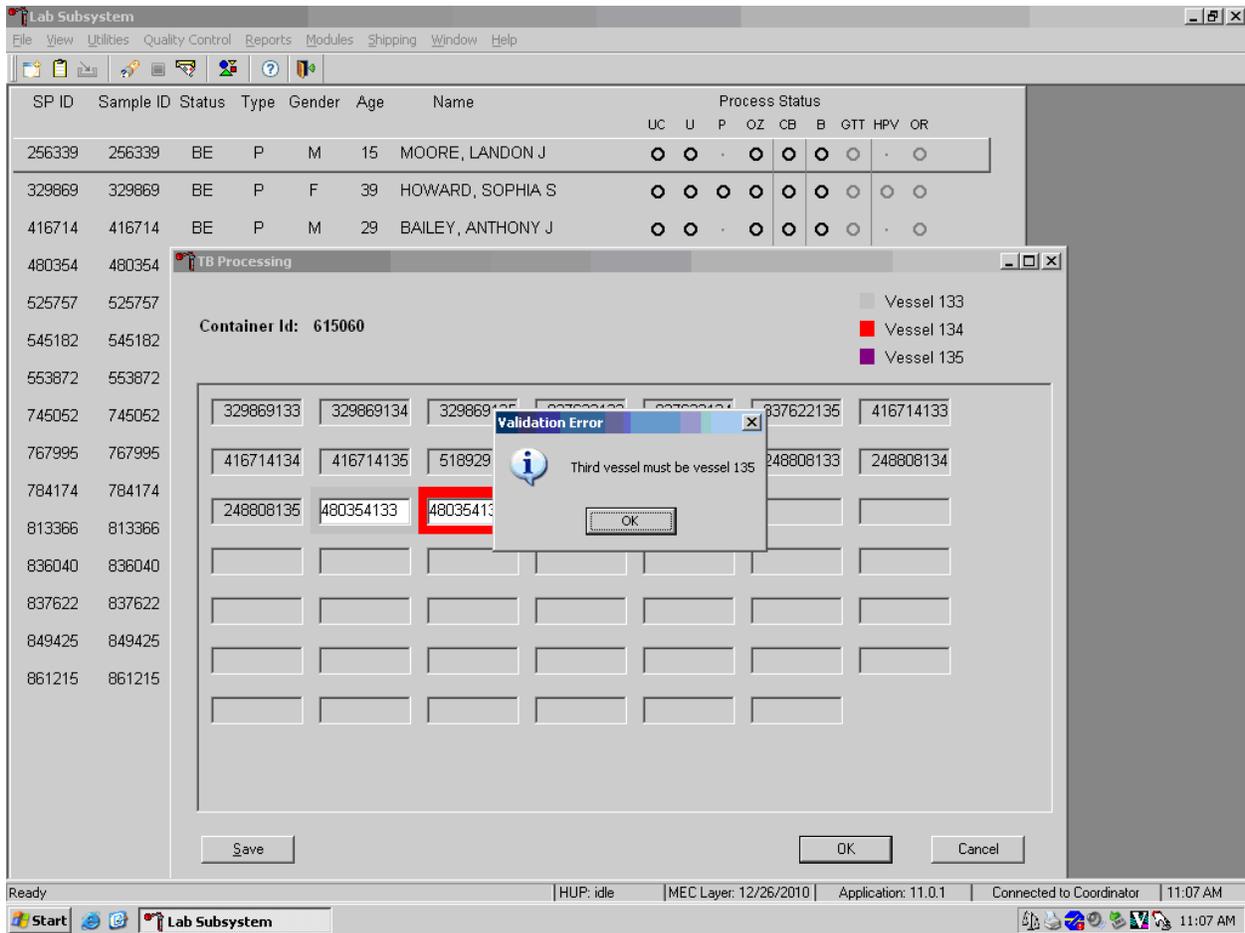
The TB Processing module requires that the tubes are scanned in according to the color prompts located in the container map. If the tubes are scanned in the wrong order or if a different SPs label is scanned prior to completing the sequence of the three tubes, error will be displayed on the screen. If any other vessel, such as 134 or 135 is scanned in the first position (gray) a validation error will be displayed. This error states, “First vessel must be vessel 133”.



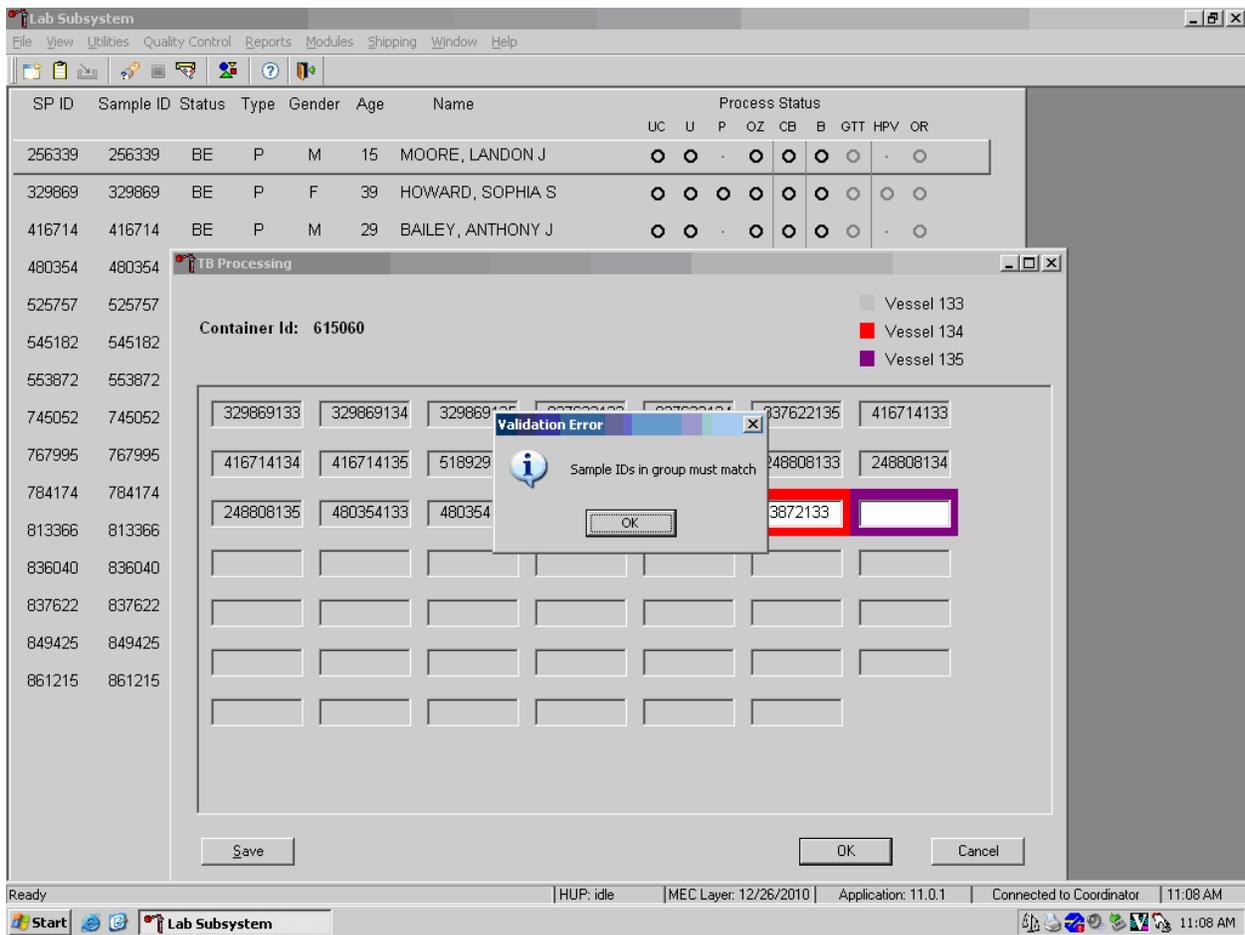
If any tube other than vessel 134, such as 133 or 135 is scanned into the second position (red), a validation error will be displayed. This error states, “Second vessel must be vessel 134.”



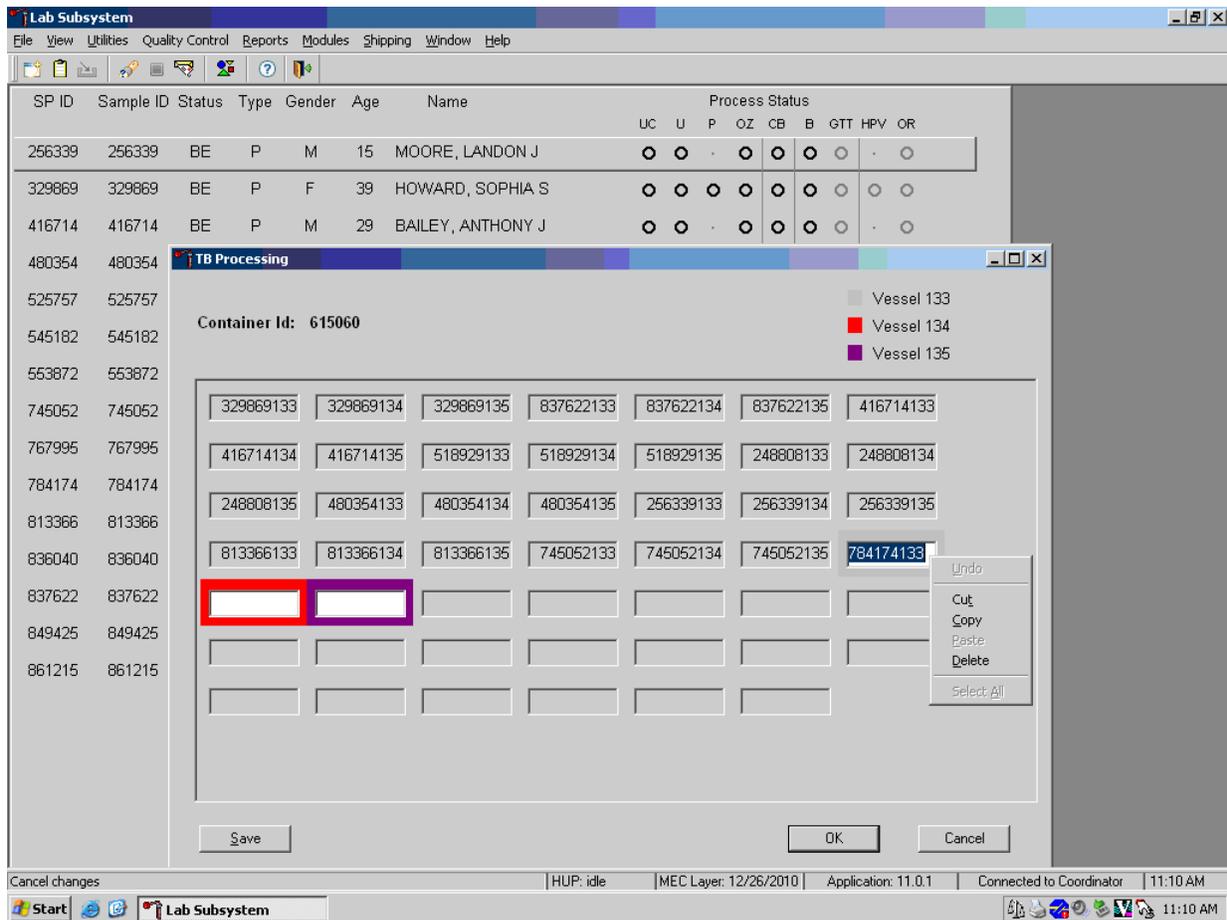
If any tube other than vessel 135, such as 133 or 134 is scanned into the third position (purple), a validation error will be displayed. This error states, “Third vessel must be vessel 135.”



If a different SP is scanned prior to completing the sequence of three for one SP, a validation error will be displayed. This error states, “Sample IDs in group must match.”



If a Sample ID was scanned in error and it needs to be removed, double click the ID you want to delete so it is highlighted. Right click to bring up a menu that contains the following options: cut, copy and delete. Click on delete to remove the highlighted sample ID.



## 8.10 Blood Specimen Storage

### 8.10.1 Blood Specimen Storage Protocol

Fill the blood vessels, enter the blood processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Exhibit 8-20.

At the beginning of each stand, generate and print a series of barcoded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a barcode 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.

Exhibit 8-20. Storage protocol for blood

<b>Shipping Location</b>	<b>Vessels</b>	<b>Conditions</b>	<b>Vessel Storage</b>	<b>Ship Frequency</b>
CDC/NCEH Molecular Biology Branch	119/120 Genetics	Refrigerated	5x5 five inch foam box	Twice week
CDC/NCEH Air Toxicant Branch	54 VOC Blood	Refrigerated	5x5 five inch foam box	Weekly
CASPIR	1 Lead/Cad/HG/Se/Mn	Frozen	9 x 9 two inch box	Weekly
CASPIR	3 RBC Folate	Frozen	10x10 two inch box	Weekly
NHANES Diabetes Laboratory	4 Glycohem	Refrigerated	9 x 9 two inch box	Weekly
CASPIR	5 Mercury, Ethyl & Methyl	Frozen	9 x 9 two inch box	Weekly
NHANES Diabetes Laboratory	9 Glucose	Frozen	9 x 9 two inch box	Weekly
NHANES Diabetes Laboratory	98 OGTT	Frozen	9 x 9 two inch box	Weekly
CASPIR	136 Se/Cu/Zn	Frozen	9x9 two inch box	Weekly
CDC/NCIRD Herpes virus Diagnostic Lab	136 CMV	Frozen	9x9 two inch box	Weekly
CASPIR	70 Vitamin D/Fatty Acids	Frozen	10x10 two inch box	Weekly
CDC/NCID Hepatitis Ref Lab	122 HAV	Frozen	9 x 9 two inch box	Weekly
CDC/NCID Hepatitis Ref Lab	87 Hepatitis ab	Frozen	9 x 9 two inch box	Weekly
CASPIR	17 Cotinine	Frozen	9 x 9 two inch box	Weekly
NHANES Diabetes Laboratory	21 Lipids	Frozen	9 x 9 two inch box	Weekly
CDC /DVRD HPV	77 HPV Serum	Frozen	9 x 9 two inch box	Weekly
Collaborative Laboratory Services	18 Biochem	Refrigerated	9 x 9 two inch box	Weekly
NHANES Diabetes Laboratory	23 Insulin	Frozen	9 x 9 two inch box	Weekly
CASPIR	12 Vit B12/MMA	Frozen	9x9 two inch box	Weekly
CDC NCID AIDS Division	22 HIV	Frozen	9 x 9 two inch box	Weekly
Emory University	24 HSV	Frozen	9 x 9 two inch box	Weekly
University of Washington	118 Thyroid	Frozen	9 x 9 two inch box	Weekly
Mayo Clinic	127 IgA-TTG/EMA	Frozen	9 x 9 two inch box	Weekly
CASPIR	137 Testosterone	Frozen	9x9 two inch box	Weekly
CASPIR	110 Folate1	Frozen	10 x 10 two inch box	Weekly
CASPIR	32-37 Xtra Sera	Frozen	9 x 9 two inch box	End of stand
CASPIR	91 Srm Pest	Frozen	9 x 9 three inch box	End of stand
CASPIR	29 Persis Pest1 89 Persis Pest2	Frozen	9 x 9 three inch box	End of stand

Exhibit 8-20. Storage protocol for blood (continued)

Shipping Location	Vessels	Conditions	Vessel Storage	Ship Frequency
CDC/NCEH Environmental Health Laboratory	90 Perfluor	Frozen	9 x 9 three inch box	End of stand
CASPIR	92 BFR 1 93 BFR 2	Frozen	9 x 9 three inch box	End of stand

### 8.11 How to Deal With System Failure

If the computer system fails, record results on a preprinted workstation 1 processing worksheet (Exhibit 8-21). Complete a Blood Processing worksheet for each SP while processing the blood specimens. Enter the results after the system is operational.

Exhibit 8-21. Workstation 1 processing worksheet

**BLOOD PROCESSING**

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

<b>ID</b>	<b>Name</b>	<b>Ages</b>	<b>Sample mL</b>	<b>Sample Type</b>	<b>Filled ✓</b>	<b>Filled Comments <i><u>I</u>cteric<u>L</u>ipemic <u>E</u>quip <u>F</u>ailure <u>C</u>lotted <u>H</u>emolyzed</i></b>	<b>Not Filled Comments <i><u>Q</u>NSSP <u>R</u>efusal <u>L</u>ab Error</i></b>	<b>Slot #</b>
119	Genetics	20+	10.0	WB				
120	Genetics	20+	10.0	WB				
54	VOC Blood	12+	10.0	WB				
1	Lead/Cad/HG /Se/Mn	1+	0.4	WB				
3	RBC Folate	1+	0.1	WB				
4	Glycohem	12+	0.4	WB				
5	Mercury, Ethyl & Methyl	1+	0.5	WB				
9	Glucose	12+	0.5	P				
98	OGTT	12+	0.5	P				
136	Se/Cu/Zn	6+	1.0	S				
138	CMV	1-5	0.4	S				
70	Vitamin D/Fatty Acids	1-5 6+	0.5 0.7	S				
14	Hep Profile	20+	1.5	S				
122	HAV	6+	1.5	S				
87	Hepatitis ab	2 3-5	0.3 0.5	S				
17	Cotinine	3-5 6-11 12+	0.8 1.1 1.8	S				
21	Lipids	6-11 12+	1.0 1.5	S				
77	HPV Serum	14-59	0.5	S				
18	Biochem	12+	0.8	S				
23	Insulin	12+	1.0	S				
12	Vit B12/MMA	20+	0.7	S				
22	HIV	18-59	0.8	S				
24	HSV	14-49	0.2	S				

Exhibit 8-21. Workstation 1 processing worksheet (continued)

**BLOOD PROCESSING**

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

<b>ID</b>	<b>Name</b>	<b>Ages</b>	<b>Sample mL</b>	<b>Sample Type</b>	<b>Filled ✓</b>	<b>Filled Comments <u>I</u>cteric<u>L</u>ipemic <u>E</u>quip <u>F</u>ailure <u>C</u>lotted <u>H</u>emolyzed</b>	<b>Not Filled Comments <u>Q</u><u>N</u><u>S</u><u>S</u><u>P</u> <u>R</u>efusal <u>L</u>ab <u>E</u>rror</b>	<b>Slot #</b>
118	Thyroid	12+	1.0	S				
127	IgA-TTG/ EMA	6+	1.0	S				
137	Testosterone	6+	0.5	S				
110	Folate1	1+	0.7	S				
32	Xtra Sera1	3+	0.5	S				
33	Xtra Sera2	3+	0.5	S				
34	Xtra Sera3	12+	1.0	S				
35	Xtra Sera4	12+	1.0	S				
36	Xtra Sera5	12+	1.0	S				
37	Xtra Sera6	12+	1.0	S				
29	Persis Pest1	12+	4.0	S				
89	Persis Pest2	12+	4.0	S				
90	Perfluor1	12+	4.0	S				
92	BFR1	12+	4.0	S				
93	BFR2	12+	4.0	S				
91	Srm Pest	12+	4.0	P				

WB = Whole Blood    P = Plasma    PC=Packed cells    S = Serum

## **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.

Biological specimens are shipped 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). A copy of the shipping manifest is included 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.

Packages are shipped using FedEx. The chief medical technologist is responsible for contacting FedEx at the start of each stand to determine availability. The facility and equipment specialist 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 facility and the equipment specialist 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 the MEC split examination sessions. Ship vessels 119/120 twice per week. Hold the containers for vessels 8, 32-37, 29/89, 90, 91, 92/93, 48, 49, 66, 67, 102, 121, 52, and 139 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>Whole Blood</b>				
CDC/NCEH Molecular Biology Branch Vessels 119/120	Genetics	Refrigerated	5 x 5 five inch box with foam insert	Twice weekly
CDC/NCEH Air Toxicant Branch Vessel 54	VOC Blood	Refrigerated	5 x 5 five inch box with foam insert	Weekly
CASPIR Vessel 1	Lead/Cad/HG	Frozen	9 x 9 two inch box	Weekly
CASPIR Vessel 3	RBC Folate	Frozen	10 x 10 two inch box	Weekly
NHANES Diabetes Laboratory Vessel 4	Glycohem	Refrigerated	9 x 9 two inch box	Weekly
CASPIR Vessel 5	Mercury, Ethyl and Methyl	Frozen	9 x 9 two inch box	Weekly
<b>Plasma</b>				
NHANES Diabetes Laboratory Vessel 9	Glucose	Frozen	9 x 9 two inch box	Weekly
NHANES Diabetes Laboratory Vessel 98	OGTT	Frozen	9 x 9 two inch box	Weekly
CDC/NCEH Pesticide Laboratory Vessel 91	Srm Pest	Frozen	9 x 9 three inch box	Full or end of stand
<b>Serum</b>				
CASPIR Vessel 136	Se/Cu/Zn	Frozen	9 x9 two inch box	Weekly
CDC/NCIRD Herpes virus Diagnostic Lab Vessel 138	CMV	Frozen	9 x9 two inch box	Weekly
CASPIR Vessel 70	Vitamin D/Fatty Acids	Frozen	10 x 10 two inch box	Weekly

Exhibit 9-1. Blood and urine shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
<b>Serum</b>				
CDC/NCID Hepatitis Ref Lab Vessel 122	HAV	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 Vessel 17	Cotinine	Frozen	9 x 9 two inch box	Weekly
NHANES Diabetes Laboratory Vessel 21	Lipids	Frozen	9 x 9 two inch box	Weekly
CDC /DVRD/Molecular Epidemiology Vessel 77	HPV Serum	Frozen	9 x 9 two inch box	Weekly
Collaborative Laboratory Services Vessel 18	Biochem	Refrigerated	9 x 9 two inch box	Weekly
NHANES Diabetes Laboratory Vessel 23	Insulin	Frozen	9 x 9 two inch box	Weekly
CASPIR Vessel 12	Vit B12/MMA	Frozen	9x9 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
University of Washington Vessel 118	Thyroid	Frozen	9 x 9 two inch box	Weekly
Mayo Clinic Vessel 127	IgA-TTG/EMA	Frozen	9 x 9 two inch box	Weekly
CASPIR Vessel 137	Testosterone	Frozen	9x9 two inch box	Weekly
CASPIR Vessel 110	Folate1	Frozen	10x10 two inch box	Weekly
CASPIR Vessels 32-37	Xtra Sera	Frozen	9 x 9 two inch box	Full or end of stand
CASPIR Vessels 29 and 89	Persis Pest1 Persis Pest2	Frozen	9 x 9 three inch box	Full or end of stand
CDC/NCEH Environmental Health Laboratory Vessel 90	Perfluor1	Frozen	9 x 9 three inch box	Full or end of stand

Exhibit 9-1. Blood and urine shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
CASPIR Vessels 92 and 93	BFR1 BFR2	Frozen	9 x 9 three inch box	Full or end of stand
<b>Urine</b>				
University of Minnesota Vessel 45	Alb/Creat	Frozen	9 x 9 three inch box	Weekly
CDC/NCID NCHSTD Vessel 46	Chlam	Frozen	5 x 5 three inch box	Weekly
CASPIR Vessel 86	Spc Arsenic	Frozen	9 x 9 three inch box	Weekly
CASPIR Vessel 48	Prior Pest	Frozen	5 x 5 three inch box	Full or end of stand
CASPIR Vessel 49	Organophos	Frozen	5 x 5 three inch box	Full or end of stand
CASPIR Vessel 62	Urn Merc	Frozen	5 x 5 three inch box	Weekly
CASPIR Vessel 50	Heavy Metal	Frozen	5 x 5 three inch box	Weekly
CASPIR Vessel 66	PAH	Frozen	9 x 9 three inch box	Full or end of stand
CDC/NCEH Environmental Health Laboratory Vessel 67	Phthalates	Frozen	9 x 9 three inch box	Full or end of stand
CDC/NCEH Air Toxicant Branch Vessel 102	Perchlorate/VO C/Thiocyante	Frozen	9 x 9 three inch box	End of stand
CASPIR Vessel 121	NNAL	Frozen	5 x 5 three inch box	End of stand
CASPIR Vessel 128	Caffeine	Frozen	10 x 10 two inch box	Weekly
CASPIR Vessel 52	Xtra Urine1	Frozen	9 x 9 three inch box	Full or end of stand
CASPIR Vessel 139	Xtra Urine2	Frozen	9 x 9 three inch box	Full or end of stand

## 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 nonsterile
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 3 inch box with 7x7 grid
5.25 x 5.25 x 3.0 inch cardboard box with 5x5 grid	Scale
10 x 10 two-inch box	10 x 10 three-inch box
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”
Overpack label	Address labels for FedEx class 9 sticker
UN 3373 label	Refrigerate Do Not Freeze label
Keep Frozen label	Avery 5160 labels
Label Zebra (1.125”)	Printer ribbon, Zebra (thermal transfer)
Sheet-fed laser labels	Wipes, Terri 13” x 18”
FedEx large boxes	FedEx Class 9 label
Clear FedEx label pouches	Dymo Labels
FedEx form 0215	FedEx preprinted return air bill – 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 assigned to workstation 1 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 pregnancy testing, urine processing, blood processing, pool blood tube, OGTT processing labels, and HPV oral rinse for all SPs

scheduled into a MEC session. The phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. The MEC physician prints the HPV swab labels.

### **Distribute labels**

- Place urine processing, pregnancy testing, and HPV oral rinse labels at workstation 3 in the laboratory.
- If the SP does not show up for the appointment, it is possible he or she will reschedule.
- Store the SP's vessels in a zip-closable bag until the end of the stand.
- If the SP has not shown up by the end of the stand, place racks in clear plastic bins or in cupboard above workstation 3.

### **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:

- Plastic rack
- Template for processing

- Vessels stored of the following sizes:
  - 2.0-mL vessel
  - 5.0-mL vessel
  - 14.0-mL tube (HPV oral rinse only)
  - 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 OGTT labels for vessel 98 at workstation 2 at the start of each session.
- Place the pre-labeled blood processing racks on the counter to the right of the centrifuges at the start of each session.

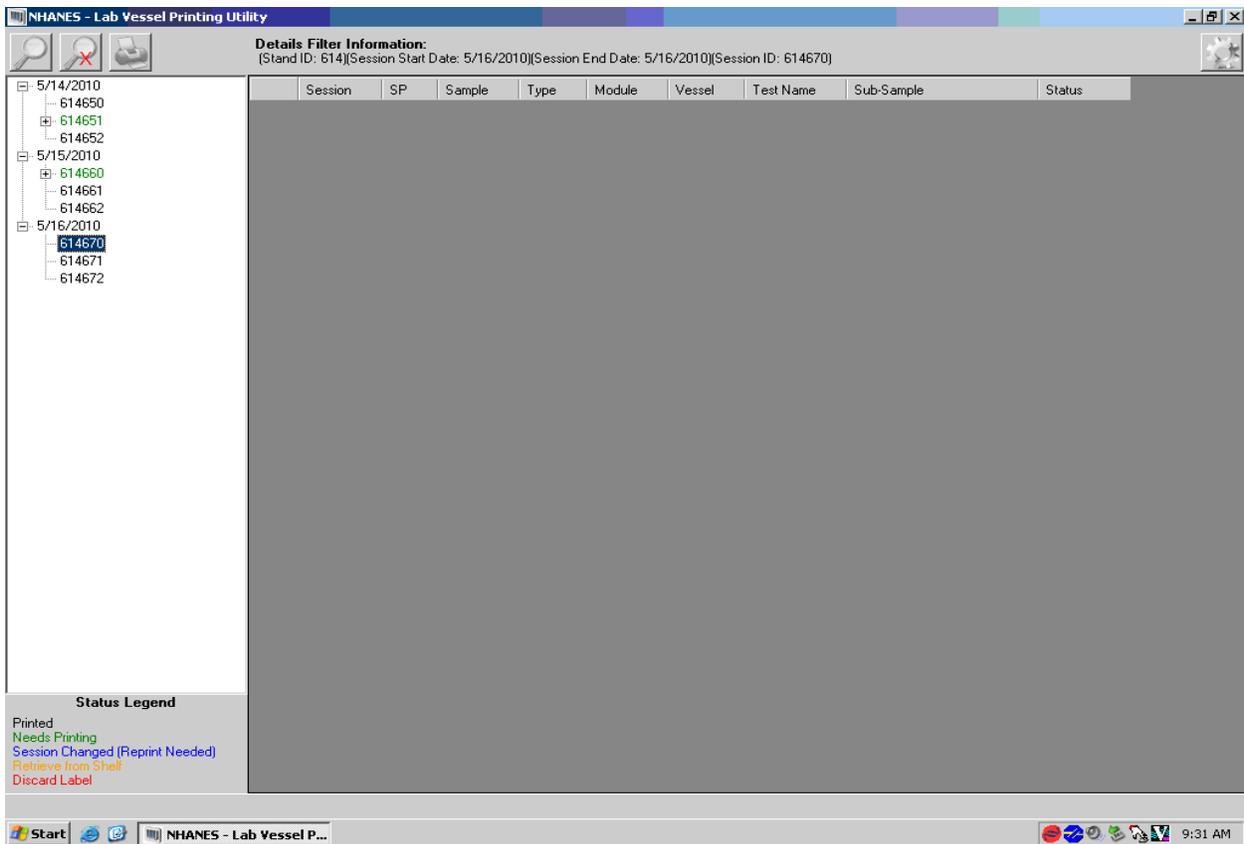
### **9.3.1 Print Vessel Labels Using the Label Print Application**

Open the Laboratory application. Log onto the computer terminal and select the Label Print Application. This application is found on the desktop of all laboratory computers and has an icon that looks like a barcode label.



### 9.3.2 Main Printing Screen

From the main printing screen, the current day and next 2 days the MEC is in session will be displayed in a tree view on the left side of the screen. The sessions will be color coded to match the legend at the bottom left hand side of the screen. Sessions in green indicate that a particular session or SPs within that session need to be printed. Sessions in black have already been printed and there are no SP profile changes. Sessions in blue indicate that an SP was added to that session or that a SP or SPs had a profile change and need to be reprinted. If an SP is removed from a session, that session will be displayed in red, which indicates label action is needed.



### 9.3.3 Filter Options

The looking glass icon is used for the filtering options, where you can filter labels by stand start and end date, session ID, SP ID, or Sample ID. After picking the criteria you would like to filter with, press the filter button. Clearing the filter takes you back to the current date, plus 2 days and the cancel button takes you back to the main printing screen.

**Details Filter Information:**  
 (Stand ID: 614)(Session Start Date: 5/14/2010)(Session End Date: 5/16/2010)

Session	SP	Sample	Type	Module	Vessel	Test Name	Sub-Sample	Status
614651	530558	530558	W	BP	1	Lead/Cad/HG		Needs Printing
614651	554728	554728	W	BP	1	Lead/Cad/HG		Needs Printing
614651	731944	731944	W	BP	1	Lead/Cad/HG		Needs Printing
614651	753743	753743	W	BP	1	Lead/Cad/HG		Needs Printing
614651	847833	847833	W	BP	1	Lead/Cad/HG		Needs Printing
614651	889468	889468	W	BP	1	Lead/Cad/HG		Needs Printing
614651	890547	890547	W	BP	1	Lead/Cad/HG		Needs Printing
614651	904789	904789	W	BP	1	Lead/Cad/HG		Needs Printing
614660	211074							Needs Printing
614660	389587							Needs Printing
614660	540529							Needs Printing
614660	565809							Needs Printing
614660	580885							Needs Printing
614651	530558							Needs Printing
614651	554728							Needs Printing
614651	731944							Needs Printing
614651	753743							Needs Printing
614651	847833							Needs Printing
614651	889468	889468	W	BP	3	RBC Folate		Needs Printing
614651	890547	890547	W	BP	3	RBC Folate		Needs Printing
614651	904789	904789	W	BP	3	RBC Folate		Needs Printing
614660	211074	211074	W	BP	3	RBC Folate		Needs Printing
614660	389587	389587	W	BP	3	RBC Folate		Needs Printing
614660	540529	540529	W	BP	3	RBC Folate		Needs Printing
614660	565809	565809	W	BP	3	RBC Folate		Needs Printing
614660	580885	580885	W	BP	3	RBC Folate		Needs Printing
614651	554728	554728	W	BP	4	Glycohem		Needs Printing
614651	731944	731944	W	BP	4	Glycohem		Needs Printing
614651	753743	753743	W	BP	4	Glycohem		Needs Printing

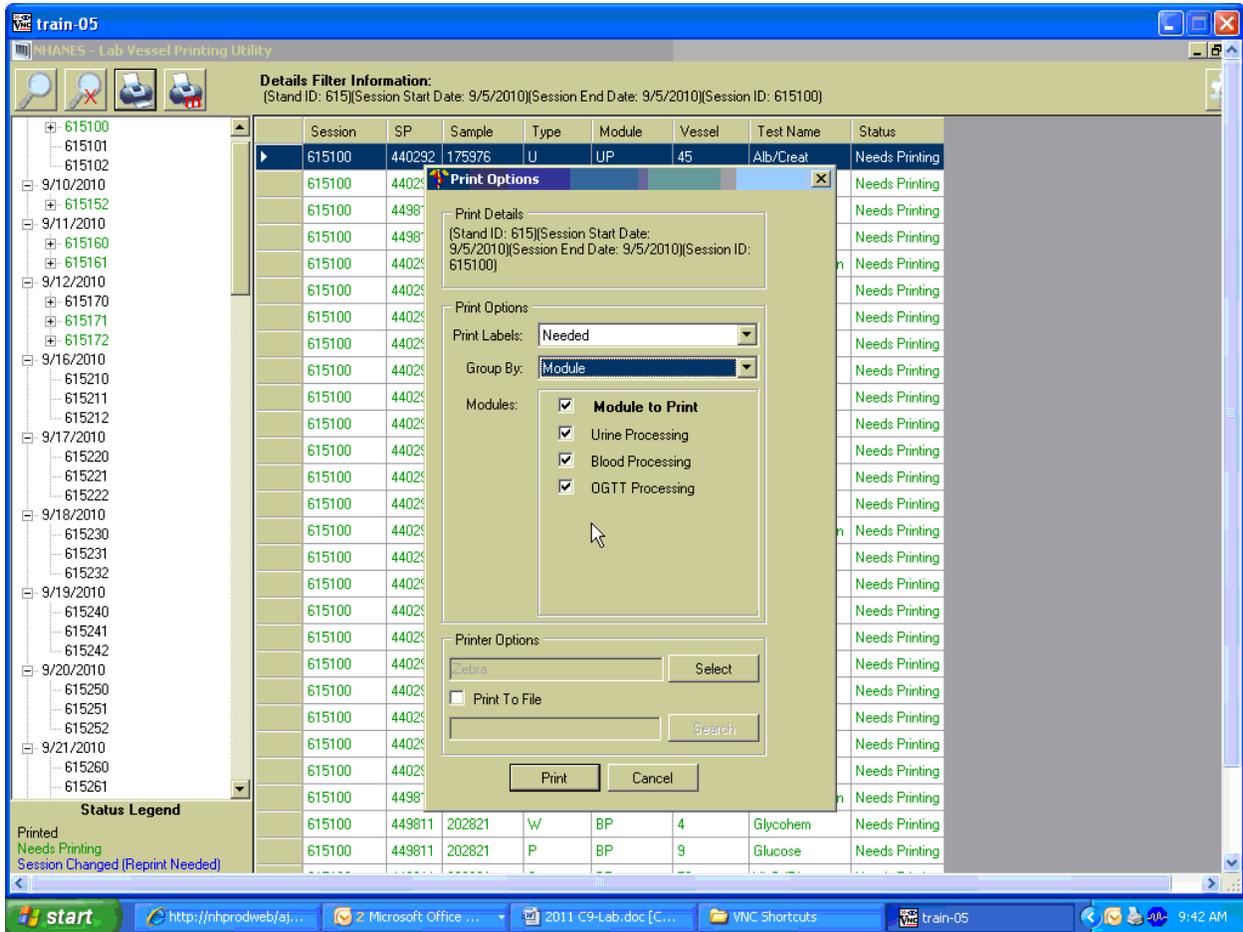
**Status Legend**  
 Printed  
 Needs Printing  
 Session Changed (Reprint Needed)  
 Retrieve from Shelf  
 Discard Label







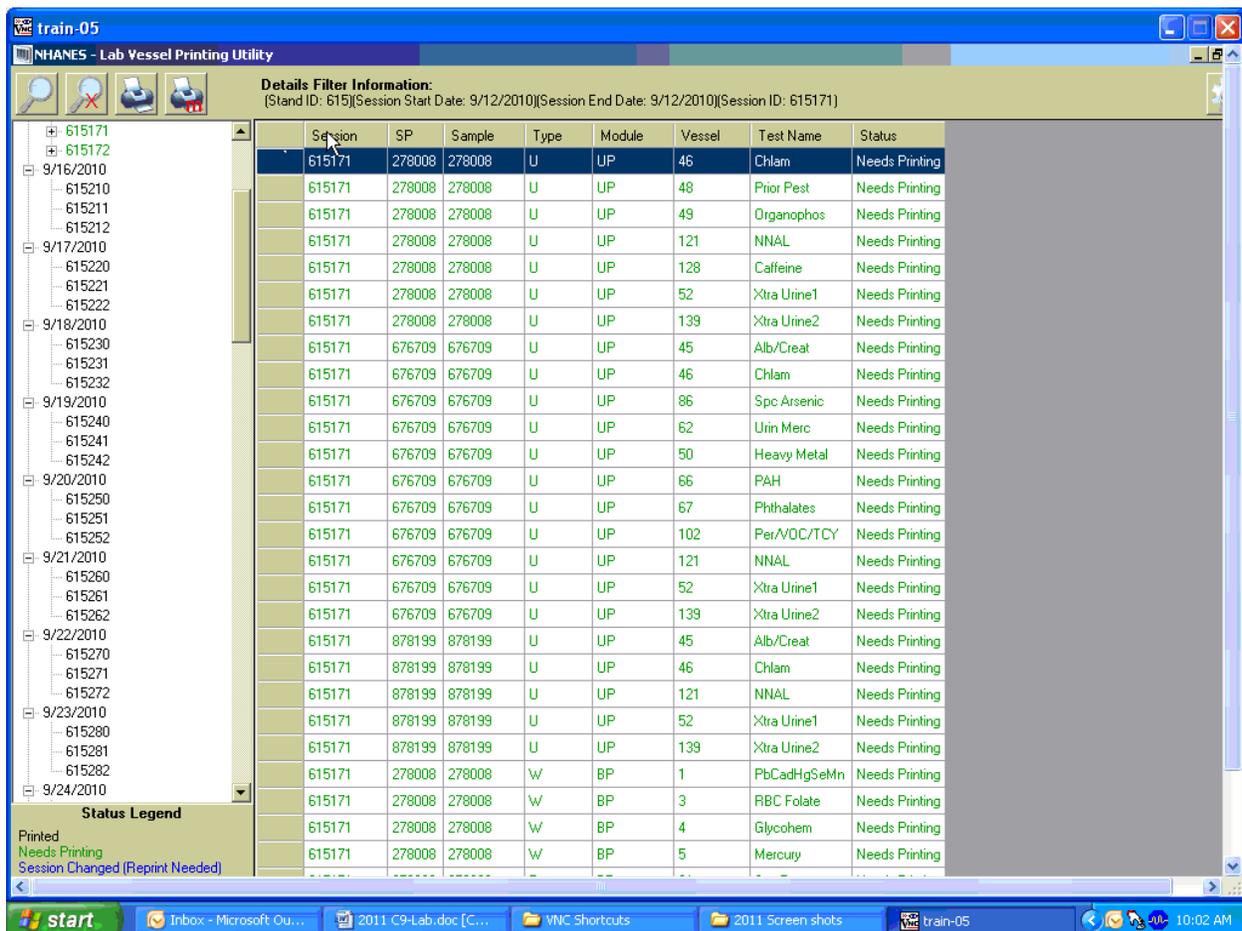
### 9.3.7 Print Options: Module Filter



Option to select all modules, a single module, or a combination of modules using the checkbox in front of the desired module.

### 9.3.8 Print Order

The print order matches the order the vessels are displayed on the print screen for the entire session. All urine vessels are printed first, which are grouped by SP ID. Do not label urine vessels, save urine labels together, which will be distributed to workstation 3 the day of the session being labeled.



If printing a morning session, the OGTT labels are printed after the blood processing labels. Label the OGTT tubes and put these SPs into a separate rack. The last module to be printed is the HPV rinse labels and they should be kept with the urine labels and distributed to workstation 3 the day of the session you are labeling.

### 9.3.9 Print Display Options

To change the display on the screen to display in numerical order for all SPs, click on “Vessel” tab and the display will change to numerical order for the entire session.

**Details Filter Information:**  
 (Stand ID: 6151) Session Start Date: 9/12/2010 Session End Date: 9/12/2010 Session ID: 615171

Session	SP	Sample	Type	Module	Vessel	Test Name	Status
615171	278008	278008	U	UP	45	Alb/Creat	Needs Printing
615171	278008	278008	U	UP	46	Chlam	Needs Printing
615171	278008	278008	U	UP	48	Prior Pest	Needs Printing
615171	278008	278008	U	UP	49	Organophos	Needs Printing
615171	278008	278008	U	UP	121	NNAL	Needs Printing
615171	278008	278008	U	UP	128	Caffeine	Needs Printing
615171	278008	278008	U	UP	52	Xtra Urine1	Needs Printing
615171	278008	278008	U	UP	139	Xtra Urine2	Needs Printing
615171	676709	676709	U	UP	45	Alb/Creat	Needs Printing
615171	676709	676709	U	UP	46	Chlam	Needs Printing
615171	676709	676709	U	UP	86	Spc Arsenic	Needs Printing
615171	676709	676709	U	UP	62	Urin Merc	Needs Printing
615171	676709	676709	U	UP	50	Heavy Metal	Needs Printing
615171	676709	676709	U	UP	66	PAH	Needs Printing
615171	676709	676709	U	UP	67	Phthalates	Needs Printing
615171	676709	676709	U	UP	102	Per/VOC/TCY	Needs Printing
615171	676709	676709	U	UP	121	NNAL	Needs Printing
615171	676709	676709	U	UP	52	Xtra Urine1	Needs Printing
615171	676709	676709	U	UP	139	Xtra Urine2	Needs Printing
615171	878199	878199	U	UP	45	Alb/Creat	Needs Printing
615171	878199	878199	U	UP	46	Chlam	Needs Printing
615171	878199	878199	U	UP	121	NNAL	Needs Printing
615171	878199	878199	U	UP	52	Xtra Urine1	Needs Printing
615171	878199	878199	U	UP	139	Xtra Urine2	Needs Printing
615171	278008	278008	W	BP	1	PbCadHgSeMn	Needs Printing
615171	278008	278008	W	BP	3	RBC Folate	Needs Printing
615171	278008	278008	W	BP	4	Glycohem	Needs Printing

**Status Legend**  
 Printed  
 Needs Printing  
 Session Changed (Reprint Needed)

### 9.3.10 Printing One SP's Labels

Using the tree on the left hand side of the screen, expand the session by clicking on the + sign to the left of the session number. This will display all the SPs scheduled for that session. Click on the SP you want displayed. Use printer icon to print using the print options described in 9.3.5 to 9.3.7.

train-05  
NHANES - Lab Vessel Printing Utility

Details Filter Information:  
(Stand ID: 615)(Session Start Date: 9/12/2010)(Session End Date: 9/12/2010)(Session ID: 615171)(SP ID: 278008)

Session	SP	Sample	Type	Module	Vessel	Test Name	Status
615171	278008	278008	U	UP	46	Chlam	Needs Printing
615171	278008	278008	U	UP	48	Prior Pest	Needs Printing
615171	278008	278008	U	UP	49	Organophos	Needs Printing
615171	278008	278008	U	UP	121	NNAL	Needs Printing
615171	278008	278008	U	UP	128	Caffeine	Needs Printing
615171	278008	278008	U	UP	52	Xtra Urine1	Needs Printing
615171	278008	278008	U	UP	139	Xtra Urine2	Needs Printing
615171	278008	278008	W	BP	1	PbCadHgSeMn	Needs Printing
615171	278008	278008	W	BP	3	RBC Folate	Needs Printing
615171	278008	278008	W	BP	4	Glycohem	Needs Printing
615171	278008	278008	W	BP	5	Mercury	Needs Printing
615171	278008	278008	P	BP	91	Srm Pest	Needs Printing
615171	278008	278008	S	BP	70	Vit D/FA	Needs Printing
615171	278008	278008	S	BP	122	HAV	Needs Printing
615171	278008	278008	S	BP	17	Cotinine	Needs Printing
615171	278008	278008	S	BP	21	Lipids	Needs Printing
615171	278008	278008	S	BP	77	HPV Serum	Needs Printing
615171	278008	278008	S	BP	18	Biochem	Needs Printing
615171	278008	278008	S	BP	12	Vit B12/MMA	Needs Printing
615171	278008	278008	S	BP	22	HIV	Needs Printing
615171	278008	278008	S	BP	24	HSV	Needs Printing
615171	278008	278008	S	BP	127	IgA-TTG/EMA	Needs Printing
615171	278008	278008	S	BP	137	TST	Needs Printing
615171	278008	278008	S	BP	34	Xtra Sera3	Needs Printing
615171	278008	278008	S	BP	35	Xtra Sera4	Needs Printing
615171	278008	278008	S	BP	36	Xtra Sera5	Needs Printing
615171	278008	278008	S	BP	37	Xtra Sera6	Needs Printing

Status Legend  
Printed  
Needs Printing  
Session Changed (Reprint Needed)

### 9.3.11 Printing Individual Labels

To print a single or individual label, highlight the line you wish to be printed. Use the printer icon to print using the print options described in Sections 9.3.5 to 9.3.7.

train-05  
NHANES - Lab Vessel Printing Utility

Details Filter Information:  
(Stand ID: 61515)(Session Start Date: 9/12/2010)(Session End Date: 9/12/2010)(Session ID: 615171)(SP ID: 278008)

Session	SP	Sample	Type	Module	Vessel	Test Name	Status
615171	278008	278008	U	UP	46	Chlam	Needs Printing
615171	278008	278008	U	UP	48	Prior Pest	Needs Printing
615171	278008	278008	U	UP	49	Organophos	Needs Printing
615171	278008	278008	U	UP	121	NNAL	Needs Printing
615171	278008	278008	U	UP	128	Caffeine	Needs Printing
615171	278008	278008	U	UP	52	Xtra Urine1	Needs Printing
615171	278008	278008	U	UP	139	Xtra Urine2	Needs Printing
615171	278008	278008	W	BP	1	PbCadHgSeMn	Needs Printing
615171	278008	278008	W	BP	3	RBC Folate	Needs Printing
615171	278008	278008	W	BP	4	Glycohem	Needs Printing
615171	278008	278008	W	BP	5	Mercury	Needs Printing
615171	278008	278008	P	BP	91	Srm Pest	Needs Printing
615171	278008	278008	S	BP	70	Vit D/FA	Needs Printing
615171	278008	278008	S	BP	122	HAV	Needs Printing
615171	278008	278008	S	BP	17	Cotinine	Needs Printing
615171	278008	278008	S	BP	21	Lipids	Needs Printing
615171	278008	278008	S	BP	77	HPV Serum	Needs Printing
615171	278008	278008	S	BP	18	Biochem	Needs Printing
615171	278008	278008	S	BP	12	Vit B12/MMA	Needs Printing
615171	278008	278008	S	BP	22	HIV	Needs Printing
615171	278008	278008	S	BP	24	HSV	Needs Printing
615171	278008	278008	S	BP	127	IgA-TTG/EMA	Needs Printing
615171	278008	278008	S	BP	137	TST	Needs Printing
615171	278008	278008	S	BP	34	Xtra Sera3	Needs Printing
615171	278008	278008	S	BP	35	Xtra Sera4	Needs Printing
615171	278008	278008	S	BP	36	Xtra Sera5	Needs Printing
615171	278008	278008	S	BP	37	Xtra Sera6	Needs Printing

Status Legend  
Printed  
Needs Printing  
Session Changed (Reprint Needed)

### 9.3.12 Label Action

If an SP's profile has changed and the labels have already been printed, the SP will turn red on the heads-up display and display "Label Action Required" and blood processing won't be enabled until the label action is performed.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status									
							UC	U	P	OZ	CB	B	GTT	HPV	OR	
106777	106777	BE	P	M	63	HARRIS, ASHLEY F	<input type="radio"/>									
197633	197633	SC	P	M	7	CHO, GERALD	<input type="radio"/>									
248221	248221	CI	P	M	64	CHO, NAJ	<input type="radio"/>									
790990	790990	CI	P	F	7	GREEN, MACKENZIE H	<input type="radio"/>									
945336	945336	SC	P	F	80	CHANG, VI	<input type="radio"/>									

Open up the Lab printing application.

The session will be displayed in the tree in green, which indicates something needs to be printed. Click on the SP ID in the tree; the SP will also be displayed in green because labels will need to be printed and some will need to be discarded. Labels that need to be discarded are displayed in red.

**NHANES - Lab Vessel Printing Utility**

**Details Filter Information:**  
 (Stand ID: 61540)(Session Start Date: 10/9/2010)(Session End Date: 10/9/2010)(Session ID: 615440)(SP ID: 197633)

Session	SP	Sample	Type	Module	Vessel	Test Name	Status
615440	197633	197633	W	BP	3	RBC Folate	Printed
615440	197633	197633	W	BP	4	Glycohem	Discard Label
615440	197633	197633	W	BP	5	Mercury	Printed
615440	197633	197633	P	BP	9	Glucose	Discard Label
615440	197633	197633	S	BP	136	Se/Cu/Zn	Printed
615440	197633	197633	S	BP	70	Vit D/FA	Printed
615440	197633	197633	S	BP	122	HAV	Printed
615440	197633	197633	S	BP	17	Cotinine	Printed
615440	197633	197633	S	BP	21	Lipids	Printed
615440	197633	197633	S	BP	18	Biochem	Discard Label
615440	197633	197633	S	BP	23	Insulin	Discard Label
615440	197633	197633	S	BP	12	Vit B12/MMA	Discard Label
615440	197633	197633	S	BP	118	Thyroid	Discard Label
615440	197633	197633	S	BP	127	IgA-TTG/EMA	Printed
615440	197633	197633	S	BP	137	TST	Printed
615440	197633	197633	S	BP	110	Folate 1	Printed
615440	197633	197633	S	BP	32	Xtra Sera1	Needs Printing
615440	197633	197633	S	BP	33	Xtra Sera2	Needs Printing
615440	197633	197633	S	BP	34	Xtra Sera3	Discard Label
615440	197633	197633	S	BP	35	Xtra Sera4	Discard Label
615440	197633	197633	S	BP	36	Xtra Sera5	Discard Label
615440	197633	197633	S	BP	37	Xtra Sera6	Discard Label
615440	197633	197633	S	BP	29	Pers Pest1	Discard Label
615440	197633	197633	S	BP	89	Pers Pest2	Discard Label
615440	197633	197633	S	BP	90	Perfluor	Discard Label
615440	197633	197633	S	BP	92	BFR1	Discard Label
615440	197633	197633	S	BP	93	BFR2	Discard Label
615440	197633	197633	P	TT	98	OGTT	Discard Label
615440	197633	197633	C	OR	129	HPV Rinse	Discard Label

**Status Legend**  
 Printed  
 Needs Printing  
 Session Changed (Reprint Needed)  
 Retrieve from Shelf  
 Discard Label

Lab Vessel Printing Utility (Version: 1.5)

Start Lab Subsystem NHANES - Lab Vessel P... 3:30 PM

Click on the printer icon and print what is needed. Right click on a line that is displayed in red to mark label as discarded. Two options are available for discarding, either individually or all.

train-05  
NHANES - Lab Vessel Printing Utility

**Details Filter Information:**  
(Stand ID: 615)(Session Start Date: 10/9/2010)(Session End Date: 10/9/2010)(Session ID: 615440)(SP ID: 197633)

Session	SP	Sample	Type	Module	Vessel	Test Name	Status
615440	197633	197633	U	UP	45	Alb/Creat	Printed
615440	197633	197633	U	UP	86	Spc Arsenic	Printed
615440	197633	197633	U	UP	62	Urin Merc	Printed
615440	197633	197633	U	UP	50	Heavy Metal	Printed
615440	197633	197633	U	UP	66	PAH	Printed
615440	197633	197633	U	UP	67	Phthalates	Printed
615440	197633	197633	U	UP	102	Per/VOC/TCY	Printed
615440	197633	197633	U	UP	121	NNAL	Printed
615440	197633	197633	U	UP	52	Xtra Urine1	Printed
615440	197633	197633	U	UP	139	Xtra Urine2	Printed
615440	197633	197633	W	BP	1	PbCadHgSeMn	Printed
615440	197633	197633	W	BP	3	RBC Folate	Printed
615440	197633	197633	W	BP	4	Glycohem	Discard Label
615440	197633	197633	W	BP	5	Mercury	Printed
615440	197633	197633	W	BP	6	Glucose	Discard Label
615440	197633	197633	W	BP	7	Se/Cu/Zn	Printed
615440	197633	197633	W	BP	8	Vit D/FA	Printed
615440	197633	197633	W	BP	9	HAV	Printed
615440	197633	197633	S	BP	17	Cotinine	Printed
615440	197633	197633	S	BP	21	Lipids	Printed
615440	197633	197633	S	BP	18	Biochem	Discard Label
615440	197633	197633	S	BP	23	Insulin	Discard Label
615440	197633	197633	S	BP	12	Vit B12/MMA	Discard Label
615440	197633	197633	S	BP	118	Thyroid	Discard Label
615440	197633	197633	S	BP	127	IgA-TTG/EMA	Printed
615440	197633	197633	S	BP	137	TST	Printed
615440	197633	197633	S	BP	110	Folate 1	Printed

**Status Legend**  
Printed  
Needs Printing  
Session Changed (Reprint Needed)

Print  
Discard  
Discard All  
Retrieve Shelved Label  
Retrieve All Shelved Labels

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After completing the Label Action, return to heads-up display and allow the display to update before proceeding. After update, the SP will change from red to black and blood processing can be accessed.

train-05

Lab Subsystem: Stand:615 Session:615440 10/09/2010 08:30 am - 12:30 pm

File View Utilities Quality Control Reports Modules Shipping Window Help

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status									
							UC	U	P	OZ	CB	B	GTT	HPV	OR	
106777	106777	BE	P	M	63	HARRIS, ASHLEY F	<input type="radio"/>									
197633	197633	CI	P	M	7	CHO, GERALD	<input type="radio"/>									
248221	248221	CI	P	M	64	CHO, NANCY	<input type="radio"/>									
790990	790990	CI	P	F	7	GREEN, MACKENZIE H	<input type="radio"/>									
945336	945336	SC	P	F	80	CHANG, VI	<input type="radio"/>									

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## 9.4 Create New Container Labels

Store processed vessels and biological samples in boxes and bags (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.

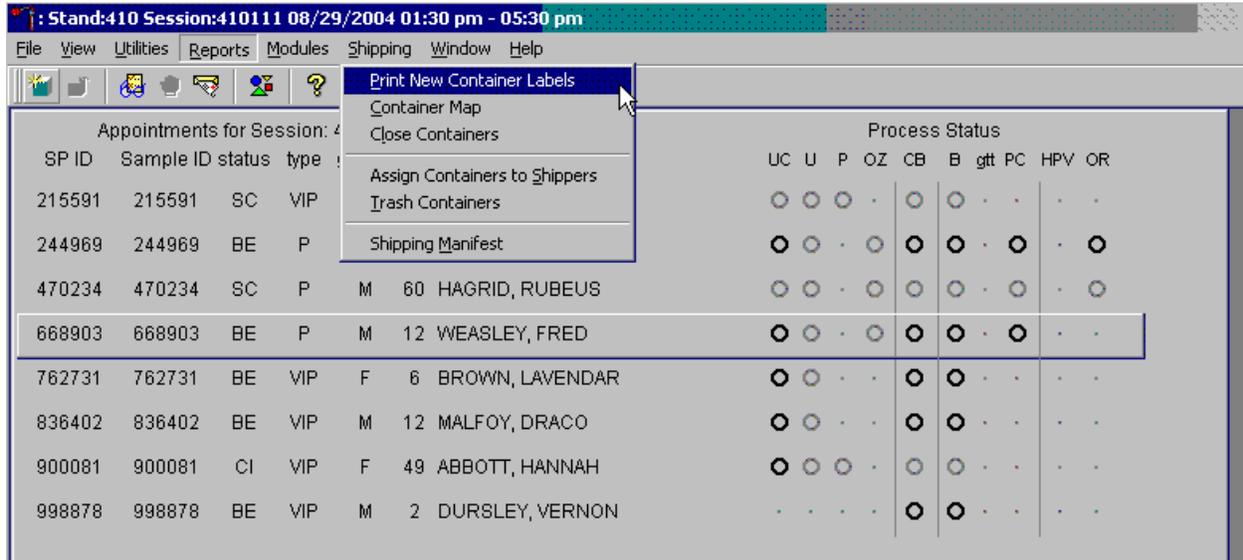
At the beginning of each stand, print and assign one new container ID for each vessel using either the {Print} module or the {Shipping} module. Print additional labels as needed. Each stand is allocated a maximum of 999 labels. The actual container label will include the vessel name, vessel ID, the size of the container (9x9 2-inch box, etc.), and the container number.

Chlam/GC (46)  
5x5 3 inch box  
  
410529

Prior Pest (48)  
5x5 3 inch box  
  
410530

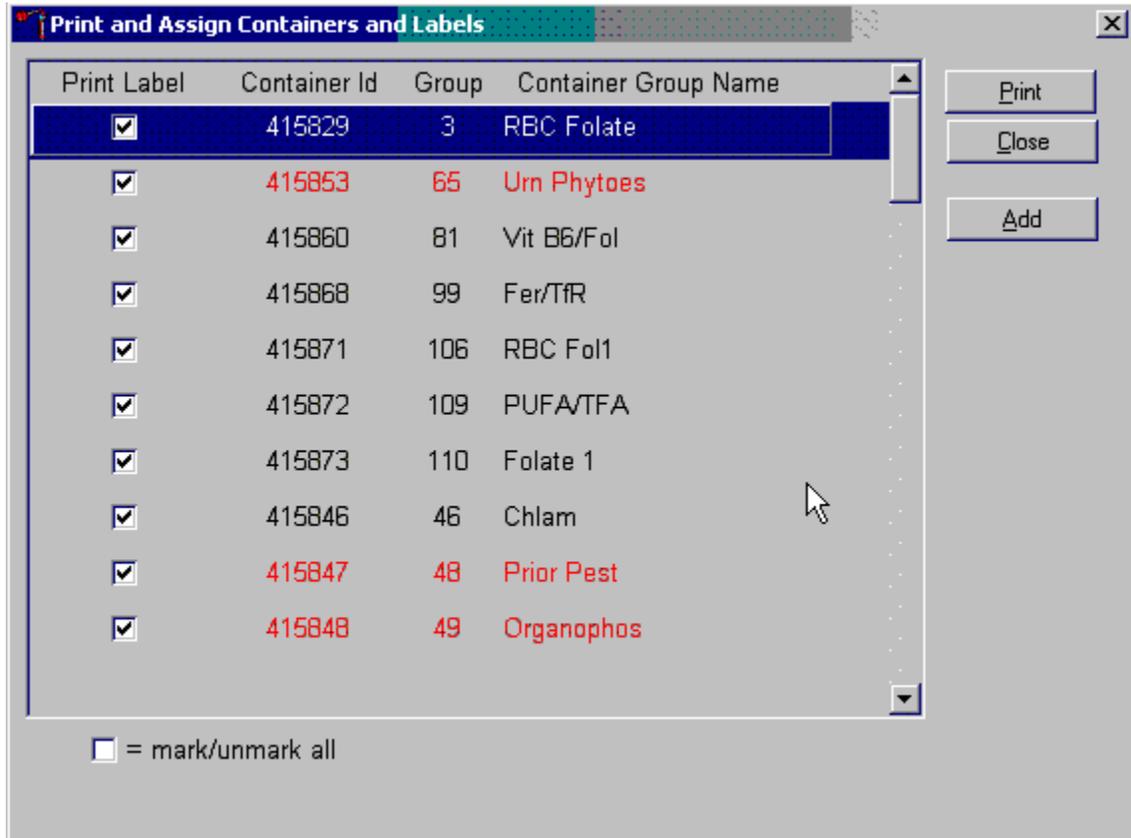
Use the shipping module within the laboratory application to print and assign new container ID numbers or labels.

Print and assign new container ID numbers using the {Shipping} module.



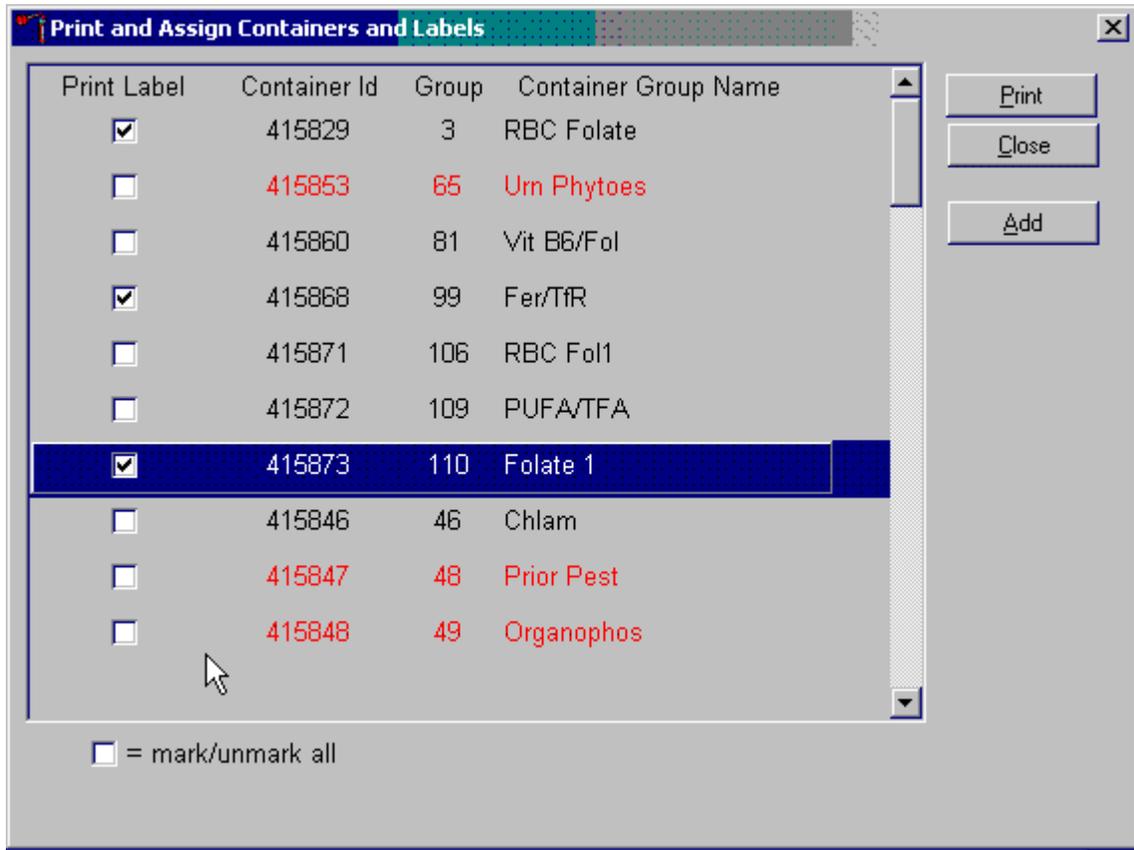
To access the {Print New Container Labels} module, use the mouse to direct the mouse arrow to {Shipping} in the menu bar and left click, drag the mouse arrow to {Print New Container Labels}, and left click or type [Alt] [S/s], [P/p].

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.



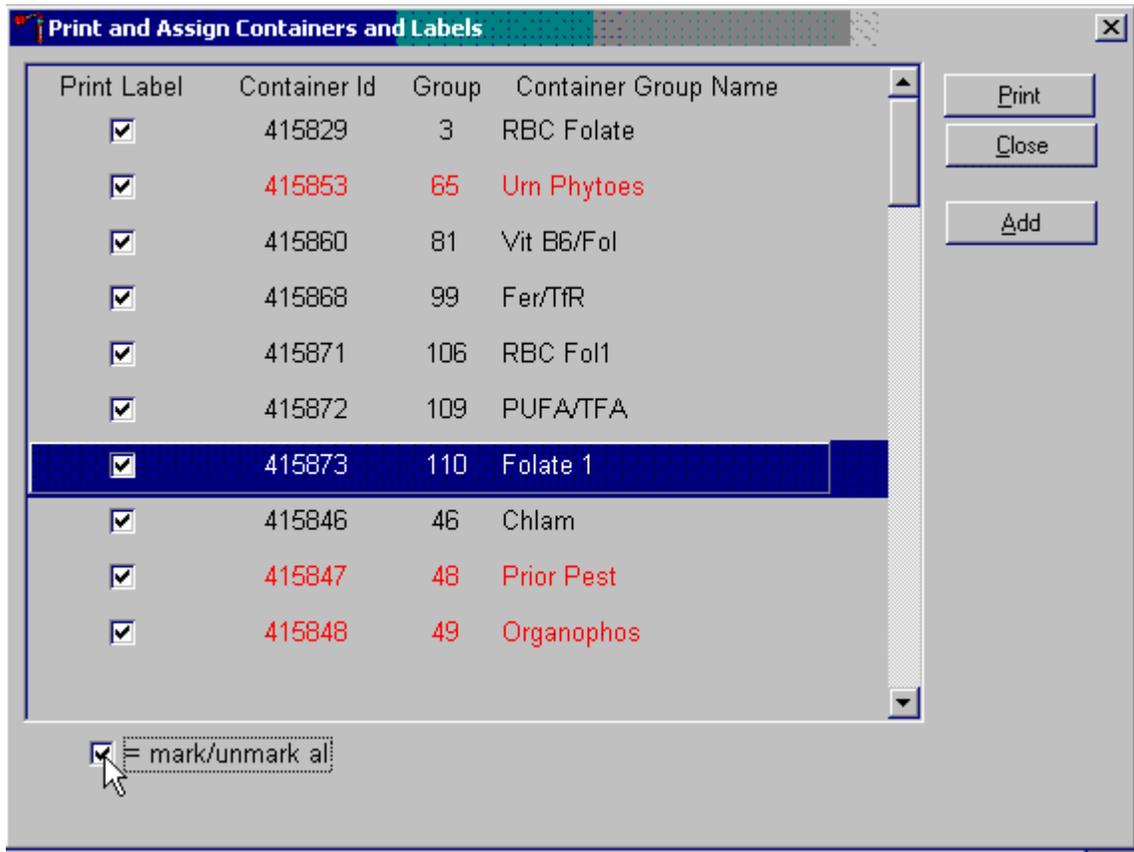
The Print and Assign Containers and Labels window displays once the {Print New Container} module is accessed. The window includes checkboxes to mark or identify specific groups, new Container Ids that are assigned to the Groups, the number of the Group, and the Container Group Name or vessel name. The 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.



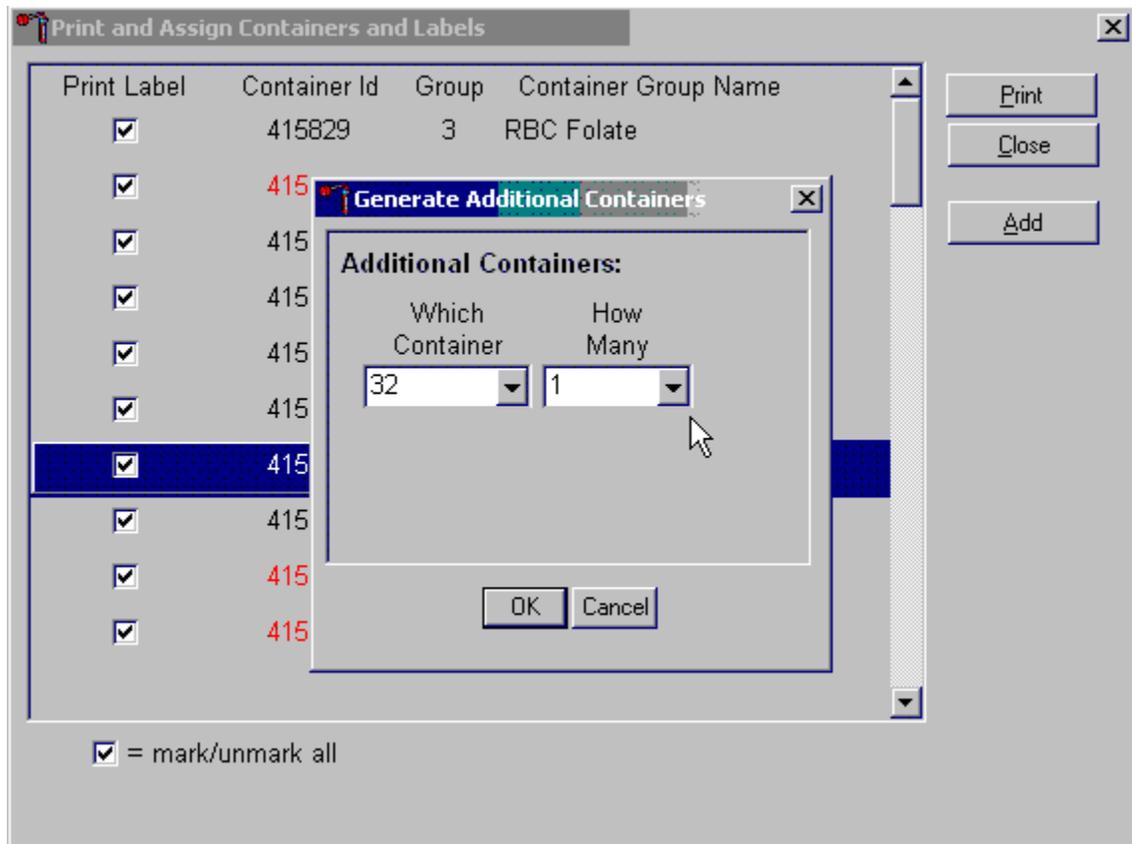
To begin the process of printing and assigning new Container IDs, mark the individual check boxes that correspond to the Group (vessel) of interest. To add a checkmark to the Print Label checkbox, use the mouse to direct the mouse arrow to the Print Label checkbox and left click.

Collectively mark all the Print Label checkboxes for all the Groups listed in the window.



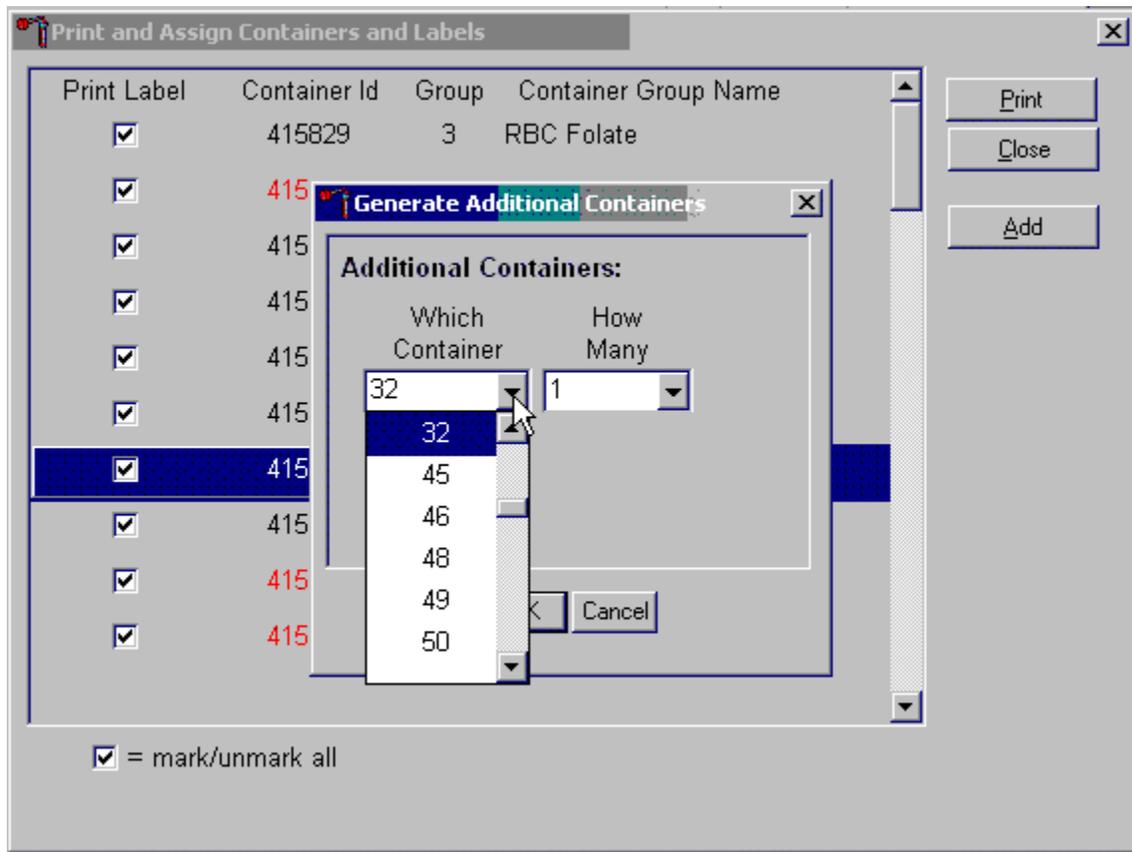
To collectively mark all the checkboxes, use the mouse to direct the mouse arrow to the mark/unmark all checkbox and left click. To collectively unmark all the checkboxes, use the mouse to direct the mouse arrow to the mark/unmark all checkboxes and left click.

Access the Generate Additional Containers window to print additional labels for any Group at any time.



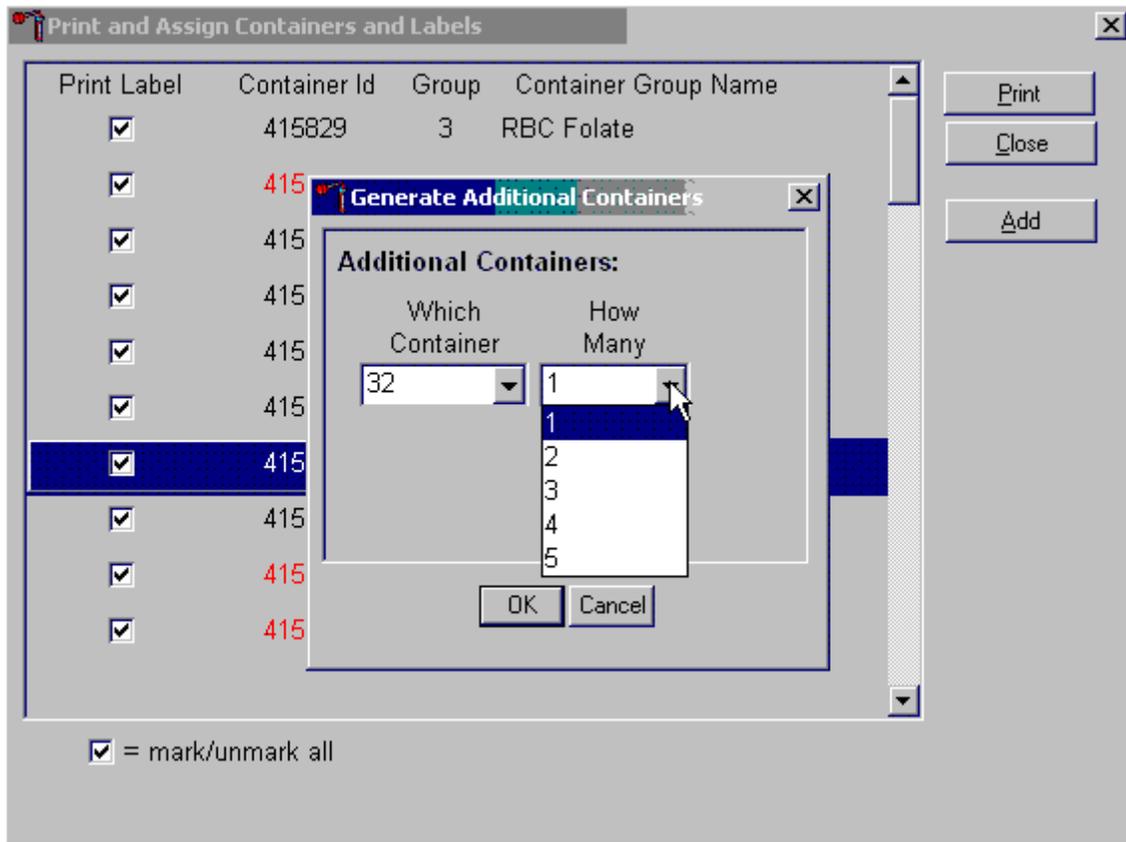
To access the Generate Additional Containers window, use the mouse to direct the mouse arrow to the "Add" button and left click, or type [Alt] [A].

The Generate Additional Containers window displays.



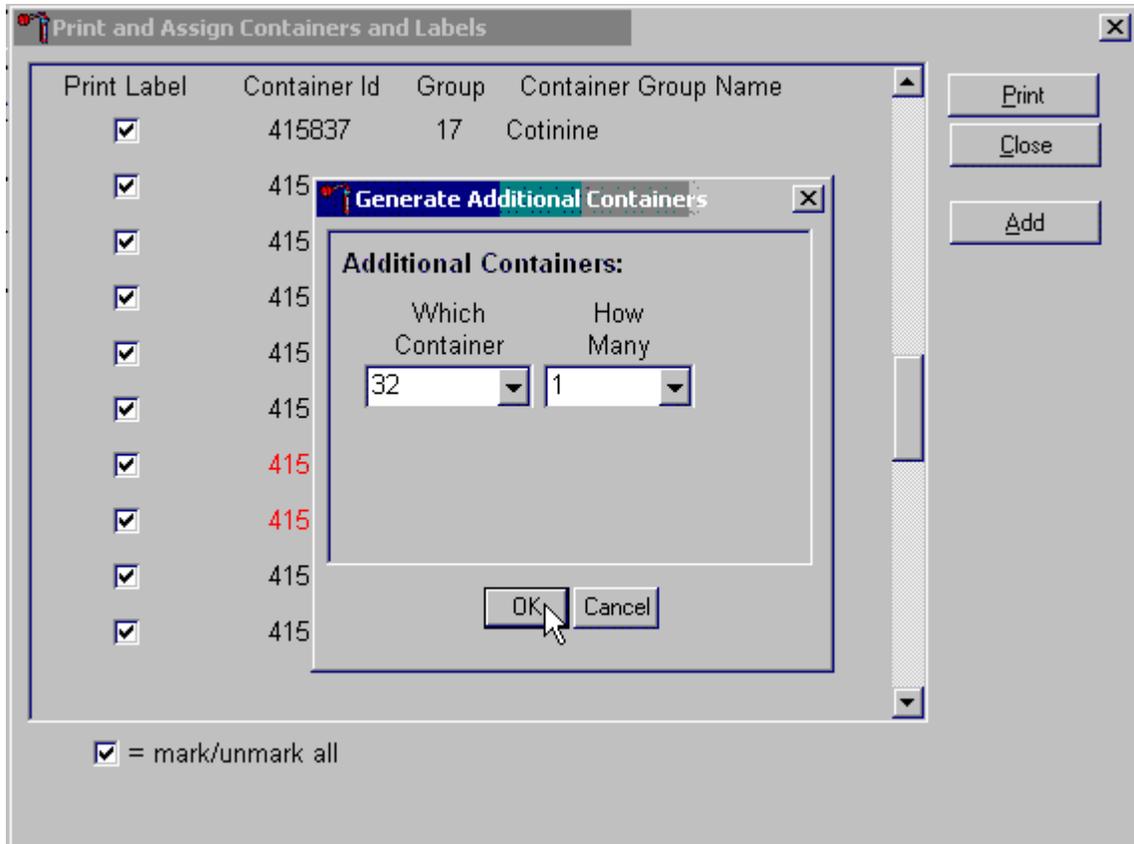
The Generate Additional Containers window includes two text boxes with drop-down lists: Which Container and How Many. The Which Container text box defaults to vessel 32. To select a vessel other than 32, use the mouse to direct the mouse arrow to the drop-down arrow and left click, drag the arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Select the number (1-5) of additional container labels.



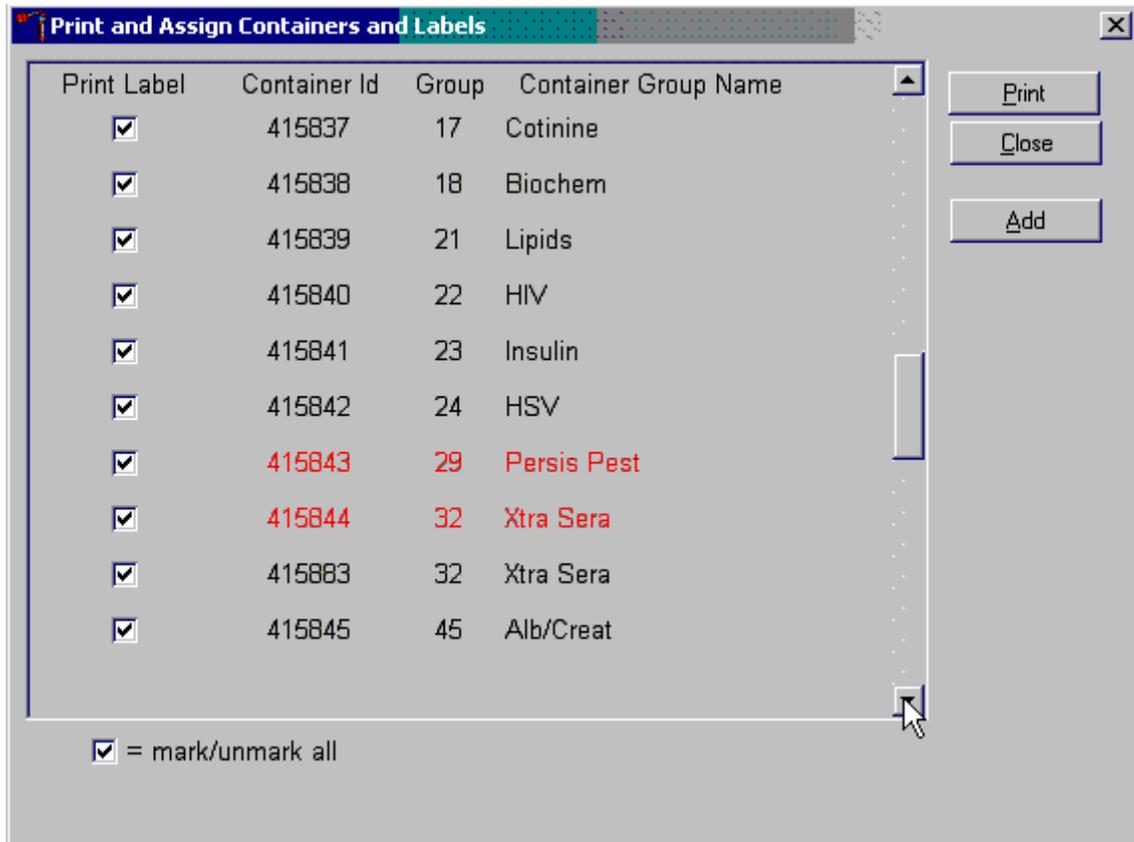
The How Many text box defaults to vessel 1. To select 2, 3, 4, or 5, use the mouse to direct the mouse arrow to the drop-down arrow and left click, then drag the arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Add these vessels to the Print and Assign Containers and Labels window or cancel the action.



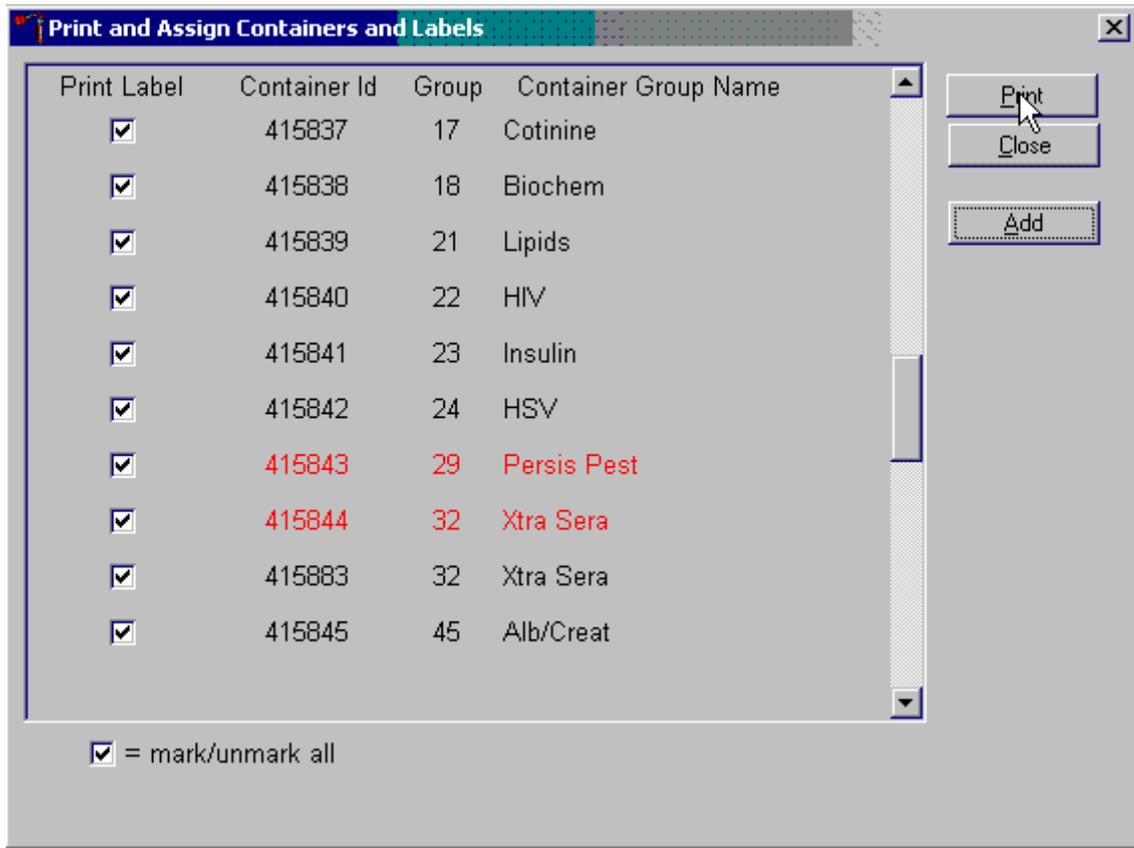
To accept the choices displayed in the Generate Additional Containers window, use the mouse to direct the mouse arrow to the “OK” button and left click or type [Enter]. To close the window without creating a new container, use the mouse to direct the mouse arrow to the “Cancel” button and left click.

If the “OK” button is selected, then the containers are added to the Print and Assign Containers and Labels window.



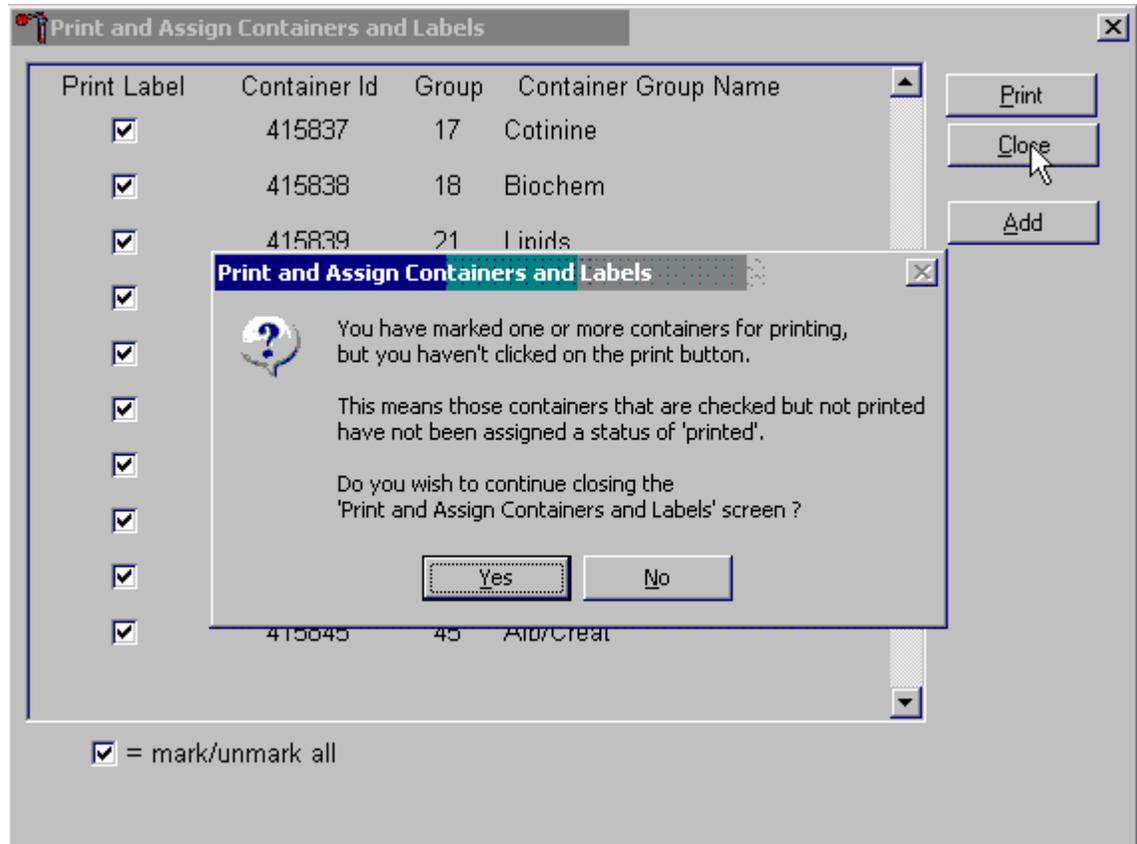
Review the information on the screen.

Complete the assignment process and print the labels.



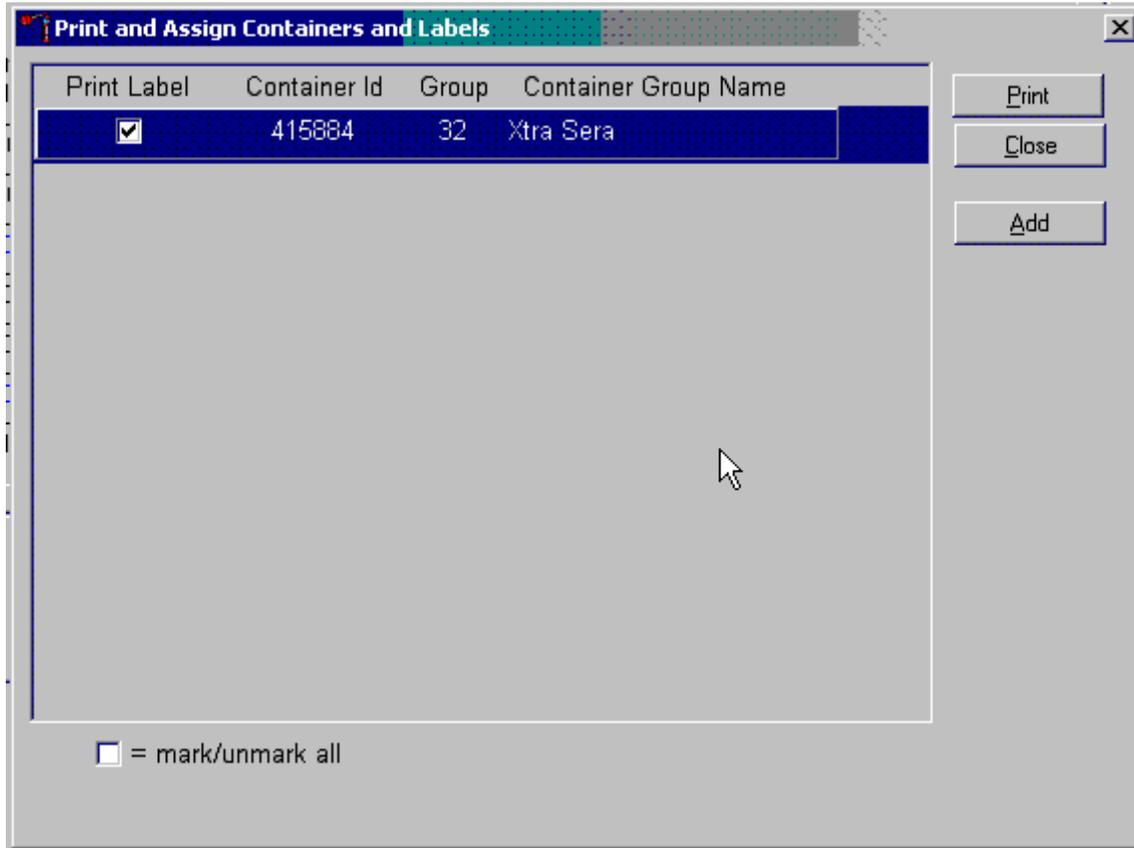
After reviewing the screen, print the labels. To print the labels, use the mouse to direct the mouse arrow to the “Print” button and left click, or type [Alt] [P/p]. To exit the window without printing any labels, use the mouse to direct the mouse arrow to the “Close” button and left click, or type [Alt] [C/c]. Affix the container ID label(s) to the container(s) of the correct type.

If the “Close” button is selected before the labels have been printed, then a Print and Assign Containers and Labels window displays.



Review the text. To close the Print and Assign Containers and Labels screen, select the “Yes” button. To return to the Print and Assign Containers and Labels screen, select the “No” button.

When a container is full, the container will automatically “close” and the Print and Assign Containers and Labels window opens with that vessel displayed and the checkmark prefilled. Alternatively, open a new container to replace the closed container by using the Print and Assign Containers and Labels window.

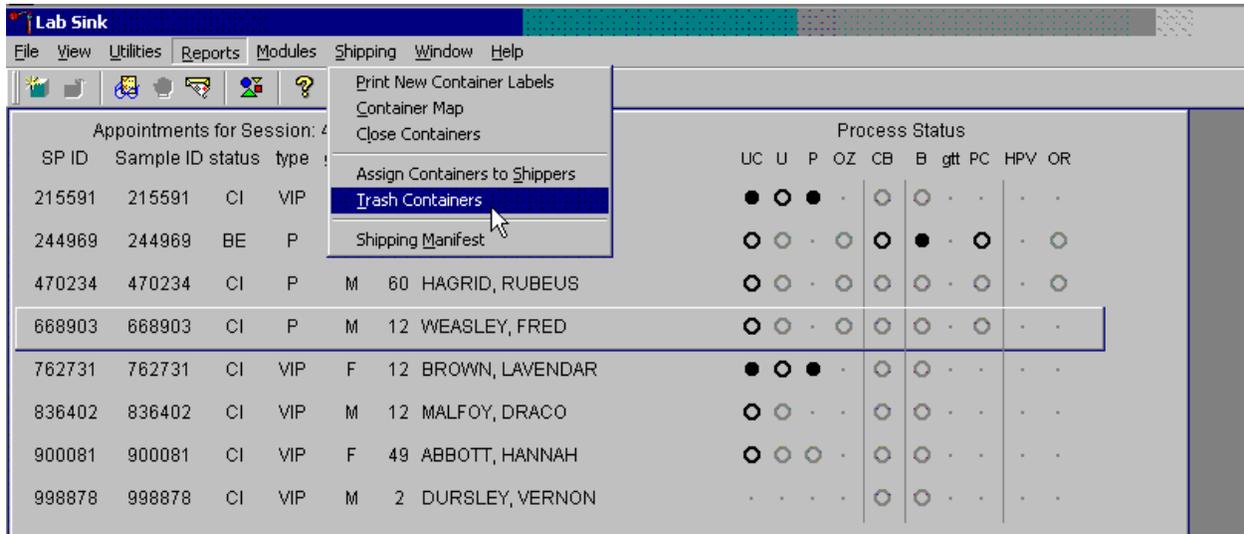


When a container is full, an opportunity to open a new container is automatically displayed on the “Print and Assign Container and Labels” window. Repeat the process of marking the checkbox and selecting the “Print” button.

## 9.5 Trash or Reprint Container Labels

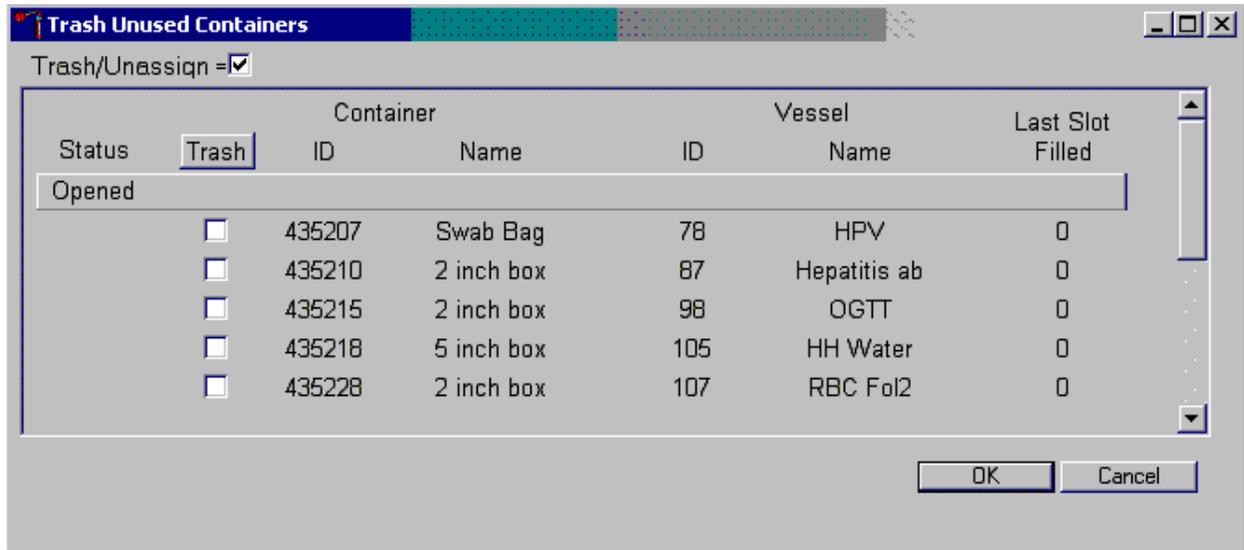
Each stand is allocated a maximum of 999 container IDs.

If unused container labels become lost or damaged, use the {Trash Containers} module to delete the container IDs. Access the {Trash Containers} module.



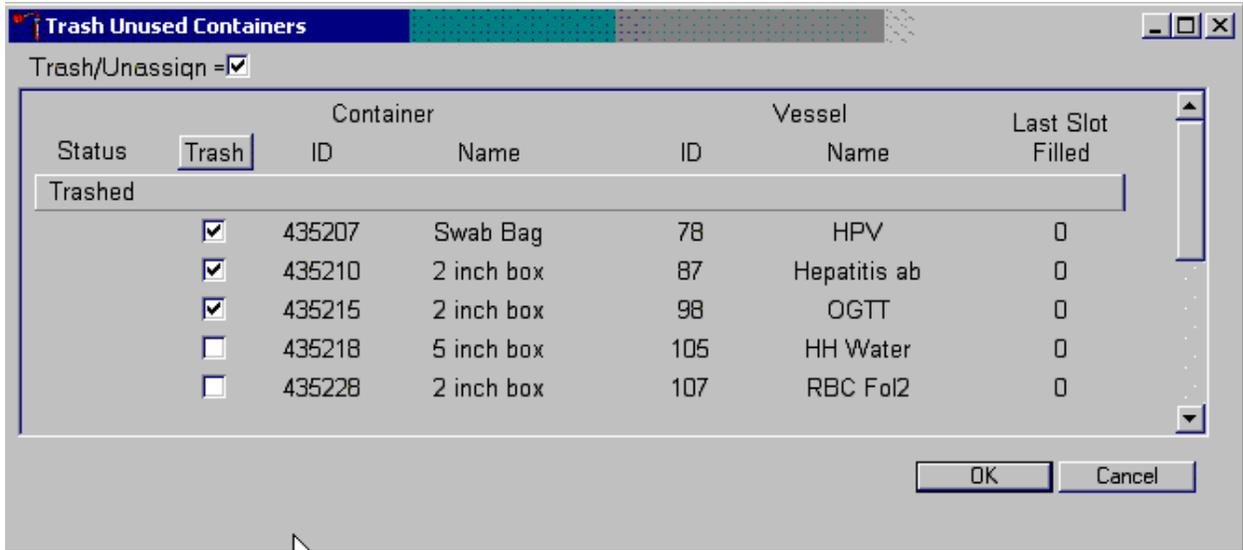
To access the {Trash Containers} module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Trash Containers}, and left click, or type [Alt] [S/s], [T/t].

The Trash Unused Containers window displays.



The status of each container ID is “Opened.” To individually mark the container IDs for deletion, use the mouse to direct the mouse arrow to the checkboxes 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. To collectively mark ALL containers, use the mouse to direct the mouse arrow to the Trash header and left click.

As the container IDs are marked for deletion, the status changes from “Opened” 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.

## 9.5.1 Reprint Container Labels for Existing Containers

Reprint labels for existing, not shipped containers.

### Reprinting Container Labels from the Container Map Screen

In the Container map screen, an option to reprint the container label has been added. Right click anywhere in the line of the container you wish to reprint the label, so it's highlighted, Click on the task "Reprint Label" and remove the label from the Dymo Printer.

The screenshot shows a software interface titled "Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm - [View Container Maps]". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The main area contains a table of containers with the following data:

Container Id	Size	Name	Vessel ID	Vessel Name	Last Filled	Priority
417013	5x5	5 inch box	119	cs	6	1
417024	9x9	2 inch box	1	Lead/Cad/HG	2	15
417025	10x10	2 inch box	3	RBC Folate	2	20
417026	9x9	2 inch box	4	Glycohem	2	30
417027	9x9	2 inch box	5	Mercury	2	35

Below the table, a detailed view for Container ID: 417013 is shown. It includes the following information:

- Type: 5 inch box
- Vessel ID: 119
- Test(s): Genetics

0	0	974475	974475	965340
965340	0	0	0	0
0	0	0	0	0
0	0	0	0	0
0	0	0	0	0

On the right side of the interface, there are two filter sections:

- Filter on Container:** with radio buttons for  Opened and  Closed.
- Show Container By:** with radio buttons for  Slot Number,  Sample ID, and  Household ID.

## 9.6 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 by FedEx priority overnight.

FedEx Priority Overnight guarantees next-business-day delivery by 10:30 a.m. to most U.S. addresses and by noon, 4:30 p.m., or 5 p.m. in remote areas. 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 a medium shipper for all international shipments.
- 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 (air bills) 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, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return air bills, 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 air bill 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 the warehouse.

## **9.7 Create Air Bills using FedEx Ship Manager**

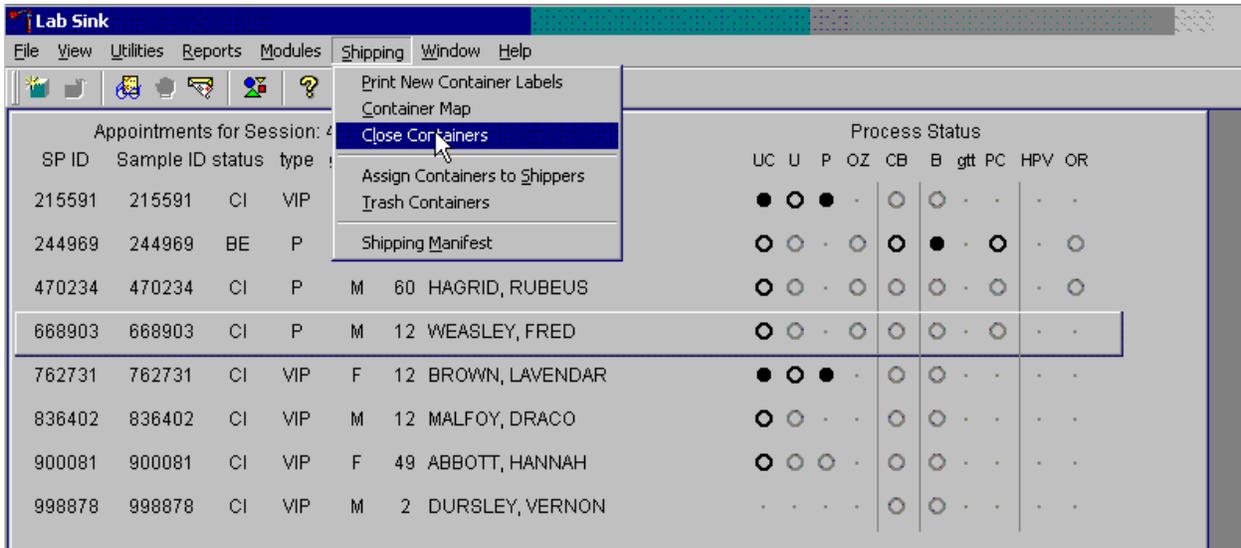
Create air bills using the Ship Manager application at FedEx.com. Each physical stand location will be designated as a department in the system. The department is set up by home office staff. The name of the department shows up as the department designation in all of the screens within Ship Manager. The department designation is “stand####” where #### is the stand number. The default point of contact for the department is Renee Storandt. The department address is the address of the MEC for the stand the department represents. The service option for the department has been restricted to FedEx Priority Overnight and FedEx Standard 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 “mecxxx” where xxx is the stand number.

Access the FedEx web site using Explorer and logon to the application. Create one air bill for each domestic shipment. Print the air bill, fold it in half, and insert it into a FedEx pouch. Attach the pouch to the shipper.

## 9.8 Close Containers

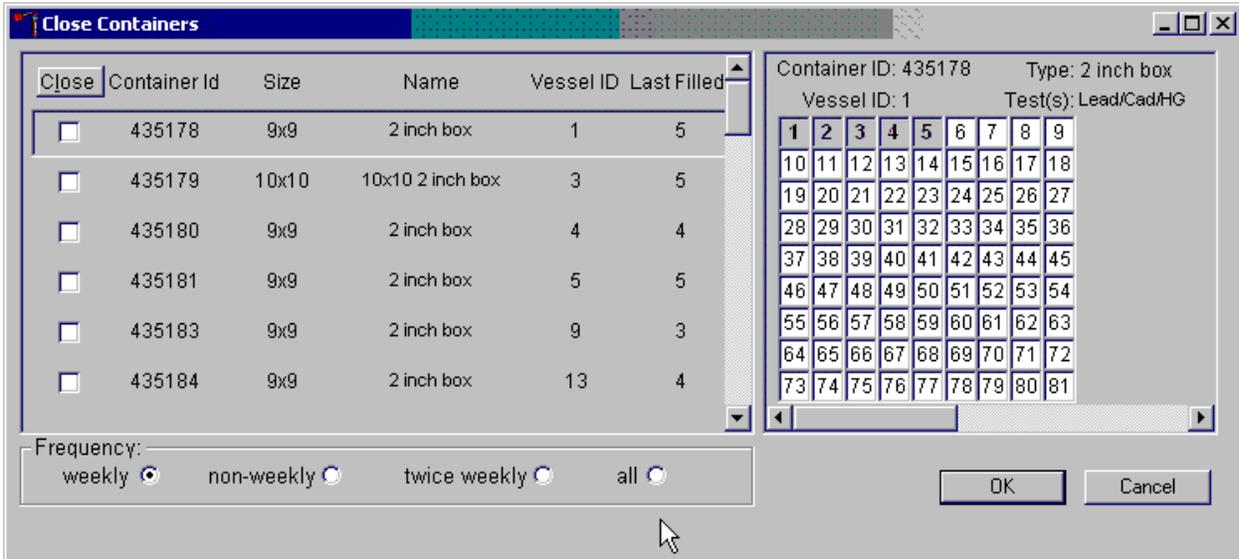
After a container is full, it is automatically closed. All open containers must be virtually and manually closed before shipping.

Access the {Close Containers} module.



To access the {Close Containers} module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the mouse arrow to {Close Containers}, and left click, or type [Alt] [S/s], [L/I].

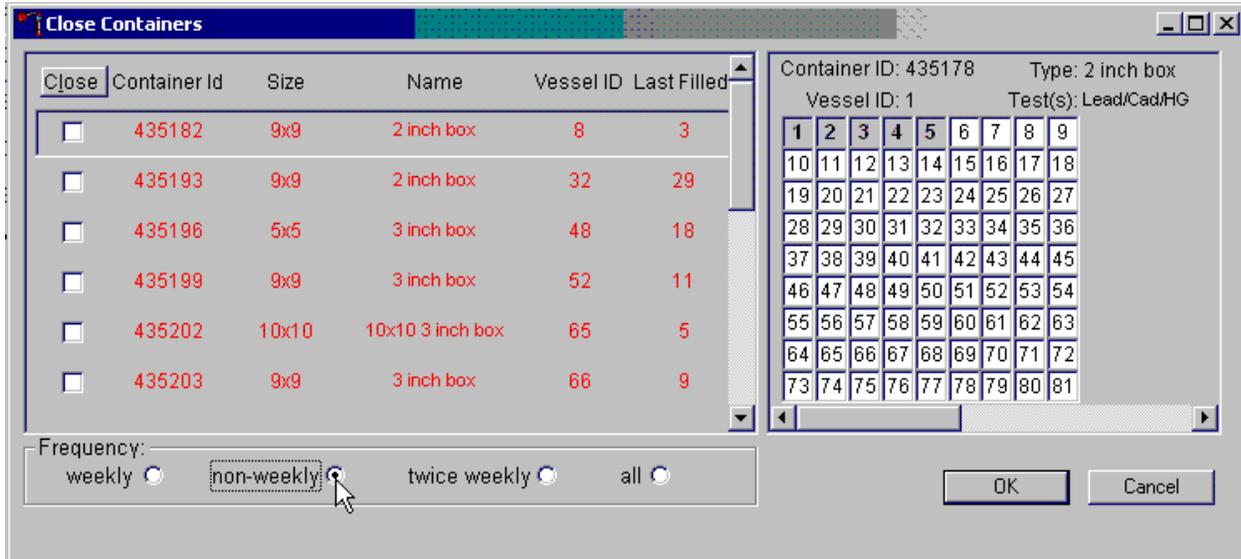
Individually close open containers or collectively close all open containers.



The left side of the Close Containers screen includes a checkbox 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.

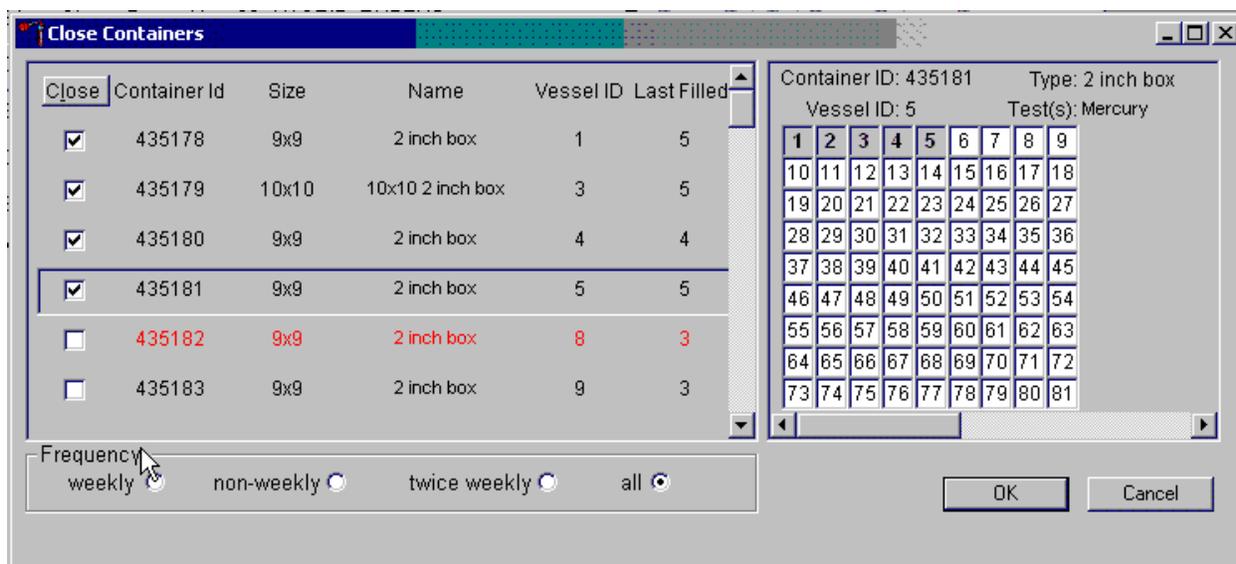
To move up and down the list, use the up and down keyboard arrows or use the mouse to direct the mouse arrow to any individual line. Use the vertical scroll bar to view all containers. To sort the lines by Container ID, Size, Name, Vessel ID or Last Filled, use the mouse to direct the mouse arrow to 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 four 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.



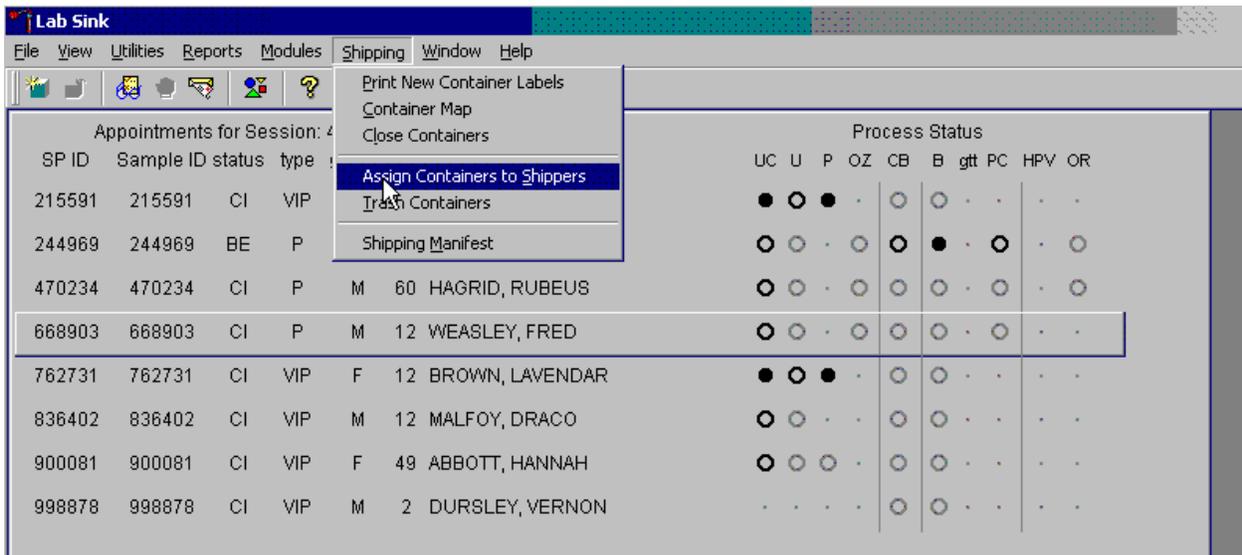
To mark individual containers, use the mouse to direct the mouse arrow to individual “Close” button checkboxes and left click. To close all open containers, use the mouse to direct the mouse arrow to the “Close” button and left click. To remove the checkmarks, use the mouse to direct the mouse arrow 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.

## 9.9 Assign Containers to Shippers

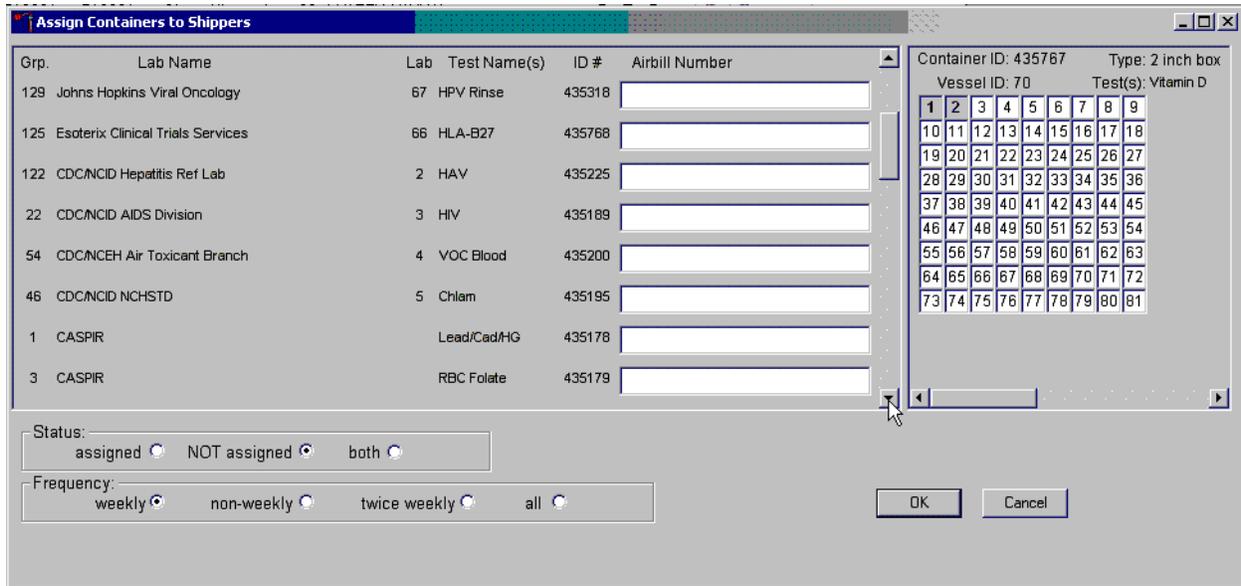
Assign closed containers to or associate closed containers with a specific air bill. To associate a specific closed container to the air bill for that laboratory, use the {Assign Container to Shippers} module.

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 Air bill 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,” “twice weekly,” and “all.” 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 air bill number into each Air bill Number text box. There are three ways to enter the air bill number.

- Use the barcode gun to scan the barcode from the FedEx Ship Manager air bill. The barcode is located in the bottom of the top half of the folded air bill. It is the tallest on the air bill. 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 barcode. Once the gun successfully scans the barcode, an audible beep is emitted.
- Use the barcode gun to scan the barcode on the second page (Recipient's Copy) of the two-part Form ID 0215. This barcode 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 barcode. Once the gun successfully scans the barcode, an audible beep is emitted.
- Use the keyboard keys to type the air bill number from either the FedEx Ship Manager air bill or the FedEx air bill form 0215.

To assign a container to the corresponding air bill:

- 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.

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
129	Johns Hopkins Viral Oncology	67	HPV Rinse	435318	<input type="text"/>
125	Esoterix Clinical Trials Services	66	HLA-B27	435768	<input type="text"/>
122	CDC/NCID Hepatitis Ref Lab	2	HAV	435225	<input type="text"/>
22	CDC/NCID AIDS Division	3	HIV	435189	<input type="text"/>
54	CDC/NCEH Air Toxicant Branch	4	VOC Blood	435200	<input type="text"/>
46	CDC/NCID NCHSTD	5	Chlam	435195	<input type="text"/>
1	CASPIR		Lead/Cad/HG	435178	<input type="text"/>
3	CASPIR		RBC Folate	435179	<input type="text"/>

Container ID: 435767    Type: 2 inch box  
Vessel ID: 70    Test(s): Vitamin D

1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18
19	20	21	22	23	24	25	26	27
28	29	30	31	32	33	34	35	36
37	38	39	40	41	42	43	44	45
46	47	48	49	50	51	52	53	54
55	56	57	58	59	60	61	62	63
64	65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80	81

Status:  
 assigned     NOT assigned     both

Frequency:  
 weekly     non-weekly     twice weekly     all

OK    Cancel

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, twice weekly, or all, and left click.

Sort the rows by Lab Name.

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
70	CASPIR		Vitamin D	435767	
126	CASPIR		PAH HB	435769	
1	CASPIR		Lead/Cad/HG	435178	
3	CASPIR		RBC Folate	435179	
106	CASPIR		RBC Foli	435219	
5	CASPIR		Mercury	435181	
109	CASPIR		PUFA/TFFA	435220	
88	CASPIR		Acrylamide	435211	

Container ID: 435767		Type: 2 inch box						
Vessel ID: 70		Test(s): Vitamin D						
1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18
19	20	21	22	23	24	25	26	27
28	29	30	31	32	33	34	35	36
37	38	39	40	41	42	43	44	45
46	47	48	49	50	51	52	53	54
55	56	57	58	59	60	61	62	63
64	65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80	81

Status: assigned  NOT assigned  both

Frequency: weekly  non-weekly  twice weekly  all

OK Cancel

To sort the rows by lab Name, use the mouse to direct the mouse arrow to the top header “Lab Name” and left click. All containers associated with a specific lab will be grouped together in ascending order.

Enter the air bill number into the Airbill Number text box.

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
70	CASPIR	Vitamin D	435767	79564329876587466789098767656787	
126	CASPIR	PAH HB	435769		
1	CASPIR	Lead/Cad/HG	435178		
3	CASPIR	RBC Folate	435179		
106	CASPIR	RBC Folt	435219		
5	CASPIR	Mercury	435181		
109	CASPIR	PUFA/TFA	435220		
88	CASPIR	Acrylamide	435211		

Status: assigned  NOT assigned  both

Frequency: weekly  non-weekly  twice weekly  all

Container ID: 435767 Type: 2 inch box  
Vessel ID: 70 Test(s): Vitamin D

1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18
19	20	21	22	23	24	25	26	27
28	29	30	31	32	33	34	35	36
37	38	39	40	41	42	43	44	45
46	47	48	49	50	51	52	53	54
55	56	57	58	59	60	61	62	63
64	65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80	81

Place the cursor in the first Airbill Number text box. Use the barcode gun to scan the air bill number. The scanned number contains 20 extra digits. The actual 12-digit air bill 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 air bill number to delete the extra numbers.

Continue the assignment process.

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
22	CDC/NCID AIDS Division	3	HIV	435189	796170389796
16	CDC/NCID DASH	64	MMRV	435766	796170389754
14	CDC/NCID Hepatitis Ref Lab	2	Hep Profile	435185	796170388765
122	CDC/NCID Hepatitis Ref Lab	2	HAV	435225	796179388765
46	CDC/NCID NCHSTD	5	Chlam	435195	796170378790
18	Collaborative Laboratory Services	40	Biochem	435187	
24	Emory University	9	HSV	435191	
125	Esoterix Clinical Trials Services	66	HLA-B27	435768	

Container ID: 435187    Type: 2 inch box  
Vessel ID: 18    Test(s): Biochem

1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18
19	20	21	22	23	24	25	26	27
28	29	30	31	32	33	34	35	36
37	38	39	40	41	42	43	44	45
46	47	48	49	50	51	52	53	54
55	56	57	58	59	60	61	62	63
64	65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80	81

Status: assigned  NOT assigned  both

Frequency: weekly  non-weekly  twice weekly  all

OK Cancel

Continue scanning the barcodes and selecting the [Tab] key until all closed containers are assigned to air bills.

Complete the assignment process.

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
22	CDC/NCID AIDS Division	3	HIV	435189	796170389796
16	CDC/NCID DASH	64	MMRV	435766	796170389754
14	CDC/NCID Hepatitis Ref Lab	2	Hep Profile	435185	796170388765
122	CDC/NCID Hepatitis Ref Lab	2	HAV	435225	796179388765
46	CDC/NCID NCHSTD	5	Chlam	435195	796170378790
18	Collaborative Laboratory Services	40	Biochem	435187	796170654345
24	Emory University	9	HSV	435191	796179656765
125	Esoterix Clinical Trials Services	66	HLA-B27	435768	796179097545

Status: assigned  NOT assigned  both

Frequency: weekly  non-weekly  twice weekly  all

Container ID: 435768 Type: 2 inch box  
Vessel ID: 125 Test(s): HLA-B27

1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18
19	20	21	22	23	24	25	26	27
28	29	30	31	32	33	34	35	36
37	38	39	40	41	42	43	44	45
46	47	48	49	50	51	52	53	54
55	56	57	58	59	60	61	62	63
64	65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80	81

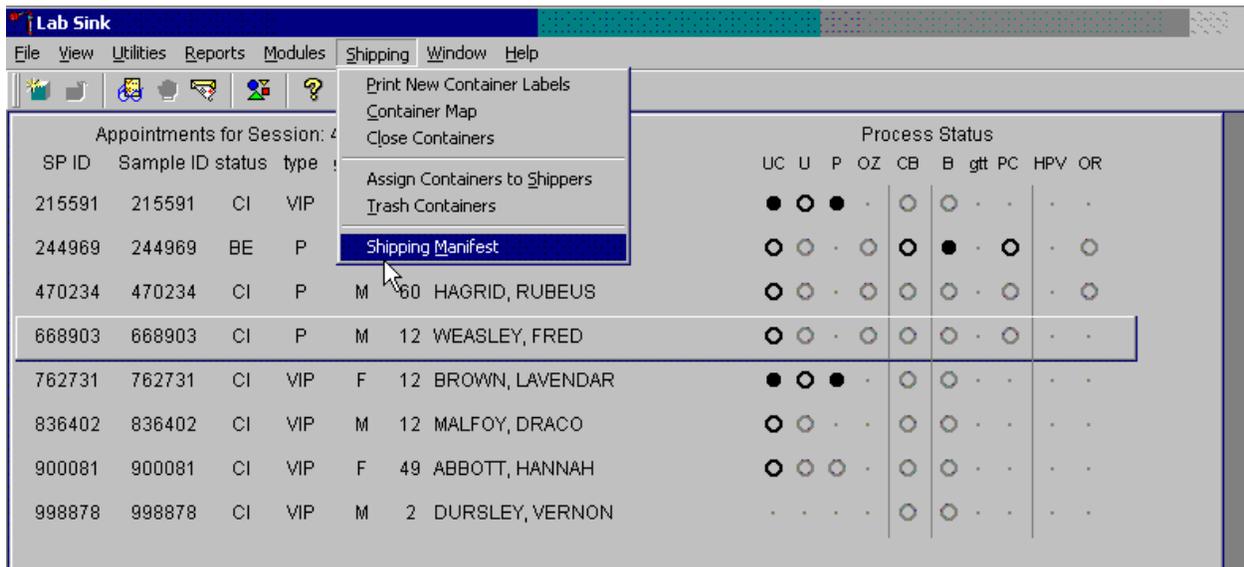
OK Cancel

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.

## 9.10 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 Shipping 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 screenshot shows a software window titled "Shipping Manifest". At the top, there is a "Filter:" section with two radio buttons: "Unprocessed" (selected) and "Previously Processed". Below this is a table with columns: "Mark for Processing", "Airbill Number", "Shipment Date", and "Ship to Lab". There are three rows of data, each with a checkbox in the "Mark for Processing" column. To the right of the table are "Process" and "Close" buttons. Below the table is a legend: "[ ] = mark/unmark all".

The lower portion of the window contains a header section with the following text:

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Health and Nutrition Examination Survey  
National Center for Health Statistics  
3311 Toledo Road, Rm 4323  
Hyattsville, Maryland 20782

**Shipping Manifest Report**

Shipment ID: 796170388765      Survey Year: 2007  
Shipment Date: 12/11/2008

Lab Name: CDC/NCID Hepatitis Ref Lab      Lab ID: 2  
Address: 1600 Clifton Road      Contact: Annemarie Wasley  
Bldg 18 Floor 3 Rm 218 MS A33      Phone: (404)639-3103  
Atlanta, GA 30329      E-Mail:

Container Id: 435185	Size: 9x9	Type: 2 inch box	Test(s):	Hep Profile
Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKWVS	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

The upper portion of the Shipping Manifest Report contains two filters (Unprocessed and Previously Processed) and one row for each air bill assigned in the {Assign Container to Shipper} module. The row includes a Mark for Processing checkbox, the Airbill Number, Shipment Date, and Ship to Lab ID, and one checkbox to mark or unmark all air bills.

The lower portion of the window includes the Shipment ID or air bill number, Shipment Date, Lab Name, Lab ID number, Address, Contact personnel, Survey Year, Container ID 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.

Select one of the filters.

Filter:  Unprocessed  Previously Processed

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input type="checkbox"/>	796179388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input type="checkbox"/>	796170389796	12/11/2008	CDC/NCID AIDS Division (3)

☐ = mark/unmark all

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Health and Nutrition Examination Survey  
National Center for Health Statistics  
3311 Toledo Road, Rm 4323  
Hyattsville, Maryland 20782

**Shipping Manifest Report**

Shipment ID: 796170388765      Survey Year: 2007  
Shipment Date: 12/11/2008

Lab Name: CDC/NCID Hepatitis Ref Lab      Lab ID: 2

Address: 1600 Clifton Road  
Bldg 18 Floor 3 Rm 218 MS A33  
Atlanta, GA 30329      Contact: Annemarie Wasley  
Phone: (404)639-3103  
E-Mail:

Container Id: 435185	Size: 9x9	Type: 2 inch box	Test(s):	Hep Profile
Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKWVS	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

Set the filter to “Unprocessed” to print manifests and generate email files for shipments created but not previously processed using this module. Set the filter to “Previously Processed” to reprint an air bill or to recreate an electronic file for shipments previously processed using this module. To filter on unprocessed air bills, use the mouse to direct the mouse arrow to the “Unprocessed” radio button and left click. To filter on previously processed air bills, use the mouse to direct the mouse arrow to the “Previously Processed” radio button and left click.

Select one or more manifests by placing a checkmark in the Mark for Processing check boxes.

Filter:  Unprocessed  Previously Processed

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input checked="" type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796179388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input type="checkbox"/>	796170389796	12/11/2008	CDC/NCID AIDS Division (3)

= mark/unmark all

**Shipping Manifest Report**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Health and Nutrition Examination Survey  
National Center for Health Statistics  
3311 Toledo Road, Rm 4323  
Hyattsville, Maryland 20782

Shipment ID: 796170388765      Survey Year: 2007  
Shipment Date: 12/11/2008

Lab Name: CDC/NCID Hepatitis Ref Lab      Lab ID: 2

Address: 1600 Clifton Road  
Bldg 18 Floor 3 Rm 218 MS A33  
Atlanta, GA 30329      Contact: Annemarie Wasley  
Phone: (404)639-3103  
E-Mail:

Container Id	Size	Type	Test(s)
435185	9x9	2 inch box	Hep Profile

Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKVVS	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

To select or mark one manifest for printing and email, use the mouse to direct the mouse arrow to the checkbox and left click. Repeat this process to include other air bills. Use the scroll bar to display all existing air bills. The lower portion of the window updates to display only marked air bills.

Collectively mark or unmark all the air bills.

Filter:  Unprocessed  Previously Processed

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input checked="" type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796179388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796170389796	12/11/2008	CDC/NCID AIDS Division (3)

mark/unmark all

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
National Health and Nutrition Examination Survey

Centers for Disease Control and Prevention  
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3311 Toledo Road, Rm 4323  
Hyattsville, Maryland 20782

### Shipping Manifest Report

Shipment ID: 796170388765      Survey Year: 2007  
Shipment Date: 12/11/2008

Lab Name: CDC/NCID Hepatitis Ref Lab      Lab ID: 2

Address: 1600 Clifton Road  
Bldg 18 Floor 3 Rm 218 MS A33  
Atlanta, GA 30329

Contact: Annemarie Wasley  
Phone: (404)639-3103  
E-Mail:

Container Id: 435185	Size: 9x9	Type: 2 inch box	Test(s):	Hep Profile
Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKWVS	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

To collectively mark all the air bills, use the mouse to direct the mouse arrow to the mark/unmark all checkbox and left click. To collectively unmark all the air bills, 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 air bills.

The right side of the window includes two buttons: Process and Close. Process the shipping manifests using the “Process” button.

Filter:  Unprocessed  Previously Processed

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input checked="" type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796179388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796170389796	12/11/2008	CDC/NCID AIDS Division (3)

mark/unmark all

**Shipping Manifest Report**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Health and Nutrition Examination Survey  
National Center for Health Statistics  
3311 Toledo Road, Rm 4323  
Hyattsville, Maryland 20782

Shipment ID: 796170388765      Survey Year: 2007  
Shipment Date: 12/11/2008

Lab Name: CDC/NCID Hepatitis Ref Lab      Lab ID: 2

Address: 1600 Clifton Road  
Bldg 18 Floor 3 Rm 218 MS A33  
Atlanta, GA 30329

Contact: Annemarie Wasley  
Phone: (404)639-3103  
E-Mail:

Container Id: 435185	Size: 9x9	Type: 2 inch box	Test(s):	Hep Profile
Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKWVS	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

Selecting the “Process” button will generate and print the Shipping Manifest Report(s). To print the manifests 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 use the mouse to direct the mouse arrow to the “Close” button and left click, or type [Shift] [C/c.]

## 9.11 Informed Consent Exclusions

The Informed Consent Exclusions window displays either when the {Close Container} or {Shipping Manifest} module is accessed. It displays when the following conditions have been met:

1. SPs initially signed their consent form thereby agreeing to have their samples tested for HIV, HPV, PSA, STD testing; and/or genetics;
2. They consent to have their vessels stored for future research; and
3. They subsequently revoke either consent; and
4. The associated vessels have already been processed.

**Informed Consent Exclusion Detected!**

step 1 - physically remove the following vessels from their associated containers as identified below.  
step 2 - mark the vessel below as removed and press okay to save your entries.

Container ID: 435199 Xtra Urine

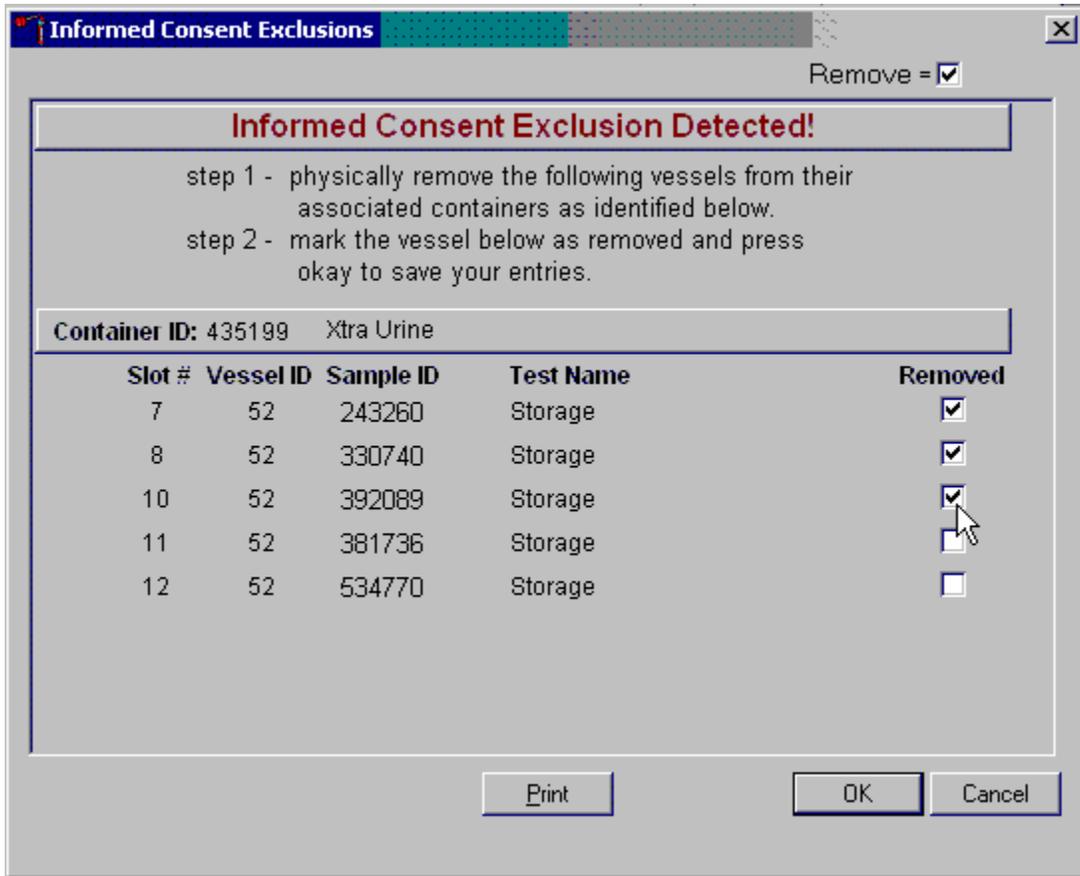
Slot #	Vessel ID	Sample ID	Test Name	Removed
7	52	243260	Storage	<input type="checkbox"/>
8	52	330740	Storage	<input type="checkbox"/>
10	52	392089	Storage	<input type="checkbox"/>
11	52	381736	Storage	<input type="checkbox"/>
12	52	534770	Storage	<input type="checkbox"/>

Print OK Cancel

The window contains two steps that must be taken in order to resolve the inconsistencies. It includes the specific container ID and slot number within the container where the vessels are located, the sample ID, and the test name. Each row represents a vessel that must be marked as removed by placing a checkmark in the checkbox. A “Print” button on the bottom of the screen allows the list to be printed.

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.



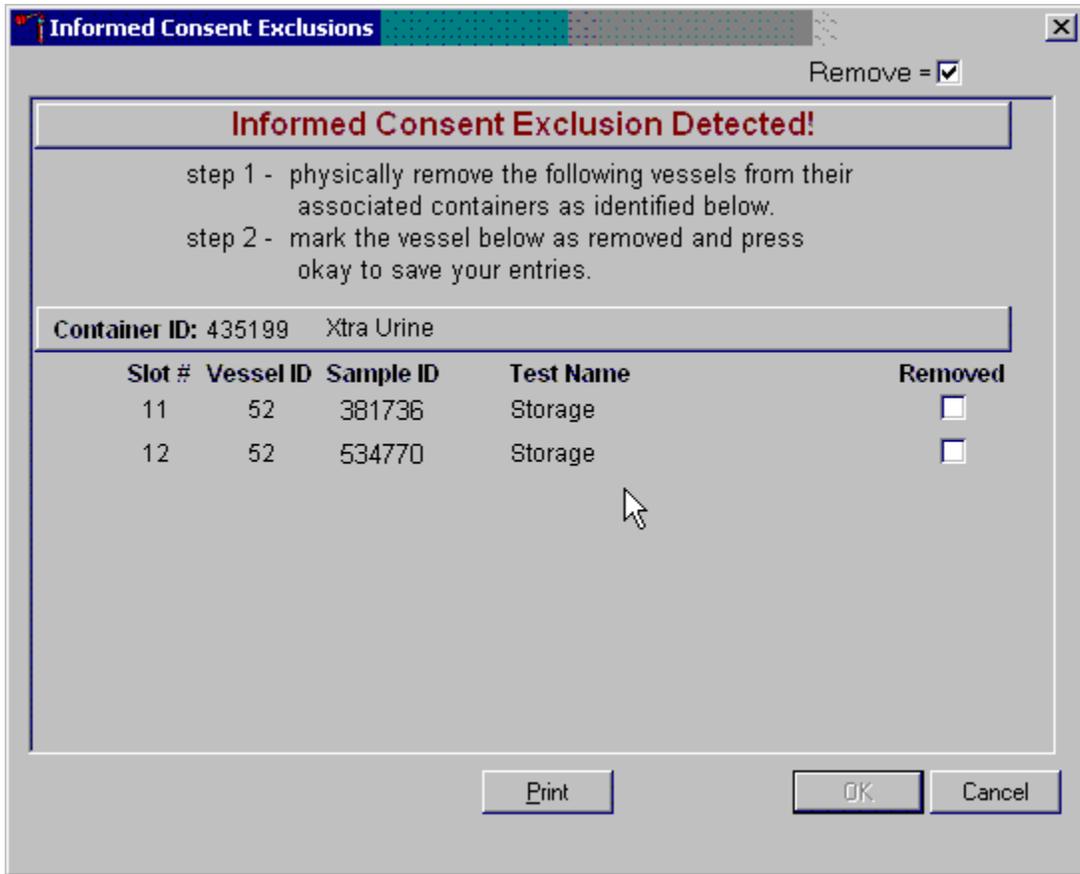
After following the exact instructions displayed in the window, record the actions taken to resolve the exclusions. To record these actions, use the mouse to direct the mouse arrow to the Removed checkboxes and left click to insert a checkmark. To record these actions in the database and to close the 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 the “Cancel” button and left click.

If all the vessels are not marked, then an Informed Consent Exclusions for Stand XXX warning pop-up box displays.



The system tracks each vessel in the {Informed Consent Exclusion} module to ensure that every vessel is marked as removed. Follow the instructions in the pop-up box, “Please physically remove these containers and mark them removed 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 checkboxes and left click to insert a checkmark. To record these actions in the database and to close the Informed Consent Exclusions window, use the mouse to direct the mouse arrow to the "OK" button and left click, or select [Enter]. Once all vessels have been marked correctly, the close container window will automatically display.

## **9.12 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.

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.

The packaging must consist of three components:

1. A primary receptacle(s);
2. A secondary packaging; and
3. A rigid outer packaging.

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 packaging must be secured in outer packaging 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.

Exhibit 9-3. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
Lab 2 CDC/NCID Hepatitis Ref Lab Attn: Annemarie Wasley Code NH4 1600 CLIFTON RD NE Bldg 18 Floor 3 Rm 218 MS A33 Atlanta, GA 30329-4018 404-639-3103	122 – HAV 87 – Hepatitis ab	Frozen	Annemarie Wasley 404-639-3103
Lab 3 CDC/NCID AIDS Division Attn: Tim Granade/Jane Feldman 1600 Clifton Road NE Bldg 17, Room 3127, MS A-25 Atlanta, GA 30329-4018 404-639-3850	22 – HIV	Frozen	Tim Granade/Jane Feldman 404-639-3850
Lab 4 CDC/NCEH Air Toxicant Branch Attn: Dr. Ben Blount 4770 Buford Highway Bldg 103 Loading Dock Atlanta, GA 30341-3717 770-488-4312	54 – VOC Blood	Refrigerated	Dr. Ben Blount 770-488-4312
Lab 5 CDC/NCID NCHSTD Attn: Carol Farshy 1600 Clifton Road NE MS A13 Atlanta, GA 30329-4019 404-639-2870	46 – Chlam	Frozen	Carol Farshy 404-639-2870

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
Lab 6 CASPIR Attn: Robert White 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-339-5942	1 – Lead/Cad/HG 3 – RBC Folate 5 – Mercury 136- Se/Cu/Zn 70 – Vitamin D 110 – VB6/Fol1 17 – Cotinine 137- Testosterone 110 – Folate1 <b>32-37 – Xtra Sera</b> <b>29/89 – Persis Pest</b> <b>91 – Srm Pest</b> <b>92/93 – BFR</b> <b>48 – Prior Pest</b> <b>49 – Organophos</b> 86 – Spc Arsenic 62 – Urn Merc 50 – Heavy Metal <b>66 – PAH</b> <b>102 – Perchlorate</b> <b>121 – NNAL</b> 128 - Caffeine <b>52/139 – Xtra urine</b>	Frozen	Robert White 770-339-5942
Lab 9 Emory University Theda Gibson 2015 UPPERGATE DR. ROOM 560 Atlanta, GA 30322-0001 404-727-5678	24 – HSV	Frozen	Theda Gibson 404-727-5678

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
Lab 16 University of Minnesota Attn: Susan Kupcho 515 Delaware Street SE Room 13-219 – MOOS Tower Minneapolis, MN 55455-0357 612-624-6153	45 – Alb/Creat	Frozen	Susan Kupcho 612-624-6153
Lab 24 CDC/Environmental Health Laboratory Attn: Antonio Calafat 4770 Buford Highway Building 110, Loading Dock Atlanta, GA 30341-3717 770-488-7886	<b>90 – Perfluor1</b> <b>67 – Phthalates</b>	Frozen	Dr. Antonia Calafat 770-488-7891
Lab 37 CDC/Human Papillomavirus Laboratory Attn: Sonya Patel 1600 Clifton Road NE MS G41 Bldg/Rm 1/1355 Atlanta, GA 30329-4018 404-639-2187	78 – HPV	Room Temperature	Sonya Patel 404-639-2187
Lab 40 Collaborative Laboratory Services Attn: Sue Vanness 1005 Pennsylvania Ave. Suite 102 Ottumwa, Iowa 52501-6408 641 684-4621	18 – Biochem 118 – Thyroid	Refrigerated Frozen	Sue Vanness 641 684-4621

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
Lab 51 NHANES Diabetes Laboratory Attn: Jean Bucksa 420 Delaware St SE Mayo L275 Minneapolis, MN 55455-0341 612-273-3645	9 – Glucose 98 – OGTT 23 – Insulin 21 – Lipids	Frozen	Jean Bucksa 612-273-3645
Lab 51 NHANES Diabetes Laboratory Attn: Jean Bucksa 420 Delaware St SE Mayo L275 Minneapolis, MN 55455-0341 612-273-3645	4 – Glycohem	Refrigerated	Jean Bucksa 612-273-3645
Lab 52 CDC/DVRD HPV Attn: Gitika Panicker 1600 Clifton Rd NE MS G-41 Bldg 1-South, Rm 1250 Atlanta, GA 30329-4018 404-639-2269	77 – HPV Serum	Frozen	Gitika PanickerMeadows 404-639-2269
Lab 58 CDC/NCEH Molecular Biology Branch Attn: Peg Gallagher 4770 BUFORD HWY F24 Room 3204 Atlanta, GA 30341-3717 770-488-4313	119/120 Genetics	Refrigerated	Cindy Sturco (770) 488-4313
Lab 65 Mayo Clinic Attn: Tricia Brantner 221 4 <sup>th</sup> Avenue SW Guggenheim 10-02 ROCHESTER, MN 55902 507-538-4128	127 – IgA-TTG/EMA	Frozen	Tricia Brantner 507-538-4128

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
Lab 66 Gillison Laboratory 2001 Polaris Pkwy # 1320 OSU – Pathology Core Facility Columbus, OH43240-2000 614-293-5942	129 – HPV Rinse	Frozen	Dr. Maura Gillison 614-293-5942
Lab 115 Seattle Children’s Hospital Attn: Anne Cent 4800 Sand Point Way NE Rm W8814 Seattle, WA 98105-3901 206-987-2088	133 - Nil 134 – TB Ag 135 - Mitogen	Refrigerated	Anne Cent 206-987-2088
Lab 116 CDC/NCIRD Herpesvirus Diagnostic Lab Attn: Sheila Dollard 1600 Clifton Rd NW Mailstop G18; Bldg 18 Room 6-133 Atlanta, GA 30329-4018 404-639-2178	138 – CMV	Frozen	Sheila Dollard 404-639-2178

Packages must be prepared as follows:

**650(a) For Liquids**

- The primary receptacle(s) must be leakproof and must not contain more than 1 L;
- The secondary packaging must be leakproof;
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacle (so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging).
- 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.

**Specific Requirements – refrigerated or frozen specimens: ice, dry ice, and liquid nitrogen**

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packaging in the original position after the ice or dry ice (solid carbon dioxide) has been dissipated. If ice is used, the packaging or overpack must be leakproof. If dry ice (solid carbon dioxide) is used, the outside packaging or overpack must be designed and constructed to permit the release of carbon dioxide gas to prevent a buildup of pressure that could rupture the packaging.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these regulations except for the following:

- a. The name, address, and telephone number of a responsible person must be provided on the waybill or on the package.

#### **Packing Instruction 904 – Dry Ice**

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 buildup 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 following 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:

- Proper shipping name (**Dry Ice** or **Carbon Dioxide, solid**);
- UN 1845;
- The number of packages; and
- The net weight of dry ice in each package.

The net weight of the dry ice must be marked on the outside of the package.

### **9.12.1 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 Exhibit 9-3, Contract Laboratory addresses, shown earlier.

### **9.12.2 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 ¼" 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 35 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 air bill.

### **9.12.3 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  $\frac{1}{4}$ " 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 25 pounds.
- Record the weight of the dry ice (20 pounds for a small shipper) on the FedEx Class 9 label.
- Secure the shipper with tape.
- Attach the air bill.

#### **9.12.4 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 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.

### **9.12.5 Label Shippers**

For all destinations, include a preprinted FedEx return air bill containing the warehouse address.

All shippers must contain a FedEx barcode label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

1. A “Keep Frozen” label and a FedEx Class 9 – Miscellaneous Dangerous Goods label on shippers containing dry ice.
2. A “Refrigerate” label on shippers containing refrigerant packs.
3. A UN 3373: - “BIOLOGICAL SUBSTANCE, CATEGORY B label on all shippers.
4. An “overpack” label on all shippers
5. 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.
6. 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.
7. Add one additional strip of tape across the FedEx pouch.

### **9.13 Container Protocol and Weekly Shipping List**

Exhibit 9-4 illustrates the Container protocol; Exhibit 9-5 illustrates the FedEx shipping list by lab name; and Exhibit 9-6 illustrates the shipping list by lab number. Use the container protocol as an aid at the start of each stand when opening new containers. Use the FedEx shipping lists as an aid when creating air bills in FedEx Ship Manager.

Exhibit 9-4. Container protocol

**2011 Container Protocol**

Lab	Vessel	Test	Lab	Vessel	Container
61	1	Lead/Cad/HG/Se/Mn	CASPIR	2 mL cryovial	9x9 two inch box
54	3	RBC Folate	CASPIR	2 mL cryovial	10x10 two inch box
51	4	Glycohem	NHANES Diabetes Laboratory	2 mL cryovial	9x9 two inch box
61	5	Mercury, Ethyl & Methyl	CASPIR	2 mL cryovial	9x9 two inch box
115	133	IN-Tube TB Nil Control	Seattle Childrens Hospital	1 ml Tube	7x7 three inch box
115	134	IN-Tube TB TB Antigen	Seattle Childrens Hospital	1 ml Tube	7x7 three inch box
115	135	IN-Tube TB Mitogen Control	Seattle Childrens Hospital	1 ml Tube	7x7 three inch box
51	9	Glucose	NHANES Diabetes Minnesota	2 mL cryovial	9x9 two inch box
51	98	OGTT	NHANES Diabetes Minnesota	2 mL cryovial	9x9 two inch box
61	136	Se/Cu/Zn	CASPIR	2 mL cryovial	9x9 two inch box
116	138	CMV	CDC/NCIRD Herpesvirus Diagnostic Lab	2 mL cryovial	9x9 two inch box
54	70	Vitamin D/Fatty Acids	CASPIR	2 mL cryovial	10x10 two inch box
2	14	Hep profile	CDC/NCID Hepatitis Ref Lab	2 mL cryovial	9x9 two inch box
2	122	HAV	CDC/NCID Hepatitis Ref Lab	2 mL cryovial	9x9 two inch box
2	87	Hepatit ab	CDC/NCID Hepatitis Ref Lab	2 mL cryovial	9x9 two inch box
59	17	Cotinine	CASPIR	2 mL cryovial	9x9 two inch box
51	21	Lipids	NHANES Diabetes Laboratory	2 mL cryovial	9x9 two inch box
52	77	HPV Serum	CDC/DVRD HPV Collaborative Laboratory Services	2 mL cryovial	9x9 two inch box
40	18	Biochem	NHANES Diabetes Laboratory	2 mL cryovial	9x9 two inch box
51	23	Insulin	NHANES Diabetes Laboratory	2 mL cryovial	9x9 two inch box
54	12	Vit B12/MMA	CASPIR	2 mL cryovial	9x9 two inch box
3	22	HIV	CDC/NCID AIDS Division	2 mL cryovial	9x9 two inch box
9	24	HSV	Emory University Collaborative Laboratory Services	2 mL cryovial	9x9 two inch box
40	118	Thyroid	Collaborative Laboratory Services	2 mL cryovial	9x9 two inch box
65	127	IgA-TTG/EMA	Mayo Clinic	2 mL cryovial	9x9 two inch box
60	137	Testosterone	CASPIR	2 mL cryovial	9x9 two inch box
54	110	Fol	CASPIR	2 mL cryovial	10x10 two inch box
<b>6</b>	<b>32-37</b>	<b>Xtra sera1</b>	<b>CASPIR</b>	<b>2 mL cryovial</b>	<b>9x9 two inch box</b>
<b>28</b>	<b>29/89</b>	<b>Persis Pest1</b>	<b>CASPIR</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<b>24</b>	<b>90</b>	<b>Perfluor</b>	<b>CDC/NCEH Environmental Health Lab</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<b>28</b>	<b>92/93</b>	<b>BFR1</b>	<b>CASPIR</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<b>26</b>	<b>91</b>	<b>SRM Pesticide</b>	<b>CDC/NCEH Pesticide Laboratory</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>

Exhibit 9-4. Container protocol (continued)

2011 Container Protocol					
Lab	Vessel	Test	Lab	Vessel	Container
16	45	Alb/Creat	University of Minnesota	5 mL cryovial	9x9 three inch box
5	46	Chlam	CDC/NCID NCHSTD	14 mL Falcon	5x5 three inch box
61	86	Spc Arsenic	CASPIR	5 mL cryovial	9x9 three inch box
<b>26</b>	<b>48</b>	<b>Prior Pest</b>	<b>CDC/NCEH Pesticide Laboratory</b>	<b>10 mL VWR screwcap</b>	<b>5x5 three inch box</b>
<b>26</b>	<b>49</b>	<b>Organophos</b>	<b>CDC/NCEH Pesticide Laboratory</b>	<b>10 mL VWR screwcap</b>	<b>5x5 three inch box</b>
61	62	Urn Merc	CASPIR	10 mL VWR screwcap with green dot	5x5 three inch box
61	50	Heavy Metal	CASPIR	14 mL Falcon	5x5 three inch box
<b>31</b>	<b>66</b>	<b>PAH</b>	<b>CASPIR</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<b>24</b>	<b>67</b>	<b>Phthalates</b>	<b>CDC/NCEH Environmental Health Lab</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<b>4</b>	<b>102</b>	<b>Perchlorate/VOC/ Thiocyanate</b>	<b>CASPIR</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<b>59</b>	<b>121</b>	<b>NNAL</b>	<b>CASPIR</b>	<b>10 mL VWR screwcap</b>	<b>5x5 three inch box</b>
54	128	Caffeine	CASPIR	2 mL cryovial	10x10 two inch box
<b>6</b>	<b>52</b>	<b>Xtra Urine 1</b>	<b>CASPIR</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<b>6</b>		<b>Xtra Urine 2</b>	<b>CASPIR</b>	<b>5 mL cryovial</b>	<b>9x9 three inch box</b>
<i>4</i>	<i>54</i>	<i>VOC Blood</i>	<i>CDC/NCEH Air Toxicant Branch</i>	<i>10 mL Gray tube</i>	<i>5x5 five inch foam box</i>
<i>58</i>	<i>119</i> <i>120</i>	<i>Genetics</i>	<i>CDC/NCEH Molecular Biology Branch</i>	<i>10 mL EDTA tube</i>	<i>5x5 five inch foam box</i>
37	78	HPV	CDC/Human Papillomavirus Lab	Swab	9x12 Ziplock bag
67	129	HPV Rinse	Johns Hopkins Viral Oncology	14 mL Falcon tube	5x5 three inch box
<b>Bold - ship at end of stand</b>				<i>Italics = ship refrigerated</i>	

Exhibit 9-5. FedEx shipping list by lab number

2011 FedEx by Laboratory Number							
LAB	VESSEL	TEST	LAB	CONDITIONS	Dry Ice (Lbs.)	Dry Ice (Kg.)	Weight
2	122	HAV	CDC/NCID Hepatitis Ref Lab	Frozen	20	9	25
	87	Hepatitis Ab					
3	22	HIV	CDC/NCID AIDS Division	Frozen	20	9	25
4	54	VOC Blood	CDC/NCEH Air Toxicant Branch	Refrigerated			10
5	46	Chlam	CDC/NCID NCHSTD	Frozen	20	9	25
6	1	Lead/Cad/HG/Se/Mn	CASPIR	Frozen	30	14	35
	3	RBC Folate					
	5	Mercury					
	136	Se/Cu/Zn					
	70	Vit D/FA					
	17	Cotinine					
	12	Vit B <sub>12</sub> /MMA					
	137	Testosterone					
	110	Folate1					
	<b>32-37</b>	<b>Xtra Sera</b>					
	<b>29/89</b>	<b>Persis Pest1</b>					
	<b>91</b>	<b>SRM Pest</b>					
	<b>92/93</b>	<b>BFR1</b>					
	<b>48</b>	<b>Prior Pest</b>					
	<b>49</b>	<b>Organophos</b>					
	86	Spc Arsenic					
	62	Urn Merc					
	50	Heavy Metal					
<b>66</b>	<b>PAH</b>						
<b>102</b>	<b>Perchlorate</b>						
<b>121</b>	<b>NNAL</b>						
128	Caffeine						
<b>52/139</b>	<b>Xtra Urine</b>						
9	24	HSV	Emory University	Frozen	20	9	25

Exhibit 9-5. FedEx shipping list by lab number (continued)

16	45	Alb/Creat	University of Minnesota	Frozen	20	9	25
24	90	Perfluor	CDC/NCEH Environmental Health Lab	Frozen	30	14	35
	67	Phthalates					
37	78	HPV	CDC/Human Papillomavirus Lab	Room Temp			1
40	18	Biochem	Collaborative Laboratory Services	Refrigerated			10
40	118	Thyroid	Collaborative Laboratory Services	Frozen	20	9	25
51	4	Glycohem	NHANES Diabetes Laboratory	Refrigerated			10
51	21	Lipids	NHANES Diabetes Laboratory	Frozen	30	14	35
	23	Insulin					
	9	Glucose					
	98	OGTT					
52	77	HPV Serum	CDC/DVRD HPV	Frozen	20	9	25
58	119/120	Genetics	CDC/NCEH Molecular Biology Branch	Refrigerated			10
65	127	IgA-TTG/EMA	Mayo Clinic	Frozen	20	9	25
67	129	HPV Rinse	Gillison Laboratory, Ohio State Univ	Refrigerated			10
115	133	In-Tube TB Nil	Seattle Children's Hospital	Refrigerated			10
	134	In-Tube TB Antigen					
	135	In-Tube TB Mitogen					
116	138	CMV	CDC/NCIRD Herpesvirus Diagnostic Lab	Frozen	20	9	25

Gray fill – Ship Refrigerated

Bold- Ship at end of stand or when full.

Blood

Urine

Other

## 10. HPV SWAB PROCESSING

### 10.1 Introduction

The purpose of collecting vaginal swabs is to obtain suitable biological specimens to test for human papillomavirus (HPV). 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.

Primary female SPs aged 14-59 collect the HPV swab. The physician prints the appropriate label. Each label includes the test name, 6-digit SP ID concatenated with the vessel ID, and the corresponding barcode. The physician counsels each eligible SP and introduces her to the vaginal collection technique using a prepared collection kit. The collection kit is designed for SPs aged 14-59 and it includes illustrated collection instructions and one Epicentre® Dacron swab with foam tip. The physician removes the appropriate swab from the collection kit and labels the Epicentre® Dacron swab

with the foam tip with the label displaying the vessel ID #78, The physician then places the swab(s) back in the collection kit and gives the collection kit to the eligible SP.

The SP self-collects the appropriate swab in the mobile examination center (MEC) bathroom, places the swab back in its original container, and places the swab back in 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 HPV module, and stores the swab at room temperature. The laboratory staff ships the specimens to the CDC laboratory weekly.

The laboratory staff also processes serum for vessel 77 (HPV Serum) on SPs aged 14-59 as part of an SP's blood processing profile. The vessels are stored at -20°C and shipped to the CDC/Human Papillomavirus Laboratory weekly.

## **10.2 Supplies**

The supplies needed for HPV processing and storage are listed in Exhibit 10-1.

Exhibit 10-1. Equipment and supplies – HPV processing and storage

Large padded envelope	Zip closable bag (9" x 12" clear)
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## **10.3 Protocol**

Exhibit 10-2 illustrates the SP's protocol for HPV 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 10-2. HPV processing protocol

ID	Test name	Ages	Sample	Sample type	Vessel type	Appointment type
78	HPV	14-59 females	1 swab	Vaginal swab	Epicentre® Dacron swab	Primary only

### 10.4 Labeling Vessels

The physician prints the vessel label. It is possible to reprint the label in the lab using the Ad Hoc functionality.

### 10.5 HPV Protocol

Process the Epicentre® Dacron swab with the foam for HPV. Verify that the swab is labeled correctly and that the label is legible.

Access the HPV Processing module for all SPs.

- 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 HPV module and store the swab at room temperature.

### 10.6 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 Lipids vessel (#21) and before the Biochem vessel (#18.) 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/DVRD HPV weekly.

Select the correct SP and access the Blood Processing module.

The screenshot shows the 'Lab Sink' application window. The title bar reads 'Lab Sink'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. Below the menu bar is a toolbar with several icons. The main area displays a table titled 'Appointments for Session: 430072'. The table has columns for 'SP ID', 'Sample ID', 'status', 'type', 'gender', 'age', 'name', and 'Process Status'. The 'Process Status' columns are 'UC', 'U', 'P', 'OZ', 'CB', 'B', and 'glt'. The first row is highlighted, and a context menu is open over it, listing various processing options. 'Blood Processing' is selected in the menu.

SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	glt
446446	446446	BE	P	F	18	CHAVEZ, ESPERANZA S	●	●	●	●	●	●	-
649229	649229	SC	P	M	12	PODESTA, SILAS	○	○	-	○	○	○	-
779621	779621	SC	P	M	58	CHAVEZ, HUGO D	○	○	-	○	○	○	-
941922	941922	SC	P	F	6	PODESTA, SIMONE	○	○	-	○	○	○	-
947213	947213	SC	P	M	14	PODESTA, STUART	○	○	-	○	○	○	-
969075	969075	SC	P	M	18	CHAVEZ, HECTOR L	○	○	-	○	○	○	-

Context Menu Options:

- Urine Processing
- Blood Processing**
- WTT Processing
- Packed Cell Processing
- HPV Processing
- Oral Rinse Processing
- Urine Collection
- Pregnancy Testing
- Osmolality
- Hematology ▶
- Refresh
- Labels ▶

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].

Record processing results for vessel 77 (HPV Serum) in the Blood Processing module.

**BP: 446446**  
B processing

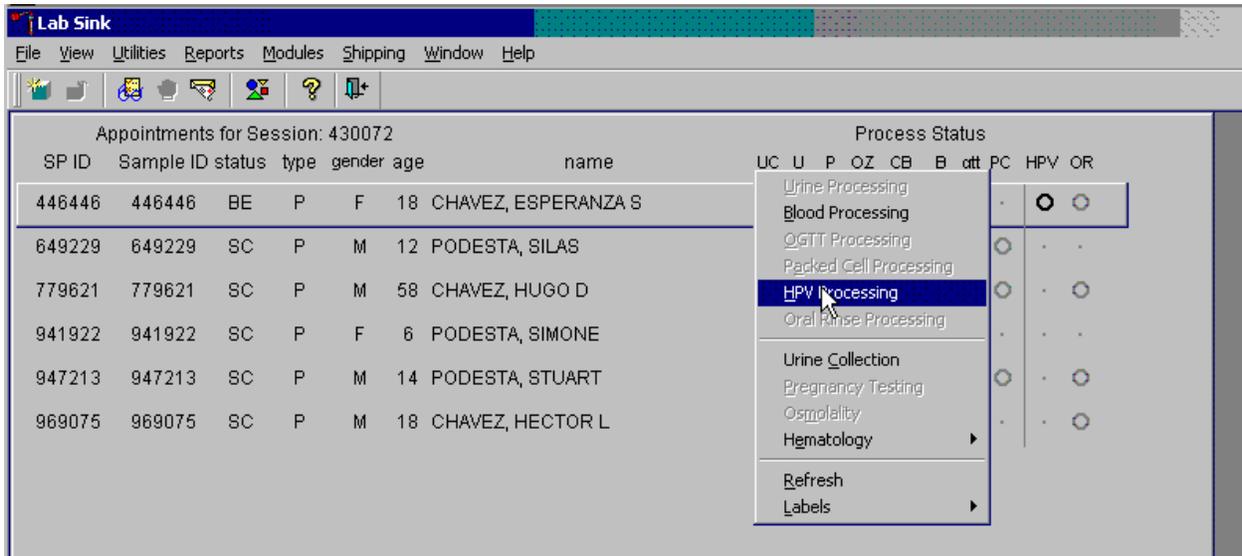
Tech ID: 1126    Sample ID: 446446    Name: CHAVEZ, ESPERANZA S    Gender: F    Age: 18  
 SP ID: 446446    Appt Type: Primary    Fasting Req: No Fasting Required

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
21	Lipids		1.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415783	1
77	HPV Serum		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415802	1
18	Biochem		0.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415782	1
22	HIV		0.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415784	1
24	HSV		0.2	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415786	1
127	IgA-TTG/EMA		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415825	1
16	MMRV		1.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415780	1
32	Xtra Sera1		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415788	1
33	Xtra Sera2		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415788	2
34	Xtra Sera3		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415788	3
35	Xtra Sera4		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415788	4
36	Xtra Sera5		1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415788	5

Buttons: Save, Phlebotomy, OK, Cancel

Primary SPs aged 14-59 are eligible for the HPV serum test. Pool the serum and aliquot 0.5-mL into a pre-labeled 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 small shipper, add sufficient dry ice, and ship weekly to CDC/DVRD HPV. Use existing procedures described in Chapter 9 to pack, label, and ship the shipper.

Select the correct SP and access the HPV 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 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 HPV Processing module, drag the mouse arrow to {HPV 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 the correct module, and left click or type [S/s].

Document processing results.

The screenshot shows a software window titled "HPV: 446446" with a subtitle "HPV processing". The window contains a form with the following fields:

- Tech ID: 1126
- Sample ID: 446446
- SP ID: 446446
- Name: CHAVEZ, ESPERANZA S
- Gender: F
- Age: 18
- Appt Type: Primary
- Fasting Req: No Fasting Required

Below the form is a table with the following columns: Vessel ID, Test Name, Sample Volume, Sample Type, Vessel Volume, Vessel Name, Filled, Comment, Container ID, and Slot#. The table contains one row of data:

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

At the bottom of the window are three buttons: "Save", "OK", and "Cancel".

The HPV Processing window contains the following information for SPs: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, App (appointment) type, 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, and a Container ID and Container Slot# column. 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.

HPV: 446446  
HPV processing

Tech ID: 1126    Sample ID: 446446    Name: CHAVEZ, ESPERANZA S    Gender: F    Age: 18  
SP ID: 446446    Appt Type: Primary    Fasting Req: No Fasting Required

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No		0415803	1

Save    OK    Cancel

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.

Mark vessel 78 as Filled –"No" if the swab was not collected.

HPV: 446446  
HPV processing

Tech ID: 1126    Sample ID: 446446    Name: CHAVEZ, ESPERANZA S    Gender: F    Age: 18  
SP ID: 446446    Appt Type: Primary    Fasting Req: No Fasting Required

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

Save    OK    Cancel

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.

Enter a quality control comment for vessel 78, when the swab is dry and the judgment is that the SP did not attempt to collect the sample(s).

HPV: 446446  
HPV processing

Tech ID: 1126    Sample ID: 446446    Name: CHAVEZ, ESPERANZA S    Gender: F    Age: 18  
SP ID: 446446    Appt Type: Primary    Fasting Req: No Fasting Required

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none) (none) inadequate sample		

Save    OK    Cancel

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].

Store the Epicentre® Dacron swab in the assigned 9” x 12” plastic bag at room temperature; review the information in the HPV-Processing window, and save the data to the database.

The screenshot shows a software window titled "HPV: 446446" with a subtitle "HPV processing". The window contains a form with patient information and a table of vessels.

**Patient Information:**

- Tech ID: 1126
- Sample ID: 446446
- Name: CHAVEZ, ESPERANZA S
- Gender: F
- Age: 18
- SP ID: 446446
- Appt Type: Primary
- Fasting Req: No Fasting Required

**Vessel Information Table:**

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No		0415803	1

At the bottom of the window, there are three buttons: "Save", "OK", and "Cancel".

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save the 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 the 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.

The process status circle in the heads-up display fills in completely for SPs whose vessel 78 recorded as collected or Filled –"Yes." Do not enter a result until the swab arrives in the laboratory. At the end of each session, review the results for each SP. Access each record and enter the Filled –"No" result for all vessels for SPs for whom no swab was received.

## 10.7 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. Store vessels in numbered storage containers according to each vessel as indicated in Exhibit 10-3.

Store each vessel in the appropriate slot in the correct container immediately after processing. Check the slot assignment of containers associated with vessel 78 at the end of each session by accessing the Container Map report. Verify the contents of each container against the container map.

Exhibit 10-3. Storage protocol for HPV

Shipping Location	Vessel	Condition	Vessel Storage
CDC/DVRD HPV	77 HPV Serum	Frozen	9 x 9 two-inch box
CDC/Human Papillomavirus Laboratory	78 HPV	Room temperature	9" x 12" plastic bag

## 10.8 Shipping Procedures

Ship vessel 77 according to procedures described in Section 9.13. Ship vessel 78 in a padded envelope 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 with each shipment. Exhibit 10-4, the Shipping protocol, illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Exhibit 10-4. Shipping protocol

Laboratory	Vessel	Test Name	Vessel Storage	Shipping Frequency
CDC/DVRD HPV	77	HPV Serum	Frozen	Weekly
CDC/Human Papillomavirus Laboratory	78	HPV	Room Temperature	Weekly

**10.8.1 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 in a large padded envelope.
- Place the appropriate shipping manifest in a 9" x 12" plastic bag and seal.
- Place a plastic envelope containing the appropriate shipping manifest in 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.

**10.8.2 Label Shippers**

All shippers must contain a FedEx barcoded 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.
- Add one additional strip of tape across the FedEx pouch.

**10.9 How to Deal With System Failure**

If the computer system fails, record results on a preprinted HPV Processing worksheet (Exhibit 10-5). Complete a workstation 2 worksheet for each SP while processing the HPV specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 10-5. HPV Processing worksheet

**HPV PROCESSING**

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

ID	Name	Ages Gender	Sample mL	Sample Type	pH	Filled ✓	Slot #
78	HPV	14-59 females	1 swab	Epicentre® Dacron Swab			

## **11. HPV ORAL RINSE PROCESSING**

### **11.1 Introduction**

The overall goal of collecting an oral rinse is to perform the first population-based study of oral HPV infection to determine the prevalence and type distribution of infection and to investigate the demographic and behavioral factors associated with infection.

Testing for 37 types of HPV will be accomplished by means of a multiples polymerase-chain reaction (PCR) assay targeted to the L1 region of the viral genome, using PGMY09/11 L1 primer pools and primers for Beta globulin followed by hybridization to a linear probe array (Roche Molecular.)

The HPV oral rinse is collected by the dental hygienist during the oral health exam on primary SPs aged 14 – 69. The SP is asked to swish a 10mL sample of Scope mouthwash (or a sterile saline solution if preferred by the SP) in their mouth and then expectorate the sample into a sterile collection cup. The cap is secured on the cup, a label is attached, and the sample is then taken to the MEC laboratory for processing.

The hygienist places the cup in the MEC laboratory in the same area as the urine collection samples. The HPV oral rinse samples are easily distinguished from the urine collection samples by the color of the sample (blue-green unless the clear sterile saline solution is used) and the collection cup (clear and cylindrical with a screw on metal cap) which is much smaller than the urine collection cup.

The MEC laboratory technologists process the sample by transferring the HPV oral rinse from the collection cup to a 14mL Falcon snap cap tube. It is critical to transfer the entire sample from the collection cup to the processing vessel. The technologists use the OR (oral rinse) module to document collection status. All SPs are listed on one screen so the samples can be batch processed. They make sure that the snap cap is pressed down fully to prevent leakage during shipment.

The sample is stored frozen at -20 degrees Celsius and shipped weekly to Lab 67, Gillison Laboratory, 2001 Polaris PKWY # 1320 OSU - Pathology Core Facility Columbus, OH 43240-2000 (614)293-5942.

## 11.2 Supplies

The supplies needed for HPV Rinse processing and storage are listed in Exhibit 11-1.

Exhibit 11-1. Equipment and supplies – HPV processing and storage

14-mL snap cap test tube	Small Styrofoam shipper (14 x 14 x 12)
Three-inch 5 x 5 cardboard grid	STP-310 Pressure vessel
Absorbent sheets (2 x 2)	
Packaging tape 2"	Plastic bag 9" x 12"
Overpack label	
Rubber bands	Dry ice

## 11.3 Protocol

Exhibit 11-2 illustrates the SP's protocol for HPV Rinse 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 11-2. HPV Rinse processing protocol

ID	Test name	Ages	Sample	Sample type	Vessel type	Appointment type
129	HPV Rinse	14-69	1	Oral rinse	14-mL snap cap tube	Primary only

## **11.4 Labeling Vessels**

The dental hygienist prints the label for the specimen cup. The medical technologist assigned to workstation 3 prints the **vessel** labels for all eligible SPs and places these labels at workstation 2. It is possible to reprint the vessel label in the lab using the ad hoc functionality.

## **11.5 HPV Rinse Protocol**

Process the oral rinse for HPV Rinse. Verify that the specimen container is labeled correctly and that the label is legible.

Access the OR Processing module for all SPs.

- Vessel 129 – HPV Rinse
  - Verify that the SP ID on the label matches the SP ID on the processing screen.
  - Label the 14-mL Falcon snap cap tube.
  - Pour the oral rinse from the specimen container into the Falcon tube.
  - Snap the cap firmly on the Falcon tube.
  - Record the processing results in the OR module.
  - Store the vessel in a three inch tall box with a 5 x 5 grid.
  - Store the container in the freezer.
  - Ship weekly frozen.

## 11.6 Record 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. Record oral rinse processing results for vessel 129 using the “OR” module.

Appointments for Session: 410111							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	gtt	PC	HPV	OR
215591	215591	SC	VIP	F	59	PATEL, PAVARTI	○	○	○	○	○	○	○	○	○	○
244969	244969	BE	P	M	42	JORDAN, LEE	●	○	○	○	○	○	○	○	○	●
470234	470234	SC	P	M	60	HAGRID, RUBEUS	○	○	○	○	○	○	○	○	○	○
668903	668903	CI	P	M	12	WEASLEY, FRED	●	○	○	○	○	○	○	○	○	○
762731	762731	CI	VIP	F	6	BROWN, LAVENDAR	●	○	○	○	○	○	○	○	○	○
836402	836402	SC	VIP	M	12	MALFOY, DRACO	○	○	○	○	○	○	○	○	○	○
900081	900081	SC	VIP	F	49	ABBOTT, HANNAH	○	○	○	○	○	○	○	○	○	○
998878	998878	CI	VIP	M	2	DURSLEY, VERNON	○	○	○	○	○	○	○	○	○	○

The “OR” module is grayed out until at least one SP has the oral rinse collected in the oral health component. Once one SP has the oral rinse marked as collected, the processing circle for that SP turns black.

Select the correct SP and access the Oral Rinse Processing module.

Appointments for Session: 410111							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	glt	PC	HPV	OR
215591	215591	SC	VIP	F	59	PATEL, PAVARTI	○	○	○	○	○	○	○	○	○	○
244969	244969	BE	P	M	42	JORDAN, LEE	○	○	○	○	○	○	○	○	○	○
470234	470234	SC	P	M	60	HAGRID, RUBEUE	○	○	○	○	○	○	○	○	○	○
668903	668903	CI	P	M	12	WEASLEY, FRED	○	○	○	○	○	○	○	○	○	○
762731	762731	CI	VIP	F	6	BROWN, LAVEND	○	○	○	○	○	○	○	○	○	○
836402	836402	SC	VIP	M	12	MALFOY, DRACO	○	○	○	○	○	○	○	○	○	○
900081	900081	SC	VIP	F	49	ABBOTT, HANNAH	○	○	○	○	○	○	○	○	○	○
998878	998878	CI	VIP	M	2	DURSLEY, VERN	○	○	○	○	○	○	○	○	○	○

- Urine Processing
- Blood Processing
- Q&TT Processing
- Packed Cell Processing
- HPV Processing
- Oral Rinse Processing**
- Urine Collection
- Pregnancy Testing
- Osmolality
- Hematology ▶
- Refresh
- Labels ▶

To access the OR module, use the mouse to direct the mouse arrow to the SP on the heads-up display, left click, drag the mouse arrow to Oral Rinse Processing, and right click.

Record the vessel 129 processing results in the Oral Rinse processing window. All SPs are included in the same window but are listed separately by row.

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
244969	JORDAN, LEE	M	42	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		
470234	HAGRID, RUBEUS	M	60	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		

The Oral Rinse processing window lists the vessel requirements across the top. SPs are listed separately in rows. The upper section of the Oral Rinse window contains the following information: Tech ID, Vessel ID (129), Test Name (HPV Rinse), Total Volume (14 ml), Vessel Name (17 x 100), and Sample Volume (10.0.) The lower section of the window contains columns for Sample ID, Person Name (Last, First), Gender, Age, Filled Yes and No radio buttons, Comments text box, and a Container ID/Slot # column N. Use the Save button to save the results to the database. Use the OK button to save the results to the database and close the module. Use the Cancel button to close the window without saving any data to the database.

Record oral rinse processing results for each SP. Individually mark each vessel as Filled–“Yes.”

The screenshot shows a software window titled "Oral Rinse". At the top, there is a header bar with the title and standard window controls. Below the header, there is a summary section with the following information:

- Tech ID: 1126
- Test Name: HPV Rinse
- Total Volume: 14 ml
- Vessel ID: 129
- Vessel Name: 17 x 100
- Sample Volume: 10.0

Below the summary is a table with the following columns: Sample ID, Person Name, Gender, Age, Filled, Comments, Container ID, and Slot#. The table contains two rows of data:

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
244969	JORDAN, LEE	M	42	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415882	1
470234	HAGRID, RUBEUS	M	60	<input type="radio"/> Yes <input type="radio"/> No	(none)		

At the bottom of the window, there are three buttons: "Save", "OK", and "Cancel".

Only SPs who have had the oral rinse marked as collected in the Oral Health application are eligible to be processed. Once the sample is collected, the row changes from gray to black, indicating that the SP is ready to be marked as processed. To mark an individual 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.

There are no quality comment codes available to describe the quality of the specimen or to explain why a vessel is marked as not filled.

Record oral rinse processing results for each SP. Individually mark each vessel as Filled–“No.”

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
244969	JORDAN, LEE	M	42	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
470234	HAGRID, RUBEUS	M	60	<input type="radio"/> Yes <input type="radio"/> No	(none)		

To mark vessel 129 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” do not require a comment.

Continue to enter results as vessels are processed. Review the information in the Oral Rinse 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.

## 11.7 Specimen Storage

Record the processing result for the HPV Rinse and store the vessel in a 3-inch tall container with a 5 x 5 grid. Store the container in the refrigerator.

Check the slot assignment of containers associated with vessel 129 at the end of each session by accessing the Container Map report. Verify the contents of each container against the container map.

Exhibit 11-3. Storage protocol for HPV

Shipping Location	Vessel	Condition	Vessel Storage
Lab 67 Gillison Laboratory 2001 Polaris PKWY # 1320 OSU - Pathology Core Facility Columbus, OH 43240-2000 (614)293-5942	129 HPV Rinse	Frozen	5 x 5 three-inch box

## 11.8 Shipping Procedures

Ship vessel 129 according to procedures described in Section 9.13. Exhibit 9-4, the Shipping protocol, illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Exhibit 11-4. Shipping protocol

Laboratory	Vessel	Test Name	Vessel Storage	Shipping Frequency
Gillison Laboratory 2001 Polaris PKWY # 1320 OSU - Pathology Core Facility Columbus, OH 43240-2000 (614)293-5942	129	HPV Rinse	Frozen	Weekly

Pack shipper according to the procedure described in Section 9.13.

**11.9 How to Deal With System Failure**

If the computer system fails, record results on a preprinted HPV Oral Rinse Processing worksheet (Exhibit 11-5). Complete a workstation 2 worksheet for each SP while processing the HPV specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 11-5. HPV Oral Rinse Processing worksheet

**HPV ORAL RINSE PROCESSING**

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

ID	Name	Ages	Gender	Sample mL	Sample Type	Filled ✓	Slot #
129	HPV Rinse	14-69		1 oral rinse	10-ml Scope		

**National Health and Nutrition Examination Survey  
National Center for Health Statistics  
United States Public Health Service  
Procedure: Osmolality Testing  
January 2011**

Prepared by \_\_\_\_\_

Date Adopted \_\_\_\_\_

Approved by \_\_\_\_\_  
Director

Signed \_\_\_\_\_  
Director

Dated \_\_\_\_\_  
Director

Reviewed by \_\_\_\_\_

Date Reviewed \_\_\_\_\_

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## 12. OSMOLALITY TESTING

### Introduction

Perform Urine Osmolality Determination on primary sample participants (SPs) who are 6 years and older and dry run odd and even volunteers aged 12+. Perform the test using the random urine specimens collected at the MEC. There are no SP safety exclusions for this test. Perform the test in the MEC laboratory using the Osmette II osmometer instrument.

### I. Purpose and Principle of Test

#### A. Purpose

The osmolality test is a determination of the number of osmotically active solutes present in the urine. It is performed to help evaluate the body's water balance and its ability to produce and concentrate urine. Increased urine output may be due to increased fluid intake, lack of appropriate amounts of ADH, or diabetes mellitus (increased glucose levels leading to increased urine output). Decreased urine output may be due to a variety of causes including decreased blood flow to the kidneys, an appropriate response to dehydration, or damage to tubular cells in the kidneys. Urine sodium and creatinine are often performed along with urine osmolality. Sometimes a urine osmotic gap is calculated and used to help evaluate the kidney's ability to excrete acid and reabsorb bicarbonate, to detect the presence of osmotically active molecules, and to compare with the plasma osmotic gap.

Urine osmolality is dynamic and will fluctuate as the body responds to and corrects temporary water imbalances. Urine osmolality tests must be evaluated in the context of the participant's clinical presentation and along with the findings of other tests, such as sodium, glucose, and BUN. When participants have increased urine output and a low osmolality, then they are either ridding their body of excess fluids or unable to concentrate urine appropriately (which may be due to diabetes insipidus, a lack of ADH). If they have increased urine output and a high osmolality, then it may be due to diabetes mellitus. If participants have decreased urine output and high osmolality, they may be dehydrated; if they have low or normal osmolality, they may have kidney damage. Osmolality results are not diagnostic;

they suggest that a participant has an imbalance but they do not pinpoint the cause. Urine osmolality may be increased with:

- [Congestive Heart Failure](#)
- Hyponatremia
- Inappropriate ADH secretion
- [Liver Damage](#)
- Shock

Urine osmolality may be decreased with:

- Diabetes insipidus
- Excess fluid intake
- [Hypercalcemia](#)
- [Hypokalemia](#)
- Kidney tubular damage

Within NHANES the osmolality test will be used in conjunction with the urine flow rate. The urine flow rate evaluates the weight of solids in water. Osmolality and urine flow rate usually change in parallel to each other. When large and heavy molecules (such as glucose and protein) are present in the urine, however, the results will diverge. The flow rate will be increased more, due to the weight of the molecules, while urine osmolality will be increased less, reflecting the number of molecules.

## **B. Principle**

The urine osmolality determination is based upon the principle that increased concentration of a solute in a solution causes lowering of its freezing point. This method is referred to as freezing point depression osmometry. A sample of the specimen to be analyzed is aspirated into the sample tube, which is then placed in the cooling chamber of the osmometer. The sample is super cooled below the freezing point. Then crystallization is initiated by rapidly vibrating the sample to seed it with air bubbles. After seeding, the sample temperature rises because of the heat of fusion released during the freezing process.

The temperature rises until the equilibrium plateau is reached (Figure 12-1). During the equilibrium plateau only a small fraction of the water is frozen. The sample continues to freeze as the temperature begins to decrease again because of the colder environment.

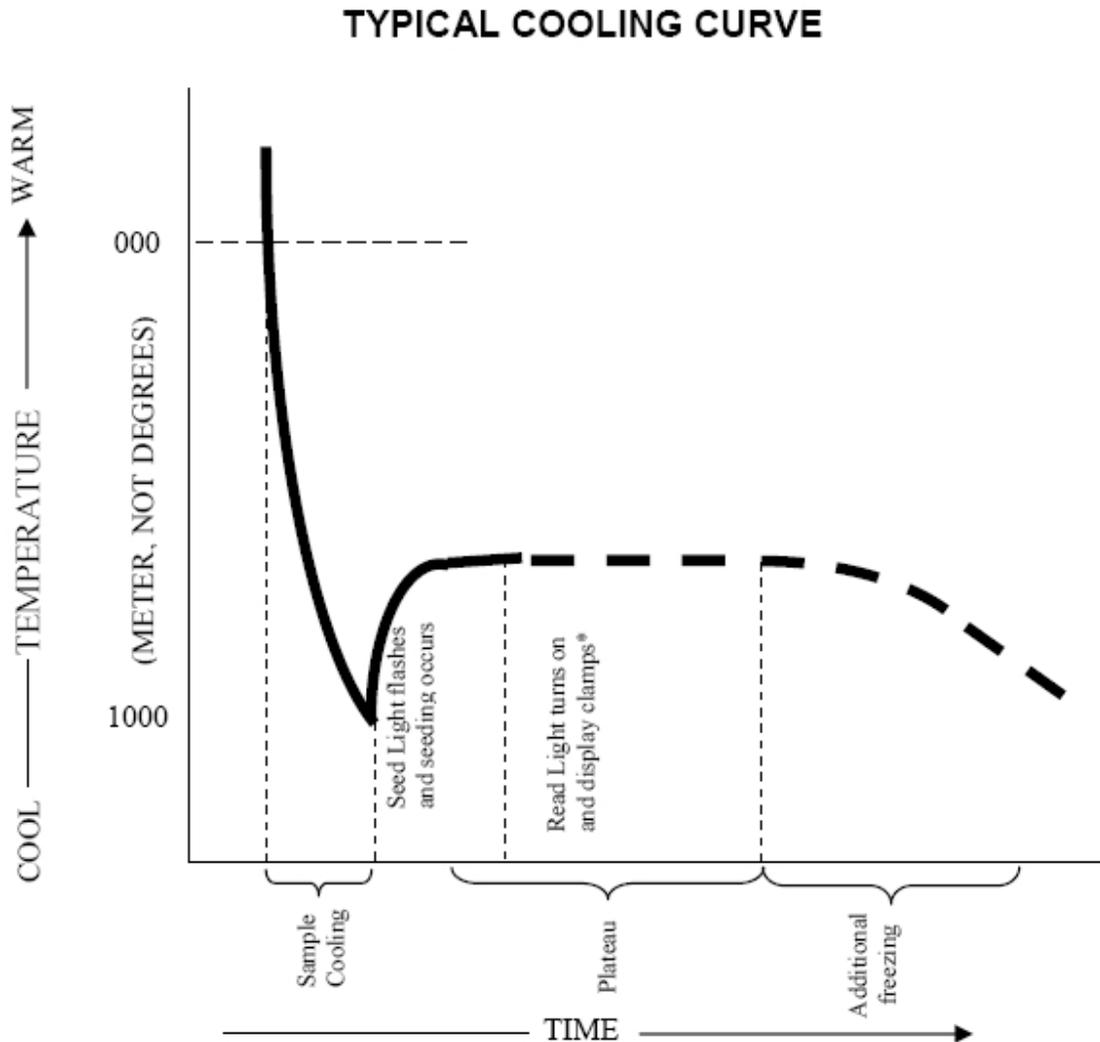


Figure 12-1. Typical cooling curve

Crystallization causes the release of the heat of fusion of water causing a constant temperature or a plateau. This temperature plateau is the freezing point of the urine specimen and is measured by the use of thermistors. Osmometers read directly in mOsm/kg (milli osmoles per kilogram of water) water by converting the thermistor probe (a precise temperature sensor) readings and directly comparing it with readings obtained using standard aqueous salt solutions of known osmolality (Standards).

The temperature at the plateau is the freezing point of the sample and can be converted to units of osmolality (osmotic concentration) by observing that 1.0 osmole depresses the freezing point of water by 1.858°C, where 1.0 osmole = 1.0 mole of osmotically active particles.

The most commonly used technique for converting the reading to units of mOsm/kg H<sub>2</sub>O is direct comparison with Standards of known osmolality. Osmolality is expressed in units of milliOsmoles (mOsm) per kg of water or mOsm/kg where one mOsm is equivalent to one millimole of dissolved solute particles. A solution containing 1 osmole (1000 mOsm) of dissolved solute per kg of water lowers the freezing point of water by 1.858°C. Thus, the freezing point depression of the urine specimen can be converted to units of osmolality or osmotic concentration by dividing it by 1.858.

## **II. Special Safety Precautions**

All specimens may be potentially positive for infectious agents including HIV and the hepatitis B and C viruses. Observe universal precautions. It is mandatory to wear gloves and a lab coat when handling all human urine products and Quantimetrix® controls. Dispose of all biological samples in a biohazard container and wipe down all work surfaces with 10 percent bleach solution at the end of each session.

The mobile examination center (MEC) *Working Safely with Hazardous Chemicals* manual contains the material safety data sheets (MSDS) for both the Precision Systems Standards and CONTROL solutions and the Quantimetrix Human Urine Controls.

Neither the Precision Systems Standards nor CONTROL solutions, nor the Quantimetrix Human Urine controls contain any ingredients that have been determined to be health hazards pursuant to Federal OSHA standards.

The Quantimetrix Human Urine Controls contains human urine. It is recommended that such samples be handled at the Centers for Disease Control Biosafety Level 2.

### **III. Computerization: Integrated Survey and Information System (ISIS)**

The Osmette II automatically transmits successfully completed SP results to the MEC automated ISIS system. The session number and technologist ID are automatically captured. The medical technologist reviews all SP results in the Osmolality module within the ISIS Laboratory application. The Osmolality QC module captures the QC results from the osmometer. The medical technologist enters the control lot number and expiration date. The Laboratory application evaluates the osmolality data for accuracy based on a preset precision limit. 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**

The urine sample is collected as a clean catch in a sterile 500-mL capacity container. The volume of the collection is calculated and the medical technologist records the sample as collected in the ISIS Laboratory application.

#### **B. Specimen Preparation**

The technologist prepares for the urine osmolality test by recording urine collection as either complete or quantity not sufficient (QNS). Once at least 2-mL of urine has been collected on female SPs eligible for pregnancy tests, or 1-mL on all other SPs eligible for urine collection, the urine osmolality test may be completed on the SP. The urine osmolality test requires at least 1-mL of urine. Do not perform osmolality on urines that are cloudy or bloody. Do not spin urine prior to performing the osmolality.

QNS urine samples should be held at ambient temperature until enough urine is obtained from the SP and pooled with the previous specimen(s). This pooling process results in the urine having the same concentration as the environmental samples.

**V. Procedure for Microscopic Examination**

Not Applicable - Do not prepare differential microscopic slides.

**VI. Equipment, Reagents, and Supplies**

The ISIS Laboratory application stores and maintains the lot numbers and expiration dates of QC controls and calibration standards.

**A. Equipment**

1. OSMETTE II™ Model 5005, Automatic Osmometer (Precision Systems, Inc). The four Osmette II serial numbers and locations are:

Osmette	Location	Serial Number	NCHS Property Tag
1	MEC 1	LL0809C	174145
2	MEC 2	LL0807C	174142
3	MEC 3	LL0808C	174144
4	Westat (backup)	LL0806C	174113

2. 10 µl Pipette (Precision Systems, Inc.). Use one pipette in each MEC. Keep one backup pipette in each MEC and two backup pipettes in the NHANES warehouse.

## **B. Controls and Calibrators**

Use the Precision Systems Osmometry Standards to calibrate the Osmette II machines and validate the calibration. Use the Precision Systems CON-TROL reference standard glass ampules to validate the Standards. Both are manufactured by Precision Systems:

Precision Systems, Inc.

16 Tech Circle

Natick, MA 01760-1029

508-655-7010

1. Precision Systems Osmometry Standards are aqueous solutions of known osmolality containing high purity sodium chloride for the calibration of osmometers. Standard osmolalities are listed on the bottle label. Acceptable ranges are used for quality control only.
  - 100 mOsm, 125-mL bottle (catalogue #2101) – acceptable range 96-104 mOsm
  - 500 mOsm, 125-mL bottle (catalogue #2105) – acceptable range 496-504 mOsm
  - 1,500 mOsm, 125-mL bottle (catalogue #2115) – acceptable range 1485-1515 mOsm
  - 2,000 mOsm, 125-mL bottle (catalogue #2120) – acceptable range 1980-2020 mOsm
  
2. Precision Systems CON-TROL reference standards are aqueous solutions of known osmolality containing high purity sodium chloride for validation of calibration standards. CON-TROL osmolalities are listed on the glass ampule.
  - CON-TROL 100, 100 mOsm reference solution, 5mL ampule (catalogue #2201) – acceptable range 98-102 mOsm
  - CON-TROL 500, 500 mOsm reference solution, 5mL ampule (catalogue #2203) – acceptable range 496-504 mOsm

## **Controls**

The Quantimetrix Human Urine Controls are intended as a means of monitoring human urine assay methods to validate quantification of patient samples. Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method. The controls are manufactured by the Quantimetrix Corporation.

Quantimetrix  
2005 Manhattan Beach Blvd.  
Redondo Beach, CA 90278-1205  
(310) 563-0006

3. Quantimetrix Human Urine Control, Level 1 and 2 are supplied as a ready-to-use liquid requiring no reconstitution. They are prepared from human urine. The Human Urine Controls are fortified to target levels with human proteins and reagent grade chemicals. Preservatives have been added to inhibit microbial growth.
  - Human Urine Control, Level 1 Catalog #1431-31, three 10-mL bottles
  - Human Urine Control, Level 2 Catalog #1432-31, three 10-mL bottles

## **C. Supplies**

1. 50-ml Precision Systems sample tubes (Precision Systems catalog #2023)
2. Teflon pipette tip piston replacements (Precision Systems catalog #2036)
3. 10  $\mu$ l disposable pipette tips (Precision Systems catalog #2048)
4. Cleanettes (Precision Systems catalog #2048)
5. Distilled water
6. Kimwipes
7. Latex or nitrile gloves
8. Disposable lab jacket – 48 inches long
9. Dow 311 Valve Lubricant

## **VII. Calibration**

Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. The Osmette II stores calibrations. All subsequent valid calibration values are added and averaged into previous calibrations.

### **A. Precalibration**

Perform a calibration after the instrument has been turned on and running for at least 10 to 15 minutes to allow for the Osmette temperature to completely equilibrate.

1. Precalibration procedure
  - a. Run a 100 mOsm standard through the machine to clean the well and ensure that the electronics and cooler are cycling correctly.

### **B. Osmette Total Calibration with Standards**

Use the Precision Systems 100, 500, 1,500, and 2,000 standards to complete a total calibration. Perform a total calibration:

- At the start of each stand before analyzing samples.
- After cleaning or doing any maintenance on the equipment.
- If the error message “OUTSIDE CALIBRATION” displays.
- If the Precision Systems Representative suggests a calibration.
- Acceptable ranges for Standards used in the calibration procedure:
  - Water and 100 Standard – acceptable range +/-1
  - 500 Standard – acceptable range +/-2
  - 1500 Standard – acceptable range +/-4
  - 2000 Standard – acceptable range +/-6

- **Note:** Run each standard three times. Each standard can be run up to six times as the instrument uses each standard result as a running average. If the standards are out-of-range, the calibration must be started over by exiting the calibration mode and then re-entering the calibration mode.

#### Calibration Procedure

1. Press “CALIBRATE” button.
2. Wipe the well with a Cleanette.
3. Run two distilled water samples. Record the result reading of each in the Lab Start of Stand QC Module.
4. Run two 100 mOsm Standards. Record the result reading of each in the Lab Start of Stand QC Module. Wipe the sample well with a Cleanette.
5. Run three 500 mOsm Standards. Record the result reading of each in the Lab Start of Stand QC Module. Wipe the sample well with a Cleanette.
6. Run three 1,500 mOsm Standards. Record the result reading of each in the Lab Start of Stand QC Module. Wipe the sample well with a Cleanette.
7. Run three 2,000 mOsm Standards. Record the result reading of each in the Lab Start of Stand QC Module. Wipe the sample well with a Cleanette.
8. Press the “CALIBRATE” button again to complete the calibration process. If the “CALIBRATE” button is not pressed again at the end of calibration, the calibration will not be saved.

#### C. **Osmette Troubleshooting Calibration with Standards When QC is Not Within the Acceptable Range**

- Note: Run each standard three times. Each standard can be run up to six times as the instrument uses each standard result as a running average. If the standards are out of range, the calibration must be started over by exiting the calibration mode and then re-entering the calibration mode.
- Acceptable ranges for Standards used in the calibration procedure:
  - Water and 100 Standard – acceptable range +/-1
  - 500 Standards – acceptable range +/-2
  - 1500 Standard – acceptable range +/-4
  - 2000 Standard – acceptable range +/-6

## Calibration Procedure

1. Run a 100 mOsm standard through the machine to clean the well and ensure the electronics and cooler are cycling correctly.
2. Press “CAL” button.
3. Run two 100 mOsm reference standards. Wipe the sample well with a Cleanette.
4. Run three 500 mOsm reference standards. Wipe the sample well with a Cleanette.
5. Run three 1500 mOsm Standards. Record the result reading of each in the Lab Start of Stand QC Module. Wipe the sample well with a Cleanette.
6. Run three 2000 mOsm Standards. Record the result reading of each in the Lab Start of Stand QC Module. Wipe the sample well with a Cleanette.
7. Press the “CALIBRATE” button again to complete the calibration process. If you do not press the “CALIBRATE” button again at the end of calibration, the calibration will not be saved.

## **VIII. Assay Procedure**

Run SP urine collection samples in duplicate and average the two results. If the difference between the two values exceeds 40 (four times the SD of 10%), then run the sample a third time. Average the closest two of the three results. If the final result is based on a single run, then a comment “results based on single run” will automatically be appended to the result. Results are saved in whole numbers.

Osmolality test results will not be reported back to the participant. There are no panic or action limits for this test. If the measured value is  $>2,000$  mOsm/kg, then the result will be reported as “2,000” with “out-of-range” comment.

## **A. Osmette II Instrument Placement**

Allow at least 3 inches on both sides and back of the instrument for placement of the Osmette. The Osmette should not be placed near a heat source or in direct sunlight. Do not block the air outlet (at rear of instrument) and the air intake (at front right side of instrument). Any blockage of the air intake or outlet will slow the cooling of the Cooler Well, so that it will take longer to reach operating temperature. The instrument work area must be free of vibration (avoid benches with centrifuges).

## **B. Instrument Buttons and Functions**

1. Plug the OSMETTE II into a grounded AC outlet of the proper voltage (115 v AC).
2. The ON/OFF button is located on the rear of the machine. It is a black rocker button. Always make sure the button is in the OFF position when plugging in the instrument.
3. The SPEC button is an unlabeled button on the rear of the machine. The button is a thin white unlabeled stick projecting from the back of the instrument. This button frequently acts as a cancel button. Stops both stabilizing, reading, digit entry, or any special function: acts as an escape key.
4. The CALIBRATE button initiates instrument calibration. The CAL button is located on the right front console of the instrument.
5. The RUN button initiates running a reading, whether calibrating or running an unknown. The RUN button is located on the right front console of the instrument.
6. The shutter is a metal cover that will automatically close and protect the cooler well. The shutter opens when the instrument is turned on. It will close to clamp around the pipette when a sample is run. It will close after approximately 10 minutes of inactivity to protect the cooler well from dust and debris. Always check to ensure the shutter is open before wiping the cooler well or running a sample. To open the shutter after it has automatically closed, the instrument operator must manually open the shutter:
  - Press the SPEC button on the back of the machine.
  - Press the run key twice to display “SPEC2” on the Osmette screen.
  - Press the CALIBRATE key. The shutter will open.

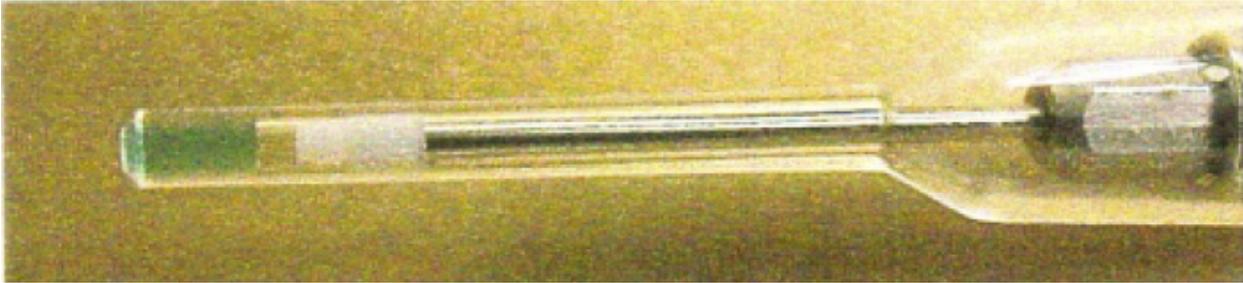
The shutter closes after 10 minutes of inactivity regardless of the pipette or Cleanette sitting in the cooler well. The medical technologist should avoid leaving the pipette in the instrument after a sample has been run. The medical technologist should also not leave Cleanettes in the cooler well between samples. If a sample (or Cleanette) is left sitting in the cooler well and the shutter has clamped around it, follow the above instructions to open the shutter. Do not manually force it open or pull the pipette or Cleanette out.

### C. **Proper Pipetting Technique**

Proper pipetting technique is critical for accurate osmolality results. Take several steps to ensure that the pipette is functioning properly:

1. Check the pipette calibration daily as described in VIII. F and Section 15.10.
2. Wipe the pipette wire and Teflon tip with a Kimwipe before attaching a disposable pipette tip. This will absorb any residual moisture from the previous sample and prevent inadvertently drawing the sample too far up into the pipette tip from residual liquid attraction.
3. When placing a disposable pipette tip on the pipette, ensure that the pipette tip snaps onto the pipette. If it is not properly seated, the entire pipette tip will come off when the piston is depressed. Check this by depressing the pipette piston once when a new pipette tip is attached and before drawing the sample. If the pipette tip immediately comes off, firmly reattach it. If that does not correct the problem, discard the pipette tip and affix another one to the pipette. Recheck.
4. If the disposable pipette tip is properly seated on the pipette and the Teflon tip does not give any resistance against the pipette tip when depressing the pipette piston, change the Teflon tip.
5. Ensure that, when the pipette is placed in the sample, that the pipette tip is fully submerged to avoid accidentally drawing air bubbles in the sample.
6. Wipe the end of the pipette tip with a Kimwipe after drawing the sample. Make sure that the end of the drawn sample is flush with the very tip of the pipette. Overwiping the sample may draw some of the sample out of the end of the pipette and lead to premature sample freezing from air bubbles. If the sample is not flush with the end of the pipette, discard the sample and pipette tip and redraw the sample.
7. Check to make sure there are no other air bubbles in the sample. If there are other air bubbles visible in the sample, discard the sample and pipette tip and redraw the sample.
8. Always check the air bubble between the sample and the Teflon tip. Familiarity with the correct air bubble size is critical to recognizing a properly functioning pipette. The correct air bubble size is shown in Exhibit 12-1. If the air bubble appears smaller or larger than the picture, dispose of the plastic pipette tip and drawn sample and check the pipette calibration. Check to make sure sufficient resistance is felt from the Teflon tip when a new disposable pipette tip is inserted on the instrument. Inspect the pipette for any undetected damage, such as a bent pipette wire. Ensure that there is enough sample for a full sample draw and that the disposable pipette tip is properly seated on the instrument.

Exhibit 12-1. Note the air bubble between the blue-green liquid sample and the white Teflon pipette tip



9. When placing the pipette into the Osmette II, ensure that the pipette is placed in with the thumb and forefingers (the same finger position as gripping a dart) as opposed to the same hand position used for pipetting. This is to prevent the thumb accidentally bumping or depressing the piston, even just a tiny bit, while the pipette is in the osmometer.

#### D. Running SP Samples

It is **critical** that the Osmo application is running on the ISIS computer before running any SP samples. This application captures results from the Osmette II. Any samples run without the Osmo application running will be lost and will need to be rerun. To open the Osmo application, double click on the icon of a pipette on the desktop:



The application icon will display in the system tray when the application is running. It is very faint, but will turn green when data are transmitted from the Osmette to the ISIS computer. Double check to make sure this icon is visible before running SP samples.



1. Switch (at rear of instrument) to ON, and allow the cooler well to cool down. Allow the instrument to run for 15 minutes to warm up to equilibrate all the circuitry before running SP samples or QC.
2. Notice that the green display turns on, displaying “COOLER STABILIZING.”

3. In a few minutes, the display will change to “WIPE BEFORE NEXT SAMPLE,” indicating that the refrigeration system has reached operation temperature and the instrument is ready to use. Do not attempt to use the OSMETTE until this change, as the refrigeration system will be too warm to give satisfactory results.
4. Push a Cleanette all the way to the bottom of the cooler well. The Cleanette is placed in the cooler well and twisted to soak up moisture from the previous samples. The tip of the Cleanette will cover the probe when inserted all the way into the well. Rotate it to remove any moisture. Be careful to insert the Cleanette in a straight down motion. Twist the Cleanette in the cooler well by spinning the Cleanette between thumb and forefingers – do not bend the Cleanette while wiping the well. Remove it by pulling it straight out to avoid bending the probe. Remove and dispose of the Cleanette after use. A fresh Cleanette is used with each sample.

**Do not place a sample in an unwiped cooler well.**

5. Examine the urine collection sample. If blood is present, do not run the sample. This is to protect the probe from additional protein. Mark the sample as not done with comment code “blood present.” If particulate matter is present, centrifuge the sample before running as described in Section IV.B.
6. Attach a clean, dry pipette tip to the pipette. Verify the function of the pipette as described in Section VII.B.
7. Scan the barcode (Figure 12-2) on the urine collection cup.



Figure 12-2. Example of a urine collection barcode label

8. Using the Osmette II pipette draw 10 uL of sample directly out of the urine collection cup. Carefully pipette samples to avoid capturing air in the bottom of the pipette tip. Dry the outside of the pipette tip with a Kimwipe tissue. Do not wipe the pipette with any other material.
9. Place the pipette tip in the cooler well. The Thermistor Probe is located at the bottom center of the cooler well. The pipette places the pipette tip with the sample into the bottom of the cooler well, surrounding the Thermistor Probe with the sample. The sample remains in the pipette tip, with the pipette attached, when it is placed in the cooler well.

10. Press RUN to initiate the osmolality test. The instrument screen will display the sample ID of the specimen. If no sample ID is displayed, use the SPEC button to cancel the test. Scan in the barcode for the sample before rerunning the test.
11. Observe the Display: The number displayed is an indication of the approach to the seeding temperature. The sample is fully cooled when this number decreases to 0. During this process the Osmette shutter will clamp onto the pipette to secure the pipette for seeding.

**Do not attempt to remove the pipette while the shutter is clamped to the pipette.**

12. When the display reaches approximately 0, the sample is automatically seeded by a vibration of the shutter. If the display does not reach 0, and vibration does not occur, READ will not be displayed, and no reading can be made. Rerun the sample.
13. After a few seconds, READ will be displayed, together with the result in mOsm. The shutter will then open to allow for removal of the pipette and for cleaning the cooler well.
14. The osmolality measurement is complete. Before leaving the instrument or placing a new sample in the cooler well, use a fresh Cleanette to wipe the cooler well.

**Do not leave the Cleanette in the cooler well.**

15. Eject the used pipette tip into the biohazards container and wipe the Teflon tip of the pipette with a Kimwipe before attaching a new disposable pipette tip for the next sample.

#### **E. Daily Shut-down Procedures**

1. Wipe cooler well with a Cleanette before turning off the instrument. This is to ensure that there is no residual moisture in the cooler well before shutting off the instrument.
2. Turn off the instrument using the rocker button located on the back of the instrument. Turn the instrument off after each session. There is no standby mode for the instrument and turning it off when not in use will prolong the instrument's life.

#### **F. Verifying the Pipette Calibration**

The pipette requires two small instruments to verify that it is calibrated correctly and will draw the proper amount of solution into the disposable pipette tip. One calibrator resides in the clear red box with the replacement Teflon tips. This calibrator is made of a hard black plastic and is about an inch long. It has a nib on one end. This calibrator measures the size of the bubble that is held between the Teflon tip and the sample when in the disposable pipette tip. To ensure the bubble is the proper size place a clean disposable pipette tip on the pipette. Depress the plunger. Insert the nib into the end of the

disposable pipette tip. The end of the nib should just touch the end of the Teflon tip; the tip should not push the tool out, and oppositely there should be no space gap between the tool and the Teflon tip.

If the bubble is not properly calibrated, remove the disposable pipette tip and unscrew the lock nut at the base of the pipette wire. Hold the plunger firmly with one hand while unscrewing the lock nut with the other. Use a pair of pliers if necessary. Unscrew the lock nut until it is loose. The pipette wire will also feel loose. Be careful not to turn the pipette wire accidentally when unscrewing the lock nut. Controlled, small turns will adjust the pipette wire to change the calibration setting. Turn the pipette wire in a clockwise direction (if looking at the end of the pipette tip head on) to pull the pipette tip up into the pipette and therefore make the bubble size larger. Turn the wire clockwise to adjust the pipette so the calibration tool will insert further up into the end of the clean pipette tip. Turning the wire counterclockwise adjusts the pipette so that the calibration tool will close the gap between the calibration tool and the Teflon tip. The tool and the tip should just touch when properly calibrated. When the desired adjustment has been made, tighten the lock nut down with your fingers.

Place a clean disposable pipette tip on the pipette. Use the black calibration tool again to check the bubble size. Readjust if needed by following the above procedure. Once the calibration is successful, tighten the lock nut so that it will not come loose during regular use. Be careful not to damage the pipette.

The second instrument required to calibrate the pipette resides on the pipette itself. The end of the plunger opposite the tip has a tool that reads “Calib Gage & Key.” This tool can be unscrewed from the end. The length of the tool measures the correct draw amount for the pipette. To measure the draw amount place a clean disposable pipette tip on the pipette. Without depressing the plunger, insert the calibration gage into the end of the disposable pipette tip. The end of the calibration gage should just touch the end of the Teflon tip.

If the draw amount is not properly calibrated, twist the pipette plunger around until the nut on the inside of the plunger aligns with the hole in the side of the pipette body. Use the tiny hex wrench on the end of the calibration gauge to carefully turn – usually not more than a quarter turn – the nut inside the hole to loosen plunger. Use the slack in plunger to move wire with Teflon tip towards end of pipette tip. Use the hex wrench as a gauge to push the wire with Teflon tip back so it’s calibrated. Immediately tighten the hex nut. Verify that the pipette is calibrated by depressing the piston and use the calibration

gage to see if the draw amount is now correct. Readjust if needed by following the above procedure. Be sure to replace the calibration gage in the end of the pipette when calibration is complete.

### **Changing the Osmette II Pipette Teflon Tip**

Change the Teflon tip if any of the below are encountered:

- The beginning of each stand.
- The resistance of the tip when depressing the pipette appears to be too loose.
- The air bubble separation above the sample is gone after a reading.
- The readings are erratic.

Replace the Teflon pipette tip. Remove the pipette tip from the disposable pipette tip or the protective cover. The Teflon tip is the tiny white plastic on the end of the pipette wire. The tip can be removed several ways. Any method is acceptable as long as care is taken to not bend the pipette wire or damage the pipette in any other way. A razor blade can be used to carefully cut along the side of the tip to cause it to release from the end of the wire. The tip will also come off by using a fingernail and some patience to work a space between the tip and wire and then push the tip off.

Locate the small clear red box labeled “Osmette Teflon Tips and Calibrator.” Use one of the new Teflon tips inside the box as the replacement. The Teflon tip has one end that is solid and one end with a hole. The end with the hole should be placed on the end of the pipette wire. Ensure that the wire is fully inserted into the new tip. There should be no gap between the white tip and the pipette wire.

### **G. Cleaning, Opening, and Oiling the Osmette II Probe**

The Osmette II may need to have the probe cleaned for several reasons:

- The instrument displays a large amount of “NO FREEZE” errors.
- The instrument displays a large amount of “PRE FREEZE” errors.
- The readings are erratic.

Clean the Osmette II probe. Wet the end of a Cleanette with an alcohol prep pad. Use as many pads as needed to ensure the end of the Cleanette is wet. Insert the wet end of the Cleanette into the probe well and wipe by rotating the Cleanette left and right. Remove the Cleanette. Wet the end of a Cleanette with distilled water. Insert the wet end of the Cleanette into the probe well and wipe by rotating the Cleanette left and right. Remove the Cleanette. Insert a dry Cleanette into the probe well and wipe by rotating the Cleanette left and right. Remove the Cleanette. This process should clean any residual proteins left in the well.

Over time some sample may leak out into the probe chamber because of leakage due to loss of surface tension (as in the case of proteins in the sample or improperly drawn samples). The only way to clean this residue is to open the probe chamber and wipe off the entire probe, base, and chamber. Open the Osmette II for cleaning the probe chamber. Ensure that the power button on the back of the Osmette is switched to "Off." Unplug the instrument from both the electrical outlet and the computer. Very gently turn the instrument over and lay it on its top so that the underside is tilted towards you. The bottom of the instrument is exposed. There is a black plastic piece on the underside of the instrument known as the "coffin" for its shape. The coffin acts as a cover for the probe. Open the coffin by using a Phillips head screwdriver to loosen the single screw on the left hand, broad end of the coffin. Carefully remove the loose screw and place it somewhere secure so it will not get lost. The loose end of the coffin can now swing up to reveal an opening underneath.

Inside the opening is a large black piece with a white circle in the middle. The white circle is made out of a rubbery, softer material. In the white circle is a white hard plastic donut with a white wire coming out. Using gloved hands, use your fingertips to gently unscrew the white donut by turning it to the left. Once the donut is loose, gently pull it straight out of the probe chamber, being careful not to touch the probe tip to the sides of the chamber. The probe is on the end of the white plastic donut. It is made of a fine metal wire, much like a pin. At its base is a flat surface with a black circle surrounded by a metal circle.

To clean the Osmette II, use only a Cleanette to wipe around the base of the probe (black circle and metal circle) to remove any residual sample not picked up by normal cleaning. Look down into the probe chamber on the instrument. On each side of the chamber are threads to fasten the donut back in place. Use a cleanette to wipe around the threads and the ring at the bottom of the chamber to absorb any residual sample.

On a rare occasion the probe base may need to be oiled. Only oil the probe if recommended by the Precision Systems technician. To oil the probe use a tiny dab of Dow 311 industrial lubricant on the end of a Cleanette. Wipe the lubricant around the base of the probe (black and metal circles). The lubricant should be spread very thinly. The purpose of the lubricant is to ensure that no sample seeps down into the break between the black circle and the metal circle at the base of the probe. The lubricant also helps to create surface tension to hold the sample in the pipette tip. Use a clean Cleanette to wipe off any globs of lubricant on the base of the probe.

Once cleaning and/or oiling is complete, put the Osmette II back together. Carefully direct the probe back down into the probe chamber. Use your fingers to gently tighten the white plastic donut into the white circle. The donut should only be finger tight; do not overtighten. Swing the coffin back down into place so that the hole in the coffin for the screw lines up with the hole in the osmette, and the probe opening is completely covered. Use the screw and Phillips head screwdriver to fasten in place. Do not over fasten.

## **IX. Reportable Range of Results**

The Osmette II is intended to measure aqueous solution concentrations from 0-2000 mOsm/kg H<sub>2</sub>O.

## **X. Quality Control**

### **A. Standards and CON-TROL Principle**

Both the Precision Systems Standards and CON-TROL Standards are aqueous solutions of known osmolality. CON-TROL Standards are used to verify the accuracy of the Standards by equal comparison. The Standards verify the accuracy of the Osmette II instrument by running a solution of known osmolality as an unknown.

### **B. Standards and CON-TROL Storage and Handling**

Precision Systems Standards should be stored in upright bottles at room temperature. They should not be diluted.

Always:

- Squeeze a small amount of the Standards solution into a disposable container or into the sink. This is to clear out the pour spout and remove any salt crystals that may have formed.
- Pour (never pipette) the Standards into the Precision Systems sample tubes and immediately snap the cap shut on the sample tubes. Clearly label the tubes with the Standards level using a permanent marker.
- Use only the amount of solution needed to gain acceptable pipetting technique and results. Under normal circumstances, this will be about two to five drops of Standards solution.
- Recap or snap down the pour spout on the Standards bottle quickly after dispensing. This is to prevent evaporation, which will change the osmolality of the solution, and to prevent microbiological contamination.
- Discard the sample tubes containing Standards after calibration or a QC process. This is to ensure fresh standards are used for every procedure. Never return a Standard to the bottle.

Discard Standards bottles when:

- There is evidence of turbidity or other microbiological contamination.
- Crystals appear on the outside of the bottle or ampule.
- The current date is past the expiration date on the bottle.
- Only 30 percent of the contents of the bottle remains.

Open the Precision Systems CON-TROL Standards glass ampules carefully. To use, pour directly from the ampule into the Precision Systems disposable test tube. Never pipette directly from the ampule. Discard the ampule after one use; never save and reuse an open ampule.

### C. **Dropper Urine Chemistry Controls Principle**

The **Dropper Urine Chemistry** Controls are intended as a means of monitoring human urine osmolality results to validate quantitation of patient samples. Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method. The typical precision of the OSMETTE may be expected to be <2 mOsm/kg H<sub>2</sub>O for 1 SD for serum, urine and salt standards for concentrations below 500 mOsm, and <1.0% for readings above 500 mOsm.

## **D. Quantimetrix Controls Storage and Handling**

The Quantimetrix Human Urine Controls are supplied as a ready-to-use liquid requiring no reconstitution. They are prepared from human urine. The Human Urine Controls are fortified to target levels with human proteins and reagent grade chemicals. Preservatives have been added to inhibit microbial growth.

Though the Quantimetrix Human Urine Controls have been tested nonreactive for Hepatitis and HIV antibodies, no known test product can assure that a product derived from human blood does not contain these viruses. Therefore, the controls should be handled according to the Centers for Disease Control's Biosafety Level 2 recommendations.

Always:

- Treat the controls as an SP sample.
- Store the controls refrigerated at 2 – 8 ° C. When stored at this temperature, the controls are stable until the expiration date stated on the label.
- Use only the amount of solution needed to gain acceptable pipetting technique and results. Under normal circumstances, this will be about two to three drops of Standards solution.
- Invert the bottle gently to ensure homogeneity of the solution before dispensing. Avoid foaming.
- Dispense the Quantimetrix controls into a Precision Systems sample tube before running the sample. Be sure to label the sample tube using a permanent marker.
- Recap the Quantimetrix control bottle immediately after dispensing the test amount and promptly return the bottle to the refrigerator.
- Allow the sample to sit for 30 minutes to come to room temperature before running the control sample.

Discard the controls when:

- The controls are past the marked expiration date.
- The control has been opened and it is 24 months from the date of manufacture or past the expiration date, whichever comes first.
- The control displays signs of turbidity.
- There is any evidence of microbial contamination.

## E. Running Quality Control Samples

It is **critical** that the ISIS Osmo application is running on the ISIS computer before running Quantimetrix control QC samples. This application captures results from the Osmette II. Any Quantimetrix QC samples run without the Osmo application running will be lost and will need to be rerun. Precision Systems Standards and CON-TROL results are recorded manually and do not require the Osmo application to be running.

To open the Osmo application, double click on the icon of a pipette on the desktop:



The application icon will display in the system tray when the application is running. It is very faint, but will turn green when data are transmitted from the Osmette to the ISIS computer. Double check to make sure this icon is visible before running Quantimetrix samples.



Start the Osmette II instrument and run samples.

1. Switch (at rear of instrument) to ON, and allow the Cooler Well to cool down. Allow the instrument to run for 15 minutes to warm up to equilibrate all the circuitry before QC samples.
2. Note that the green display turns on, displaying “COOLER STABILIZING.”
3. In a few minutes, the display will change to “WIPE BEFORE NEXT SAMPLE,” indicating that the refrigeration system has reached operation temperature and the instrument is ready to use. Do not attempt to use the OSMETTE until this change, as the refrigeration system will be too warm to give satisfactory results.
4. Push a Cleanette all the way to the bottom of the cooler well. The Cleanette is placed in the cooler well and twisted to soak up moisture from the previous samples. The tip of the Cleanette will cover the probe when inserted all the way into the well. Rotate it to remove any moisture. Be careful to insert the Cleanette in a straight down motion. Twist the Cleanette in the cooler well by spinning the Cleanette between thumb and forefingers – do not bend the Cleanette while wiping the well. Remove it by pulling it straight out to avoid bending the probe. Remove and dispose of the Cleanette after use. A fresh Cleanette is used with each sample.

**Do not place a sample in an unwiped cooler well.**

5. Attach a clean, dry pipette tip to the pipette. Verify the function of the pipette as described in Section VII.B.
6. For Quantimetrix QC samples, scan the barcode for the appropriate QC level:



Figure 12-3. Example of Quantimetrix barcode labels

This step is not required for Precision Systems Standards and CON-TROL samples.

7. Using the Osmette II pipette draw 10 uL of sample directly out of the Precision Systems sample tube. Carefully pipette samples to avoid capturing air in the bottom of the pipette tip. Dry the outside of the pipette tip with a Kimwipe tissue. Do not wipe the pipette with any other material.
8. Place the pipette tip into the cooler well. The Thermistor Probe is located at the bottom center of the cooler well. The pipette places the pipette tip with the sample into the bottom of the cooler well, surrounding the Thermistor Probe with the sample. The sample remains in the pipette tip, with the pipette attached, when it is placed in the cooler well.
9. Press RUN to initiate the osmolality test.
10. Observe the Display: The number displayed is an indication of the approach to the seeding temperature. The sample is fully cooled when this number decreases to 0. During this process the Osmette shutter will clamp onto the pipette to secure the pipette for seeding.

**Do not attempt to remove the pipette while the shutter is clamped to the pipette.**

11. When the display reaches approximately 0, the sample is automatically seeded by a vibration of the shutter. If the display does not reach 0, and vibration does not occur, READ will not be displayed, and no reading can be made. Rerun the sample.

12. After a few seconds, READ will be displayed, together with the result in mOsm. The shutter will then open to allow for removal of the pipette and for cleaning the cooler well.
13. The osmolality measurement is complete. Before leaving the instrument or placing a new QC sample in the cooler well, use a fresh Cleanette to wipe the cooler well.

**Do not leave the Cleanette in the cooler well.**

14. Eject the used pipette tip into the biohazards container and wipe the Teflon tip of the pipette with a Kimwipe before attaching a new disposable pipette tip for the next QC sample.
15. Run each Quantimetrix Human Urine Control twice, adding a third run if needed.
16. Run each Standard or CON-TROL according to the run iterations defined in the QC module, repeating runs if necessary.

**F. Record Precision Systems Standards and CON-TROLS in ISIS**

Access the ISIS QC module. Manually enter the QC results.

The screenshot shows the 'Lab Sink' application window with the 'Quality Control' module active. A menu is open over the 'Quality Control' header, listing various options like 'Exam Pause', 'Observations', 'IC Exclusions', 'Send Message', 'UFO Sighting', 'Set Session', 'English', 'Spanish', 'Toolbars...', 'System Configuration', 'Pregnancy QC', 'Coulter QC Lot Info', 'Osmolality QC', 'Regen SP Data', and '1 Heads-Up for Session: 430941'. The main window displays a table of samples with their process status.

SP ID	name	UC	U	P	OZ	CB	B	gtt	PC	HPV	OR
326440	ER_5, PATTY	●	●	●	●	●	●	●	●	●	●
335106	CHER_3, JACQUIE	○	○	○	○	○	○	○	○	○	○
338509	RIS_3, NICOLE	○	○	○	○	○	○	○	○	○	○
338808	OND#5, NEIL	●	●	○	●	●	●	●	●	○	○
343296	NSON_6, CLAY	○	○	○	○	○	○	○	○	○	○
347272	SNICK	○	○	○	○	○	○	○	○	○	○
347354	RIS_4, PENNY	○	○	○	○	○	○	○	○	○	○
349929	ER_6, SHERYL	●	○	○	○	○	○	○	○	○	○
351184	BELL_6, NELLIE	○	○	○	○	○	○	○	○	○	○
361379	361379 CI P F 68 DRAKE_5, ALMA	○	○	○	○	○	○	○	○	○	○
362603	362603 SC P F 18 MILLER_4, SHELIA	○	○	○	○	○	○	○	○	○	○
362865	362865 SC P F 34 LOPEZ_7, LYDIA	○	○	○	○	○	○	○	○	○	○
367472	367472 SC P F 19 DRAKE_5, WENDY	○	○	○	○	○	○	○	○	○	○
375805	375805 EX P F 49 MILLER_4, PATTY	○	○	○	○	○	○	○	○	○	○
375816	375816 SC P F 30 HOLLAND_7, LISA	○	○	○	○	○	○	○	○	○	○

Quality Control | HUP: idle | MEC Layer: 12/11/2008 | Application: 9.0.0

Standards and CON-TROL QC are found under the Lab Quality Control module.

Lab Sink

Start of Stand | **Daily** | Weekly | End of Stand | Supply Use | NCHS QC

QC Check	Done	Result	Comment
Freezer #1 cleaned?	<input type="checkbox"/>		
Freezer #2 cleaned?			
Freezer #3 cleaned?			
Freezer #4 cleaned?	<input type="checkbox"/>		

(yes/no)

OK Cancel

Lab Sink

Please enter in your user id

OK Cancel

Enter the user ID of the tech running the QC samples.

Lab Sink

Start of Stand | **Daily** | Weekly | End of Stand | Supply Use | NCHS QC

QC Check	Done	Result	Comment
Change Osmometer Teflon Pipette Tip	<input type="checkbox"/>		
Osmette Total Calibration Distilled Water 1	<input type="checkbox"/>		
Osmette Total Calibration Distilled Water 2	<input type="checkbox"/>		
Osmette Total Calibration 100 Standard 1	<input type="checkbox"/>		

(yes/no)

result

result

96 - 104

OK Cancel

Under the Start of Stand tab, use the scroll bar on the right side of the screen to scroll down to the beginning of the Osmette Start of Stand QC tasks.

Lab Sink

Start of Stand | **Daily** | Weekly | End of Stand | Supply Use | NCHS QC

QC Check	Done	Result	Comment
Change Osmometer Teflon Pipette Tip	<input checked="" type="checkbox"/>	yes (yes/no)	
Osmette Total Calibration Distilled Water 1	<input checked="" type="checkbox"/>	1 result	
Osmette Total Calibration Distilled Water 2	<input checked="" type="checkbox"/>	0 result	
Osmette Total Calibration 100 Standard 1	<input type="checkbox"/>	 96 - 104	

OK Cancel

The first task is to change the Osmometer Teflon Pipette tip. As each task is completed, direct the mouse to the box under the “Done” column and right click. This will place a checkmark in the box to verify that the task was completed. Note the desired entry under each box in the “Result” column. This is the type of result that should be entered in the Result column. A result (yes/no) indicates a response to verify that the task was completed. Some tasks require a result entry. If there is a valid range displayed below the box, make sure that the result entered is within that range. If the result is out of range, make a note in the comment column.

For Osmolality QC, each required run of a QC is listed. If additional runs for a type of QC are required, note the results in the Comment column.

Osmolality QC appears under the Daily QC tab.

Lab Sink

Start of Stand | **Daily** | Weekly | End of Stand | Supply Use | NCHS QC

QC Check	Done	Result	Comment
Verify Osmometer Pipette Calibration	<input checked="" type="checkbox"/>	yes (yes/no)	
Osmette Calibration Check 100 Standard 1	<input checked="" type="checkbox"/>	101 96 - 104	
Osmette Calibration Check 100 Standard 2	<input checked="" type="checkbox"/>	98 96 - 104	
Osmette Calibration Check 1500 Standard 1	<input type="checkbox"/>	 1485 - 1515	

OK Cancel

Osmolality QC appears under the Weekly QC tab.

Lab Sink

Start of Stand | Daily | **Weekly** | End of Stand | Supply Use | NCHS QC

QC Check	Done	Result	Comment
Osmette Standards Check 100 Standard 1	<input checked="" type="checkbox"/>	100 96 - 104	
Osmette Standards Check 100 Standard 2	<input checked="" type="checkbox"/>	101 96 - 104	
Osmette Standards Check 100 CON-TROL 1	<input checked="" type="checkbox"/>	100 result	
Osmette Standards Check 100 CON-TROL 2	<input type="checkbox"/>	 result	

OK Cancel

Enter lot and expiration dates under the Supply Use tab.

Lab Sink

Start of Stand | Daily | Weekly | End of Stand | Supply Use | NCHS QC

QC Check	Done	Result	Comment
Osmette 2000 Standard lot number and expiration date	<input checked="" type="checkbox"/>		104231, 04/30/2010
Osmette Quantimetrix Level 1 lot number and expiration date	<input checked="" type="checkbox"/>		43301, 09/30/2009
Osmette Quantimetrix Level 2 lot number and expiration date	<input type="checkbox"/>		
Osmette CON-TROL ampules 100 lot number and expiration date	<input type="checkbox"/>		

OK Cancel

**G. Record Quantimetrix Human Urine Controls in ISIS**

1. Enter Quantimetrix QC Lot Information.

The ISIS maintains the capability to record all Quantimetrix Human Urine Control data and results. The data are used to monitor quality control results. Enter data for each lot number each time a new lot number is put into use. Manually enter the Quantimetrix data using information contained in the package insert and the predefined mean and range from NCHS.

Access the Osmolality QC module from the Utilities menu.



Direct the mouse arrow to the “Utilities” menu option near the top of the screen. Left click and drag the mouse down to “Osmolality QC” without releasing the left mouse button. Once “Osmolality QC” is highlighted, release the mouse button.

The Osmolality QC window will appear.

**Osmolality Quality Control** [X]

Lot Number	Qc Type	Date	Runs

---

**Osmolality Quality Control Details**

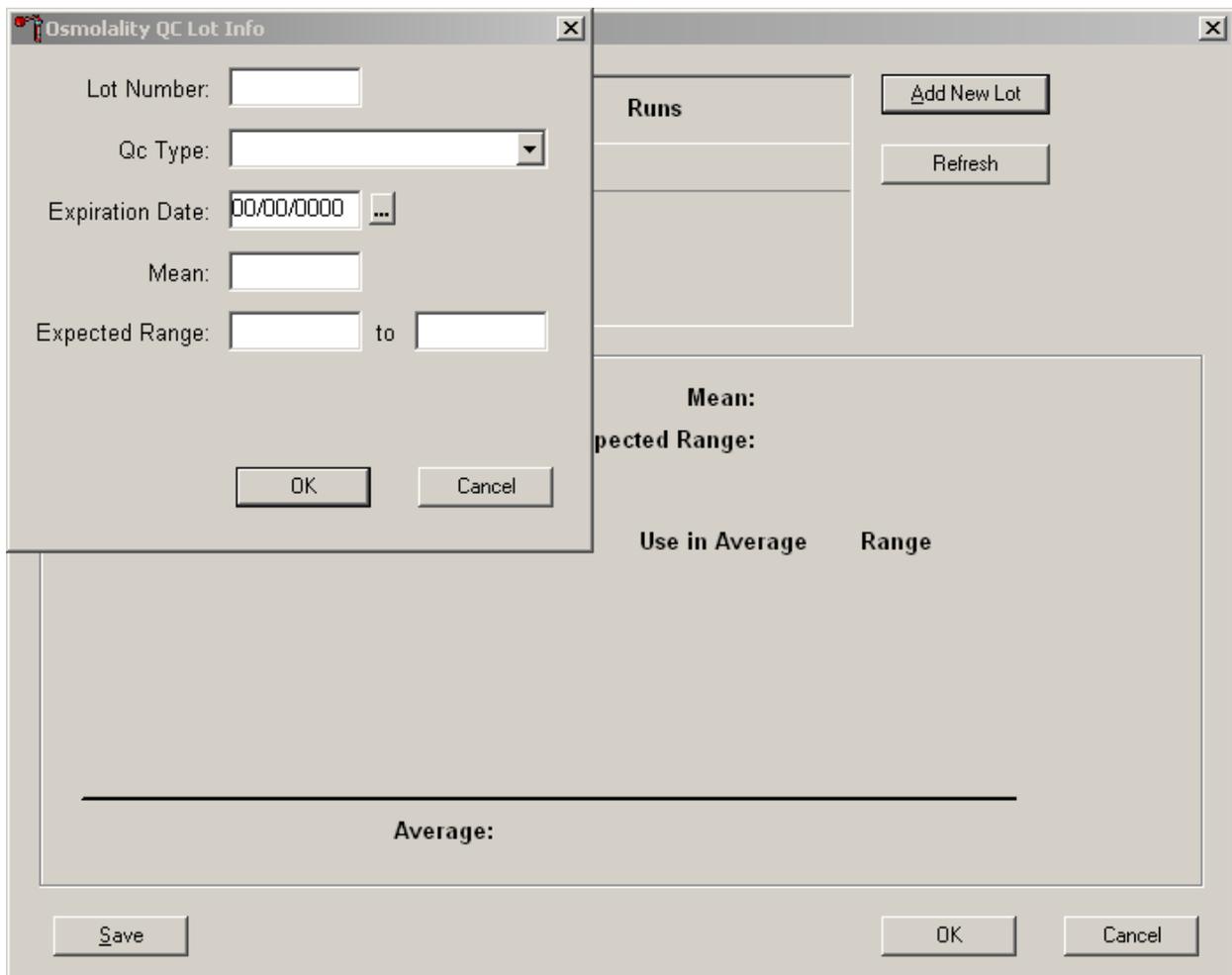
**Lot Number:** \_\_\_\_\_ **Mean:** \_\_\_\_\_  
**Expiration Date:** \_\_\_\_\_ **Expected Range:** \_\_\_\_\_

Id	Date / Time	Result	Use in Average	Range

---

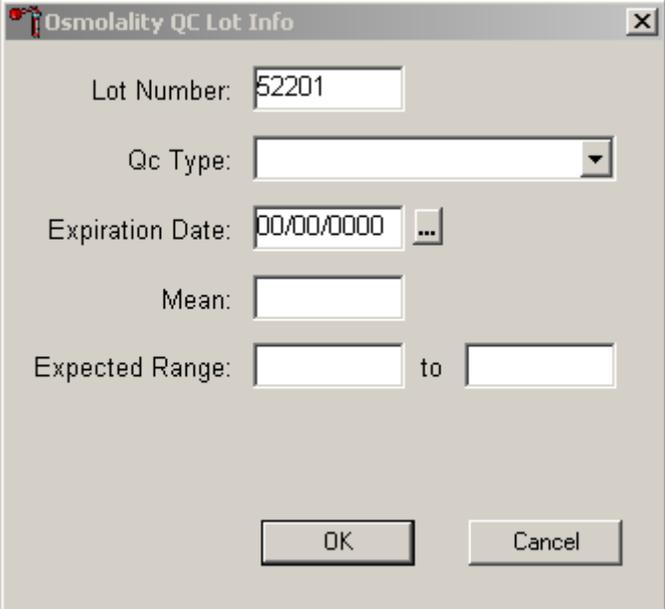
**Average:** \_\_\_\_\_

Add new Quantimetrix QC lot information.



Direct the mouse over the “Add New Lot” button and left click. A small window, “Osmolality QC Lot Info,” will appear. Enter the Quantimetrix QC information in this window. The data entry values are found in the package insert of each box of Quantimetrix Human Urine Control.

Enter the lot number in the entry box “Lot Number:”



Osmolality QC Lot Info

Lot Number: 52201

Qc Type: [dropdown]

Expiration Date: 00/00/0000 ...

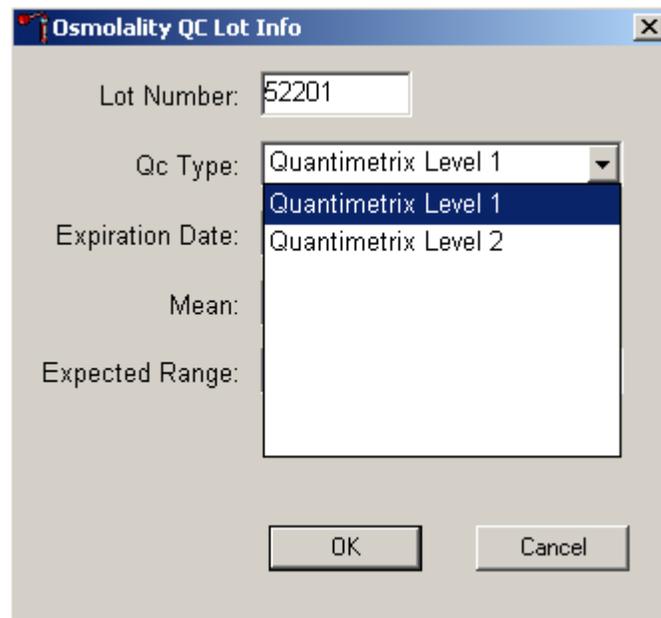
Mean: [input]

Expected Range: [input] to [input]

OK Cancel

Direct the mouse over the Lot Number field and left click. Use the number pad on the keyboard to enter the lot number on the package insert.

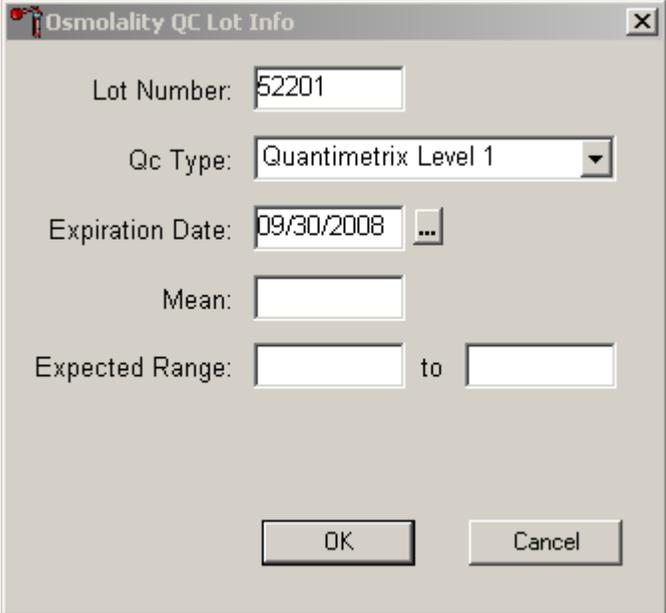
Each set of QC has a high and low control defined by the lot number. The value of each QC can be determined by looking at the last digit of the QC Lot Number. “01” is Level 1 and “02” is Level 2. Select the QC control type from the drop-down list.



The image shows a software dialog box titled "Osmolality QC Lot Info". It contains several input fields and a dropdown menu. The "Lot Number" field is filled with "52201". The "Qc Type" dropdown menu is open, displaying two options: "Quantimetrix Level 1" (which is highlighted) and "Quantimetrix Level 2". The "Expiration Date", "Mean", and "Expected Range" fields are currently empty. At the bottom of the dialog, there are two buttons: "OK" and "Cancel".

Direct the mouse arrow over the down arrow and left click to view the drop-down selections for Quantimetrix levels. Direct the mouse arrow so the desired Quantimetrix Level is highlighted and left click.

Enter the expiration date of the human urine controls.



Osmolality QC Lot Info

Lot Number: 52201

Qc Type: Quantimetrix Level 1

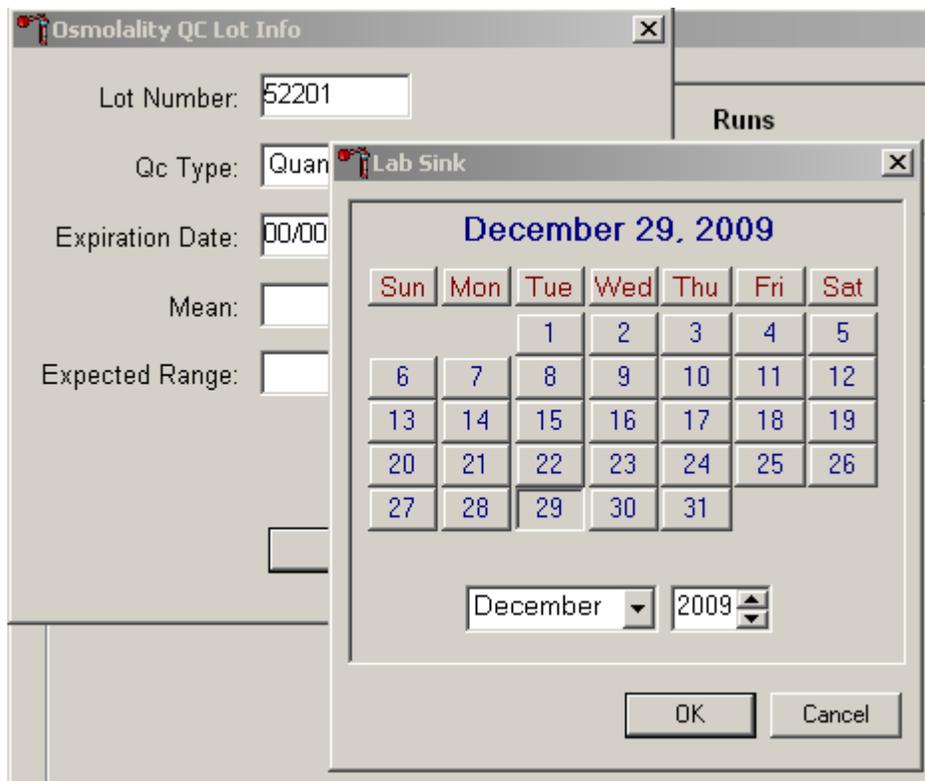
Expiration Date: 09/30/2008 ...

Mean:

Expected Range: to

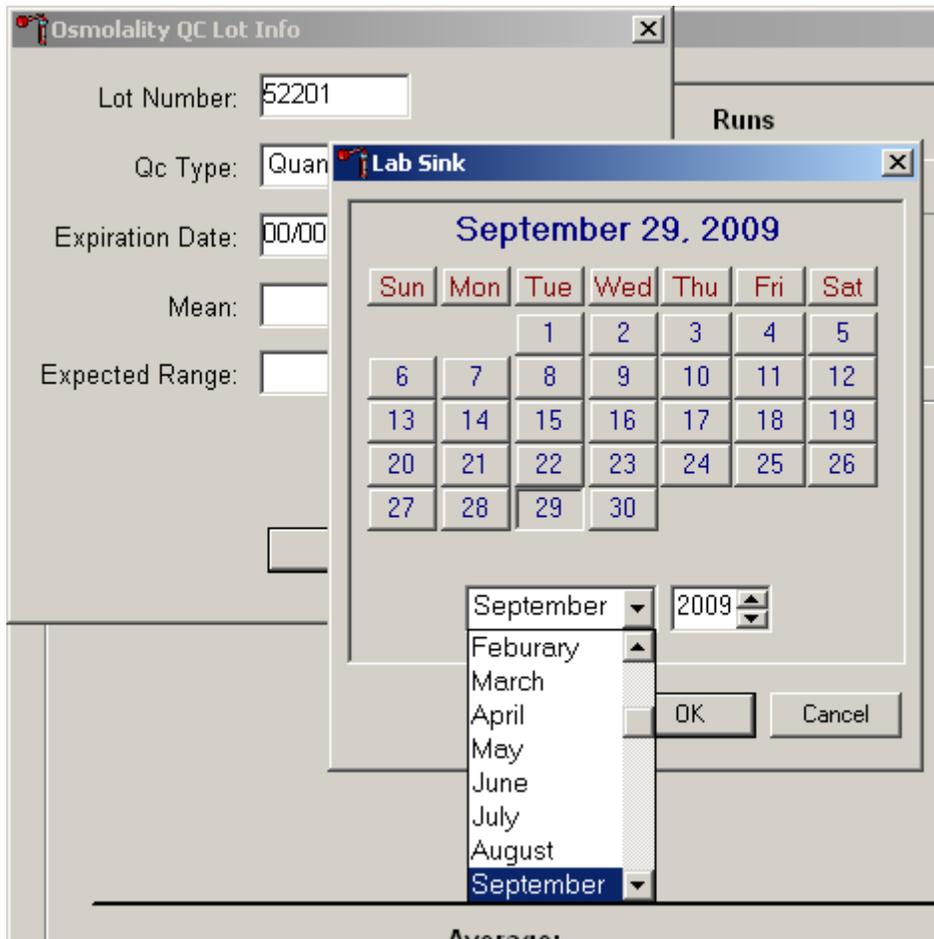
OK Cancel

Direct the mouse to the Expiration Date field and left click. Alternatively, press the [Tab] key to move from the QC Type field to the Expiration Date field. Enter the date in MM/DD/YYYY format. Alternatively, direct the mouse over to the ellipsis [...] button and left click to select the calendar function.



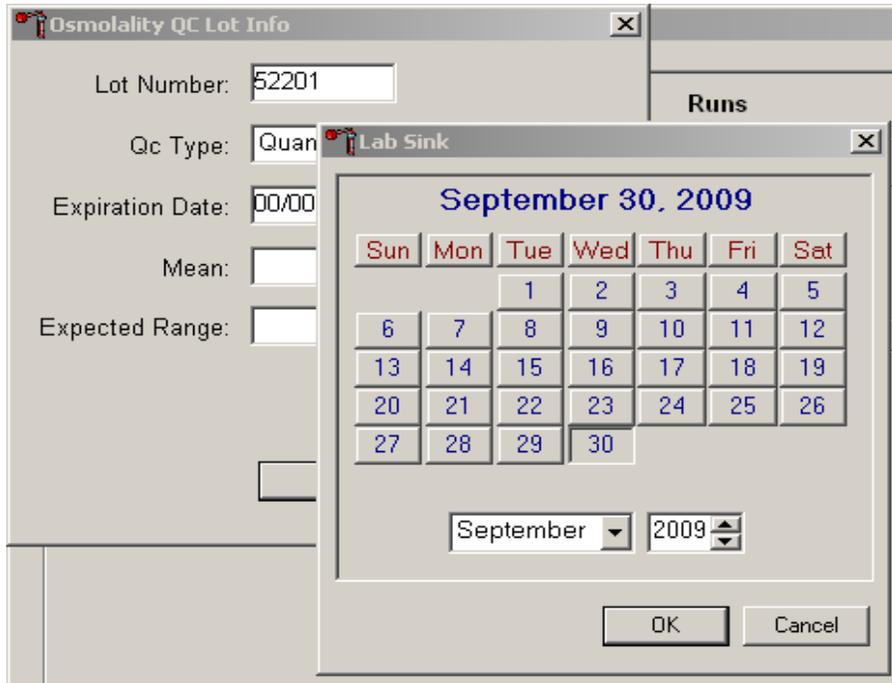
Use the up and down arrow buttons to scroll to the correct year of the expiration date.

Use the drop-down list to select the correct month.

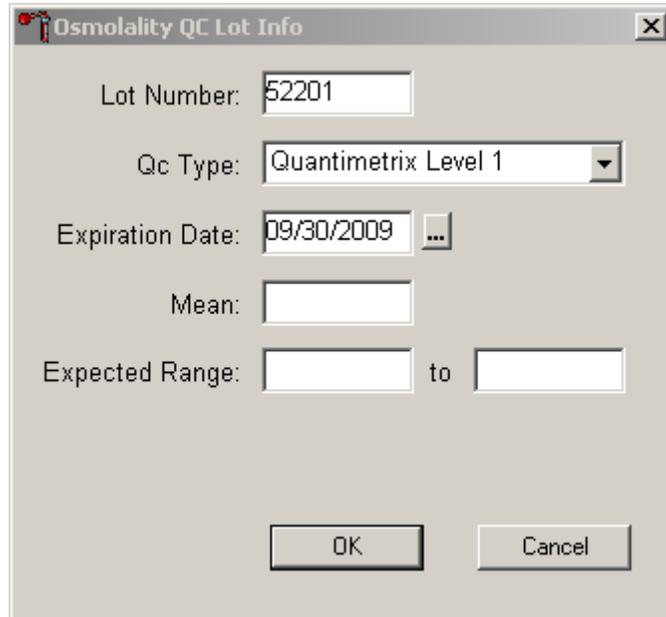


Direct the mouse arrow to the down arrow and left click to view the drop-down menu months. Use the scroll bar to view all month selections. To select the month, direct the mouse arrow to the month and left click.

Select the last day of the expiration month by clicking on the day in the calendar.



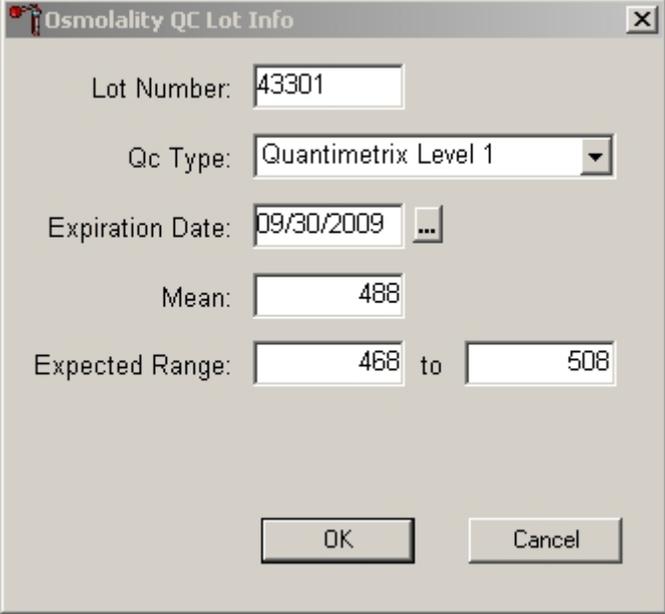
Direct the mouse arrow over the "OK" button and left click.



The calendar window will disappear and the selected date will automatically fill in the Expiration Date field.

Enter the predefined mean and range for each lot number. These numbers are defined by NCHS based on a test of each new lot number. **Do not use the information included in the package insert for these fields.**

Enter the mean.



The screenshot shows a dialog box titled "Osmolality QC Lot Info". It contains the following fields and values:

- Lot Number: 43301
- Qc Type: Quantimetrix Level 1
- Expiration Date: 09/30/2009
- Mean: 488
- Expected Range: 468 to 508

At the bottom of the dialog box, there are two buttons: "OK" and "Cancel".

Direct the mouse arrow over the Mean entry field and left click. Alternatively, press the [Tab] key to move to the Mean field from the Expiration Date field. Enter the mean in the Mean field.

Enter the expected range.

Osmolality QC Lot Info

Lot Number: 43302

Qc Type: Quantimetrix Level 2

Expiration Date: 09/30/2009

Mean: 838

Expected Range: 820 to 856

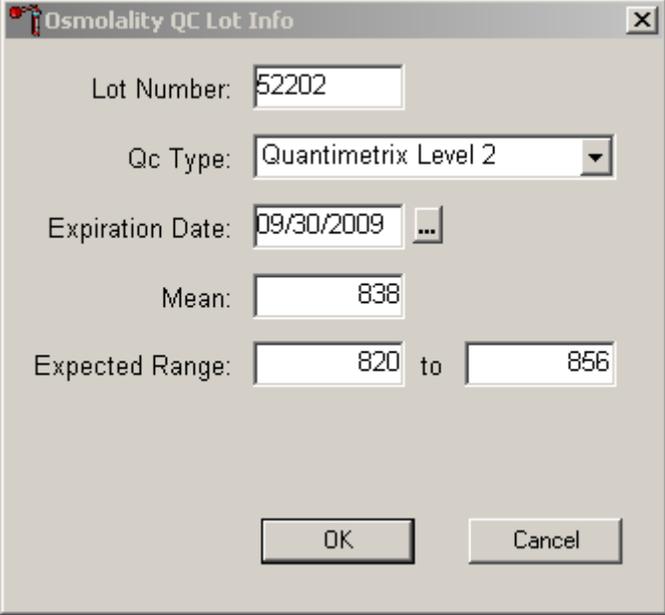
OK Cancel

Direct the mouse arrow over the first Expected Range entry field and left click. Alternatively, press the [Tab] key to move to the Expected Range field from the Mean field. Enter the low range value in the first entry field. Direct the mouse arrow over the second Expected Range field and left click. Alternatively, press the [Tab] key to move to the second Expected Range field. Using the keyboard number pad, type the high range value in the second entry field.

Direct the mouse arrow to the OK button and left click. Alternatively, press the [Enter] key.



Add the Level 2 lot information by directing the mouse to “Add New Lot” and left clicking. Enter the information in the Osmolality QC Lot Info window using the same steps as the first lot above. Be sure to enter the correct mean and range for the Level 2.



The image shows a dialog box titled "Osmolality QC Lot Info" with a close button (X) in the top right corner. The dialog contains the following fields and controls:

- Lot Number:
- Qc Type:  (dropdown menu)
- Expiration Date:  (calendar icon)
- Mean:
- Expected Range:  to
- Buttons:  and

Direct the mouse arrow to the OK button and left click. Alternatively, press the [Enter] key.





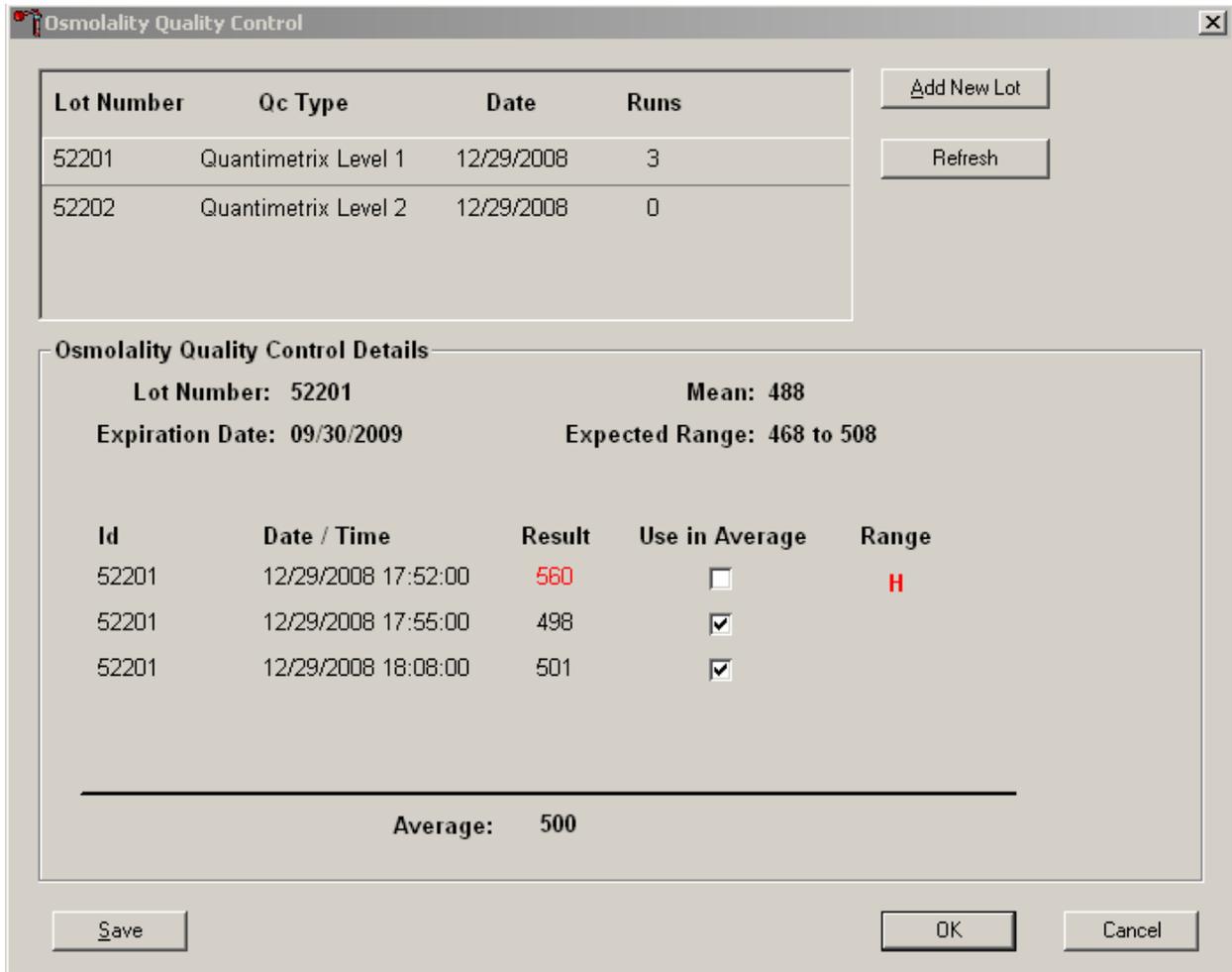












After the calibration, the third run is transmitted from the Osmette and falls within the expected range. The application automatically selects the two runs that fall within range to average their results.

To save the average result of the selected runs without exiting the window, direct the mouse arrow to the “Save” button and left click. To save the average result of the selected runs and exit the window, direct the mouse arrow to the “OK” button and left click. To cancel any changes made in the screen, direct the mouse arrow to the “Cancel” button and left click.

## **H. Proficiency Testing**

Evaluation and participation in the College of American Pathologists (CAP) proficiency-testing program is part of the comprehensive quality control program. The CAP samples for osmolality are shipped three times per year. Each Urine Chemistry (General) “U” shipment includes six 15.0-mL urine specimens. Follow all CAP instructions 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.

## **I. Linearity for Osmolality**

CAP LN6 verifies the reportable range of the Precision Osmette II instrument. Survey LN6 corresponds to CAP Urine Chemistry (General) Survey U. Each shipment of Survey LN6 includes 15 4.0-mL liquid specimens. Linearity was performed at installation and will be repeated in November of each year. 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.

## **XI. Interpretation of Results and Remedial Action**

### **A. Sample Person Parameter Value Review and Remedial Actions.**

If a sufficient, acceptable quality sample is submitted for osmolality testing, the medical technologist should run the sample twice. The two runs should have a difference no greater than 40, and the average of the two runs will be saved to the database as the osmolality result. The computer application will automatically select runs that it evaluates to meet the criteria for saving to the database. However, it is ultimately the responsibility of the medical technologist to evaluate each run and determine whether the result should be used in the average and save to the database. The application will not prevent any result from being used in an average if selected by the medical technologist, or any two results selected by the medical technologist from being saved to the database.

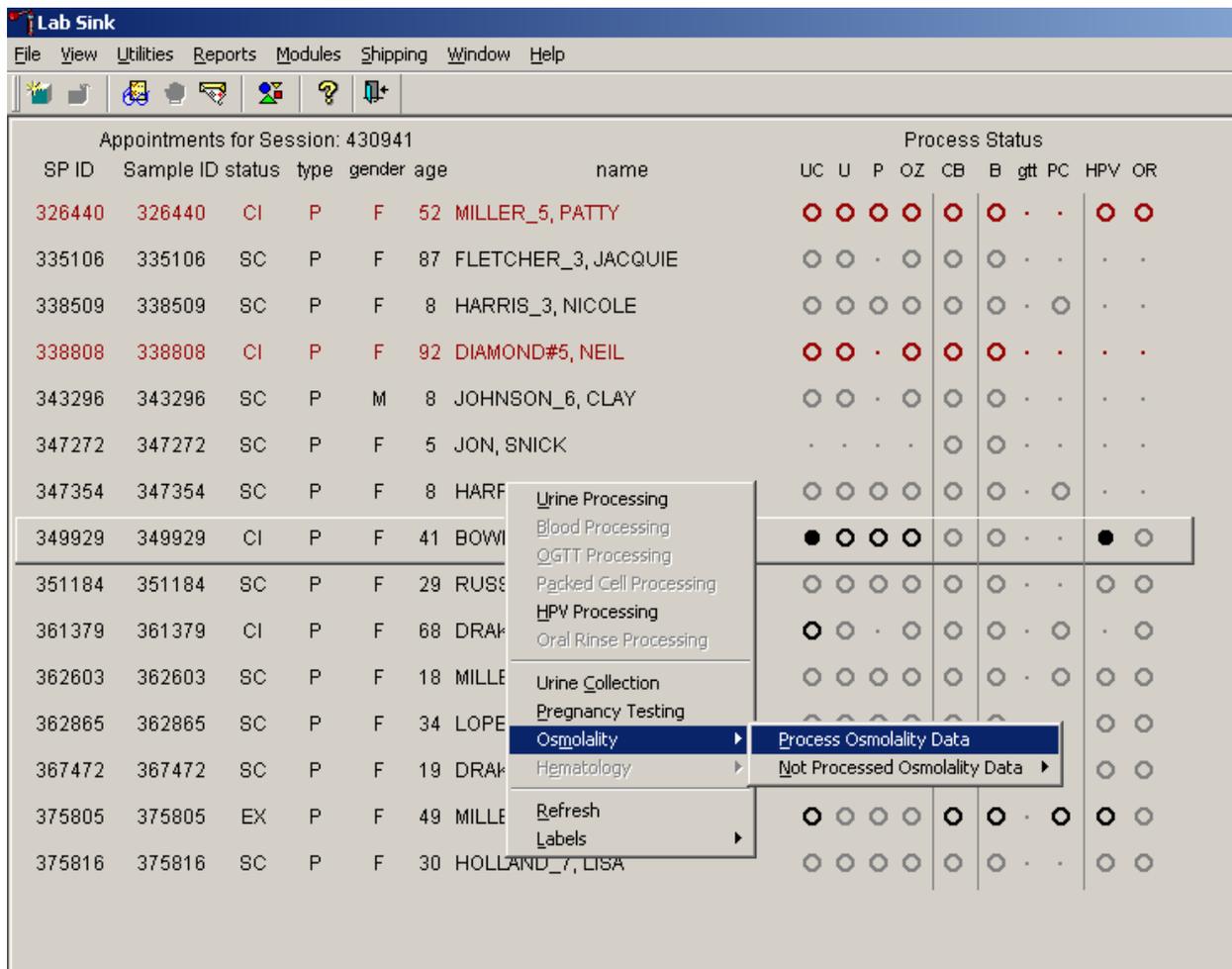
1. Access the Osmolality module, reject a blood contaminated sample, or record a reason for no osmolality results.

Open the Osmolality module.

Appointments for S							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	gtt	PC	HPV	OR
724352	724352	SC	P	M	47	MILLER_1, HARVEY	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
728152	728152	SC	P	M	6	HOLLAND_1, BLAKE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
728291	728291	BE	P	M	8	JOHNSON_1, CLAY	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
754740	754740	BE	P	M	24	PARKER_1, RUDY	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
778058	778058	SC	P	F	42	RODENHAUSEN, KAREN	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
789290	789290	SC	P	F	39	WALLACE_1, JILL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
797474	797474	SC	P	F	31	HARRIS_1, MARIA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
814480	814480	SC	P	F	68	DRAKE_1, ALMA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
820803	820803	CI	P	F	46	SMITH_1, TYLER	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>					
828086	828086	SC	P	M	28	TAYLOR_1, BEN	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
866059	866059	SC	P	M	18	CLEAVER_1, WALLY	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
870408	870408	SC	P	M	5	ESTRADA_1, PACO	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
885421	885421	SC	P	M	41	WALLACE_3, KEVIN	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
951940	951940	SC	P	M	51	RIDDLE, PAUL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					

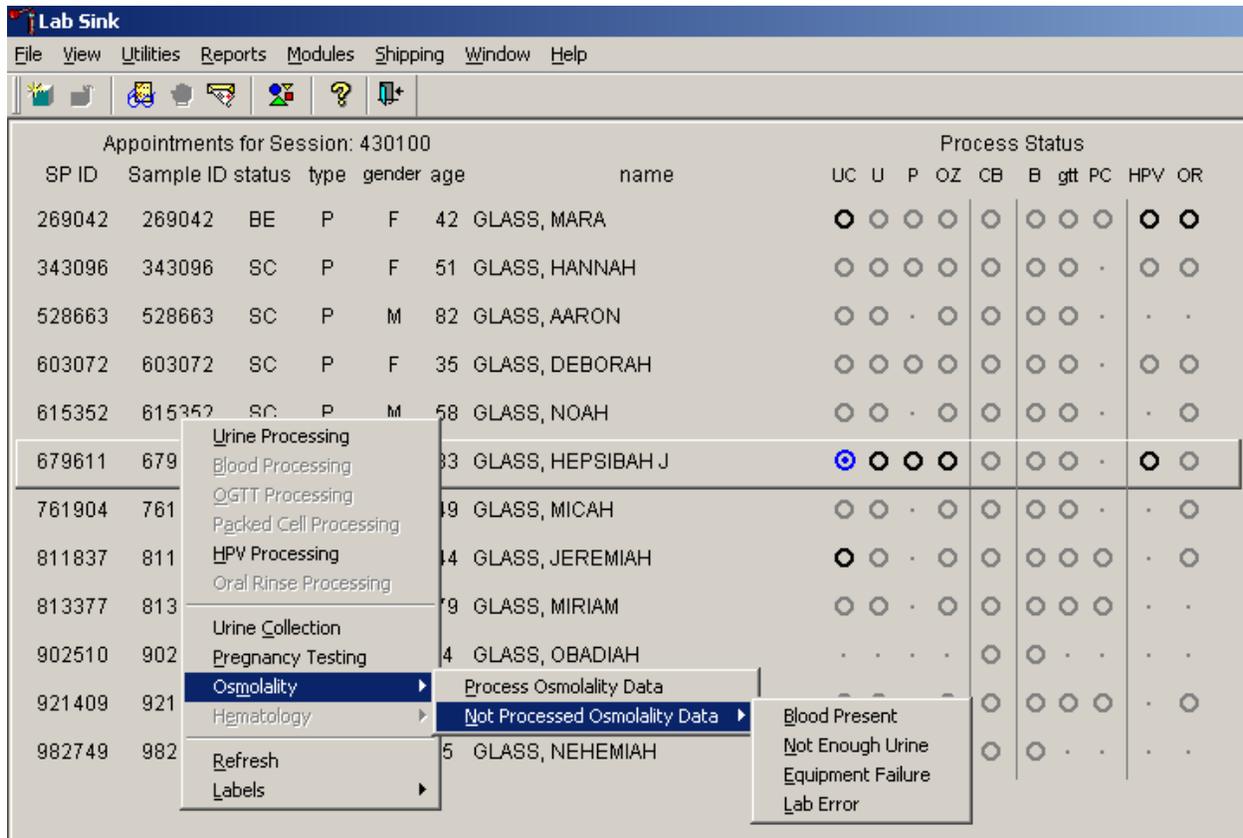
To open the Osmolality module, use the mouse to direct the mouse arrow to {Modules}, in the top menu bar, left click, drag the mouse arrow to {Osmolality}, and right click, or type [Alt][M/m], [O/o].

Alternatively, open the Osmolality module from the heads-up display.



To access the Osmolality module, use the mouse to direct the mouse arrow to any SP, right click, drag the mouse arrow to {Osmolality} then to {Process Osmolality Data}, and right click or right click and type [Shift] [M/m] [P/p]. 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 {Osmolality} then to {Process Osmolality Data}, and right click or right click and type [Shift] [M/m] [P/p].

Either open the module or reject the specimen or add a reason or comment for every Osmolality record where urine was collected AND there are no Osmolality results.



Open the module {Process Osmolality Data} or record a reason why Osmolality is not being run {Not Processed Osmolality Data}. Select or record a comment for every Osmolality that is not run. To complete opening or accessing the Osmolality module, use the mouse to direct the mouse arrow to {Process Osmolality Data} and right click or type [P/p.] To record a reason why Osmolality 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 Osmolality Data}, and drag the mouse arrow to the correct reason and right click. Alternatively, type [Shift] [M/m] [N/n] and [B/b] for Blood Present, [N/n] for Not Enough Urine, [E/e] for Equipment Failure, or [L/l] for Lab Error.

Lab Sink

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 430100

SP ID	Sample ID	status	type	gender	age	name	Process Status											
							UC	U	P	OZ	CB	B	glt	PC	HPV	OR		
269042	269042	BE	P	F	42	GLASS, MARA	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
343096	343096	SC	P	F	51	GLASS, HANNAH	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
528663	528663	SC	P	M	82	GLASS, AARON	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
603072	603072	SC	P	F	35	GLASS, DEBORAH	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
615352	615352	SC	P	M	58	GLASS, NOAH	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
679611	679611	CI	P	F	33	GLASS, HEPSIBAH J	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>							
761904	761904	SC	P	M	49	GLASS, MICAH	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
811837	811837	CI	P	M	44	GLASS, JEREMIAH	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
813377	813377	SC	P	F	79	GLASS, MIR	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
902510	902510	SC	P	M	4	GLASS, OB	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
921409	921409	SC	P	M	62	GLASS, JO	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
982749	982749	CI	P	M	5	GLASS, NEI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Osmolality Data Not Processed

Would you like to mark sample id 679611 as blood present ?

Yes No

The system will ask for verification that the sample id should be marked as “not done” for the selected reason. To verify the reason, direct the mouse arrow over the Yes button and left click. Alternatively, type [Shift] [Y/y]. To cancel the selection, direct the mouse arrow over the No button and left click. Alternatively, type [Shift] [N/n].

Appointments for Session: 430100							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	gft	PC	HPV	OR
269042	269042	BE	P	F	42	GLASS, MARA	○	○	○	○	○	○	○	○	○	○
343096	343096	SC	P	F	51	GLASS, HANNAH	○	○	○	○	○	○	○	○	○	○
528663	528663	SC	P	M	82	GLASS, AARON	○	○	○	○	○	○	○	○	○	○
603072	603072	SC	P	F	35	GLASS, DEBORAH	○	○	○	○	○	○	○	○	○	○
615352	615352	SC	P	M	58	GLASS, NOAH	○	○	○	○	○	○	○	○	○	○
679611	679611	CI	P	F	33	GLASS, HEPSIBAH J	⊙	○	○	●	○	○	○	○	○	○
761904	761904	SC	P	M	49	GLASS, MICAH	○	○	○	○	○	○	○	○	○	○
811837	811837	CI	P	M	44	GLASS, JEREMIAH	⊙	○	○	○	○	○	○	○	○	○
813377	813377	SC	P	F	79	GLASS, MIRIAM	○	○	○	○	○	○	○	○	○	○
902510	902510	SC	P	M	4	GLASS, OBADIAH	○	○	○	○	○	○	○	○	○	○
921409	921409	SC	P	M	62	GLASS, JONAH	○	○	○	○	○	○	○	○	○	○
982749	982749	CI	P	M	5	GLASS, NEHEMIAH	○	○	○	○	○	○	○	○	○	○

The bubble for osmolality will fill in as black on the heads-up screen if the module is marked as “not done” with a comment code.

2. View Osmolality Module

Open the module {Process Osmolality Data}.

Lab Sink

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 430431

SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	gtt	PC	HPV	OR	Process Status
724352	724352	SC	P	M	47	MILLER_1, HARVEY	○	○	·	○	○	·	·	·	·	○	
728152	728152	SC	P	M	6	HOLLAND_1, BLAKE	○	○	·	○	○	·	·	·	·	·	
728291	728291	BE	P	M	8	JOHNSON_1, CLAY	⊙	○	·	○	○	·	·	·	·	·	
754740	754740	BE	P	M	24	PARKER_1, RUDY	●	○	·	○	○	·	·	·	·	·	
778058	778058	SC	P	F	42	RODENHAUSEN, KAREN	○	○	○	○	○	·	·	·	·	·	
789290	789290	SC	P	F	39	WALLACE_1, JILL	○	○	○	○	○	·	·	·	·	·	
797474	797474	SC	P	F	31	HARRIS_1, MARIA	○	○	○	○	○	·	·	·	·	·	
814480	814480	SC	P	F	68	DRAKE_1, ALMA	○	○	○	○	○	·	·	·	·	·	
820803	820803	BE	P	F	46	SMITH_1, TYLER	●	○	○	○	○	·	·	·	·	·	
828086	828086	CI	P	M	28	TAYLOR_1, BEN	⊙	○	·	○	○	·	·	·	·	·	
866059	866059	SC	P	M	18	CLEAVER_1, WALLY	○	○	○	○	○	·	·	·	·	·	
870408	870408	SC	P	M	5	ESTRADA_1, PACO	·	·	·	○	○	·	·	·	·	·	
885421	885421	SC	P	M	41	WALLACE_3, KEVIN	○	○	·	○	○	·	·	·	·	·	
951940	951940	SC	P	M	51	RIDDLE, PAUL	○	○	·	○	○	·	·	·	·	·	

Urine Processing  
 Blood Processing  
 OGTT Processing  
 Packed Cell Processing  
 HPV Processing  
 Oral Rinse Processing  
 Urine Collection  
 Pregnancy Testing  
 Osmolality  
 Hematology  
 Refresh  
 Labels

Process Osmolality Data  
 Not Processed Osmolality Data

The Osmolality module displays.

Urine Osmolality Processing: 430431

Sp ID	Sample ID	Name	Gender	Age
797474	797474	HARRIS_1, MARIA	F	31
814480	814480	DRAKE_1, ALMA	F	68
820803	820803	SMITH_1, TYLER	F	46
828086	828086	TAYLOR_1, BEN	M	28
866059	866059	CLEAVER_1, WALLY	M	18
885421	885421	WALLACE_3, KEVIN	M	41
951940	951940	RIDDLE, PAUL	M	51

**Osmolality Results**

Id	Date / Time	Result	Use in Average	Precision
Average:				
Comment:		(none)		

Save      OK      Cancel

SPs eligible for osmolality testing appear in black on the upper part of the window. SPs are eligible for osmolality testing if their urine collection status is complete or QNS. If no osmolality runs have been transmitted from the Osmette II for a selected SP, no runs will be displayed in the lower portion of the screen. Press “OK” or “Cancel” to exit the screen.

- Record an osmolality result when there is only enough sample for one run.

If a run has been transmitted from the Osmette II for a selected SP, the run(s) will display in the lower portion of the screen.

Urine Osmolality Processing: 430431

Sp ID	Sample ID	Name	Gender	Age
797474	797474	HARRIS_1, MARIA	F	31
814480	814480	DRAKE_1, ALMA	F	68
820803	820803	SMITH_1, TYLER	F	46
828086	828086	TAYLOR_1, BEN	M	28
866059	866059	CLEAVER_1, WALLY	M	18
885421	885421	WALLACE_3, KEVIN	M	41
951940	951940	RIDDLE, PAUL	M	51

**Osmolality Results**

Id	Date / Time	Result	Use in Average	Precision
828086	12/30/2008 15:39:00	544	<input type="checkbox"/>	

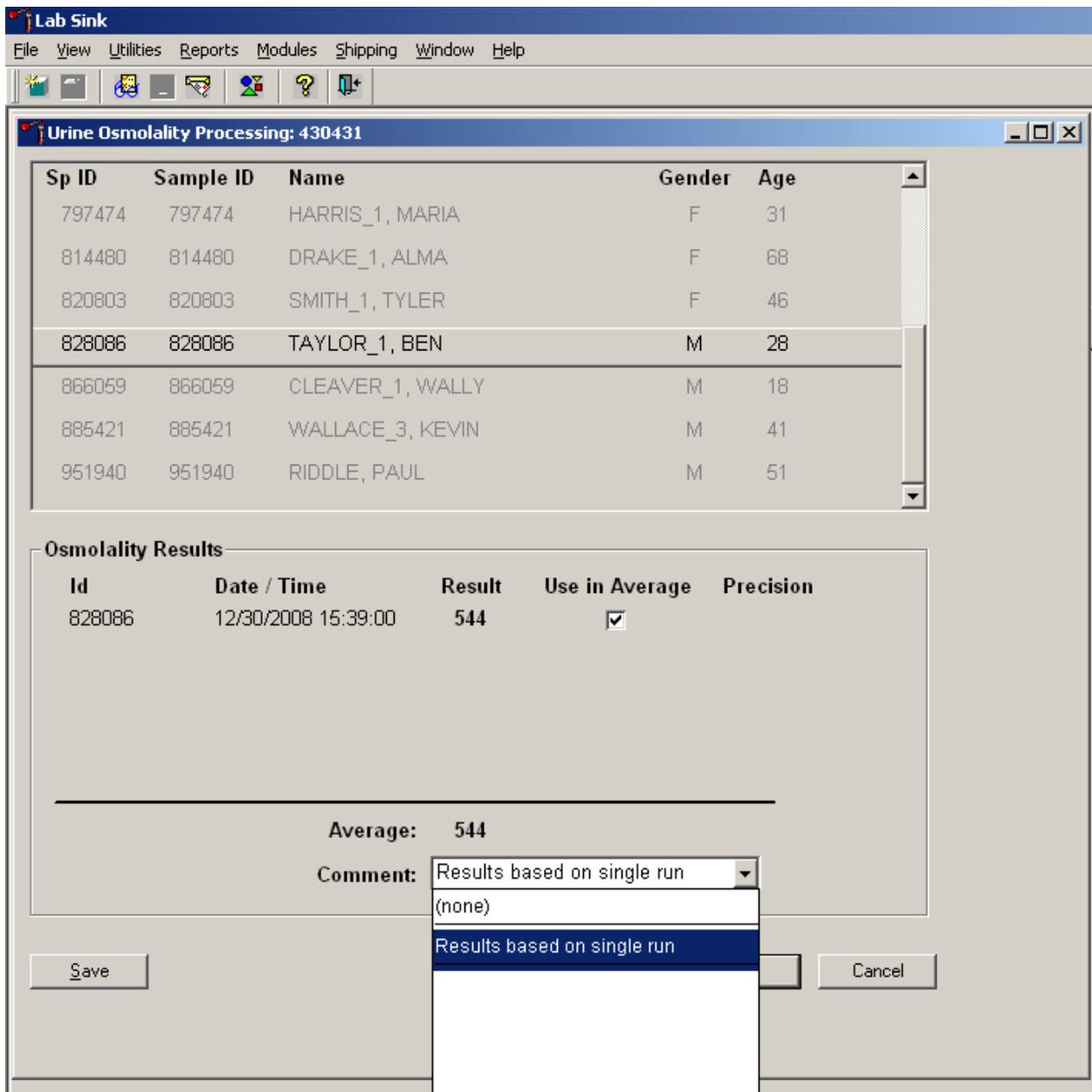
---

Average:

Comment: (none)

Save OK Cancel

One run displays in the Osmolality Results portion of the screen. If there is only enough sample for one run, select the “Use in Average” box by directing the mouse arrow over the box and left click. The average will appear under the line.



Select the comment “Results based on single run” by directing the mouse arrow to the down arrow and left click. Drag the mouse to the comment and left click. The comment will appear in the “Comment” field.

Save the result and comment code by directing the mouse arrow to the “Save” button and left click. Alternatively, direct the mouse arrow to the “OK” button and left click to save the result and exit the screen.

The osmolality module will display as a solid black circle on the heads-up screen to indicate that the osmolality test has been completed for that SP.

4. Procedure for evaluating and handling precision limits

Multiple runs appear in the Osmolality Results section if more than one run has been transmitted from the Osmette II.

The screenshot displays a software window titled "Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm - [Urine Osmolality Processing: 430040]". The interface includes a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar with various icons. The main content area is divided into two sections.

The upper section contains a table of patient information:

Sp ID	Sample ID	Name	Gender	Age
965340	965340	OSBOURNE_1, OZZY	M	28
973550	973550	WEAVER_1, JOE	M	43
974475	974475	BUTLER_1, RICKY	M	23
975531	975531	JONES, JIMMY	M	15
976733	976733	CLEAVER_1, WARD	M	40
978919	978919	CLEAVER_1, THEADORE	M	12
984632	984632	LOPEZ_1, CARLOS	F	9
991969	991969	BUTLER_1, REBECCA	F	59

A "Refresh" button is located to the right of this table.

The lower section contains a table of test results:

Id	Date / Time	Result	Use in Average	Precision
974475	11/05/2009 04:36 PM	995	<input type="checkbox"/>	★
974475	11/05/2009 04:37 PM	999	<input type="checkbox"/>	★

Below the results table, there is an "Average:" section showing a value of "0". A "Comment:" field is present with a dropdown menu currently set to "(none)".

If both runs are within a range of 40 from each other, the application will automatically recommend the two runs with blue stars, which indicates that both results are within precision limits. The average of both runs will be displayed when a checkmark is placed under the Use in Average boxes for each run. No further runs are necessary to save the averaged result from a system perspective; however, each run should be evaluated by the medical technologist. It is the technologist's responsibility to determine if additional runs are necessary. To save the results without exiting the screen, direct the mouse arrow to the "Save" button and left click. To save the data and exit the screen, direct the mouse arrow to

the “OK” button and left click. To cancel and exit without saving any changes made in the window, direct the mouse arrow to the “Cancel” button and left click.

Results are run that have a difference greater than 40.

Sp ID	Sample ID	Name	Gender	Age
724352	724352	MILLER_1, HARVEY	M	47
728152	728152	HOLLAND_1, BLAKE	M	6
728291	728291	JOHNSON_1, CLAY	M	8
754740	754740	PARKER_1, RUDY	M	24
778058	778058	RODENHAUSEN, KAREN	F	42
789290	789290	WALLACE_1, JILL	F	39
797474	797474	HARRIS_1, MARIA	F	31

Id	Date / Time	Result	Use in Average	Precision
754740	12/29/2008 18:22:00	502	<input type="checkbox"/>	X
754740	12/29/2008 18:27:00	292	<input type="checkbox"/>	X

Average: \_\_\_\_\_

Comment: (none) [v]

Save      OK      Cancel

If two runs have a difference greater than 40, the runs will both appear in red with an “X” under the Precision column. Neither run will be selected to use in the average. The medical technologist should run the sample a third time.

Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm - [Urine Osmolality Processing: 430040]

File View Utilities Reports Modules Shipping Window Help

Sp ID	Sample ID	Name	Gender	Age
965340	965340	OSBOURNE_1, OZZY	M	28
973550	973550	WEAVER_1, JOE	M	43
974475	974475	BUTLER_1, RICKY	M	23
975531	975531	JONES, JIMMY	M	15
976733	976733	CLEAVER_1, WARD	M	40
978919	978919	CLEAVER_1, THEODORE	M	12
984632	984632	LOPEZ_1, CARLOS	F	9
991969	991969	BUTLER_1, REBECCA	F	59

Refresh

Id	Date / Time	Result	Use in Average	Precision
965340	11/05/2009 04:42 PM	507	<input type="checkbox"/> *	X
965340	11/05/2009 04:43 PM	325	<input type="checkbox"/>	X
965340	11/05/2009 04:44 PM	501	<input type="checkbox"/> *	

Average: 0

Comment: (none)

Save New Run OK Cancel

Ready HUP: idle MEC Layer: 9/3/2009 Application: 9.1.3 Connected to Coordinator 04:43 PM

If the sample is run a third time and two of the results have a difference less than 40, those two runs will be recommended with blue stars to be averaged. No precision flags will appear. No further runs are necessary to save the averaged result from a system perspective; however, each run should be evaluated by the medical technologist. It is the technologist's responsibility to determine if additional runs are necessary.

The runs can be unchecked manually if desired by directing the mouse over the checkmark and left clicking. The run is deselected when no checkmark appears in the "Use in Average" column. To select the run again, direct the mouse over the box and left click to display the checkmark.

Osmolality has been repeated three times and all runs are out of precision.

Urine Osmolality Processing: 430100

Sp ID	Sample ID	Name	Gender	Age
269042	269042	GLASS, MARA	F	42
343096	343096	GLASS, HANNAH	F	51
528663	528663	GLASS, AARON	M	82
603072	603072	GLASS, DEBORAH	F	35
615352	615352	GLASS, NOAH	M	58
679611	679611	GLASS, HEPSIBAH J	F	33
761904	761904	GLASS, MICAH	M	49

**Osmolality Results**

Id	Date / Time	Result	Use in Average	Precision
269042	12/31/2008 16:03:00	712	<input type="checkbox"/>	X
269042	12/31/2008 16:11:00	504	<input type="checkbox"/>	X
269042	12/31/2008 16:15:00	1522	<input type="checkbox"/>	X

Average: \_\_\_\_\_

Comment: (none)

Save OK Cancel

Three runs display in the Osmolality Processing screen and all are red with “X” flags in the Precision column. Three runs that are all out of precision should indicate to the medical technologist that the instrument is malfunctioning. Begin troubleshooting steps by checking the pipette functioning and calibration, and clean the Osmette II probe as described in Chapter 15, Operational Issues.

5. Urine Osmolality Module Comments

Comment	Use when:
Laboratory error	There was a technologist error.
Result based on single run	The quantity of specimen is insufficient to run it more than once.
Equipment failure	Unable to run osmolalities due to problem with the instrument.
Blood present	The urine is contaminated with blood. Do not run an osmolality test.
Not enough urine	There is insufficient blood to perform at least one complete osmolality test.
Cloudy specimen	Do not run an osmolality test on this specimen.
Out of range	Osmolality is greater than 2000.

**B. Osmette II Instrument Messages**

1. Review the message and remedial action

The Osmette II displays several error messages. Note the error message and take remedial action.

Display	Cause and Action
PREFREEZE	Air bubbles or other particles caused the sample to prefreeze. Check sample for particulate matter that should be centrifuged. Rerun sample, checking for proper pipetting technique.
NO FREEZE	The sample did not freeze. Rerun the sample. If the instrument gives an extraordinary amount of NO FREEZE messages, contact Precision Systems for support.
NO SAMPLE	No sample was inserted into the cooling well, or the cooling block is malfunctioning. Check to make sure a sample was inserted into the instrument. Rerun the sample. If the message continues to appear, contact Precision Systems for support.
BUTTON ON	One or more of the buttons were pressed during the power-on sequence. Turn off the machine and turn it back on, ensuring that nothing is touching and accidentally depressing the SPEC, CALIBRATION, or RUN keys.

The following messages require service from Precision Systems.	
Timer	Contact the chief medical technologist and Precision Systems for support.
RAM	
A/D Status	
MUX	
Battery	
No Probe	
Novram not Init	

**XII. Limitations of Method: Specimen Rejection, Interfering Substances and Conditions**

This method limits samples to human urine.

**A. Specimen Rejection**

1. Reject blood-contaminated specimens.

**B. Interfering Substances and Conditions**

1. Particulate matter will cause the sample to pre-seed when supercooled, interrupting the measurement cycle. Undissolved particles or precipitate in the sample may be eliminated by centrifuging the sample.
2. Samples that have bubbles in the pipette sample may give incorrect or not reproducible results. Double checking the pipetted sample for bubbles and discarding improperly pipetted samples will reduce the chance of inaccurate results due to air bubbles.

**XIII. Reference Ranges**

The reference for normal urine osmolality is 501400 mOsm/kg H<sub>2</sub>O .

**XIV. Action Limits**

Not applicable.

**XV. Specimen Storage and Handling during Testing**

**A. Specimen Storage**

1. Store specimens refrigerated until processed.
2. Run within 4 hours after collection.

**XVI. Alternative Method for Performing Test or Storing Specimens if Test System Fails**

There is no alternative method for this test. Store urine in the refrigerator for no more than 4 hours.

**XVII. Test Results Reporting System: Protocol for Reporting Action Limits**

All records, including QA/QC data, will be maintained for 10 years. Use only numerical identifiers for SP results.

**XVIII. Transfer or Referral of Specimens; Procedures for Specimen Accountability and Tracking**

In general, when specimens are received, the specimen ID number, and a name identifying the container ID and slot number is entered into the Integrated Survey Information System (ISIS) database. New checkmarks are printed and the specimens are analyzed within 4 hours in the MEC. The specimen ID is scanned by a checkmark reader. The date and time of data entry, date and time analysis completed, and the identity of the person who accepts or rejects the results, are documented in the ISIS database. Logs are kept which include the date and time samples arrive, are processed, tested, frozen, and returned to NHANES for long-term storage.

The project supervisor is responsible for keeping a logbook containing the ID numbers of specimens prepared incorrectly, those with labeling problems, and those with abnormal results, with

information about these discrepancies. It is recommended that records, including related QA/QC data, be maintained for 10 years after completion of the NHANES study.

**XIX. Quality Control Summary Statistics and Graphs**

Chapter 14 includes a separate detailed description of the comprehensive quality control plan. Compare all three instruments using the CAP proficiency results.

**XX. References**

1. Precision Systems Osmette II Operating Manual Model 5005, Precision Systems, Inc. 2006

## **13. OGTT APPLICATION**

### **13.1 OGTT Application – Section Two (Blood Draw)**

If an SP consumed the entire calibrated dose of the Trutol solution in 10 minutes and 1 hour and 45 minutes have elapsed, then he or she is eligible to return to phlebotomy to have (1) one additional 2-mL gray top drawn and (2) any tubes that were not drawn during the initial venipuncture examination drawn.

A pop-up message window will alert the coordinator and the phlebotomist when an SP is eligible to return to phlebotomy for the second blood draw. To close or remove the Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right corner to the X and left click.

Logon to the OGTT application and log the SP into the component.

The blood draw screen is divided into two sections.

The screenshot shows a software window titled "Glucose Tolerance Test". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The status bar at the top displays "OGTT: Stand:430 Session:430110 12/14/2004 08:30 am - 12:30 pm". Below this, patient information is shown: "SP ID: 480759", "Name: ROOP, STANLEY", "Age: 34 years", "Gender: Male", "Date: 12/08/2008", and "Time: 11:37 AM". The main section is titled "Blood Draw".

Under "GTT Tubes", there is a checkbox for "Obtained all" and a spinner control for "2 ml gray" set to "0". A text box containing "480759" is visible to the right.

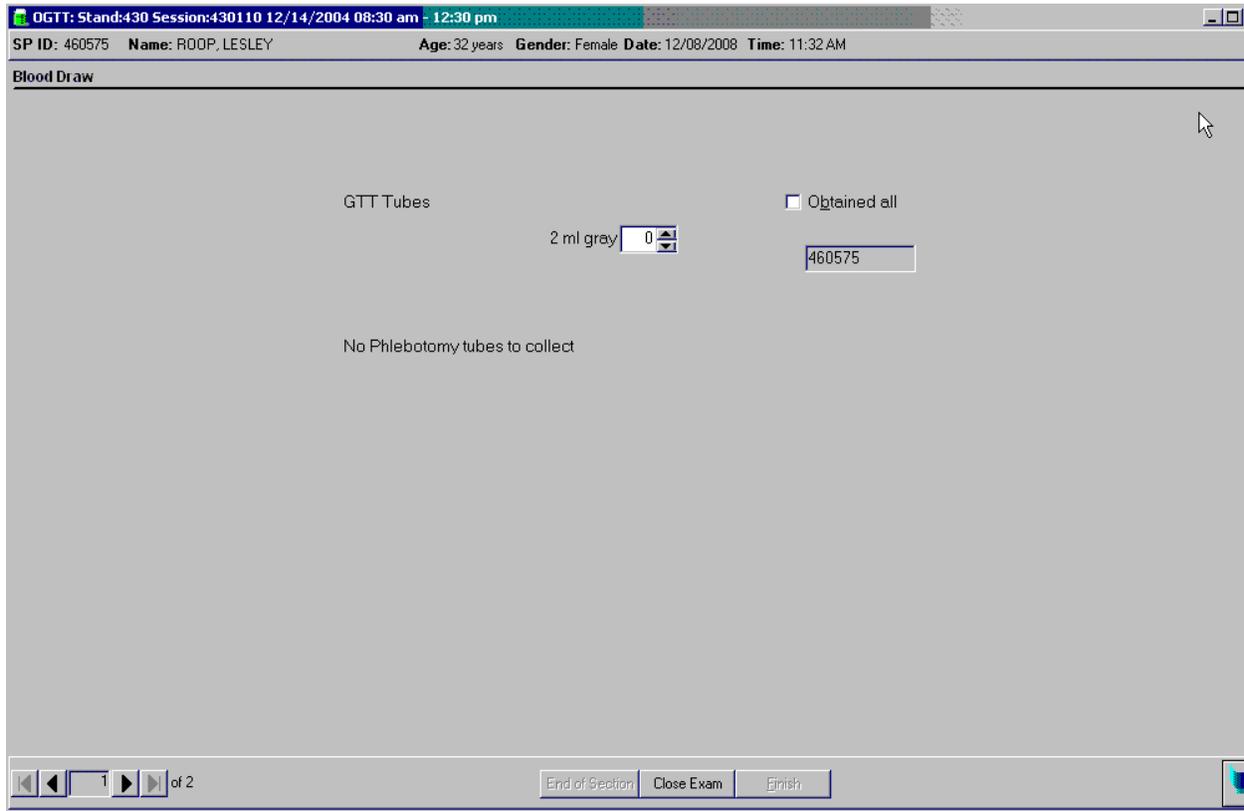
Under "Phlebotomy tubes not collected", there is a checkbox for "Obtained all" and a list of tubes with spinner controls:

- 15 ml red 0 of 3
- 10 ml red 0 of 1
- 10 ml red 0 of 2
- 10 ml EDTA 0 of 2

A text box containing "480759" is also present to the right of this section. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish".

The upper section is identical to the venipuncture screen in the phlebotomy examination except that it contains only one 2-mL gray top tube. The bottom half of the screen lists any tubes that were not drawn during the initial venipuncture examination. The sections function exactly like the venipuncture screen in the phlebotomy examination.

If all of the blood tubes were drawn during the phlebotomy examination, then only the first half of the blood draw screen will contain the 2-mL gray top tube. The lower section of the blood draw screen will indicate that there are “No phlebotomy tubes to collect.”



Draw the additional 2-mL gray top tube and then any tubes that were missed during the phlebotomy examination first. Draw all tubes according to the protocol described in Chapter 4.

Labels will print for all the tubes marked as collected, including the second 2-mL gray top tube. The label for the second 2-mL gray top tube contains a bar code with the SP ID concatenated with the vessel ID (# 98) and includes the test name “OGTT.”

Immediately after completing the venipuncture, enter the results of the blood draw and any comments about the venipuncture.

OGTT: Stand:430 Session:430110 12/14/2004 08:30 am - 12:30 pm

SP ID: 460575 Name: ROOP, LESLEY Age: 32 years Gender: Female Date: 12/08/2008 Time: 11:32 AM

**Blood Draw**

GTT Tubes

2 ml gray 1

Obtained all

460575

No Phlebotomy tubes to collect

1 of 2

End of Section Close Exam Finish

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.

## Verify the Blood Draw Section Status.

The screenshot shows a software window titled "Blood Draw Section Status". At the top, a status bar displays "OGTT: Stand:430 Session:430110 12/14/2004 08:30 am - 12:30 pm". Below this, a header bar shows "SP ID: 460575 Name: RDDP, LESLEY Age: 32 years Gender: Female Date: 12/08/2008 Time: 11:32 AM". The main content area is titled "Blood Draw Section Status" and contains a form with the following elements:

- A "Status" section with three radio buttons: "Complete" (selected), "Partial", and "Not Done".
- A "Comments" section with a dropdown menu.
- An "Other text" section with a text input field.

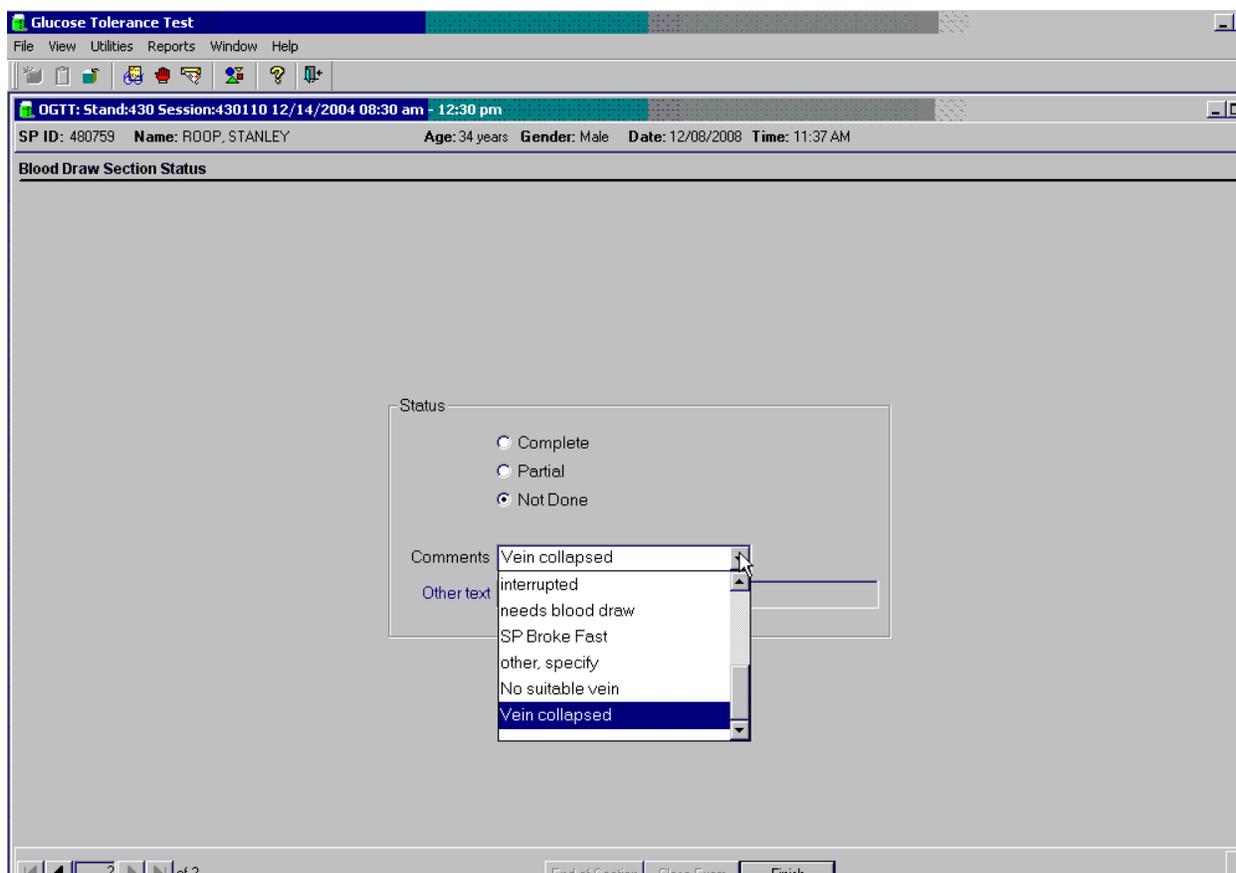
At the bottom of the window, there is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons. A status bar at the very bottom of the screen shows "Ready", "MEC Layer: 12/3/2008", "Application: 6.1.11", "Connected to Coordinator", "SP assigned to room", and "11:36 AM".

The Blood Draw Section Status is complete if the second 2-mL gray top tube is collected.

If any blood tubes were not drawn during the initial phlebotomy examination and they were drawn during the blood draw section of the OGTT examination, then the phlebotomy section status will automatically update to reflect the additional tubes drawn during the OGTT examination.

**Remove the Dymo label from the SP's gown and ask the SP if he or she is allergic to peanuts. If not, then offer the SP peanut butter crackers and juice. If the SP is allergic to peanuts or does not know, then offer the standard crackers and juice.**

Use comment codes to explain Not Done status codes.



The blood draw section status is Not Done if the second 2-mL gray top tube is not collected. **Once the tube is marked as not obtained, the comment will default to “needs blood draw.”** Correct the comment by selecting the most appropriate comment code. 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.
SP refusal	The SP refuses to have his or 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	Not applicable
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 becomes ill or an emergency occurs and the test cannot be performed on the SP.
Interrupted	Not applicable
Needs blood draw	The system uses this code as a default after the SP consumed the Trutol. Correct this code depending on the situation.
SP broke fast	Use this code if the SP ate or drank anything other than plain water after they drank the Trutol and before the blood draw.
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.
No suitable vein	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.
Vein collapsed	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.

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 select [Enter] when this blue arrow is highlighted.

## 13.2 Laboratory Processing

### 13.2.1 Laboratory Overview

The vessel for OGTT is #98 (Exhibit 13-1). Use the gtt processing module to record the blood processing results. Labels for the OGTT vessel print for all SPs after the last blood processing set of labels. Keep the OGTT labels together and place them in the lab with the blood processing racks. Do not label the vessels in advance; label each vessel as it is processed.

Exhibit 13-1. Primary SP's OGTT processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
98	OGTT	12+	0.5	Plasma	Gray	2-mL	Morning SPs only

### 13.2.2 Process the 2-mL Gray Top Tube for OGTT

Centrifuge and separate the plasma from the 2-mL gray top tube within 30 minutes from the time the blood was collected. Process the specimen even if the contents of the gray tube are clotted.

- 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 11-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 98 (OGTT.)

#### Vessel 98

- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 98 (OGTT) on primary 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 gtt module as described in Section 8.7.3 of the *Laboratory Procedures Manual*.
- Store all specimens immediately as outlined in Section 8.10 of the *Laboratory Procedures Manual*.

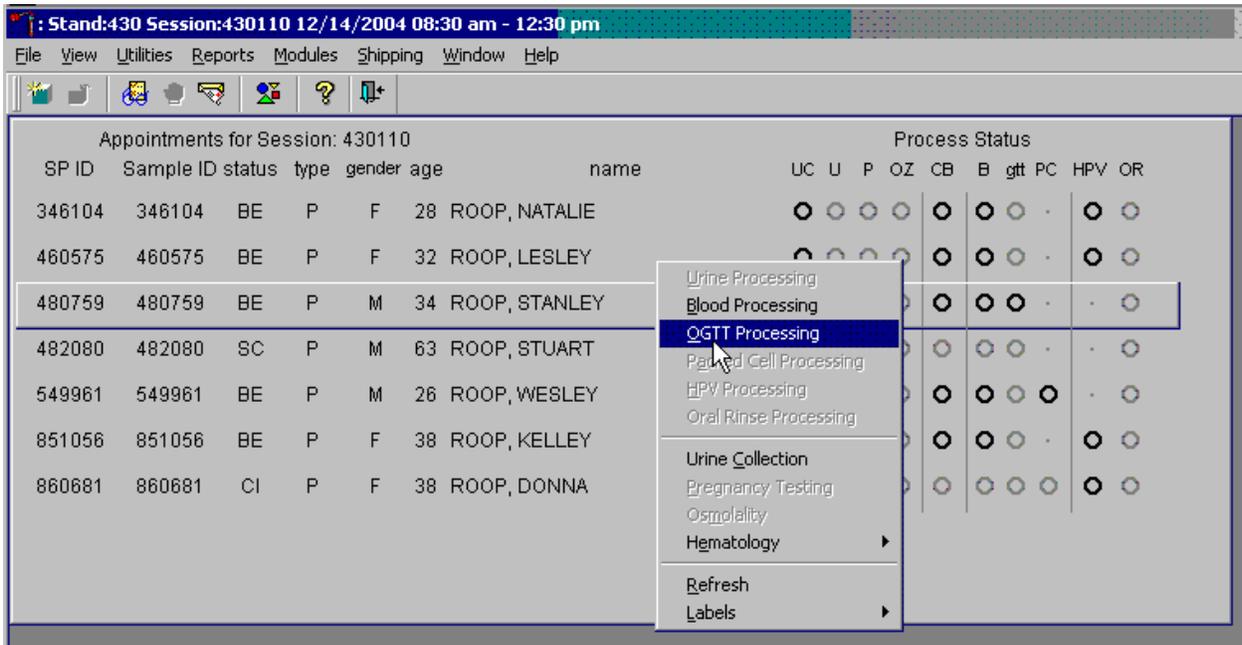
### 13.2.3 Record the Results of Specimen Processing

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. Record blood processing results for vessel 98 using the “gtt” module.

Appointments for Session: 430110							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	gtt	PC	HPV	OR
346104	346104	BE	P	F	28	ROOP, NATALIE	○	○	○	○	○	○	○	○	○	○
460575	460575	BE	P	F	32	ROOP, LESLEY	○	○	○	○	○	○	○	○	○	○
480759	480759	BE	P	M	34	ROOP, STANLEY	○	○	○	○	○	○	○	○	○	○
482080	482080	SC	P	M	63	ROOP, STUART	○	○	○	○	○	○	○	○	○	○
549961	549961	SC	P	M	26	ROOP, WESLEY	○	○	○	○	○	○	○	○	○	○
851056	851056	SC	P	F	38	ROOP, KELLEY	○	○	○	○	○	○	○	○	○	○
860681	860681	SC	P	F	38	ROOP, DONNA	○	○	○	○	○	○	○	○	○	○

The “gtt” module is grayed out until at least one SP has the second 2-mL gray top tube drawn. Once one SP has the second 2-mL gray top tube drawn, the processing circle for that SP turns black.

Select the correct SP and access the OGTT Processing module.



To access the OGTT Processing module, use the mouse to direct the mouse arrow to the SP on the heads-up display, left click, drag the mouse arrow to OGTT Processing, and right click.

Record the vessel 98 processing results in the OGTT processing window. All SPs are included in the same window but are listed separately by rows.

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
346104	ROOP, NATALIE	F	28	<input type="radio"/> Yes <input type="radio"/> No	(none)		
460575	ROOP, LESLEY	F	32	<input type="radio"/> Yes <input type="radio"/> No	(none)		
480759	ROOP, STANLEY	M	34	<input type="radio"/> Yes <input type="radio"/> No	(none)		
482080	ROOP, STUART	M	63	<input type="radio"/> Yes <input type="radio"/> No	(none)		
549961	ROOP, WESLEY	M	26	<input type="radio"/> Yes <input type="radio"/> No	(none)		
851056	ROOP, KELLEY	F	38	<input type="radio"/> Yes <input type="radio"/> No	(none)		

The OGTT processing window lists the vessel requirements across the top. SPs are listed separately in rows. The upper section of the Glucose Tolerance Test window contains the following information: Tech ID, Vessel ID (98), Test Name (OGTT), Total Volume (2 ml), Vessel Name (Nalge cryovial), and Sample Volume (0.5.) The lower section of the window contains columns for Sample ID, Person Name (Last, First), Gender, Age, Filled Yes and No radio buttons, Comments text box, and a Container ID/Slot # column N. Use the Save button to save the results to the database. Use the OK button to save the results to the database and close the module. Use the Cancel button to close the window without saving any data to the database.

Record blood processing results for each SP. Individually mark each vessel as Filled–“Yes.”

The screenshot shows the 'OGTT' (Glucose Tolerance Test) application window. At the top, it displays test parameters: Tech ID: 1126, Vessel ID: 98, Test Name: OGTT, Vessel Name: Nalge Cryovial, Total Volume: 2 ml, and Sample Volume: 0.5. Below this is a table with columns for Sample ID, Person Name, Gender, Age, Filled (radio buttons for Yes/No), Comments (dropdown menu), and Container ID/Slot#. The table lists six patients, with the third row (Stanley Roop) highlighted in black, indicating it is ready for processing. At the bottom, there are 'Save', 'OK', and 'Cancel' buttons.

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
346104	ROOP, NATALIE	F	28	<input type="radio"/> Yes <input type="radio"/> No	(none)		
460575	ROOP, LESLEY	F	32	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415811	1
480759	ROOP, STANLEY	M	34	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415811	2
482080	ROOP, STUART	M	63	<input type="radio"/> Yes <input type="radio"/> No	(none)		
549961	ROOP, WESLEY	M	26	<input type="radio"/> Yes <input type="radio"/> No	(none)		
851056	ROOP, KELLEY	F	38	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Only SPs who have had the second 2-mL gray top tubes marked as collected in the OGTT application are eligible to be processed. Once the tube is collected, the row changes from gray to black, indicating that the SP is ready to be marked as processed. To mark an individual 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.

Quality comment codes are available to describe the quality of the specimen.

Comment for filled vessels	Use when:
clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
equipment failure	Pipettes are malfunctioning.
hemolyzed	There is a 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 mg/L.
icteric	There is a 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 1130 umol/L.
lipemic	There is a 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 11.6 mmol/L.

Attach a comment to an individual filled vessel.

The screenshot shows a software window titled "OGTT" with a subtitle "Glucose Tolerance Test". At the top, there are fields for "Tech ID: 1126", "Vessel ID: 98", "Test Name: OGTT", "Vessel Name: Nalge Cryovial", "Total Volume: 2 ml", and "Sample Volume: 0.5". Below this is a table with columns: "Sample ID", "Person Name", "Gender", "Age", "Filled", "Comments", "Container ID", and "Slot#". The table contains six rows of data. The "Filled" column has radio buttons for "Yes" and "No". The "Comments" column has a dropdown menu. The dropdown menu is open, showing options: "(none)", "clotted", "equipment failure", "hemolyzed", "icteric", and "lipemic". A mouse cursor is pointing at the dropdown arrow. At the bottom of the window are buttons for "Save", "OK", and "Cancel".

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
346104	ROOP, NATALIE	F	28	<input type="radio"/> Yes <input type="radio"/> No	(none)		
460575	ROOP, LESLEY	F	32	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415811	1
480759	ROOP, STANLEY	M	34	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	15811	2
482080	ROOP, STUART	M	63	<input type="radio"/> Yes <input type="radio"/> No	equipment failure		
549961	ROOP, WESLEY	M	26	<input type="radio"/> Yes <input type="radio"/> No	hemolyzed		
851056	ROOP, KELLEY	F	38	<input type="radio"/> Yes <input type="radio"/> No	icteric		

To attach a quality control comment to a 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 (c, e, h, i, l).

Record blood processing results for each SP. Individually mark each vessel as Filled–“No.”

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
346104	ROOP, NATALIE	F	28	<input type="radio"/> Yes <input type="radio"/> No	(none)		
460575	ROOP, LESLEY	F	32	<input type="radio"/> Yes <input type="radio"/> No	(none)		
480759	ROOP, STANLEY	M	34	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415811	2
482080	ROOP, STUART	M	63	<input type="radio"/> Yes <input type="radio"/> No	(none)		
549961	ROOP, WESLEY	M	26	<input type="radio"/> Yes <input type="radio"/> No	(none)		
851056	ROOP, KELLEY	F	38	<input type="radio"/> Yes <input type="radio"/> No	(none)		

To mark vessel 98 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.

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:
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 refused the blood draw.

Attach a comment to an individual Filled-“No” vessel.

The screenshot shows a software window titled "OGTT" with a subtitle "Glucose Tolerance Test". At the top, there are fields for "Tech ID: 1126", "Vessel ID: 98", "Test Name: OGTT", "Vessel Name: Nalge Cryovial", "Total Volume: 2 ml", and "Sample Volume: 0.5". Below this is a table with columns: "Sample ID", "Person Name", "Gender", "Age", "Filled", "Comments", "Container ID", and "Slot#". The table contains six rows of data. The "Filled" column has radio buttons for "Yes" and "No". The "Comments" column has a dropdown menu. The dropdown menu is open for the row with Sample ID 480759, showing options: "(none)", "laboratory error", "quantity not sufficient", and "SP refusal". At the bottom of the window are buttons for "Save", "OK", and "Cancel".

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
346104	ROOP, NATALIE	F	28	<input type="radio"/> Yes <input type="radio"/> No	(none)		
460575	ROOP, LESLEY	F	32	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415811	2
480759	ROOP, STANLEY	M	34	<input type="radio"/> Yes <input type="radio"/> No	(none)		
482080	ROOP, STUART	M	63	<input type="radio"/> Yes <input type="radio"/> No	(none)		
549961	ROOP, WESLEY	M	26	<input type="radio"/> Yes <input type="radio"/> No	(none)		
851056	ROOP, KELLEY	F	38	<input type="radio"/> Yes <input type="radio"/> No	(none)		

To attach a Filled-“No” comment to a 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.

Continue to enter results as vessels are processed. Review the information in the OGTT processing window and save the data to the database.

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
346104	ROOP, NATALIE	F	28	<input type="radio"/> Yes <input type="radio"/> No	(none)		
460575	ROOP, LESLEY	F	32	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415811	2
480759	ROOP, STANLEY	M	34	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415811	3
482080	ROOP, STUART	M	63	<input type="radio"/> Yes <input type="radio"/> No	(none)		
549961	ROOP, WESLEY	M	26	<input type="radio"/> Yes <input type="radio"/> No	(none)		
851056	ROOP, KELLEY	F	38	<input type="radio"/> Yes <input type="radio"/> No	(none)		

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.

It is not possible to mark vessels 9 (glucose) and 23 (insulin) in the blood processing module after the second 2-mL gray top tube has been marked as collected in phlebotomy. They are grayed out on the blood processing window.

The screenshot shows the 'Lab Shipping' application window. The main window title is 'BP: 695392' and the sub-window title is 'B processing'. The patient information is as follows:

- Tech ID: 1126
- Sample ID: 695392
- Name: MEYERS, RICHARD
- Gender: M
- Age: 38
- SP ID: 695392
- Appt Type: Primary
- Fasting Req: Morning - 9 Hour

Below the patient information is a table of vessels for processing:

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
100	IgE	1.0	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
81	Vitamin B6	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)		
12	Folate/B12	1.0	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
13	CRP	0.3	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
14	Hep Profile	1.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
17	Cotinine	1.8	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

At the bottom of the window, there are buttons for 'Save', 'Phlebotomy', 'OK', and 'Cancel'. The status bar at the bottom shows 'Cancel changes', 'HUP: idle', 'MEC Layer: 11/22/2004', 'Application: Ver 12.11.22A', 'Connected to Coordinator', and '10:31 AM'.

Process the blood from the first venipuncture as soon as possible. Contact the system programmer if the blood tubes for vessels 9 and 23 were drawn before the second 2-mL gray top tube was marked as collected in phlebotomy.

During the OGTT blood draw (2 hours after the initial venipuncture and after the SP has consumed the Trutol), the phlebotomist will draw any tubes that were missed during the first venipuncture. Add the “Post OGTT draw” comment to any blood vessel processed or filled from blood collected during the OGTT blood draw.

B processing

Tech ID: 1126	Sample ID: 480759	Name: ROOP, STANLEY	Gender: M	Age: 34
	SP ID: 480759	Appt Type: Primary	Fasting Req: Morning - Fast	

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
22	HIV		0.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0435743	1
24	HSV		0.2	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0435745	1
127	IgA-TTG/EMA		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0435764	1
16	MMRV		1.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435739	1
32	Xtra Sera1		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	17
33	Xtra Sera2		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	18
34	Xtra Sera3		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	19
35	Xtra Sera4		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	20
36	Xtra Sera5		1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	21
37	Xtra Sera6		1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	22
38	Xtra Sera7		1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	23
39	Xtra Sera8		1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435675	24
92	BFR1		4.0	S	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435697	3
93	BFR2		4.0	S	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0435697	4

Save    Phlebotomy    OK    Cancel

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 (c, e, h, I, l, p).

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, p).

#### 13.2.4 Vessel 98 Storage Protocol

Fill the vessels, enter the OGTT processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Exhibit 13-2.

Exhibit 13-2. Storage protocol for GTT

Shipping Location	Vessels	Conditions	Vessel Storage
NHANES Diabetes Laboratory	98 OGTT	Frozen	9 x 9 two inch box

#### 13.2.5 Vessel 98 Shipping Protocol

Ship the OGTT container weekly on dry ice to the NHANES Diabetes Laboratory. Exhibit 13-3 describes the shipping protocol.

Exhibit 13-3. GTT shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
<b>Blood</b>				
NHANES Diabetes Laboratory Vessel 98	OGTT	Frozen	9 x 9 two inch box	Weekly

Pack the container in the same shipper as vessels 9, 23 and 21. Close the container using procedures described in Section 9.9 of the *Laboratory Procedures Manual*. Assign the closed container(s) to or associate closed containers with the same airbill that was created for the frozen shipper being sent to the NHANES Diabetes Lab. Exhibit 13-4 includes the contract laboratory address. Use procedures described in Section 9.10 of the *Laboratory Procedures Manual*. Follow the steps listed in Section 9.11 to create the shipping manifest and to send the electronic file. Pack and label the shipper using procedures described in Section 9.13 of the *Laboratory Procedures Manual*.

Exhibit 13-4. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name telephone number
NHANES Diabetes Laboratory 1120 Delaware St SE Mayo L275 Minneapolis, MN 551155	9/Glucose 23/Insulin 98/OGTT 21/Lipids	Frozen	Jean Bucksa (612) 273-36115

### 13.2.6 Performing the OGTT on SPs Who Do Not Speak English

When the MEC staff must conduct the OGTT procedure with an SP who does not speak English and the staff member 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 examination.

#### 13.2.6.1 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.

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].

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English <i>Ctrl+E</i>	Toggle option to set exam language to English.
Spanish <i>Ctrl+S</i>	Toggle option to set exam language to Spanish.

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## 14. QUALITY CONTROL AND QUALITY ASSURANCE – POLICIES AND PROCEDURES

National Health and Nutrition Examination Survey  
National Center for Health Statistics  
Centers for Disease Control and Prevention  
Public Health Service  
Department of Health and Human Services

Current revision: January 2011

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  
ERB - ethics 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 Financing Administration  
ISIS - Integrated Survey and Information System  
PC - personal computer  
LAN - local area network  
SP – survey participant

This policies and procedures quality control and quality assurance chapter is an adjunct to the Westat Policies Manual.

## **14.1 Safety**

### **14.1.1 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, 2011*. 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.

## **14.2 Specimen Submission and Handling**

### **14.2.1 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 survey participant, 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 heavy metals.

## **14.2.2 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 survey participant's name.

## **14.2.3 Questions on Specimen Submission and Handling**

The chief medical technologist addresses questions concerning specimen collection including handling and testing.

## **14.3 Test Requisition**

### **14.3.1 Introduction**

Under a congressional mandate (Section 306 of the Public Health Service Act 42 U.S.C.242k) since 1960, NCHS has collected data on the health of the people of the United States through interviews and extensive physical examinations. Seven surveys using health examination procedures have been completed since 1960. 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 this survey involves about 7,000 survey participants per year, of whom about 5,000 per year are expected to be examined. Data collection began in January 2005 and continues for about 8 years at 15 different locations (stands) per year.

NHANES performs a complete blood count on survey participants 1 year and older, urine osmolality on SPs age 6+ and urine and/or serum pregnancy tests on female SPs aged 12-59 years, and girls 8-13 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 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.

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.

### **14.3.2 Laboratory Tests**

“Panic” or abnormally high CBC results are reported to the survey participant. 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 survey participant to obtain any other pertinent information, which might facilitate the laboratory measurement process.

Osmolality results are not reported to the survey participant. Pregnancy test results are reported immediately since other MEC components are not assigned until the results of the pregnancy test are documented.

### **14.3.3 Human Subjects Review**

The NCHS ERB 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.

## **14.4 Test Records**

### **14.4.1 Introduction**

The purpose of test records is to ensure correct and reliable identification of survey participant specimens and to report accurate test results. The laboratory test record system is distinguished from the test report that is provided to the survey participant.

## **14.4.2 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 that specimen was collected by 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.

## **14.5 Test Report**

### **14.5.1 Introduction**

The laboratory report is provided promptly to the survey participant. This occurs as soon as the quality control has been reviewed and approved. The laboratory maintains confidentiality of the survey participant 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 survey participant.

### **14.5.2 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 survey participant'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 survey participants' (SPs') data are reported.

Review and approval of the CBC and pregnancy test results by the MEC physician are documented. Review by the MEC physician includes an evaluation of the consistency of survey participant results with information that may be available on the survey participant (e.g., age, sex). All SPs' CBC 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 survey participant 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 survey participant. Each method includes a description of actions taken such as when results are markedly elevated or are "panic values." The survey participant 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.

### **14.5.3 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.

#### **14.5.4 Format of the Test Report**

The test report includes:

- Name and address of NCHS;
- Test result;
- Units of measurement;
- Reference range for each analyte, if available;
- 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” replace 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.

#### **14.5.5 Format for Laboratory Report Cover Letter**

An example of the Laboratory Report cover letter (report of findings) is available upon request.

#### **14.5.6 Format for Listing of Laboratory Results**

An example of the laboratory results is available upon request.

## 14.6 Quality Control

### 14.6.1 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; 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:

1. **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.
2. **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.

3. **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.
4. **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.
5. **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.

#### **14.6.2 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.

#### **14.6.3 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 survey participant 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 survey participant samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for survey participant test results.”
- **QC Requirements of Each Analytical Run** – Analysis of survey participant samples is organized into analytical runs. The minimum QC requirement for an analytical run, which is analyzing survey participant specimens, is that the run includes four internal (“bench”) QC specimens.

#### **14.6.4 Overview of the Relationship between Internal QC, Proficiency Testing, and External QC**

A Beckman Coulter® technical representative performs HMX 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 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® HMX 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 or has a value determined by repetitive testing using a reference or definitive test method”) that is useful for monitoring method performance.

The Osmette II is used to perform osmolality on urine samples. The osmolality test is a determination of the number of osmotically active solutes present in the urine. It is performed to help evaluate the body’s water balance, its ability to produce and concentrate urine. Urine osmolality is dynamic and will fluctuate as the body responds to and corrects temporary water imbalances.

The Osmette II is calibrated at the beginning of each stand using the manufacturer’s procedure for total calibration. A calibration standards check is performed weekly. This procedure verifies that the two bottled Standards that are in use are accurate when compared to the same concentration of previously unopened reference standards (CON-TROL ampule Reference Standards). A calibration check procedure is performed daily. This involves running two Standards and two levels of QC material in duplicate. The pipettor is calibrated at the start of each stand and the Teflon tip is changed.

## **14.6.5 Internal (“Bench”) QC**

### **Complete Blood Count**

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 are possible. The 5C® Cell Control 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 are captured by and stored in the ISIS. Any 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® HMX. 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.

### **Osmolality**

Urine Osmolality Determination is performed on primary survey participants (SPs) who are 6 years and older and dry run odd and even volunteers age 12+. The test is performed using the random urine specimens collected at the MEC. There are no SP safety exclusions for this test. The test is performed in the MEC laboratory using the Osmette II instrument. SP samples are run in duplicate and the two results are averaged. If the difference between the two values exceeds a preset precision limit, then the sample is run a third time. The closest two results are reaveraged. It is possible to delete one or more results. If the final result is based on a single run, then a comment, “results based on single run” will automatically be appended to the result. Results are saved in whole numbers. Osmolality test results will not be reported back to the participant. If the measured value is >2000 mOsm/kg then the result will be reported as “2000” with “out of range comment.”

Quality control materials include a set of standard bottled solutions with exact concentration of Sodium Chloride (NaCl - Inorganic Salt) and deionized water. In addition, two levels of a human urine controls [Quantimetrix Level 1 (484) and the Level 2 (828)] QC material are used as quality control material for the Osmette II. At the start of each stand the instrument is calibrated and the pipette is calibrated and the Teflon tip is changed.

Two levels of standards, 100 and 1500 milliosmoles, and the two levels of human urine controls (Quantimetrix Level 1 [484] and the Level 2 [828]) QC material are run daily during the first session or run just before the first sample. However, no sample can be imported or transmitted until the QC results are acceptable. The QC module captures the lot number, expiration date and any relevant statistics like mean and standard deviation of the Quantimetrix material. The Quantimetrix QC samples are run in duplicate and the results are averaged. If the difference between the two values exceeds a preset precision limit, then the sample is run a third time and the closest two results are then averaged. It is possible to delete one or more results. If the final result is based on a single run, then a comment, “results based on single run” will automatically be appended to the result. Results are saved in whole numbers. The limits for the 100 standard is  $\pm 1SD$  with a spread < 6. The limits for the 1500 standard is  $\pm 0.5 SD$ .

Weekly quality control is a standard verification procedure. This includes running two 100 and 500 standards and comparing them to 100 and 500 CON-TROL reference standards. All results should be within 2SD of the target value. If results are  $> 2SD$  from the Standard target value, the instrument is recalibrated with CON-TROL Reference Standards, and Controls (I and II levels) are run.

#### **14.6.6 Coulter Interlaboratory Quality Assurance Program (IQAP)**

All HMX 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.

#### **14.6.7 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.

CAP samples for osmolality are shipped three times per year. Each Urine Chemistry (General) "U" shipment includes six 15.0-mL urine specimens.

### **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.

These samples should be handled and analyzed in a manner identical to SP samples. Results are recorded on the CAP forms and are sent to the address specified by the CAP Surveys Program Support. A copy of the CAP form is sent to the home office at the end of the stand.

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  
3313 Toledo Road  
Hyattsville, MD 20782

#### **14.6.8 Calibration Verification**

Calibration verification is defined by CLIA as “the assaying of calibration materials in the same manner as survey participant specimens to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for survey participant 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 HMX 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® HMX 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.

The Osmette II is calibrated the start of each stand and after any major maintenance. Follow the calibration procedure described in Section VII of Chapter 12.

#### **14.6.9 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.

CAP LN6 verifies the reportable range of the Precision Osmette II instrument. Survey LN6 corresponds to CAP Urine Chemistry (General) Survey U. Each shipment of Survey LN6 includes 15 4.0-mL liquid specimens. Linearity was performed at installation and will be repeated in November of each year. 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.

#### **14.6.10 Quality Control Records**

Records of all quality control results are maintained for at least 7 years. Quality control results are captured and stored in the ISIS and are available via the IntraWeb. A QC logbook is maintained which documents 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 and calibration.

- New lot number crossover studies are performed on Coulter 5C Cell Controls and Osmolality Human Urine Controls. The new lot is run against the old lot 20 times, before the new lot is put into use.

### **14.7 Test Methods, Equipment, Reagents, Supplies, and Facilities**

#### **14.7.1 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.

#### **14.7.2 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 and sent back to the home office at the end of each stand. The technologist documents any unusual occurrence in the automated Unusual Occurrence Log or repair of the Beckman Coulter® HMX in the automated Equipment Tracking System.

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 in the automated Supply Use Control Log. The technical supervisor reviews the Supply Use Control Log at the end of each stand.

#### **14.7.3 Facilities**

Laboratories are arranged to ensure that adequate space, ventilation, and utilities are available for all phases of testing: preanalytic, analytic, and postanalytic.

## **14.8 Analytical Procedure Manual**

### **14.8.1 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.

### **14.8.2 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 survey participant 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; and
- Safety considerations for performing the method.

### **14.8.3 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.

### **14.8.4 Method Performance Specifications**

Method performance specifications for each analytical method are established or verified:

- Accuracy – accuracy of each analytical method will be determined by analysis of calibrators 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.

## **14.9 Equipment Maintenance and Function Checks**

### **14.9.1 Introduction**

Laboratory equipment is checked regularly to ensure acceptable performance. Maintenance (including preventive maintenance) and function checks are documented in the Laboratory and Phlebotomy Quality Control modules in the Integrated Survey and Information System (ISIS). The frequency of maintenance and function checks follows manufacturers' recommendations, when available. Manufacturers' 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 automated Unusual Occurrence Log.

### **14.9.2 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.

### 14.9.3 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®, Vacutainer, Precision Instruments, and Quantimetix 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 Isoton Coulter Clenz HMX Pack Lyse-S III	2-25°C (36-77°F)	17-25°C (63-77°F)
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)
Precision standard solutions	Not greater than 77°F	17-25°C (63 to 77°F)
Precision CON-TROL reference standards	Not greater than 77°F	17-25°C (63 to 77°F)
Quantimetrix Level 1 and 2 material	2-8°C (36-46°F)	2-8°C (36 to 46°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 (35 to 46°F)
Beckman centrifuge (room temperature)	-5 to +25°C (23-77°F)	17-25°C (62 to 77°F)
Revco freezer	-30°C (-22°F) Limit	-26 to -34°C (-15 to -29°F)
Jewett freezer	-20°C (-4°F) Limit	-18 to -23°C (0 to -10°F)
Jewett refrigerator	2-5°C (35 to 41°F)	2-8°C (35 to 46°F)
LFBS	0.450	0.350 to 0.550
Phlebotomy refrigerator	None	2-8°C (35 to 46°F)
Mettler Toledo Scale	One 100g weight (start of stand QC)	+/- 1.0 grams
Mettler Toledo Scale	Two 300g weights (start of stand QC)	+/- 6.0 grams
Mettler Toledo Scale	One 500g weight (daily QC)	+/- 5.0 grams
Mettler Toledo Scale	One 20g weight (daily QC)	+/- 0.2 grams

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 for the -20°C Jewett model is -18 to -23°C. The range of allowable temperature for the -30°C Revco model is -26 to -34°C. If the range is exceeded, the technologist contacts the MEC manager.

A separate automated continuous TempGuard 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 Facilities Equipment Specialists (FES) 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.

SPs are given a urine collection cup and instructed to void completely into the urine container when they check into the MEC and change into their exam clothing. The container is brought back to the MEC laboratory and placed on the counter near the Mettler Toledo scale at workstation 2.

No later than 15 minutes after the specimen arrives in the laboratory the medical technologist places the cup on the scale and scans in the specimen. The lab application calculates the volume of urine and compares the volume collected to the amount needed for the protocol. The volume and date and time of urine collection are also captured.

## **14.10 Calibration and Calibration Verification**

### **14.10.1 Introduction**

Calibration and calibration verification are specified in the documentation of the CBC analytical procedure.

## **14.10.2 Comparison of Methods Performed on Multiple Instruments or at Multiple Sites**

At least once every 6 to 8 weeks, each of the three HMX instruments is calibrated with S-Cal. CAP data are analyzed by regression analysis and at least two of the three instruments are compared to each other three times per year.

At least once every 6 to 8 weeks, each of the three Osmette II instruments is calibrated. CAP data are analyzed by regression analysis and at least two of the three instruments are compared to each other three times per year.

## **14.11 Remedial Actions**

### **14.11.1 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 survey participant 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 survey participant results, the MEC physician notifies the survey participant by phone, followed by the issuance of a corrected report within a time period suitable to the survey participant, 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.

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

### **14.12.1 Introduction**

One of the purposes of the ISIS is to store survey participant results for retrieval in a period acceptable for the intended use of the data. Survey participant test results are stored in a database. The ISIS consists of the PC databases used for storing survey participant 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 survey participant 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.

### **14.12.2 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.

### **14.12.3 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.

#### **14.12.4 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.

#### **14.13 Communications and Complaints**

##### **14.13.1 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 or 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.

#### **14.14 Quality Promotion**

##### **14.14.1 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.

## **14.15 Quality Assurance Program**

### **14.15.1 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 done." In the case where blood was drawn but no results were transmitted, the preliminary or final Report of Findings states, "Data Not available at this time."
- 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.

#### **14.15.2 Quality Audit: Survey Participant Test Management**

The quality audit for survey participant 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 survey participant preparation, specimen collection, labeling, preservation, and transportation;
  - Any changes which need to be made in completeness and relevance of survey participant 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; and
  - 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.

### **14.15.3 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 the 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 the 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.

### **14.15.4 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 1 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.

#### **14.15.5 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 that 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 that no remedial action is needed. At least once every 6 months, the technical supervisor and laboratory director review the results of quality audits.

#### **14.16 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 survey participant 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, 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).

## 15. OPERATIONAL ISSUES

### 15.1 Start of Stand Activities

The Westat warehouse manager sends supplies for all stands, schedules shipments so that they arrive on or before setup day, and ships supplies requiring refrigeration so that they arrive the day before set up. Store laboratory supplies in the laboratory cabinets or in the MEC trailer compartments.

The advance arrangement staff may assist in completing some setup activities. On setup 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 and test the functionality of all instruments and equipment. Notify the MEC manager if additional supplies are required and document all instrument and equipment malfunctions in the automated Unusual Field Occurrence utility. Record all lot numbers and expiration dates for consumables (phlebotomy and lab) in the Supply Use Control Log, which is located in the respective QC module.

Mark and store miscellaneous hardware and original packing boxed 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® HMX instrument and printer.

#### **Phlebotomy Room**

- The Phlebotomists' responsibilities include the following tasks:
  - Inventory consumables and nonconsumables.
  - Check the sink for hot and cold running water and proper drainage.
  - Remove the wood block from the refrigerator door.
  - Unlock all cabinets.

- Release the phlebotomy chair restraint.
  - Unlock all four casters.
  - Pull up on the black lever on the lock and loosen just enough to separate the S bolts.
- Release the phlebotomy cart restraint.
- Turn on the refrigerator in phlebotomy, OGTT, and spare room.
- Verify the refrigerator's operation.
- Check the function of the telephone intercom.
- Clean the refrigerators.
- Install the wall thermometer.
- Clean all work surfaces and storage areas.
- Stock and organize supplies.
- Record all lot numbers and expiration dates in the automated Supply Use Control Log.
- Check the computer operations.
- Store the chair and cart restraint and the wood block in the bottom right drawer.

### **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 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 refrigerator temperature probes back into the bottles.
- Plug in the refrigerators and freezers.
- Verify freezer and refrigerator operation.
- Check light, blowers, and magnehelic pressure gauge reading in the Laminar Flow Biological Safety Cabinet (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® HMX. Complete the calibration before performing routine CBCs on SPs.
- Unpack the Mettler Toledo scale and store carrying case in an easily accessible area. Perform the QC on the Toledo Scale and complete the QC before performing routine urine flow rates on SPs
- Unpack the Osmette II osmometer. Change the Teflon tip of the Osmette II pipette. Run a total calibration on the Osmette II. Complete the calibration before performing routine osmolality tests.
- Refrigerate the serum and urine pregnancy controls, and Beckman Coulter® Latron and 5C Cell controls as soon as they arrive.
- Clean and disinfect 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.

## **15.2 End of Stand Activities**

For security reasons, lock all needles in the drawer each day after examinations are complete. Turn off the centrifuges. Reboot 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. Safely discard all biohazardous waste. Repack the Osmette II in its original box with protective padding and the Metler Toledo scale in the blue carrying case.

### **Packing Phlebotomy Room**

- Phlebotomists' responsibilities include the following tasks:
  - Inventory consumables and nonconsumables.
  - Turn off and clean the refrigerators in the phlebotomy, OGTT, and spare rooms.

- Place wood blocks with Velcro strips on the refrigerator doors to prevent the doors from closing or moving. Be careful not to damage the rubber gasket on the door.
- Pack all 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 countertops; 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.
- Bolt the room doors in the open position.
- Close and lock all cabinets.
- Lock all needles in the cabinets.
- Restrain the phlebotomy chair.
  - Attach the S bolt on the end of the orange belt to each of the two wall brackets (under the drop-down chair).
  - Attach the center S bolts to each other in the center of the orange belt.
  - Tighten the belt by pulling on the free end of the belt.
- Restrain the phlebotomy cart in the staff lounge on the wall between the ISIS rack and the outside entry door to the staff lounge.

### **Packing the Laboratory**

- Medical technologists' responsibilities include the following tasks:
  - Inventory 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 Latron and 5C Cell control cum statistics (files) and graphs.

- 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, pregnancy controls, and Quantimetrix urine 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.
  - Disinfect and clean the pipettes.
  - Replace the 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.
  - Turn off the Mettler Toledo scale. Disconnect the scale from the tan serial cable and black AC adapter power cord. Tape the serial cable and power cord to the countertop. Repack the Mettler Toledo scale in the blue carrying case making sure to remove and store the weigh pan in the lid of the carrying case and cover the scale cone with the plastic cone protector.
  - Turn off the Osmette II. Pack the Osmette II in the shipping box with foam padding. Make sure the foam padding surrounds the entire instrument so it is secure for transport.
  - Unplug the LFBSC.
  - Close and lock centrifuge lids and turn off centrifuges.

- Pack all tube rockers, Zebra printer, and TB incubator 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 lock.
- 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 to create a label to send the following hard-copy documentation to the technical supervisor at the home office:

- Beckman Coulter® Latron and C Cell Control printouts
- Beckman Coulter® Start Up printouts
- Beckman Coulter® Calibration printouts
- Beckman Coulter® Latex CBC/Diff cumulative statistic and graph printouts
- Beckman Coulter® Error file printout
- Beckman Coulter® Linearity printouts
- Proficiency testing copies (hematology, urine and serum hCG, and osmolality)

At the end of each stand use FedEx 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
- Unopened Quantimetrix Human Urine controls – refrigerated

Pack supplies using procedures described in Chapter 9.

### 15.3 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.

The equipment and supplies associated with the MEC laboratory are listed in Exhibit 15-1, Equipment and supplies.

Exhibit 15-1. Equipment and supplies

-30 Revco freezer ULT 430A18	Five Jewett temperature monitoring units 8ER-1B
Two Beckman Coulter Allegra centrifuges	Laminar flow biological safety cabinet
Two refrigerators (OGTT and right side of trailer 3)	One Jewett refrigerator (phlebotomy)
Precision Instruments Osmette II Osmometer	Mettler Toledo scale
Two Thermolyne Vari-Mix M48700 (lab)	One Thermolyne Speci-Mix (phlebotomy)
Two Maxi-Mixer (lab)	One Thermolyne Speci-Mix (lab)
Two solar wall thermometers (lab)	One solar wall thermometer (phlebotomy)
Two Jewett refrigerators UC5B	Thermometer (centrifuge calibration)

Store supplies in the trailer compartments.

### 15.3.1 General Inventory Procedures

- Since item units can change, verify the “unit of measure” 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.
- “PAR Level” represents the number of units the component is to begin a stand with. Note that PAR Levels are set and adjusted by home component staff only. Any/all recommendations to adjust an item’s PAR level should be directed to Home Component Staff.
- Do not write any notes, comments, etc. on the Start-of-Stand Inventory Count Sheets or the End-of-Stand Inventory Count Sheets. Comments or concerns should be written on a separate sheet of paper and attached to the inventory sheet.
- 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, Sani-cloth wipes, blood tubes, etc. deteriorate over time. Always use inventory with the closest expiration date first.
- Multiple inventory items onboard the MEC contain lot numbers and expiration dates. When performing physical inventory counts, pay close attention to these items and mark inventory sheets accordingly for each lot number/expiration date per item.
- Do not purchase items listed on the inventory sheets. Every item listed on the inventory sheet is supplied by the NHANES Warehouse. Purchasing items locally creates chaos with the Inventory Management System.
- Do not borrow items from other components. Any additional inventory needed by a component should be requested from the NHANES Warehouse. Inventory 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.

### 15.3.2 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, PAR level, 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.
- Please write legibly for all counts.
- Place a number in each “count” box. Do not leave any count box empty. If there is no stock remaining for a specific item, place a “zero” in the count box.
- Do not count partial units; record only whole numbers in the count box. Do not write entries such as: ½, partial, some, many, a few, couple, .5, or multiple.
- If the PAR for an item is more than one (1) and the “unit of measure” is open, do not count that container. Only count the remaining number of items that have not been opened.
- If the PAR for an item is only one (1) unit and it is more than ½ empty, place a zero (0) in the count box. A full unit will be supplied to the component at the opening of the next site.
- All active lot numbers and expiration dates are listed on the inventory count sheets if they are applicable for that item. Record the number of supplies remaining for each lot number/expiration date in the count box. If there is no inventory remaining for a listed lot number/expiration date, then place a “zero” in the count box.
- Any item that has expired during the MEC site or will expire before the MEC re-opens at its next location should be removed from the component. If an item is removed, a “zero” should be entered in the count box on the End-of-Stand Inventory Count Sheet for that item. A Delete/Expired Inventory Count Sheet must be filled out, per component, showing the quantity for each item removed from the component. This additional inventory sheet must be attached to the End-of-Stand Inventory Count Sheet for that component when turned into the MEC manager.

### 15.3.3 Mid-Stand Inventory Procedures

Mid-Stand Inventory is performed by each component on the MEC. The Mid-Stand Inventory is performed approximately 2-2½ weeks into an operating site. This inventory provides the opportunity for MEC staff to request additional supplies from the warehouse that will be needed to complete the current MEC site. The Mid-Stand Inventory is conducted via UFO entry (per component).

**NOTE: The mid-stand inventory is only to provide additional supplies needed to complete the current site, it is not designed to bring all supplies up to full par level.**

- Each component is to review all remaining inventory to determine if additional supplies are needed to complete the current MEC site.
- A “UFO” will be entered (sighted) by one MEC staff member per component.
- MEC staff will enter a “UFO” by component name and then use “Inventory/Supplies” for the type of UFO entry.
- In the description field, the MEC staff member will request the supply(s) needed for the component.
- Entries are to be made as: item description then quantity requested (per item).
- If no additional supplies are needed for the component, then the entry “Nothing Needed” is to be written in the description field.
- Do not request items in the UFO that are not currently on the component inventory list.
- Do not request changes to set par levels in mid-stand UFOs.
- Do not enter equipment issues in a UFO listed as “Inventory/Supplies.”
- All completed UFO entries will be reviewed by the MEC manager for that MEC before the warehouse will pull and ship supplies requested.
- Once the supplies have been pulled by the warehouse and packed for shipping to the MEC, the warehouse manager will finalize the UFO.
- Mid-Stand deliveries are arranged between the MEC manager and the warehouse manager.

#### **15.3.4 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 part 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 returns 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.
- Previous EOS Count added to the Ship to Stand Count Box should equal PAR Level.
- If the total inventory equals the set PAR level, place a checkmark on the right side of the Ship to Stand Count Box (per item).
- If there is a discrepancy, write the physical count on hand to the right of the Ship to Stand Count box (per item).
- If the quantity for an item is higher than the set PAR level, the excess should be removed from the component (leaving PAR) and returned to the warehouse. If an item(s) is being returned to the warehouse, have the MEC manager print a “Transfer Inventory to Warehouse Count Sheet” for the component. Print your name on the inventory sheet. Mark only the quantities for item(s) that are being returned. Give the excess inventory along with the “Transfer Inventory Sheet” to the MEC manager to ship supplies back to the warehouse.

#### **15.3.5 Consumables vs. Nonconsumables**

Inventory items are divided into two categories—consumable and nonconsumable. Inventory both types of items during each inventory. The definition for a consumable item is anything that is typically consumed during an examination. A nonconsumable item is one that can be used more than once

*(example: stopwatches, test tube racks, safety glasses, storage boxes, etc).* There are times when nonconsumable items will need to be replaced. These instances would include items that are used in an emergency, when the item expires, or when the item breaks *(example: physician medical kit supplies, stopwatches, thermometers, CPR masks, etc.)*.

### **15.3.6 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. This form looks similar to the “End of Stand Count Sheets.” Print your name in the “Count By” field and mark only the items (with quantity being returned) in the count boxes that are being shipped back to the warehouse. Give the items to be returned along with the “Transfer Inventory to Warehouse Inventory Sheet” to the MEC manager to ship 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.

### **15.3.7 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. Print your name in the “Count By” field and mark only the item(s) in the count box that have expired or broken, and which are being removed from the MEC. 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. Unless the item is a tool (piece of equipment), under most circumstances the item can be disposed of there in the field and there is no need to return the item to the warehouse. Check with the MEC manager or call the warehouse manager to verify the need to ship the expired/broken item back to the warehouse.

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.

## 15.4 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 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

- Collect the amount of blood specified in the Dry Run Venipuncture Protocol (see Exhibit 15-1). This amount is less than the blood required from a routine examinee.
- Prepare split samples for each volunteer.
  - Collect 4-mL of urine and process as specified in Dry Run Urine Processing Protocol (see Exhibit 15-2).
  - Process the blood as directed in the Dry Run Blood Processing Protocols (see Exhibits 15-3, 15-4, and 15-5).
  - Store these split samples and ship them to contract laboratories for analysis with the first routine shipment.

### 15.4.1 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 two 4-mL EDTA, two 2-mL gray, and four 15-mL red top tubes. If the last digit is an even number, then the volunteer’s protocol includes four 3-mL EDTA, two 2-mL gray, and four 15-mL red top tubes. Since both even and odd dry run volunteers are eligible for the oral glucose tolerance test, their profiles include two additional 2-mL gray tubes.

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.

Exhibit 15-2. Dry run venipuncture protocol

Tube type (in priority order)	Last digit in SP ID = Odd	Last digit in SP ID = Even
4-mL EDTA	2	2
2-mL Gray	2	2
3 mL Red		2
15-mL Red	2	4
6 mL Royal Blue	2	

- 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 (110355), and a Sample ID (616625). Both the SP ID and the Sample ID display under the “Obtained all” checkbox.

Phlebotomy: Stand:430 Session:430000 12/03/2004 08:30 am - 12:30 pm

SP ID: 110355 Name: TRAHERNE, MADELINE Age: 22 years Gender: Female Date: 12/12/2008 Time: 11:05 AM

**Venipuncture**

4 ml lavender  of 2

2 ml grey  of 2

15 ml red  of 4

Obtained all

110355

616625

Comment:

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 the Vacutainer® tubes for each volunteer; label half of the tubes with the SP ID and the other half with the Sample ID. If only one tube is drawn, discard the tube. If less than four of the 15-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.

For dry run volunteers with the SP ID and Sample ID ending in an odd number:

- Place one label with the original SP ID on one of the two 3-mL EDTA tubes and place the other label with the Sample ID on the other 4-mL EDTA tube.
- Place the label with the original SP ID on one tube of the pair of 2-mL gray tubes and place the label with the Sample ID on the other 2-mL gray tube.
- Place the labels with the original SP ID on two of the four 15-mL red tubes and place the labels with the Sample ID on the other two 15-mL red tubes.

For dry run volunteers with the SP ID and Sample ID ending in an even number:

- Place two of the labels with the original SP ID on one pair of 3-mL EDTA tubes and place the other two labels with the Sample ID on the other pair of 3-mL EDTA tubes.
- Place the label with the original SP ID on one tube of the pair of 2-mL gray tubes and place the label with the Sample ID on the other 2-mL gray tube.
- Place the labels with the original SP ID on two of the four 15-mL red tubes and place the labels with the Sample ID on the other two 15-mL red tubes.

## 15.4.2 Urine Processing and Pregnancy Testing

Access the laboratory application and logon using the MEC Logon window.

Appointments for Session: 430010

SP ID	Sample ID	status	type	gender	age	name	Process Status									
							UC	U	P	OZ	CB	B	ggt	PC	HPV	OR
119114	119114	SC	D	M	72	RAMOS, STEPHEN	○	○	-	○	○	○	○	-	-	-
119114	491426	SC	D	M	72	RAMOS, STEPHEN	-	○	-	○	○	○	○	-	-	-
281786	281786	SC	D	M	42	RAMOS, MARTIN	○	○	-	○	○	○	○	-	-	-
281786	493106	SC	D	M	42	RAMOS, MARTIN	-	○	-	○	○	○	○	-	-	-
350948	350948	SC	D	M	74	RAMOS, JACKSON	○	○	-	○	○	○	○	-	-	-
350948	498908	SC	D	M	74	RAMOS, JACKSON	-	○	-	○	○	○	○	-	-	-
412754	412754	SC	D	F	25	DEMARCO, JILL	○	○	○	○	○	○	○	-	-	-
412754	499102	SC	D	F	25	DEMARCO, JILL	-	○	-	○	○	○	○	-	-	-
439242	439242	SC	D	F	49	DEMARCO, LEANNE	○	○	○	○	○	○	○	-	-	-
439242	499492	SC	D	F	49	DEMARCO, LEANNE	-	○	-	○	○	○	○	-	-	-

Two distinct IDs are assigned to each volunteer—the original SP ID and a second unique Sample ID.

Place urine and pregnancy labels at workstation 3. 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: 430010							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	gtt	PC	HPV	OR
119114	119114	SC	D	M	72	RAMOS, STEPHEN	○	○	·	○	○	○	○	·	·	·
119114	491426	SC	D	M	72	RAMOS, STEPHEN	·	○	·	○	○	○	○	·	·	·
281786	281786	SC	D	M	42	RAMOS, MARTIN	○	○	·	○	○	○	○	·	·	·
281786	493106	SC	D	M	42	RAMOS, MARTIN	·	○	·	○	○	○	○	·	·	·
350948	350948	SC	D	M	74	RAMOS, JACKSON	○	○	·	○	○	○	○	·	·	·
350948	498908	SC	D	M	74	RAMOS, JACKSON	·	○	·	○	○	○	○	·	·	·
412754	412754	SC	D	F	25	DEMARCO, JILL	○	○	○	○	○	○	○	·	·	·
412754	499102	SC	D	F	25	DEMARCO, JILL	·	○	·	○	○	○	○	·	·	·
439242	439242	SC	D	F	49	DEMARCO, LEANNE	○	○	○	○	○	○	○	·	·	·
439242	499492	SC	D	F	49	DEMARCO, LEANNE	·	○	·	○	○	○	○	·	·	·

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 with an SP ID and Sample ID ending in either an odd or even digit are eligible for urine collection and processing, osmolality, CBC, GTT, blood processing, and the pregnancy test (if female.) 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. Notice that one urine collection result and one pregnancy test are required for each dry run volunteer when the SP ID and Sample ID end in an odd or even digit.

Collect at least 4-5-mL urine from all dry run volunteers. The MEC coordinator instructs each volunteer to void as soon as they feel they are able to provide a urine specimen. The coordinator or local assistant transports the initial specimen to the laboratory. All dry run volunteers are eligible for at least one urine test.

Place the urine collection cup on the scale and scan in the urine collection specimen barcode as described in Chapter 5, Section 5.4.

Document the urine collection in the laboratory application.

Appointments for Session: 430010							Process Status					
SP ID	Sample ID	status	type	gender	age	name	CB	B	glt	PC	HPV	OR
119114	119114	CI	D	M	72	RAMOS, STEPHEN	○	○	○	.	.	.
119114	491426	CI	D	M	72	RAMOS, STEPHEN	○	○	○	.	.	.
281786	281786	SC	D	M	42	RAMOS, MARTIN	○	○	○	.	.	.
281786	493106	SC	D	M	42	RAMOS, MARTIN	○	○	○	.	.	.
350948	350948	SC	D	M	74	RAMOS, JACKSON	○	○	○	.	.	.
350948	498908	SC	D	M	74	RAMOS, JACKSON	○	○	○	.	.	.
412754	412754	SC	D	F	25	DEMARCO, JILL	○	○	○	.	.	.
412754	499102	SC	D	F	25	DEMARCO, JILL	○	○	○	.	.	.
439242	439242	SC	D	F	49	DEMARCO, LEANNE	○	○	○	.	.	.
439242	499492	SC	D	F	49	DEMARCO, LEANNE	○	○	○	.	.	.

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 screenshot shows a window titled "Urine Collection Verification: 430010". It contains a table of SPs and a form for data entry.

Sp ID	Sample ID	Name	Gender	Age
119114	119114	RAMOS, STEPHEN	M	72
281786	281786	RAMOS, MARTIN	M	42
350948	350948	RAMOS, JACKSON	M	74
412754	412754	DEMARCO, JILL	F	25
439242	439242	DEMARCO, LEANNE	F	49
454419	454419	DEMARCO, NAOMI	F	48
565311	565311	RAMOS, LEONARD	M	67

Below the table, the selected SP's details are shown: **SP ID: 119114 NAME: RAMOS, STEPHEN AGE: 72 Gender: M**

Collection	Volume (mL)	Collection Date:Time	Status	Comment Code	Verified
1	<input type="text"/>	<input type="text"/>	(none) ▼	(none) ▼	<input type="checkbox"/>

**Total Collected:**  
**Total Required: 3**

Buttons:

The top of the urine collection window contains columns for the SP ID, Sample ID, Person Name (last, first), Gender, and Age. The row for checked-in SPs is indicated in black, while SPs who have not checked into the MEC session are gray. Only dry run volunteers who have checked into the MEC session are available for processing. SPs who have a urine collection ready for verification display in blue. Use the scroll bar to view all SPs scheduled into the session.

Verify the sufficiency of the quantity of urine received in the laboratory. Use the measuring tool to verify the amount of urine reported from the scale.

Sp ID	Sample ID	Name	Gender	Age
119114	119114	RAMOS, STEPHEN	M	72
281786	281786	RAMOS, MARTIN	M	42
350948	350948	RAMOS, JACKSON	M	74
412754	412754	DEMARCO, JILL	F	25
439242	439242	DEMARCO, LEANNE	F	49
454419	454419	DEMARCO, NAOMI	F	48
565311	565311	RAMOS, LEONARD	M	67

SP ID: 119114 NAME: RAMOS, STEPHEN AGE: 72 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	138	12/13/2008 09:30 AM	Yes	(none)	<input type="checkbox"/>

Total Collected: 138  
Total Required: 3

New Collection Save Cancel

If the SP has submitted a urine collection that has been weighed and scanned into the database the volume, collection status, and collection date and time will automatically display in the lower portion of the Urine Collection screen.

If the collection did not meet the minimum protocol requirement, the application will automatically insert “QNS” in the Status result text field and “quantity not sufficient” in the Comment Code text box.

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

**SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F**

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>

**Total Collected: 3**  
**Total Required: 4**

Buttons:

A QNS status immediately prompts and notifies the coordinator to ask the SP for an additional urine sample.

A second instance of urine collection for the first QNS sample or third instance of urine collection for the second QNS sample will appear below the current sample.

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F

Collection	Volume (mL)	Collection Date:Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input type="checkbox"/>

Total Collected: 28  
Total Required: 4

New Collection Save Cancel

If the quantity of urine collection does meet the requirement of the urine protocol, the application will automatically select a status of “Yes” and no additional collections will appear.

Evaluate the quantity of urine received in the laboratory. Compare the number displayed in the Total Collected column and the actual volume of urine in the cup.

**Urine Collection Verification: 430000**

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

**SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F**

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input type="checkbox"/>

**Total Collected: 28**  
**Total Required: 4**

Adjust the Volume (mL) if necessary by using the mouse to direct the mouse arrow to the text box under the Volume (mL) column. Right click on the text box to enable the cursor in the box. Make changes using the number pad on the keyboard. Once any necessary adjustments have been made, use the mouse to direct the mouse arrow to the box under the Collection Date/Time column or press the Tab key.

A prompt will pop up asking if you would like to subtract the weight of the cup. If the volume of the sample was transmitted from the scale and you have made a manual adjustment to that reading, select “No.”

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.

The laboratory application will automatically assign the comment code “quantity not sufficient” for all urine collections that are calculated as QNS by the scale application. The laboratory technician may also assign this comment code to all samples that are changed to QNS during the verification process.

**Urine Collection Verification: 430000**

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

**SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F**

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input checked="" type="checkbox"/>

**Total Collected: 28**  
**Total Required: 4**

Comment Code dropdown menu options:

- (none)
- communications problem
- SP unable to comply
- quantity not sufficient
- SP refusal
- SP ill/emergency

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.

Verify the results of the urine collection.

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F

Collection	Volume (mL)	Collection Date:Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input checked="" type="checkbox"/>

Total Collected: 28  
Total Required: 4

New Collection Save Cancel

To verify, use the mouse to direct the mouse arrow to the “Verify” checkbox. Left click on the checkbox and a checkmark will appear in the box. Verifying the results will save the results to the database.

To save a result to the database without exiting the module or removing the window, use the mouse to direct the mouse arrow to the “Verify” checkbox. Left click on the checkbox. Alternately, 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  Close Window button and left click.

### 15.4.3 Urine Processing

Use the urine processing labels printed in advance to label the SP’s urine vessels. The urine processing protocol is displayed in Exhibit 15-3. Dry run volunteers are eligible for at least one vessel – 45. 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).

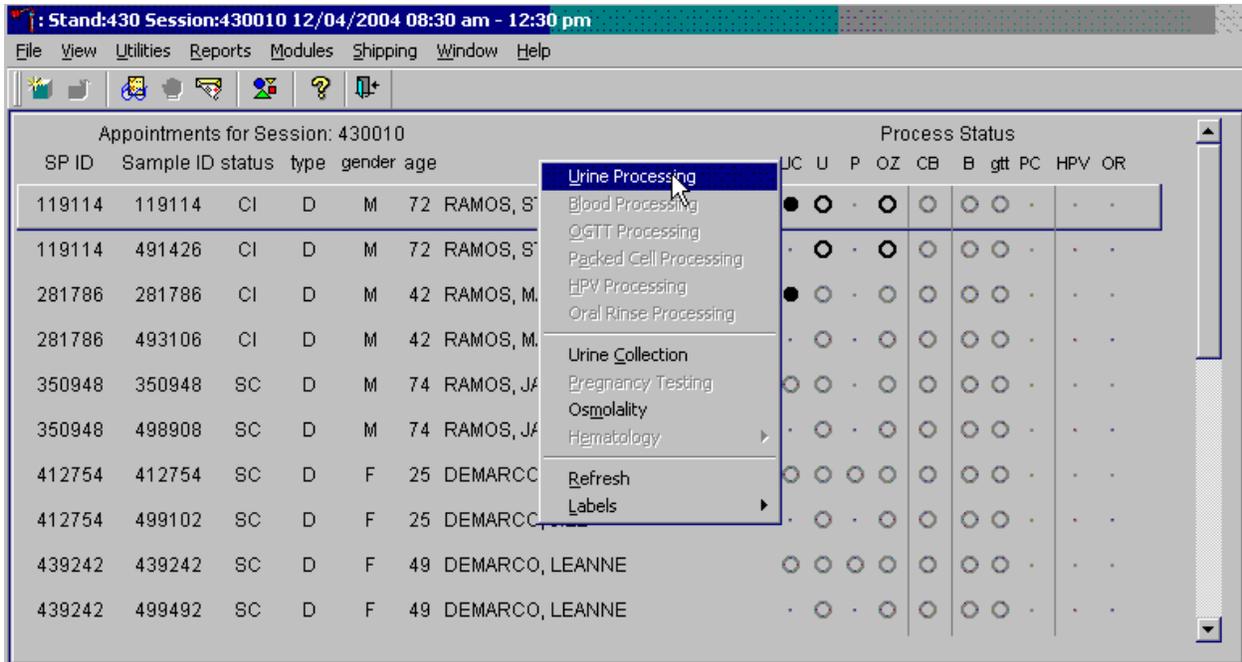
Exhibit 15-3. Dry run urine processing protocol

ID	Assay	Sample size mL	Vessel
45	Alb/Creat	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 Sample ID.
- Aliquot 3-mL urine into the vessels using a large plastic transfer pipette.
- Enter the results of urine processing for the original SP ID and again for the Sample ID.

After filling the urine specimen vessels for each dry run volunteer, use the Urine Processing module to enter the urine processing results.



The volunteer's urine processing screen displays.

UR: 119114

U processing

Tech ID: 1700    Sample ID: 119114    Name: RAMOS, STEPHEN    Gender: M    Age: 72  
 SP ID: 119114    Appt Type: Dry Run    Fasting Req: Morning - Fast

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)		

Save    OK    Cancel

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 the 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.

UR: 491426  
U processing

Tech ID: 1126    Sample ID: 491426    Name: RAMOS, STEPHEN    Gender: M    Age: 72  
 SP ID: 119114    Appt Type: Dry Run    Fasting Req: Morning - Fast

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)	0415789	4

---

UR: 119114  
U processing

Tech ID: 1126    Sample ID: 119114    Name: RAMOS, STEPHEN    Gender: M    Age: 72  
 SP ID: 119114    Appt Type: Dry Run    Fasting Req: Morning - Fast

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)	0415789	3

Save    OK    Cancel

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.

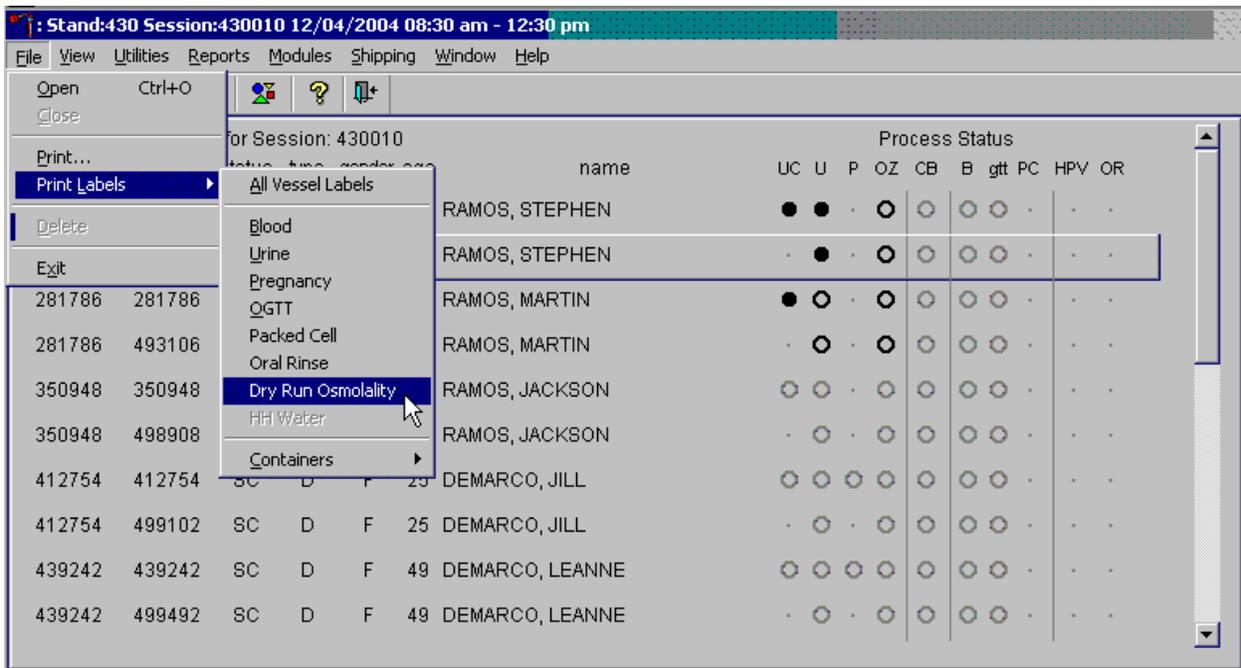
Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink. Flush the sink with water. Discard urine cup in the biohazard trash.

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.

#### 15.4.4 Osmolality

The urine processing technologist performs the osmolality test on dry run volunteers in duplicate—one test for each Sample ID—and documents the results following the procedures in Chapter 12. The osmolality test run on the sample where the SP ID and Sample ID are the same can be scanned in using the barcode initially labeled on the urine collection container. The duplicate osmolality test, run where the SP ID is not equal to the Sample ID, needs to have an additional label printed, placed on the container, and scanned.

Access the Dry Run Osmolality labels.



The labels print on the Dymo printer at workstation 2. Compare the printed label with the label on the urine cup. If the SP name and ID match, place the osmolality urine collection label on the lid of the urine collection cup. Scan this barcode in when running the duplicate osmolality test. When running the initial osmolality test, scan in the original urine collection label.

### 15.4.5 Hematology

The technologist at workstation 3 runs two CBCs, in duplicate, for each dry run volunteer after the blood processing technologist processes whole blood from the 3-mL EDTA tubes according to the whole blood processing protocol (see Exhibit 15-4). Run the first CBC in duplicate on the first 3-mL EDTA 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 EDTA tube using the Sample ID. Evaluate results, and save the data using procedures described in Chapter 7.

### 15.4.6 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; one set of labels contains the SP ID and the second set of labels contains the Sample ID. Prepare two blood processing racks (one with the SP ID labels and one with the Sample ID labels) using the blood-processing template for ages 12+.

Exhibit 15-4. Dry run processing protocol – whole blood

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG/Se/Mn	Both	0.4	Whole Blood	4-mL EDTA	2-mL
3	RBC Folate	Even	0.1	Whole Blood	4-mL EDTA	2-mL
4	Glycohem	Odd	0.4	Whole Blood	4-mL EDTA	2-mL
5	Mercury	Even	0.5	Whole Blood	4-mL EDTA	2-mL

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 Sample ID.

For volunteers whose SP ID and Sample ID ends in an odd digit, process one of the 4-mL EDTA tubes for Lead/Cad/HG/Se/Mn, RBC F<sub>ol</sub>1, and Glycohem. For volunteers whose SP ID and Sample ID ends in an even digit, process one of the 4-mL EDTA tubes for Lead/Cad/HG/Se/Mn, RBC Folate, and Mercury. Use processing procedures described in Chapter 8. Match the EDTA tube with the SP ID to the corresponding blood processing rack. Match the second EDTA tube with the Sample ID to the corresponding blood processing rack.

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. When the SP ID ends in an even or an odd digit, process each of the 2-mL gray top tubes for OGTT using the same procedures described in the Oral Glucose Tolerance test in Chapter 13.

Process pooled serum for the dry run volunteers using the Dry run blood processing protocol – serum (Exhibit 15-5).

Exhibit 15-5. Dry run blood processing protocol - serum

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
136	Se/Cu/Zn	Odd	1.0	Serum	6 mL Royal Blue	2 mL
70	Vitamin D	Odd	0.7	0.3	Serum	15-mL Red
122	HAV	Even	1.5	0.3	Serum	15-mL Red
17	Cotinine	Even	1.8	Serum	15-mL Red	2-mL
21	Lipids	Both	1.5	Serum	15-mL Red	2-mL
18	Biochem	Both	0.8	Serum	15-mL Red	2-mL
23	Insulin	Odd	1.0	Serum	15-mL Red	2-mL
118	Thyroid	Both	1.0	Seum	15-mL Red	2-mL
127	IgA-TTG/EMA	Both	0.5	Serum	15-mL Red	2-mL
137	Testosterone	Odd	0.5	Seum	15 mL Red	2-mL
110	Folate1	Odd	0.7	Serum	15-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 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.

The screenshot displays two overlapping windows from a laboratory information system. The top window, titled "BP: 491426", shows patient information for "RAMOS, STEPHEN" (Sample ID: 491426, SP ID: 119114) and a table of vessels. The bottom window, titled "BP: 119114", shows the same patient information but with a different Sample ID (119114) and a different set of vessels. Both windows have "Filled" status columns with radio buttons for "Yes" and "No".

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
14	Hep Profile		1.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415779	3
17	Cotinine		1.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415781	5
21	Lipids	●	1.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415783	5
18	Biochem		0.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415782	4
75	PSA									
118	Thyroid									
127	IgA-TTG/EMA									

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.

### 15.4.7 Shipping Dry Run Specimens

Ship the split sample blood and urine vessels with samples from the regular sessions following procedures described in Chapter 9.

## 15.5 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.

- 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.
- 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:
    1. Apply the lubricant onto a swab.
    2. Draw the coated swab through a paper towel to remove excess lubricant.
    3. Lightly coat the inside of the drive hole with the lubricant remaining on the swab.
- 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.
- 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 embedded 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.

## **15.6 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. Do not store anything on the top grill.

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. Temperatures are automatically captured, graphed, and available in real time.

## **15.7 Use of the Temperature Recording Instrument**

The TempGuard system is a multiple device monitor and alarm system that is equipped with an integrated autodialer and data logging capabilities. The TempGuard system automatically monitors the interior temperature of the refrigerators, freezers, and room temperature.

The system can monitor up to 8 temperature sensors and each sensor must have a probe submerged into a bottle of resin. The configuration in the MEC, is as follows:

TempGuard Port	Refrigerator/Freezer Name
1	Refrigerator # 1
2	Refrigerator # 2
3	Freezer # 3
4	Freezer # 4
5	Freezer # 5
6	Freezer # 6
7	Room Temp

The TempGuard system has been programmed with the following: upper and lower limits for all units including the room temperature and a 60-second delay for the allowable time the freezer door can be left open before the system will alarm. The system has the capability to send out calls and emails to alert staff to temperature issues.

### **Checking TempGuard Sensors**

All temperature sensors connected will have their temperature readings displayed next to the sensor number on the display

## **Disabling Alarm**

1. Push the black button on the left side of the TempGuard to see any alarm conditions.
2. Hold the button for 5 seconds to confirm the alarm condition.
3. Alarm Conditions must be confirmed individually.
4. The alarm relay will de-energize, and the TempGuard will stop making callouts for the current alarm condition.

## **Start of Stand Set-Up (performed by the FES)**

Programming the Autodialer Functions (need to update MEC Manager phone # at each stand)

1. Enter the "Full Access" PIN (Enter **0000**).
2. From the Program Menu, Select **1** to set telephone numbers.
3. You will hear "**Select contact.**"
4. Select **1** for the first contact number (FES phone #).
  - Enter your phone number, using this format "**1 + area code + 7 digit #**"
5. You will hear "Contact 1 is xxxxxxx" or "Contact x is Empty, press one to change."
6. Press 1 to make a change or enter a telephone number.
7. You will hear "Enter number then press pound."
8. Enter the number, followed by the # key.
  - Entering the # key will erase the currently programmed contact telephone number.
9. You will hear the telephone number you just entered.
10. You will be prompted to select another contact to program.
11. Select **2** for the second contact number (MEC Mangers #).
  - For Dan enter "**1-301-526-8190**"
  - For Lenea enter "**1-240-246-4356**"
12. Press **0** to return to the Program Menu.

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.

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), which is determined by the probe in the antifreeze solution. The range of allowable temperature for the -30 Revco model is -26 to -34°C. If the range is exceeded, the technologist contacts the MEC manager.

## **15.8 Use of the Class II Type A Biological Safety Cabinet**

The Labgard Model NU-425 Class II, Type A2, Laminar Flow Biological Safety Cabinet (LFBSC), with proper technique, provides an effective partial containment system for safe manipulation of moderate- and high-risk microorganisms (see Exhibit 15-6). 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 High Efficiency Particulate Air (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 magnehelic 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.

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 automated Unusual Field Occurrence utility.

## Exhibit 15-6. Operating the laminar flow biological safety cabinet

### **Operating the NU-425, Laminar Flow Biological Safety Cabinet\***

#### **1.1 Operator Controls & Indicators**

The following is a description of the controls and indicators found on both the front panel (see Drawing BCD-05322) and cabinet.

##### **1.1.1 Circuit Breaker-Blower (Top of Control Center)**

The motor/blower is protected with a circuit breaker. The circuit breaker in conjunction with the motor's thermal protector is designed to open under locked rotor or half-wave power conditions. Should the circuit breaker open (pop-out button will appear) merely depress to reset. If the circuit breaker continually opens, a failure has occurred in the motor or solid-state speed controller. Consult a qualified repair technician or NuAire, Inc. for replacement.

##### **1.1.2 Circuit Breaker-Outlets (Top of Control Center)**

The duplex outlet located in the sidewall of the work area is protected with a 3 amp circuit breaker. The circuit breaker may trip at 110 percent of load rating but will trip at 145 percent of load rating in less than 2 seconds. Should the circuit breaker open, (pop-out button will appear), unplug the appliance plugged into the outlet and merely depress the pop-out button to reset.

##### **1.1.3 Fluorescent/U.V. Light Switch**

This switch provides on/off control for the fluorescent light and/or the ultraviolet (U.V.) light if present (optional). With the U.V. light option, the switch provides for on-center off-on operation so that both the fluorescent light and the U.V. light cannot be energized at the same time. The UV light is also interlocked, so it will only operate if the sliding window is closed. Proper care should be exercised when the U.V. light is on.

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\* Adapted from *Operation and Maintenance Manual* by NuAire, Inc., 2005.

#### **1.1.4 Outlet Switch**

This switch provides on/off control for the 115 VAC power available in the outlet(s) within the cabinet workzone.

#### **1.1.5 Blower Switch**

The blower switch applies power to the internal motor/blower when in the ON position. The blower switch also has a second set of poles, which are available for use as a contact closure for an exhaust system. In addition, power can be applied to the accessory outlet located on the upper left corner of the cabinet, behind the front window assembly.

The purpose of the outlet is to provide "switched" power for the following (see also 8.1.11):

- Exhaust transition with integral blower
- To power a low power appliance, such as the low airflow alarm.

The rating of the outlet is 115 VAC at 2 amp maximum.

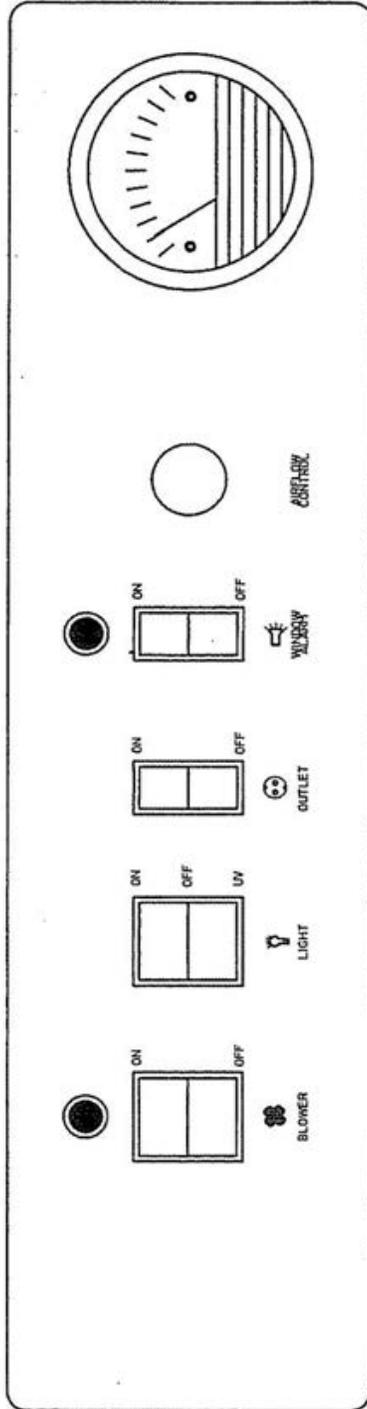
#### **1.1.6 Indicator Light**

An indicator light is located above the Blower on/off switch and indicates when power is applied to the blower.

#### **1.1.7 Audible Alarm Enable**

As the sliding window is raised above its normal working height, a micro switch located in the glide channel activates both an audible and visual alarm. This switch disables the audible alarm but will not disable the red indicator visual alarm.

REV	ECO	DESCRIPTION	DATE	BY
B		UPDATE DRAWING	10/5/01	JR DSH



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DATE	2/7/95	TITLE	FRONT PANEL
BY	TJ		NU-425
CHKD	JR	MATERIAL	
UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES		NUMBER	BCD-05322
		DO NOT SCALE DRAWING	SHEET 1 OF 1

### **1.1.8 Airflow Control**

The operating airflows within the cabinet (i.e. 70 LFPM (.35 m/s) downflow and 105 LFPM (.53 m/s) air inflow barrier) are controlled by a potentiometer and an exhaust damper. The potentiometer controls the operating voltage applied to the motor/blower. The potentiometer is adjustable over 270 degrees with a slotted screwdriver, which varies the applied voltage from 70 to 115 VAC. THIS ADJUSTMENT SHOULD ONLY BE MADE BY A QUALIFIED TECHNICIAN EMPLOYING THE PROPER INSTRUMENTS IN ORDER TO INSURE AIRFLOWS PER NSF STD. NO. 49.

### **1.1.9 Minihelic Gauge**

The unit is equipped with a minihelic gauge. The minihelic gauge displays the static pressure within the pressure plenum supplying the downflow and exhaust filters. The gauge is calibrated in “inches of water gauge” pressure. As the HEPA filters load with particulate matter, the amount of static pressure will increase, giving an indication of the “health” of the cabinet. The initial pressure reading will be approximately 0.5” w.g. + 0.1” w.g. depending on altitude from sea level. At each 0.1” w.g. increment increase, the cabinet airflow should be checked by a qualified technician, unless certified on a yearly (or sooner) basis.

### **1.1.10 Sliding Window Operation**

The cabinet has a full counter balanced and removable sliding tempered glass window with two operational features. As the window is raised above its specified operating height, an audible alarm alerts the operator of possible compromised personnel protection. At the same time, an audible and visual alarm is activated. The audible alarm may be switched off while the visual alarm remains until lowered to the safe operating position. When the window is lowered below 2 inches (50mm), the motor/blower automatically shuts down, to prevent stress on the motor/blower in the form of overheating. The maximum window height is 19 1/2 inches (495mm).

### **1.1.11 Convenience/Accessory Outlet**

A convenience/accessory outlet is located in the upper left hand corner in back of the window assembly. The outlet is normally wired “hot” through the motor/blower circuit breaker. If an accessory is purchased, the outlet is defined as an accessory outlet supplying 115 VAC at 2.0 Amp maximum, and is wired to the blower switch (see electrical schematic).

## **1.2 Operating Guidelines**

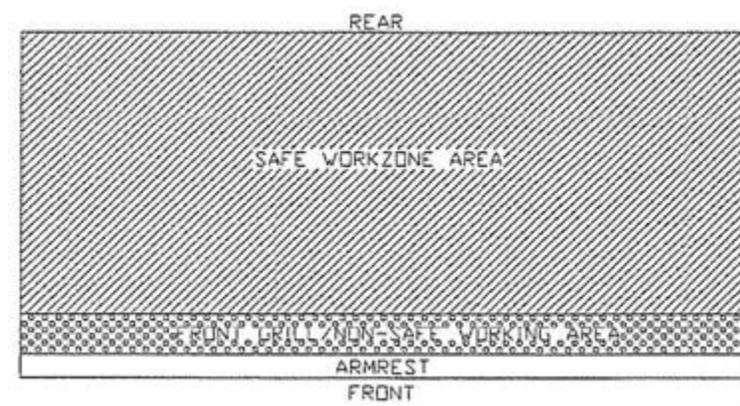
The intent herein is to present general operational guidelines that will aid in the use of the Laminar Flow Biological Safety Cabinet (LFBSC) to control airborne contaminants of low to moderate risk as stated in Technical Report No. FPS 56500000001 prepared by Dow Chemical U.S.A. for the National Cancer Institute, May 1, 1972.

Procedure protocols defined in terms of the barrier or control concepts unique to LFBSC must be developed in order to obtain a maximum potential for safety and protection. The pre-planning necessary to develop these protocols is based on several fundamental considerations, each of which will contribute to optimum benefits from the equipment:

- Know your “safe working area”
- Minimize disruption of “air curtain”
- Minimize room activity
- Utilize unidirectional airflow
- Employ aseptic techniques

### **1.2.1 Know Your “Safe Working Area”**

The LFBSC safe working area is basically the worktray or depressed area. All work should be performed on or above the worktray. The area on or above the front grill is a non-safe working area.



### 1.2.2 Minimize Penetration of “Air Curtain”

The minimum number of items necessary should be placed into the cabinet to prevent overloading, but the work should also be planned to minimize the number of times an operator’s hands and arms must enter and leave the air curtain at the open face. The ideal situation is to have everything needed for the complete procedure placed in the hood before starting, so that nothing need pass in or out through the air barrier at the face until the procedure is completed. This is especially important in working with moderate risk agents.

Unnecessary raising of the hands inside the cabinet above the level of the work opening should be avoided. This presents an inclined plane from hands to elbows along which the downflow of air may run to, and possibly out, the open face.

**NOTE:** When working with agents of lower risk, it is not as important for all materials to be placed in the cabinet before starting, or for the procedure to be completely finished before materials are removed. Also, the time period for a unit may be continued over a more extended period during which entries and withdrawals from the cabinet may be made.

### 1.2.3 Minimize Room Activity

Activity in the room itself should be held to a minimum. Unnecessary activity may create disruptive air currents as well as interfere with the work of the operator. A person walking past the front

of a cabinet can cause draft velocities up to 175 fpm (.89 m/s), which are sufficient to disrupt the air balance of the laminar flow unit.

#### **1.2.4 Utilize Unidirectional Air Flow**

The operator must keep two important facts in mind: ( 1) The air, as supplied to the work area through filters from the top, is contaminant free and (2) Airborne contamination generated in the work area is controlled by the unidirectional flow of parallel air streams in a top-to-bottom direction.

A solid object placed in a laminar air stream will disrupt the parallel flow and consequently, the capability of controlling lateral movement of airborne particulates. A cone of turbulence extends below the object and laminarity of the air stream is not regained until a point is reached downstream, approximately equal to three to six times the diameter of the object. Within the parameters of this cone, particles may be carried laterally by multidirectional eddy currents.

Transfer of viable materials and manipulations which may generate aerosols should not be performed above sterile or uninoculated materials. Items should be localized on the work surface in “clean” and “dirty” groups.

#### **1.2.5 Employ Aseptic Technique**

The operator must not assume an attitude of “let the cabinet do it” when performing procedures within a LFBSC. Properly balanced and properly used cabinets will do an excellent job of controlling airborne contamination and containing viable agents, but the cabinet will not eliminate contact transmission of contamination. Normal laboratory contamination control procedures and basic aseptic techniques are necessary to obtain maximum benefit from the cabinet. For example, open bottle, tube or flask mounts should be kept as parallel as possible to the downflow to minimize capture of chance particulates. This precaution is merely an extension of good aseptic technique as practiced on open bench tops. The good laboratory practices designed to minimize creation and/or release of aerosols to the environment should not be discontinued.

Items of equipment in direct contact with the etiologic agent must remain in the cabinet until enclosed or until surface-decontaminated. Trays of discard pipettes must be covered before removal from the cabinet (aluminum foil may substitute for fabricated covers).

If an accident occurs which spills or splatters suspensions of etiologic agent around the work area, all surfaces and items in the cabinet must be surface-decontaminated before being removed.

### **1.3 Operating Sequence**

#### **1.3.1 Start Up**

Turn on cabinet blower and lights, check air intake and exhaust portals of the cabinet to make sure they are unobstructed.

Good procedure includes the decontamination or wipedown of cabinet surfaces with chemical disinfectant before work commences. This practice eliminates the need for UV lights, whose primary utility in this application is inactivation of surface contamination since the filters effectively remove all airborne contaminants. UV lights, therefore, are not recommended in the LFBSC.

Allow blowers to operate for a minimum of 15 minutes before aseptic manipulations are begun in the cabinet, If the filtered air exhausted from the unit is discharged into the room, as in some installations, an additional advantage is obtained from purification (filtration) of the room air circulated through the equipment. Because of this characteristic contributing to the quality of the laboratory environment, some owners of LFBSC leave them in operation beyond the time of actual use.

#### **1.3.2 Wipedown**

The interior surfaces of the workspace should next be disinfected (see cleaning procedures) by wiping them thoroughly with 70% alcohol or similar non-corrosive anti microbial agents. USE OF CHLORINATED OR HALOGEN MATERIALS IN THE CABINET MAY DAMAGE STAINLESS STEEL.

### **1.3.3 Materials & Equipment**

The apparatus and materials should next be placed into the cabinet. Care must be exercised that no items be placed over the front intake grills. Materials should be arranged so that clean, dirty (used), and virus materials are well separated. Passage of contaminated materials over uninoculated cultures or clean glassware should be avoided and transfer of viable materials should be performed as deeply into the cabinet (away from open face) as possible.

### **1.3.4 Air Purge**

Additional purging of the workspace without user activity should be allowed for 2-3 minutes after materials and apparatus have been placed in it. This will rid the area of all “loose” contamination that may have been introduced with the items.

### **1.3.5 Perform Work**

The work can now be performed. The technician performing the work is encouraged to wear a long-sleeved gown with knit cuffs and rubber gloves. This will minimize the shedding of skin flora into the work area and concurrently protect the hands and arms from viable agent contamination. At a minimum, the hands and arms should be washed well with germicidal soap before and after work in the cabinet. For the preparation of antineoplastic drugs, the following procedures summarize those contained in OSHA Instruction PUB 8-1.1, “Work Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs.” The above document should be thoroughly studied/reviewed prior to drug preparation in the cabinet.

- A sterile plastic-backed absorbent drape should be placed on the work surface during mixing procedures. The drape should be exchanged whenever significant spillage occurs, or at the end of each production sequence.
- Vials should be vented with a filter needle to eliminate internal pressure or vacuum.
- Before opening ampoules, care should be taken to insure that no liquid remains in the tip of the ampoule. A sterile gauze sponge should be wrapped around the neck of the ampoule while opening.

- Final drug measurement should be performed prior to removing the needle from the stopper of the vial.
- A non-splash collection vessel should be available in the biological safety cabinet to discard excess drug solutions.

### **1.3.6 Terminal Purging & Wipedown**

Following completion of work, allow the cabinet to run for 2-3 minute period without personnel activity to purge the unit. The decontamination of the interior surfaces should be repeated after removal of all materials, cultures, apparatus, etc. A careful check of grills and diffuser grids should be made for spilled or splashed nutrients which may support fungus growth and resulting spore liberation that contaminates the protected work environment.

### **1.3.7 Paper Catch/Prefilter**

A permanent paper catch is installed behind the rear divider panel of the work zone. This area forms the return air path to the motor/blower; and if the airflow is blocked, it could seriously affect the performance of the cabinet. Therefore, THE PAPER CATCH SHOULD BE CHECKED AND CLEANED NO LESS THAN A WEEKLY BASIS; DAILY basis if procedures dictate the use of paper products. Any paper removed must be properly disposed of as Contaminated Hazardous Waste. The above procedures also apply to all units configured with a prefilter.

### **1.3.8 Shut Down**

Turn off blowers and lights. Do not use cabinet as a depository for excess lab equipment during periods of non-operation.

## **1.4 Ergonomics**

Ergonomics, the study or accommodation of work practices is extremely important for proper cabinet usage and user health and safety. An evaluation of normal work practices should be performed with each user when working in a cabinet. Evaluation criteria should be at a minimum:

- Proper user posture
- Effective workzone layout for work practice
- Vision or sightlines

For each of the above evaluation criterion, several aids may be supplied to accommodate the user.

- Ergonomic chair - Be sure feet are resting on the floor, chair foot support or foot rest. Also be sure back is fully supported with proper chair adjustments.
- Forearm/armrest support - The cabinet is provided with a forearm support on the work access opening. Periodic mini-breaks during work practice should be taken resting forearm to avoid stress and fatigue.
- Effective workzone layout - Always prepare your work procedure to minimize reach to avoid neck and shoulder stress and fatigue. Rotating tables are optional to maximum workzone and minimize reach.
- Vision and sightline - Always prepare your work procedure to eliminate glare and bright reflections on the window. Keep your window clean and sightlines clear to your effect workzone.

## **1.5 Cleaning Procedures**

Cleaning the cabinet is an important function in terms of both containment and sterility. Use the following procedure to effectively clean or surface disinfect the cabinet workzone surfaces.

- Raise the sliding window to a full-open position, if desired.
- Press the audible alarm silence or cleaning key on the front control panel to silence the audible alarm during the cleaning process.
- Apply appropriate disinfecting solution to cabinet surfaces. Most surface disinfectants require a specific contact time, depending upon the microbiological agents used

within the cabinet. **Consult appropriate disinfectant documentation for proper application and safety precautions.**

- **NOTE:** Disinfectants that use chlorides and halogens will cause damage to the stainless steel surfaces if left on for long periods of time.
- After the specified contact time, wipe up excess disinfectant.

## **15.9 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 automated Unusual Field Occurrence utility and inform the MEC manager immediately.

## **15.10 Precision Instruments Osmette II**

The Osmette II is a scientific instrument used to measure osmolality. Care must be used in packing and unpacking the instrument. When the instrument is unpacked, keep the foam cushions in the instrument box until the stand closes. Repack the instrument for transportation in the original box using the thick foam pads to cushion the instrument on all sides.

### **Changing the Osmette II Pipette Teflon Tip**

Change the Teflon tip if any of the below are encountered:

- The beginning of each stand.
- The resistance of the tip when depressing the pipette appears to be too loose.
- The air bubble separation above the sample is gone after a reading.
- The readings are erratic.

Replace the Teflon pipette tip. Remove the pipette tip from the disposable pipette tip or the protective cover. The Teflon tip is the tiny white plastic on the end of the pipette wire. The tip can be removed several ways. Any method is acceptable as long as care is taken to not bend the pipette wire or

damage the pipette in any other way. A razor blade can be used to carefully cut along the side of the tip to cause it to release from the end of the wire. The tip will also come off by using a fingernail and some patience to work a space between the tip and wire and then push the tip off.

Locate the small clear red box labeled “Osmette Teflon Tips and Calibrator.” Use one of the new Teflon tips inside the box as the replacement. The Teflon tip has one end that is solid and one end with a hole. The end with the hole should be placed on the end of the pipette wire. Ensure that the wire is fully inserted into the new tip. There should be no gap between the white tip and the pipette wire.

### **Verifying the Pipette Calibration**

The pipette requires two small instruments to verify that it is calibrated correctly and will draw the proper amount of solution into the disposable pipette tip. One calibrator resides in the clear red box with the replacement Teflon tips. This calibrator is made of a hard black plastic and is about an inch long. It has a nib on one end. This calibrator measures the size of the bubble that is held between the Teflon tip and the sample when in the disposable pipette tip. To ensure the bubble is the proper size, place a clean disposable pipette tip on the pipette. Depress the plunger. Insert the nib into the end of the disposable pipette tip. The end of the nib should just touch the end of the Teflon tip; the tip should not push the tool out, and oppositely there should be no space gap between the tool and the Teflon tip.

If the bubble is not properly calibrated, remove the disposable pipette tip and unscrew the lock nut at the base of the pipette wire. Hold the plunger firmly with one hand while unscrewing the lock nut with the other. Use a pair of pliers if necessary. Unscrew the lock nut until it is loose. The pipette wire will also feel loose. Be careful not to turn the pipette wire accidentally when unscrewing the lock nut. Controlled, small turns will adjust the pipette wire to change the calibration setting. Turn the pipette wire in a clockwise direction (if looking at the end of the pipette tip head on) to pull the pipette tip up into the pipette and therefore make the bubble size larger. Turn the wire clockwise to adjust the pipette so the calibration tool will insert further up into the end of the clean pipette tip. Turning the wire counterclockwise adjusts the pipette so that the calibration tool will close the gap between the calibration tool and the Teflon tip. The tool and the tip should just touch when properly calibrated. When the desired adjustment has been made, tighten the lock nut down with your fingers.

Place a clean disposable pipette tip on the pipette. Use the black calibration tool again to check the bubble size. Readjust if needed by following the above procedure. Once the calibration is successful, tighten the lock nut so that it will not come loose during regular use. Be careful not to damage the pipette.

The second instrument required to calibrate the pipette resides on the pipette itself. The end of the plunger opposite the tip has a tool that reads “Calib Gage & Key.” This tool can be unscrewed from the end. The length of the tool measures the correct draw amount for the pipette. To measure the draw amount place a clean disposable pipette tip on the pipette. Without depressing the plunger, insert the calibration gauge into the end of the disposable pipette tip. The end of the calibration gauge should just touch the end of the Teflon tip.

If the draw amount is not properly calibrated, twist the pipette plunger around until the nut on the inside of the plunger aligns with the hole in the side of the pipette body. Use the tiny hex wrench on the end of the calibration gauge to carefully turn—usually not more than a quarter turn—the nut inside the hole. Redepress the piston and use the calibration gauge to see if the draw amount is now correct. Readjust if needed by following the above procedure. Be sure to replace the calibration gauge in the end of the pipette when calibration is complete.

### **Cleaning, Opening, and Oiling the Osmette II Probe**

The Osmette II may need to have the probe cleaned for several reasons:

- The instrument displays a large amount of “NO FREEZE” errors.
- The instrument displays a large amount of “PRE-FREEZE” errors.
- The readings are erratic.

Clean the Osmette II probe. Wet the end of a Cleanette with an alcohol prep pad. Use as many pads as needed to ensure the end of the Cleanette is wet. Insert the wet end of the Cleanette into the probe well and wipe by rotating the Cleanette left and right. Remove the Cleanette. Wet the end of a Cleanette with distilled water. Insert the wet end of the Cleanette into the probe well and wipe by rotating the Cleanette left and right. Remove the Cleanette. Insert a dry Cleanette into the probe well and wipe by

rotating the Cleanette left and right. Remove the Cleanette. This process should clean any residual proteins left in the well.

Over time some sample may leak out into the probe chamber because of leakage due to loss of surface tension (as in the case of proteins in the sample or improperly drawn samples). The only way to clean this residue is to open the probe chamber and wipe off the entire probe, base, and chamber. Open the Osmette II for cleaning the probe chamber. Ensure that the Power button on the back of the Osmette is switched to “Off.” Unplug the instrument from both the electrical outlet and the computer. Very gently turn the instrument over and lay it on its top so that the underside is tilted toward you. The bottom of the instrument is exposed. There is a black plastic piece on the underside of the instrument known as the “coffin” for its shape. The coffin acts as a cover for the probe. Open the coffin by using a Phillips head screwdriver to loosen the single screw on the left, broad end of the coffin. Carefully remove the loose screw and place it somewhere secure so it will not get lost. The loose end of the coffin can now swing up to reveal an opening underneath.

Inside the opening is a large black piece with a white circle in the middle. The white circle is made out of a rubbery, softer material. In the white circle is a white, hard, plastic donut with a white wire coming out. Using gloved hands, use your fingertips to gently unscrew the white donut by turning it to the left. Once the donut is loose, gently pull it straight out of the probe chamber, being careful not to touch the probe tip to the sides of the chamber. The probe is on the end of the white plastic donut. It is made of a fine metal wire, much like a pin. At its base is a flat surface with a black circle surrounded by a metal circle.

To clean the Osmette II, use only a Cleanette to wipe around the base of the probe (black circle and metal circle) to remove any residual sample not picked up by normal cleaning. Look down into the probe chamber on the instrument. On each side of the chamber are threads to fasten the donut back in place. Use a cleanette to wipe around the threads and the ring at the bottom of the chamber to absorb any residual sample.

On a rare occasion the probe base may need to be oiled. Only oil the probe if recommended by the Precision Systems technician. To oil the probe, use a tiny dab of Dow 311 industrial lubricant on the end of a Cleanette. Wipe the lubricant around the base of the probe (black and metal circles). The lubricant should be spread very thinly. The purpose of the lubricant is to ensure that no sample seeps down into the break between the black circle and the metal circle at the base of the probe. The lubricant

also helps to create surface tension to hold the sample in the pipette tip. Use a clean Cleanette to wipe off any globs of lubricant on the base of the probe.

Once cleaning and/or oiling is complete, put the Osmette II back together. Carefully direct the probe back down into the probe chamber. Use your fingers to gently tighten the white plastic donut into the white circle. The donut should only be finger tight; do not overtighten. Swing the coffin back down into place so that the hole in the coffin for the screw lines up with the hole in the osmette, and the probe opening is completely covered. Use the screw and Phillips head screwdriver to fasten in place. Do not over fasten.

### **15.11 Mettler Toledo Scale**

The Mettler Toledo scale is a very sensitive precision weighing instrument with a weighing limit of 600 grams. Handle the scale with care at all times. Do not weigh anything on the scale other than urine cups and specimens. The weigh pan will get dirty during use. Clean the weigh pan as needed by removing the metal plate from the scale and cleaning with Windex. Replace the weigh pan when clean.

Always use the clear acrylic scale cover to protect the scale from damage while not in use. Use the scale cover to protect from drafts when weighing samples.

#### **Scale Set Up**

Open the blue carrying case. Remove scale from case and place on the counter next to the barcode scanner. Verify that the scale is free of dust and debris. If needed, use the brush in Care Pac M to brush away dust and debris.

Locate the tan serial cable taped to counter. The serial cable has a broad end with a trapezoid input with a screw on either side. It looks like this:



Insert the male end of the cable into the back of the scale. Use the screws to firmly fasten the cable to the back of the scale.

Locate the black AC adapter power cord taped to the counter. Place the round end in the round hole labeled “Power” on the back side of the scale. The LCD display on the front of the scale should say “OFF.” Remove the small, round, plastic cone protector from the top of the scale. Be sure to place the cone protector back into the blue carrying case so that it does not get lost.

Remove the weigh pan from the case lid. Gently place the pan on top of the scale, being sure to align the notch on the bottom of the pan with the bump on the right side of the cone. The pan should fit snugly and not wobble around when properly seated.

**Never move or turn over the scale without first placing the cone protector on the scale’s cone.**

Balance the scale using the liquid level in the back right corner of the scale. Adjust the feet of the scale by screwing them in or out until the bubble in the liquid level stays within the center circle.

## **Scale Teardown**

Place the carrying case on the counter near the scale. Turn off the scale by pressing and holding the On/off button. Hold until “OFF” appears on the LCD display. Gently remove weigh pan from scale. Slide weigh pan back into slot in lid of carrying case. Remove the protective cone cover from the carrying case and place over the cone.

Turn the scale around on the counter so the back of the scale is visible. Unplug the AC adapter power cord from the back of the scale. Tape the end of the power cord to the counter so it is easily found at the next setup.

Unplug the serial cable from the back of the scale by unscrewing the two screws and gently pulling the end of the serial cable away from the back of the scale. Tape the cord to the counter so it is easily found at the next setup.

Place the scale in the protective carrying case. Close the lid and snap black locks tightly closed so that the lid and bottom of the case do not come apart. Place the carrying case back into the box for transport to the next stand.

Place the Care Pac M back into the box for transport. Make sure one Styrofoam bumper is on the bottom of the box and set the Care Pac M down into the bumper. Fit the second bumper on top of the Care Pac M and close the box. If Care Pac M has been packed properly, the box should close easily and completely.

## 15.12 Laboratory Quality Control Module

Document the following items in the Laboratory QC module based on the frequency described in the following table.

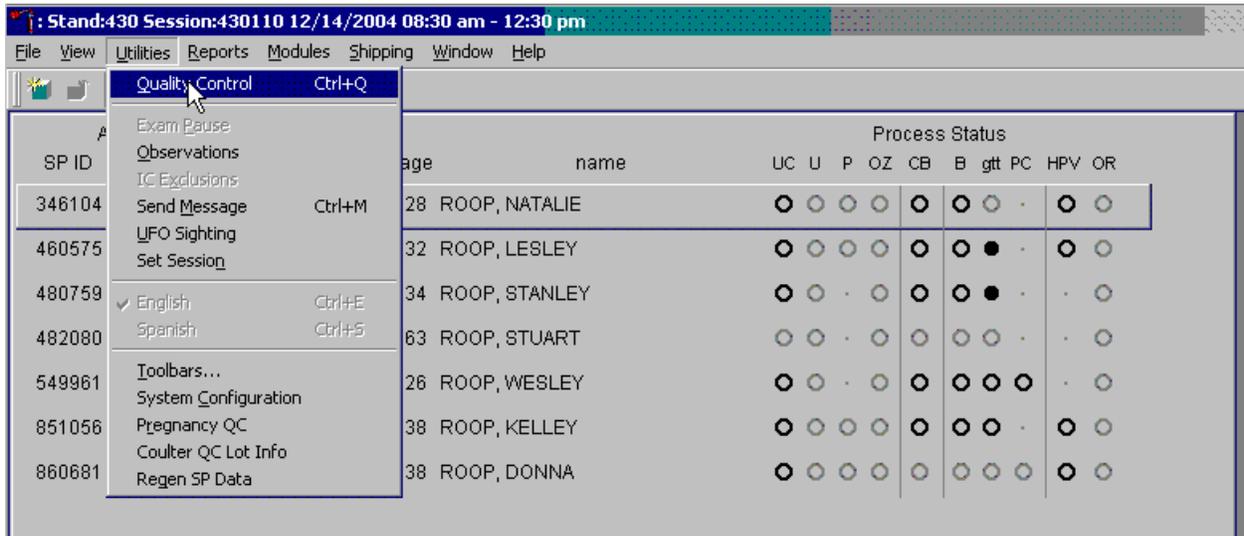
Frequency	Item	Acceptable result
<b>Start of Stand</b>		
	Freezer #3 cleaned	Yes
	Freezer #4 cleaned	Yes
	Freezer #5 cleaned	Yes
	Freezer #6 cleaned	Yes
	Refrigerator #1 cleaned	Yes
	Refrigerator #2 cleaned	Yes
	Centrifuge #1 cleaned	Yes
	Centrifuge #2 cleaned	Yes
	ULBSC cleaned	Yes
	Magnahelic gauge reading	0.350-0.550
	Hood certification expiration date	After current date
	Class 6 one hundred gram weight +/- 1.0 g	99 - 101
	Two Class 6 three hundred gram weight +/- 6.0 g	594 - 606
	Change Osmometer Teflon Pipette Tip	Yes
	Osmette Total Calibration Distilled Water 1	≤1
	Osmette Total Calibration Distilled Water 2	≤1
	Osmette Total Calibration 100 Standard 1	99-101
	Osmette Total Calibration 100 Standard 2	99-101
	Osmette Total Calibration 500 Standard 1	498-502
	Osmette Total Calibration 500 Standard 2	498-502
	Osmette Total Calibration 500 Standard 3	498-502
	Osmette Total Calibration 1500 Standard 1	1496-1504
	Osmette Total Calibration 1500 Standard 2	1496-1504
	Osmette Total Calibration 1500 Standard 3	1496-1504
	Osmette Total Calibration 2000 Standard 1	1994-2006

Frequency	Item	Acceptable result
	Osmette Total Calibration 2000 Standard 2	1994-2006
	Osmette Total Calibration 2000 Standard 3	1994-2006
<b>Daily</b>		
	Freezer #3 temperature reading	-28.0 to -33.0°C
	Freezer #4 temperature reading	-28.0 to -33.0°C
	Freezer #5 temperature reading	-28.0 to -33.0°C
	Freezer #6 temperature reading	-28.0 to -33.0°C
	Centrifuge #1 refrigerated reading	4 to 8°C
	Centrifuge #2 room temperature reading	17 to 25°C
	Magnahelic gauge readings	0.350-0.550
	Refrigerator #1 temperature reading	-18 to -23°C or -28 to -33°C
	Refrigerator #2 temperature reading	-18 to -23°C or -28 to -33°C
	Workstation 1 room temperature reading	17 to 25°C
	Workstation 2 room temperature reading	17 to 25°C
	Class F2 twenty gram weight +/- 0.2 g	19.8-20.2
	Class F2 five hundred gram weight +/- 5.0 g	495-505
	Verify Osmometer Pipette Calibration	Yes
	Osmette Daily QC Check 100 Standard 1	96-104
	Osmette Daily QC Check 100 Standard 2	96-104
	Osmette Daily QC Check 1500 Standard 1 (result 1485 - 1515)	1485-1515
	Osmette Daily QC Check 1500 Standard 2	1485-1515
	Osmette Quantimetrix Level 1 Control	Yes
	Osmette Quantimetrix Level 2 Control	Yes
<b>Weekly</b>		
	HMX Latron and 5C Cell Control QC data transmitted?	Yes
	Osmette Standards Check 100 Standard 1	96-104
	Osmette Standards Check 100 Standard 2	96-104
	Osmette Standards Check 100 CON-TROL 1 (result)	98-102
	Osmette Standards Check 100 CON-TROL 2	98-102
	Osmette Standards Check 500 Standard 1	496-504

Frequency	Item	Acceptable result
	Osmette Standards Check 500 Standard 2	496-504
	Osmette Standards Check 500 CON-TROL 1	496-504
	Osmette Standards Check 500 CON-TROL 2	496-504
	Flush eyewash for 5 minutes	Yes
<b>End of Stand</b>		
	Freezer #3 cleaned	Yes
	Freezer #4 cleaned	Yes
	Freezer #5 cleaned	Yes
	Freezer #6 cleaned	Yes
	Refrigerator #1 cleaned	Yes
	Refrigerator #2 cleaned	Yes
	Centrifuge #1 cleaned?	Yes
	Centrifuge #2 cleaned?	Yes
	LFBSC cleaned?	Yes
	Coulter printouts sent to home office	Yes
	HMX Latron and 5C Cell Control QC data transmitted?	Yes

Document all instrument quality control activities in the Laboratory QC module.

Access the Laboratory 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.

The screenshot shows the 'Lab Sink' application window. At the top, there are tabs for 'Start of Stand', 'Daily', 'Weekly', 'End of Stand', 'Supply Use', and 'NCHS QC'. Below the tabs is a table with columns 'QC Check', 'Done', 'Result', and 'Comment'. The table contains four rows for 'Freezer #1 cleaned?' through 'Freezer #4 cleaned?'. The 'Done' column has checkboxes, and the 'Result' column has text input fields. A dialog box titled 'Lab Sink' is overlaid on the table, asking the user to 'Please enter in your user id' with an input field and 'OK'/'Cancel' buttons. A mouse cursor is pointing at the 'OK' button in the dialog box.

QC Check	Done	Result	Comment
Freezer #1 cleaned?	<input checked="" type="checkbox"/>	yes	
Freezer #2 cleaned?	<input type="checkbox"/>		
Freezer #3 cleaned?	<input type="checkbox"/>		
Freezer #4 cleaned?	<input checked="" type="checkbox"/>		

Enter user ID as last name\_first initial. Type in the user ID and use the mouse to direct the mouse arrow to the “OK” button, and left click or select [Enter]. 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.

The screenshot shows a software window titled "Lab Sink" with a menu bar containing "Start of Stand", "Daily", "Weekly", "End of Stand", "Supply Use", and "NCHS QC". The "Start of Stand" tab is selected. Below the menu bar is a table with the following structure:

QC Check	Done	Result	Comment
Freezer #1 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>
Freezer #2 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>
Freezer #3 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>
Freezer #4 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>

At the bottom right of the window are "OK" and "Cancel" buttons.

Select the correct activity (Start of Stand, Daily, 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 Sink" with a menu bar containing "Start of Stand", "Daily", "Weekly", "End of Stand", "Supply Use", and "NCHS QC". Below the menu bar is a table with three columns: "QC Check", "Done", "Result", and "Comment". The table contains four rows of data, each representing a freezer temperature reading. All "Done" checkboxes are checked, and the "Result" column contains numerical values followed by "degrees C". The "Comment" column is empty for all rows. At the bottom right of the window are "OK" and "Cancel" buttons.

QC Check	Done	Result	Comment
Freezer #1 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input checked="" type="checkbox"/>	-31 degrees C	
Freezer #2 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input checked="" type="checkbox"/>	-29 degrees C	
Freezer #3 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input checked="" type="checkbox"/>	-30 degrees C	
Freezer #4 temperature reading (-18 to -23 °C) or (-28 to -33 °C)	<input checked="" type="checkbox"/>	-21 degrees C	

To record an activity as complete or done, use the mouse to direct the mouse arrow to the checkbox in the Done column, and left click to insert a checkmark. 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 Sink" with a menu bar containing "Start of Stand", "Daily", "Weekly", "End of Stand", "Supply Use", and "NCHS QC". Below the menu bar is a table with the following columns: "QC Check", "Done", "Result", and "Comment".

QC Check	Done	Result	Comment
Workstation 2 room temp reading (17 to 25 °C)	<input checked="" type="checkbox"/>	28 degrees	Air conditioner not working. Notified FES, mec manager and chief med tech.
Flush eyewash for 5 minutes	<input checked="" type="checkbox"/>	Done	
Class F2 twenty gram weight +/- 0.2 g	<input checked="" type="checkbox"/>	20.0 enter weight	
Class F2 five hundred gram weight +/- 5.0 g	<input checked="" type="checkbox"/>	501.0 enter weight	

At the bottom right of the window are "OK" and "Cancel" buttons.

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 the lot numbers and expiration dates in the Supply Use activity. This activity lists every inventory item associated with the component. Record the pregnancy test kit and the serum and urine pregnancy control lot numbers and expiration dates even though these are captured in the Pregnancy QC module.

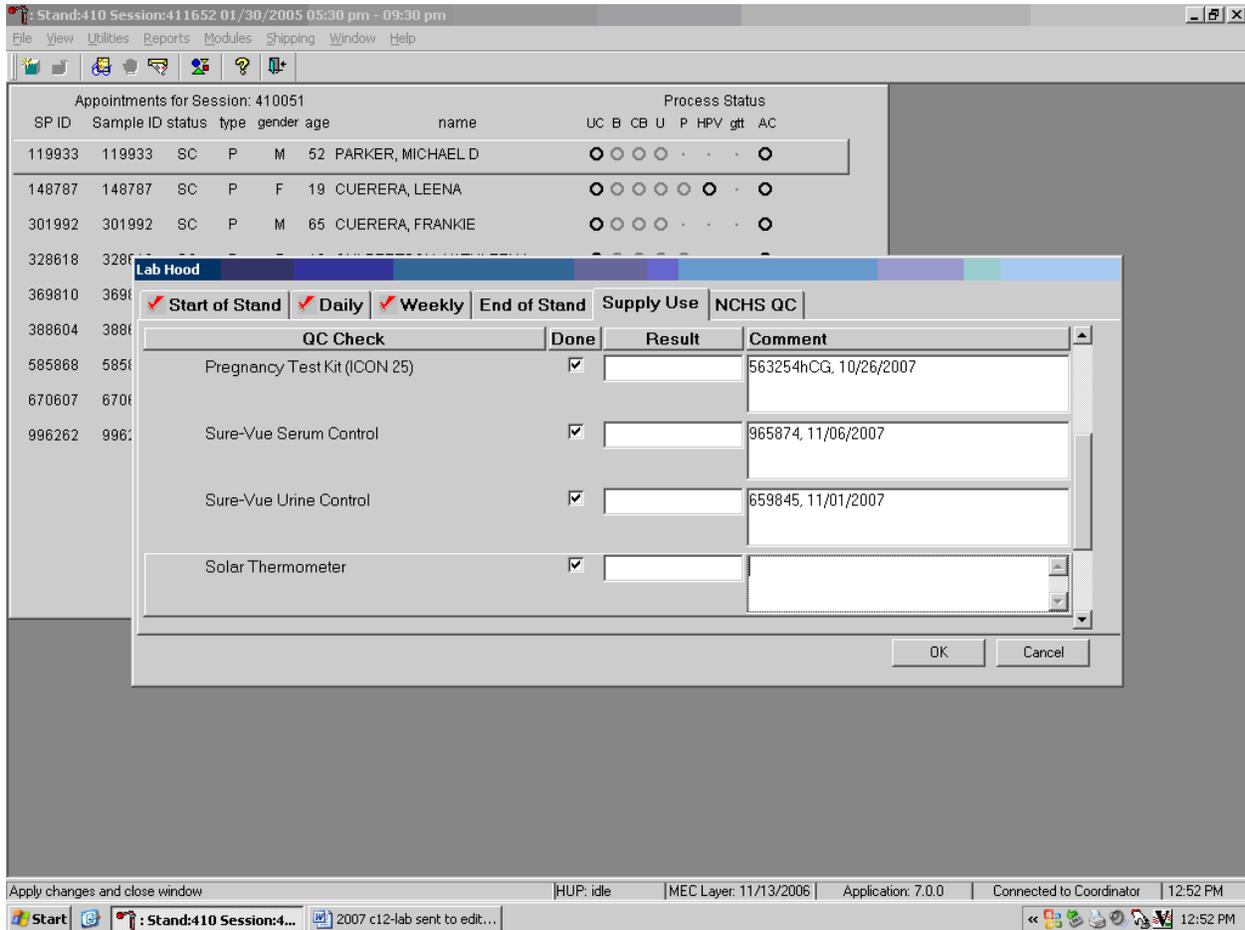
QC Check	Done	Result	Comment
Sure-Vue Urine Control	<input checked="" type="checkbox"/>		865874, 12/30/2008
Sure-Vue Serum Control	<input checked="" type="checkbox"/>		965874, 12/30/2008
Pregnancy Test Kit (ICON 25)	<input checked="" type="checkbox"/>		5948hCG, 01/15/2009
Sterile saline	<input type="checkbox"/>		

Mark each checkbox 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 checkbox in the Done column, and left click to insert a checkmark. 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 record the stand week (Week 1, Week 2, etc), add a comma, and record the date the reagent was reconstituted using the MM/DD/YYYY format.
- For the timers and thermometers, record the calibration date (14/06), 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/YYYY format.

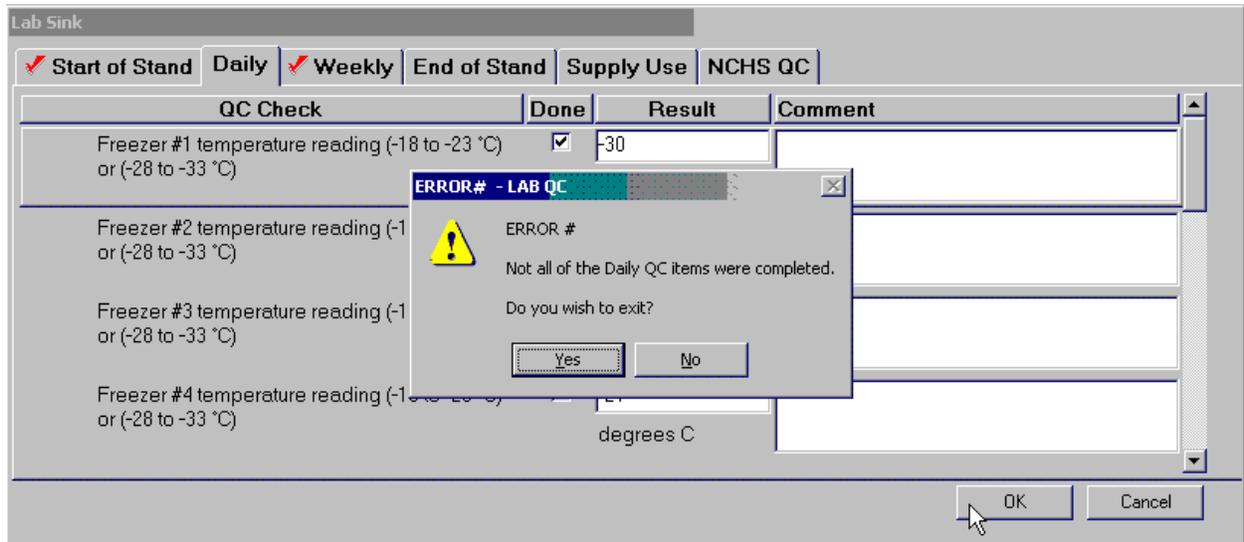
There is no frequency requirement for this activity within the QC application.

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 checkmark on the top of the file header indicates that all QC activities associated with that requirement were successfully recorded and saved to the database.

QC Check	Done	Result	Comment
Freezer #1 cleaned?	<input checked="" type="checkbox"/>	<input type="text"/> (yes/no)	<input type="text"/>
Freezer #2 cleaned?	<input checked="" type="checkbox"/>	<input type="text"/> (yes/no)	<input type="text"/>
Freezer #3 cleaned?	<input checked="" type="checkbox"/>	<input type="text"/> (yes/no)	<input type="text"/>
Freezer #4 cleaned?	<input checked="" type="checkbox"/>	<input type="text"/> (yes/no)	<input type="text"/>

### 15.13 Unusual Field Occurrence (UFO)

Document any unusual occurrence using the Unusual Field Occurrence utility. The hard-copy Unusual Occurrence Log (see Exhibit 15-7) is available as a backup. 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. Refer to the *UFO User Guide* for complete instructions.

Exhibit 15-7. 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.

#### **15.14 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. This hard-copy Supply Use Control Log (Exhibit 15-8) is available as a backup.

Enter information into the appropriate column(s):

- Reagent or Supply Name,
- Beginning Stand Date,
- Lot Number,



- 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.

### **15.15 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.
- Only authorized service personnel may carry out repairs.
- 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 percent 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 the 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  $\mu$ 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  $\mu$ 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.

### **15.16 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.

#### **15.16.1 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.

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.

- **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 Instruction 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 refrigerators and freezers are located in a stacked configuration across from the Coulter. Three freezers are stacked on top of the rack and two refrigerators with the remaining freezer are located on the bottom. Refrigerators and freezers are numbered according to which port they are in on the TempGuard system. Freezers are numbered 3-6 and the refrigerators are numbered 1 and 2. Port 7 is for room temperature monitoring. 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. 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 TempGuard reading reaches 7°C, add 14 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 HMX**

- **Overview** – The Coulter consists of the HMX, the monitor, hard drive, and printer. The HMX 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.

### **15.16.2 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 Temperature Guard system installed. This 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 designated 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 Temperature Guard

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 14 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 the 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 TempGuard reading reaches -10°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. Turn off the affected unit, by flipping the corresponding wall switch to the left of the units.

### **15.16.3 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 14 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 TempGuard 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 14 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.

## Appendix A

International Air Transport Association (IATA)  
Dangerous Goods Regulations  
January 2011

**APPENDIX A**  
**INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) DANGEROUS GOODS**  
**REGULATIONS**

**A.1 General Provisions**

Dangerous goods can be transported safely by air transport provided certain principles are strictly followed. The International Air Transport Association (IATA) publishes dangerous goods regulations. NHANES shipments fall under these regulations because diagnostic specimens (UN 3373) 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 specific 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

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\* Notations in parentheses throughout this appendix represent the appropriate section in the *IATA Dangerous Goods Regulations*.

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 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. There is a provision for a 3-month window that allows for recurrent training conducted within the final 3 months of the 24-month period to be considered to have been completed on the expiry date of the 24-month period (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 curricula must include (1.5.2.2):

- 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.

A record of training must be maintained, which must include the following (1.5.5):

- 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
- Evidence which shows that 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;
- Limitations;

- General requirements for shippers;
- Classifications;
- List of dangerous goods;
- General packing requirements;
- Packing instructions;
- Labeling and marking;
- Shipper's Declaration and other relevant documentation;
- Recognition of Undeclared Dangerous Goods;
- Provisions for passengers and crew; and
- 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 on 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 2.5 kg (5 lbs.) per person when used to pack perishables not subject to these Regulations, provided the checked baggage (package) permits release of carbon dioxide gas (2.3.4.6).

## **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 Division 6.2 – Infectious Substances (3.6.2)**

Division 6.2 defines infectious substances as substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals. (3.6.2.1).

Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900, or UN 3373, as appropriate (3.6.2.2.1). Infectious substances are divided into two categories, Category A and Category B. Category A is an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, or life-threatening or fatal disease in otherwise healthy humans or animals. The proper shipping name for UN 2814 is *Infectious substance, affecting humans*. The proper shipping name for UN 2900 is *Infectious substance, affecting animals*. Category B is an infectious substance which does not meet the criteria for inclusion in Category A (3.6.2.2.2.1). Infectious substances in Category B must be assigned to UN3373. The proper name of UN 3373 is *Biological substance Category B* (3.6.2.2.2.2).

Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is packed in packaging that will prevent any leakage and that is marked with the words “Exempt human specimen” or “Exempt animal specimen” (3.6.2.2.3.6). The packaging must consist of three components: a leakproof primary receptacle(s), a leakproof secondary receptacle, and an outer packaging of adequate strength for its mass and intended use, and with at least

one surface having minimum dimensions of 100 mm x 100mm. For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material. When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them (3.6.2.2.3.6).

### **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 (3.9.1.1). 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**

UN 3373 *Biological substance Category B* specimens must comply with packing instruction 650 (Pg 463).

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. 167). 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. The relevant packing instruction is 904 (Pg 499). A special provision directs that packing tests are not considered necessary (4.4 A48 Pg 317) and when dry ice is used as a refrigerant for other dangerous goods loaded in a unit load device or other type of pallet, the quantity limits per package of 200 kg do not apply. (4.4 A151 Pg 323).

### **A.4 General Packing Provisions**

The shipper is responsible for all aspects of the packing of dangerous goods in compliance with these Regulations (5.0.1.1). 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 (5.0.2.1).

- Packing Group I – Substances presenting high danger
- Packing Group II – Substances presenting medium danger
- Packing Group III – Substances presenting low danger

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) (5.0.2.4.1).

New, remanufactured, reused, or reconditioned packaging must be manufactured and tested under a program of quality assurance to ensure that such packaging meets requirements (5.0.2.5).

Packaging for which retention of liquid is a basic function, must be capable of withstanding, without leakage, an internal pressure that 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 650 - UN 3373 (Pg 461-463)**

Packaging must be of good quality materials, strong enough to withstand the shocks and loading normally encountered during transport, including trans-shipment 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.

The packaging must consist of three components:

1. A primary receptacle(s);
2. A secondary packaging; and
3. A rigid outer packaging.

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 packaging must be secured in outer packaging 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 leakproof and must not contain more than 1 L.
- The secondary packaging must be leakproof.
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.

- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacle (so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging).
- 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 siftproof and must not exceed the outer packaging weight limit.
- The secondary packaging must be siftproof.
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.
- The outer packaging must not contain more than 4 kg. This includes ice, dry ice, or liquid nitrogen when used to keep specimens cold.
- If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent material, must be used.

#### **Package Testing**

- Each completed package must be capable of successfully passing the following drop tests described in 6.5.1.1 except that the height of the drop must not be less than 1.2m. Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging.

#### **For Liquids and Solids**

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
- Packages must have one side with dimensions of not less than 100 mm x 100 mm (4 in. x 4 in.)

- For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of contrasting color and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm (2 in.), the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high.
- The proper shipping name “Biological Substance, Category B” letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark.



Unless all package markings are clearly visible, the following conditions apply when packages are placed in an overpack:

- The overpack must be marked with the work “Overpack;” and
- The package markings must be reproduced on the outside of the overpack.

**Specific Requirements – refrigerated or frozen specimens: ice, dry ice, and liquid nitrogen**

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice (solid carbon dioxide) has been dissipated. If ice is used, the packaging or overpack must be leakproof. If dry ice (solid carbon dioxide) is used, the outside packaging or overpack must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packaging.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

- Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these regulations except for the following:
  - (a) The name, address, and telephone number of the shipper and consignee must be provided on each package;
  - (b) The name, and telephone number of a person responsible must be provided on the air waybill or on the package;
  - (c) The classification must be in accordance to 3.6.2 (see Section A.3.1);
  - (d) The incident reporting requirements in 9.6.1 must be met; and
  - (e) The inspection for damage or leakage requirements in 9.4.1 and 9.4.2.

9.6.1 – 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.

9.4.1 - Packages and overpacks containing dangerous goods must be inspected for signs of damage or leakage upon unloading from the aircraft or unit load device. If evidence of damage or leakage is found, the position where the dangerous goods or unit load was stowed on the aircraft must be inspected for damage or contamination and any hazardous contamination removed. The special responsibilities of operators regarding infectious substances are detailed in 9.4.2. (9.4.1)

9.4.2 – If any person responsible for the carriage of packages containing infectious substances becomes aware of damage to or leakage from such a package, that person must:

- Avoid handling the package or keep handling to a minimum;
- Inspect adjacent packages for contamination and put aside any that may be contaminated;
- Inform the appropriate public health authority, and provide information on any other countries of transit where persons may have been exposed to danger; and
- Notify the shipper and/or consignee.

- If an air waybill is used, the “Nature and Quantity of Goods” box should show the text “BIOLOGICAL SUBSTANCE, CATEGORY B.”
- A Shipper’s Declaration for Dangerous Goods is not required.

- Clear instructions on filing and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package to enable the package to be correctly prepared for transport.

#### **A.4.2 Packing Instruction 904 - Dry Ice (Pg 499)**

This instruction applies to UN 1845 on passenger and cargo aircraft. The General Packaging Requirements of 5.0.2 must be met.

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 following 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:

- UN 1845;
- Proper shipping name (**Dry Ice** or **Carbon Dioxide, solid**);
- 9 (the word "Class" may be included prior to the number "9");
- The number of packages; and
- The net weight of dry ice in each package.

The net weight of the dry ice must be marked on the outside of the package.

## **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 of each packaging type must be tested as provided 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).

Unless all markings representative of all dangerous goods in the overpack are clearly visible, the overpack must be marked with the word “Overpack” (7.1.4).

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) (BIOLOGICAL SUBSTANCE, CATEGORY B is UN 3373 and 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 (7.1.5.1e)
- The name and telephone number of a responsible person (7.1.5.1f); and
- For packages containing UN 3373: - “BIOLOGICAL SUBSTANCE, CATEGORY B.” (7.1.5.1h).

#### Empty Packaging

- Other than Class 7, a packaging which previously contained dangerous goods must be marked as required for those dangerous goods unless steps such as cleaning, purging of vapors, or refilling with a nondangerous substance are taken to nullify any hazard (7.1.5.6).

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. A secondary hazard label or labels must also be applied for each article and substance having subsidiary risk (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).

Before an empty packaging which had previously contained infectious substances is referred to the shipper, or sent elsewhere, it must be thoroughly disinfected or sanitized and any label or marking indicating that it had contained an infectious substance must be removed or obliterated. (7.2.3.12.2)

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**

Except as otherwise specified, a “Shipper’s Declaration for Dangerous Goods form and 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 diagnostic specimens (Pg 463) or dry ice (Pg 499).

If a Shipper’s Declaration is not required for dangerous goods, the Nature and Quantity of Goods” box of the Air Waybill must show in sequence (8.2.3):

- UN or ID number;
- Proper Shipping Name;
- Class or Division number;
- Number of packages; and
- Net quantity per package.

For UN 3373, it is only necessary to show the text “BIOLOGICAL SUBSTANCE; CATEGORY B” and “UN 3373.” For dry ice, it is not necessary to show the packing group and packing instruction number on the air waybill.

## **A.8 References**

1. *IATA Dangerous Goods Regulations*, 50th Edition, effective January 1, 2009, ISBN 978-92-9233-006-4
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. What are the two categories of infectious substances?
  - \_\_\_\_\_
  - \_\_\_\_\_
7. What is the proper shipping name of UN 3373? \_\_\_\_\_
8. To what UN hazard class does dry ice belong? \_\_\_\_\_
9. What is the dry ice UN number? \_\_\_\_\_

10. 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)

11. Define “Exempt human specimen.”

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12. What packing instruction regulates UN3373? \_\_\_\_\_

13. List the three packaging components in packing instruction 650:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

14. Properly prepared shipments containing liquids must meet the following 6 conditions:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

15. An itemized list of contents must be placed between the secondary packaging and the outer packaging. (T or F)

16. The proper shipping name “Biological Substance, Category B” letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark. (T or F)
17. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or overpack. Interior supports must be provided to secure secondary packagings in the original position after all the ice or dry ice has dissipated. (T or F)
18. The weight of dry ice is required on the outside of the packaging. (T or F)
19. The performance tests are designed to ensure that there will be \_\_\_\_\_ under normal transport conditions.
20. All markings must be:
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
21. For Class 9 goods (dry ice), the package is required to bear the \_\_\_\_\_ label. (T or F)
22. 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)
23. An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). (T or F)

**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. What are the two categories of infectious substances?
  - Category A
  - Category B
7. What is the proper shipping name of UN 3373? Biological Substance Category B
8. To what UN hazard class does dry ice belong? Class 9

9. What is the dry ice UN number? UN 1845
10. 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) True
11. Define “Exempt human specimen.”  
Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is packed in packaging that will prevent any leakage and that is marked with the words “Exempt human specimen.”
12. What packing instruction regulates UN3373? Packing instruction 650
13. List the three packaging components in packing instruction 650.
- Primary receptacle
  - A secondary packaging
  - A rigid outer packaging
14. Properly prepared shipments containing liquids must meet the following 6 conditions:
- The primary receptacle must be leakproof.
  - The secondary packaging must be leakproof.
  - Fragile receptacles must be individually wrapped or separated to prevent contact.
  - Absorbent material must be placed between primary receptacle and secondary packaging.
  - Primary receptacle or secondary packaging must be capable of withstanding an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40°C to +55°C.
  - The outer package must not contain more than 4 L.

15. An itemized list of contents must be placed between the secondary packaging and the outer packaging. (T or F) True
16. The proper shipping name “Biological Substance, Category B” letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark. (T or F) True
17. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or overpack. Interior supports must be provided to secure secondary packagings in the original position after all the ice or dry ice has dissipated. (T or F) True
18. The weight of dry ice is required on the outside of the packaging. (T or F) True
19. The performance tests are designed to ensure that there will be no loss of contents under normal transport conditions.
20. 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.
21. For Class 9 goods (dry ice), the package is required to bear the Class 9 “Miscellaneous” dangerous goods label. (T or F) True
22. 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
23. An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). (T or F) True

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.

This 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 (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**

- Phlebotomist
- Medical technologist
- Dental hygienist

#### **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 Category 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 unfixated 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, and biological safety cabinets are examples of engineering controls used in the NHANES.

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.

Engineering 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). 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 leakproof containers until properly reprocessed. These containers are identified as containing potentially infectious materials and are not allowed to overfill.
- Employees are instructed not to 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 it is 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 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.

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 gloves.

Staff members other than those in Categories 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 are worn when performing venipuncture, and laboratory procedures. Personal protective equipment is provided to the staff. Disposable impervious lab jackets are provided to the medical technologists, phlebotomists, and health technologists performing the oral health examination. 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 and are available onsite. Disposable, powder-free hypoallergenic nonlatex powder-free gloves are provided to the medical technologists, phlebotomist, and dental examiners. 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 the health technologists during the oral health examination 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 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 allow to overfill.
- 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 semiliquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semiliquid 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. Leakproof 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, nonintact 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's physician, 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 immunoglobulin), hepatitis B vaccine, and HIV PEP (postexposure prophylaxis) 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 followup 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's Forms 300 and 301 (See Section 5.6 in Chapter 5 of the *Infection Control Procedures Manual*). 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 whether 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 followup. 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, followup 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 (See Exhibit 5-3 in Chapter 5 of the *Infection Control Procedures Manual*.) 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's Forms 300 and 301, 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 followup;
- 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 this 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 followup 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’s Forms 300 and 301 as an injury. The OSHA’s Forms 300 and 301 serve 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’s Forms 300 and 301 are 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: (1) modification of definitions relating to

engineering controls; (2) revision and updating of the Exposure Control Plan; (3) solicitation of employee input; and (4) recordkeeping.

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.

Annual formal evaluations have been conducted since 2000. A notebook detailing each evaluation is kept at the Westat home office and is available for review and inspection.

**ATTACHMENT A**  
**Safety Blood Collection Set**  
**Evaluation Form – Stands 245 and 246**  
**Page 1**

**Your Name** \_\_\_\_\_  
**Today's Date** \_\_\_\_\_  
**Product Name** \_\_\_\_\_  
**Product Needle Size** \_\_\_\_\_

Key Performance Issues	Yes/ True	No/ False	Don't Know/ Not Applicable		
			50%	25%	0%
1. The product is satisfactory for standard phlebotomy purposes					
2. The product is equally satisfactory for different or diverse patient populations (adults, children, heavy, thin, etc.) Comment:					
3. What percentage of typical clinical procedures does this product address?	100%	75%	50%	25%	0%
4. The product is satisfactory for SPs with fragile veins					
5. The product is simple to operate					
6. The use of this product requires no training					
7. The safety feature activated with a one-handed technique					
8. The safety feature worked reliably					
9. Both hands remain behind the needle during engagement of safety feature					
10. The safety feature did not interfere with the blood draw					
11. This product allowed me to see what I needed to see during the blood draw					
12. The safety feature could not be bypassed					
13. The use of this product did not create any extra risk of sprays, blood leakage, and/or drips					
14. The product could be disposed of into the sharps container that is available for my use					

**Feedback**

15. About how many times did you use the blood collection set before you were comfortable using it? (check one)
- 1 time     
  5 times     
  10 times     
  15 times     
  20 times     
  I never felt comfortable
16. Did you have any problems with this device?  Yes       No  
 If yes, please briefly explain below.

**Feedback (continued)**

17. Which device would you rather use: (Please check one)

1. The product we normally use

2. This test one

3. Other, please indicate

\_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**ATTACHMENT B  
Sharps Disposal  
Evaluation Form**

Date: \_\_\_\_\_  
 Position: \_\_\_\_\_  
 Manufacturer: \_\_\_\_\_

Name: \_\_\_\_\_  
 Stand: \_\_\_\_\_  
 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:	Inactivation of 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:	Exposure that occurs from droplet contamination (splashes, spatters) of the eyes, nose, or mouth.
Parenteral exposure:	Exposure that occurs from 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 semiliquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semiliquid 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 sharps 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.

#### **Work Practice 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, processing blood specimens, processing urine, processing vaginal swabs, and performing hematology testing. Disposable, powder-free hypoallergenic 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 leakproof 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 leakproof 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 percent 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

### Laboratory Protocol

Table C-1. Phlebotomy protocol

Venipuncture Protocol (January 2011)

Tube Type	Primary 1-2	Primary 3-5	Primary 6-11	Primary 12-19	Primary 20+	Dry Run Odd 12+	Dry Run Even 12+	VIP Guest 1-2	VIP Guest 3-5	VIP Guest 6-11	VIP Guest 12+	Guests 1-11	Guests 12+
3-mL Lavender	1	1	1					1	1	1	1	1	1
4-mL Lavender				1	1	2	2						
3 – 1 mL TB In-Tubes			1	1	1								
2-mL Gray				1	1	2	2				1		
6 mL Royal Blue			1	1	1	2							
3-mL Red	2	1						1	1				1
7-mL Red		1	1	1						1			
15-mL Red				2	3	2	4						
10-mL Red			1								1		
10-mL Red <sup>0</sup>				5	5								
7-mL EDTA <sup>1</sup>				1	1								
10-mL EDTA <sup>2</sup>					2								
10-mL Gray <sup>3</sup>				1	1								
2-mL Gray <sup>4</sup>				1	1	2	2						
Milliliters	9-mL	13-mL	29-mL	121-mL	149-mL	58-mL	76-mL	6-mL	6-mL	10-mL	15-mL	3-mL	6-mL
Ounces	0.3	0.4	1.0	4.1	5.0	2.0	2.6	0.2	0.2	0.3	0.5	0.1	0.2
Tablespoons	0.6	0.8	2.0	8.2	10.0	4.0	5.2	0.4	0.4	0.7	1.0	0.2	0.4

<sup>0</sup> SPs selected for inclusion in the Persistent Pesticides, BFR subsamples, Perfluorinated and Srm Pesticide subsamples

<sup>1</sup> SPs selected for inclusion in the SRM Pesticide subsample.

<sup>2</sup> Genetics tubes; must meet IC Exclusion criteria

<sup>3</sup> SPs selected for inclusion in the VOC subsample

<sup>4</sup> Glucose tolerance test

Table C-2. Final lab container protocol

Lab	Vessel	Test	Lab	P 1-2	P 3-5	P 6-11	P 12-19	P 20+	Shipping Freq	Vessel	Container	DR Odd	DR Even	VIP 1-2	VIP 3-5	VIP 6-11	VIP 12+	Guest	Changes 2011
			<b>Whole Blood</b>																HLA B27 deleted for 2010
61	1	Lead/Cad/Hg/Sa/Mn	CASPIR	1.5	1.5	1.5	1.5	1.5	Weekly	2 mL cryovial	9x9 two inch box	1.5	1.5	1.5	1.5	1.5	1.5	1.5	Added Se and Mn
64	3	RBC Folate	CASPIR	0.4	0.4	0.4	0.4	0.4	Weekly	2 mL cryovial	10x10 two inch box	0.4	0.4	0.4	0.4	0.4	0.4	0.4	Full sample for MA
57	4	Glycohem	NHANES Diabetes Laboratory				0.4	0.4	Weekly refrigerator	2 mL cryovial	9x9 two inch box	0.4							
61	5	Mercury, Ethyl and Methyl	CASPIR	0.5	0.5	0.5	0.5	0.5	Weekly	2 mL cryovial	9x9 two inch box		0.5	0.5	0.5	0.5	0.5	0.5	Added Methyl and Ethyl Mercury
		Whole blood total		2.5	2.5	2.5	2.5	2.5				2.3	2.5	2.5	2.5	2.5	2.5	2.5	1.5
		EDTA tube size		3	3	3	4	4				4	4	3	3	3	3	3	3
		Number of EDTA		1	1	1	1	1				2	2	1	1	1	1	1	1
115	133	IN-Tube TB Nil Control	TBD			1.0	1.0	1.0	Weekly		7x7 three inch box								New test
115	134	IN-Tube TB Antigen	TBD			1.0	1.0	1.0	Weekly										New test
115	135	IN-Tube TB Mitogen Control	TBD			1.0	1.0	1.0	Weekly										New test
			<b>IN-TUBE TB</b>			3.0	3.0	3.0											
			<b>NaFI Plasma</b>																
51	9	Glucose	NHANES Diabetes Laboratory				0.5	0.5	Weekly	2 mL cryovial	9x9 two inch box	0.5	0.5					0.5	morning only
		2 mL Gray					2	2				2	2					2	
		Number of gray					1	1				2	2					1	
51	98	OGTT	NHANES Diabetes Laboratory				0.5	0.5	Weekly	2 mL cryovial	9x9 two inch box	0.5	0.5						morning only
		2 mL Gray					2	2				2	2					2	
		Number of gray					1	1				2	2					2	
			<b>Serum</b>																
61	136	Sa/Cu/Zn	CDC/NCIRD Herpesvirus Diagnostic Lab	0.4	0.4		1.0	1.0	Weekly Frozen	2 mL cryovial	9x9 two inch box	1.0							1/3 subsample 1,2,5,11; Use 6mL royal blue top tube - no preservatives
116	138	CMV							Weekly Frozen	2 mL cryovial	9x9 two inch box								New test
54	70	Vitamin D/PUFA	CASPIR	0.5	0.5	0.7	0.7	0.7	Weekly	2 mL cryovial	10x10 two inch box	0.7							LC/MS/MS NEW, add to dry run odd; PUFA add red colored cap inserts to 12+ morning sessions only.
2	122	HAV	CDC/NCID Hepatitis Ref Lab			1.5	1.5	1.5	Weekly	2 mL cryovial	9x9 two inch box		1.5						Age 6-19 - including dry run
2	87	Hepati ab	CDC/NCID Hepatitis Ref Lab	0.3	0.5				Weekly	2 mL cryovial	9x9 two inch box								Age 2-5 yrs
59	17	Cotinine	CASPIR		0.8	1	1.8	1.8	Weekly	2 mL cryovial	9x9 two inch box		1.8						Ship in same shipper as vessels 9, 98, 23. Total Cholesterol/HDL age 6+, Triglycerides/LDL/ApoB morning only 12+ (flag.) Triglycerides/ApoB - place a colored insert in the vessel cap for adults 12+ examined in morning session.
51	21	Lipids	NHANES Diabetes Laboratory			1.0	1.5	1.5	Weekly	2 mL cryovial	9x9 two inch box	1.5	1.5					1.5	1.5
57	17	HPV Siamem	CDC/OVHD HPV				0.5	0.5	Weekly	2 mL cryovial	9x9 two inch box								14 to 59
40	18	Biochem	Collaborative Laboratory Services				0.8	0.8	Weekly refrigerator	2 mL cryovial	9x9 two inch box	0.8	0.8					0.8	0.8
51	23	Insulin	NHANES Diabetes Laboratory				1.0	1.0	Weekly	2 mL cryovial	9x9 two inch box	1.0							morning only
54	12	Vit B12/MMA	CASPIR					0.7	Weekly	2 mL cryovial	9x9 two inch box		0.7						
3	22	HIV	CDC/NCID AIDS Division				0.8	0.8	Weekly	2 mL cryovial	9x9 two inch box								Age change from 18 to 49 to 18-59
5	24	HSV	Emory University				0.2	0.2	Weekly	2 mL cryovial	9x9 two inch box								1/3 subsample 1, 2, 5, 11 - process on a full sample of dry runs, 2010 change to lab 40 from 11
40	118	Thyroid	University of Washington				1.0	1.0	Weekly	2 mL cryovial	9x9 two inch box	1.0	1.0						6+ yr Celiac disease NEW, add to dry run both
65	127	IgA-TTG/EMA	Mayo Clinic				0.5	0.5	End of stand	2 mL cryovial	9x9 two inch box	0.5	0.5						New test
60	137	Testosterone					0.5	0.5	Weekly Frozen	2 mL cryovial	9x9 two inch box	0.5							Full sample for MA
26	119	Folate 1	CASPIR	0.7	0.7	0.7	0.7	0.7	Weekly	2 mL cryovial	10x10 two inch box	0.7		0.7	0.7	0.7	0.7	0.7	Changed test volume for age 12+ from 0.7 to 0.5, eliminated age 1-2
6	32	Xtra sera1	CASPIR		0.5	0.5	--	--	End of stand	2 mL cryovial	9x9 two inch box								Eliminated subsample and age 1-2
6	33	Xtra sera2	CASPIR		0.5	0.5	--	--	End of stand	2 mL cryovial	9x9 two inch box								Eliminated subsample and age 1-2
6	34	Xtra sera3	CASPIR		--	--	1.0	1.0	End of stand	2 mL cryovial	9x9 two inch box								Eliminated age 6-11
6	35	Xtra sera4	CASPIR				1.0	1.0	End of stand	2 mL cryovial	9x9 two inch box								Eliminated age 6-11, Changed test volume from 0.5 to 1.0
6	36	Xtra sera5	CASPIR				1.0	1.0	End of stand	2 mL cryovial	9x9 two inch box								Eliminated age 6-11, Changed test volume from 0.5 to 1.0
6	37	Xtra sera6	CASPIR				1.0	1.0	End of stand	2 mL cryovial	9x9 two inch box								Eliminated age 6-11, Changed test volume from 0.5 to 1.0
		Serum total		1.9	3.9	7.9	16.5	17.2				7.7	7.8	0.7	0.7	2.2	3.0	0.8	
		Serum yield		2.4	4	9.2	17.2	20.4				19.2	18.0	1.2	1.2	2.8	4.0	1.2	
		Red tube size		3	7	10	15	15				15	15	3	3	7	10	3	
		Number of Red		2	1	1	2	3				2	4	1	1	1	1	1	
		Red tube size			3	7	7	3				6							
		Number of Red			1	1	1					2							
		Blue tube size				6	6	6											
		Number of Blue				1	1	1											
28	29	Persis Pest1	CASPIR				4.0	4.0	End of stand	5 mL cryovial	9x9 three inch box								1/3 Subsample 1,2,5,11
28	89	Persis Pest2	CASPIR				4.0	4.0	End of stand	5 mL cryovial	9x9 three inch box								1/3 Subsample 1,2,5,11
24	90	Perflour	CDC/NCEH Environmental Health Laboratory				4.0	4.0	End of stand	5 mL cryovial	9x9 three inch box								1/3 subsample 4,6,8,9; switched to 1,2,5,11 for 2011
28	92	BF1	CASPIR				4.0	4.0	End of stand	5 mL cryovial	9x9 three inch box								1/3 Subsample 0,3,7,10; switched to 1,2,5,11 for 2011
28	93	BF2	CASPIR				4.0	4.0	End of stand	5 mL cryovial	9x9 three inch box								1/3 Subsample 0,3,7,10; switched to 1,2,5,11 for 2011
		10-mL Red tube					10	10											
		Number					5	5											
26	91	SRM Pesticide	CDC/NCEH Pesticide Laboratory				4.0	4.0	End of stand	5 mL cryovial	9x9 three inch box								1/3 subsample 4,6,8,9 for 2011
		7-mL EDTA					7	7											
		Number of 7-mL					1	1											
			<b>Genetics</b>					20											Age 20+ Use K2 EDTA
58	119	Genetics	CDC/NCEH Molecular Biology Branch					10	Twice a week	10 mL EDTA tube	5x5 five inch foam box								
58	120	Genetics						10	Refrigerated	10 mL EDTA tube									Mix, store upright in refrigerator and ship in padded containers twice per week
		Number of 10-mL EDTA						2											
4	54	VOC Blood	CDC/NCEH Air Toxicant Branch				10	10	Weekly Refrigerator	10 mL Gray tube	5x5 five inch foam box								12+ Household 1/2 subsample 1,2,4,5,10,11 Must overlap with vessel 62 (1,2,5,11) Includes VOC and perchlorate
		CDC 10-mL Gray					10	10											
		Number of Gray					1	1											
			<b>Total blood draw</b>	9	13	23	115	143				58	76	6	6	10	15	6	
			<b>Urine</b>																
16	45	Alb/Creat	University of Minnesota			3	3	3	Weekly	5 mL cryovial	9x9 three inch box	3	3					3	3
5	46	Chlam	CDC/NCID NCHSTD				12	12	Weekly	14 mL Falcon	5x5 three inch box								Eliminate GC, change 10 mL VWR to 14-mL Falcon
61	86	Spc Arsenic	CASPIR			3	3	3	Weekly	5 mL cryovial	9x9 three inch box								1/3 subsample 1, 2, 5, 11
26	48	Prior Pest	CDC/NCEH Pesticide Laboratory			7	7	7	End of stand	10 mL VWR screw	5x5 three inch box								1/3 subsample 4, 6, 8, 9
26	49	Organophos	CDC/NCEH Pesticide Laboratory			7	7	7	End of stand	10 mL VWR screw	5x5 three inch box								1/3 subsample 4, 6, 8, 9 Changed test volume from 7 to 8
61	62	Urin Merc	CASPIR			5	5	5	Weekly	10 mL VWR screw	5x5 three inch box								1/3 subsample 1, 2, 5, 11
61	50	Heavy Metal	CASPIR			6	6	6	Weekly	10 mL VWR screw	5x5 three inch box								1/3 subsample 1, 2, 5, 11
31	66	PAH	CASPIR			3	3	3	End of stand	5 mL cryovial	9x9 three inch box								1/3 subsample 0,3,7,10 Changed to 1,2,5,11 for 2011
24	67	Phthalates	CDC/NCEH Environmental Health Laboratory			3	3	3	End of stand	5 mL cryovial	9x9 three inch box								1/3 subsample 0, 3, 7, 10. Changed to 1,2,5,11 for 2011
4	102	Perchlorate/VOC/Thiocyan	CASPIR			5	5												

## Appendix D

### Laboratory and Phlebotomy Inventory

**APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY**

**LABORATORY INVENTORY**

**CONSUMABLE ITEMS**

<b><u>Part number</u></b>	<b><u>Description</u></b>	<b><u>Par level</u></b>	<b><u>Unit distribution</u></b>
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**EXAM SUPPLIES**

56616-032	Absorbent Bench Pad - blue chuck	15	each
FA201-10	Absorbent Sheets (2" x 2")	5	pack
SO – AA – 1%	Ascorbic Acid – 1%	30	each
SO – AA – 7%	Ascorbic Acid – 7%	30	vial
58-104	Alcohol Wipes	1	box
RD 06173	Aluminum Foil - 50 Sq. Feet Roll	1	roll
24-54	Applicator Sticks, cotton tipped	1	bag
19-086333	Applicator Sticks, wooden	1	Box
12-007-187	Bench Kote Paper - 46" x 57" Paper for Lab Counter	2	Case
108M	Bio-Hazard Bags (25" x 35")	1	Box
14-830-132	Bio-Hazard Container (8 Gallon)	20	Each
SO-Bleach	Bleach - Regular - 5 - 5.25 Hydrochloride, Fragra	2	Gallon
1441266	Bleach Right Disinfecting Spray - 32 Ounce Spray Bottle	3	Bottle
23-751610	Deionized Water - 1 Gallon Plastic Bottle	3	Gallon
19-037-189	Glove Liners – Full Finger	1	Pack
531333	Gloves, Sterling Nitrile Gray(Lg.)	20	Box
531332	Gloves, Sterling Nitrile Gray (Med.)	8	Box
531331	Gloves, Sterling Nitrile Gray (Sm.)	20	Box
G31-500	Glycerin - 500mL Brown Glass Bottle	1	Bottle
GOJ-9639-12CT	Handsoap-Waterless (Purell)	2	Bottle
34155	Kimwipes (4 1/2 x 8 1/2)	3	Box
47745-078	Pipette Tips 1000uL - 5 Racks of 96 tips each / per case	2	Box
47745-074	Pipette Tips 200uL	2	Box
47745-180	Pipette Tips 5mL (Bulk Pack) - 500 Pcs. per case	1	Case
06-66997	Towlettes, Sani-Cloth (Cleaner)	2	Bottle
414004-012	Transfer Pipette (15mL ,8.0 Bulb Clear) - 250 per box	2	Box
86.1171	Transfer Pipette (3.5 clear, plastic)	6	Box
15-235-61	Wipes, Terri (23" x 11")	1	Box

<u>Part number</u>	<u>Description</u>	<u>Par level</u>	<u>Unit distribution</u>
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**OFFICE SUPPLIES**

2251	3-Hole Copier Paper - 500 sheets per pack	2	Pack
MAXMF2-HD-FRMTD	Diskettes, 3.5	1	Box
107708	Dymo Costar Label (1"x2 1/8") - 500 labels per roll	2	box
AVE 5165	Label - Full Sheet 8.5" x 11" - Lab Label	2	box
AVE 5160	Labels, Mailing Label 1" x 2 5/8"	1	box
31055	Labels, Zebra (1" x 2.625", clear) – Black Bar Added	12	roll
HEWQ2610A	Laser Printer Toner Cartridge – HP2300DN	1	each
SAN 30001	Magic Markers - Sharpie - Fine Point	6	each
AVE 08888	Magic Markers, Black	2	each
95.954	Magic Markers, Felt Tip Fine Line (Waterproof)	4	each
MMM 670-5AU	Post-It Page Markers - 100 pcs per pad / 5 colors	3	pack
FED1104S	Printer Ribbon, Zebra (Thermal Transfer)	12	roll
SPR-33-1LB	Rubber Bands, #33	1	box
PK-122-5Z2F005	Toner Cartridge - Kyocera - For Lab Coulter Printer	1	each

**HEMATOLOGY SUPPLIES**

7547116	Coulter 5C Cell Control - REFRIGERATED	2	pack
8546931	Coulter Clenz - 10 Liter	2	box
8547166	Coulter HMX Pak	3	box
8546733	Coulter Isoton III	7	box
7546914	Coulter Latron Control - REFRIGERATED	1	pack
7546915	Coulter Latron Primer - REFRIGERATED	1	pack
8546983	Coulter Lyse-S	3	bottle
624519	Coulter S-Cal - REFRIGERATED	1	pack

**SPECIALIZED STICKERS & LABELS**

	FEDEX Class 9 Label - Dry Ice Label	1	roll
8CD-130239R	Sticker, "Keep Frozen " - 500 / roll	2	roll
8CD-130242R	Sticker, "Refrigerate Do Not Freeze" - 500 / roll	1	roll

**PREGNANCY TEST SUPPLIES**

22247114	Pregnancy Test Kit (ICON 25) - Non-Refrigerated	9	box
SA087712	Sure-Vue hCG Serum Control Set - Refrigerated	1	pack
SA087413	Sure-Vue hCG Urine Control Set - Refrigerated	1	pack

<u>Part number</u>	<u>Description</u>	<u>Par level</u>	<u>Unit distribution</u>
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**JACKETS, GOWNS & SLIPPERS**

1A-32187	Disposable Lab Jackets - 48 Inches Long, Lite Blue	1	box
18-022838	Lab Jackets, Disp. (Blue, 2XL) – Kimberly Clark	10	each
10078	Lab Jackets, Disp. (Blue, Lg.) – Kimberly Clark	10	each
10067	Lab Jackets, Disp. (Blue, Med.) – Kimberly Clark	20	each
10087	Lab Jackets, Disp. (Blue, XL) – Kimberly Clark	10	each

**TUBES, VIALS, FILTERS**

62.559.001	Conical Tube (50mL, red top) - 25 Pieces Per Bag/300 per case	16	bag
15-350-49	Cryogenic Vial Color Coders - Red Only	4	pack
SO-10mL	CryoPro 10mL Vial - WITH ADDITIVE (urine/mercury)	150	each
14224-382	CryoPro Cryogenic 10mL Vial - Screw On Cap	4	case
14-959-11B	Falcon Culture Test Tube (14 mL)	20	bag
679800-5840	Nalgene Cryovial (2.0 mL, Non-Sterile)	12	case
03-337-7D	Nalgene Cryovial (2.0 mL, Sterile)	2	case
03-337-7H	Nalgene Cryovial (5.0 mL, Sterile)	10	case
02-681-50	Serum Filter Tube (13mm x 4")	2	pack
02-681-52	Serum Filter Tube (16mm x 6")	20	pack

**SHIPPING SUPPLIES**

1A-55968	Bag, Ziplock (9" x 12" Clear) - Bitran Replacement Bag	1	case
CJ-3-D-25	Box, Cardboard 3" with 5X5 grid, white	70	each
RB-2-100	Box, Cardboard 2" with 10 x 10 grid	80	each
BX-2-D-81	Box, Cardboard 2" with 9 x 9 grid	220	each
CJ-3-D-49-2.25	Box, Cardboard 3" with 7 x 7 grid	25	each
CJ-3-D-81	Box, Cardboard 3" with 9 x 9 grid, white	40	each
95.064.925	Box, Cardboard 5.25" x 5.25" with foam insert	45	each
STP 710	Combination Bag and Envelope System - 50 Units per case	2	case
STP 730	Combination Bag and Envelope System - 50 Units per case	4	case
STP 740	Combination Bag and Envelope System - 50 Units per case	1	case
SEL 10190	Envelopes, Large Padded - 10.5" x 16"	10	each
	FEDEX Airbill Pouches	2	pack
	FEDEX Blank Airbills	1	pack
	FEDEX Large Box	1	each
	FEDEX Preprinted Airbill - Warehouse - Stand		
	Specific/Throw Away At	200	each
240-20	News-Pak (newsprint on roll)	1	roll
03-528-18	Shipper (Insulated, Styrofoam, Medium) - 16 x 16 x 16	48	each
03-530-71	Shipper (Insulated, Styrofoam, Small) - 14 x 14 x 10	40	each
MMM 3710-2-TT	Tape, 2" Packing	10	roll
03-528C	U-Tek Large Refrigerant Packs (24 oz.)	14	case

<u>Part number</u>	<u>Description</u>	<u>Par level</u>	<u>Unit distribution</u>
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**COMPONENT TOOLS**

6Y762	Valve Grease - Dow Corning Lubricant #111	1	tube
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**MEC SUPPLIES**

PC22160	Tissues – Facial	2	box
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**OSMOLALITY SUPPLIES**

1431-31	Dropper Urine Chemistry Control – Level 1 – 3 bottles – Refrigerated	1	box
1432-31	Dropper Urine Chemistry Control – Level 2 – 3 bottles – Refrigerated	1	box
15-907	Inventory Label tape – Write On Inventory Label	1	roll
FS2A5x20	Osmo. Replacement Fuse – 5mm x 20mm, 2 amp/250 Volt	2	each
2036	Osmo Piston Replacement	6	each
01-216-2	Osmo. Plastic Ampule Opener – 5mL-10mL Safety Shield	10	each
2101	Osmometer 100 milliosmoles - Std Solution - 125 mL Bottle	1	bottle
2115	Osmometer 1500 milliosmoles - Std Solution - 125 mL Bottle	1	bottle
2120	Osmometer 2000 milliosmoles - Std Solution - 125 mL Bottle	1	bottle
2105	Osmometer 500 milliosmoles - Std Solution - 125 mL Bottle	1	bottle
2023	Osmometer 50uL Disposable Sample Tubes - 500/pack	1	pack
2201	Osmometer CON-TROL 100 mOsm - Ref Solution - 5mL ampules, 12/pk	1	pack
2205	Osmometer CON-TROL 500 mOsm - Ref Solution - 5mL ampules, 12/pk	1	pack
2048	Osmometer Pipette Tips and Cleanettes - 1000 per pack	2	pack

**NON-CONSUMABLE SUPPLIES**

**OFFICE SUPPLIES**

OIC 83100	Clipboard	2	each
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**SPARE PARTS & TOOLS**

11779	Cordless Screwdriver w/ Socket - NEW - Craftsman 4.8 Volt Unit	1	each
22-46-139-7	Eppendorf Pipettor 100-5000uL	1	each
22-46-138-9	Eppendorf Pipettor 50-1000uL	2	each
22-46-136-2	Eppendorf Pipettor 5-100uL	1	each
8395	Glass Fuse – 1 amp/250 volts – Centrifuge	2	each
99833	Hammer (16 oz. Claw) - Used for breaking down dry ice	2	each
NC9818625	Pipettor Battery - Spare / Backup Battery	1	each
22461559	Pipettor Charging Stand	1	each
40822	Screwdriver (4 in 1 multi-tip screwdriver)	1	each
66-039-6	Screwdriver Set - 6 piece precision - Mfg. Name: Stanley	1	each

<u>Part number</u>	<u>Description</u>	<u>Par level</u>	<u>Unit distribution</u>
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**SHIPPING SUPPLIES**

14-241B	Aluminum Ice Scoop	1	each
8A-18116	Full Face Shield	1	each
11-394-200	Gloves, Cryo Insulated, Large	2	pair
11-394-305	Gloves, Cryo Insulated, Medium	2	pair
1E-24039	Leather Utility Gloves	1	pair
SPR 01750	Tape Gun, 2"	2	each

**COMPONENT TOOLS**

BPT - Custom	Blood Processing Template - All Ages 1-2, 3-5, 6-11, 12+	100	each
21-102-52	Cube Rack (Clear) for Absorbic Acid - 4 Way Flipper Rack	2	each
03-572-5	Bottle Brush – 11”	2	each
21-102-52	Cube Rack (Clear) for Ascorbic Acid	2	each
15-059-147	Exact -Temp Refrigerator Thermometer - Red Liquid Therm. with Bottle	1	each
15-059-145	Exact-Temp Freezer Thermometer (Ultra-Low, -90C) - Red Liquid Therm. with Bottle	2	each
OA-9188	Flashlight - Black	1	each
ML4042	Footstool – Metal	2	each
03-007-38	Graduated Cylinder 10mL	1	each
08-572-7C	Graduated Cylinder 50mL	1	each
7BC-12097-2	LAB- Wash Bottle- DI Water – Clear Squeeze Bottle	1	each
60985-444	Multicolor 4-Way Flip Racks - Set of 4 Racks	1	each
14-809-101	Nalge 13mm Half Rack - Unwire Plastic	3	each
14-809-134	Nalge 16mm Full Rack - Unwire Plastic	4	each
14-809-117	Nalge 16mm Half Rack - Unwire Plastic	5	each
03-337-7E	Nalgene Cryovial Rack - Plastic, 50 Well Tray	100	each
06-662-42	Programmable Outlet Strip – For use w/ TB Incubator	1	each
9A-33810	Protective Eyewear	3	each
WX-167	Public Alert Radio - Weather Radio	1	each
15-077-941	TB Traceable Sentury Thermometer w/ Probe - For use w/ TB Incubator	1	each
03-576	Test Tube Brush – 9”	2	each
15-078J	Thermometer, Calibration - For Centerfuge	1	each
15-077-19	Thermometer, Solar	2	each
06-662-51	Timer	1	each
06-662-3	Timer, Triple Display	2	each

**OSMOLALITY SUPPLIES**

2046	Osmo. Pipette Tip Cover – Plastic – One on each pipette, 2 spares	4	each
2025	Osmometer 10uL Pipette - Metal / Manual Pipette	23	each

## PHLEBOTOMY INVENTORY

### CONSUMABLE ITEMS

<u>Part number</u>	<u>Description</u>	<u>Par level</u>	<u>Unit distribution</u>
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#### **EXAM SUPPLIES**

7000HP	Air Sickness Bags	2	each
58-104	Alcohol Wipes	7	box
17-98797E	Ammonia Ampules	1	box
AB95	Band-aids - Cartoon Characters	1	box
7FQ-47126	Band-aids (3/4" x 3" Flex Adhesive) - Coverlet	5	box
ML1419	Bio-Hazard Autoclave Trash bag – 5 Gallon Bag	1	case
ML8532	Bio-Hazard Sharps Container – 8 Quart Container	10	each
367281	Butterfly Needle 21g Safety - Lok - 50 pcs. box / 4 boxes per case	6	box
367283	Butterfly Needle 23g Safety - Lok - 50 pcs. box / 4 boxes per case	1	box
19-003-428D	Co-Flex NL Cohesive Bandage 1Inch - Multi - Colored Rolls	1	case
Wet Wipes	Disposable Baby Wipes - Plastic Container	1	box
82004-826	Gauze Pads (2 x 2)	8	pack
GOJ-9639 12CT	Handsoap-Waterless (Purcell) -	2	bottle
209269	Heel Warmers (Infant)	12	each
713267	NIPRO 19G X 3/4" Butterfly Needle – 50 pieces/box	6	box
519018	NIPRO Luer Adapter – 100 per box	3	box
18-917	Pillow Cover - for 17" x 23" pillows	20	each
934-0852	Pillow, (disposable, 17 x 23)	1	each
530212	Squeeze Ball (for drawing blood) - Foam 3" Ball	2	each
Sticker	Sticker, Cartoon (Kids)	8	roll
02-6576	Tourniquets, Stretch (Blue, Vcutnr.)	20	box
06-66997	Towlettes, Sani-Cloth (Cleaner)	2	bottle
1530-0	Transpore Paper (1/2 " x 10 yds)	1	roll
1527-0	Transpore Tape (1/2 " x 10 yds)	1	roll

#### **OFFICE SUPPLIES**

DUR PC1500	Batteries, AA	6	each
107708	Dymo Costar Label (1"x2 1/8") - 500 labels per roll	8	box
37001	Magic Marker – Ultra Fine Sharpie	4	each
BC40R14N	Replacement Light Bulb – 40w Phillips Spot Light	1	each

#### **FORMS**

List of Reported Tests (Handout) - Counted Individually	10	each
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#### **VOC SUPPLIES**

BD Vacutainer 10mL Gray - VOC Blood Draw Tube	175	each
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<u>Part number</u>	<u>Description</u>	<u>Par level</u>	<u>Unit distribution</u>
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**TB SUPPLIES**

T0590-0301	Quantiferon TB Blood Tube	4	case
492105	TB Syringe – 27g ½” Needle	4	box
TB-Vial	Tubersol Antigen – 5mL Glass Vial – Refrigerated	9	vial

**FASTING SNACK SUPPLIES**

	Animal Crackers	288	each
7403512	Juice, Apple - Motts	200	each
	Juice, Orange - Minute Maid	150	each
PC9904	Plastic Drinking Straw - Individually Wrapped	1	box
188670	Plastic Medicine Cup - 1 Ounce	1	sleeve
TGP401526P	Trutol Glucose Bevarage - Fruit Punch - 24 per case	48	each
401025FB	Trutol Glucose Bevarage - Lemon / Lime - 24 per case	30	each
401223FB	Trutol Glucose Bevarage - Orange - 24 per case	48	each

**TUBES, VIALS, FILTERS**

366643	BD Hemogard 10 mL EDTA Lavender Top	4	tray
367921	BD Hemogard 2 mL Gray Top	3	tray
367856	BD Hemogard 3mL EDTA Lavender Top	3	tray
366668	BD Hemogard 3mL Red Top	1	tray
367861	BD Hemogard 4 mL EDTA Purple Top	6	tray
368380	BD Hemogard 6 mL Royal Blue	3	tray
366450	BD Hemogard 7mL EDTA Lavender Top	1	tray
366431	BD Hemogard 7mL Red Top	2	tray
366430	BD Vacutainer 10mL Red Top	5	tray
22-289-953	BD Vacutainer Tube Holder - 250 pcs. bag / 4 bags per case	500	each
8881301819	KS Vacutainer 15mL Red Top	8	tray

**EMERGENCY SUPPLIES**

8BZ-153919	Emergency Blanket – Disposable – Single Use	1	each
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**COMPONENT TOOLS**

415S0023BY	NOTRAX, Floor Mat - Shielded Sof-Tred, 2x3	1	each
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**MEC SUPPLIES**

PC22160	Tissues - Facial	2	box
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## **NON-CONSUMABLE SUPPLIES**

<b><u>Part number</u></b>	<b><u>Description</u></b>	<b><u>Par level</u></b>	<b><u>Unit distribution</u></b>
<b>TB SUPPLIES</b>			
<b>EMERGENCY SUPPLIES</b>			
232-237	Plastic TB Supply Basket - Black	1	each
	TB Rulers (6" Custom Plastic, Clear)	6	each
<b>EMERGENCY SUPPLIES</b>			
	CPR Mask – Adult	1	each
<b>COMPONENT TOOLS</b>			
ML10043	Bio-Hazard Trashcan – 7 Gallon Red Can	1	each
ML4042	Footstool - Bariatric- Metal Reinforced One Step Stool`	1	each
681771	Goose Neck Lamp – Clip On	1	each
14-809-130	Nalge 13mm Full Rack - Unwire Plastic	1	each
14-809-101	Nalge 13mm Half Rack - Unwire Plastic	2	each
14-809-117	Nalge 16mm Half Rack - Unwire Plastic	7	each
61220-714	Refrigerator Thermometer – Frio Temp – TB Refrigerator	2	each
SECA	Scale – Portable	1	each
30-1310-05	Scissors - Lister bandage (5 1/2 " Stainless Steel)	1	each
10037078	TB Acrylic Supply Tray 3"x 9"x 2", Clear	2	each
2460	TB Antigen Vial Storage Box w/ Lid – 1.0 Liter Plastic	1	each
15-077-19	Thermometer, Solar	1	each