

**NHANES 2005-2006 Data Release
November 2007**

**General Information
for the Public Files of the 2005-2006 Laboratory Data**

Laboratory Component Description

The NHANES 2005-2006 laboratory data files include findings from analyses of blood, urine, vaginal swabs, as well as dust and water samples. Blood, urine and the vaginal swab specimens were collected at the mobile examination centers (MECs). The dust and water samples were collected in participants' homes.

The specific laboratory test target populations are based on the survey participants' gender and age, at the time of the Household Interview. Blood and urine collection methods and exclusion criteria are described in this section. The collection of vaginal swabs, water samples, and dust samples is described in the respective manuals for the physician, household interviewer and allergy technician.

The urine collection procedure consisted of urine specimen collection and processing, and pregnancy testing. The blood collection procedure consisted of administering a questionnaire to screen for conditions that exclude participants from the blood draw. Fasting status was also recorded.

Venipuncture Exclusion Criteria

The following exclusion criteria applied to all tests that required blood specimens:

- Hemophiliacs
- Participants who received chemotherapy within the last 4 weeks
- The presence of rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, withered arms or limbs missing, damaged, sclerosed or occluded veins, allergies to cleansing reagents, burned or scarred tissue, shunt or intravenous lines on both arms.

Beginning in 2005, an oral glucose tolerance test (OGTT) was added to the laboratory protocol. A fasting glucose blood test was performed on all participants 12 years and older, who were examined in the morning session, after a 9 hour fast. After the initial venipuncture, participants were asked to drink a calibrated dose (generally 75 grams of glucose) of Trutol™ and had a second venipuncture 2 hours (plus or minus 15 minutes) after drinking the Trutol™.

There were seven OGTT exclusion criteria, including hemophilia and chemotherapy safety exclusions, fasting < 9 hours, taking insulin or oral medications for diabetes, refusing phlebotomy, and not drinking all the entire Trutol™ solution within the allotted time.

Data Collection

Automated data collection procedures were used. In the MECs and analytical laboratories, data for the laboratory component was recorded directly into a computerized database. Survey forms were also automated. The laboratory data collection and reporting systems were integrated with the main NHANES survey database. The complete blood count and pregnancy analyses were performed in the MEC laboratory. Other laboratory analyses were conducted off-site. For 2005-2006, 28 laboratories, across the United States, analyzed NHANES specimens.

Laboratory Component Staff

The NHANES 2005-2006 laboratory staff consisted of medical technologists and phlebotomists. The American Society for Clinical Pathologists or other organizations certified these staff members.

Training

All laboratory staff completed comprehensive training in standardized laboratory procedures, before they began working in the MEC. The medical technologists hold baccalaureates in medical technology. The MEC phlebotomists completed comprehensive training in pediatric phlebotomy techniques, including instruction by a pediatric nurse practitioner. All MEC staff completed required training in safety, subject privacy and confidentiality, and cardio-pulmonary resuscitation (CPR).

Spanish Language Instructions

Standardized scripts were used to describe the laboratory procedures to survey participants. All scripts were developed and pretested in both English and Spanish. The MEC staff were trained extensively, to ensure the quality and comparability of staff interactions with Spanish-speaking respondents.

Data Collection Forms

Detailed specimen collection and processing instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Each chapter in the LPM specifies the procedures to be used for collecting, labeling, processing, preserving, and transporting specimens for each method used in the survey.

Quality Control Procedures:

Mobile Examination Center (MEC)

Laboratory team performance was monitored using several techniques. NCHS and contract consultants used structured quality assurance evaluations, during unscheduled site visits, to evaluate the quality of the laboratory work and the implementation of required quality control procedures. Laboratory staff were observed and given feedback with respect to equipment operation, specimen collection and preparation, interaction with survey participants, and implementation of the survey protocol. Formal staff retraining sessions were conducted annually to ensure that required skill levels were maintained.

The NHANES quality control and quality assurance protocols met the 1988 Clinical Laboratory Improvement Act requirements. Detailed quality control and quality assurance instructions are discussed in the NHANES LPM.

Laboratory

As part of the overall quality assurance process for the survey, all collection materials, vacutainer tubes, and storage containers used for trace elements assays were initially pre-screened by the CDC/NCEH, Environmental Health Laboratory Sciences Laboratory for background contamination levels of lead, cadmium, total and speciated mercury. Lead, cadmium, and total and speciated mercury are fairly ubiquitous contaminants. Blood was collected in red-top tubes after the acceptability of the test tubes had been confirmed. Special lead-free tubes were not required. Ordinary EDTA tubes were similarly used, after prescreening confirmed that they had no contamination.

Analytical Laboratories

NCHS used several methods to monitor the quality of the analyses performed by the NHANES contract laboratories. In the MEC, these methods included analyzing “blind” split samples collected during practice (“dry run”) sessions. In addition, contract laboratories randomly performed repeat testing on two percent of all specimens.

NCHS developed and distributed a quality control (QC) protocol to each NHANES contract laboratory. The Westgard rules, to be used when running NHANES specimens, were included in the protocols. Progress reports, prepared by the contract laboratories, documented problems encountered during shipping or receipt of specimens. Summary statistics for each control pool, QC graphs, instrument calibration, reagents, and any special considerations were submitted to NCHS and Westat quarterly. The reports were reviewed for trends or shifts in the data. The laboratories were required to explain any identified areas of concern. NCHS and Westat reviewed the progress reports.

Data Processing and Preparation

The NHANES data processing guidelines provided NCHS and contractor staff with standards for naming variables, filling missing values, and handling missing records. NCHS staff, assisted by contract staff, developed data editing specifications that checked data sets for valid codes, ranges, and skip pattern consistencies and examined the consistency of values between interrelated variables. Comments were reviewed and recoded. NCHS staff verified extremely high and low values. Numerous consistency checks were performed during data preparation. Nevertheless, data users should examine variable ranges, frequencies and other descriptive statistics before analyzing the data.

Low Detection Limits

For laboratory tests with a lower detection limit, results below the lower detection limit were replaced with a value equal to the detection limit, divided by the square root of two. This value was created to help users distinguish a nondetectable laboratory test result from a measured laboratory test result.

Special Notes for the Laboratory Data

The analysis of NHANES 2005-2006 phlebotomy data must be conducted using the appropriate survey design and demographic variables. The NHANES 2005-2006 Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. The questionnaire files also contain the survey design variables and sample weight variables. The Phlebotomy File includes auxiliary information such as fasting status, the time of venipuncture, and the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.