

NHANES 2001-2002 Data Release
May 2004

**General Information about the NHANES 2001-2002 Laboratory Methodology and
Public Data Files**

Laboratory Component Description

The NHANES 2001-2002 laboratory data files include findings from analyses of blood, urine, and swabs. Specimens were collected at the mobile examination centers (MECs). The specific laboratory test target populations are based on the survey participant's gender and age at the time of the Household Interview. Blood and urine collection methods and exclusion criteria are described in this section.

The NHANES laboratory component tasks include the collection, processing, storage, and shipment of blood, urine, and other biological and environmental specimens to analytic laboratories. Currently, 32 laboratories across the United States analyze NHANES laboratory specimens.

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

Venipuncture Exclusion Criteria: The following exclusion criteria apply to all tests that require 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.

Data Collection

Automated data collection procedures were used. In the MECs and analytical laboratories, data for the laboratory component is recorded directly into a computerized database. Survey forms are also automated. The data collection and reporting systems are integrated with the main NHANES survey database. While the complete blood count and pregnancy analyses are performed in the MEC laboratory, most of the laboratory analyses are conducted off-site.

Laboratory Component Staff

The NHANES 2001-2002 laboratory staff consists of medical technologists and phlebotomists. The American Society for Clinical Pathologists or a similar organization certifies the medical technologists and the phlebotomists.

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 complete 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

All NHANES laboratory protocol scripts that were used to describe the laboratory procedures to survey participants were developed and pretested in English and Spanish. Extensive training was completed with MEC staff 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 is 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 implementation of the 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 are conducted annually to ensure that required skill levels are maintained.

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

Laboratory Quality Control

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 prescreened 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; and blood may be collected in red-top tubes after the acceptability of the test tubes has been confirmed. Special lead-free tubes are not required. Ordinary EDTA tubes may similarly be used after prescreening has confirmed no contamination.

Monitoring Analytical Laboratories

NCHS uses several methods to monitor the quality of the analyses performed by the NHANES contract laboratories. In the MEC, these methods include performing second examinations on previously examined participants and “blind” split samples collected during practice (“dry run”) sessions. In addition, contract laboratories randomly perform 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 are included in the protocols. Progress reports prepared by the contract laboratories document problems encountered during shipping or receipt of specimens; summary statistics for each control pool, QC graphs, instrument calibration, reagents, and any special considerations are submitted to NCHS and Westat quarterly. The reports are reviewed for trends or shifts in the data. The laboratories are required to explain any identified areas of concern. NCHS and Westat review the progress reports.

Data Processing and Preparation

The NHANES data processing guidelines provide 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 check data sets for valid codes, ranges, and skip pattern consistencies and examine the consistency of values between interrelated variables. Comments are 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 and 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 are replaced with a value equal to the detection limit divided by the square root of two. This value is created to help the user distinguish a nondetectable laboratory test result from a measured laboratory test result.

Special Notes for the Laboratory Data

The analysis of NHANES 2001-2002 phlebotomy data must be conducted using the appropriate survey design and demographic variables. The NHANES 2001-2002 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 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.