National Health and Nutrition Examination Survey 2003-2004

Documentation, Codebook, and Frequencies

MEC Laboratory Component: C-reactive Protein (CRP), Bone Alkaline Phosphatase (BAP), and Parathyroid Hormone (PTH)

Survey Years:
2003 to 2004

SAS Export File:
L11_C.XPT

February 2006

NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 11 – C-reactive Protein (CRP), Bone Alkaline Phosphatase (BAP), and Parathyroid Hormone (PTH)

Years of Coverage: 2003–2004 **First Published:** February 2006 **Last Revised:** N/A

Component Description

C-reactive protein (CRP)

C-reactive protein is considered one of the best measures of the acute-phase response to an infectious disease or other cause of tissue damage and inflammation. It is used to correct the iron status measures, which are affected by inflammation. It can also be used to measure the body's response to inflammation from chronic conditions, such as arthritis, and environmental exposures to agents such as tobacco smoke.

Bone Alkaline Phosphatase (BAP)

To assist in the evaluation of skeletal status, one marker of bone turnover is being measured: bone alkaline phosphatase in serum.

Parathyroid Hormone (PTH)

Evaluation of bone mineral status will utilize an evaluation of vitamin D status based on two analytes: serum 25-hydroxyvitamin D and parathyroid hormone (PTH). Vitamin D is essential for active intestinal calcium absorption and plays a central role in maintaining calcium homeostasis and skeletal integrity. In addition, vitamin D has recently been linked to other non-skeletal conditions of public health significance, such as hypertension and cancer. Vitamin D is derived mainly from cutaneous synthesis in the presence of ultraviolet sunlight, whereas dietary intake constitutes a minor fraction. Serum 25(OH)D is the best indicator of vitamin D status. It is converted in the kidney, stimulated by PTH, to the hormonally active metabolite 1,25-dihydroxyvitamin D [1,25 (OH)2D]. Serum PTH concentration is a very sensitive indicator of calcium homeostasis and vitamin D deficiency. The inclusion of this measure to the NHANES laboratory protocol will increase the usefulness of the vitamin D measurement in evaluating vitamin D status, particularly as it relates to skeletal status. The inclusion of both of these markers in the NHANES survey will provide a more complete picture of vitamin D status.

Eligible Sample

CRP: Participants aged 1 year and older.

BAP: Participants aged 8–49 years.

PTH: Participants aged 6 years and older.

Description of Laboratory Methodology

CRP

This method quantified CRP by latex-enhanced nephelometry. Particle-enhanced assays were based on the reaction between a soluble analyte and the corresponding antigen or antibody bound to polystyrene particles. For the quantification of CRP, particles consisting of a polystyrene core and a hydrophilic shell were used to link anti-CRP antibodies covalently. A dilute solution of test sample was mixed with latex particles coated with mouse monoclonal anti-CRP antibodies. CRP present in the test sample forms an antigen antibody complex with the latex particles.

An automatic blank subtraction was performed. CRP concentrations were calculated by using a calibration curve. Data reduction of the signals was performed by using a storable logit-log function for the calibration curve performed data reduction of the signals. These assays were performed on a Behring Nephelometer for quantitative CRP determination.

BAP

The Tandem-MP Ostase ImmunoEnzymetric Assay is an *in vitro* device for the quantitative measurement of Skeletal Alkaline Phosphatase (sALP), an indicator of osteoblastic activity, in human serum. This device is intended to be used as an aid in the management of postmenopausal osteoporosis and Paget's disease.

The Ostase Assay is a solid-phase, monoclonal antibody immuno-enzymetric assay. Samples containing sALP are reacted with a solution containing a biotin-labeled, sALP-specific monoclonal antibody. The reaction takes place in a plastic well strip (solid phase) coated with strepavidin and enclosed in a plastic frame. Following the formation of a solid-phase/capture antibody/sALP complex, the microplate is washed to remove unbound sALP and is then incubated with an enzyme substrate. The amount of substrate turnover is determined colorimetrically by measuring the absorbance of the quenched reaction at 405 nm in a microplate reader. The absorbance is proportional to the concentration of sALP present in the test sample. The calculation of sALP concentration in the sample is based on concurrent testing of sALP Calibrators and the Zero Diluent/Calibrator.

The Ostase assay is an *in vitro* device for the quantitative measurement of skeletal alkaline phosphatase (sALP) in human serum. Changes in sALP have been shown to be useful in participants undergoing therapy for metabolic bone disorders. It may also be an indicator of vitamin D deficiency in some participants.

PTH

The Elecsys 1010 analyzer is a fully automatic run-oriented analyzer system for the determination of immunological tests using the ECL/Origen electrochemiluminescent process. All components and reagents for routine analysis are integrated in or on the analyzer. PTH is measured on the Elecsys 1010 using a sandwich principle.

(a) 1st incubation. A 50 µL sample of a biotinylated monoclonal PTH-specific antibody and monoclonal PTH-specific antibody labeled with a ruthenium complex form a sandwich complex.

(b) 2nd incubation. After the addition of streptavidin-labeled microparticles, the complex produced is bound to the solid phase via biotin-streptavidin interaction.

(c) The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission (which is measured by a photomultiplier).

(d) Results are determined by means of a calibration curve. This curve is instrument-specifically generated by a two-point calibration and a master curve provided via the reagent barcode.

PTH is an 84 amino acid peptide produced by the parathyroid gland. Because the PTH molecule undergoes extensive proteolytic modifications, human serum contains both the intact molecule and several fragments. The biologically active N-terminal fragment has a half-life of only a few minutes. The secretory activity of the parathyroid gland can be determined by the selective measurement of the (mainly) intact parathyroid hormone. This Elecsys 1010 method is for the *in vitro* quantitative determination of intact parathyroid hormone in human serum and plasma. Together with vitamin D and calcitonin, PTH brings about the mobilization of calcium and phosphate from the skeletal system and increases the uptake of calcium in the intestine and the excretion of phosphate via the kidneys. Secretion of PTH is inhibited by high calcium concentrations and is promoted by low calcium concentrations. The ratios of intact hormone to peptide fragments may vary from individual to individual as well as between patients with hyperparathyroidism or chronic renal failure. The concentration of metabolically inactive PTH fragments increases in renal failure.

There were no changes to the equipment, lab method, or lab site from the previous 2 years.

A detailed description of the laboratory method used can be found on the NHANES website.

Laboratory Quality Control and Monitoring

The NHANES quality control and quality assurance protocols (QA/QC) meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed quality control and quality assurance instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols.

A detailed description of the quality assurance and quality control procedures can be found on the NHANES website.

Data Processing and Editing

Blood specimens are processed, stored and shipped to University of Washington, Seattle, WA. Detailed specimen collection and processing instructions are discussed in the NHANES LPM. Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Description of Laboratory Methodology section.

The age range for CRP changed to 1 year and older in 2003–2004 from 3 years and older from the previous 2 years. The age range for BAP changed to 8–49 years in 2003–2004 from 8 years and older in the previous 2 years.

There were no top coding or derived variables in this file.

Detailed instructions on specimen collection and processing can be found on the NHANES website.

Analytic Notes

The analysis of NHANES 2003–2004 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2003–2004 Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain sample weights for these age groups. The phlebotomy file includes auxiliary information such as 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.

References

N/A

Locator Fields

Title: C-reactive protein (CRP), Bone Alkaline Phosphatase (BAP), and Parathyroid Hormone (PTH)

Contact Number: 1-866-441-NCHS

Years of Content: 2003–2004

First Published: February 2006

Revised: N/A

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: C-reactive protein (CRP), Bone Alkaline Phosphatase (BAP), and Parathyroid Hormone (PTH)

Record Source: NHANES 2003–2004

Survey Methodology: NHANES 2003–2004 is a stratified multistage probability sample of the civilian non-institutionalized population of the U.S.

Medium: NHANES Web site; SAS transport files

National Health and Nutrition Examination Survey
Codebook for Data Production (2003-2004)

C-reactive Protein (CRP), Bone Alkaline Phosphatase (BAP), and Parathyroid Hormone (PTH) (L11_C)

Person Level Data

February 2006

SEQN	Target
	B(1 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Respondent sequence number
English Text: Respondent sequence number.	
English Instructions:	

LBXCRP	Target
	B(1 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	C-reactive protein(mg/dL)
English Text: C-reactive protein (mg/dL)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
0.02 to 25.4	Range of Values	7200	7200	
0.01	Below Limit of Detection	1054	8254	
.	Missing	925	9179	

LBXBAP	Target
	B(8 Yrs. to 49 Yrs.)
Hard Edits	**SAS Label**
	Bone alkaline phosphotase (ug/L)
English Text: Bone alkaline phosphotase (ug/L)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
2.8 to 445	Range of Values	4877	4877	
.	Missing	452	5329	

LBXPT21	Target
	B(6 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Parathyroid Hormone(Elecys method) pg/mL
English Text: Parathyroid Hormone(Elecys method) pg/mL	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
9 to 1491	Range of Values	7334	7334	
6	Below Limit of Detection	10	7344	
.	Missing	638	7982	