NHANES 2001-2002 Data Release
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Documentation for Laboratory Results

Laboratory 11 – C-reactive protein (CRP) and Fibrinogen

(1) Documentation File Date- December 12, 2003

(2) Documentation File Name- Laboratory 11 – C-reactive protein (CRP) and Fibrinogen

(3) Survey Years Included in this File Release-2001-2002

(4) Component Description

4.1 C-reactive protein

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.

4.2 Fibrinogen

Fibrinogen is an essential blood-clotting factor and is involved in a range of other functions, including platelet aggregation and smooth muscle proliferation. A growing body of evidence has identified fibrinogen as an important risk factor for cardiovascular disease, the major cause of death in the U.S. The objective of including this measure was to provide data on laboratory, clinical, and socio-demographic correlates of fibrinogen levels. Of particular importance in NHANES, the data can be used to study the relationship between fibrinogen levels and clinically measured lower extremity arterial blood flow as assessed by the Ankle-Brachial Index in the Lower Extremity Disease component.

(5) Sample Description:

5.1 Eligible Sample

C-reactive protein (CRP)

Participants aged 3 years and older were tested.

5.2 Fibrinogen

Participants aged 40 years and older were tested.

(6) Description of the Laboratory Methodology

6.1 C-reactive protein
This method quantified C-reactive protein (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 in order 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.

6.2 Fibrinogen

On the STA-Compact, the Clauss clotting method determined the fibrinogen concentration in plasma quantitatively. This test method involves measuring the rate of fibrinogen to fibrin conversion in diluted sample under the influence of excess thrombin. Since under these conditions the fibrinogen content was rate limiting, the clotting time can be used as a measure of the concentration of the fibrinogen and in fact, the clotting time is inversely proportional to the level of fibrinogen in the plasma.

Clot detection by the STA-Compact involved an electromagnetic-mechanical system. The oscillation of a steel ball within the cuvette with the thrombin and diluted plasma was monitored by the STA-Compact. When the oscillation of the steel ball was stopped by clot formation, the sensor registered the time in seconds. The time was translated into fibrinogen concentration from a fibrinogen standard curve, stored on the STA Compact.

 (7) 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 <u>NHANES Laboratory/Medical Technologists Procedures Manual (LPM)</u>. Read the LABDOC file for detailed QA/QC protocols.

(8) Data Processing and Editing

Blood specimens are processed, stored and shipped to University of Washington, Seattle, Washington. Detailed specimen collection and processing instructions are discussed in the <u>NHANES Laboratory/Medical Technologists Procedures Manual (LPM)</u>. Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Analytic methodology section.

(9) Data Access:

All data are publicly available.

(10) Analytic Notes for Data Users:

10.1 The analysis of NHANES 2001-2002 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2001-2002 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 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.