NHANES 2001-2002 Data Release
May 2004
Documentation for Laboratory Results

Laboratory 11PSA - Prostate specific antigen (PSA)

(1) Documentation File Date- April 19, 2004

(2) Documentation File Name- Laboratory 11PSA - Prostate specific antigen

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

(4) Component Description

Total and free prostate specific antigens (PSA) were measured among men age 40 years and older. PSA exclusion questions (KIQ115, KIQ185, KIQ190, KIQ195, KIQ201, KIQ241, KIQ281, KIQ301, and KIQ311) were asked during the physician's examination. PSA immunoassay was performed on blood specimens using the Hybritech tests (Beckman Coulter, Fullerton, CA).

(5) Eligible Sample

Male participants aged 40 years and older were tested for PSA. Those who reported having any of the following conditions were not eligible for PSA testing:

Current infection or inflammation of the prostate gland (KIQ115)
Rectal exam in the past week (KIQ185)
Prostate biopsy in the past month (KIQ190)
Cystoscopy in the past month (KIQ195)
History of prostate cancer (KIQ201)

(6) Description of the Laboratory Methodology

6.1 Free prostate specific antigen

The Access Hybritech free PSA assay is a two-site immunoenzymatic "sandwich" assay. A sample was added to a reaction vessel with mouse monoclonal anti-free PSA alkaline phosphatase conjugate, and paramagnetic particles coated with a second mouse monoclonal anti-free PSA antibody. The free PSA in the sample bound to the immobilized monoclonal anti-free PSA on the solid phase while, at the same time, the monoclonal anti-PSA conjugate reacted with a different antigenic site on the sample free PSA. Separation in a magnetic field and washing removes material not bound to the solid phase. A chemiluminescent

substrate, Lumi-Phos^{tm} 530 was added to the reaction vessel and light generated by the reaction was measured with a luminometer. The light production was proportional to the concentration of free PSA in the sample. The amount of analyte in the sample was determined by means of a stored, multi-point calibration curve.

6.2 Total prostate specific antigen

Total PSA values were obtained using the Hybritech PSA method on the Beckman Access. A second sample was added to a reaction vessel with mouse monoclonal anti-PSA alkaline phosphatase conjugate and paramagnetic particles coated with a second mouse monoclonal anti-PSA antibody. The PSA in the sample bound to the immobilized monoclonal anti-PSA on the solid phase while, at the same time, the monoclonal anti-PSA conjugate reacted with a different antigenic site on the sample PSA. The light production was proportional to the concentration of PSA in the sample.

6.3 Prostate specific antigen ratio

This ratio was calculated by dividing the free PSA by the total PSA:
LBDP3 = round ((LBXP2/LBXP1)*100)

(7) 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 NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Analytic methodology section.

(8) Analytic Notes for Data Users:

8.1 The analysis of NHANES 2001-2002 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2001-2002 Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interview and MEC examination. 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.

8.2 Data on health conditions that would make a sample person ineligible for PSA testing are missing for some people (n=60) with non-missing PSA lab data. This happened mainly because some sample persons did not attend the

physician's examination component of the MEC examination where such data were collected. It is advisable to exclude these observations for PSA analyses.