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

Laboratory 16 – Urinary Creatinine and Albumin

(1) Documentation File Date – Septmber 3, 2003

(2) Documentation File Name-Laboratory 16 – Urinary Creatinine and Albumin

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

(4) Component Description

Urinary albumin and creatinine were measured. Related survey questionnaire data include information on analgesic product use and incontinence.

(5) Sample Description:

5.1 Eligible Sample

Participants aged 6 years and older were tested.

(6) Description of the Laboratory Methodology

6.1 Urinary creatinine

Creatinine analysis uses a Jaffé rate reaction, in which creatinine reacts with picrate in an alkaline solution to form a red creatinine-picrate complex. The reaction is measured with a CX3 analyzer. The rate of the color development is measured 25.6 sec after sample injection at 520 nm and at 560 nm. The rate difference between the two wavelengths is proportional to the concentration of creatinine in the reaction cup. The procedures described below are the standard protocols of the Fairview University Medical Center (FUMC)[11a,11b,11c,11d,11e]

Creatinine, the waste product derived from creatine, is released into the plasma at a relatively constant rate. The amount of creatinine per unit of muscle mass is constant; therefore, creatinine is the best indicator of impaired kidney function.

6.2 Urinary albumin

A solid-phase fluorescent immunoassay for the measurement of human urinary albumin is described by Chavers et al.[11f]. The fluorescent immunoassay is a noncompetitive, double-antibody method for the determination of human albumin in urine. Antibody to human albumin is covalently attached to derivatized polyacrylamide beads. The solid-phase antibody is reacted with a urine specimen. The urine albumin-antigen complexes with the solid-phase antibody.

This complex then reacts with fluorescein-labeled antibody. Remove the unattached fluorescent antibody by washing during centrifugation. Determine the fluorescence of the stable solid-phase antibody complex with a fluorometer. The fluorescence is directly proportional to the amount of urine albumin present. The standard curve is 0.5-20 µg/mL albumin.

Increased microalbuminuria is a sign of renal disease and may be predictive of nephropathy risk in patients with insulin-dependent diabetes. Results of the fluorescent immunoassay (FIA) are reproducible, and the test is accurate and sensitive for the detection of human urinary albumin excretion. It is especially useful for measurement of low levels of urinary albumin not detectable by dipstick methods. The FIA assay resembles the radio-immunoassay (RIA) in technique and sensitivity without the potential health hazards associated with the handling of isotopes in the laboratory[11f]

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

(8) Data Processing and Editing

Urine specimens were processed, stored and shipped to University of Minnesota, Minneapolis, Minnesota for analysis. 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 Description of the Laboratory Methodology section.

(9) Data Access:

All data are publicly available.

(10) Analytic Notes for Data Users:

The analysis of NHANES 2001-2002 laboratory data must be conducted with the key survey design and basic demographic variable. The NHANES 2001-2002 Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain all survey design variables and 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.

(11) References

a. Creatinine Measurement Module Operating and Service Instructions, Beckman ASTRA. Brea (CA): Beckman Instruments, Inc., 1979.

b. Operating and Service Instructions, Beckman ASTRA. Brea (CA): Beckman Instruments, Inc., 1986.

c. Maintenance Guide, Beckman ASTRA. Brea (CA): Beckman Instruments, Inc., 1982.

d. Tietz NW, editor, Textbook of clinical chemistry. Philadelphia: WB Saunders Company, 1986:775-85, 1173-202, 1266-81, 1347-55, 1386-92.

e. Kaplan LA, Pesce AJ, editors, Clinical Chemistry Theory, Analysis and Correlation. St. Louis: CV Mosby Company, 1984:416-8, 1032-5, 1044-5, 1051-6, 1075-8, 1234-9, 1247-53, 1257-61.

f. Chavers BM, Simonson J, Michael AF. A solid-phase fluorescent immunoassay for the measurement of human urinary albumin. Kidney Int. 1984;25:576-8.