# National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Albumin & Creatinine - Urine (ALB\_CR\_I)

Data File: ALB\_CR\_I.xpt

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Last Revised: NA

### Component Description

Albumin measurements are used in the diagnosis and treatment of diseases involving the liver and/or kidneys. These measurements are frequently used to assess nutritional status, due to plasma levels of albumin being dependent on protein intake. Increased microalbuminuria is a sign of renal disease and may be predictive of nephropathy risk in patients with type 1 and type 2 diabetes. It is also associated with hypertension and cardiac disease.

Creatinine is produced by creatine and creatinine phosphate as a result of muscle metabolic processes. It is then excreted by glomerular filtration during normal renal function. Creatinine may be measured in both serum and urine. Creatinine measurement is useful in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urinary analytes (e.g., total protein and microalbumin).

## Eligible Sample

Examined participants aged 3 years and older were eligible.

## **Description of Laboratory Methodology**

#### **Urinary Albumin**

A solid-phase fluorescent immunoassay for the measurement of human urinary albumin is described by Chavers et al. (Chavers, BM, Kidney Int. 1984; 25:576–578). The fluorescent immunoassay is a non-competitive, 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, and the urine albumin-antigen complexes with the solid-phase antibody. This complex then reacts with fluorescein-labeled antibody. The unattached fluorescent antibody is then removed by washing during centrifugation. The fluorescence of the stable solid-phase antibody complex is determined with a fluorometer; the fluorescence is directly proportional to the amount of urine albumin present. The standard curve is  $0.5-20~\mu g/mL$  of albumin.

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 the 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 (Chavers, BM, Kidney Int. 1984; 25:576–578).

#### **Urinary Creatinine**

Creatinine is produced by creatine and creatinine phosphate as a result of muscle metabolic processes. It is then excreted by glomerular filtration during normal renal function. Creatinine may be measured in both serum and urine. Creatinine measurement is useful in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urinary analytes (e.g. total protein, microalbumin).

In this enzymatic method creatinine is converted to creatine under the activity of creatininase. Creatine is then acted upon by creatinase to form sarcosine and urea. Sarcosine oxidase converts sarcosine to glycine and hydrogen peroxide, and the hydrogen peroxide reacts with chromophore in the presence of peroxidase to produce a color product that is measured at 546 nm (secondary wavelength = 700 nm). This is an endpoint reaction that agrees well with recognized HPLC methods, and it has the advantage over Jaffe picric acid-based methods that are susceptible to interferences from non-creatinine chromogens.

Refer to the Laboratory Method Files section for detailed description of the laboratory methods used.

There were no changes to the lab method, lab equipment, or lab site for this component in the NHANES 2015-2016 cycle.

### Laboratory Method Files

Urine Creatinine (September 2017)

Urine Albumin (September 2017)

### Laboratory Quality Assurance and Monitoring

Urine samples are processed, stored, and shipped to University of Minnesota, Minneapolis, MN for analysis.

Detailed instructions on specimen collection and processing are discussed in the NHANES Laboratory Procedures Manual (LPM). Vials are stored under appropriate frozen (-30°C) conditions until they are shipped to University of Minnesota for testing.

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed QA/QC instructions are discussed in the NHANES LPM.

#### **Mobile Examination Centers (MECs)**

Laboratory team performance is monitored using several techniques. NCHS and contract consultants use a structured competency assessment evaluation during visits to evaluate both the quality of the laboratory work and the quality-control procedures. Each laboratory staff member is observed for equipment operation, specimen collection and preparation; testing procedures and constructive feedback are given to each staff member. Formal retraining sessions are conducted annually to ensure that required skill levels were maintained.

#### **Analytical Laboratories**

NHANES uses several methods to monitor the quality of the analyses performed by the contract laboratories. In the MEC, these methods include performing blind split samples collected on "dry run" sessions. In addition, contract laboratories randomly perform repeat testing on 2% of all specimens.

NCHS developed and distributed a quality control protocol for all CDC and contract laboratories which outlined the use of Westgard rules (Westgard et al., 1981) when

running NHANES specimens. Progress reports containing any 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 quarterly. The reports are reviewed for trends or shifts in the data. The laboratories are required to explain any identified areas of concern.

All QC procedures recommended by the manufacturers were followed. Reported results for all assays meet the University of Minnesota quality control and quality assurance performance criteria for accuracy and precision, similar to the Westgard rules.

### Data Processing and Editing

The data were reviewed. Incomplete data or improbable values were sent to the performing laboratory for confirmation.

URDACT, the urine albumin/creatinine ratio was created in this data file:

The random urine albumin (URXUMA) in ug/mL and urine creatinine (URXUCR) in mg/dL were converted to the albumin/creatinine ratio (URDACT) in mg/g:

URDACT = URXUMA/URXUCR x 100, round to .01

### **Analytic Notes**

Refer to the 2015-2016 Laboratory Data Overview for general information on NHANES laboratory data.

#### **Demographic and Other Related Variables**

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES 2015-2016 Demographics File contains demographic data, health indicators, and other related information collected during household interviews as well as the sample design variables. The recommended procedure for variance estimation requires use of stratum and PSU variables (SDMVSTRA and SDMVPSU, respectively) in the demographic data file.

This laboratory data file can be linked to the other NHANES data files using the unique survey participant identifier (i.e., SEQN).

#### **Detection Limits**

The detection limits were constant for all of the analytes in the data set. Two variables are provided for each of these analytes. The variable name ending in "LC" (ex., URXUMALC) indicates whether the result was below the limit of detection: the value "0" means that the result was at or above the limit of detection, "1" indicates that the result was below the limit of detection. For analytes with analytic results below the lower limit of detection (ex., URXUMALC=1), an imputed fill value was placed in the analyte results field. This value is the lower limit of detection divided by the square root of 2 (LLOD/sqrt[2]). The other variable prefixed URX (ex., URXUMA) provides the analytic result for that analyte.

The lower limit of detection (LLOD) in ug/ml for albumin and in mg/dL for creatinine is:

Variable Name	Name SAS Label	
URXUMA	Albumin, Urine	0.30 μg/mL
URXUCR	Creatinine, urine (mg/dL)	1.10 mg/dL

Please refer to the NHANES Analytic Guidelines and the on-line NHANES Tutorial for further details on the use of sample weights and other analytic issues.

### References

- Burtis, CA, Ashwood, EA, Bruns, DE, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis. Elsevier Inc., 2006.
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- National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. Table 14: Prevalence of Stages of Chronic Kidney Disease and Levels of Kidney Function in the US. Am J Kidney Dis 39:S1-S266, 2002 (suppl 1).
- NHANES Laboratory Procedural Manual. Section 5: Urine Specimen Collection and Processing, http://www.cdc.gov/nchs/data/nhanes/nhanes\_09\_10/Lab.pdf
  NHANES home urine collection manual Available From: Available from: http://www.cdc.gov/nchs/data/nhanes/nhanes 09 10/HomeUrine.pdf
- Operating and Service Instructions, Beckman ASTRA. Brea (CA): Beckman Instruments, Inc., 1986.
- Tietz NW, editor, Textbook of Clinical Chemistry. Philadelphia: WB Saunders Company, 1986;775–1392.
- Westgard J.O., Barry P.L., Hunt M.R., Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem (1981) 27:493-501.

# Codebook and Frequencies

### SEQN - Respondent sequence number

Variable Name: SEQN

SAS Label: Respondent sequence number

**English Text**: Respondent sequence number.

Target: Both males and females 3 YEARS - 150 YEARS

# URXUMA - Albumin, urine (ug/mL)

Variable Name: URXUMA

SAS Label: Albumin, urine (ug/mL)

English Text: Albumin, urine (ug/mL)

Target: Both males and females 3 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to I tem
0.21 to 9730	Range of Values	8280	8280	
	Missing	328	8608	

# URDUMALC - Albumin, urine comment code

Variable Name: URDUMALC

SAS Label: Albumin, urine comment code

English Text: Albumin, urine comment code

Target: Both males and females 3 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0	At or above the detection limit	8277	8277	
1	Below lower detection limit	3	8280	
	Missing	328	8608	

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# URXUMS - Albumin, urine (mg/L)

Variable Name: URXUMS

SAS Label: Albumin, urine (mg/L)

English Text: Albumin, urine (mg/L)

Target: Both males and females 3 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to I tem
0.21 to 9730	Range of Values	8280	8280	
	Missing	328	8608	

# URXUCR - Creatinine, urine (mg/dL)

Variable Name: URXUCR

SAS Label: Creatinine, urine (mg/dL)

**English Text**: Creatinine, urine (mg/dL)

Target: Both males and females 3 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to I tem
2 to 705	Range of Values	8280	8280	
	Missing	328	8608	

# URDUCRLC - Creatinine, urine comment code

Variable Name: URDUCRLC

SAS Label: Creatinine, urine comment code

English Text: Creatinine, urine comment code

Target: Both males and females 3 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0	At or above the detection limit	8274	8274	
1	Below lower detection limit	6	8280	
	Missing	328	8608	

# URXCRS - Creatinine, urine (umol/L)

Variable Name: URXCRS

SAS Label: Creatinine, urine (umol/L)

**English Text**: Creatinine, urine (umol/L)

Target: Both males and females 3 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to I tem
176.8 to 62322	Range of Values	8280	8280	
	Missing	328	8608	

# URDACT - Albumin creatinine ratio (mg/g)

Variable Name: URDACT

SAS Label: Albumin creatinine ratio (mg/g)

**English Text:** Albumin creatinine ratio (mg/g)

Target: Both males and females 3 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to I tem
0.22 to 21152.17	Range of Values	8280	8280	
	Missing	328	8608	