

Attachment C.

Protocol for Collection of Second Urine Specimen (ages 6+)

**National Health and Nutrition Examination Survey (NHANES)
Second Urine Specimen Collection Pilot Study**

OMB no. 0920-0237
Expires: 11/30/2009

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Second Urine Specimen Collection Protocol:

Eligibility: Only sample persons aged 6 years or older are eligible for one or more parts of the urine flow component.

Informed Consent: Informed consent will be obtained as a part of standard NHANES consenting procedures.

Exclusion Criteria: There are no exclusions for the Urinary Flow Rate component and urine collection does not pose a risk to participants.

Study Design: Pilot 2 of a Second Urine Specimen Collection to Measure Albumin and Creatinine:

Specimen Collection:

A second urine sample will be collected from a subsample of NHANES examinees to assess persistent albuminuria and confirm the presence of kidney damage. Depending on the results of the first urine specimen analysis, a second urine sample will be collected in the participants' home.

Laboratory Testing:

A casual urine specimen consisting of a complete void will be collected on all NHANES examinees 6 years and older in NHANES 2009-10. Prior to 2009, survey participants were asked to fill a single cup of urine rather than multiple urine cups as is required for a complete void. The urine specimens will be analyzed for urinary creatinine and albumin. Based on the results of the analyses a second urine collection will be requested of a subset of examinees

The results from the first urine test will be reported to NCHS within 21 days of collection. The urine albumin to urine creatinine ratio (ACR) as calculated by $(\text{urine albumin}/\text{urine creatinine}) * 100$ will be calculated. Participants whose albumin/creatinine ratio value was greater than 10 ug/mg will be asked to provide a second urine sample.

The survey contractor (Westat, Inc.) will mail a second urine collection kit to the eligible participants. The kit will have instructions on how to collect the urine at home and return the urine specimen to the testing laboratory. In order to have a larger sample size during the pilot, an additional five percent of participants, without ACR values greater than 10 ug/mg, will also be chosen at random to participate in the home urine collection.

Report of Findings:

These ACR results will be reported to the participant.