|  |
| --- |
| **Urinary Creatinine Assay for Kidney Function** |
| **Protocol Id** | 141601 |
| **Version#** | 1 |
| **Description of Protocol** | This protocol provides basic instructions for collecting and processing urine according to National Health and Nutrition Examination Survey (NHANES) methods. Creatinine concentration in a participant’s morning urine sample is measured according to the Jaffe rate method. The protocol also lists reference ranges for healthy adults. |
| **Specific Instructions** | The Diabetes Working Group recommends that the urine creatinine assay be performed on urine collected during a participant’s morning void, but notes that a random sample is also acceptable.The Sickle Cell Disease Research and Scientific Panel notes that urine creatinine is used to standardize the excretion of certain solutes in urine (urine concentration of solute "x" divided by the urine concentration of creatinine), and avoids a 24-hour urine collections. In a steady state, the urine excretion rate of creatinine is constant for a particular individual, thus providing a method to detect changes in their excretion rates in a longitudinal fashion. However, the urinary excretion of creatinine reflects the level of muscle mass, which is affected by nutrition, gender and age characteristics. Since muscle mass may be decreased in some individuals with sickle cell disease, caution should be used when comparing values in adults vs children or vs non-sickle cell disease populations. |
| **Protocol Text** | The following is a summary version of the full National Health and Nutrition Examination Survey 2007-2008 protocol.**Urine Collection***Editor’s Note:**Please review chapter 5 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey2007-2008 for a full description of urine collection and processing procedures:*[2007-2008 NHANES Lab Manual](file:///C%3A%5CUsers%5Chpan%5CDownloads%5Ctoolkit_content%5Csupplemental_info%5Cdiabetes%5Cadditional_info%5CNHANES_Lab_Manual.pdf)*.*The coordinator explains the following instructions to the subject before urine collection:• Wash hands with soap and water;• It is important that the cup and cap not touch or come into contact with any parts of the body, clothing, or external surfaces; and• Close container to minimize exposure to air.Refrigerate all insufficient urine samples. When additional urine is obtained, pool the urine, mix, and process.**Record the Results of Urine Specimen Collection**Note whether or not urine was collected, whether the volume of urine was sufficient or required a second specimen.Note whether blood is present / visible in the specimen.**Process the Urine for the Urinary Creatinine Assay**Pour 3-mL of the specimen for urine creatinine into a 5-mL vessel.*Note from the Diabetes Working Group: Urine should be stored at -80°C until testing and shipped on dry ice to prevent thawing.***Laboratory Procedure for Urinary Creatinine**The Diabetes Working Group recommends that urine creatinine concentration be determined according to the Jaffe rate method developed by the University of Minnesota for use in the National Health and Nutrition Examination Survey:[Urine Creatinine Laboratory Assay](file:///C%3A%5CUsers%5Chpan%5CDownloads%5Ctoolkit_content%5Csupplemental_info%5Cdiabetes%5Cadditional_info%5CNHANES_Urinary_Creatinine.pdf)*.*To aid comparability, the Diabetes Working Group recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.**REFERENCE RANGES**

|  |  |
| --- | --- |
| **Age, years** | **Range per day** |
| 2-3 | 6-22 mg/kg/d |
| 4-16 | 12-30 mg/kg/d |
| >16, male | 1.0-2.0 g/d |
| >16, female | 0.8-1.8 g/d |

 |
| **Selection Rationale** | The National Health and Nutrition Examination Survey 2007-2008 protocol was selected as the best practice methodology and one of the most widely used protocols to measure urine creatinine. Additionally, the Jaffe protocol used by National Health and Nutrition Examination Survey and developed by the University of Minnesota has been used in other studies, including Atherosclerosis Risk in Communities (ARIC) and Family Investigation of Nephropathy and Diabetes (FIND). |
| **Source** | Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. Laboratory Procedures Manual. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2007.Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. University of Minnesota Laboratory Procedures Manual for Urinary Creatinine by Beckman Synchron CX3 Clinical Analyzer. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2007. |
| **Language** | English, Spanish |
| **Participant** | Participant 6 years of age or older. |
| **Personnel and Training Required** | Personnel to collect the urineLaboratory to perform the Jaffe rate assay |
| **Equipment Needs** | Supplies to collect and process urine |
| **Standards** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Standard** | **Name** | **ID** | **Source** |
| Common Data Elements (CDE) | Urinary Creatinine Protein Assessment Value | 2183351 | [CDE Browser](https://cdebrowser.nci.nih.gov/CDEBrowser/search?elementDetails=9&FirstTimer=0&PageId=ElementDetailsGroup&publicId=2183351&version=1.0) |
| Logical Observation Identifiers Names and Codes (LOINC) | Urinary creatinine assay proto | 62811-5 | [LOINC](http://s.details.loinc.org/LOINC/62811-5.html?sections=Web) |

 |
| **General References** | Allon, M., Lawson, L., Eckman, J.R., Delaney, V., & Bourke, E. (1988). Effects of nonsteroidal antiinflammatory drugs on renal function in sickle cell anemia. Kidney International, 34, 500-506.de Jong, P.E., de Jong-Van Den Berg, T.W., Sewrajsingh, G.S., Schouten, H., Donker, A.J.M., & Statius van Eps, L.W. (1980). The influence of indomethacin on renal hemodynamics in sickle cell anemia. Clinical Science, 59, 245-250.Guasch, A., Cua, M., & Mitch, W.E. (1996). Early detection and the course of glomerular injury in patients with sickle cell anemia. Kidney International, 49, 786-791.Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. (2013). KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney International Supplement, 3, 1-150. |
| **Protocol Type** | Bioassay |
| **Derived Variables** | **Microalbuminaria**Ratio of urine microalbumin to urine creatinine

|  |  |
| --- | --- |
|  | Ratio of albumin / creatinine (ug/mg) |
| Normal | <30 |
| Microalbuminaria | 30-299 |
| Macroalbuminaria | >299 |

American Diabetes Association. (2010). Diagnosis and classification of diabetes mellitus. *Diabetes Care*, 33 (Supplement 1), S11 - S61. |
| **Requirements** |

|  |  |
| --- | --- |
| **Requirement Category** | **Required** |
| Average time of greater than 15 minutes in an unaffected individualAverage time of greater than 15 minutes in an unaffected individual | No |
| Major equipmentThis measure requires a specialized measurement device that may not be readily available in every setting where genome wide association studies are being conducted. Examples of specialized equipment are DEXA, Echocardiography, and Spirometry | No |
| Specialized requirements for biospecimen collectionThis protocol requires that blood, urine, etc. be collected from the study participants. | No |
| Specialized trainingThis measure requires staff training in the protocol methodology and/or in the conduct of the data analysis. | No |

 |