



New Reference Material for Diagnosing Kidney Disease

<http://www.firstlight.cn> 2007-03-19

March 16, 2007, The National Institute of Standards and Technology (NIST) has developed a new reference material to help improve the accuracy of clinical diagnostic tests for chronic kidney disease. The new Standard Reference Material (SRM) consists of samples of frozen human blood serum certified by NIST for two different concentrations of creatinine.

Chronic kidney disease (CKD) is a growing problem in the United States. It can be caused by high blood pressure, diabetes and other disorders. If left untreated, it eventually can lead to kidney failure. The National Kidney Disease Outcome Quality Initiative* reported that end-stage renal disease has dramatically increased in the past two decades, and estimated that close to 20 million Americans probably have early stages of CKD.

Timely diagnosis is a significant problem. Kidney function is measured by “glomerular filtration rate” (GFR), which provides an estimate of how well the kidneys are removing waste and excess fluid from the blood. GFR cannot be measured directly in a clinical setting, so instead physicians test for blood serum levels of creatinine, a metabolic by-product of muscles. Plugging the creatinine level into an equation that factors in other variables, including age, gender and race, yields an estimated GFR value. Detecting relatively small changes in serum creatinine levels is key to early diagnosis of CKD, but studies summarized in a recent paper** from the National Kidney Disease Education Program (NKDEP, an initiative of the National Institutes of Health) noted that the current variability in serum creatinine measurements is too large to detect small increases in creatinine.

The new NIST SRM 967, Creatinine in Frozen Human Serum, was developed in collaboration with the NKDEP and the College of American Pathologists (CAP) to meet the need for improved calibration of clinical instruments and procedures for measuring serum creatinine. The SRM consists of frozen human serum with two different levels of creatinine. Level 1 (0.75 mg/dL) is within the normal range of serum creatinine levels, while Level 2 (3.92 mg/dL) is intended to correspond to levels found in chronic kidney disease.

[存档文本](#)