How Well Do You Know Your Urine Albumin?

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Renal disease is a major global health concern of the 21st century, and it is estimated that approximately 27 million adults within the United States have been diagnosed with chronic kidney disease (CKD).[1] CKD is defined as the presence of structural or functional abnormalities of the kidney and is associated with increased mortality/morbidity and significant health care costs. Urine albumin is a major diagnostic and prognostic biomarker of renal disease and is critical for clinical decisions associated with renal therapy. Therefore, accurate measurement of urine albumin is vital to the clinical diagnosis of renal dysfunction and the evaluation of renal treatment efficacy. Although urine albumin-specific assays are routinely used in clinical laboratories to assess patient samples, there are distinct biochemical (analyte heterogeneity) and analytical (inter-method variability) challenges that affect the precision of urine albumin measurements. To support the accuracy and comparability of clinical urine albumin measurements, the National Institute of Standards and Technology (NIST) is partnering with the National Kidney Disease Education Program (NKDEP) and the International Federation of Clinical Chemistry (IFCC) Working Group for the Standardization of Albumin Assays in Urine (WG-SAU) to develop a reference measurement system for urine albumin.[2] The development of a reference measurement system for urine albumin will create a chain of traceability that will link routine clinical measurements to the International System of Units (SI units) through a series of higher-order reference measurement procedures (RMPs) and reference materials. [3]

The “Urine Albumin Team” at NIST has developed the following components of the urine albumin reference measurement system: a multiplexed candidate RMP that utilizes isotope dilution-mass spectrometry (ID-MS) and multiple reaction monitoring (MRM) to target and quantify full-length urine albumin; a primary reference material to be used as a calibrator for higher-order urine albumin methods; and a secondary reference material to be used as a matrix-based quality control for commercially-available urine albumin assays.[4] The candidate RMP incorporates an isotopically-labeled (^{15}N) full-length recombinant human serum albumin (^{15}N-*r*HSA) material as the internal standard, which permits the absolute quantitation of full-length urine albumin via a mass spectrometry-based approach. Use of the full-length internal standard facilitates the quantification of multiple regions of the albumin

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molecule to reduce the influence of albumin heterogeneity in the measurement and subsequently increases the precision and accuracy of the urine albumin measurement. The high degree of selectivity and sensitivity of the multiplexed urine albumin candidate RMP coupled with the highly purified primary reference material (SRM 2925: Human Serum Albumin Solution) will support the value-assignment efforts of the matrix-based urine albumin secondary reference material. The NIST SRM 3666: Albumin and Creatinine in Frozen Human Urine, will function as a secondary (matrix-based) reference material and is essential to the urine albumin reference measurement system because it resembles the samples encountered in clinical laboratories. The secondary urine albumin reference material can be used as a quality assessment tool for clinical laboratories and also as a quality control material for assay manufacturers to verify the accuracy of their urine albumin measurements.

Therefore, the development of a reference measurement system for urine albumin should draw us closer to knowing the true status of our urine albumin.

What’s your urine albumin status...

References

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