



## **Educational Discussion: Accuracy Based Urine**

### **2017-A Accuracy Based Urine**

The ABU-A Survey used pooled real urine specimens selected to achieve specified albumin concentrations. The Survey materials are expected to be free of artifactual matrix effects, and therefore comparisons may be made between participants' results, or method group mean or median values, and to the reference method values for urine albumin. Similarly, a participant's results can be compared to the method group mean or median values for urine calcium and creatinine.

As was observed in previous ABU Surveys, the agreement among different methods for urine creatinine and calcium was good. The lowest and highest median values for calcium were 6%-8% different, and for creatinine were 14%-15% different.

Discrepancies were observed for urine albumin among results from different manufacturers that are large enough to affect clinical decisions regarding kidney damage. The number of participants who used each method type was small so only the medians can be compared and there is some uncertainty in those values. Urine albumin results for Siemens Dimension Vista immunonephelometric method and for Vitros FS series immuno-turbidimetric method agreed well with the reference method which was isotope dilution-liquid chromatography-tandem mass spectrometry.

The Abbott, Beckman and Roche immuno-turbidimetric methods agreed with each other but were 13%-15% low at 36 mg/L urine albumin and 9.5%-16% low at 184 mg/L urine albumin compared to the reference method. Considering the uncertainty due to the small number of participants in each method group, this amount of bias is close to the  $\pm 13\%$  maximum recommended by the Laboratory Working Group of the National Kidney Disease Education Program (J Applied Laboratory Medicine 2017, in press). The bias for these three methods at 16 mg/L urine albumin was 20%-26% that exceeds the recommended maximum bias. Taken together, these results suggest that improvement in calibration bias is needed for these three methods.

Urine albumin is reported as albumin to creatinine ratio (ACR) consequently the bias from each analyte influences the ratio. When results from all methods were combined, the difference between the lowest and highest ACR values were 76% at 15 mg/g, 49% at 60 mg/g, and 65% at 237 mg/g. These differences are quite large and will cause misclassification of risk of kidney disease at the commonly used decision values of 30 mg/g for microalbuminuria and 300 mg/g for macroalbuminuria.

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Accuracy Based Testing Committee