

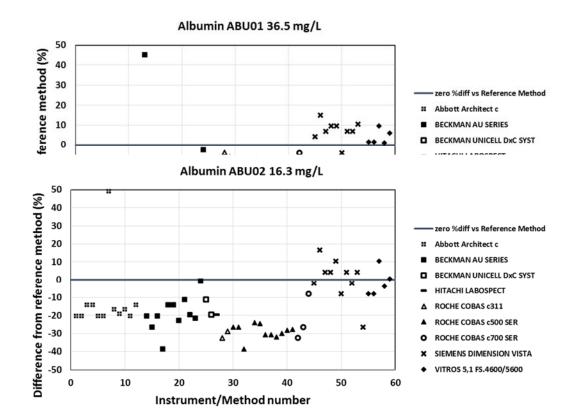
**Educational Discussion: Accuracy Based Urine** 

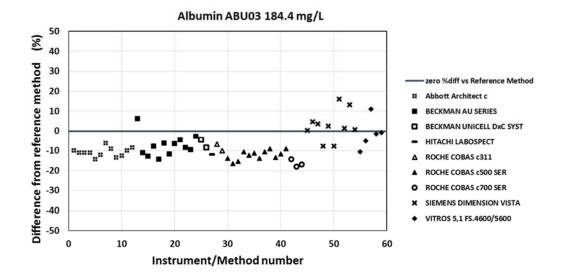
#### 2019-A

### Performance of Urine Albumin in the ABU-A 2019 Survey

The ABU Survey includes 3 different fresh-frozen pooled urine specimens in each mailing. The fresh-frozen pooled urine specimens are from donors who had normal or elevated urine albumin. The urine was kept cold during collection and storage, pooled, filtered and frozen in aliquots at -70°C within 5 days of collection. No supplements or preservatives were added. The fresh-frozen urine specimens were allowed to thaw in transit to participants. The fresh-frozen urine specimens are expected to be free of influence from matrix effects, and therefore comparisons made between participants' results, or among method group mean/median values, reflect performance expected for patients' specimens.

The figures that follow show the percent difference for urine albumin measurements compared to a candidate IDMS reference method performed by the Renal Testing Laboratory at Mayo Clinic. At the present time, there is not a certified reference material for albumin so the calibration of the candidate reference method is traceable to calibrators prepared from commercially available human albumin.



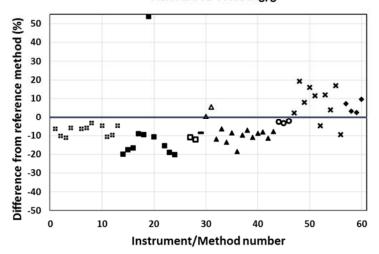


The results for urine albumin from individual laboratories are reasonably consistent among methods used by the laboratories at all 3 concentrations. Most measurement procedures produced lower results than the candidate IDMS reference method. Results from Siemens Dimension Vista and Vitros agreed well with the IDMS values for all of the ABU specimens. For specimens ABU-01 and ABU-02, one laboratory using the Beckman AU series method and one laboratory using the Abbott Architect c series method had a value biased much higher than that of other laboratories suggesting an error in that laboratory not reflecting typical performance for that manufacturer's method.

The results for urine creatinine had reasonably good agreement among different laboratories and methods with median values 51.9-55.8 mg/dL, 83.3-88.5 mg/dL and 66.4-69.8 mg/dL for specimens ABU-01, ABU-02 and ABU-03 respectively.

The following figures show the percent difference for the urine albumin/creatinine ratio (ACR) reported for individual laboratories compared to the target ACR derived from creatinine measurements obtained using the Centers for Disease Control reference measurement procedure and albumin measurements obtained using the candidate IDMS reference method.

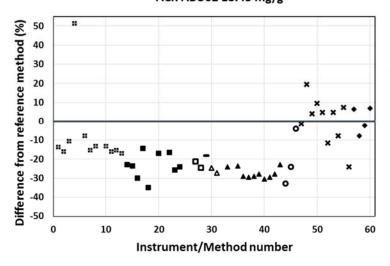
## ACR ABU01 66.30 mg/g



#### zero %diff vs Reference Method

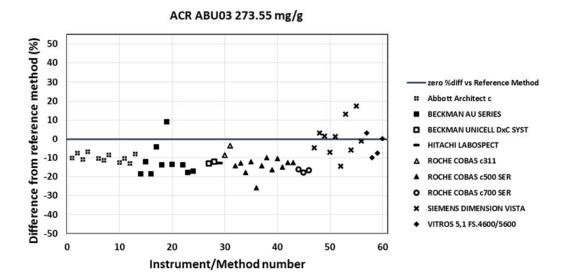
- # Abbott Architect c
- BECKMAN AU SERIES
- BECKMAN UNICELL DxC SYST
- HITACHI LABOSPECT
- ▲ ROCHE COBAS c311
- ROCHE COBAS c500 SER
- ROCHE COBAS c700 SER
- SIEMENS DIMENSION VISTA
- VITROS 5,1 FS.4600/5600

## ACR ABU02 18.43 mg/g



# -zero %diff vs Reference Method

- # Abbott Architect c
- BECKMAN AU SERIES
- BECKMAN UNICELL DxC SYST
- HITACHI LABOSPECT
- ▲ ROCHE COBAS c311
- ▲ ROCHE COBAS c500 SER
- O ROCHE COBAS c700 SER
- **★** SIEMENS DIMENSION VISTA
- VITROS 5,1 FS.4600/5600



The results for ACR had a pattern of differences that is very similar to that for albumin alone. Considering that urine creatinine results were consistent among all peer groups, the ACR differences were primarily due to differences in urine albumin results. The Laboratory Working Group of the National Kidney Disease Education Program is collaborating with the IFCC Working Group for Standardization of Urine in Albumin to develop a standardization program for urine albumin measurements.

## Other analytes

The results for urine calcium had good agreement among different methods with median values 6.1-6.5 mg/dL, 9.9-10.4 mg/dL and 6.8-7.3 mg/dL for specimens ABU-01, ABU-02 and ABU-03 respectively. The results for urine protein had reasonably good agreement but the number of participants who reported values was small making conclusions less robust.

Lorin Bachmann, PhD and Greg Miller, PhD Accuracy Based Programs Committee