



CPAL

Central Pennsylvania Alliance
Laboratory

Technical Bulletin

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Urine Creatinine -Change in Calibrator Traceability-

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Ordering Information and Suggested Codes:

Mnemonic:	MALBC
Test Name:	Microalbumin/Creatinine Group
Test Number:	3000380
Specimen:	Urine
LOINC Codes	34535-5
CPT Codes	82043,82570

Effective Date: July 16, 2018

Performed: Monday through Friday

Introduction:

In order to improve the traceability of the Urine Calibrator for Urine Creatinine, Beckman Coulter changed the traceability from the National Institute of Standards *NIST SRM 914a* (creatinine standard using deionized water) to an Isotope Dilution Mass Spectrometry (IDMS) reference method using the higher order reference material, *NIST SRM 3667* (creatinine in frozen human urine). As a result of this improvement, a decrease of approximately 13.5% in urine creatinine results for commercial controls and patient samples will be observed. This decrease in results will create a more homogenous group in External Quality Assurance scheme results for Urine Creatinine such as the College of American Pathologist (CAP), and will therefore align better with peers.

Validation Studies:

Calibrator Correlation:

Forty specimens were split and processed utilizing the current Beckman Coulter urine creatinine calibrator and the new urine creatinine calibrator with the new traceability. Quantitative analysis yielded a correlation coefficient (R) of 0.9999 with a slope of 0.872 and an intercept of -0.638 (Figure 1). Overall bias for the current calibrator vs the new calibrator was -13.170%. This is in alignment with Beckman Coulter's performance expectations.

Figure 1: Calibrator Coorelation

EP Evaluator®

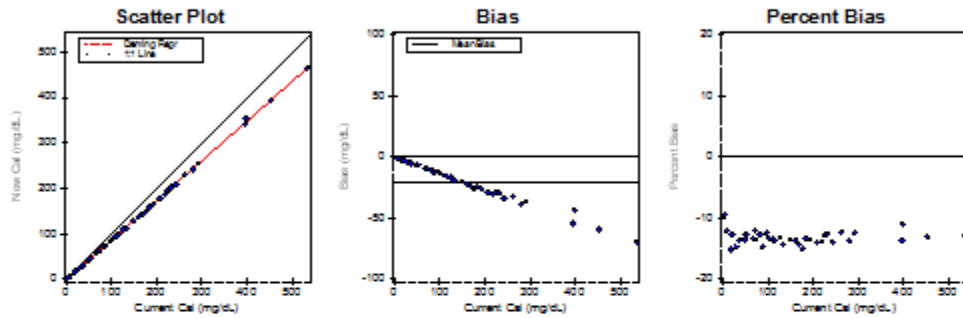
Clinical Laboratory – Wellspan Health

Urine creatinine

Alternate (Quantitative) Method Comparison

X Method Current Cal

Y Method New Cal



Regression Analysis

	Deming	Regular
Slope	0.872 (0.868 to 0.877)	0.872 (0.868 to 0.877)
Intercept	-0.638 (-1.571 to 0.295)	-0.623 (-1.556 to 0.310)
Std Err Est	1.817	1.817

95% Confidence intervals are shown in parentheses

Supporting Statistics

Corr Coef (R)	0.9999	SubRange Bounds	None
Bias	-20.585 (-13.170 %)	Points (Plotted/Total)	39/40
X Mean ± SD	156.306 ± 128.989	Outliers	1
Y Mean ± SD	135.722 ± 112.530	Scatter Plot Bounds	None
Std Dev Diff	16.571		

References:

1. Product Announcement Letter, Beckman Coulter, January 2018.