Evaluation of Whole Blood Creatinine and Urea Assays versus Abbott ARCHITECT c8000

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Introduction:
A fast reliable result of whole blood creatinine and BUN (blood urea nitrogen) could provide timely information to staffs in radiology, and ED for diagnosis and treatment of patients with renal disease. A Basic Metabolic Panel (BMP) cartridge based on electrochemical enzymatic creatinine and urea sensors for the GEM Premier analyzer (Instrumentation Laboratory) is currently in development. This is in addition to the electrolytes and metabolites offered on the GEM Premier analyzers. The goal of this evaluation is to compare the analytical performance of whole blood creatinine and urea in patient samples on the GEM Premier analyzer to current laboratory methods.

Method:
167 random heparinized whole blood samples were obtained from various sources (ED, radiology, ICU and Outpatient). Whole blood (WB) and Plasma samples were analysed on the GEM (IL) and Plasma on the ARCHITECT c8000 analyzer (Abbott Laboratory).

Results:

Creatinine
WB creatinine analysis compared well with the Jaffe method on reference analyzer.
GEM WB creatinine = 0.946 (Abbott plasma creatinine) – 0.029 (R² = 0.937)

The repeatability (CR, Coefficient of Repeatability) was measured as 0.18 mg/dL between 0.45 – 6.61 mg/dL with 115 patient samples which were assayed twice on GEM.

Negative interference by creatine on creatinine measurement was observed in patient samples with high creatine levels. The patient conditions were unknown as of the cause of high creatine levels. Creatine interference is detected by a built-in creatine sensor on the GEM.

Urea
WB urea analysis compared well with the Abbott plasma assay. The correlation showed slight positive bias on the GEM at lower concentrations and slight negative bias at higher concentrations.
GEM WB urea = 0.902 (Abbott plasma urea) + 3.29 (R² = 0.989)

The repeatability (CR, Coefficient of Repeatability) was measured as 2.2 mg/dL between 4 – 124 mg/dL with 115 patient samples which were assayed twice on GEM.

Conclusion:
Good correlation was observed between the GEM Premier whole blood creatinine and BUN assay verses the current laboratory methods. Based on its simplicity, convenience, and comparable accuracy, the GEM system is capable to provide reliable WB basic metabolic panel information in POCT environment where turnaround time is critical.