Evaluation of Whole Blood BUN, Creatinine and tCO$_2$ Assays vs. Roche Modular Chemistry Analyzer

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Introduction

Described is the performance of a new cartridge in development for GEM Premier system (Instrumentation Laboratory) to monitor basic metabolic panel in clinical patients. Complementing the existing menu on the GEM Premier 4000, the new cartridge enables fast, accurate and reliable measurements of BUN (or urea), creatinine and tCO$_2$ using electrochemical sensing technologies. Analytical results of these new sensors in the GEM system showed excellent correlation with the reference laboratory method in randomized blood samples collected from hospital patients.

Method

A total of 309 arterial and venous whole blood samples were collected. Whole blood (WB) and plasma samples were analyzed on the GEM system and plasma on Roche Cobas Modular using enzymatic methods. To evaluate overall precision of the GEM system, two replicate measurements were done on 74 WB samples. One GEM system and one cartridge with 3-month shelf-life were used in the clinical evaluation.

Result

BUN

The BUN levels as measured by the reference method were 1-90 mg/dL. WB BUN values by the GEM compared well with the plasma values by the reference method. Using the total allowable error of 9% or $\pm$ 2 mg/dL as the limiting ranges, the correlation data showed slightly positive bias on the GEM at lower levels and negative at higher levels (> 50 mg/dL). The coefficient of repeatability (CR) from the paired samples was 1.68 mg/dL.

GEM WB BUN = 0.894* (Roche plasma BUN) + 2.89 [R^2 = 0.986]

Creatinine

The creatinine levels as measured by the reference method were 0.2-8.6 mg/dL. WB creatinine values by the GEM were in good agreement with the plasma values by the reference method. The coefficient of repeatability (CR) from the paired samples was 0.083 mg/dL.

GEM WB creatinine = 0.953* (Roche plasma creatinine) – 0.081 [R^2 = 0.964]

Negative interference from high creatine levels on creatinine measurement was observed in several patient samples. Creatine interference was detected by the GEM via a built-in creatine sensor.

tCO$_2$

The tCO2 levels as measured by the reference method were 17.4-36.1 mmol/L. WB tCO$_2$ values by the GEM correlated well with the plasma values by the reference method. The coefficient of repeatability (CR) from the paired samples was 1.05 mmol/L.

GEM WB tCO$_2$ = 0.988* (Roche plasma tCO$_2$) – 0.59 [R^2 = 0.952]

Conclusion

Good agreement was observed between the GEM system and the reference laboratory methods. Based on its simplicity, convenience, and comparable accuracy to reference method, the GEM system can provide reliable WB basic metabolic panel information in POCT environment where turnaround time is critical.