Traceability and Accuracy Evaluation of POC StatStrip Blood Glucose Monitoring System and ABL 835 Bloodgas Analyzer to a Primary IDMS aligned Reference Measurement Procedure

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Background and aim: New guidelines have recently emerged (ISO and CLSI) and are about to emerge (FDA) outlining tighter performance criteria for POC glucose methods used in hospitals or for self-monitoring. To date limited evaluations have been undertaken against the emerging criteria. Primary reference methods used for performance evaluations should be traceable to the highest level order of methodology, isotope dilution GC Mass Spectrometry (ID-GCMS). The aim of this study was to reassess the performance of two POC glucose methods routinely used in our institute in comparison to our IDMS aligned primary reference method and to assess the results according to recent ISO 15197 and CLSI POCT 12 guidelines.

Methods: Our plasma hexokinase method (HK) has previously been shown to be aligned to ID-GCMS gold standard method using NIST standards and Eurotrol whole blood and plasma samples. The performance of two POC glucose methods routinely used in our institution StatStrip Glucose (Nova Biomedical) and ABL 835 (Radiometer) were assessed according to new ISO 15197 and CLSI POCT 12 guidelines. Arterial and venous whole blood samples were collected in Li-heparin syringes from adult ICU patients. The whole blood was tested using both StatStrip and ABL 835 and then immediately spun down and the plasma tested on the plasma hexokinase method (Roche COBAS Modular P800).

Results:
StatStrip Glucose showed excellent correlation to plasma hexokinase method
Glucose levels ranged from 0.5 mmol/L to 23.00 mmol/L. StatStrip Glucose showed a good correlation with the primary reference method. The correlation coefficient (r) for StatStrip Glucose was 0.973 with a slope of 0.958 and an intercept of 0.261 and for ABL was 0.975 with a slope of 1.001 and an intercept of 0.303. StatStrip Glucose demonstrated a mean % bias of 0.68% and ABL a mean % bias of 6.47% compared to the primary reference method. Both ABL and StatStrip Glucose met CLSI POCT 12-A3 and ISO 15197 2013 performance criteria.

Conclusion: Re-evaluation of routine POCT glucose methods is important in light of new recent guidelines with tighter performance criteria. Both StatStrip blood glucose POC meter and ABL 835 bloodgas analyzer met and exceeded the new CLSI POCT12-A3 and ISO15197:2013 criteria. Both methods have also demonstrated traceability to the ID-GCMS aligned hexokinase methods over several years.