

Comparison of the Nova Biomedical StatStrip Glucose Meter to an IDMS Hexokinase Glucose Method in Oncology and Renal Insufficient Patients – Demonstration of Utility in Critically Ill Patients

David Sartori¹, Athena Petrides¹, Chris Crutchfield¹, Leandra Soto¹, Lois Phelan¹, Jeffrey DuBois², Steven Presti², William Clarke¹

1) Johns Hopkins University School of Medicine, Department of Pathology, Baltimore, MD 21287

2) Nova Biomedical, Waltham, MA 02454

Background: In January 2014, the US Food and Drug Administration (FDA) deemed the use of previously approved glucose meters on critically ill patients as off label use and required manufactures to submit separate 510(k) requests to obtain approval for use in the critically ill population. The FDA expressed concern that acutely ill patients may have underlying physiological and/or pathological factors that could lead to interferences with glucose meters assays. In an IRB approved study, we collected remnant whole blood specimens from patients treated in our oncology units as well as from patients with renal insufficiency to compare whole blood glucose analyses using a Radiometer ABL 827 blood gas analyzer and a Nova Biomedical StatStrip glucose meter, as well as to the Roche Cobas c8000 IDMS traceable hexokinase method. We present the results of 78 oncology patients and 36 renal insufficient patients.

Methods: Arterial or venous whole blood (WB) remnant specimens in either a balanced heparinized syringe or in a lithium heparin, green top, blood collection tube collected for blood gas and/or WB analyses performed on an Radiometer 827 Blood Gas analyzer were obtained within 5 minutes of blood gas analysis. Whole blood glucose was then measured on two different Nova Biomedical StatStrip glucose meters in a blinded fashion to the operator. The remaining remnant specimen was divided into two aliquots and the aliquots centrifuged at ~1,500g for 5 min at room temperature. One fresh plasma aliquot was then analyzed on a Roche Cobas c8000 analyzer using the hexokinase isotope dilution mass spectrometry (IDMS) reference method in duplicate, in addition to measuring albumin and triglycerides. The second plasma aliquot was then frozen at -80 °C for additional GC-IDMS reference testing not yet performed. Patient's medical diagnosis and medications administered within the last 3 days were collected to determine possible interferences with the testing methods in the event of discordant results. Data analysis was performed following the Clinical and Laboratory Standards Institute (CLSI) POCT 12-A3 (2013).

Results: Throughout the study, four different Nova Biomedical StatStrip blood glucose meter systems were used (2 for an N = 23 and 2 for an N = 7). A single lot of strips (Lot #0313112309) was used and two levels of QC were used (QC Level 1 Lot # 0413326301 EXP 05/2016 and QC Level 3 Lot # 0413312303 EXP 05/2016). Day to day precision was calculated for each QC level (QC 1: SD 1.6 – 2.8 and %CV 2.8 – 4.7; QC 3: SD 6.3 – 12.4 and %CV 2.2 – 4.4). Per POCT 12-A3, 12/12 oncology specimens with reference glucose concentrations < 100 mg/dL were within ± 12 mg/dL. For specimens ≥100 mg/dL, 66/66 specimens were within 12.5% of the reference glucose concentrations. For the renal insufficient patients with WB creatinine ≥2.0 mg/dL, 7/8 specimens with reference glucose concentrations < 100 mg/dL were within ± 12 mg/dL. For specimens ≥100 mg/dL, 25/27 specimens were within 12.5% of the reference glucose concentrations. One specimen was >600 mg/dL which is the instrument's upper limit of linearity. Additionally, a Parkes error grid was prepared which specifies 5 risk levels associated with accuracy of a glucose measurement. Zone A defines the zone of clinical accurate measurements with no effect on clinical action. Zone B defines the zone of altered clinical action with little to no effect on clinical outcome. Zone C, D, and E defines the zones of altered clinical action with increasing negative effect on clinical outcome. For the oncology patients in this study, 75/76 specimens were within Zone A and 1/76 specimens were in Zone B. Likewise, for the renal insufficiency patients, 35/36 specimens were in Zone A with 1/36 specimens in Zone B.

Conclusion: Based on this study, the use of the Nova Biomedical StatStrip blood glucose meter system is appropriate for patients being treated for cancer and/or in those who are renal insufficient. Mean bias of the meters is 0.22% and 2.11% respectively.