

Analytical Evaluation of New Combined POC Blood Glucose/Ketone Monitoring System

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Background and Aim: Point-of-Care (POC) glucose and ketone (β -hydroxybutyrate) blood monitoring systems play an important role in the glycemic management of patients with diabetic ketoacidosis (DKA). It is important that blood glucose monitoring systems (BGMS) and blood ketone monitoring systems (BKMS) give accurate and reliable results which are not affected by interfering factors found in the blood of hospitalized patients. In Japan we have recently introduced the Nipro StatStrip XP3 and CT3 combined BGMS/BKMS. The BGMS/BKMS combined system can measure glucose and ketone by switching sensor (strip). The aim of this study was to assess the analytical performance of the newly introduced whole blood glucose/ ketone monitoring system.

Methods: The precision and linearity of the Nipro StatStrip XP3 Glu/Ket and CT3 Glu/Ket (with connectivity functionality) were assessed with whole blood samples. For comparison, Pocket ChemBG (Arkray) glucose meter and Freestyle Neo (Abbott) ketone meter were also assessed. The glucose laboratory reference method was GA-1150 (Arkray) and the ketone laboratory method was Wako BHB reagents (Wako) run on a LABOSPECT008 Automatic Analyzer (Hitachi). Precision was evaluated using 3 different glucose and ketone levels. For hematocrit interference study, five different hematocrit levels were evaluated at 3 different glucose and 3 different ketone levels. Interference of glucose measurements was assessed with ascorbic acid and oxygen and interference of ketone measurements was assessed with ascorbic acid, glucose and acetoacetate.

Results: Within-run precision of Nipro StatStrip Glucose and Pocket Chem BG demonstrated a CV% of 3.63% and 2.46% respectively at the highest glucose concentration tested. For Nipro StatStrip Ketone and Abbott Freestyle Neo demonstrated CV% of 4.17%, and 1.25%, respectively. The accuracy of Nipro StatStrip glucose and ketone measurements were unaffected by hematocrit or any of the other interfering substances, however, the accuracy of Pocket Chem BG glucose measurements was affected by hematocrit and ascorbic acid. The accuracy of Freestyle Neo ketone measurements was affected by hematocrit and ascorbic acid.

Conclusion. The Nipro StatStrip XP3 and CT3 combined BGMS/BKMS demonstrated good analytical performance and the accuracy of measurements was not affected by hematocrit, and other interfering substances.