

## Analytical performance assessment of two POC ketone assays

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**Introduction** – The accumulation of ketones in uncontrolled diabetes patients may result in diabetic ketoacidosis (DKA). If left untreated, DKA can lead to coma and death. Various studies have already demonstrated that blood beta hydroxybutyrate (BHB) measurement is the most effective for detecting ketosis and tracking the resolution of DKA. Therefore, Point-of-care (POC) ketone testing plays a central role in the therapeutic management of diabetes patients. Little is known about the accuracy of POC ketone assays and the influence of endogenous and exogenous interferences commonly occurring in critically ill hospitalised patients. The aim of our study was to assess the analytical and clinical performance of two point of care whole-blood ketone meters (BKM), Statstrip (Nova Biomedical, Waltham, MA, USA) and Optium Freestyle (Abbott, Alameda, CA, USA).

**Methods** – An analytical evaluation according to Clinical and Laboratory Standards Institute (CLSI) protocols for precision, method comparison, and interference was done. The interferences assessed included acetoacetate, acetone, ascorbic acid, glucose, haematocrit and lipemia. For the method comparison, BHB spiked heparinized whole blood samples were used and compared towards the central laboratory reference method, i.e. Randox reagents (Ranbut enzymatic reagents) on cobas 6000 c 501 analyzer (Roche Diagnostics, Mannheim, Germany). A method comparison using clinical heparinized whole blood patients samples is performed in parallel. During a three month period all patients tested for ketones in the OLV hospitals Aalst, Belgium were measured in duplo on Statstrip and Optium BKMS were used. After analysis on the BKMS these samples were immediately centrifuged and measured on cobas c501 analyzer. The data are statistically analyzed with Excel 2010 (Microsoft, USA) using deming regression and Bland-Altman residual plots analysis.

**Results** –The accuracies of both Optium and StatStrip ketone measurements were unaffected by the interferences tested with exception of varying hematocrit that influenced ketone measurements on both POC devices. The influence of haematocrit is more important on the Optium than on the Statstrip BKMS. Although Optium Freestyle showed better precision results, both POC devices fulfilled the precision performance criteria ( $SD < 0,1$  mmol/L for BHB results  $< 1$  mmol/L and  $CV\% < 10\%$  for BHB results  $\geq 1$  mmol/L). Method comparison showed good correlation throughout the whole measuring range with the reference method for both POC assays ( $r^2=0,99$ ) and within a total allowable error (TEa)  $< 0,3$  mmol/L for BHB results  $< 1$  mmol/L and  $TEa < 30\%$  for BHB results  $\geq 1$  mmol/L. At low concentrations ( $< 1$  mmol/L) Optium Freestyle reveals a slightly underestimation of the BHB results (mean difference=  $-27,4\%$  [ $-32,9$ ;  $-21,8$ ]), while StatStrip Ketone shows minor overestimation (mean difference=  $17,2\%$  [ $1,4$ ;  $32,98$ ]).

**Conclusion** – Both Optium and StatStrip ketone assays are analytical suitable to be used on hospital wards to diagnose DKA and guide therapeutic management of diabetic patients. However, awareness of the haematocrit interference is important, **certainly** especially for the Optium Freestyle BKMS. The results of the ongoing clinical method comparison are important to confirm our analytical findings.