

Assessment of the Accuracy and Imprecision of the StatStrip Ketones POC Monitoring Device Compared to Central Lab Methods

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Background: Proper, early, and accurate assessment of ketosis by the diabetic patient or health care professional is important in diagnosis and prevention of an acute condition known as diabetic ketoacidosis (DKA). An accurate quantitative easy to use method for measurement of ketones in whole blood has not been available in the Point of Care (POC) in Japan until recently. The traditional methods were qualitative nitroprusside methods that primarily detect acetone and acetoacetic acid. The StatStrip ketones meter (Nova Biomedical, Waltham, MA USA) was developed to measure beta hydroxybutyrate (β HB) in capillary whole blood specimens obtained by skin puncture. β HB represents ~80% of the “ketone bodies” present in the blood, which is the metabolite of greatest interest clinically. We evaluated the performance 2 POC ketone devices by compared the StatStrip and Optium Freestyle results to the Wako photometric method adapted to the clinical chemistry analyzer.

Materials and methods: Prior to the clinical evaluation a thorough lab analytical analysis was conducted to compare 2 POC devices, StatStrip Ketone and Optium Freestyle with the Wako ketone reagent method adapted (Wako, Tokyo, Japan) on a Hitachi LABOSPECT008 Automatic Analyzer (Hitachi High-Technologies, Tokyo, Japan). Following an IRB approved protocol, capillary and venous blood were collected from consented patients with the ketone level simultaneously measured on the StatStrip Ketone meter, Optium Freestyle meter, and the Wako ketone reagent method adapted to chemistry analyzer. The results were analyzed statistically for slope, intercept, correlation coefficient (r), and bias. Imprecision data was also collected and analyzed for the duration of the study.

Results: Both StatStrip Ketone and Optium Ketone demonstrated a close correlation to the laboratory method. StatStrip Ketone results had a slight negative bias (mean % bias -2.40%) whereas the Optium Ketone results showed a greater negative bias (mean % bias -17.97%).

Meter	r^2	Intercept (mmol/L)	Slope	Mean difference mmol/L (method – reference)	sd of differences (method – reference)	Mean % bias	Sample number
StatStrip	0.988	-0.062	1.048	0.0	0.24	-2.40	19
Optium	0.963	-0.152	1.008	-0.1	0.37	-17.97	18

Conclusions: This analytical assessment of StatStrip Ketone demonstrates that the meter correlates closely to the laboratory method. Although Optimum Ketone showed an acceptable correlation with the laboratory method there was more variability with results. The application to capillary blood in comparison to venous blood in ketonemic diabetic patients is ongoing and will be presented at the meeting.