Validation of the NOVA POCT StatStrip β-ketone test in a laboratory and clinical setting

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Background: Each year in Belgium 2000 patients are newly diagnosed with type 1 and 23 500 patients with type 2 diabetes mellitus (DM).[1] Diabetic ketoacidosis (DKA) is a severe acute complication of DM, with a prevalence around 30% in type 1 DM and 6% in type 2 DM.[2] Guidelines advocate whole-blood measurement of beta-hydroxybutyrate (βHB) for the management of DKA, making Point-of-Care testing (POCT) devices for glucose and ketones an important and live-saving tool.[3,4] On request of our Emergency Department the POCT hospital meter StatStrip® (Nova Biomedical, Waltham, MA, USA) was installed on trial.

Aim: To determine performance, possible interferences and correlation to a reference method of the POCT hospital meter StatStrip® for measurement of whole-blood βHB.

Materials and methods: The performance reliability was tested on eight StatStrip devices by means of assayed quality controls (QC) in two concentrations, according to CLSI-EP15 A3 protocol. For the correlation with our reference spectrophotometric method (Ranbut Assay®, Randox on Spectramax®) seventeen healthy volunteers fasted for 14h, 16h or 20h. βHB-values were obtained right before and after breaking their fast through fingerprick with StatStrip ketones meter. For the correlation at higher concentrations of βHB, samples are ongoingly collected from patients who present with symptoms of DKA at the Emergency Department and are triaged with the StatStrip ketones meter. An additional study will focus on interfering substances and their potential impact on the POCT meter (data to be included in the poster).

Results: Imprecision and accuracy (overall mean of all devices)

Quality Control	Target value (mmol/L)	Mean (mmol/L)	CV within run (%)	CV within lab (%)	Bias (%)
Level 2	0.7	0.69	10.4	14.7	3.2
Level 3	2.7	2.86	6.4	9.5	6.1

The FDA and CLSI acceptance criteria (CV% ≤10%) are met for QC level 3. Due to the low target value for QC level 2 the CV% are slightly higher than recommended. It should be noticed that values below 1.5 mmol/L are not considered clinically relevant in ER. The bias classifies as excellent (<10%) according to the criteria of the Belgian WIV-ISP institution.

Correlation of volunteers samples

N° of samples	r^2	Intercept	Slope	Linearity	SD of differences
17	0.76 (p<0.001)	0,01943	1,2025	No significant deviation from linearity (P=0,95)	0,09140 (CI -0,179 to 0,179)

The Bland-Altman plot did not show any consistent bias. According to Passing-Bablok regression, the slope (CI 0,7380 to 3,2258) and intercept (CI -0,2323 to 0,1255) are not significantly different from 1 and 0 respectively.

Conclusion: The StatStrip ketones meter shows a satisfactory analytical performance in regard to repeatability and reproducibility and a satisfactory correlation with the reference laboratory method in samples of healthy volunteers after fasting. Further assessment will be performed in patients presenting with symptoms of DKA in the Emergency Department. An extended study aimed at defining the impact of potential interfering substances is ongoing (results will be included in the poster that will be presented at the meeting).

References

1. IDF Clinical Guidelines Task Force. Global guideline for type 2 diabetes. Brussels: International Diabetes Federation, 2005:45-7.
2. Dabelea D, Rewers A, Stafford J et al. Trends in the Prevalence of Ketoacidosis at Diabetes Diagnosis: The SEARCH for Diabetes in Youth Study. Pediatrics. 2014;133(4):e938-45.
3. Savage M, Dhatariya K, Kilvert A et al. Joint British Diabetes Societies guideline for the management of diabetic ketoacidosis. Diabetic Med. 2011;28:508-515.
4. Wolfsdorf J, Craig M, Daneman D et al. ISPAD clinical practice consensus guidelines 2009. Diabetic ketoacidosis. Pediatr Diabetes. 2009; 10(suppl 12):118-133.