C17

PERFORMANCE EVALUATION OF AFINION®2 POINT-OF-CARE DEVICES FOR MEASURING GLYCATED HEMOGLOBIN

C. Lhermerout[1], L. Lutteri[1], E. Cavalier[1], R. Gadisseur[1]

[1]CHU de Liège, Liege, Belgium

Objectives: Glycated hemoglobin (HbA1c) is a key marker for the monitoring of diabetic patients and the effectiveness of their treatment, as its level reflects blood glucose over the lifespan of red blood cells. The aim of this study was to validate Afinion®2 point-of-care testing (POCT) devices for measuring HbA1c in under 3 minutes before use in pediatric department.

Material and Methods: We evaluated the performance of two Afinion®2 POCT devices (Abbott Laboratories) for measuring HbA1c levels using a colorimetric assay, following CLSI-EP standards with a total allowable error of 3.14% (EFLM guidelines). Precision was evaluated over 5 days using two control levels (42 and 67 mmol/mol), analyzed in duplicate. A bias was calculated against the method's mean for each control level. The manufacturer's announced reference range for HbA1c (20-42 mmol/mol) was verified by testing 20 healthy subjects. Two method comparisons were carried out. The Afinion®2 device was first compared to the laboratory's reference method of capillary electrophoresis on the Capillarys 3 Octa®(Sebia), using 20 patient samples. A second comparison was performed between the two Afinion devices on the same set of 20 samples. Among these 20 patients included in both comparisons, three had heterozygous AS hemoglobin.

Results: The repeatability and total imprecision of the Afinion®2 devices demonstrated mean coefficients of variation (CV) of 0.75% and 1.0%, respectively. No device had a bias exceeding the desirable bias (1.82%). The recommended reference range was confirmed, with all patients' values included within a narrower range (30–37 mmol/mol). Comparison between the Afinion and Capillarys method showed a non-significant bias of -1.1%, with a slope of 0.984 (95%CI: 0.939–1.02) and an intercept of 0.512 (95%CI: -1.98–2.65). The two Afinion devices showed good agreement, with a slope of 1.01 (95%CI: 1.00–1.05), an intercept of -0.428 (95%CI: -2.10–0.500), and a non-significant bias of 0.6% mmol/mol.

Conclusions: Total imprecision CV was within the minimal biological CV (<1.2%), and bias was within the desirable biological bias (<1.82%). The total error remained within the 3.14% limit, validating the method according to CLSI-EP standards.