EVALUATION OF THE HbA1c KIT ON SEBIA MINICAP FLEX PIERCING

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BACKGROUND - AIM

HbA1c is a valuable marker to diagnose and monitor diabetes mellitus and can be measured via different analytical methods: immunossay, enzymatic, affinity chromatography and ion-exchange chromatography. Few years ago, capillary electrophoresis has emerged as a new separation method offering high resolution separation and accurate quantification of the HbA1c analyte. Numerous scientific articles have been published demonstrating the good analytical performances of this method on the CAPILLARYS 2 Flex Piercing analyzer (Sebia, France) [1-4]. Recently, a smaller version of the Capillary 2 Flex Piercing has been released, the MINICAP Flex Piercing (Sebia, France), a 2-capillary multi-parameter instrument offering a comprehensive test menu on serum and whole blood (Protein, Immunology, Hepatitis, Lipid, Cardiac, COT). Aim of this study was to report the evaluation of the HbA1c kit on MINICAP Flex Piercing. To our knowledge, this is the first report on the evaluation of this system for HbA1c testing.

METHODS

The aim of this study was to assess the analytical performances of the MINICAP Flex Piercing for routine HbA1c measurement. A systematic evaluation of the HbA1c kit on the MINICAP Flex Piercing was undertaken during an international multicentric study involving the National Laboratory of Health (Dudelange, Luxembourg) and the Regional Hospital of Metz-Thionville (France).

The broadly evaluated CAPILLARYS 2 Flex Piercing HbA1c method has been used as the comparative method for the correlation study. Linear regression analysis was done on 72 samples with no hemoglobin abnormalities covering a wide range of HbA1c values (from 31 to 139 mmol/mol).

Between-run precision study was assessed on 3 different samples that were analyzed 4 times per day during 5 consecutive days (n=40). The mean, Standard Deviation (SD) and Coefficient of Variation (CV) were calculated for each sample.

Six samples, for which target values were assigned by an IFCC Secondary Reference Method in one approved laboratory of the IFCC Network for HbA1c, were run in duplicate on the MINICAP Flex Piercing HbA1c method. Results were compared with the IFCC target values to assess the trueness of the method.

Linearity of the MINICAP Flex Piercing HbA1c method was determined by doing serial dilutions between one sample with low HbA1c level (21 mmol/mol) and one with high HbA1c level (127 mmol/mol). Coefficient of correlation between the measured values and the theoretical values was then calculated.

16 samples with common Hb disorders [4 HbA5, 4 HbA6, 3 HbA2 and 5 beta-thalassemia trait samples] were run on the MINICAP Flex Piercing HbA1c method. CAPILLARYS 2 Flex Piercing HbA1c method was used as the comparative method since it has been demonstrated that this instrument is not influenced by the presence of these hemoglobinopathies for the measurement of the HbA1c.

The interference of the Labile HbA1c fraction (LAL1c) on the HbA1c measurement by MINICAP Flex Piercing was assessed in 3 different samples incubated with glucose solutions at different concentrations during 3 hours at 37°C. The increase of LAL1c values was assessed on the Bio-Rad Variant II analyzer.

RESULTS

- The MINICAP Flex Piercing HbA1c was compared to the CAPILLARYS 2 Flex Piercing HbA1c and a strong correlation between both methods was achieved on normal samples (R=0.99). The correlation for samples with hemoglobin variants (e.g. S, C and E) or β-thalassemia trait was also excellent (R=0.99), suggesting that these hemoglobin disorders do not affect the HbA1c measurement.

- The profiles obtained on the MINICAP Flex Piercing are strictly identical to the ones obtained on the CAPILLARYS 2 Flex Piercing HbA1c. We observed the same power of separation of the HbA1c fraction and similar high resolution separation of the Hb variants.

- The between-run CVs were lower than 2.02% in IFCC units and 1.26% in NGSP units.

- Linearity was determined over a range of 21 to 127 mmol/mol of HbA1c, and a high correlation between theoretical and observed values (R=0.99) was achieved.

- The use of samples with target values assigned by an approved laboratory of the IFCC Network for HbA1c indicated a good accuracy of the method, with minimum bias ranging from -1 to 1.5 mmol/mol.

- Labile HbA1c increase did not significantly alter the accuracy of the HbA1c determination by MINICAP Flex Piercing, while it did interfere on ion-exchange chromatography method.

CONCLUSION

This comprehensive study shows that the analytical performances of the MINICAP Flex Piercing analyzer for HbA1c assay are in accordance with the most stringent quality criteria required for clinical use, the instrument can thus be recommended for implementation in clinical laboratories for routine practice.

REFERENCES