Suitability and performances of the new CAPILLARYS 3 TERA for high volume testing activity

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Background
Capillary electrophoresis (CE) is a high resolution separation method that was recently adopted for the measurement of HbA1c. Several scientific studies have already demonstrated the robustness of this method in regard to analytical interferences (Labile A1c, Carbamylated Hb, Hb variants…) [1-4]. After one year experience in our laboratory using CE technology for routine HbA1c testing, we evaluated the performances of the new CAPILLARYS 3 TERA instrument (Sebia, France), a fully automated and high throughput multiparameter CE instrument with 12 capillaries in parallel.

Material & Methods
This evaluation was conducted during 8 weeks over 8,000 samples sent to the laboratory for routine HbA1c testing and 1,500 samples for Serum Protein Electrophoresis (SPE), analyzed on the CAPILLARYS 3 TERA to assess its robustness and ease-of-use. The between run precision was evaluated on the 2-levels daily HbA1c controls (Sebia, France) that were processed on the 12 capillaries during 40 consecutive days (n=480). The comparison was based on the correlation between our current capillary electrophoresis instruments (CAPILLARYS 2 Flex Piercing, Sebia, France) and the CAPILLARYS 3 TERA on 863 whole blood samples covering a wide range of HbA1c values. The mean deviation between the 2 systems was calculated at 3 different HbA1c levels: 30, 60 and 90 mmol/mol. Limits of agreement were defined as ±√[(3SD test method)²+(3SD comparison method)²], with Standard Deviation (SD) calculated from the precision study on QC Level 1 and 2.

Results
The between-run CVs were 1.94% and 1.13% for the HbA1c Control Level 1 (mean value= 33 mmol/mol and 5.2%, respectively); the between-run CVs were 1.35% and 1.00% for the HbA1c Control Level 2 (mean value= 68 mmol/mol and 8.4%, respectively). The correlation between CAPILLARYS 2 Flex Piercing and CAPILLARYS 3 TERA on HbA1c results proved to be excellent with a linear regression y= 1.001x + 0.005 and a mean bias= 0.01% for HbA1c results expressed in NGSP units (min= -1.1%; max= 1.3%), and y= 1.001x + 0.089 and a mean bias= 0.1 mmol/mol for HbA1c results expressed in IFCC units (min= -21 mmol/mol; max= 123 mmol/mol). The mean deviations at 30, 60 and 90 mmol/mol were successively 0.12, 0.15 and 0.18 mmol/mol (which is < 0.02% when expressed in NGSP units). No result was outside the limits of agreement.

Conclusion
This extensive evaluation of CAPILLARYS 3 TERA instrument over nearly 10,000 samples showed that this new multiparameter instrument is reliable, easy to use and can absorb high volume testing activity thanks to its full automation and high throughput (70 HbA1c tests/h). We found excellent correlation and precision when compared to the CAPILLARYS 2 Flex Piercing with resolution and separation profiles being similar.

References: