

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

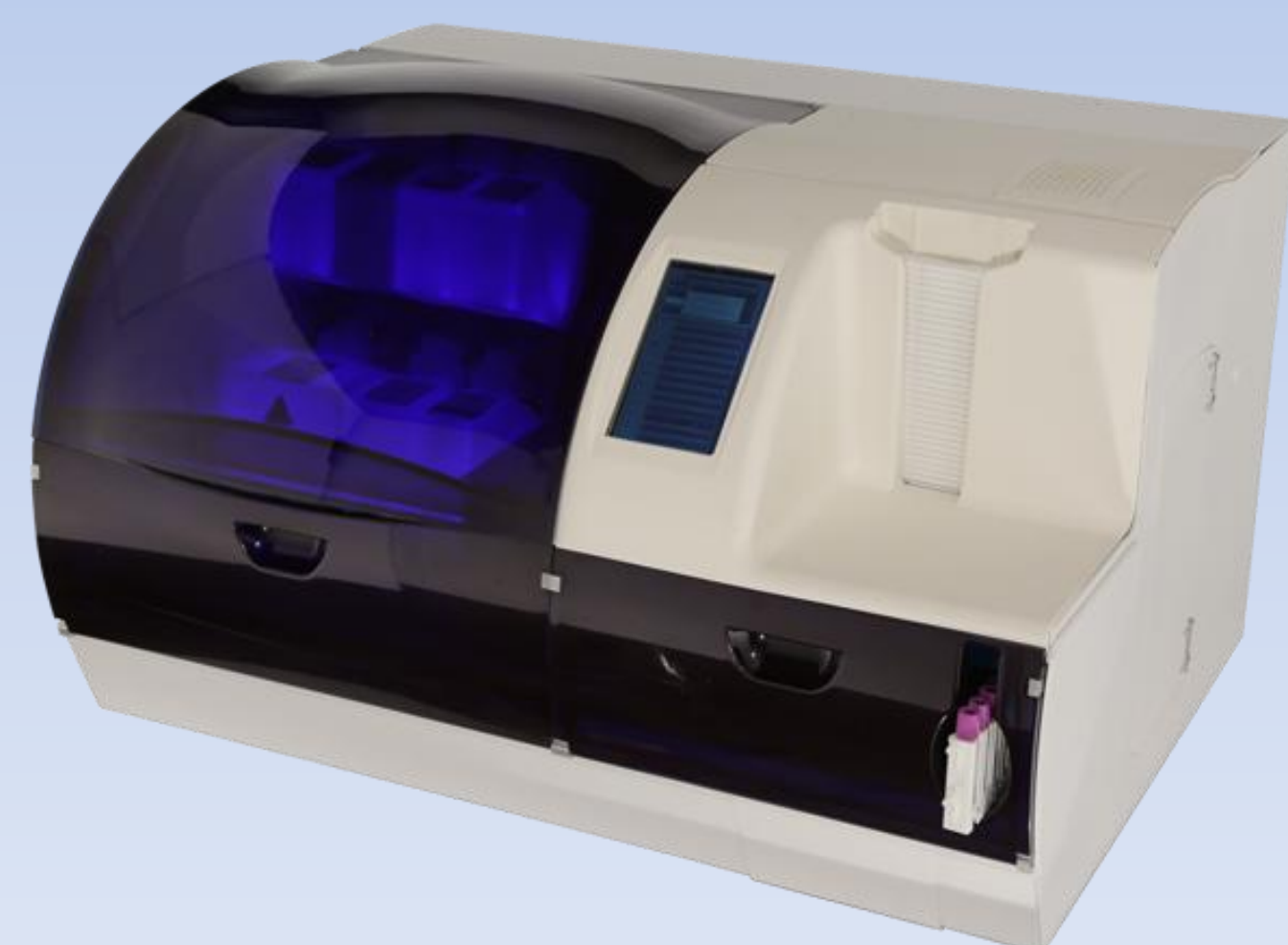
Marc Van de Loo¹, Nadia Baidjibay¹, Denis Simonin²

¹ Laboratoires BIO 7, Parc du Bois Chaland, CP 8010 Lisses, 91008 EVRY, France

² SEBIA, Parc Technologique Léonard de Vinci, CP 8010 Lisses, 91008 EVRY, France

Background

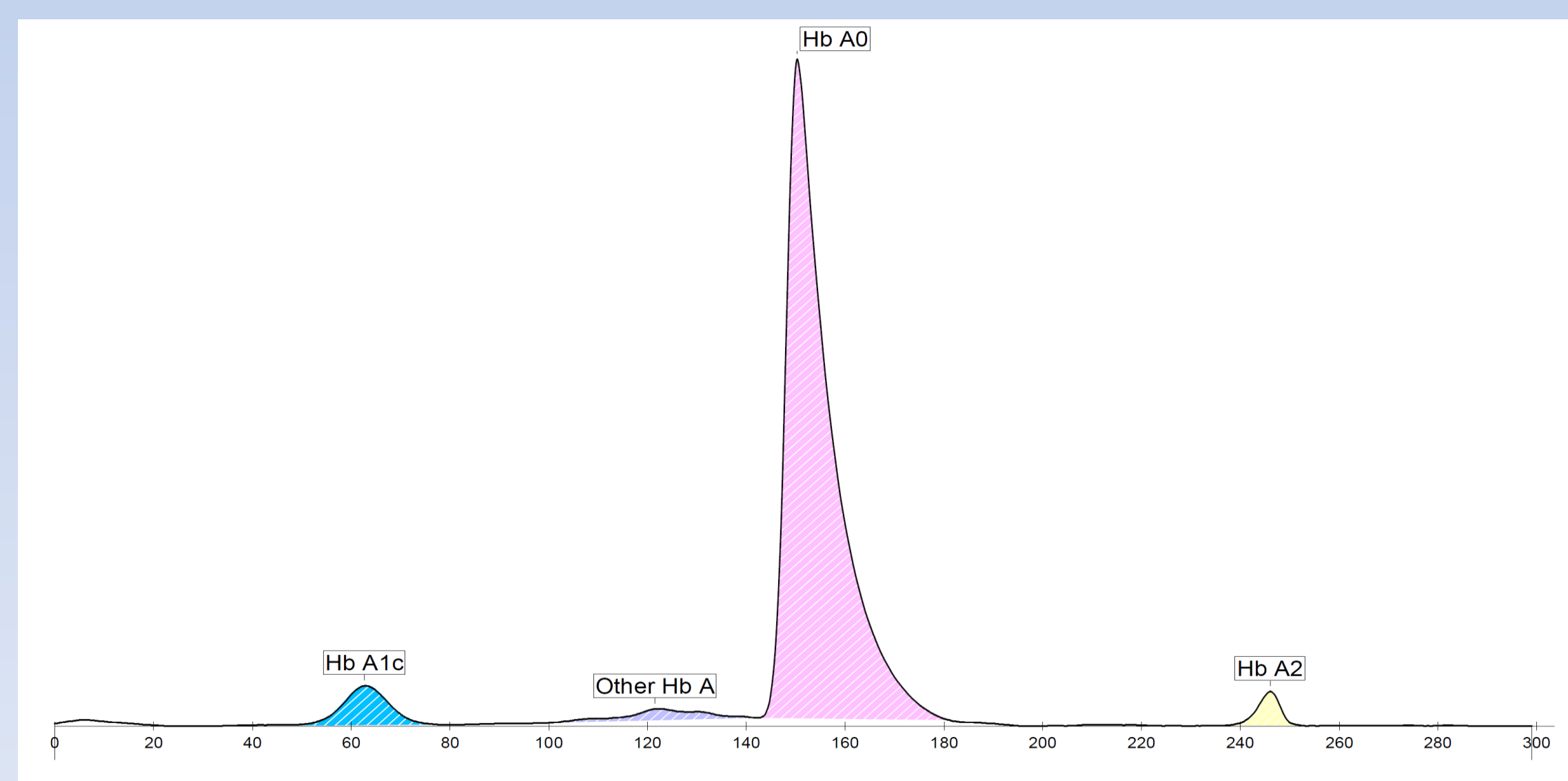
Capillary electrophoresis (CE) is a high resolution separation method that was recently adapted for the measurement of HbA1c. Several scientific studies have already demonstrated the robustness of this method in regard to analytical interferences (Labile A1c, Carbamylated Hb, Hb variants...) [1-4]. After 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.



CAPILLARYS 3 TERA

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 90mmol/mol. Limits of agreement were defined as $\pm\sqrt{(3SD \text{ test method})^2 + (3SD \text{ comparison method})^2}$, with Standard Deviation (SD) calculated from the precision study on QC Level 1 and 2.



HbA1c profile on CAPILLARYS 3 TERA

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.

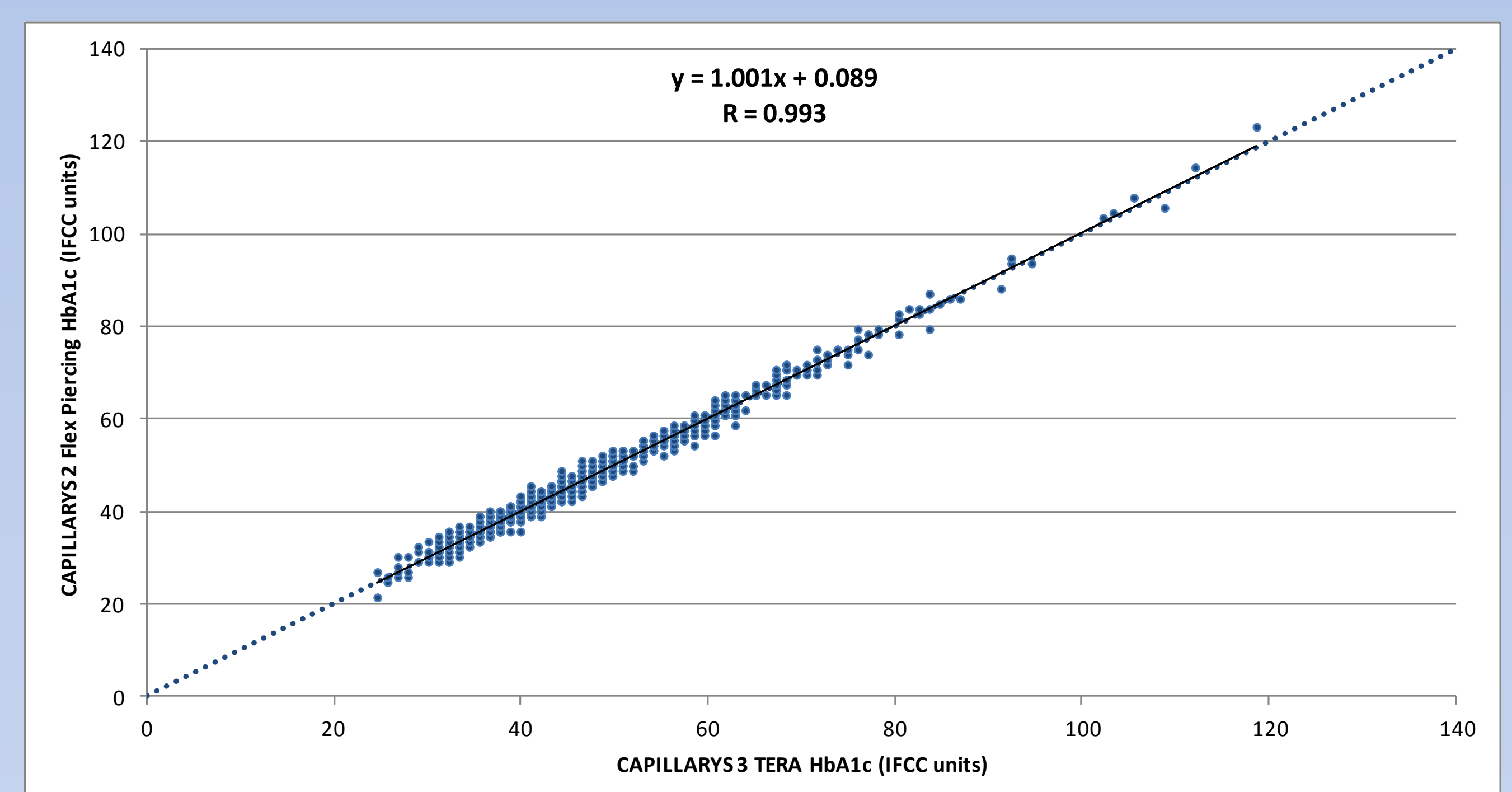
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- Woodworth A, Korpi-Steiner N, Miller JJ, Rao LV, Yundt-Pacheco J, Kuchipudi L, Parvin CA, Rhea JM, Molinaro R. Utilization of Assay Performance Characteristics to Estimate Hemoglobin A1c Result Reliability. Clinical Chemistry 60:8 (2014) ; 1073-1079

Results

The between-run CVs were 1.94% and 1.13% for the HbA1c Control Level 1 (mean value= 33mmol/mol and 5.2%, respectively); the between-run CVs were 1.35% and 1.00% for the HbA1c Control Level 2 (mean value= 68mmol/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=4.1%; max=13.4%), and $y = 1.001x + 0.089$ and a mean bias= 0.1mmol/mol for HbA1c results expressed in IFCC units (min=21mmol/mol; max=123mmol/mol). The mean deviations at 30, 60 and 90mmol/mol were successively 0.12, 0.15 and 0.18mmol/mol (which is < 0.02% when expressed in NGSP units). No result was outside the limits of agreement.

	Control Level 1 n= 480		Control Level 2 n= 480	
	IFCC unit	NGSP unit	IFCC unit	NGSP unit
Mean value	33 mmol/mol	5.20%	68 mmol/mol	8.40%
Between-run CV	1.94%	1.13%	1.35%	1.00%

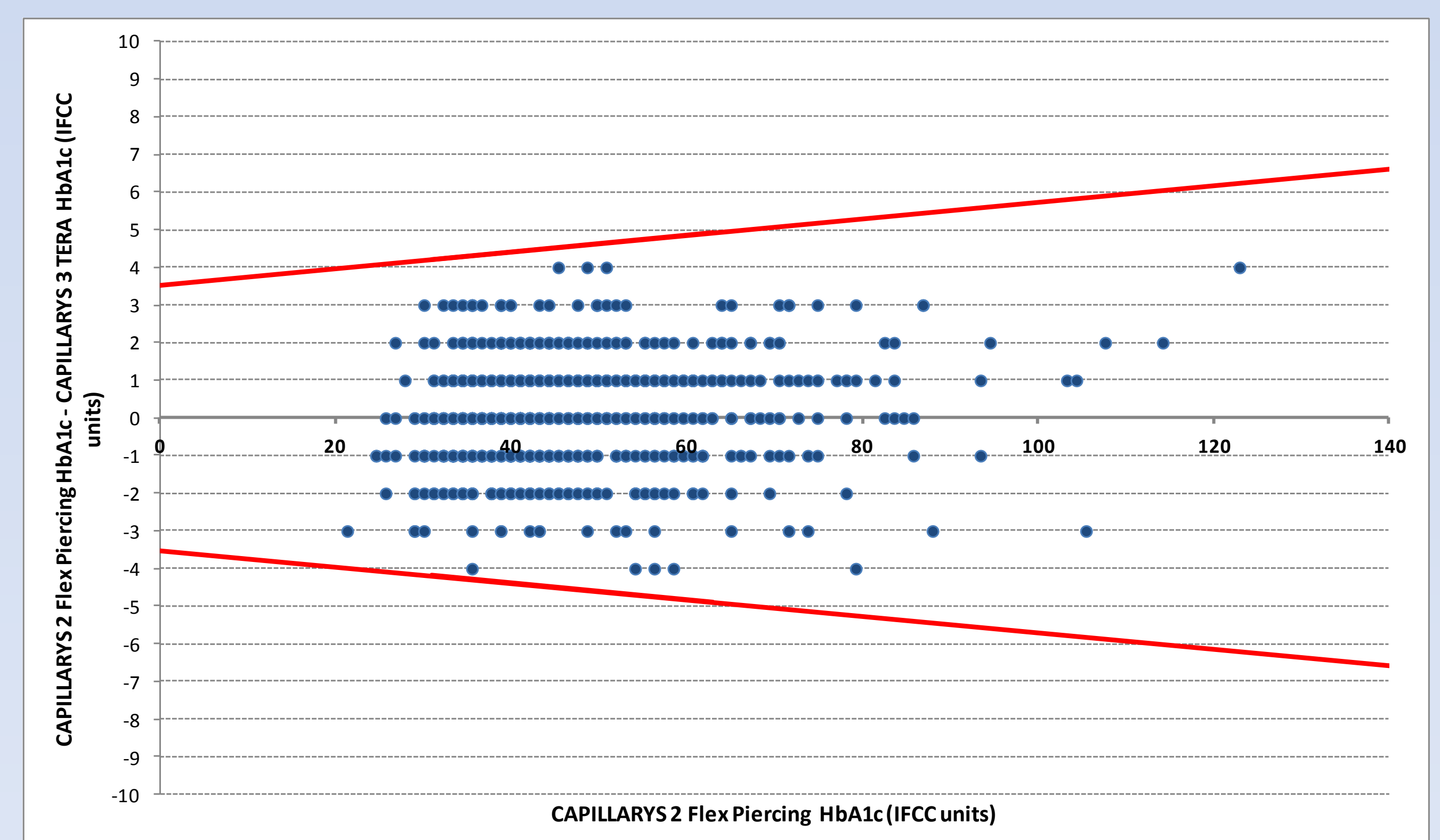
Precision of the CAPILLARYS 3 TERA HbA1c



Linear Regression between CAPILLARYS 2 Flex Piercing and CAPILLARYS 3 TERA

Deviation from CAPILLARYS 2 Flex Piercing target	at 30 mmol/mol	+ 0.12 mmol/mol
	at 60 mmol/mol	+ 0.15 mmol/mol
	at 90 mmol/mol	+ 0.18 mmol/mol

Trueness of the CAPILLARYS 3 TERA HbA1c



Difference Plot between CAPILLARYS 2 Flex Piercing and CAPILLARYS 3 TERA
X-axis: HbA1c values obtained on CAPILLARYS 2 Flex Piercing, in IFCC units;
Y-axis: absolute difference between CAPILLARYS 2 Flex Piercing and CAPILLARYS 3 TERA, in IFCC units;
Red lines represent the limits of agreement