INTRODUCTION

Carbohydrate-deficient transferrin (CDT) is a well-recognized highly specific marker of chronic alcohol abuse. Capillary electrophoresis allows the separation of the transferrin fractions and the quantification of the CDT. The CDT assay on Capillaries 3 TERA instrument (Sebia, Lisses, France) has been developed recently, according to the IFCC working group on CDT (WG-CDT) standardization recommendations.

METHODS

The reproducibility for both values – CDT and CDT\textsubscript{IFCC} – between lots and between instruments were assessed following the EPS procedure. Eight different serum samples including 5 serum samples, 1 Normal CDT Control (No. 7), 1 High CDT Control (No. 1) and 1 Intermediate CDT Control (No. 8) were analyzed. The correlation between our current Capillaries 2 CDT assay and Capillaries 3 TERA were based on the analysis of 30 samples covering a wide range of CDT values (0.9 – 11.4% CDT IFCC, 0.4 – 14.6% CDT). The linearity of the CAPILLARIES 3 CDT/CDT\textsubscript{IFCC} procedure was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI- USA) EP8-A1 guideline “Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline”. Two different serum samples, S1 (Serum with elevated CDT level: CDT = 24.6 % & CDT\textsubscript{IFCC} = 16.4 %) and S2 (Serum with normal CDT level: CDT = 0.4 % & CDT\textsubscript{IFCC} = 1.1 %, [T] = 2.8g/l) were mixed within different proportions and the mixtures were run with the CAPILLARIES CDT\textsubscript{IFCC} procedure. Each mixture, samples were analyzed in triplicate.

RESULTS

The new CDT test on Capillaries 3 TERA instrument was designed according to the IFCC working group on CDT (WG-CDT) standardization recommendations. Thus, the assay allows to obtain both kind of results – “classic” CDT (CDT = 2-sialo + O-sialo fractions) and/or calibrated CDT\textsubscript{IFCC} results when using 2 levels calibrators (CDT\textsubscript{IFCC} = IFCC-calibrated 2-sialo fraction) with the same PHORESIS software version. The CDT CAPILLARIES CALIBRATORS are designed for the calibration of the CDT\textsubscript{IFCC} value. The test throughput is 66 samples per hour. CAPI 3 CDT technique is not prone to any of the tested interferences (Hemoglobin, Bilirubin) (data not shown).

The Capillaries 3 CDT assay shows an excellent correlation with Capillaries CDT, \( R^2 = 0.998 \) for CDT\textsubscript{IFCC} and 0.9973 for CDT.

The total reproducibility (CV) was below 4.3% for CDT\textsubscript{IFCC} and below 7.7% for CDT.

The tests were determined to be linear within the entire ranges studied for CDT and CDT\textsubscript{IFCC} percentage : between 1.1% and 16.4 % CDT\textsubscript{IFCC} , between 0.4% and 24.6% CDT.

CONCLUSION

Capillaries 3 TERA represents the last generation of Sebia multib-parametric capillary electrophoresis instruments which combines precision, quality of separation and high throughput. The range of tests includes serum proteins, immunotyping, whole blood testing on caped tubes, allowing the HbAc\textsubscript{c} measurement as well as hemoglobin fractions separation and quantification. The new Capillaries 3 CDT test was evaluated. Excellent correlation for CDT & CDT\textsubscript{IFCC} Values were found with the existing Capillaries CDT test, as well as a good precision and linearity. Using CDT calibrators, consistent results with the recommendations of the IFCC working group for standardization of CDT measurement can be obtained.

REFERENCES

IFCC approved reference procedure for the alcohol consumption biomarker carbohydrate-deficient transferrin (CDT): Its validation and use
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Hemoglobinisation of measurement results of the alcohol biomarker carbohydrate-deficient transferrin by use of the toolbox of technical procedures of the international consortium for harmonization of clinical laboratory results

Standardization and use of the alcohol biomarker carbohydrate-deficient transferrin (CDT)

Sebia, Lisses, France