

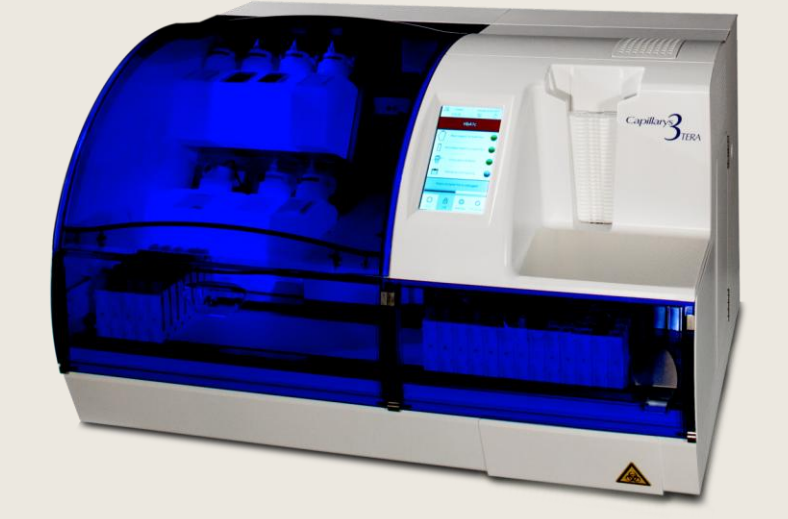
Standardization of the CDT Measurement: Validation of the New CDT/CDT_{IFCC} Test on CAPILLARYS 3 TERA

Gérald Deschamps, Gaëlle Proczek, Sophie Herb, Laura Cartier, Denis Simonin, Frédéric Robert

Sebia, Lisses, France

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 CapillaryS 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_{IFCC} between lots and between instruments were assessed following the EP5 procedure. Eight different serum samples including 5 serum samples, 1 Normal CDT Control (No. 6), 1 High CDT Control (No. 7) and 1 Intermediate CDT Control (No. 8) were analyzed.

The correlation between our current CapillaryS 2 CDT assay and CapillaryS 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 CAPILLARYS 3 CDT/CDT-IFCC procedure was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI- USA) EP6-A 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-IFCC = 16,4 % & 0-sialo = 7,4, [Tf] = 2,1g/L, S2 : Serum with normal CDT level : CDT = 0,4 % & CDT-IFCC = 1,1 %, [Tf] = 2,8g/L) were mixed within different proportions and the mixtures were run with the CAPILLARYS CDT_{IFCC} procedure. For each mixture, samples were analyzed in triplicate.

RESULTS

The new CDT test on CapillaryS 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 + 0-sialo fractions) and/or calibrated CDT_{IFCC} results when using 2 levels calibrators (CDT_{IFCC} = IFCC-calibrated 2-sialo fraction) with the same PHORESIS software version. The CDT CAPILLARY CALIBRATORS are designed for the calibration of the CDT_{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 total reproducibility (CV) was below 4.3% for CDT_{IFCC} and below 7.7% for CDT

Sample No.	% CDT		Repeatability		Total reproducibility		% CDT _{IFCC}		Repeatability		Total reproducibility	
	Mean (%)	CV (%)	CV (%)	CV (%)	CV (%)	CV (%)	CV (%)	CV (%)	CV (%)	CV (%)	CV (%)	
1	0,6	7,0%	7,0%	7,7%	1,2	3,0%	4,3%					
2	1,4	3,9%	3,9%	4,9%	1,9	2,7%	3,6%					
3	4,7	1,8%	1,8%	2,3%	3,9	1,3%	2,0%					
4	14,1	0,7%	0,7%	0,9%	10,0	0,7%	1,6%					
5	21,8	0,6%	0,6%	0,9%	14,9	0,5%	1,7%					
6	0,9	5,7%	5,7%	6,4%	1,5	3,0%	4,1%					
7	5,8	3,1%	3,1%	3,5%	5,1	1,0%	1,8%					
8	2,4	2,8%	2,8%	3,4%	2,9	2,0%	2,5%					
CV (%) ranges		0,6%	7,0%	0,9%	7,7%	0,5%	3,0%	1,6%	4,3%			

Table 1. Reproducibility between lots and between instruments

The CapillaryS 3 CDT assay shows an excellent correlation with CapillaryS CDT, R²=0.998 for CDT_{IFCC} and 0.9973 for CDT

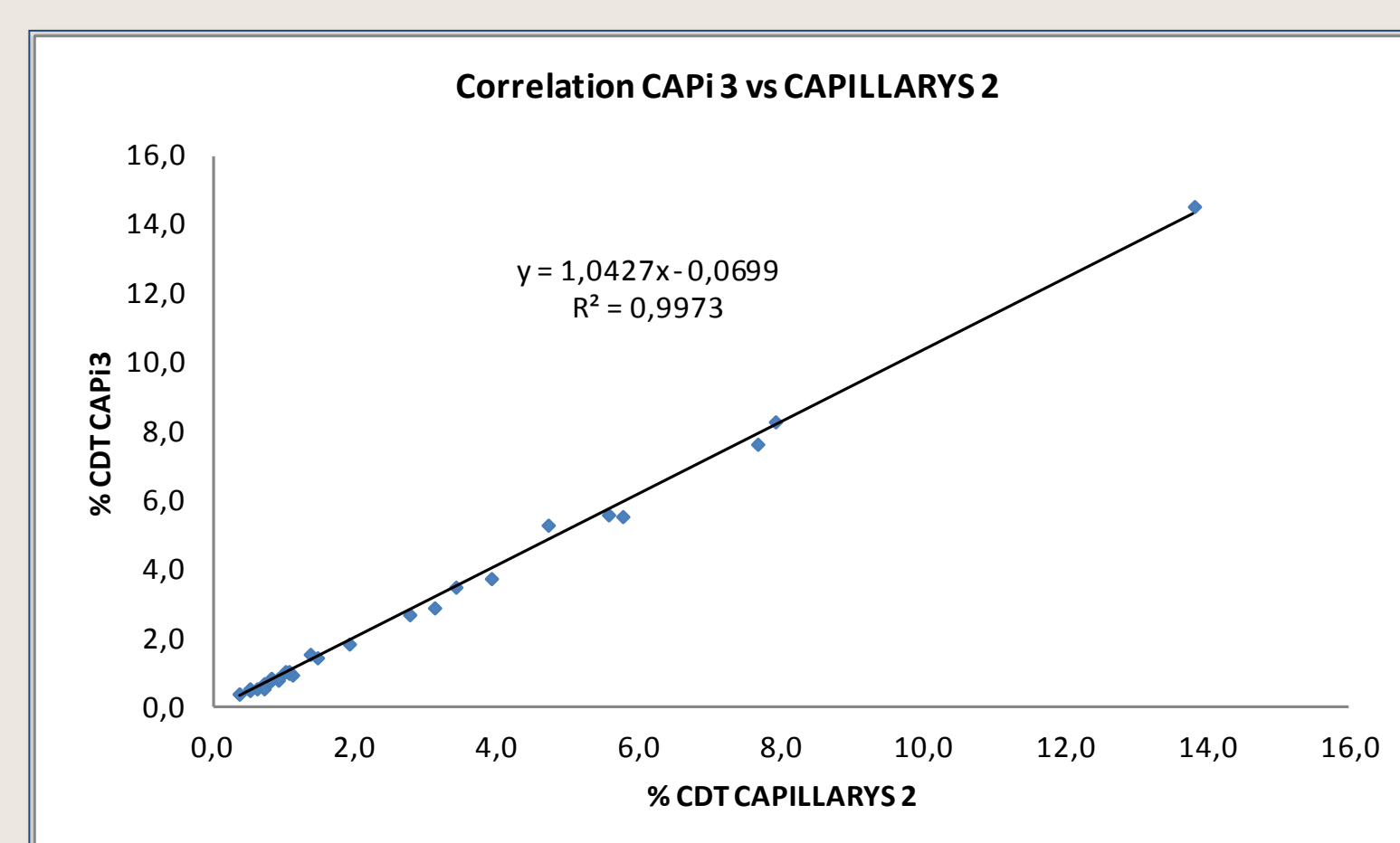
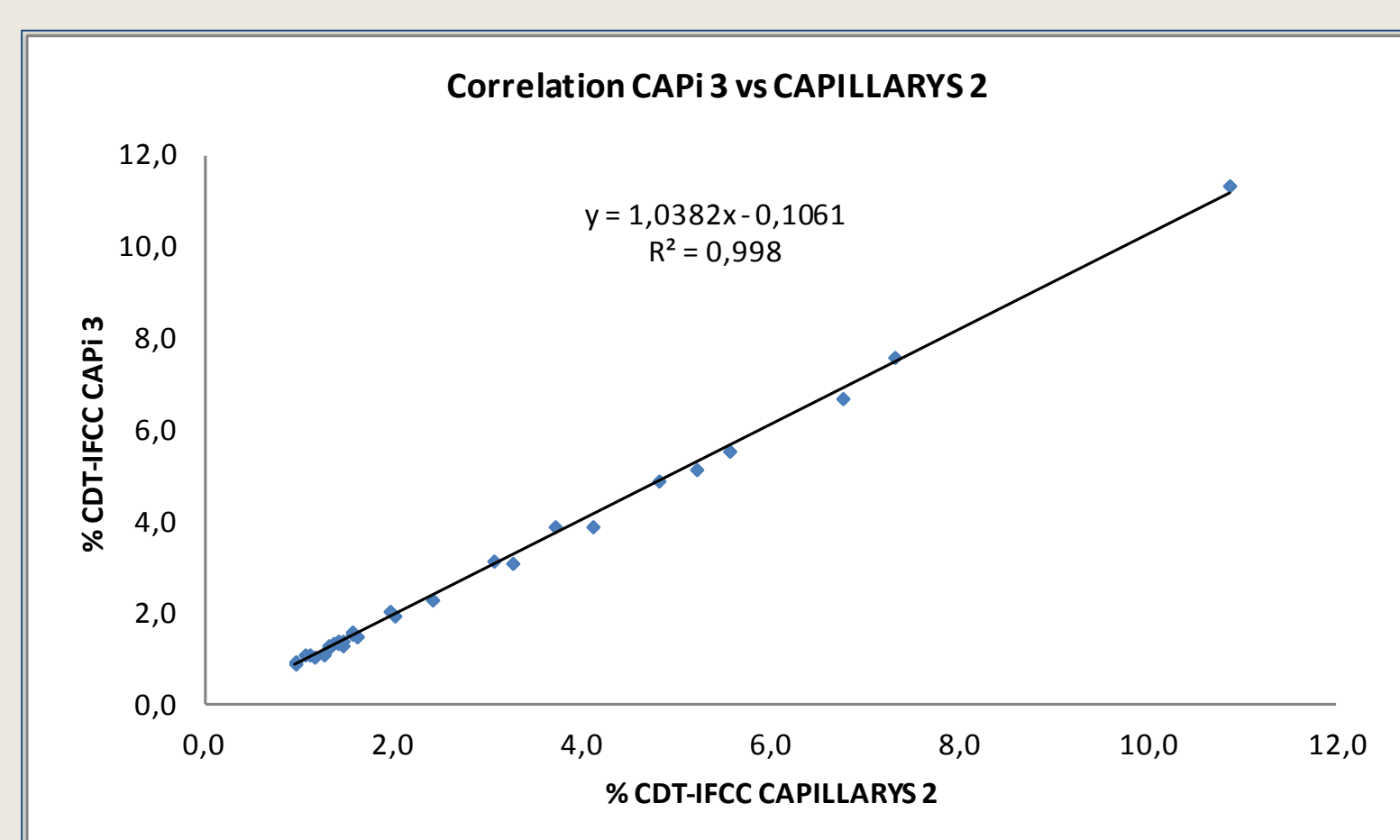


Fig 1. Correlation between CDT_{IFCC} and CDT values on CAPILLARYS 3 TERA and CAPILLARYS 2

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

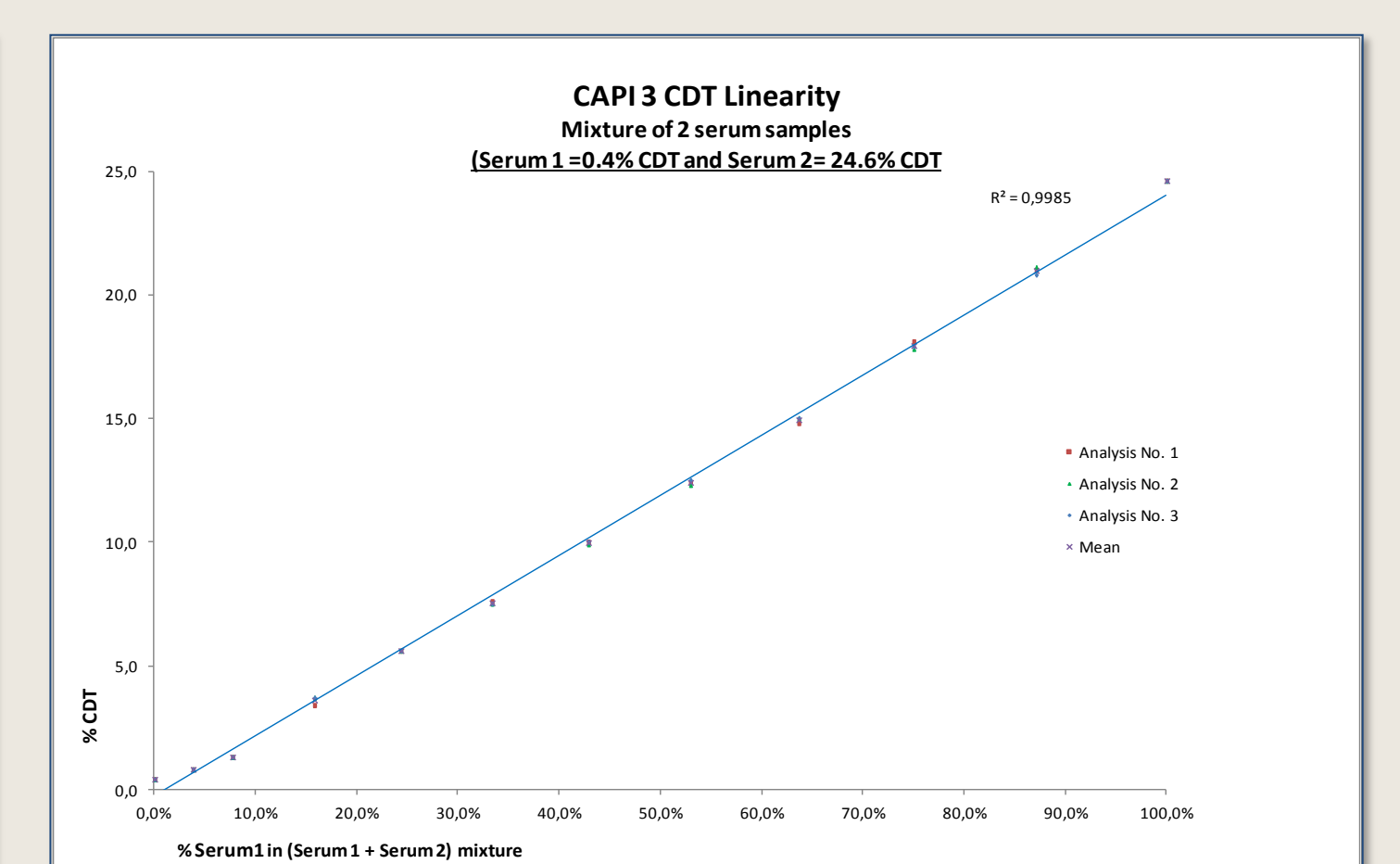
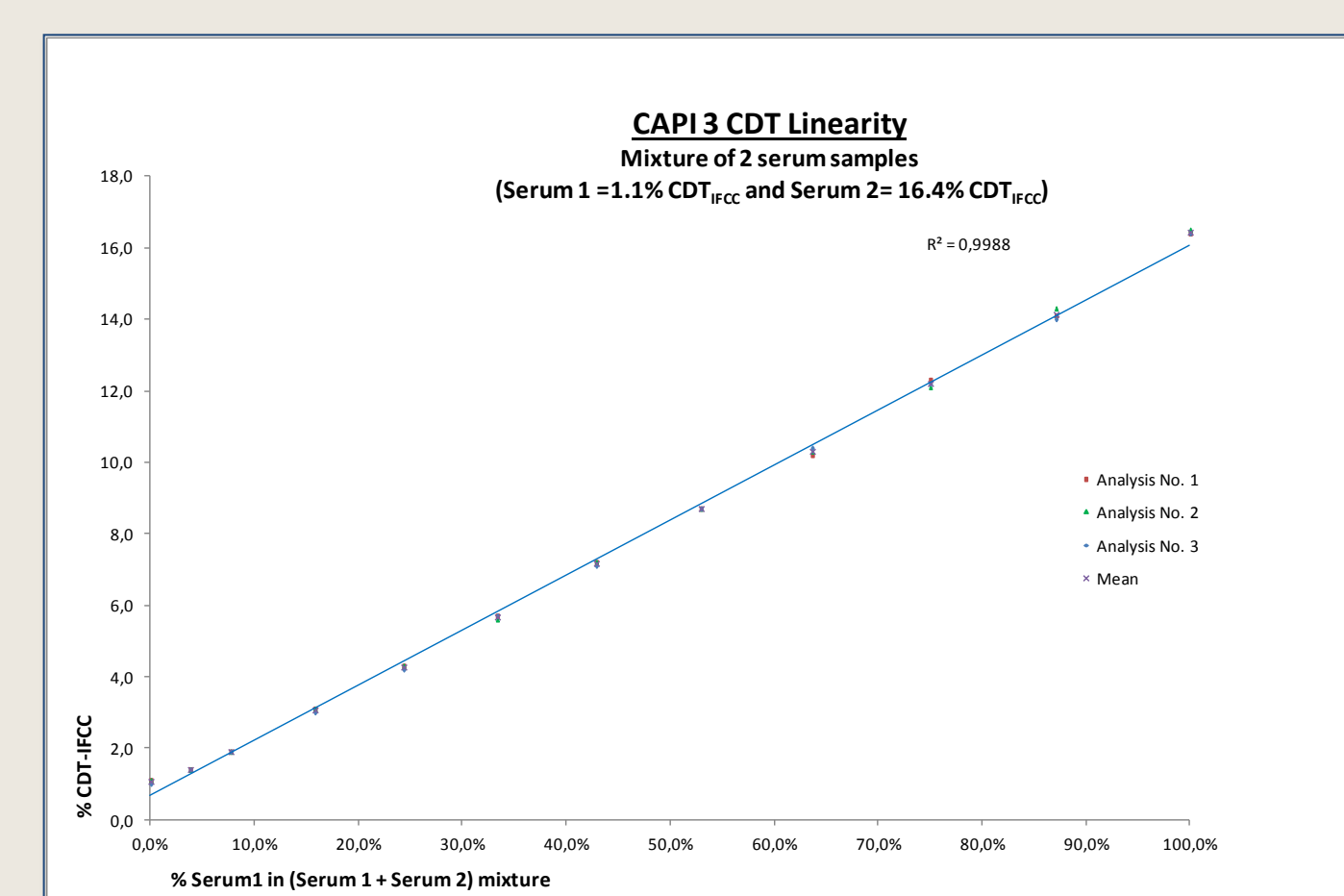


Fig 2. Linearity of CDT_{IFCC} and CDT assay on CAPILLARYS 3 TERA

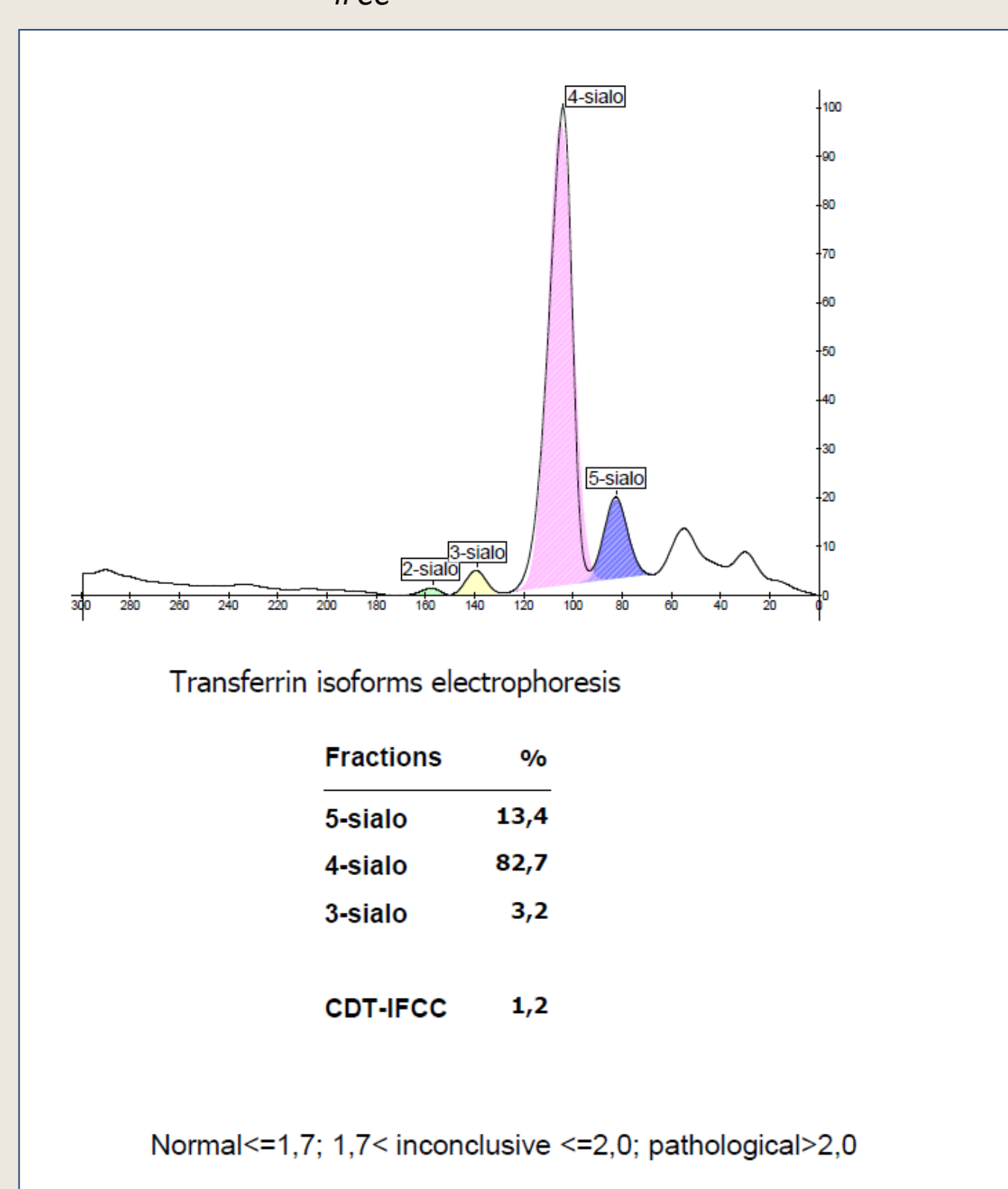


Fig. 3 Patient report (calibrated instrument) Profile with normal CDT_{IFCC} value

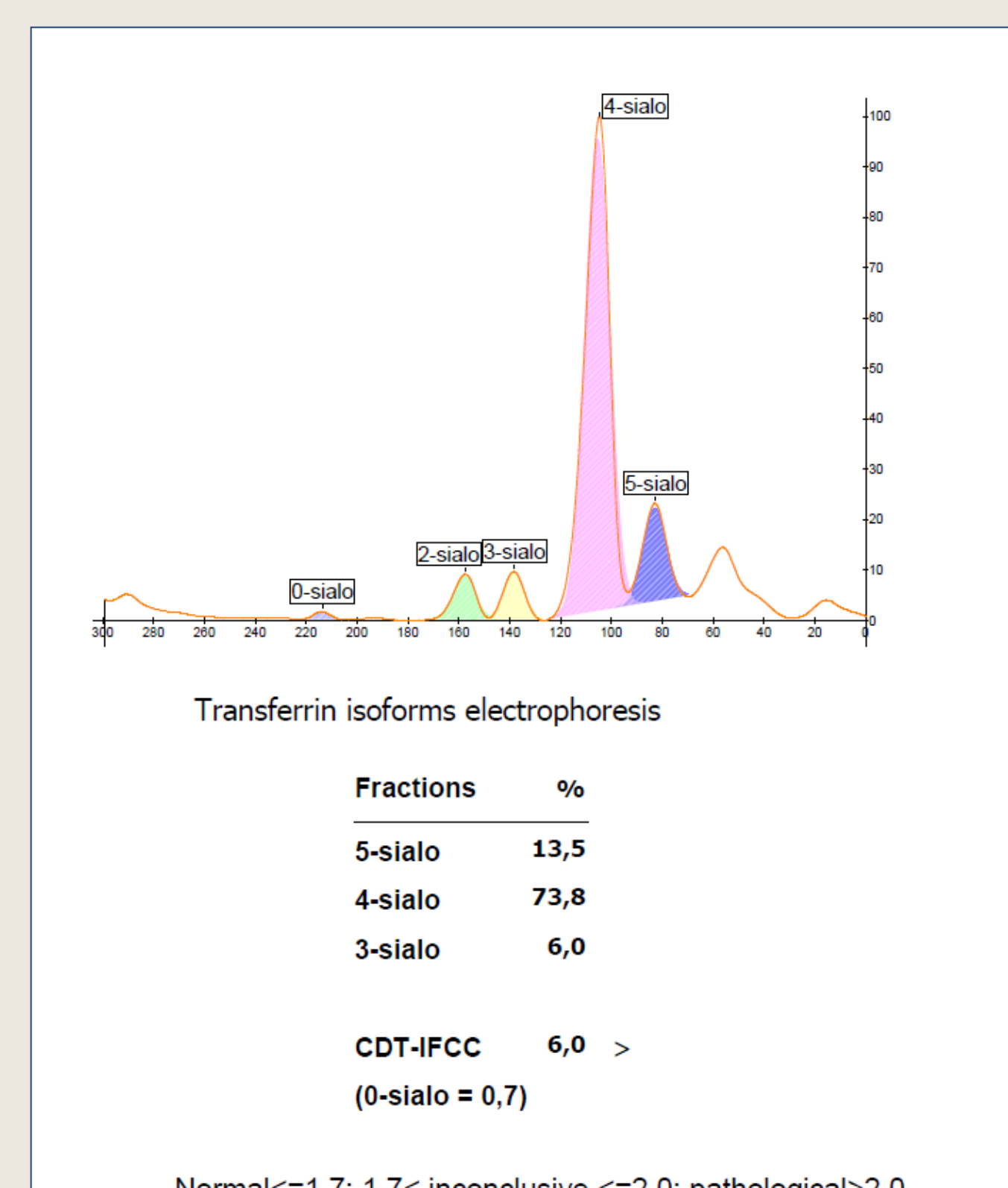


Fig. 4 Patient report (calibrated instrument) Profile with elevated CDT_{IFCC} value

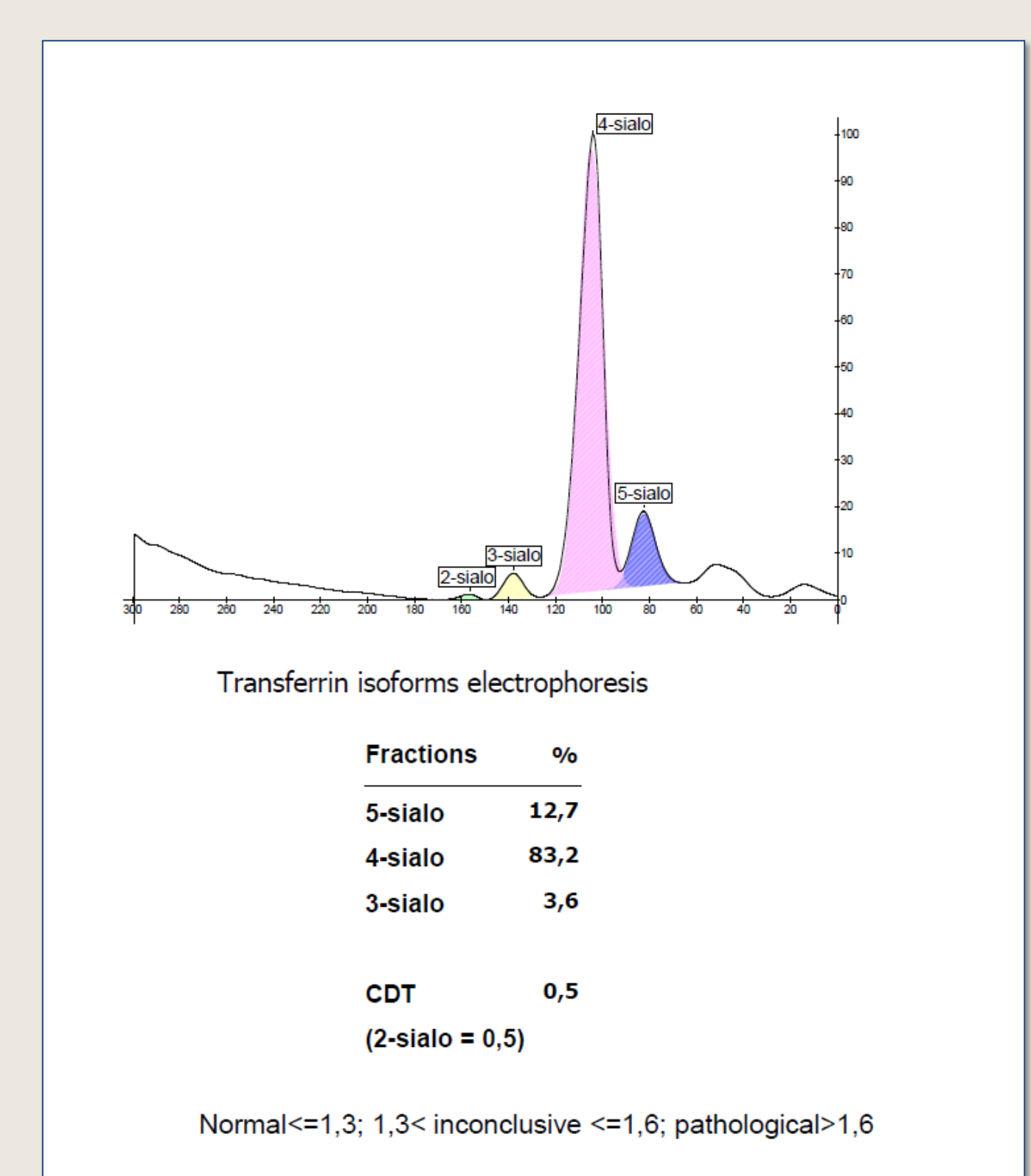


Fig. 5 Patient report (non-calibrated instrument) Profile with normal CDT value

CONCLUSION

CapillaryS 3 TERA represents the last generation of Sebia multiparametric capillary electrophoresis instruments which combines precision, quality of separation and high throughput. The range of tests includes serum proteins, immunotyping, whole blood testing on capped tubes, allowing the HbA1c measurement as well as hemoglobin fractions separation and quantification. The new CapillaryS 3 CDT test was evaluated. Excellent correlation for CDT & CDT_{IFCC} values were found with the existing CapillaryS 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

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