Performance evaluation of automated C1 esterase measurement on the new coagulation analyzer Ceveron® c100

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INTRODUCTION

Background: The most important laboratory parameter for correct diagnosis of hereditary angioedema (HAE) or angioedema due to acquired C1-Inhibitor (C1-INH) deficiency is reduced C1-INH function. Fully automated and precise measurement of C1-INH function is a valuable diagnostic cool.

Aim: Aim of the study was to evaluate assay performance of the chromogenic C1-INH assay on the new coagulation analyzer Ceveron® c100 in regards of accuracy and precision between runs.

MATERIALS AND METHODS

Method: To evaluate assay performance, lyophilized plasma samples were measured automated on the coagulation analyzer Ceveron® c100 with the chromogenic C1-INH assay kit. The assay is based on the inhibition of an excess of added Esterase by the C1-INH in the plasma sample, as measured by a chromogenic C1-INH substrate. The precision, accuracy, detection limit (LoD) and linearity of automated measurement of C1-INH were verified.

RESULTS

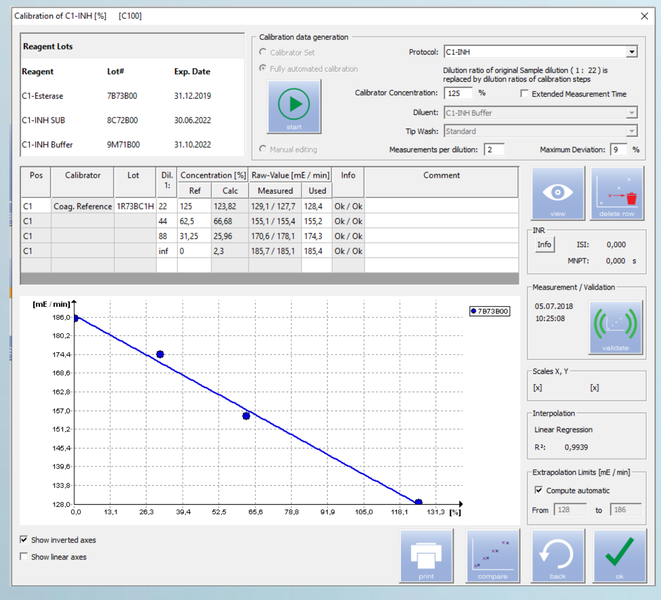


Fig. 1 Calibration curve on Ceveron c100 analyzer was made in the range of 0-125 IU/dL using the standard analyzer settings for C1-INH calibration with a calibration plasma traceable to the WHO 1st International Standard for C1-Inhibitor, plasma.

R^2 = 1.0± 0.1

	Mean IU/dL C1-INH timepoint 1	Mean IU/dL C1-INH timepoint 2	% deviation
Coagulation Control N 1P72BC1K	128.8	125.9	-2.30
Coagulation Control A 3P72BC1K	54.0	51.6	-4.40

Tab. 1 To proof the stability of calibration curves, recovery of controls was calculated at different time points. Recovery of controls

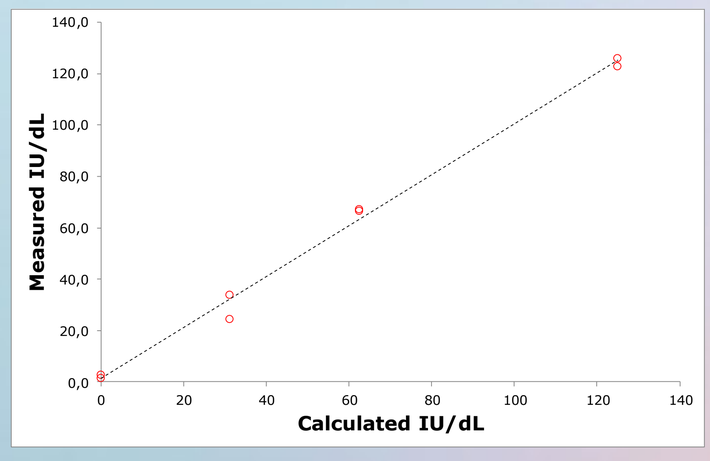
The detection limit for C1-INH was determined with 6.60 IU/dL and lower limit of blanc with 2.2 IU/dL

Performance of C1-INH measurements

Ceveron® c100 Intra-assay CVs		Sample 1 n=11	Sample 2 n=11	Sample 3 n=11	Sample 4 n=11
C1-Inh	mean	89.0	53.6	78.7	71.3
	SD	4.1	3.8	4.4	4.8
[IU/dL]	CV	4.57%	7.07%	5.62%	6.72%

Ceveron® c100 Inter-assay CVs		Sample 1 n=3	Sample 2 n=3
C1-Inh	mean	110.8	48.0
[IU/dL]	CV	6.36%	9.19%

Tab. 2a an 2b Precision was very good with intra-assay and inter-assay variations < 10%.



Linear regression		correlation	
1/slope	R square	Correlation coeffi-	P value
0.9908	0.9944	0.993	< 0.0001

Fig. 3 Dilution linearity was tested from 125 IU/dL C1-INH to 0.

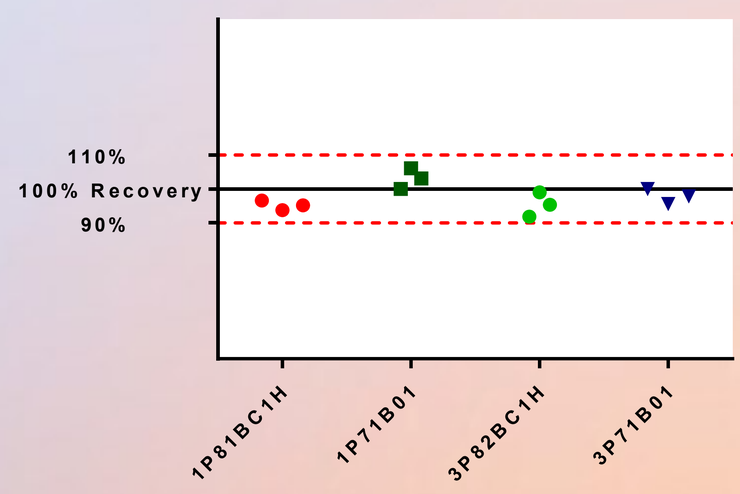


Fig. 4 Recovery of controls was within 100% ± 10% of target value

CONCLUSIONS

Our data demonstrate that using the chromogenic assay kit TECHNOCHROM® C1-INH in optimized settings on Ceveron® c100 the determination of functional C1-INH can be performed with very good performance within less than 10 minutes.

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PB0123 ISTH Melbourne 2019