

Precision Performances Evaluation of sthemO Routine tests on the sthemO 301 Analyzer

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INTRODUCTION

Prothrombin time (PT), (activated) partial thromboplastin time (APTT), fibrinogen (Fib) level determination through Clauss method and Thrombin time assays all belong to the routine hemostasis tests panel. As such, laboratories carryout most of these assays very frequently and their precision performance is critical to provide a valuable tests.

The new Stago analyzer sthemO 301 is developed with new and dedicated applications and reagents for routine hemostasis tests : sthemO PT M, sthemO PTT A, sthemO CK Prest, sthemO Fib M and sthemO Thrombin M.

The aim of the study presented was to assess the Single site and Multi site precisions of these applications according to the CLSI EP05-A3.

MATERIALS & METHODS

The precision studies was conducted using the new Stago analyzer sthemO 301 on one site (Intra site) or three sites (Multi site) on plasma samples covering the whole measuring range for each test.

The Intra-site study is carried out over 20 days (2 run per day, 2 replicates) on 3 analyzers. Data are presented for one lot on the combination of the three analyzers (n=240 measures).

For the Multi sites study, a total of 10 runs (5 days, 2 run per day, 3 replicates) were carry out with 1 lot of each reagent on 1 sthemO 301 per site (n=90 measures).

sthemO Daily / Complete QC 1&2 (QC level 1&2) are usable for 24 hours.

All reagents and analyzers were from Stago, France.

No accessories (stirring bar and reducer) are needed, and preparation time is optimized for routine reagent :

Reagents	sthemO family	
	Preparation time	accessories
sthemO PT M	5 min.	none
sthemO Thrombin M	15 min.	none
sthemO CK Prest	15 min.	none
sthemO PTT A	15 min.	none
sthemO Fib M	ready to use	none

RESULTS

Intra-site precision for one lot/all lots combined and for all instruments combined was calculated from the intra-site study.

Table 1 : Intra-site precision for sthemO PT M

Samples	PT in seconds			PT INR		
	Mean (sec)	Within run CV %	Within lab CV%	Mean (INR)	Within run CV %	Within lab CV%
QC level 1	13.9	0.6%	1.7%	1.12	0.7%	1.7%
QC level 2	31.8	0.9%	2.4%	2.48	0.9%	2.2%
Normal	13.0	0.9%	1.7%	/	/	/
VKA	96.3	1.4%	6.8%	7.3	1.4%	6.6%
Deficient V	46.4	0.2%	0.7%	/	/	/

Table 2 : Intra-site precision for sthemO Thrombin

Samples	Mean (sec)	Within run CV %	Within lab CV%
QC level 1	18.3	0.9%	1.8%
Normal	15.0	0.9%	2.5%
QC abnormal	35.0	1.1%	4.3%
Plasma UFH 1	53.3	2.9%	6.5%
Plasma UFH 2	65.9	2.9%	7.0%

The International Normalized Ratio was calculated from :
International Sensitivity Index of the lot (0.97)
and from the Mean Normal Prothrombin Time of the lot (12.4 seconds)

PT

Thrombin time

Table 3 : Intra-site precision for sthemO CK Prest

Samples	Mean (sec)	Within run CV %	Within lab CV%
QC level 1	29.0	0.7%	1.8%
QC level 2	50.1	1.4%	2.8%
Normal	31.1	1.5%	2.4%
Plasma UFH	55.4	0.6%	1.7%
Deficient IX	123.7	0.8%	1.9%

kaolin aPTT

Table 4 : Intra-site precision for sthemO PTT A

Samples	Mean (sec)	Within run CV %	Within lab CV%
QC level 1	34.5	1.0%	2.8%
QC level 2	63.6	0.9%	2.7%
Normal	36.4	0.9%	3.0%
Plasma UFH	101.3	1.0%	2.2%
Deficient IX	149.1	1.9%	4.3%

silica aPTT

Table 5 : Intra-site site precision for sthemO Fib M

Samples	Mean (g/L)	Within run CV %	Within lab CV%
QC level 1	2.73	1.2%	1.5%
QC level 2	1.20	3.1%	3.7%
Normal	2.47	3.0%	4.7%
Hypofibrinogen	0.56	1.8%	2.1%
Hyperfibrinogen	10.32	1.7%	2.9%

Fibrinogen

Table 6 : Multi-site precision for sthemO Fib M

Samples	Mean (g/L)	Within run CV %	Within lab CV%
QC level 1	2.75	1.5%	2.4%
QC level 2	1.21	3.0%	3.3%
Normal	2.53	1.5%	3.0%
Hypofibrinogen	0.56	1.8%	2.1%
Hyperfibrinogen	10.36	1.7%	2.6%

CONCLUSION

The reagents for routine tests on sthemO 301 are precise and reproducible over the whole range and the CV% results are in accordance with GFHT recommendations (Groupe Français d'études sur l'Hémostase et la Thrombose).

The CV% obtained provide evidence that with the new Stago system (analyzer /reagents) will constitute a reliable support tool for the clinical laboratory.

In addition, preparation of reagents is **easy** on sthemO analyzer.