Analytical Performances Evaluation of the thrombophilia hemostasis test panel on sthemO 301 analyzer

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INTRODUCTION

The strategy for exploring possible cause of a venous thromboembolic event (VTE) combines a clinical investigation with a hemostasis assessment in search of inherited or acquired risk factors among which the thrombophilia test panel of the coagulation bench.

The 3 main inhibitors involved are antithrombin (AT), protein C (PC) and protein S (PS).

OBJECTIVES

To accompany the new sthemO 301 analyzer, some applications with dedicated reagents able to quantify the AT, the protein C and protein S levels were developed:

- sthemO AT L (amidolytic activity)
- sthemO PC chrom (amidolytic activity)
- sthemO PC clot M (chronometric activity)
- sthemO PS clot (chronometric activity)
- sthemO PS Free L (immunoturbidimetry)

The objectives of the studies are to evaluated the main performances of these reagents on sthemO 301 analyzer, according to the most recent versions of CLSI guidelines.

MATERIALS AND METHODS

All the studies were done on the new analyzer sthemO 301 with the different reagents mentioned above.

The following studies were performed regarding the different CLSI guidelines:

- Limit of detection (LoD): CLSI EP17-A2
- Limit of quantification (LoQ): CLSI EP17-A2 (total error approach)
- Linearity of the method: CLSI EP06
- Single-site analysis: CLSI EP05-A3

All tests are calibrated except sthemO Free PS (precalibrated).

The levels of calibrators are determined against their respective standards of the corresponding International Standards for the relevant parameter.

All reagents and analyzers were from Stago, France.

MEASURING RANGE

Table 1: measuring range results

	LoD	LoQ	Measuring range
sthemO AT L	9%	17%	9 - 200%
sthemO PC chrom	3%	10%	3 - 200%
sthemO PC clot M	3%	14%	3 - 200 %
sthemO PS clot	10%	17%	10 - 200%
sthemO PS Free L	6%	10%	6 - 200%

- LoD = Printout limits
- LoQ = Validation criteria

SINGLE-SITE PRECISION

Table 2: single-site precision results

		Mean (%)	% CV_R	% CV_{WL}
sthemO AT L	sthemO Daily/Complete QC level 1	99	1.4	3.2
	sthemO Daily/Complete QC level 2	44	2.3	8.0
sthemO PC chrom	sthemO Daily/Complete QC level 1	101	1.5	4.7
	sthemO Daily/Complete QC level 2	43	2.2	4.0
sthemO PC clot M	sthemO Daily/Complete QC level 1	96	2.3	5.1
	sthemO Daily/Complete QC level 2	50	2.7	5.5
sthemO PS clot	sthemO Daily/Complete QC level 1	85	2.7	5.0
	sthemO Daily/Complete QC level 2	43	2.5	6.0
sthemO PS Free L	sthemO Daily/Complete QC level 1	77	1.5	2.3
	sthemO Daily/Complete QC level 2	34	2.5	3.1

➢ Satisfactory CVs for all applications for repeatability (CV_R) and within lab between analyzer (CV_{WL}) precision

CONCLUSION

The sthemO AT L , sthemO PS clot, sthemO Free PS L, sthemO PC chrom and sthemO PC clot M assays demonstrate good performances on sthemO 301 and can be used for the quantitative determination of coagulation inhibitors in human citrated plasma. The thrombophilia test panel will be complete when the assays to screen and confirm the presence of LA/APA will be available.