Analytical Performances Evaluation of the sthemO DDi M Assay on the sthemO 301 Analyzer

Emilie Frisan[1], Emilie Ribeill[1], Vincent Genty[2], Ludovic Chaillet[2], Jia Yin Yang[1], Audrey Molet[1], Sakina Mohamed[1], Sylvie Langlet[4], Flavien Gregoire[4], Audrey Carlo[3], Nathalie Barat[1] and Claire Legros[1]

[1] Stago, Gennevilliers, France [2] Amarok Biotechnologies, Saint Malo [3] Stago, Asnieres sur Seine, France [4] Stago, Laboratoire de Génération de données, France

INTRODUCTION

D-dimers (DDi) are the terminal products of fibrin degradation by plasmin. DDi level determination is used, in conjunction with a clinical pretest probability (PTP) assessment model, to exclude venous thromboembolism in outpatients or as an aid to diagnose and monitor disseminated intravascular coagulation. High D-dimer levels can also be observed in several medical and clinical situations, among which COVID-19 infection.
Many DDi levels measurement methods and assays are available for clinical laboratories. A new assay using monoclonal antibodies adsorbed on latex particles, sthemO DDi M, has been designed for quantitative DDi levels measurement on sthemO 301 analyzer.

AIM

The objectives of the studies are to evaluated the main performances of the sthemO DDi M reagent, on sthemO 301 analyzer, according to CLSI guidelines.

MATERIALS & METHODS

The studies were performed with the sthemO DDi M reagent.
It is pre-calibrated test: this pre-calibration is valid for all the kits of the same lot.
Quality controls were performed with sthemO DDi QC 1&2.
The following studies were conducted using the sthemO 301 according to CLSI guidelines :

Measuring Range	Stability
- Linearity: EP06-Ed2 - Limit of detection (LoD): EP17 A2 - Limit of quantitation (LoQ): EP17 A2 (Total error approach)	According to EP25 A. The stability study was tested on sthemO DDi QC levels 1&2 and three different samples (including threshold sample)

Precision	
Intra-site:	Multi-site:
According to EP05 A3. The intra-site precision study was carried out over twenty days with two runs per day (two replicates per run), with one lot of sthemO DDi M on analyzers.	According to EP05 A3. The multi-site precision study was carried out over five days with two runs per day (three replicates per run), with one lot of sthemO DDi M on analyzers.

REAGENTS PREPARATION

The sthemO DDi M reagent is ready to use.
The sthemO DDI QC 1&2 are ready to use and no accessories are needed.

RESULTS

MEASURING RANGE

The LoD and LoQ were determined using four batches of sthemO DDi M on four analyzers.
The linearity was established using six batches of sthemO DDi M on six analyzers.

Table 1 : sthemO DDi M measuring range

LoD (µg/mL)	LoQ (µg/mL)	Measuring range
0.190	0.220	0.190 - 30.000 µg/mL

PRECISION

Table 2 : between Analyzer precision
one sthemO DDi M batch on 3 sthemO 301

	CV% repeatability single site (n=240)		CV% Between Analyzer single site (n=240)	
	Mean (µg/mL)	CV (%)	Mean (µg/mL)	CV (%)
sthemO DDI QC 1	0.749	1.0	0.749	1.3
sthemO DDI QC 2	1.901	0.6	1.901	0.9
Threshold plasma	0.518	2.6	0.518	3.1
Sample 1	2.172	1.0	2.172	1.9
Sample 2	21.690	2.5	21.690	2.9

Table 3 : Multi site precision
one sthemO DDi M batch on 3 sthemO 301

	CV% Total Reproducibility multi site (n=90)	
	Mean (µg/mL)	CV (%)
sthemO DDi QC level 1	0.769	1.7
sthemO DDi QC level 2	2.014	1.4
Threshold plasma	0.524	2.6
Sample 1	2.176	1.9
Sample 2	21.867	4.2

➢ Precision results demonstrate the very good consistency between the CV% of repeatability and reproducibility.

DOSE HOOK EFFECT

An algorithm has been developed to manage the detection of the hook effect automatically by the analyzer. This algorithm use a different wavelength than the test. The Hook effect has been tested up to 500.000 µg/mL.

STABILITY

The sthemO DDi M is stable 15 days in their original vials on the sthemO 301.
The sthemO DDi QC levels 1&2 are stable 3 days in their original vials on analyzer. These controls are also stable 15 days in their original vials after several cycles of tests on board and storage at 2-8°C.

CONCLUSION

The sthemO DDi M assay demonstrates very good performances on sthemO 301, verifying it can be used for the quantitative determination of D-dimers in human citrated plasma in medical explorations.