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## Background

Thrombin generation (TG) is known for more than 60 years. Several developments have been done through the years to improve its usability but it remains a research use tool because of a lack of standardization of methods.

Typical inter-day precision of TG assays is around 10 to 30% depending on the parameter analyzed. It depends on the concentration and the source of tissue factor (TF) in the reagent, the use of external or local normal plasma to normalize the results, the operator as well as the method.<sup>1,2</sup>

## Objectives

ST Genesia, a new analyzer intended to measure thrombin generation in a fully automated way, was evaluated in our lab for validation purposes.

Aside from biological outcomes of our protocol in the anticoagulant treatment setting, the purpose of this evaluation was also to determine how precise could become TG measurement.

## Methods

41 independent runs of measurement were performed with the same batch of STG - DrugScreen on ST Genesia. On each run, 3 freeze-dried samples were tested prior to testing fresh or frozen patient samples. 2 of these samples were internal quality control samples (hypocoagulable and normocoagulable) and 1 is intended to be used as reference plasma for normalizing results.<sup>2</sup>

## Conclusions

Automation, enhanced control of temperature throughout the assay and standardization of thrombin generation measurement help to achieve highly reproducible results, first step to introduce this assay in the clinical lab.

## Results

Mean, standard deviation and coefficient of variation achieved are reported in the table below.

n=41	Sample 1 = STG – QualiTest Norm DS			Sample 2 = STG – QualiTest Low DS			Sample 3 = STG – RefPlasma DS		
	Mean	SD	CV	Mean	SD	CV	Mean	SD	CV
<b>Lag time (min)</b>	0.92	0.04	4.6%	1.18	0.05	4.1%	0.98	0.05	5.2%
<b>Peak (nM)</b>	501.92	16.17	3.2%	206.80	10.12	4.9%	486.25	16.50	3.4%
<b>Time to Peak (min)</b>	1.97	0.07	3.6%	2.32	0.10	4.3%	2.17	0.08	3.5%
<b>ETP (nM.min)</b>	1602.66	65.24	4.1%	522.55	20.55	3.9%	1740.53	67.63	3.9%
<b>Velocity Index (nM/min)</b>	718.69	55.87	7.8%	244.02	23.37	9.6%	598.74	49.27	8.2%

## Disclosure

Dr. Douxfils reports personal fees from Stago for this work, personal fees from Daiichi-Sankyo and Roche outside the submitted work; Stago provided financial support to this work.

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## References

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