Performances Evaluation of a New Coagulation Analyzer, Sta R Max²

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BACKGROUND/INTRODUCTION

StaR Max² is a new high throughput coagulation analyzer developped by Diagnostica Stago, able to perform clotting, chromogenic and immunoturbidimetric tests simultaneously, using a Viscosity Based Detection System. It is also equipped with a preanalytical module including check volume function. In this study, the analytical perfomances of this new instrument were evaluated using **Prothrombin Time (PT)**, **Activated Partial Thromboplastin Time (APTT)** and **Fibrinogen (Fib)** for clotting method, **Antithrombin (AT)** for chromogenic method and **D-Dimer (DDi)** for immunoturbidimetric method. Method comparison with the STAR Evolution instrument was also performed on the same parameters.

AIMS

The aim of this evaluation was the validation of this new instrument before integration in the routine lab, by comparison with the STAR Evolution which is the instrument currently used.

MATERIAL & METHODS

Quality controls and pool of plasmas were used for intra-run precision. For inter-run precisions, quality controls were run twice a day for a period of at least 15 days. Two levels were evaluated for all parameters. For method comparisons, fresh plasma samples from patients were used. Reagents STA® -Neoplastine® R for PT, STA®-PTTA for APTT, STA®-Liquid Fib for fibrinogen, STA®-Stachrom®ATIII for AT and STA®-Liatest® D-DI PLUS for Ddi, all from Stago were used for this study . Analytical performances were assessed by calculating mean, standard deviation and coefficient of variation for intra-run and inter-run precisions. Method comparisons were analyzed using linear regression and Bland & Altman. Graphs were drawn from Medcalc software (Version V14.12.0).

RESULTS FOR ANALYTICAL PERFORMANCES

INTRA-RUN PRECISION ON STAR MAX²

Test	n	mean	Standard Deviation	Coefficient of variation
PT (sec.)	32	14,06	0,161	1,14
	32	29,86	0,268	0,90
APTT (sec.)	32	32,11	0,167	0,52
	32	64,55	0,264	0,41
FIB (g/L)	31	2,97	0,053	1,77
	31	1,59	0,057	3,57
AT (%)	32	116,25	1,437	1,24
	32	56,66	1,516	2,68
Ddi (µg/mL)	32	0,48	0,053	NA
	32	1,53	0,048	NA

INTER-RUN PRECISION ON STAR MAX²

Test	n	mean	Standard Deviation	Coefficient of variation
PT (%)	43	84,3	2,94	3,49
	41	26,22	0,725	2,77
APTT (sec.)	34	33,66	1,002	2,98
	33	65,09	1,914	2,94
FIB (g/L)	34	2,92	0,070	2,41
	33	1,14	0,034	3,04
AT (%)	51	108,35	7,584	7,00
	52	49	5,951	12,14
DDi (µg/mL)	33	0,248	0,052	NA
	33	2,21	0,066	NA

Results from intra-run and inter-run precisions are good and compliant with the specifications given by the GFHT (« Groupe Français d'études sur l'Hémostase et la Thrombose ») and GRAAL (« GRoupe d'Aide à l'Accréditation des Laboratoires ») which is a group created by Stago to propose acceptance criteria for method validation process. Coefficients of variation (CV) were below 5% for most parameters in the normal and pathological range and SD below 0,1 µg/mL for Ddi.

RESULTS FOR METHOD COMPARISON

Results of the method comparisons for PT(%), APTT (sec), Fib (g/L), AT(%) and Ddi (µg/mL) are shown in figures 1 to 5.

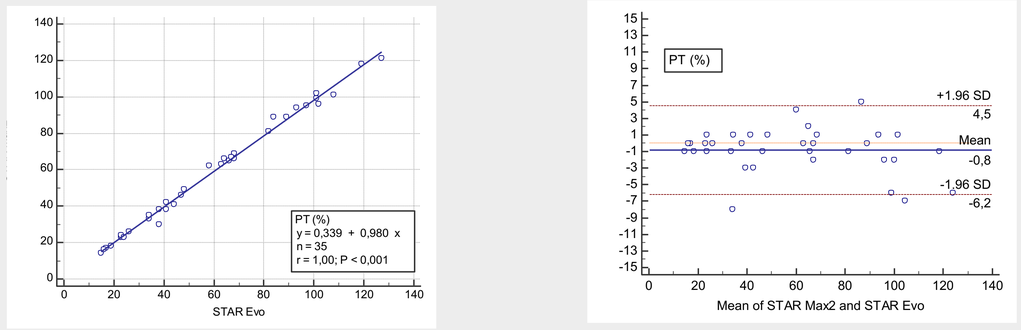

Fig. 1 Linear regression & Bland & Altman graphs
StaR Max² vs STAR Evo PT %

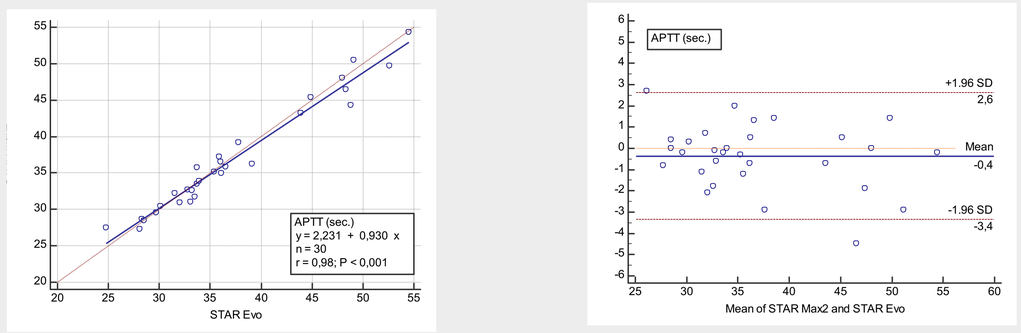

Fig. 2 Linear regression & Bland & Altman graphs
StaR Max² vs STAR Evo APTT sec

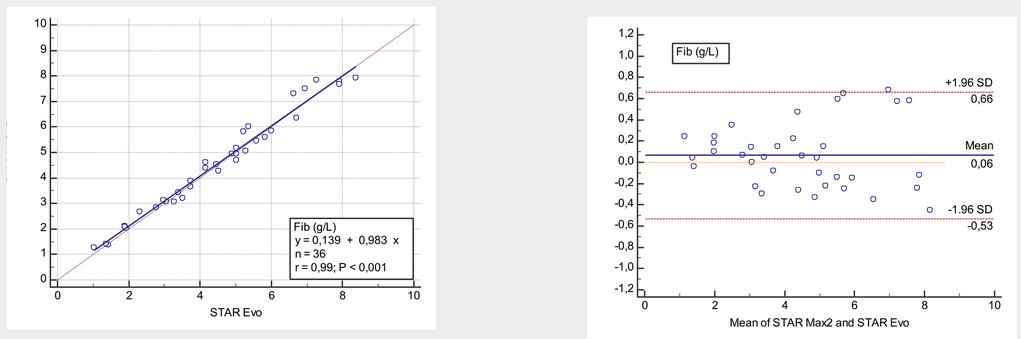

Fig. 3 Linear regression & Bland & Altman graphs
StaR Max² vs STAR Evo Fib g/L

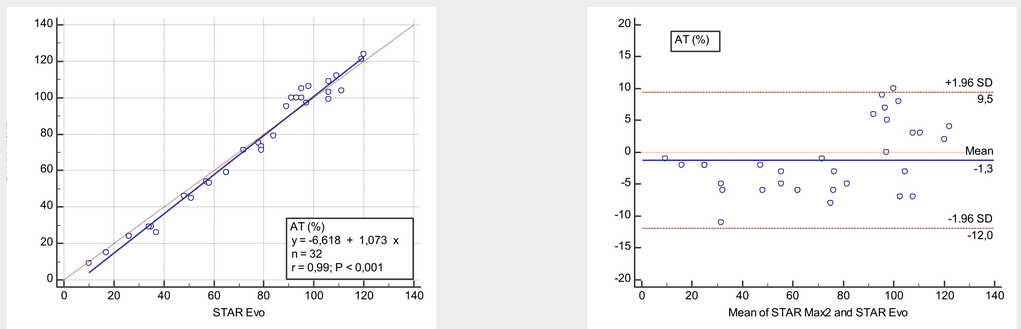

Fig. 4 Linear regression & Bland & Altman graphs
StaR Max² vs STAR Evo AT %

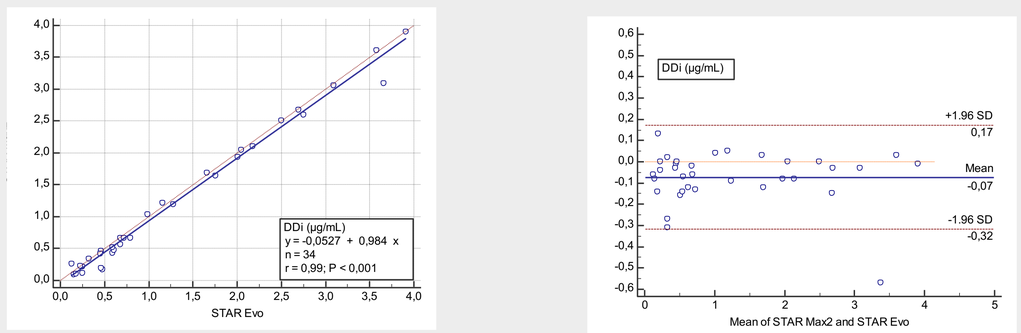

Fig. 5 Linear regression & Bland & Altman graphs
StaR Max² vs STAR Evo Ddi µg/mL

Method comparisons for all parameters tested on the two instruments show good correlations. All the tests evaluated, which represent the different methodologies performed by StaR Max², have slope coefficients and correlation coefficients very close to 1 meaning that results are very similar on all the working range on both instruments.

CONCLUSION

The performance of the new analyzer (StaR Max²) is highly equivalent to the analyzer currently used at the lab both in analytical performances and patients results. This will allow us to switch on the StaR Max² in a transparent manner for clinicians.