Performances evaluation of a new PT reagent
STA® - NeoPTimal for PT/INR measurement and exogenous coagulation factors assays

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INTRODUCTION & OBJECTIVES

Quick Prothrombin Time (PT) is a routine clotting assay used to explore vitamin-K dependant factors (factors II, VII, IX and X) and non vitamin-K dependant factors (fibrinogen and factor V). PT expressed as International Normalized Ratio (INR) is the only test used for Vitamin K Antagonist (VKA) therapy monitoring.

A new PT reagent, **STA® - NeoPTimal** (Stago, Asnières sur Seine, France) prepared from rabbit tissue factor with ISI close to 1 (0,9 to 1,1) was tested and compared to two well known used reagent, STA® - Neoplastine® R (recombinant human thromboplastin) and STA® - Neoplastine® CI PLUS (rabbit tissue factor) with ISI close to 1,2 both manufactured by Stago. PT and exogenous factors assays were performed on a **STA R Max²®**, a new coagulation analyser manufactured by Stago.

MATERIAL & METHODS

All tests were performed in the University Hospital of Charleroi (Belgium). We selected a wide range of normal and abnormal fresh plasmas: healthy patients (60 samples), patients with hepatic failure (58 samples) and patients on a VKA therapy (112 samples).

Method comparison for factor assays was performed on STA® - Neoplastine® R and STA® - NeoPTimal on a minimum of 30 samples.

Analytical performances were evaluated with intra-run precisions and inter-run precisions on quality controls. They were assessed by calculating mean, standard deviation and coefficient of variation for intra-run and inter-run precisions.

CONCLUSION

The evaluation of the new thromboplastin **STA® - NeoPTimal** shows good results. The analytical performances are compliant with expected specifications. Method comparisons show good consistency for **STA® - NeoPTimal** versus STA-Neoplastine CI PLUS® and **STA® - NeoPTimal** versus STA® - Neoplastine® R for PT/INR. The factor assays correlations demonstrate good results between the two thromboplastins tested.

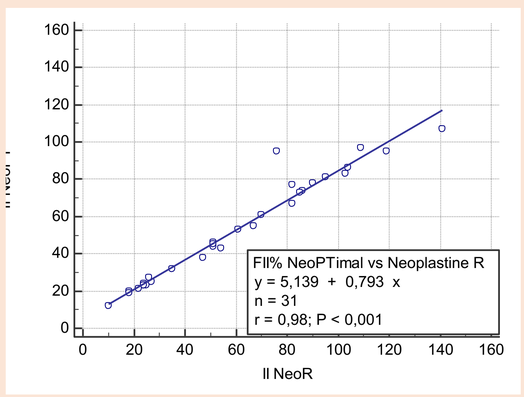
ANALYTICAL PERFORMANCES RESULTS

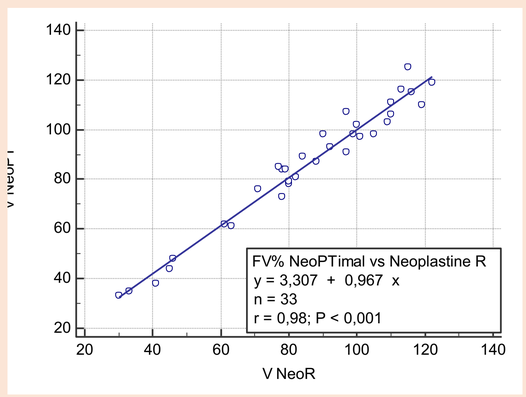
Figure 1: Analytical performances of STA® - NeoPTimal

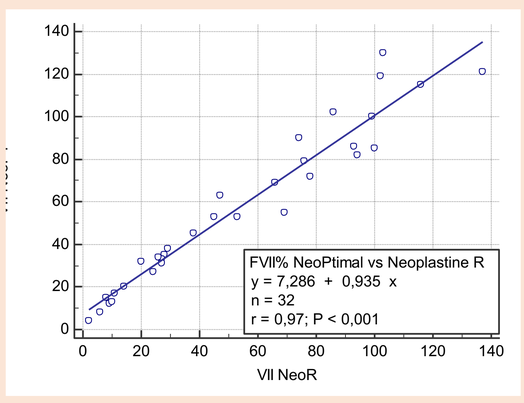
	Intra-run precision		Inter-run precision	
	Level 1	Level 2	Level 1	Level 2
n	32	32	53	49
Mean	13,39 sec.	29,31 sec.	83,75%	28,82%
SD	0,130	0,206	2,731	1,409
CV (%)	0,97	0,41	3,26	4,89

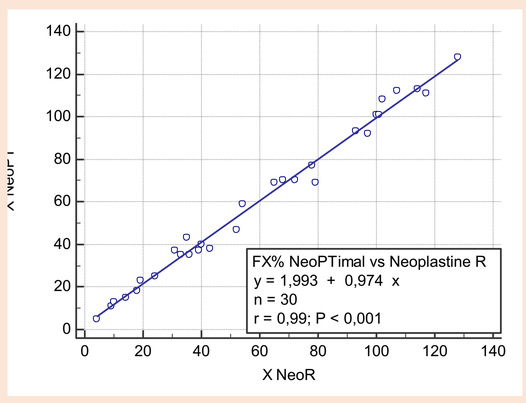
Results from intra-run and inter-run precisions are good and compliant with the specifications given by GRAAL (« GRoupe d'Aide à l'Accréditation des Laboratoires ») which is a group created by Stago to propose acceptance criteria for method validation process.

EXOGENOUS FACTOR ASSAYS RESULTS



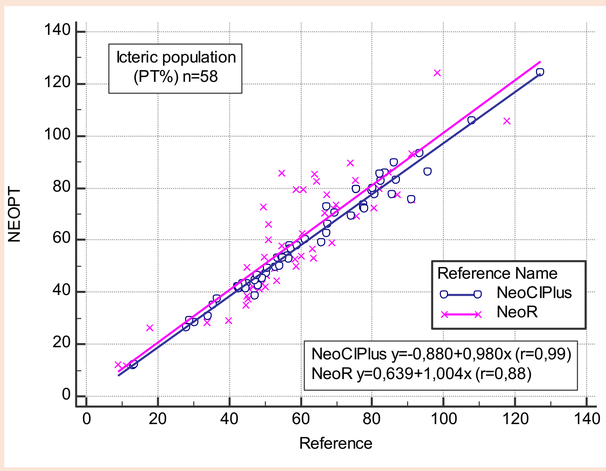


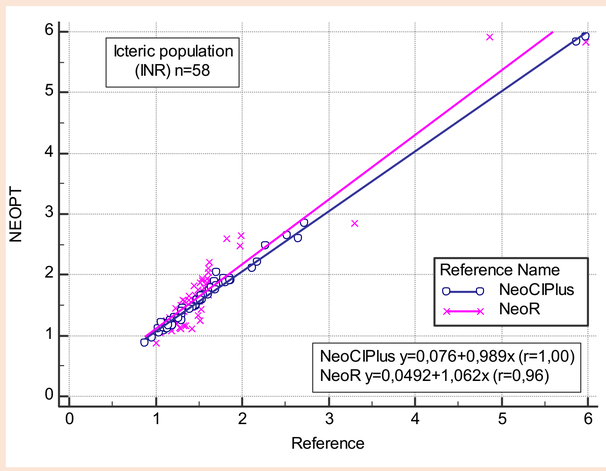




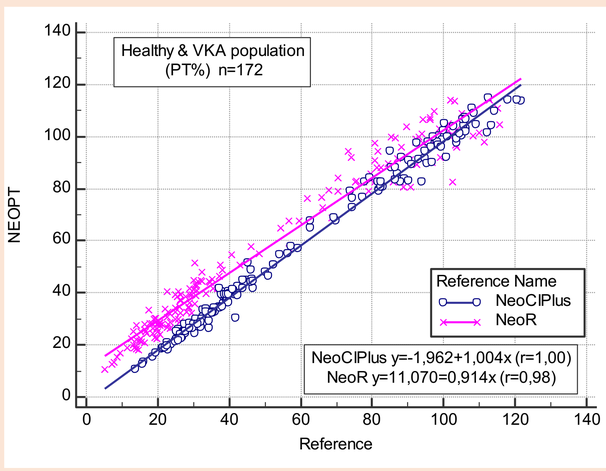
Results show good correlations between the two thromboplastins for exogenous factor population. The same deficient reagent was used to dose factor V, VII and X. Factor II was performed using a different deficient reagent for each thromboplastin (STA® - ImmunoDef II for STA® - Neoplastine® R and STA® - Deficient II for STA® - NeoPTimal).

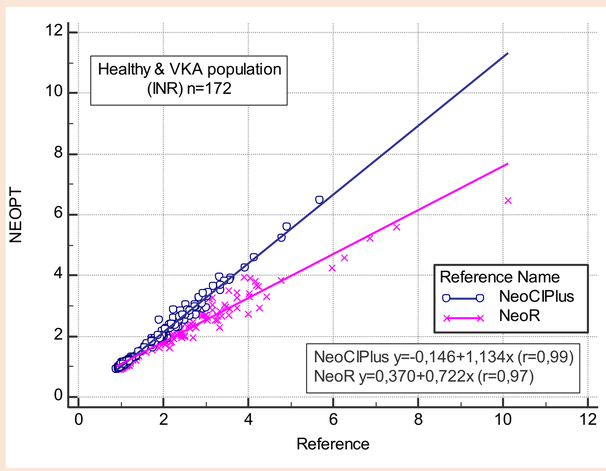
PT/INR RESULTS





Hepatic population: correlations show good regression coefficients: 1,00 when we compare the new thromboplastin with another extraction thromboplastin and 0,96 when we compare with the recombinant thromboplastin.





Healthy & VKA populations: correlation is very good between both extraction thromboplastins showing a regression coefficient of 1,00 for PT% and 0,99 for INR. Correlation with recombinant thromboplastin shows regression coefficients of 0,98 for PT% and 0,97 for INR.
Differences observed between STA® - NeoPTimal and STA® - Neoplastine® R on Healthy/VKA population could be explained by the different sensitivity of thromboplastin from different origins (rabbit brain versus human recombinant) to FVII deficiency.