

# Validation of a new thromboplastin with ISI close to 1



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## INTRODUCTION

Prothrombin time (PT) is a screening test exploring extrinsic coagulation pathway. This test is daily used in the hemostasis laboratory as prolonged PT are observed in different clinical or therapeutical settings such as vitamin K antagonists treatment. STA<sup>®</sup>-NeoPTimal is a new thromboplastin obtained from rabbit brain extract, with an International Sensitivity Index (ISI) close to 1.0.

## AIM

Evaluate the precision of STA<sup>®</sup>-NeoPTimal, a thromboplastin from extraction with an ISI close to 1.0, and compare it with Innovin<sup>®</sup>, thromboplastin from recombinant source, also with an ISI close to 1.0 and already used routinely in the laboratory.

## MATERIALS AND METHODS

The study was performed on December 27, 2017 in the laboratory Analizar in Bogota, Colombia.

Precision was assessed through 10 replicates on the two quality controls of the assay.

The results obtained with **STA<sup>®</sup>-NeoPTimal** on **STA<sup>®</sup> Compact Max** (Annar Diagnóstica, Colombia) were compared with results from samples previously analyzed with **Innovin<sup>®</sup>** (Siemens Healthcare S.A.S., Colombia) measured on **CA 560** analyzer (Sysmex, Colombia) (n=31, INR 0.89 to 7.50).

## RESULTS

- **Precision:** coefficients of variation obtained with normal and pathological quality controls levels were 0.76% and 0.89% respectively.
- **Method comparison:** data from linear and Passing-Bablok regressions of the method comparison are displayed in the table below. Figure 1 is the Passing-Bablok representation for INR results.

PT in	n	Linear regression		Passing-Bablok regression	
		Equation	r	Equation	r
seconds	31	$y = 1.65 + 1.23x$	0.985	$y = 0.13 + 1.37x$	0.937
INR	31	$y = 0.27 + 0.86x$	0.984	$y = 0.08 + 0.99x$	0.933

Table: Comparison STA<sup>®</sup>-NeoPTimal with Innovin<sup>®</sup>: equations and correlation coefficients.

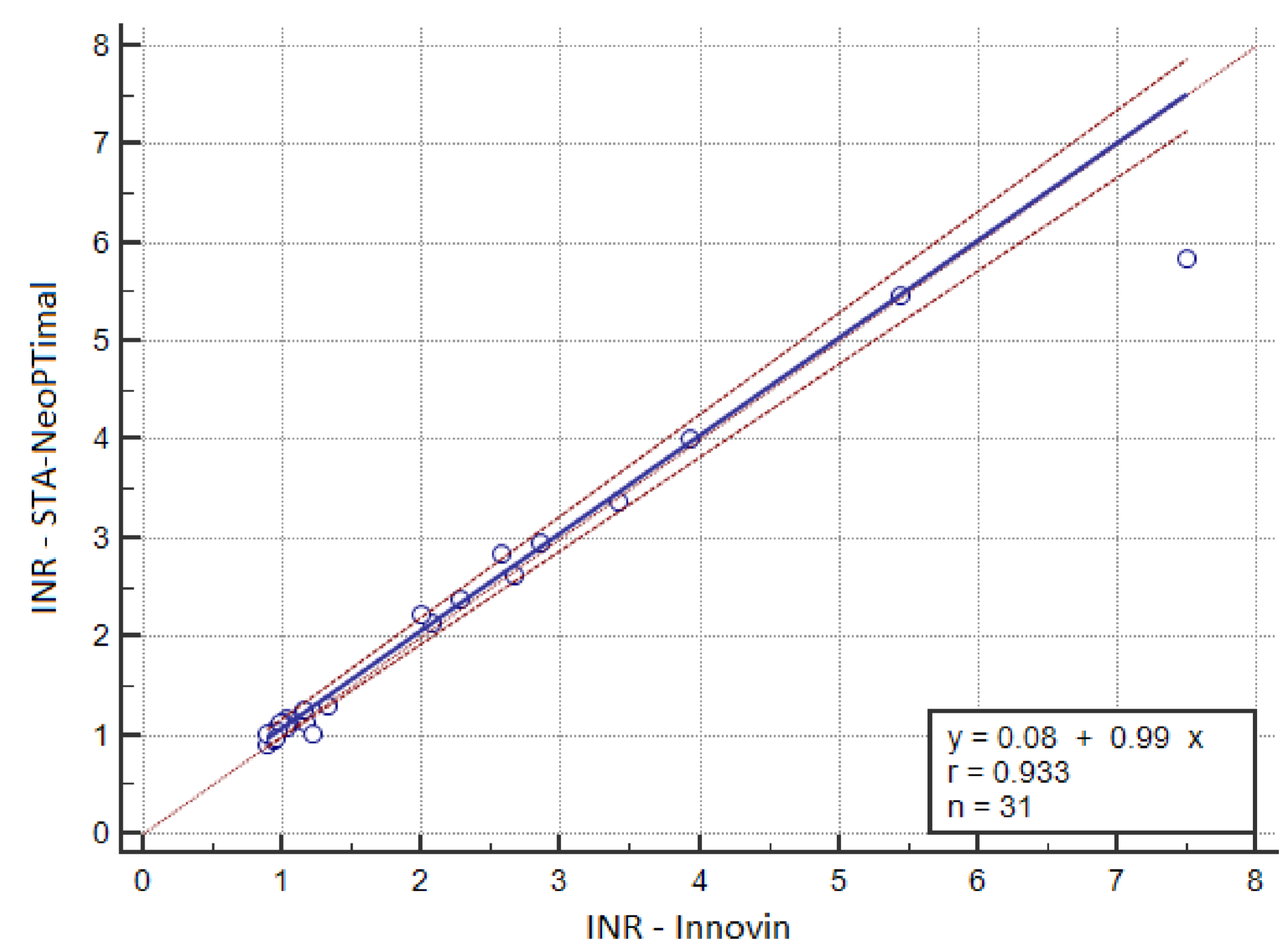


Figure 1: Comparison STA<sup>®</sup>-NeoPTimal with Innovin<sup>®</sup> on INR results: Passing-Bablok regression

## DISCUSSION

Precision met our validation criteria.

The method comparison analyses show excellent correlation coefficients, all above 0.98. When using Passing-Bablok regressions, that will give less power to extreme values in the regression, the regression slope for the INR comparison and its 95% confidence interval meet the 0.9-1.1 acceptance criteria.

## CONCLUSION

Results obtained with **STA<sup>®</sup>-NeoPTimal** show that this new thromboplastin reagent **can be used in the routine laboratory**, with an excellent correlation on INR when compared to another thromboplastin from recombinant source.

### References:

- Kamal AH, Tefferi A, Pruthi RK, *How to interpret and pursue an abnormal prothrombin time, activated partial thromboplastin time, and bleeding time in adults.* Mayo Clin. Proc., 82, 864-873, 2007
- Riley RS, Rowe D, Fisher LM, *Clinical utilization of the international normalized ratio (INR).* J. Clin. Lab. Anal., 14, 101-114, 2000.
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