Analytical Validation and Method Comparison of the HORIBA Medical Yumizen G1550® versus Stago STA-R Evolution® System

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Introduction

Today on the market, two main methods are available to study coagulation, optical methods and mechanical methods. The Stago company is present in many medical biology laboratories in France for historical reasons. This supplier communicates the fact that viscometric detection makes it possible to be partially free from HIL analytical interference. Technological developments in optical methods now enable these to offer equivalent analytical performance. For example, on a worldwide scale, the optical method used by Siemens Healthineers serves as a reference.

Objectives

The Yumizen G 1550® system evaluated in this study uses the optical methods of photometry and turbidimetry. The purpose of this study is to compare the STA-R Evolution® and the Yumizen G 1550®, in terms of analytical performance on healthy and pathological plasmas for the parameters PT, aPTT, and fibrinogen.

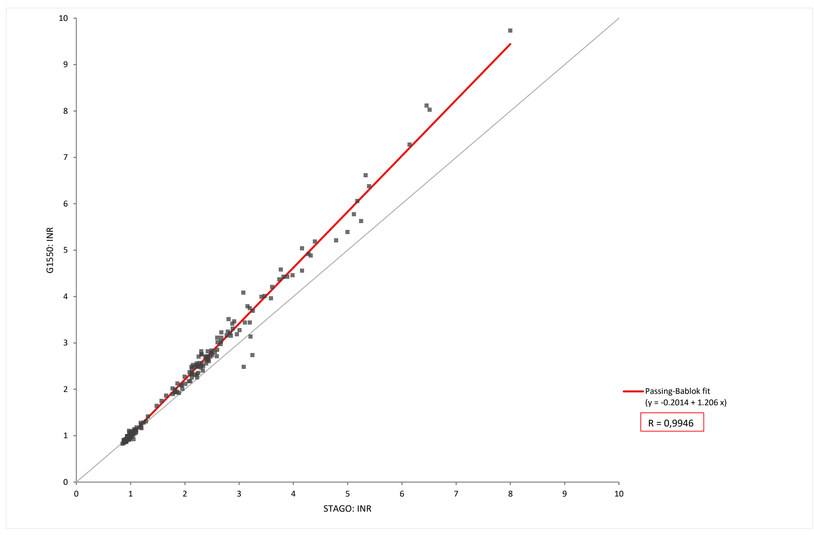
Materials and methods

The samples to be used for correlation testing were obtained without prior selection, at the Saint-Laurent-de-la-Salanque central laboratory, which processes samples from MEDILAB's 14 satellite laboratories. These samples were obtained exclusively in the city and without using adjoining clinics. The majority of samples were obtained for preoperative check-ups or follow-up of anticoagulant treatment (INR). It should be noted that none of the patients included in the study had replacement of oral anticoagulant therapies (VKA) with parenteral heparin. They were collected according to pre-analytical recommendations: CLSI Jan 2008: H21-A5 (3.2% BD Vacutainer® citrate tube, storage at 22 +/- 2°C after centrifugation for 10 minutes at 2200 rpm, APTT < 4h, PTT < 8h). The parameters used for the study were PT, aPTT, and Fibrinogen. The associated HORIBA reagents were: Yumizen G PT-LIQ® (animal tissue extract, liquid and ready-to-use, ISI = 1.29), Yumizen G APTT LIQ® reagent (which uses ellagic acid with characteristics close to kaolin), and Yumizen G FIB 5® (which uses the Clauss method). The associated Stago reagents were: STA-NeoPTimal® (liquid and ready-to-use, ISI = 1.05), STA-Cephascreen® and STA-Liquid Fib®. The first step was to perform MNAPTT and MNPT on a sample of 20 healthy patients. The assessment was based on a repeatability and reproducibility study on PTT, APTT, DDI and Fibrinogen parameters. Repeatability was based on more than 20 runs of internal quality controls (Yumizen G CTRL I&II), high and low level. Reproducibility was carried out on 2 or 3 daily runs of the same quality controls. The correlation tests were carried out on a sampling of about 200 plasmas, taken at random and covering as well as possible all the measurement range. The tests were carried out simultaneously on each of the two systems, in the shortest possible time, to limit the bias of the runing time. The raw data was collected in a Microsoft Excel® file provided by HORIBA Medical®. Correlation analysis was performed according to the recommendations of CLSI EP9-A3(5) using Passing-Bablok regression. The bias study was performed by Bland-Altman differential analysis.

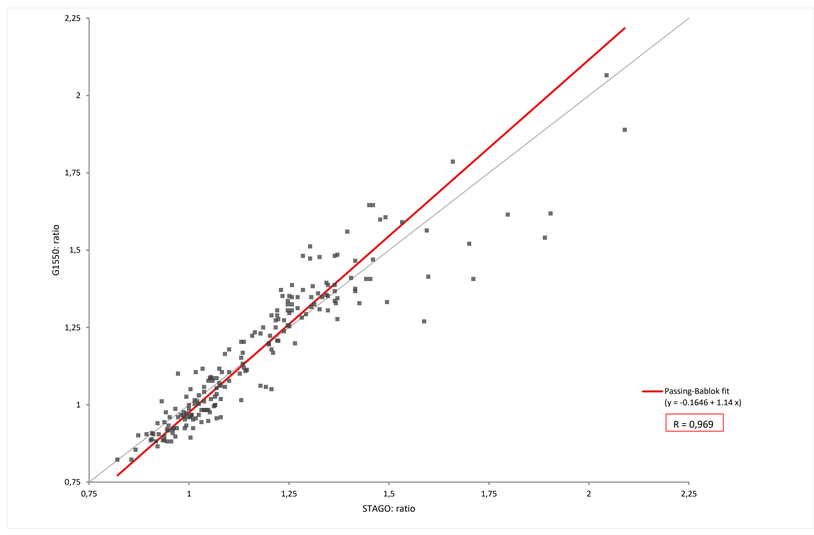
Results

	CV value	CV GRAAL Analytical objectives Recommended
PTliq I	0,64%	< 1,5%
PTliq II	1,17%	< 2,0%
aPTTliq I	1,43%	< 1,5%
aPTTliq II	0,97%	< 2,0%
Fib I	2,21%	< 4,0%
Fib II	1,92%	< 5,0%

Summary table of repeatability CVs according to GRAAL V2010 recommendations



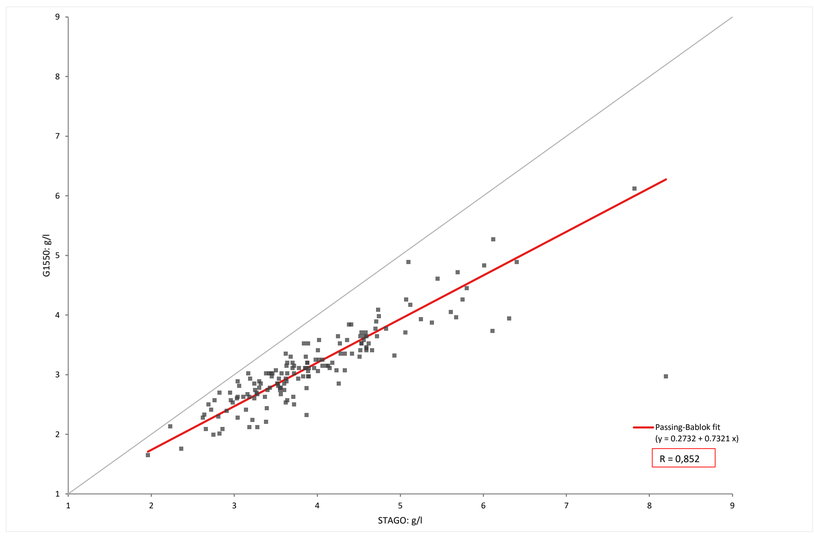
Passing Bablock INR HORIBA PTL vs STAGO NEOPTIMAL



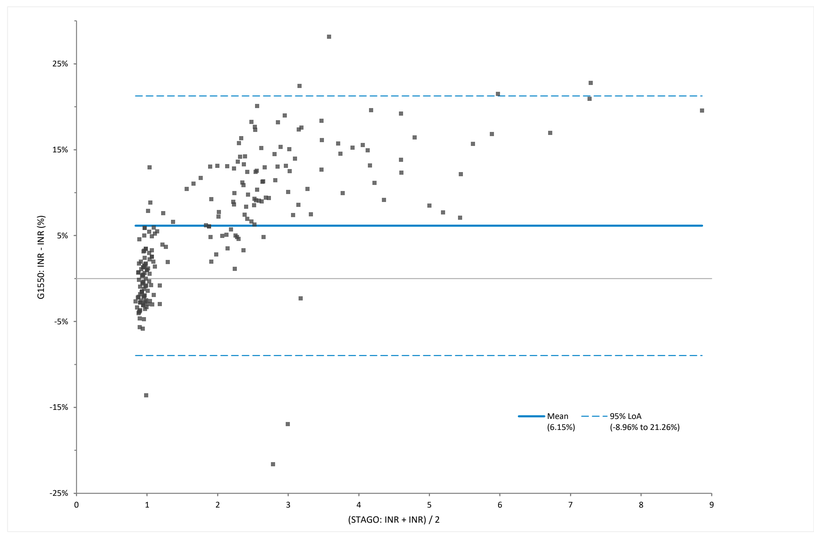
Passing-Bablock HORIBA APTT Liq vs STAGO CEPHASCREEN

	CV value	Recommended GEHT CV	GEHT CV Acceptable
PTliq I	1,15%	< 2,9%	< 3,6%
PTliq II	2,14%	< 6%	< 7,5%
aPTTliq I	1,31%	< 3,9%	< 4,9%
aPTTliq II	1,01%	< 3,9%	< 4,9%
Fib I	2,85%	< 6,5%	< 7,6%
Fib II	5,36%	< 6,5%	< 7,6%

Summary table of reproducibility CVs according to GEHT 2014 recommendations



Passing-Bablock HORIBA Fib vs STAGO Fib



Bland-Altman INR HORIBA vs STAGO

Discussion

Our work reports results in line with the recommendations of the learned societies in hemostasis (GRAAL and GEHT). We note a perfect correlation of INR in the therapeutic range 1-4 but a relative overestimation of INR outside the therapeutic range (INR > 5). This is probably due to the ISI of the PT-LIQ® reagent being too far away from 1.00 on the test lot (ISI = 1.29). For fibrinogen and aPTT, the correlations are acceptable.

Conclusion

During the study we validated the Yumizen G 1550® system. With regard to the GEHT and GRAAL recommendations on the parameters PT, aPTT, and Fibrinogen, the repeatability and reproducibility studies are in compliance. The method comparison with the STA-R Evolution® gives us comparable values for the three parameters mentioned above even if the correlation remains imperfect (especially for high INRs).