**Performance evaluation of the new point-of-care coagulation analyzer Xprecia stride for measuring INR in VKA-treated patients – comparison with local laboratory automated reference method**

Authors:

Lecut C.1, Peters P.1, Bossu O.2, Gothot A.1

Authors’ affiliations:

1 Department of Laboratory Hematology, University Hospital of Liège, Liège, Belgium

2 Siemens Healthcare SA/NV, Beersel, Belgium

Abstract:

**Background**

Vitamin K antagonist (VKA) therapy requires frequent monitoring of prothrombin time (PT), expressed as International Normalized Ratio (INR), for optimal anticoagulation. INR testing is routinely performed on laboratory automated hemostasis analyzers but over the past few years, portable coagulometers were developed to be used as point-of-care (POC) devices. The Xprecia stride (Siemens Healthcare) is a new POC coagulation analyzer designed to monitor INR on fingerprick blood samples.

**Aims**

The aim of our study was to compare the performances of the Xprecia Stride coagulation analyzer to our laboratory automated reference method (Thromborel S®/BCS XP system).

**Methods**

83 consecutive patients on VKA therapy were enrolled over a 9 months period (august 2015 - april 2016). 20 of these patients were seen twice during the period of inclusion. The cohort consisted in 59% male/41% female, of age ranging from 23 to 86 years old (median: 55 y).

Blood sampling consisted in two separate fingerprick blood drops for duplicate INR testing using Xprecia stride, and an additional venous sample was collected on 3.2% sodium citrate anticoagulant for standard laboratory INR determination. Venous blood samples were centrifuged 10 min at 2500 g and the platelet-poor plasma was immediately assessed on a BCS XP system using Thromborel S® reagent (reference method).

Xprecia stride employs single-use reagent test strips. Its PT reagent is a recombinant human tissue thromboplastin, analog to the Dade® Innovin® reagent.

The two methods were compared using Pearson correlation test and Deming linear regression analysis using GraphPad Prism® software. Bias versus the reference method was also calculated. Repeatability was assessed on 102 pairs of capillary blood samples. Coefficient of variation (%CV) was calculated across four INR ranges : 1-2; 2-3, 3-4 and >4.

In addition, normal values were verified on 30 healthy donors and reported as percentile 2.5% and 97.5%.

**Results**

INRs measured with the Xprecia stride correlated strongly with the results obtained with our laboratory reference method, with a Pearson coefficient of 0.92. The Deming regression analysis yielded a slope of 1.15 (95% confidence interval: 1.07 – 1.22) and an intercept of -0.37 (95% CI: -0.54 - -0.19), demonstrating a slight systematic proportional bias. The absolute difference in INR measurements between the two methods was 0.03 units, the results obtained with the Xprecia stride being overall 1.5% lower. Across INR ranges, the minimum bias was -0.10 for INR 1-2 and the maximum bias was +0.43 for INR >4.

Repeatability study showed that the mean CV was 3.6%, with the lowest CV = 2.7% for INR range 2-3 and highest CV = 5.5% for INR 3-4. These results fulfilled the desirable specifications published by the French society of Thrombosis and Hemostasis, that is a CV < 5.3% for INR 1-2 and < 7.5% for INR > 2.

The expected normal values, as determined by the manufacturer, were 0.9 – 1.1. These reference values were verified on 30 healthy subjects: the INR ranged from 0.9 to 1.3. Although the upper limit of the interval was slightly higher, the reference range was nearly identical to that expected.

**Conclusions**

Overall, INR testing with the Xprecia Stride coagulation analyzer showed strong correlation with the laboratory automated reference method and good analytical performances in term of repeatability. These results confirm that the Xprecia Stride may be used at the point of care for reliable INR measurements.

Category: Clinical & Laboratory