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Evaluation of the Point-of-care Xprecia Stride Coagulation Analyzer* for PT/INR for Warfarin Monitoring

Lessard C, Vanderslice N.
Siemens Healthcare, Norwood, MA, USA

Abstract

Background: The Xprecia Stride™ Coagulation Analyzer from Siemens Healthcare is a novel, handheld point-of-care (POC) device that generates rapid PT/INR results from fingerstick samples for monitoring of oral anticoagulant therapy (OAT), specifically warfarin, a vitamin K antagonist. This external validation study assessed the clinical correlation of the Xprecia Stride PT/INR test against an established laboratory hemostasis method (BCS® XP System) as well as an alternateive point-of-care device (CoaguChek XS system).

Aims: The aim of the study was to demonstrate the strong correlation between Xprecia Stride Coagulation Analyzer test results and a central laboratory assay as well as an alternative point-of-care system.

Methods: Test methods were based on the following Clinical Laboratory Standards Institute (CLSI) guidelines: Evaluation of Precision Performance of Quantitative Measurement Methods (EP05-A2), Measurement Procedure Comparison and Bias Estimation Using Patient Samples (EP09-A3), and Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory (EP28-A3c).

Results: Passing Bablok regression analysis yielded a slope of 1.00 and an intercept of 0.10, with $R^2 = 0.91$ across the range of 0.8 to 7.7 INR, when the Xprecia Stride analyzer was compared to the BCS XP System. Passing Bablok regression analysis yielded a slope of 0.94 and an intercept of -0.02, with an R^2=0.94 across the range of 0.9 to 7.7 INR, when the Xprecia Stride analyzer was compared to the CoaguChek XS system. Repeatability using whole blood demonstrated %CVs were <5.8 across the reportable range. LQC at two levels demonstrated repeatability precision %CVs that were <3.6 and within-laboratory %CVs that were <7.0. The expected range for the PT/INR on the Xprecia Stride analyzer was 0.9 to 1.1 for subjects not on OAT.

Summary/Conclusions: The Xprecia Stride PT/INR test results demonstrated a strong correlation to both the BCS XP System as well as the CoaguChek XS system.

Background

The Xprecia Stride analyzer is intended for multiple-patient use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of oral anticoagulation therapy with warfarin, a vitamin K antagonist. The analyzer uses fresh capillary whole blood and is intended for professional in vitro diagnostic use at the point-of-care.

A clinical trial study with subjects currently on warfarin therapy and not receiving warfarin therapy at four sites with a minimum of three typical point of care operators was performed to:

- Demonstrate clinical substantial equivalence of capillary samples with laboratory method, using Dade® Innovin® recombinant human tissue thromboplastin reagent (INR v INR).
  - Total number of subjects in study was 414.
- Demonstrate clinical substantial equivalence of capillary samples with the CoaguChek XS system (INR v INR).
  - Total number of subjects in study was 406.
- Validate the repeatability of the Xprecia Stride PT/INR analyzer across the measuring range of the system for capillary samples.
- Validate the hematocrit range of the Xprecia Stride analyzer for capillary samples.

PT liquid quality control testing was conducted at each site using two levels of PT liquid quality control analyzed in duplicate every day for a minimum of 20 days.

Methods

Two fingerstick samples were taken:

- Each was tested on one Xprecia Stride PT/INR analyzer and one CoaguChek XS system.
- Three different lots of Xprecia Stride test strips were used at each site during the course of the study.

Methods (cont.)

- One 3.2% (0.109 M) sodium citrated whole-blood tube was centrifuged, and the plasma was shipped frozen to the laboratory site to be tested on a BCS XP laboratory analyzer using Dade Innovin reagent.
- One EDTA tube was tested for hematrocrit on the site's laboratory instrument.
- The system uses electrochemical technology to measure the PT/INR. A sample chamber in the strip is filled with blood sample by capillary action. The strip contains dried reagents consisting of thromboplastin, an electroactive thrombin substrate, and other reagents. An electroactive group released from the thrombin substrate is detected at the electrodes in the strip; the current produced is analyzed by an algorithm to determine the result.

Results

The repeatability of the Xprecia Stride analyzer was assessed for the pooled data from all four sites.

Table 1. Repeatability: capillary blood.

Parameter	BCS XP INR <2.0	BCS XP INR 2.0 to 3.0	BCS XP INR 4.6 to 8.0
Mean INR	1	2.6	5.5
Repeat. SD (INR)	0.06	0.14	0.24
%CV (INR)	5.8	5.3	4.4
Min Stride INR	0.9	1.7	3.6
Max Stride INR	1.5	4	7.8
N sample pairs	84	220	43

Table 2. Intermediate precision: liquid quality control.

Analyzer	Parameter	LQC 1	LQC 2
Site 1	Mean INR	1.27	3.18
	Repeatability SD	0.03	0.06
	Repeatability %CV	2.5	1.8
	Within-laboratory SD	0.05	0.15
	Within-laboratory %CV	3.9	4.9
Site 2	Mean INR	1.29	3.22
	Repeatability SD	0.03	0.07
	Repeatability %CV	2.3	2.2
	Within-laboratory SD	0.04	0.10
	Within-laboratory %CV	2.8	3.1
Site 3	Mean INR	1.20	3.18
	Repeatability SD	0.02	0.05
	Repeatability %CV	1.9	1.6
	Within-laboratory SD	0.02	0.08
	Within-laboratory %CV	1.9	2.7
Site 4	Mean INR	1.24	3.11
	Repeatability SD	0.04	0.11
	Repeatability %CV	3.3	3.6
	Within-laboratory SD	0.06	0.22
	Within-laboratory %CV	4.6	7.0

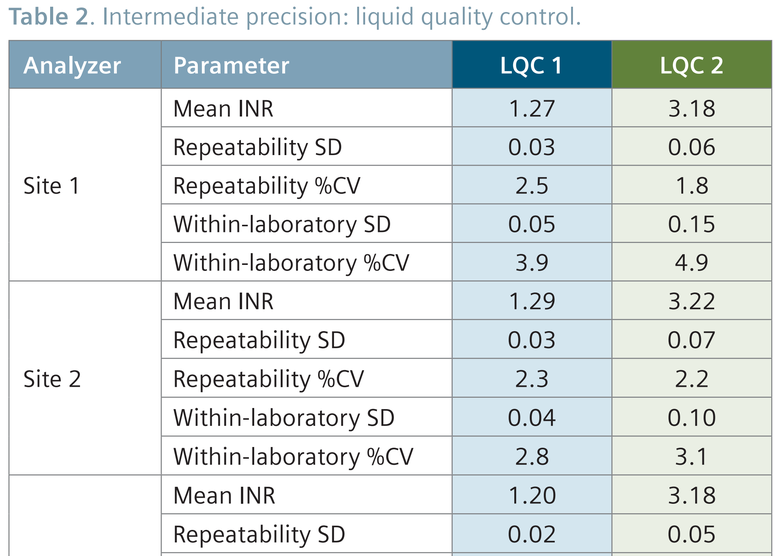

Figure 1. Xprecia Stride analyzer vs BCS XP System INR.

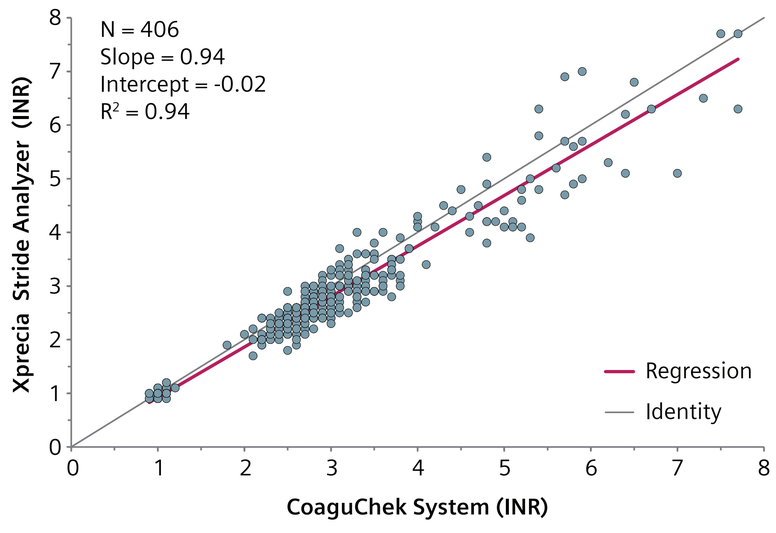

Figure 2. Xprecia Stride analyzer vs. CoaguChek INR analyzer.

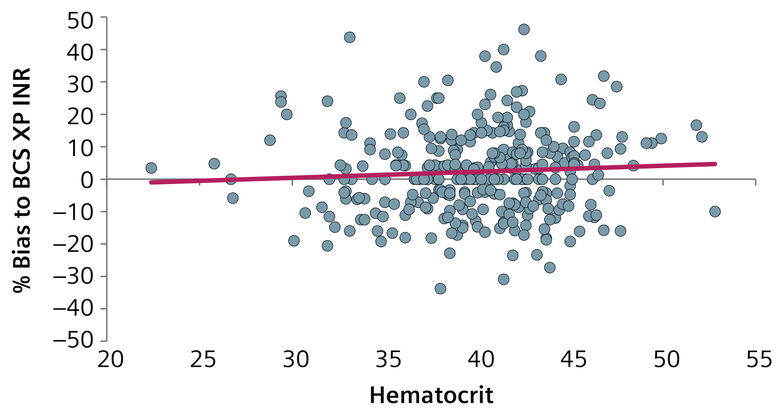

Figure 3. Xprecia Stride analyzer hematocrit range.

Normal range: Based on test samples from 120 nonanticoagulated subjects, the normal INR range for the Xprecia Stride analyzer is 0.9 to 1.1.

Conclusions

- The repeatability precision using whole blood meets the system acceptance criteria for all INR ranges.
- The intermediate precision using PT liquid quality controls levels 1 and 2 meets the system precision acceptance criteria.
- The Xprecia Stride analyzer is validated according to its intended use with capillary blood samples for a range of 0.8 to 8.0 INR when compared to a laboratory method using Dade Innovin recombinant human tissue thromboplastin reagent (INR v INR).
- The Xprecia Stride analyzer is validated according to its intended use with capillary blood samples for a range of 0.8 to 8.0 INR when compared to a point-of-care method using Dade Innovin recombinant human tissue thromboplastin reagent (INR v INR).
- It has been verified that, over the hematocrit range of 22 to 53% there is no significant effect of sample hematocrit on the INR result.

References:

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*Under FDA review. Not available for sale in the U.S. Product availability varies by country.

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