A new PT/INR Monitoring system shows similar Performance to another POC system and compares well with routine-use laboratory benchtop system

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Introduction: The Xprecia Prime™ Coagulation system by Universal Biosensors has received FDA 510(k) approval and CLIA waiver. It is designed for monitoring Oral Anticoagulation Therapy (OAT) using capillary blood, reporting results as INR or PT.

Study Design: Accuracy and precision of Xprecia Prime™ compared to the Sysmex® CS-2500 and Roche Coaguchek®XS was assessed in a multi-site study that involved 397 subjects and 13 operators.

Methods: Fresh capillary blood samples were tested on Xprecia Prime™ and Coaguchek® XS, while citrated venous samples were tested on Sysmex® CS-2500.

Results: Xprecia Prime™ met accuracy requirements of CLSI POCT-14 Ed.2 achieving 97% clinical agreement with the Sysmex® CS-2500 across the INR range of 0.8-8.0.

Introduction

Universal Biosensors Xprecia Prime™ Coagulation system has been granted FDA 510(k)approval (K23082) and CLIA waiver (CW230004) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. The Xprecia Prime™ Coagulation system is a point of care system designed to monitor OAT (Oral Anti-coagulation therapy) using capillary blood. It reports results as an International Normalized Ratio (INR) or Prothrombin Time (PT) in seconds and is specifically intended for monitoring PT/INR in patients undergoing anticoagulation therapy with warfarin (Coumadin™).

A study was conducted involving four Point of Care (POC) sites to evaluate the accuracy and precision of the Xprecia Prime™ system. The study compared Xprecia Prime™ to a laboratory plasma-based reference analyzer, the Sysmex® CS-2500, as well as the Roche Coaguchek®XS, a commonly used POC PT/INR system.

A total of 401 subjects were recruited by 13 operators and results were obtained from capillary blood on the Xprecia Prime™ and the Roche Coaguchek®XS. Citrated venous blood samples were also collected for the reference analyzer, the Sysmex® CS-2500.

Accuracy of the point of care systems (Xprecia Prime™ and Coaguchek®XS) was assessed by comparison of the individual results to the average of duplicates on the laboratory analyzer (Sysmex® CS-2500) according to CLSI POCT14 2nd edition. Both POC devices performed acceptably relative to the Sysmex laboratory analyzer across the reportable range of 0.8 to 8.0 INR.

Clinical agreement of 95% across all INR ranges is the defined acceptance criteria for the cumulative results as per CLSI POCT14. Xprecia Prime™ demonstrated similar performance to Roche Coaguchek®XS, when compared to the Sysmex® CS-2500 across the full reportable INR range 0.8-8.0.

Xprecia Prime™ coagulation system was also assessed for precision, by testing capillary samples in duplicates using the same sites and operators across all INR ranges.

Materials and Methods

The study was conducted by 13 individuals spread evenly across four clinical sites with no experience using a point of care PT/INR device (untrained operators). Operators collected whole blood capillary samples from each subject through a fingerstick method. These samples were then tested with both the Xprecia Prime™ and the Roche Coaguchek® XS. Additionally, a single sodium citrate (anti-coagulant) venous sample was collected from each subject and processed to plasma for testing on the Sysmex® CS-2500.

Method Comparison for Xprecia Prime™ conducted against the Sysmex® CS-2500 and Roche Coaguchek ®XS device was carried out as per CLSI, EP09c 3rd edition. The analysis utilized an Ordinary Linear Regression model (Least Squares) to compare results from Xprecia Prime™ against the Sysmex® CS-2500 and Roche Coaguchek® XS. All evaluable data points were included in the analyses, with subjects missing data from one or more analyzers being excluded only from analyses requiring those specific data points.

Results

The Xprecia Prime™ Coagulation System was compared against the Sysmex® CS-2500 at 4 point-of-care sites using 3 different strip batches for Capillary Blood. The accuracy data obtained from all sites for Capillary was N = 397, Slope = 1.1, Intercept = -0.12, Coefficient of Determination(r^2) = 0.96.

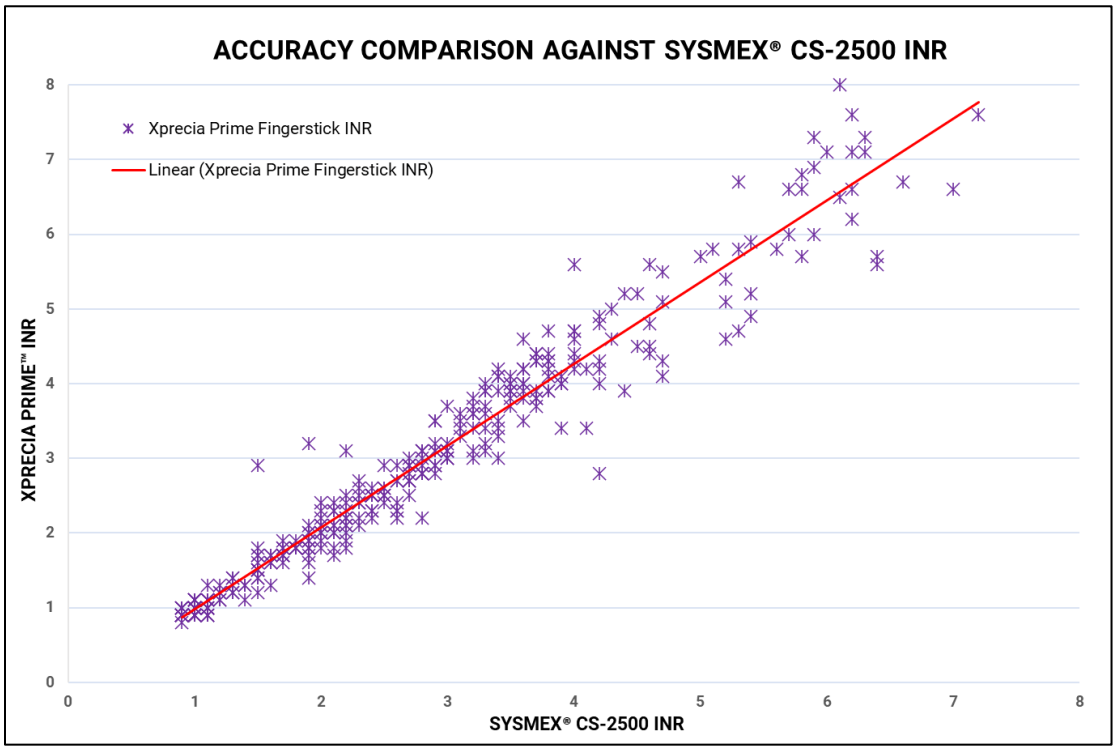

Figure1: Xprecia Prime Fingerstick INR vs Sysmex® CS-2500 INR for All Sites. (✳ Symbol Fingerstick (Capillary)).

Further, Clinical agreement was assessed based on the POCT14 acceptance limits, which defines an overall agreement of 95% across all INR ranges (cumulative results) within the agreement limits of allowable error as defined in CLSI POCT14 2nd edition.

Laboratory Reference INR Range	Allowable Difference	Percentage within allowable difference
0 to 1.9	**± 0.4INR**	98.3%
2 to 3.5	**± 20% INR**	97.7%
3.6 to 4.5	**± 20% INR**	91.8%
4.6 to 6.0	**± 25% INR**	96.6%
6.1 +	**± 30% INR**	92.3%
All Subjects	**-**	97.0%

Table 1: Percentage allowable difference for Xprecia Prime™ in comparison to the Sysmex® CS-2500.

The Xprecia Prime™ Coagulation System achieved an overall agreement of 97% within the allowable difference across all INR ranges when compared to the Sysmex® CS-2500.

Comparison of capillary INR results from The Xprecia Prime™ Coagulation System against the Roche Coaguchek® XS across all sites reported a Slope = 0.96, Intercept = -0.01, Coefficient of Determination (r^2) = 0.94 for N=401 subjects.

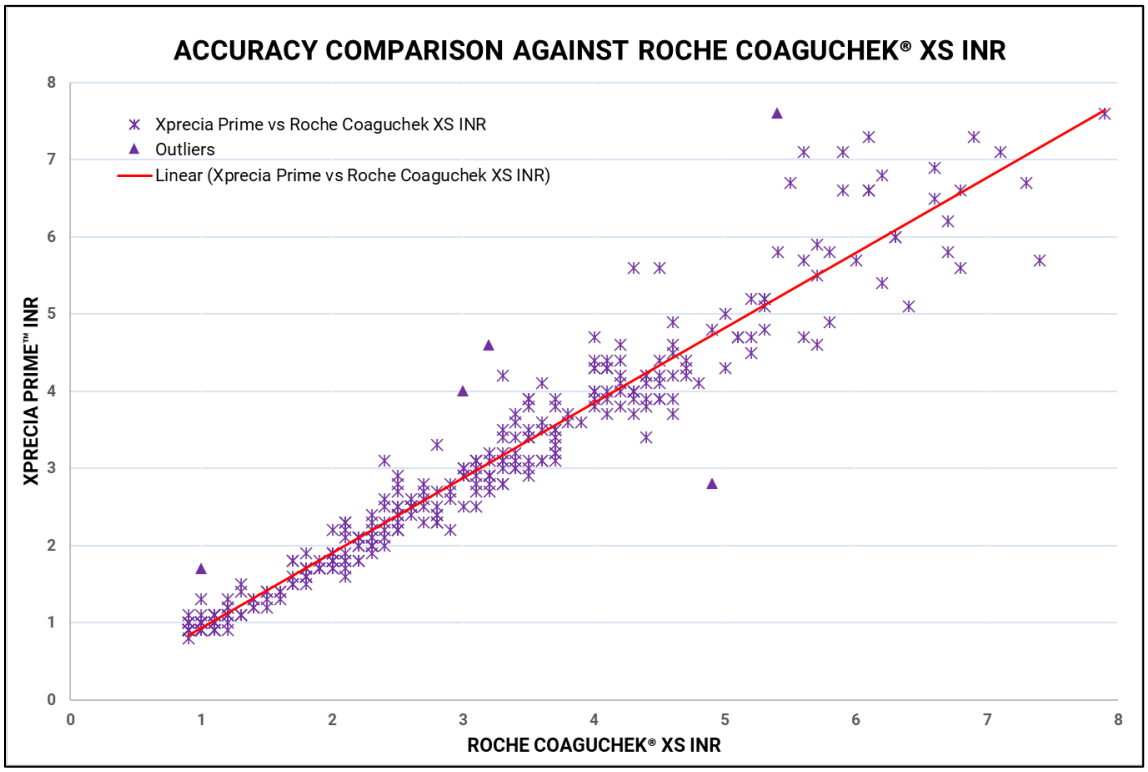

Figure2: Xprecia Prime™ Fingerstick INR vs Roche Coaguchek® XS INR for All Sites. (✳ Symbol Fingerstick (Capillary), ▲ symbol outlier).

Correlation of Xprecia Prime™ coagulation system and the Roche Coaguchek XS versus Sysmex® CS-2500 INR results was determined using linear regression analysis and showed no systemic difference between the two POC systems tested and the laboratory analyzer.

Device	Slope	Offset	r^2
Xprecia Prime™	1.01	-0.12	0.96
Roche Coaguchek® XS	1.09	-0.01	0.97

Table 2. Correlation of Xprecia Prime and Coaguchek® XS versus the Sysmex INR results.

Comparison of the two POC devices within the therapeutic and supra therapeutic INR ranges of INR2.0 – INR 4.5 demonstrates superior performance of the Xprecia Prime™ compared to the Roche Coaguchek® XS. This is evident within the acceptable limit of ±20% from the INR results obtained from the Sysmex® CS-2500 as defined in POCT 14.

INR Range	Xprecia Prime™	Roche Coaguchek® XS
0.8 - 8.0	94.80%	89.50%
2.0-3.5	97.7%	82.3%
3.6-4.5	91.8%	85.7%

Table 3: Performance of Xprecia Prime™ and Roche Coaguchek® XS compared to Sysmex® CS-2500 (reported within ± 20% of agreeable limit.

Whole blood precision was determined from sample duplicates using the same sites and operators as above. Subjects missing INR results in duplicates were excluded from precision analysis. Across all INR ranges, the Xprecia Prime™ displayed acceptable precision as indicated by a coefficient of variation (CV) of less than 5%.

N	Mean INR	SD	CV (%)
393	2.6	0.12	4.5

Table 4: Xprecia Prime™ precision on clinical data, reported as SD and CV(%)

Feedback collected from the operators that carried out the study aimed to assess their impressions of the Xprecia Prime™ system. The feedback indicated that users found the device intuitive and easy to use. All operators either agreed or strongly agreed that the Xprecia Prime™ was straightforward to operate without training, required minimal hands-on effort, and raised no safety or efficacy concerns. The positive feedback on ease of use supports the decision of CLIA waiver being granted for the Xprecia Prime™ system.

Conclusion

The report concludes that the Xprecia Prime™ system is comparable to the Sysmex® CS-2500 benchtop analyzer as well as the Roche Coaguchek® XS POC device. The accuracy and precision presented in this study demonstrates the strong performance of the Xprecia Prime™ System relative to the laboratory analyzer and another POC system. User feedback suggests the system is easy to use and supports use in CLIA waived facilities.

References

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