The Leeds Teaching Hospitals NHS
NHS Trust

Validation of Siemens Xprecia Stride™ Coagulation Analyser at Leeds Teaching Hospital

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Introduction

Leeds Anticoagulant Service currently serves over 10,000 patients in the Leeds area. The service is undergoing a service development to provide a more clinically responsive and patient centred service. As part of the development, the service is moving towards provision of INR by point of care testing (POCT). Leeds Anticoagulant Service undertook an evaluation of the Siemens Xprecia Stride, against current technology.

The purpose and scope of the evaluation was to review the results of the data obtained during the Leeds Teaching Hospitals clinical equivalence method comparison study using the ACL Top® with HemosIL® RecombiPlasTin reagent and the Roche CoaguChek® XS Pro device.

ACL TOP

The laboratory reference results were obtained using plasma from a 3.2% (0.109 M) sodium citrate sample that had been centrifuged and run on a single ACL Top with RecombiPlasTin reagent (Instrumentation Laboratory, Bedford, MA).

CoaguChek XS Pro

The point of care results were obtained using whole blood capillary samples. (Roche Diagnostics Indianapolis, IN)

Methods

Subjects for Data Analysis

Population 1 - Warfarin
Subjects receiving warfarin treatment for at least 3 months
Population 2 - Normals
Subjects not receiving any anticoagulation therapy nor having a known coagulation disorder
Population 3 – Initiation
Subjects being initiated on warfarin (ie less than 3 months on oral anticoagulation)

Subject Distribution

The following is a summary of the distribution of subjects that were used in the method comparison analysis for the various data collection INR ranges

INR Values ACL TOP	Normals	Wafarin <2.0	2.0 – 4.5	4.6-6.0	6.1 – 8.0	Total
Total for INR range	22	39	108	4	0	173

Table 1: INR range distribution

Acceptance Criteria

Over the Measurement Range:
Slope: 95% confidence interval within 0.80 – 1.20
Intercept +0.3 to -0.3
Coefficient of determination (r^2) ≥ 0.82

Metric		
INR Test Range based on medical decision points	Median Bias	Allowable Difference (90% of biases)
0.8to1.9	±0.3	±0.5
2.0 to 4.5	±0.3	±30%
4.6 to 6.0	±0.7	±30%*

*Only applicable for data sets with n≥ 10 in this INR test range

Table 2: Acceptance Criteria.

Sampling

Capillary Testing Procedure

Xprecia Stride and Coaguchek analysers were prepared following the Instructions For Use. The puncture site was prepared for lancing, fingerstick performed and result recorded on Siemens Xprecia Stride and Roche Coaguchek XS Pro.

Venous Testing Procedure

Venous whole blood was collected in 1 x 5mL 3.2% (0.109 M) sodium citrate collection tube. The citrated blood was centrifuged to generate a platelet poor plasma sample that was tested on the laboratory ACL Top® . Hemolysed samples were rejected and data excluded from final analysis.

Accuracy

Linear regression and coefficient of determination was calculated between INR from Xprecia Stride coagulation analyser and Coagucheck XS Pro, and from Xprecia Stride coagulation analyser and ACL TOP. Correlation and bias were graphically evaluated.

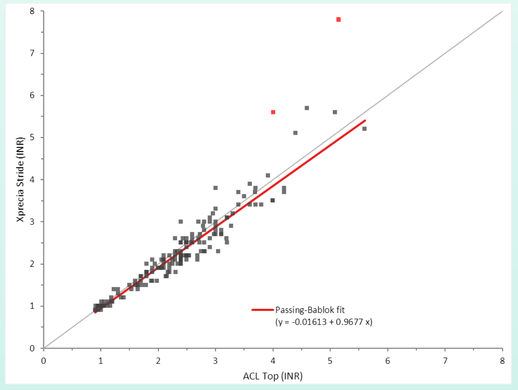
Precision

Liquid quality controls were run on two Xprecia Stride units 6 times/day for 5 days to determine a total % CV.

Results and Discussion

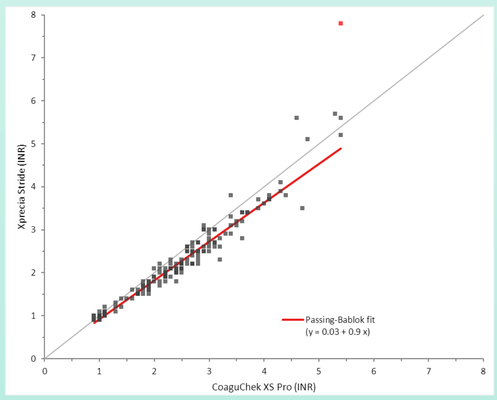
Accuracy

Passing-Bablok and Deming regression analysis showed good correlation of Stride with ACL TOP with an r^2 =0.924 and a slight negative bias over therapeutic range.



		Including outlier data		Excluding Outlier Data		
Item	Result	Lower 95%CI	Upper 95%CI	Result	Lower 95%CI	Upper 95%CI
All sites						
N	173			171		
Min INR	0.9			0.9		
Max INR	5.6			5.6		
Intercept	-0.02	-0.10	0.07	0.01	-0.10	0.08
Slope	0.97	0.91	1.00	0.95	0.90	1.0
R	0.943			0.961		
r^2	0.889			0.924		
Sy.x	0.35			0.26		
Bias at 2.0	-0.18			-0.08		
Bias at 4.5	-0.16			-0.20		

Figure 1 : Deming regression fit for Stride INR against the ACL Top using RecombiPlasTin Reagent.



		Including outlier data		Excluding Outlier Data		
Item	Result	Lower 95%CI	Upper 95%CI	Result	Lower 95%CI	Upper 95%CI
All sites						
N	168			167		
Min INR	0.9			0.9		
Max INR	5.4			5.4		
Intercept	0.03	-0.06	0.12	0.05	-0.03	0.12
Slope	0.9	0.87	0.94	0.89	0.86	0.93
R	0.957			0.972		
r^2	0.916			0.945		
Sy.x	0.31			0.23		
Bias at 2.0	-0.17			-0.17		
Bias at 4.5	-0.42			-0.44		

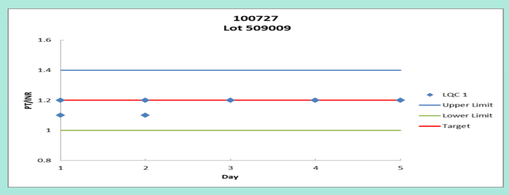
Figure 2: Deming regression fit for Stride INR against the CoaguChek XS Pro

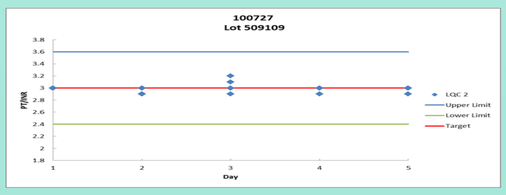
Passing-Bablok and Deming regression analysis showed good correlation of Stride with Coaguchek XS Pro with an r^2 =0.945 and a slight negative bias over therapeutic range.

There were few results obtained above INR 4.5 and further work is being undertaken to obtain data in the 4.5 to 8.0 range.

Precision

Overall precision was shown to be good with standard deviations of less than 0.1 for both normal and therapeutic range controls. Coefficients of Variation were less than 4%





Xprecia Stride 100727		Xprecia Stride 101128	
509009 exp2-8-16	LQC1	509009 exp 2-8-16	LQC 1
N (5 runs/ 6 reps per run)	30	N (5 runs/ 6 reps per run)	30
SD	0.03	SD	0.04
Mean	1.19	Mean	1.18
Target	1.20	Target	1.2
RMSD	0.04	RMSD	0.05
%RMSD	3.04	%RMSD	4.03
CV%	2.91	CV%	3.66
509109 exp 3/22/16	LQC2	509109 exp 3/22/16	LQC2
N (5 runs/ 6 reps per run)	30	N (5 runs/ 6 reps per run)	30
SD	0.06	SD	0.09
Mean	2.99	Mean	2.99
Target	3.00	Target	3.00
RMSD	0.06	RMSD	0.09
%RMSD	2.02	%RMSD	2.98
CV%	2.03	CV%	3.01

Figure 3: Precision calculation by repeat testing of QC over 5 days

Conclusions

The Siemens Xprecia Stride coagulation analyser is a compact, user friendly, point of care device that will contribute to ISO compliance in outreach centres and clinics. The units showed good correlation of results across the normal and therapeutic range.

USB output to the provided Data Management Software is available to allow export of data and set up of user identification and further functionality. The barcode reader allows for easy patient identification and staff ID, aiding governance and audit. The units will store a minimum of 300 QC and 640 patient INR results.

The units require a very low blood volume of 6uL, and contain on-board tutorials shown on a touch sensitive screen.

Further improvements are being made to functionality regarding IT and connectivity. An EQA scheme is currently in the pilot stage, by NEQAS, Sheffield and is also available from WEQAS.

The units would benefit from addition of rechargeable battery units via a docking station.

Further investigations are being evaluated on INRs greater than 4.5 to establish bias and linearity.

References

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3 Liversidge R, Byrne C, Spencer J. BSH6002 v 1.1. Implementation of Siemens Managed Pathology Service contract (MPSC): Selection, verification & validation (v&v) of examination procedures. LTHT Standard Operating Procedure, document , April 2015