Evaluation of qLabs® System

Accuracy and Precision of the qLabs® System as Compared to CoaguChek® XS System, INRatio®2 PT/INR Monitoring System and Sysmex® CA-500 Analyzer

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INTRODUCTION

The qLabs® system is a handheld device used for monitoring prothrombin time (PT) testing, with results provided in International Normalized Ratio (INR) units. It is intended for use by healthcare professionals and patients to evaluate the PT/INR of individuals using oral anticoagulants, e.g., warfarin. qLabs® System consists of disposable test strips and an ElectroMeter.

PT/INR test measures the blood's ability to clot. Blood normally clots to slow down its flow in response to the damage of blood vessels, in order to prevent excessive bleeding. A clot formed inappropriately in the areas of heart, lung and brain, however, can hinder normal blood flow and may result in life-threatening events such as stroke and heart attack. For patients who lose their ability to properly reabsorb clots and patients who have low tolerance to clots, anticoagulation medicines (blood thinner, such as warfarin) are prescribed. Since these medications may have narrow therapeutic windows and be sensitive to diet and lifestyle, it's necessary to monitor and adjust the dosage regularly.

Careful monitoring of patients on warfarin therapy is important; under-anticoagulation increases the risk of stroke, while over-anticoagulation increases the risk of bleeding episodes. PT or INR value from the PT/INR test aids healthcare professionals and patients to maintain the appropriate therapeutic range for individuals undergoing warfarin therapy. Thus, a rapid and accurate measurement of PT or INR value is critical for the safety and effectiveness of the anticoagulation therapy.

Lightweight, portable, compact and easy to use, the qLabs® system provides real-time, lab-quality results by using a single drop of capillary or venous whole blood in less than 2 minutes, right at Point of Care or at home.

The purpose of this study was to evaluate the accuracy and precision of qLabs® system by comparing to standard traditional laboratory method and other point of care products.

METHODS

Nine (9) normal donors (those not on warfarin therapy) and four (4) therapeutic donors (those on warfarin therapy) were recruited for this study.

Prothrombin Time test results were obtained from qLabs® System, CoaguChek® XS system, INRatio®2 PT/INR Monitoring System, using capillary blood. A drop of fingerstick whole blood from the same puncture for each donor was applied on all these three systems simultaneously.

A tube of citrated venous blood was also collected from each donor. Plasma samples from the citrated blood were tested for PT and INR values by using a Sysmex CA-500 analyzer with Innovin as the thromboplastin source.

The PT results are presented in INR (International Normalized Ratio) units.

Precision

In order to evaluate the ability of each system's Precision, which is the ability to replicate measurements to give similar results, a drop of fingerstick blood from the same puncture of each donor was applied to two meters of each system. A rotation scheme was used to ensure that each meter was not always dosed at the same sequence.

Accuracy

The accuracy of each system was evaluated conducting regression plot and difference plot between the INR results from each system and those from Sysmex CA-500 Analyzer.

RESULTS/DISCUSSION

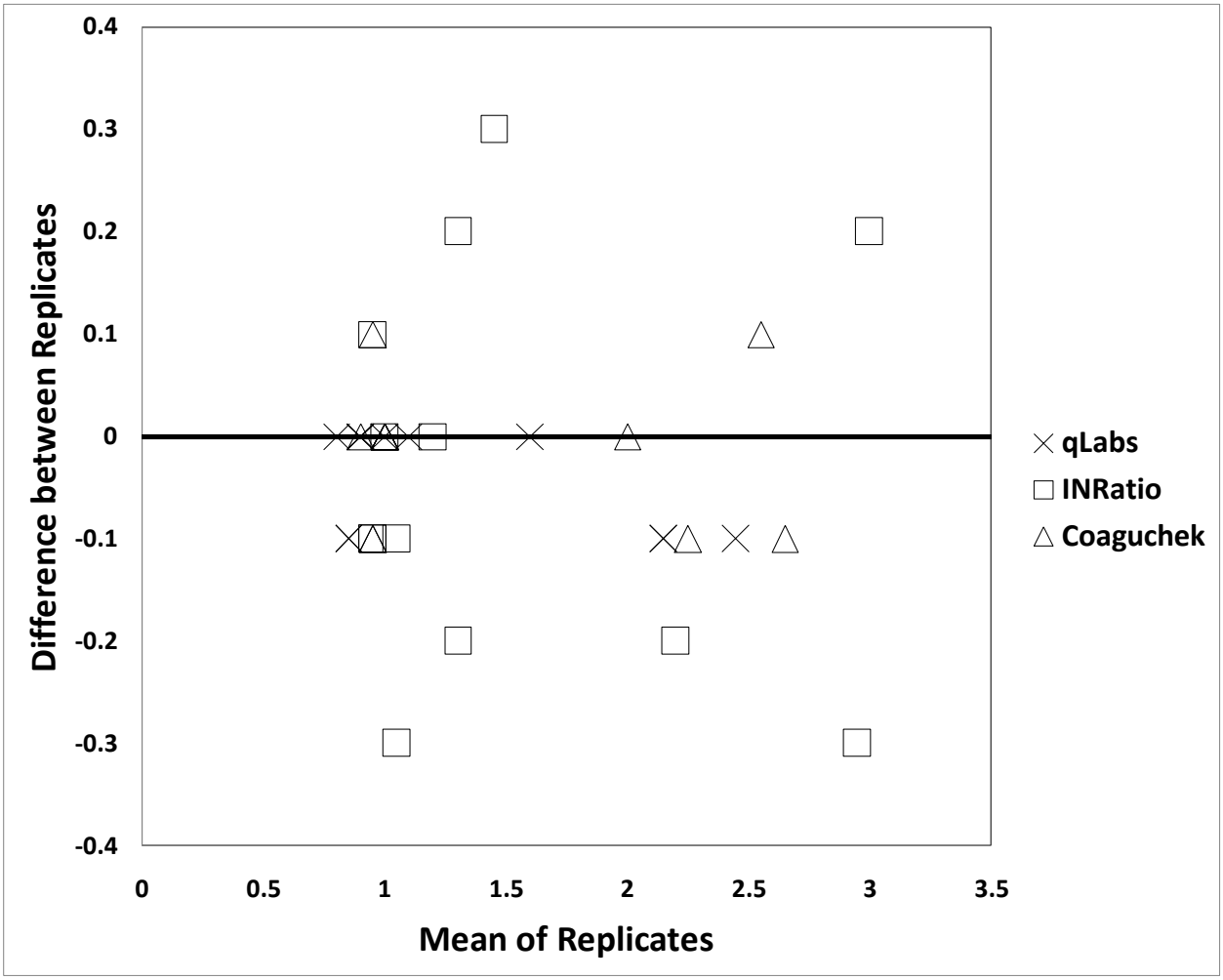
Precision

The numerical results for the capillary whole blood precision of donor duplicates for three systems are compared in Table 1; a visual representation is provided in Figure 1

Table 1: Comparison of Capillary Blood Precision

	qLabs			INRatio			CoaguChek		
	N	Mean	CV%	N	Mean	CV%	N	Mean	CV%
Normal	9	0.9	1.8	9	1.1	7.9	9	1.0	2.5
Therapeutic	4	2.1	2.4	4	2.4	8.2	4	2.4	2.1
All	13	1.3	2.0	13	1.5	8.0	13	1.4	2.4

Figure 1: Difference Plot of Replicates



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Accuracy (Method Comparison)

The correlation of the results of the qLabs, CoaguChek and INRatio 2 tests compare to the results of the Sysmex CA-500 Analyzer tests are shown in Figure 2, Figure 3 and Figure 4, respectively.

The slope, intercept and correlation coefficient yield from the linear regression (n=13) are compared in Table 2

Table 2: Comparison of Correlation (n=13)

System vs. Sysmex	Slope	Intercept	R^2
qLabs	1.043	-0.037	0.977
CoaguChek	1.200	-0.108	0.984
INRatio 2	1.244	-0.074	0.904

Figure 2: Correlation of qLabs to Sysmex CA-500

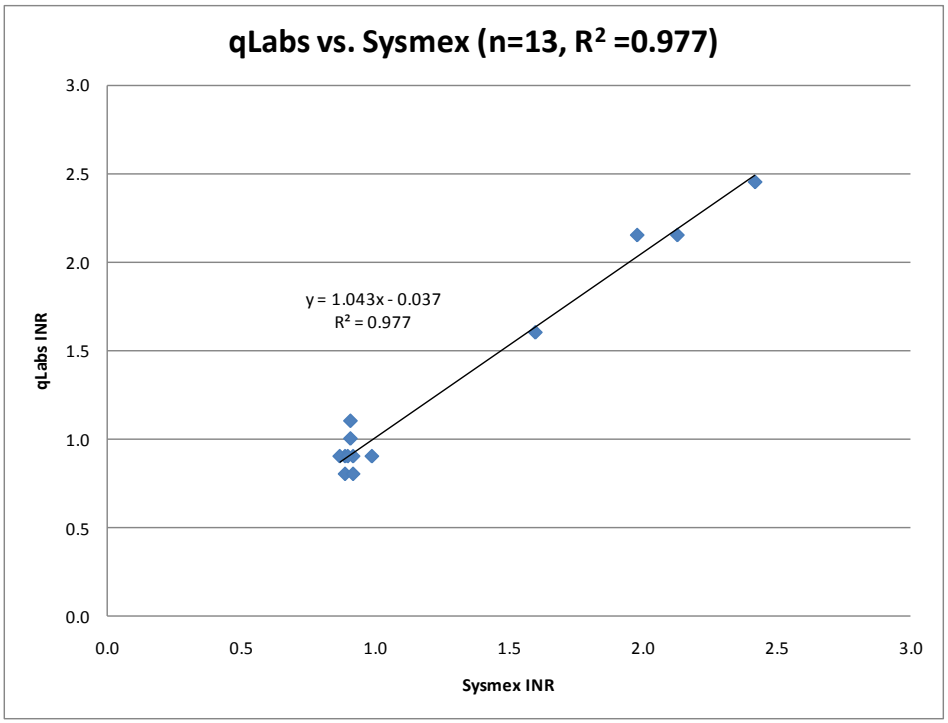


Figure 3: Correlation of CoaguChek to Sysmex CA-500

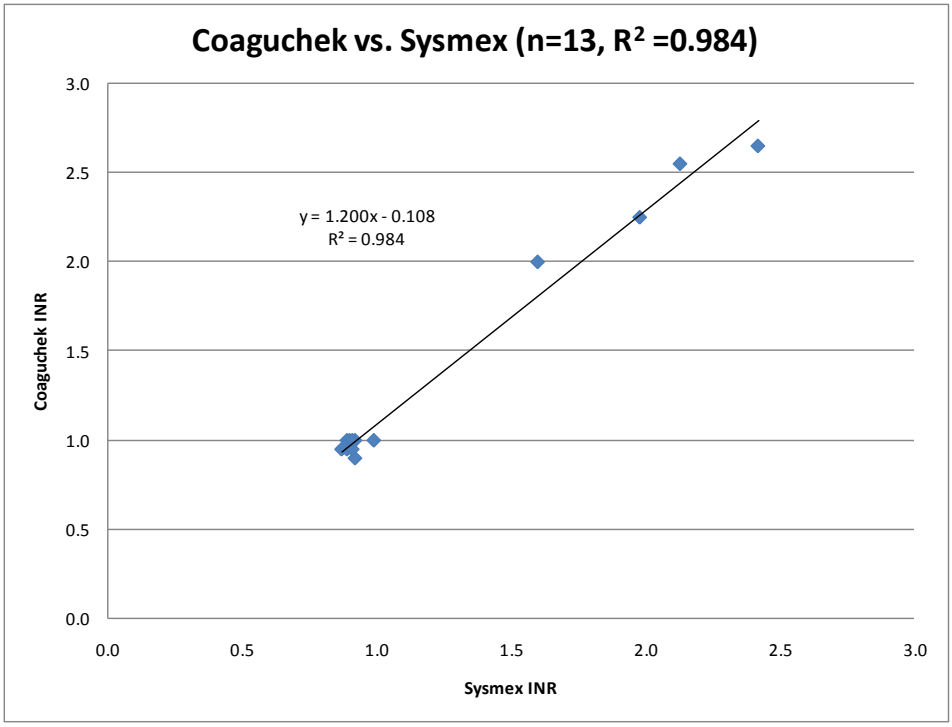
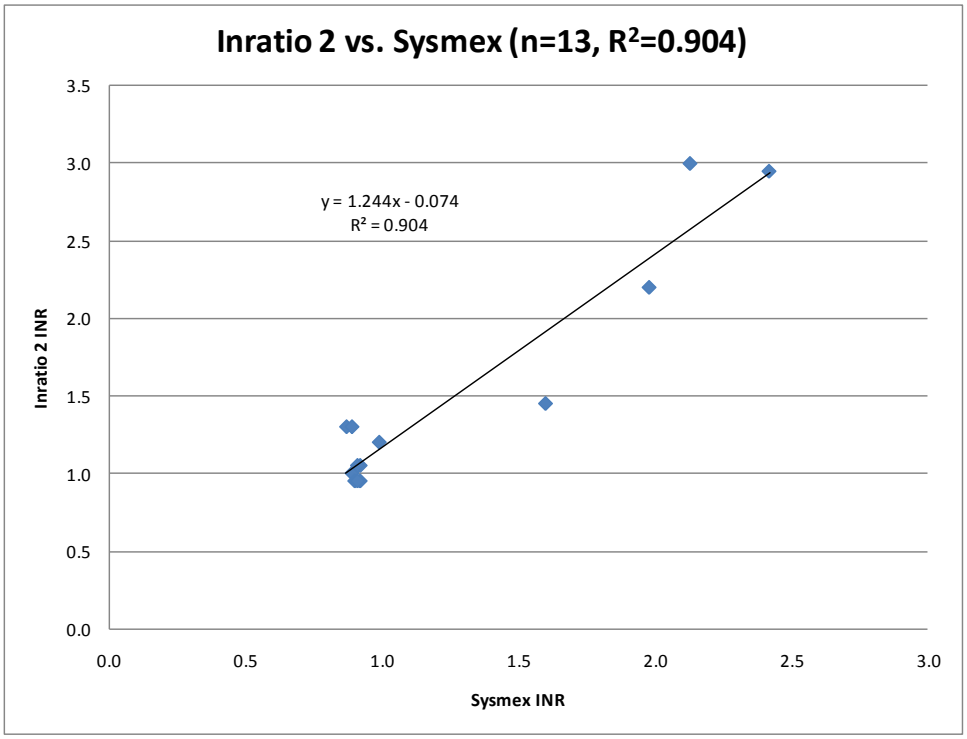


Figure 4: Correlation of INRatio 2 to Sysmex CA-500



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CONCLUSION

Although the sample size is limited, this study shows that:

- qLabs® system has precision equivalent to the CoaguChek XS system and better than INRatio 2 PT/INR Monitoring system.

- Regression statistics yields excellent correlation between Sysmex CA-500 and qLabs® system with slope much closer to 1 than that for CoaguChek XS system and INRatio 2 PT/INR Monitoring system.

These results and others support the fact that the accuracy and precision of qLabs® system is significantly equivalent to the leading system in the market.