

LumiraDx INR Test: Laboratory Accuracy Assessment with the ACL Elite and Sysmex Reference Methods

Background

The LumiraDx Platform is a novel, point of care *in vitro* diagnostic system that can be used for INR testing with fresh capillary whole blood by direct fingerstick application or using a transfer tube.

The evaluation of the accuracy and precision of the CE marked LumiraDx INR test, compared to a laboratory reference method, the IL ACL Elite Pro has been demonstrated in the recent OPTIMAL study^{1,2} where a strong correlation was seen.

The LumiraDx Instrument displays the results equivalent to laboratory plasma measurements as the International Normalised Ratio (INR). Each Test Strip Lot is calibrated to a reference that is traceable to the WHO International Reference standard rTF/09. It has been shown that comparing results obtained with the LumiraDx INR Test to those obtained with common laboratory reagents shows that the LumiraDx INR Test correlates well with ACL Elite Pro with HemosIL RecombiPlasTin 2G.

A sample comparison was carried out to demonstrate the performance of IL ACL Elite Pro (ACL) and Sysmex CS instruments (CS-2500 and CS-5100) as reference methods for the LumiraDx INR assay.

Objective

The sample collection was designed to compare the INR results from patients attending anticoagulation clinics and determined by three different INR Test methods: LumiraDx INR test (capillary blood sample), ACL Elite (plasma) and Sysmex (plasma).

Methods

101 blood samples were collected from patients attending anticoagulation clinics during which their LumiraDx INR and ACL Elite Pro INR values were established. Frozen plasma samples which were collected during routine calibration³ in sodium citrated tubes were sent to four separate laboratories for INR testing using the Sysmex laboratory analyser. The four laboratories were the University Hospital Hairmyres, University Hospital Wishaw and University Hospital Monklands in the Lanarkshire region of Scotland and one in London, The Doctors Laboratory (TDL).

At Monklands and Hairmyres, the samples were analysed using the Sysmex CS-2500 instrument. At TDL and Wishaw, the samples were analysed using the Sysmex CS-5100 instrument. All the systems were using Siemens Dade Innovin reagent following standard hospital laboratory procedures.

Passing-Bablok regression was used to perform a method comparison between the ACL Elite

Pro and Sysmex instruments for calculating INR. The same method was also used to perform a method comparison between the LumiraDx INR Assay and Sysmex instruments. As the samples used in the study were clinical calibration results, paired results for LumiraDx and ACL were available for each sample.

Data was returned to LumiraDx (Dumyat, Stirling) where statistical analysis was performed. Passing-Bablok regression was used in a method comparison of data obtained on the ACL Elite Pro and Sysmex analysers. The same method was also used to perform a method comparison between the LumiraDx INR Assay and Sysmex instruments.

Results

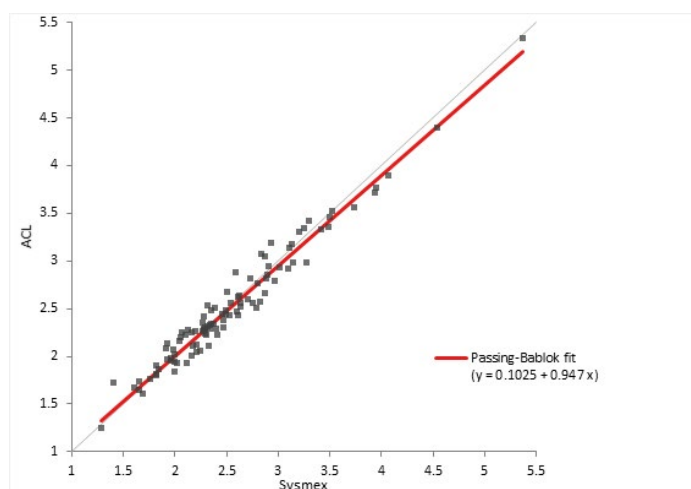
Analysis confirmed a good agreement between the LumiraDx INR test results (capillary blood sample) and those obtained from plasma samples using both the ACL Elite and also the Sysmex CS 2500/5100. Furthermore, data from the Sysmex CS 2500/5100 was demonstrated to correlate across 4 independent hospital laboratories.

Previous data from the OPTIMAL study also demonstrated that a strong correlation between the LumiraDx instrument INR test with the ACL Elite Pro reference method in samples from 366 patients⁴

LumiraDx INR Test: Laboratory Accuracy Assessment with the ACL Elite and Sysmex Reference Methods

ACL Elite Pro vs Sysmex (average results from 4 sites)

Laboratory	Slope	95%CI Upper	95%CI Lower	Intercept	95%CI Upper	95%CI Lower	n
Average over 4 sites	0.9470	0.9927	0.9019	0.1025	0.2070	-0.007072	101



Conclusion

The LumiraDx INR Test, ACL Elite Pro and the Sysmex CS2500/5100 returned comparable results, and agree closely when compared across 4 independent sites.

References

- ¹ LumiraDx Test Product Insert S-COM-ART-00133.
- ² Read the full study publication at <https://www.ncbi.nlm.nih.gov/pubmed/31773973>
- ³ Collection of venous and capillary blood samples for development of new diagnostic devices for measurement of prothrombin time/international normalised ratio study PT/INR LumiraDx Internal Report Number S-CLIN-PROT-00003.
- ⁴ Optimal Data Management and Analysis Report. LumiraDx Internal Report Number S-PASS-REP-00021.
- ⁵ INR ACL vs Sysmex Comparison. LumiraDx Internal Report Number S-PASS-REP-00032.

LumiraDx vs Sysmex (average results from 4 sites)

Laboratory	Slope	95%CI Upper	95%CI Lower	Intercept	95%CI Upper	95%CI Lower	n
Average over 4 sites	1.001	1.053	0.9436	-0.0596	0.05980	-0.1691	223

