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Laboratory accuracy assessment of a novel INR Point-of-Care Test compared with laboratory reference methods used across four independent clinical sites

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LumiraDx™

Background

The LumiraDx Platform is a novel, point of care in vitro diagnostic system that can be used for INR Testing by Healthcare Professionals.

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.

It has been shown that comparing results from the LumiraDx INR Test to those obtained with common laboratory reagents shows that the LumiraDx INR Test correlates well with IL ACL Elite Pro (ACL) with HemosIL RecombiPlasTin 2G.

Aims

A sample comparison was carried out to demonstrate the performance of the LumiraDx INR Test using capillary blood samples, with results obtained from plasma sample analysis using venous blood collected from the same patient and analysed on the IL ACL Elite Pro (ACL) and Sysmex§ CS instruments (CS-2500 and CS-5100).

Methods

101 blood samples were collected from patients attending anticoagulation clinics (taking oral anticoagulation therapy) and their INR values were established using the LumiraDx INR Test (capillary) and ACL Elite Pro (plasma). Frozen plasma samples from routine calibration testing were sent to four independent laboratories for INR testing using the Sysmex CS Instruments, with Siemens Dade® Innovin® Thromboplastin. Passing-Bablok regression was used in a method comparison of data obtained.

Results

Analysis between LumiraDx INR Test and the ACL Elite Pro has previously been demonstrated and shown good correlation[2]. Analysis in this study confirmed that there is a good agreement between the LumiraDx INR Test results (capillary blood sample) and INR result data obtained from plasma samples from the same patients run on the Sysmex CS 2500/5100 (*Table 1*.). This correlation was demonstrated using analysers in 4 independent hospital laboratories (r=0.956) (*Fig.1*).

Laboratory	Slope	95% CI Upper	95% CI Lower	Intercept	95% CI Upper	95% CI Lower	N
Average over 4 sites	1.001	1.060	0.9481	-0.06174	0.04839	-0.1860	223

Table 1:
Results from LumiraDx INR Test (capillary) vs Sysmex INR (plasma)

(average results from 4 sites)

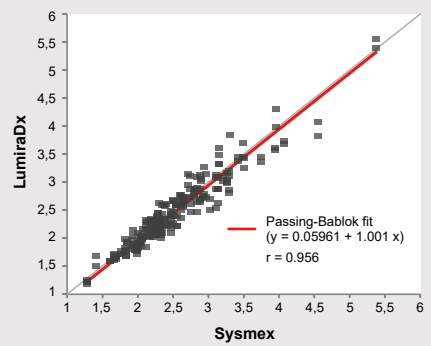

Figure 1:
LumiraDx INR Test (capillary) vs Sysmex CS2500/5100 (plasma) pooled data from 4 independent sites

Conclusion

The LumiraDx INR Test uses capillary blood samples and provides results that are well correlated with those from plasma samples run using the laboratory reference analysers, ACL Elite Pro and the Sysmex CS2500 and 5100. The results from the Sysmex were found to be comparable when run across 4 independent sites.

Funding

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References

1. LumiraDx INR Test Product Insert S-COM-ART-00133
2. Tait RC, Hung A, Gardner RS. Performance of the LumiraDx Platform INR Test in an anticoagulation clinic point-of-care setting compared with an established laboratory reference method. Clin Appl Thromb Hemost. 2019;25:1076029619890423

The LumiraDx INR Test is subject to the intended use and limitation as set out in the LumiraDx INR Test Strip Product Insert.
Product not available in the U.S.A.
¥ IL ACL Elite Pro – Instrumentation Laboratory, Bedford. MA. U.S.A
§ Sysmex CS2500/5100 – Sysmex Europe GmbH

S-COM-ART-00415 R1

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