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Evaluation of the Accuracy of INR values measured by a POCT system in a German Clinic with patients taking Phenprocoumon as VKA Therapy.

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Background

The LumiraDx INR Test can be used by healthcare professionals at the point of care to provide reliable INR monitoring of patients who are receiving VKA therapy.

The LumiraDx INR Test is a new point of care (POC) *in vitro* diagnostic system for the quantitative determination of Prothrombin Time expressed as International Normalised Ratio (INR) at the point of care (POC). Within Europe, there are country to country differences in preferential vitamin K antagonist (VKA) prescription. In Germany and surrounding countries, Phenprocoumon is the most commonly prescribed. Agreement between the LumiraDx INR test and the IL ACL Elite Pro¥ has been demonstrated previously in patients taking Coumadin[1].

Aims

The aim of this study was to evaluate the INR results in a German clinical setting with patients taking Phenprocoumon using the LumiraDx INR Test at point of care, and comparing the results to the laboratory reference methods, the ACL Elite Pro and Sysmex§ CS-5100.

Methods

This study was an observational, cross-sectional study with 102 subjects (24 female and 78 male) taking Phenprocoumon. Ages ranged from 36 - 88 years. Devices used were CE marked for INR measurement, conducted by healthcare professionals. In part 1 (25 subjects), samples of venous whole blood were analysed on the LumiraDx instrument and compared to venous plasma INR determined by both reference methods. In part 2 (77 subjects) a comparison of capillary whole blood INR (direct fingerstick application) determined by LumiraDx INR Test was made to venous plasma INR determined by the laboratory reference methods.

Results

The LumiraDx INR Results were plotted against the reference methods in part 1 and 2 and showed strong agreement across the range 1.3-5.2 INR (*Table 1*).

Sample	Reference Method	Slope	Slope CI	Intercept	Intercept CI	r
Plasma Part 1	ACL Elite Pro	1.055	[0.937, 1.161]	-0.156	[-0.375, 0.184]	0.981
Plasma Part 1	Sysmex CS5100	1.038	[0.917, 1.136]	-0.104	[-0.300, 0.225]	0.982
Plasma Part 2	ACL Elite Pro	1.002	[0.945, 1.073]	-0.029	[-0.173, 0.108]	0.959
Plasma Part 2	Sysmex CS5100	1.000	[0.923, 1.000]	-0.050	[-0.093, 0.142]	0.975
Capillary Blood Part 2	ACL Elite Pro	0.951	[0.874, 1.033]	-0.028	[-0.248, 0.154]	0.949
Capillary Blood Part 2	Sysmex CS5100	0.923	[0.846, 1.000]	0.015	[-0.200, 0.186]	0.950

Table 1:
Summary of the Method Comparison Results of the LumiraDx INR Test

Conclusion

Different VKA anticoagulation therapies, i.e. Warfarin and Phenprocoumon, do not influence the accuracy of the LumiraDx INR Test results. Overall, the LumiraDx INR Test can be used by healthcare professionals at the POC to provide reliable INR monitoring of patients who are receiving VKA therapy.

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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.

1. 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

¥ IL ACL Elite Pro – Instrumentation Laboratory, Bedford. MA. U.S.A
§ Sysmex CS2500/5100 – Sysmex Europe GmbH

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