

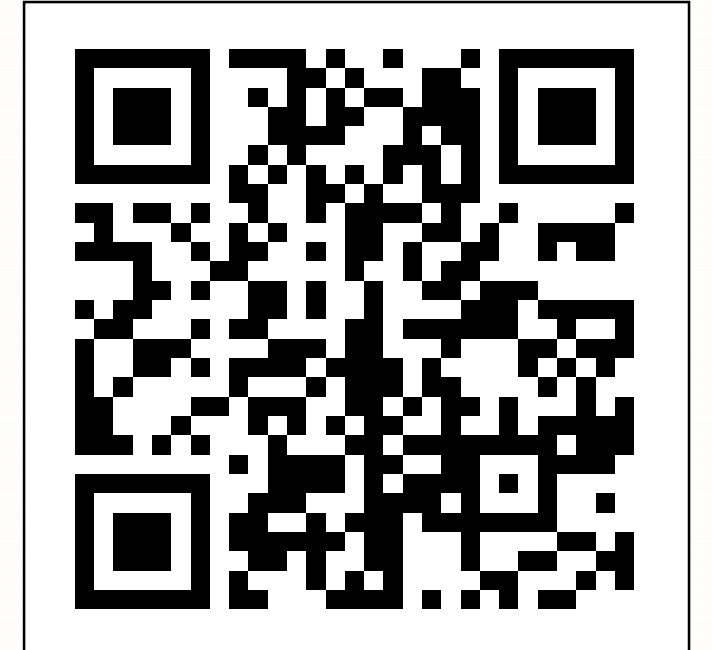
The LumiraDx Platform INR Test: Performance and ease of use in an anticoagulation clinic setting



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The LumiraDx Platform INR Test provides reliable INR monitoring when used by healthcare professionals at the point of care.

BACKGROUND

- Patients treated with vitamin K antagonist therapy require regular monitoring of international normalized ratio (INR) to maintain optimal anticoagulation.
- The LumiraDx Platform is a new point-of-care *in vitro* diagnostic system that enables INR testing using fingerstick capillary blood samples.

AIM

- To evaluate the accuracy, precision and ease of use of the LumiraDx Platform INR Test.

METHODS

- The LumiraDx INR Test is an assay in which emitted fluorescence reflects the degree of thrombin activation.
- Precision was assessed by correlating paired replicate samples from three Test Strip Lots in multiple clinic sites.
- Accuracy was determined by comparing LumiraDx INR Test results with INR measured by a laboratory reference method, the ACL Elite Pro.
- Feedback was collected from healthcare professionals via a questionnaire.

RESULTS

- Mean paired replicate precision of the LumiraDx INR Test results (% coefficient of variation) was <4.0 when paired samples were applied by either direct application or via a capillary transfer pipette.
- The LumiraDx INR results showed a strong correlation ($r = 0.965$) with the laboratory reference method.
- User feedback indicated that the instructions given by the LumiraDx system were easy to follow.

SUMMARY/CONCLUSION

- The LumiraDx Platform INR Test is capable of providing accurate and reliable INR analysis.

Demographic data of recruited individuals

VKA	n	Age (years)			INR (laboratory reference method)			
		Mean	Min.	Max.	Median	1 st Quartile	3 rd Quartile	INR max
Warfarin	340 (F=146; M=194)	71	30	94	2.48	2.07	3.02	7.51
No therapy	26 (F=17; M=9)	53	29	81	0.92	0.90	0.94	1.03

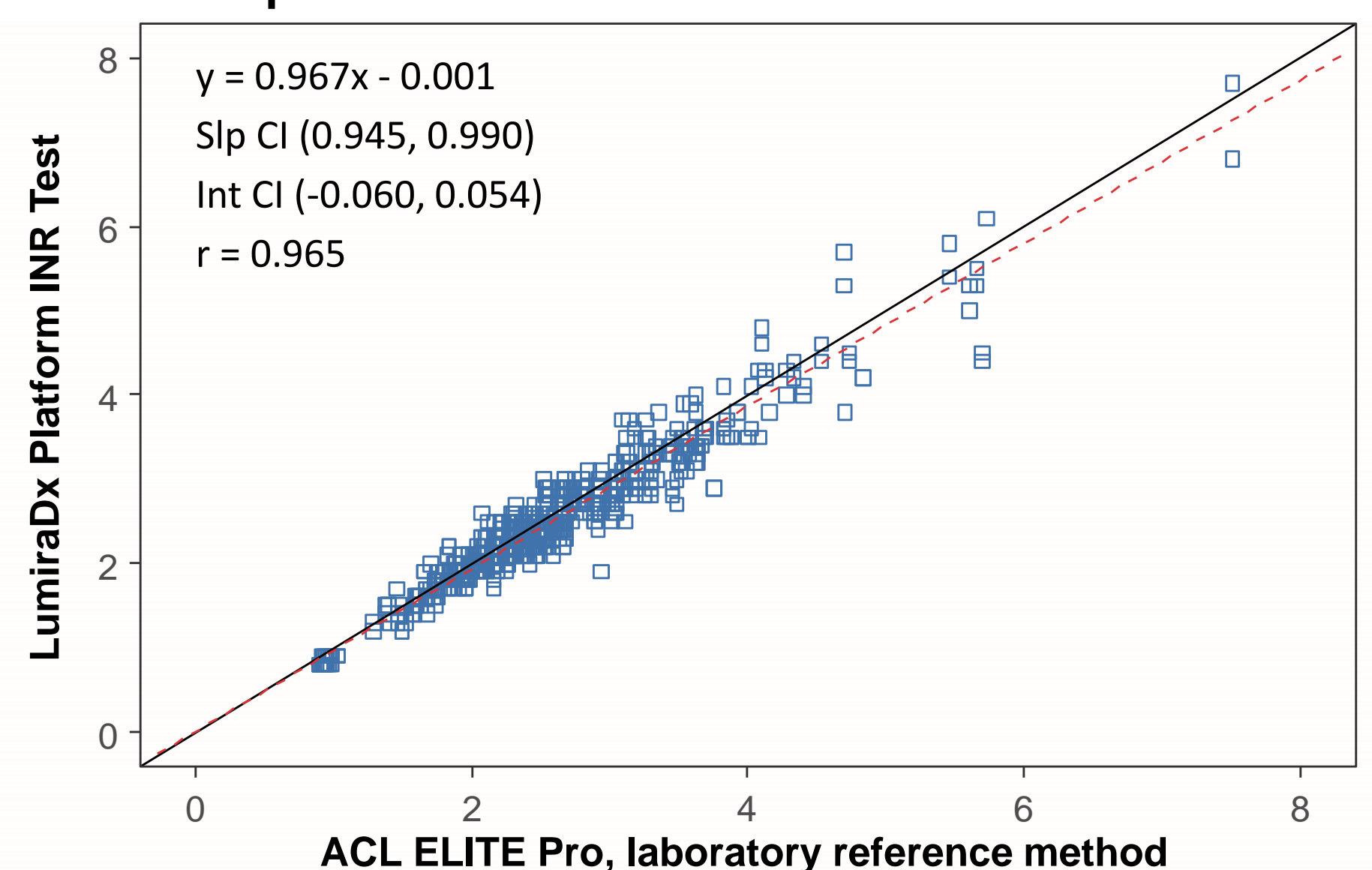
F, female; INR, international normalized ratio; M, male; n, number of patients; VKA, vitamin K antagonist

Precision of INR measurements of samples directly applied to the test strip or by transfer pipette, using three test strip lots

Lot	Direct application			Transfer pipette			Combined		
	n	Mean INR	Mean CV (%)	n	Mean INR	Mean CV (%)	n	Mean INR	Mean CV (%)
5000003	85	2.396	3.19	82	2.450	3.88	167	2.423	3.53
5000004	108	2.667	3.81	111	2.634	3.61	219	2.650	3.71
5000006	91	2.518	3.30	98	2.466	3.73	189	2.491	3.52
All	284	2.538	3.46	291	2.525	3.73	575	2.532	3.60

CV, coefficient of variation; INR, international normalized ratio; n, number of duplicate capillary blood samples.

Method comparison of INR measurements of samples directly applied to the test strip



ACL ELITE Pro, IL ACL Elite Pro (Instrumentation Laboratory; Bedford, MA, USA); Int CI, intercept confidence interval; SIp CI, slope confidence interval.

FUNDING

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