# Performance of the LumiraDx Platform INR Test in a point-of-care setting compared to an established laboratory reference method


## Background
Patients on vitamin K antagonist therapy (VKAs), such as warfarin, have a narrow therapeutic window and require regular international normalised ratio (INR) monitoring to maintain optimal coagulation. The LumiraDx Platform is a novel, point of care in vitro diagnostic system that can be used for INR testing using fingerstick blood samples. A study was conducted to evaluate the accuracy and precision of the new LumiraDx INR test, compared to a laboratory reference method, the IL ACL Elite Pro.

## Objective
Determine the accuracy and precision of the LumiraDx INR test compared to the IL ACL Elite Pro.

## Methods
The OPTIMAL Study was conducted in 11 sites by Glasgow Royal Infirmary, Queen Elizabeth Hospital and Golden Jubilee Hospitals, and NHS Lanarkshire Anticoagulation Service. Subjects (366) ranged from 29-93 years old, with a mean age of 69 years. The subjects were recipients of vitamin K antagonist (VKA) (340) and non-VKA controls (26). Once recruited they had their capillary whole blood INR levels determined by the LumiraDx INR test and their venous plasma INR levels by a laboratory reference method (IL ACL ELITE PRO) for the determination of accuracy. Precision of the INR test was assessed using paired replicate samples (direct sample application and application via capillary transfer pipettes), using three test strip lots. The accuracy of the INR measurements of capillary whole blood was assessed across the range of haematocrit 25-55% (as measured by HemoCue Hb201+). Feedback was collected from healthcare professionals via a self-completed questionnaire.

## Results
Results indicate INR measurements performed on the LumiraDx instrument are consistent with those obtained by the reference method, with a correlation of 0.965 (95% confidence interval (CI): 0.959, 0.970) when using direct application and 0.958 (95% CI: 0.950, 0.964) when using a transfer pipette. The established INR range was 0.8-7.5. Precision was measured using samples collected with a transfer pipette (n=291, mean INR 2.525, mean % coefficient of variation (CV) 3.73%) or direct application (n=284, mean INR 2.538, mean % CV 3.46), and was similar between test strip lots. Accuracy was maintained across the haematocrit range 25-55% with results confirmed by the HemoCue Hb 201+ analyser.

## Conclusion
There was a strong correlation between the LumiraDx instrument INR test with the laboratory reference method, as well as between the different application methods and test lots. Feedback from healthcare professionals indicated that overall the system was easy to prepare, follow instructions, had an easy to use interface, gave clear, easy to read results and was simple to clean. Data overall demonstrated that the LumiraDx Platform INR Test provided rapid and reliable INR analysis at the point of care.


## OPTIMAL Trial Investigators

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This trial was registered in www.Clinicaltrials.gov: NCT03682419.




**Read the full study publication at**
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