

# Evaluation of the Accuracy of INR values measured by LumiraDx in patients taking Phenprocoumon.

H. Völler<sup>1</sup>, J. Loecherbach<sup>2</sup>, J.E. Ellis<sup>2</sup>

<sup>1</sup>Klinik am See, Rehabilitation Clinic for Cardiovascular Diseases, Ruedersdorf/Berlin. <sup>2</sup>LumiraDx, London, UK. Jayne.Ellis@lumiradx.com

**This evaluation demonstrated no difference in LumiraDx Platform INR test results when patients are taking either Phenprocoumon or Coumadin as VKA therapy.**

## Background

- The LumiraDx Platform 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).
- 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.

## Aim

- To evaluate the INR results in patients taking Phenprocoumon using the LumiraDx INR Test at the point of care, and comparing the results to the laboratory reference methods, the ACL Elite Pro and Sysmex CS5100.

## Methods

- Observational, cross-sectional study of 102 subjects taking Phenprocoumon (M/F: 24/78; range: 36-88 years).
- Part 1: 25 patient plasma samples were analysed on LumiraDx INR and the IL ACL Elite Pro (Fig.1).
- Part 2 : 77 subject 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 (Fig.2).

## Results

- INR results demonstrated strong agreement with both of the reference methods across the range 1.3 – 5.2 INR (ACL Elite Pro  $r = 0.949$ ; Sysmex CS5100  $r = 0.950$  (Table 1)).

Slope	Slope CI	Intercept	Intercept CI	r	r CI
0.923	(0.846, 1.000)	0.015	(-0.200, 0.186)	0.950	(0.922, 0.969)

Table 1. Analysis of capillary blood samples (part 2): LumiraDx vs Sysmex CS5100.

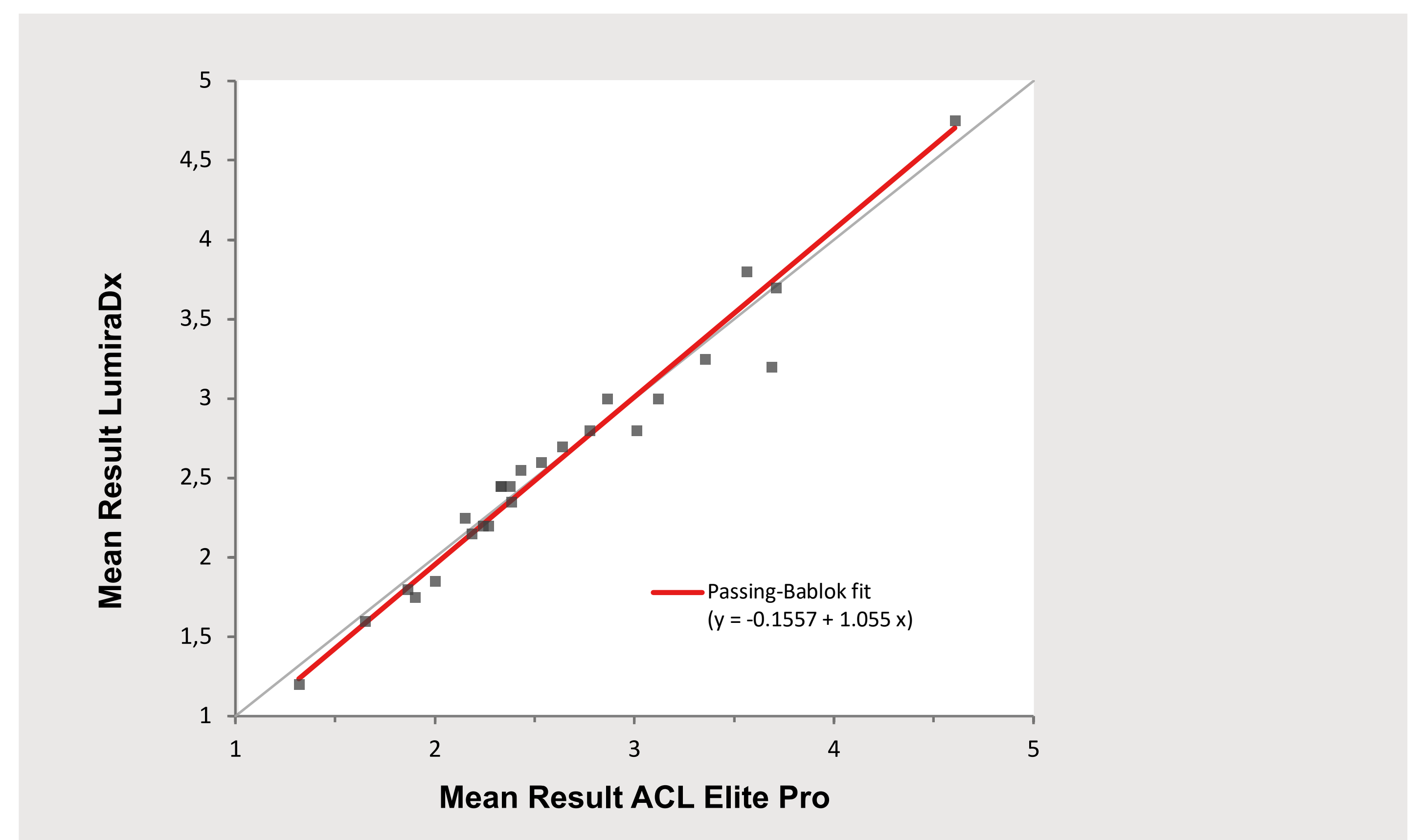


Figure 1. Analysis of plasma samples (part 1 analysis) from 25 subjects.

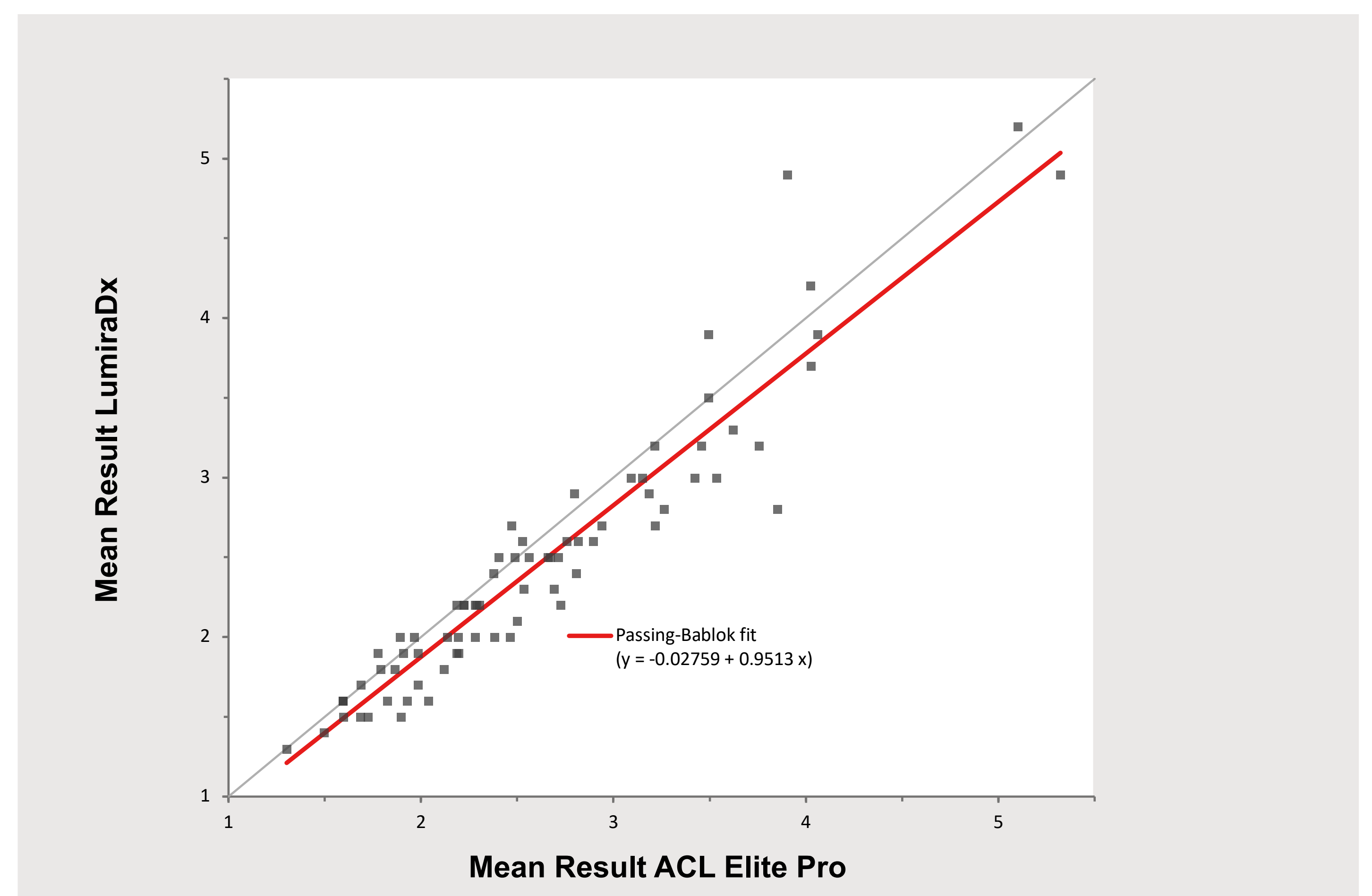


Figure 2. Fingerstick Capillary Direct Application Results from subjects taking Phenprocoumon as VKA – measured using the LumiraDx INR test vs plasma samples using the ACL Elite Pro.

## Conclusion

- Results were found to agree with those from the OPTIMAL study which included subjects on Coumadin (Warfarin), and demonstrated no difference in LumiraDx INR test results when patients are taking either Phenprocoumon or Coumadin as VKA therapy.

## Funding

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