

# Sensitivity of LumiraDx INR Testing to Interference from Antiphospholipid Antibodies (aPL)

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The LumiraDx Platform INR Test is a point of care thrombin activation assay which has low interference from Lupus Anticoagulants similar to that observed in widely used conventional thromboplastins on standard platforms.

## Background

- Antiphospholipid syndrome (APS), is an autoimmune state where aPL are associated with thrombotic and adverse obstetric events. Those with thrombotic events are anticoagulated using vitamin K antagonists (VKAs).
- Lupus anticoagulants (LA) are aPL that can interfere with phospholipid-dependent coagulation assays, leading to elevated clotting times and unwarranted VKA dose adjustments.

## Aim

- To assess whether the LumiraDx INR Test is sensitive to interference by aPL.

## Methods

- 51 LA positive frozen plasma samples, with previously reported INR results using Innovin reagent (Sysmex CS2100<sup>§</sup>), were tested on the LumiraDx INR Test, and also the ACL Elite Pro<sup>¶</sup>.
- 32 samples were LA positive patients who were not anticoagulated; two were from LA positive patients receiving Low Molecular Weight Heparin (LMWH) and 17 were LA positive, from patients receiving VKAs.

## Results

- No interference was seen in the 32 non-anticoagulated patient samples (INRs were 0.8 - 1.1).
- Of the two from patients receiving LMWH, one INR was normal another had an increased INR, indicative of interference.
- Of the 17 LA positive patients receiving VKAs, one sample gave a highly elevated INR on the LumiraDx platform and on the Sysmex in comparison to an especially LA-insensitive reagent.

## INR results from APS samples – LumiraDx INR vs ACL Elite

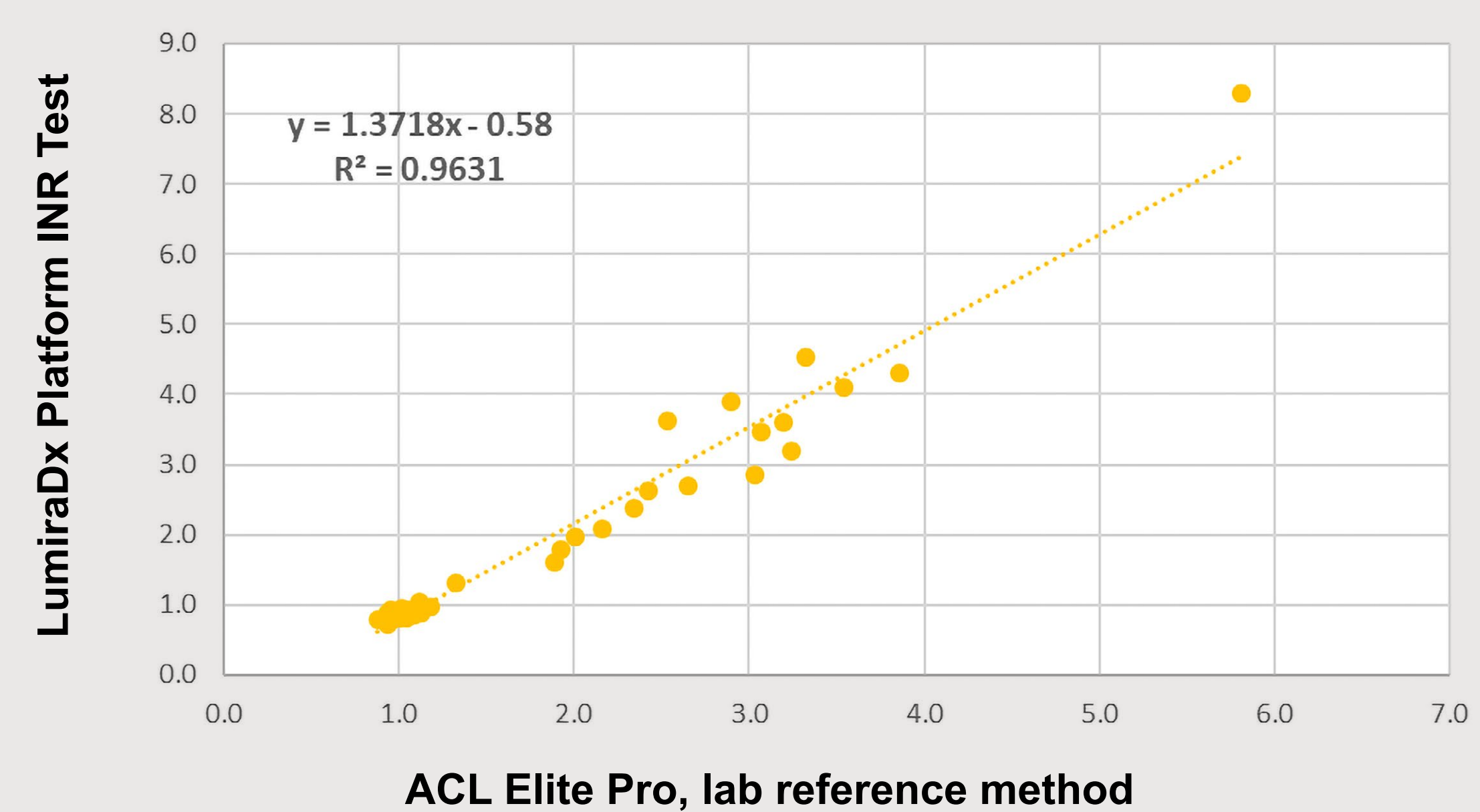


Figure 1.

## INR results from APS samples – LumiraDx INR vs Sysmex CS2100 INR

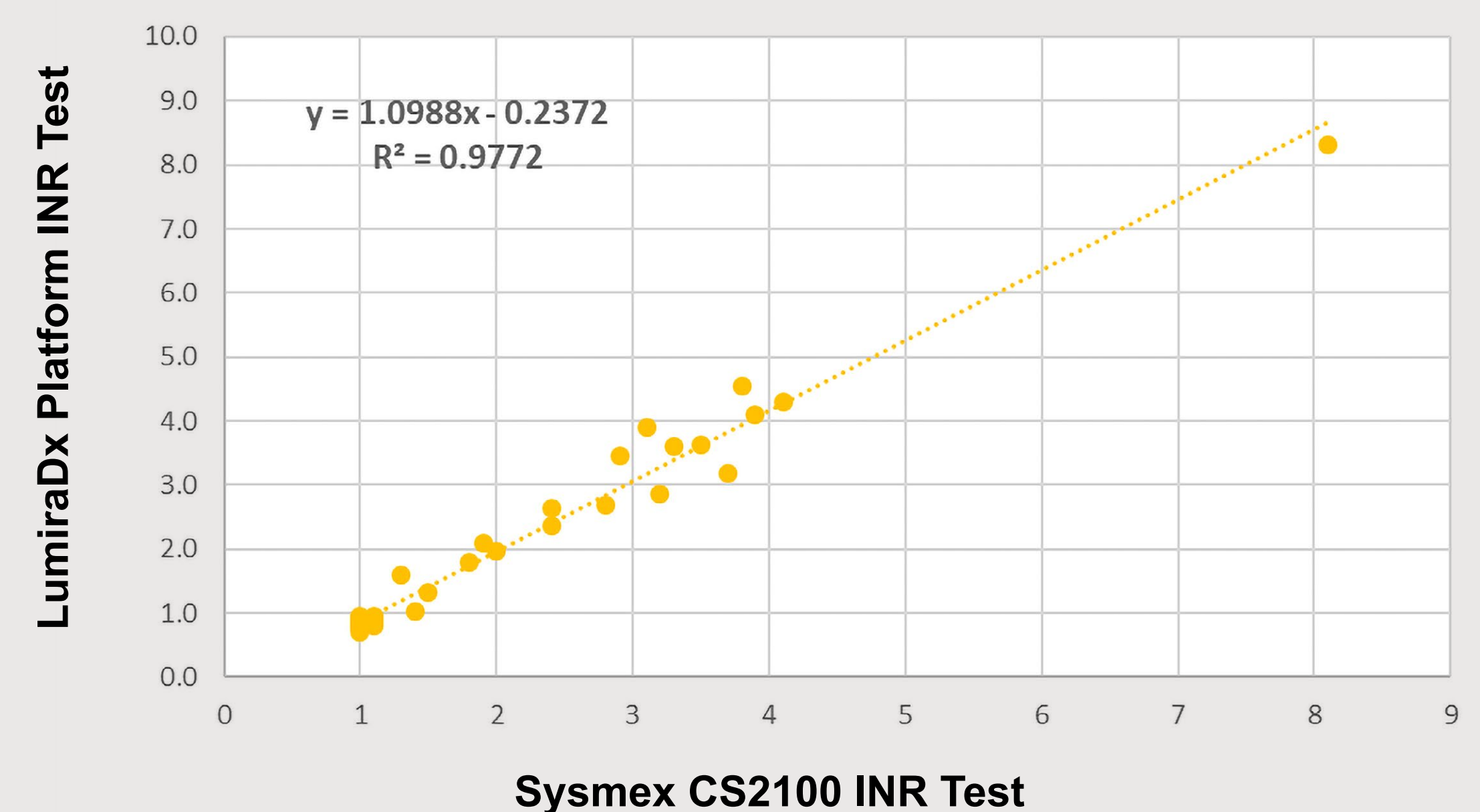


Figure 2.

## Conclusion

- The present study on a small but representative cohort suggests that LumiraDx INR Test has similarly low LA interference to widely used conventional thromboplastins on standard platforms.

## Funding

- This study was sponsored by LumiraDx UK Ltd. Dumyat Business Park, Alloa, UK. 09206123

The LumiraDx INR Test is subject to the intended use and limitations as set out in the LumiraDx INR Test Strip Product Insert.

¶ IL ACL Elite Pro – Instrumentation Laboratory, Bedford, MA. U.S.A  
 § Sysmex CS2100 - Sysmex Europe GmbH