Supplementary material

Eligibility criteria:

VKA Therapy Subjects – inclusion criteria

- Persons ≥18 years of age
- Willing and able to provide written informed consent and comply with study procedures
- Currently prescribed vitamin K antagonist therapy
- Deemed medically appropriate for study participation by the Investigator

VKA Therapy Subjects – exclusion criteria

- Persons <18 years of age
- Subject has previously participated in this study
- Subject is within 4 weeks of first prescription of vitamin K antagonist therapy
- Confirmed or suspected pregnancy
- Unwilling or unable to provide written informed consent and comply with study procedures
- Vulnerable populations deemed inappropriate for study by the Investigator
- Deemed medically inappropriate for study by the Investigator (i.e. patients with a known inherited [e.g. haemophilia or von Willebrand's disease] or acquired [e.g. liver cirrhosis] condition likely to be associated with a coagulopathy; or patients receiving non-VKA anticoagulant medications)

Non-VKA Study Subjects – inclusion criteria

- Persons ≥18 years of age
- Willing and able to provide written informed consent and comply with study procedures
- Deemed medically appropriate for study participation by the Investigator

Non-VKA study subjects – exclusion criteria

- Persons <18 years of age
- Subject has previously participated in this study
- Confirmed or suspected pregnancy
- Unwilling or unable to provide written informed consent and comply with study procedures
- Vulnerable populations deemed inappropriate for study by the Investigator
- Any persons deemed medically inappropriate for study by the Investigator

Questionnaire

A questionnaire was given to healthcare professionals to assess the acceptability of the LumiraDx INR point-of-care test in terms of ease of use, instruction and labelling materials and appropriateness of the design for the intended use and setting.

The respondents were provided with 29 questions and a key from 1–5; 1 = agree strongly, 2 = agree somewhat, 3 = neither agree nor disagree, 4 = disagree somewhat, 5 = disagree strongly.

The following questions were included in the questionnaire:

1. The materials are clear and easy to read and understand.
2. The materials provided are sufficient to conduct a test completely.
3. The materials have a clear summary of contents and structure.
4. Instructions on the instrument self-test procedures are clear and easy to understand.
5. Instructions on pre-test procedures are clear and easy to understand.
6. Instructions on sample collection and application to the test strips are clear and easy to understand.
7. Instructions on reading the test result display are clear and easy to understand.
8. Instructions on obtaining a test result from the instrument memory are clear and easy to understand.
9. Instructions on errors and troubleshooting are clear and easy to understand.
10. No special training is required to use the LumiraDx INR test beyond reading the user manual and following instructions on the instrument screen.
11. Preparing the LumiraDx instrument to take a test is simple.
12. Removing a test strip and inserting the test strip into the instrument is easy.
13. Applying an adequate patient capillary sample from a fingerstick to the test strip is simple.
14. Applying an adequate patient sample from a transfer pipette to the test strip is simple.
15. Capturing appropriate test information from the instrument and recording a test result is simple.
16. The user-interface and instrument display is simple and easy to use.
17. The instrument is easy to use with or without wearing gloves.
18. The time taken for the instrument user interface to feedback on each step of the test process is adequate.
19. The instrument provides adequate feedback on test steps, test progress and errors.
20. If an error occurred:
    1. It was clear how to resolve it.
    2. The cause of the error was clear.
21. The instrument screen and outer casing and design allows it to be easy to clean and prevent biohazard (blood) contamination.
22. The instrument provides a convenient and appropriate method for point of care INR measurement.
23. The instrument provides comparable benefits compared to your usual method of INR testing. (Please specify in the comments section.)
24. The results are displayed in an easy-to-read format.
25. The time of result display on the screen is sufficient.
26. The date and time can be easily recorded from using the instrument.
27. Allows the patient to be seen and tested quickly.
28. The instrument allows current patient testing requirements to be adhered to.
29. Provides a patient experience equivalent to, or better than, your current INR testing system.

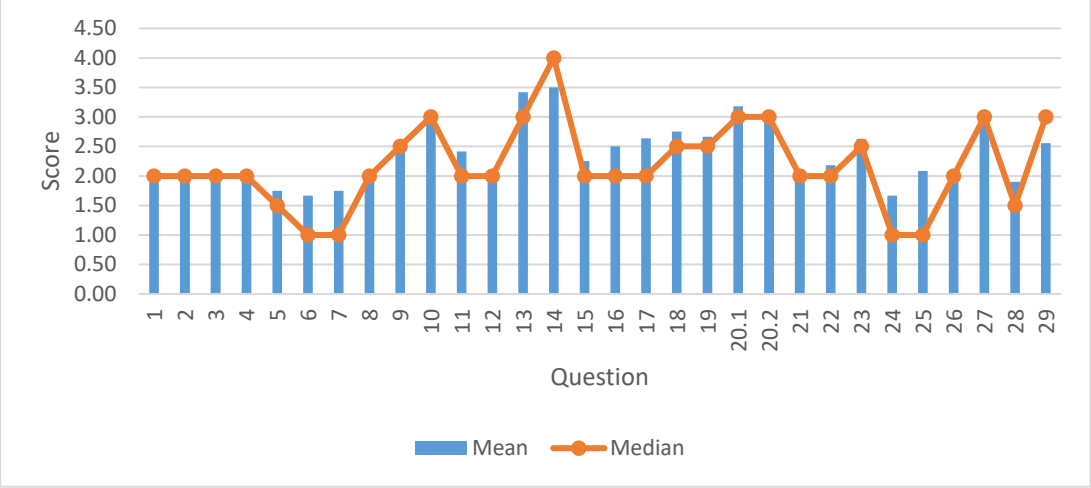

Figure S1: Questionnaire responses. A questionnaire consisting of 30 questions was completed by the healthcare professionals that were involved in testing at each of the sites of the study.