LumiraDx™ INR Test Specifications

Intended Use

- The LumiraDx INR Test is a point of care test for use with the LumiraDx Instrument – for professional use only
- Measures quantitative prothrombin time, reported as International Normalised Ratio (INR)
- Used for the monitoring of oral anticoagulation therapy with vitamin K antagonist (VKA) drugs
- Assay has not been validated for individuals younger than 18 years old

Test Description

- Thrombin activation assay – the coagulation cascade is activated by the test reagents and INR is calculated from the measured PT-time
- Emitting fluorescence is detected at a threshold point and time to reach this is measured
- Haematocrit is also determined on the strip to ensure patients are within the 25-55 % range
- Results compared to the Instrumentation Laboratory ACL Elite lab reference method

Built-in Quality Controls

Instrument and Test Strips are highly integrated and have several quality control functions. The Instrument contains a number of automated checks of the correct functioning of the Instrument at power on and during operation. This includes:

- Electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance
- Test Strip positioning, optics, hematocrit and Test Strip expiry
- Monitoring of Test Strip performance and controls during test runtime

These checks are included to ensure that:

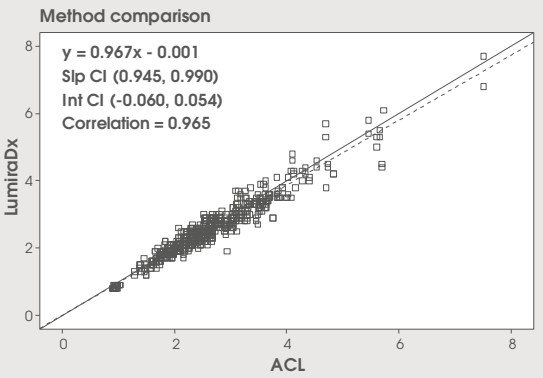
- The behaviour of the sample moving into the reaction area of the Test Strip is as expected
- The Test Strip has not previously been used
- Blood samples outside the accepted hematocrit range are identified

INR Quality Controls

Quality Controls are available from LumiraDx and are intended for liquid quality control testing performed on the Instrument when used with the INR Test Strip.

Accuracy

Direct Capillary Blood (596 samples from 326 patients) was collected from multiple sites. Reference method was ACL Elite Pro Coagulation Analyser.



Precision

Determined for capillary blood from sample duplicates collected at multiple sites. The following results represent the mean paired rep %CV for both direct and transfer tube application.

Sample	n	Mean INR	Mean % CV
Direct Application	284	2.54	3.46
Transfer Tube	291	2.53	3.73

INR Test Strip Specifications

Displayed results	INR
Storage temperature	Between 5 °C and 32 °C (41 °F and 89 °F)
Operating temperature	Between 15 °C and 30 °C (59 °F and 86 °F)
Measuring range	0.8–7.5 INR
Sample size	Capillary: 8 µL
Sample type	Fresh capillary whole blood – taken by finger-stick or via non-anticoagulated transfer tube
Time to result	INR results in 60–90 seconds*
ISI	Approx. 1.0
Interferences	See INR Test Product Insert for details

*Supratherapeutic INR > 4.0 test result could take 90-180 seconds

For more information visit www.lumiradx.com or contact the LumiraDx Customer Services by email: customerservices@lumiradx.com or at lumiradx.com.

Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets. Not currently available in the USA.

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