LumiraDx™

INR Test Specifications

For *in vitro* diagnostic use.

Intended use

The LumiraDx INR Test Strips are intended for use with the LumiraDx Instrument. It is for use by healthcare professionals for quantitative prothrombin time testing, reported as International Normalized Ratio (INR), for the monitoring of oral anticoagulation therapy with Vitamin-K Antagonist (VKA) drugs. The test uses fresh capillary blood. It is intended for use in patients 18 years of age or older.

Test description

The LumiraDx INR test is a thrombin activation assay in which a quenched substrate is cleaved by thrombin and the emitting fluorescence is detected and quantified. When a blood sample is applied to the Test Strip, the clotting cascade that proceeds naturally leads to the conversion of prothrombin to thrombin which, subsequently, recognizes a peptide sequence on the substrate. Following cleavage of this peptide sequence, the substrate becomes unquenched and emits a fluorescent signal detectable by the LumiraDx Instrument. The amount of signal detected over a specific time is converted by means of an algorithm into standardized coagulation units (INR) and the result is displayed on the touch-screen.

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:

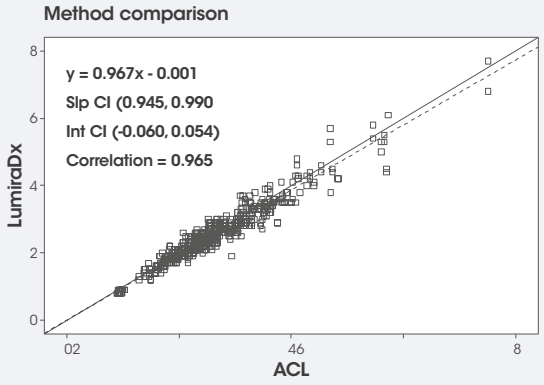
- The behaviour of the sample moving into the reaction area of the Test Strip is as expected
- The Test Strip has not previously been used
- Blood samples outside the accepted hematocrit range are identified

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 specifications

Displayed results	INR
Storage temperature	Between 5°C - 32°C (41°F - 89°F)
Operating temperature	Between 15°C - 30°C (59°F - 86°F)
Measuring range	0.8 – 8.0 INR
Sample type	Whole blood (capillary fingerstick or via non-anticoagulated transfer tube)
Sample size	Capillary: 8 µL
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 lumiradx.com or contact the LumiraDx Customer Services by email:customerservices@lumiradx.com

Not all products are 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.

Manufactured by:
LumiraDx UK Ltd,
Dumyat Business Park,
Alloa, FK10 2PB, UK.
Registration Number:
09206123

Authorized Representative in the European Union:
LumiraDx AB
Västra Vägen 5A
16961 Solna,
Sweden

lumiradx.com

S-COM-ART-00086 R2