



LumiraDx™

D-Dimer Test Specifications

For *in vitro* diagnostic use.

Intended use

The LumiraDx D-Dimer Test is an *in vitro* diagnostic test for the quantitative determination of D-Dimer in human whole blood (capillary finger stick and sodium citrated venous) and sodium citrated plasma samples. The Test can be used as an aid in the assessment and diagnosis of patients with suspected venous thromboembolism (VTE) such as deep vein thrombosis (DVT) and pulmonary embolism (PE).

Test description

D-Dimer is a degradation product of fibrin, present in the blood after a blood clot is degraded by fibrinolysis. D-Dimer testing is of clinical use when there is a suspicion of VTE and is used alongside clinical scoring systems and additional test methods.

The LumiraDx D-Dimer Test is a fluorescence immunoassay for use on the LumiraDx Platform. The quantitative Test measures D-Dimer in human whole blood (including direct fingerstick) and plasma samples.

The Test result is the mean of 3 simultaneous D-Dimer assays on our unique, multi-channel Test Strip.

Built-in Quality Controls

LumiraDx Platform Instrument and Test Strips are integrated with several control checks to ensure that the Instrument and Test are functioning correctly for every test run. These checks include:

- Electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance
- Test Strip positioning and Test Strip expiry
- Monitoring of the Test Strip performance and controls during test runtime
- The D-Dimer Test contains on Onboard Quality Control (OBC) assay
- Sufficient sample volume and hematocrit determination on the Test Strip to ensure patients are within the 22-55% range and results compensated for blood performance

D-Dimer Quality Controls

D-Dimer Quality Controls come in two levels and are available from LumiraDx to complete Quality Control assessment of the Instrument and D-Dimer Test strips.

Method comparison

The method comparison was performed using plasma samples from patients (n = 327, range = 60 - 4515 µg/L FEU (Fibrinogen Equivalent Units)). A comparison of 1767 D-Dimer measurements with the LumiraDx D-Dimer Test to the VIDAS® D-Dimer Exclusion™ II assay yielded the following statistics: Slope = 1.02, Intercept = 21, r = 0.92.

Precision

A precision study was carried out using citrated venous plasma samples. The protocol was based on CLSI EP5-A3.¹ The study was carried out on 3 levels of D-Dimer; each level was tested over 2 runs of 2 replicates per day, for twenty days.

D-Dimer concentration (µg/L FEU)	Within run precision (% CV)	Within day precision (% CV)	Between day precision (% CV)	Total precision (% CV)	n
291	9.8	11.1	0.0	11.1	80
552	9.4	9.4	2.5	9.7	80
1790	10.1	10.1	0.7	10.2	80

Fingerstick capillary, sodium citrated venous blood and sodium citrated plasma precision was calculated using the average paired replicate % CV from 98, 90 and 95 patient samples respectively with D-Dimer concentrations between 55–3335 µg/L. Calculated % CV for fingerstick capillary, venous whole blood and plasma was 9.5 %, 9.0 %, and 7.6 % respectively.

Specifications

Displayed results	D-Dimer FEU (Fibrinogen Equivalent Units) µg/L
Storage temperature	2–30 °C (36–86 °F)
Operating temperature	15–30 °C (59–86 °F)
Measuring range	190–4000 µg/L FEU Each laboratory should investigate the transferability of the expected values to its own patient population and, if necessary, determine its own reference ranges.
Sample type	Whole blood (capillary fingerstick and sodium citrated venous) and sodium citrated plasma samples
Sample size	15 µL
Time to result	Approximately 6 minutes

1. Visit www.CLSI.org for information

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

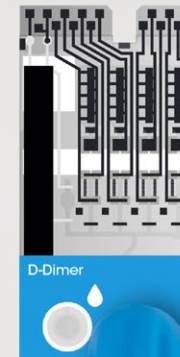
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Not all products are available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets. Not currently available in the USA.

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