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 capillary and venous whole blood and plasma samples (Sodium Citrate). The LumiraDx D-Dimer Test Strips are intended for use with the LumiraDx Instrument. It is an automated in vitro diagnostic test for near-patient testing to aid in the assessment and diagnosis of patients with suspected venous thromboembolism (VTE) such as deep vein thrombosis (DVT) and pulmonary embolism (PE).

The test can be used in conjunction with a clinical pre-test probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in patients suspected of DVT or PE. The LumiraDx D-Dimer test is for Professional Use Only. For patients ≥18 years of age.

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 an easy to use, fast microfluidic immunoassay designed to rapidly quantify D-Dimer levels in whole blood and plasma.

The test result is the mean of 3 D-Dimer assays run on the unique multi-channel Test Strip.

The LumiraDx D-Dimer test is the only direct fingerstick D-Dimer assay available at the point of care today*, aiding healthcare professionals to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) in symptomatic patients with confidence - all in only 6 minutes.

*As stated at time of publication - 24th May 2022

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 20-55% range and results compensated for blood performance

D-Dimer Quality Controls

D-Dimer Quality Controls come in two levels and are available from LumiraDx.

Method Comparison

The method comparison was performed using plasma samples from patients (n = 327, range = 60 - 4515µg/L FEU (0.060-4.515mg/L FEU). A comparison of 1767 D-Dimer measurements with the LumiraDx D-Dimer test to the VIDAS Exclusion II D-Dimer assay yielded the following statistics: Slope = 1.02, Intercept = 21, r = 0.92.

Precision

A precision study was carried out in citrated venous plasma on a protocol based on CLSI EP5-A3. The study was carried out with levels of D-Dimer, each was tested in 2 runs of 2 replicates per day, for twenty days.

D-Dimer concentration (µg/L FEU)	D-Dimer concentration (mg/L FEU)	Total precision (% CV)	n
291	0.291	11.1	80
552	0.552	9.7	80
1790	1.790	10.2	80

Clinical Performance

A prospective clinical study was performed on 585 subjects where fresh samples (capillary blood, venous (blood citrated) and plasma (citrated) were collected from patients presenting with symptoms of VTE (PE or DVT) [1,2]. Subjects also required an assessment with the Wells score and were classed as pre-test probability (PTP) 'Likely' or PTP 'Unlikely'. Those with 'Unlikely' PTP categorization were further analysed using the LumiraDx D-Dimer test with 500 µg/L FEU (0.500 mg/L FEU) D-Dimer as cut-off. The corresponding sensitivity and negative predictive values (NPV) by sample matrix are listed below with corresponding Wilson Score 95% confidence intervals (CI).

Estimate	Matrix	Patients with Suspected VTE
		Unlikely PTP
Sensitivity % (95% CI)	Venous	100.0% (74.1%-100.0%; n = 378)
	Capillary Direct	100.0% (72.2%-100.0%; n = 377)
	Plasma	100.0% (74.1%-100.0%; n = 406)
NPV % (95% CI)	Venous	100.0% (98.3%-100.%; n = 378)
	Capillary Direct	100.0% (98.1%-100.0%; n = 377)
	Plasma	100.0% (98.1%-100.0%; n = 406)

D-Dimer Test Strip Specifications

Clinical cut-off	500 µg/L FEU (0.500 mg/L FEU)
Displayed results	D-Dimer FEU (Fibrinogen Equivalent Units) µg/L or mg/L
Storage temperature	2–30 °C (36-86 °F)
Operating temperature	15–30 °C (59–86 °F)
Measuring range	190–4000 µg/L FEU (0.190-4 mg/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	6 minutes

References

1. EMBOL-1 protocol – NCT04737954 www.clinicaltrials.gov/ct2/show/NCT04737954?term=LumiraDx&draw=2&rank=3
2. NICE Guideline: Venous thromboembolism: diagnosis and anticoagulation treatment www.nice.org.uk/guidance/ng158/resources/visual-summary-pdf-8709091453

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.

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