Pariksha Biotech
A game changer in IVD

HIGH Q®
Command on Quality

High-Q D-DIMER

(Latex Enhanced Turbidimetric Immuno Assay) (LETIA)

Emergency Test for exclusion of DVT or PE

Coagulation Marker

Clinical Implications :

- Deep Vein Thrombosis (DVT)
- Pulmonary Embolism (PE)
- Disseminated Intravascular Coagulation (DIC)
- Fibrinolytic Therapy
- Tumours
- Infection
- Heart Failure
- Liver Cirrhosis

Product Attributes and Advantages

- Latex Enhanced Turbidimetric Immuno Assay (LETIA)
- Ready to use liquid stable two reagents
- Liquid Stable High Level Calibrator provided
- 2 Level Controls provided (Optional)
- Measurement at 630 nms (600-670 nms)
- 9 minutes Test Procedure at 37°C
- Linearity : 0.00 to 10.00 µg FEU /ml
- High Prozone Security up to 50 µg FEU/mL
- Excellent Precision

Pariksha Biotech
A game changer in IVD

High-Q D-DIMER

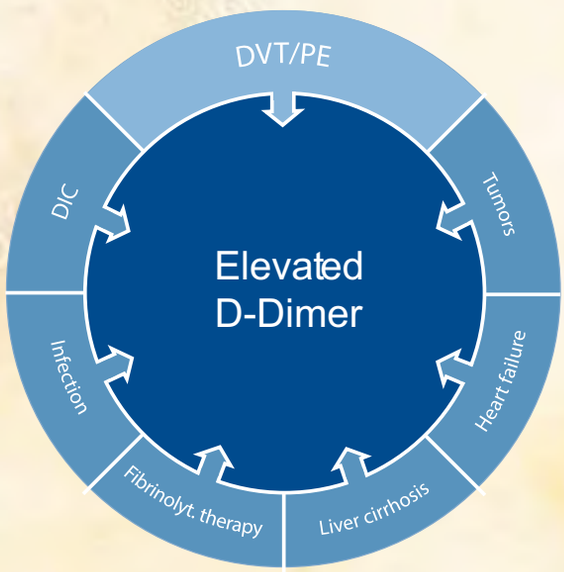
(Latex Enhanced Turbidimetric Immuno Assay)

(LETIA)

HIGH Q®
Command on Quality

Clinical Relevance

The fibrin degradation product, D-Dimer is detectable after plasmin degradation of cross-linked fibrin. Elevated D-Dimer values indicate increased thrombin activity and fibrin formation and are therefore an indirect marker of Venous Thrombotic Events (VTE). D-Dimer values are increased in various conditions, such as cancer, liver cirrhosis or infections, which make a reliable diagnosis of a thrombotic event difficult. However, D-Dimer results have a high negative predictive value (NPV) in order to exclude Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).



Diagnostic Value of D-Dimer

Individuals with signs or symptoms suggestive of a thromboembolic phenomenon are initially screened with a D-DImer test to exclude DVT or PE. DVT is ruled out in patients with D-Dimer levels below the cut-off value of 0.8 µg FEU/mL, whereby values above this cut-off have to undergo further investigations as sonography or phlebography. The High-Q D-Dimer reagent has demonstrated diagnostic sensitivity of 98% and diagnostic specificity of 95.0 % for DVT at a cut-off value of 0.8 µg FEU/mL. D-Dimer levels below 0.8 µg FEU/mL have a NPV of 99.4% for exclusion of DVT. These results are according to CLSI requirements of a diagnostic sensitivity of ≥ 97% and a NPV of ≥ 98%

D-Dimer testing in suspected VTE

↓	↓
Positive **value above cut-off**	**Negative** **value below cut-off**
↓	↓
Diagnostic imaging **(sonography / phlebography)**	**Exclusion of acute** **thrombic event**
↓ ↓	
Positive / **Negative**	
↓ ↓	
Therapy / **No action**	

Pariksha Biotech
A game changer in IVD

High-Q D-DIMER

(Latex Enhanced Turbidimetric Immuno Assay)

(LETIA)

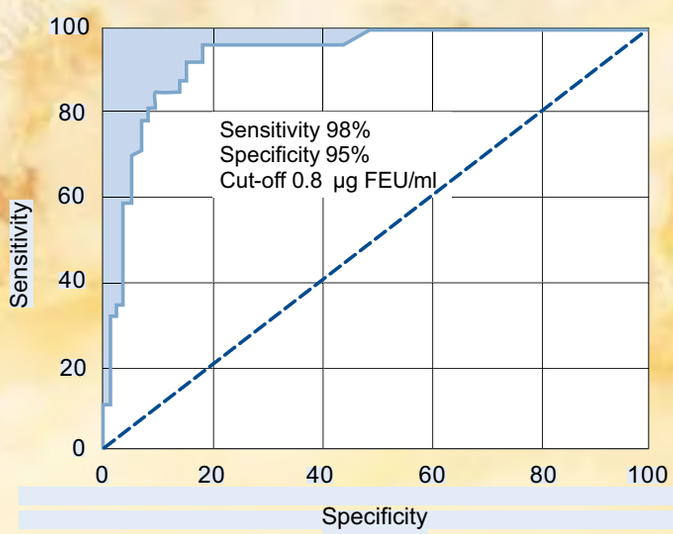
HIGH Q®
Command on Quality

Product Attributes and Advantages

- Latex Enhanced Turbidimetric Immuno Assay (LETIA)
- Ready-to-use liquid stable two reagents
- 4 Level Liquid Calibrator set provided
- 2 Level Liquid Controls provided (Optional)
- Measuring wavelength 578 nms (570-670 nms)
- 4 Minutes fixed time test procedure (5 Sec +240 Sec)
- Linearity 10 µg FEU/ml
- High prozone security up to 50 µg FEU/mL
- Superior onboard and calibration stability of 6 weeks
- Excellent precision and low limit of quantitation : 0.15 µg/mL FEU
- Results comparable to commercial D-Dimer CLIA and IFA assays

Performance Characteristics

Diagnostic Sensitivity



High-Q D-Dimer		Positive for DVT	Negative for DVT
	Positive > Cut-off 0.8 µg FEU/mL	True positive 49	False positive 10
	Negative < Cut-off 0.8 µg	False negative 1	True negative 190

n = 250, 50 confirmed DVT; 100 suspected of DVT, but not confirmed; 100 outpatients were tested for D Dimer

Precision

Intra-assay N = 20	Mean (µg FEU/mL)	CV (%)	Inter-assay N = 20	Mean (µg FEU/mL)	CV (%)
Low level sample	37.3	0.58	Low level sample	0.66	4.59
Medium level sample	59.5	0.79	Medium level sample	0.95	2.18
High level sample	113	0.33	High level sample	3.59	1.10

Pariksha Biotech
A game changer in IVD

High-Q D-DIMER

(Latex Enhanced Turbidimetric Immuno Assay)

(LETIA)

HIGH Q
Command on Quality

ASSAY SPECIFICATIONS

Method	Latex Enhanced Turbidimetric Immuno Assay (LETIA)
Sample Type & Volume	Human Na Citrate Plasma Sample Volume 50 µL
Method Correlation	N = 128 y-intercept = 0.106 Slope = 0.979 R^2 = 0.939 Samples ranged from 0.17 - 7.95 µg/mL FEU in comparison with an existing commercial D-Dimer assay method
Linearity	0.00 to 10.0 µg/mL FEU
LOD LOB LOQ	0.06 µg/mL FEU 0.09 µg/mL FEU 0.15 µg/mL FEU
Calibration Levels	4-Point Calibration
Reagent On-Board Stability	6 weeks when stored at 2-8°C

D-Dimer Assay Procedure*

*Analyzer Dependent

Bibliography:

1. Sandkamp, M et al. Clin Chem 1990;36:20-23
2. Medicon CE folder data
3. Bick R.L. et al. Thromb Res 1992;65:785-90.
4. Wo, J.H. et al. Clin Chem 1993;39:209-212
5. Gaffney PJ. Fibrinolysis Supplement 2.1993;7:2-8

ASSAY PRECISION

The precision of Pariksha's D-Dimer Assay was evaluated according to Clinical Laboratory Standards Institute EP5-A guidelines. In the study, three levels of pooled citrated plasma specimens containing 0.60 µg/mL, 2.41 µg/mL and 5.88 µg/mL FEU were tested respectively. The low plasma sample was unaltered. The other two plasma samples were spiked with D-Dimer stock solution to targeted concentrations and assayed. Three levels of D-Dimer controls containing 0.97, 2.99 and 7.47µg/mL FEU, respectively were also tested with 2 runs per day with duplicates over 20 working days with three lots of reagent and three lots of calibrators. The results are shown below:

Plasma Samples Within-Run Precision (all results using 240 Data Points N)

	Level 1	Level 2	Level 3
Mean (µg/mL FEU)	0.60	2.41	5.88
SD (µg/mL FEU)	0.03	0.05	0.08
CV (%)	5.0%	2.0%	1.4%

Plasma Samples Total Precision

	Level 1	Level 2	Level 3
Mean (µg/mL FEU)	0.60	2.41	5.88
SD (µg/mL FEU)	0.04	0.07	0.19
CV (%)	6.2%	2.7%	3.2%

Control Samples Within-Run Precision

	Level 1	Level 2	Level 3
Mean (µg/mL FEU)	0.97	2.99	7.47
SD (µg/mL FEU)	0.03	0.05	0.11
CV (%)	2.9%	1.6%	1.4%

Control Samples Total Precision

	Level 1	Level 2	Level 3
Mean (µg/mL FEU)	0.97	2.99	7.47
SD (µg/mL FEU)	0.04	0.08	0.27
CV (%)	4.4%	2.8%	3.6%

INTERFERENCE STUDIES

The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Hemoglobin:	up to 500 mg/dL	Bilirubin Conjugated:	up to 40 mg/dL
Bilirubin:	up to 40 mg/dL	Ascorbic acid:	up to 176 mg/dL
Triglycerides:	up to 1000 mg/dL	Rheumatoid Factor :	up to 100 IU/mL
Heparin:	up to 1.5 IU/mL	HAMA:	up to 490 ng/mL

Pariksha Biotech Pvt Ltd,
Plot No.1/B-14,SVICE,
Balanagar,
Hyderabad-500037
Telangana State
CIN No: U24232TG2011PTC072118
An ISO 13485 Certified Company

+91 70757 06709

info@parikshabio.com

www.parikshabio.com