Pariksha Biotech
A game changer in IVD

D Dimer Estimation Kit

High-Q D Dimer

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

HIGH®
Command on Quality

Intended Use: For the Quantitative Determination of **D Dimer** in Human Plasma

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).

High-Q Latex Enhanced Turbidimetric Immuno Assay method offers excellent analytical performance ,laboratory efficiency and workflow.

High-Q D-Dimer Assayis a cost effective dual vial liquid stable reagent system intended for the in vitro quantitative determination of fibrinogen/fibrin degradation products (D-Dimer) in human plasma.

Principle:

The blend of Monoclonal and Polyclonal anti-D-Dimer antibodies in the reagent react with the D-Dimer in the human plasma samples, forming antigen/antibody complexes that are detected as turbidity which gets quantitated photometrically at 630 nms (600-630 nms)

Kit Presentation and Calibrators:

High-Q D-Dimer Kit is available with liquid stable two reagents with Liquid Stable High Level Liquid Calibrator **(4.0 µg FEU*/ml)** .

Preparation of Calibrator: Liquid Stable High Level Calibrator (4.0µg FEU*/ml) is provided in the kit. Reconstitution is not required . Calibrator needs to be serially diluted using the Calibrator Dilution Buffer provided along with the kit as per the below mentioned procedure to get 5 Level Calibrators for calibration. Calibrate the assay every six weeks. Re calibration is necessary only when the major components of the analyzer are replaced. Controls are available as an optional facility.

Cal -5	Cal-4	Cal-3	Cal-2	Cal-1
Liquid Stable Calibrator	Cal 5 - 100 µl + 100 µl Dilution Buffer	Cal 4 - 100 µl + 100 µl Dilution Buffer	Cal 3 - 100 µl + 100 µl Dilution Buffer	Cal 2 - 100 µl + 100 µl Dilution Buffer
4.0 µg FEU*/ml	2.0 µg FEU*/ml	1.0 µg FEU*/ml	0.5 µg FEU*/ml	0.25 µg FEU*/ml

Quality Control:

Controls are available as an optional facility. Two-level liquid controls are provided optionally. Target values for D-Dimer should be verified with the standardized applications. Results outside the specified values even after re calibration could be due to reagent deterioration, instrument malfunction or error during test procedure. High-Q D dimer reagents are evaluated with

third party Quality Control materials for the better performance and acceptance through perfection in the assay

Specimens:

1) Use citrated plastic vaccutainers for blood collection.

2) Collect the blood till the brim of the citrated vaccutainer. Ensure that the blood is collected in the full volume indicated on the vaccutainer. Less volume of blood may give negative reactions as high citrate concentration in the blood affects the specific D Dimer reaction.

3) Centrifuge the blood and separate the plasma. Do not use glass containers at any stage of the preparation or storage of the sample. Do not use turbid samples. D-Dimer is stable up to 7 days at 2 – 8°C or 2 months at –20°C when frozen.

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Assay Procedure: (Fixed Time- 5 point Spline Calibration with 5 Calibrator Levels):

System Parameters:

Reaction Type (Mode)	Fixed Time- Linear
Reaction Direction	Increasing
Wave Length	630 nm (600-670 nms)
Flow Cell Temp.	37°C
Delay Time	5 Seconds
Measuring Time	240 Seconds
Blank	Distilled Water Blank
Reagent Volume	375 µl (R1) + 125 µl (R2)
Sample Volume)	50 µl
Calibrators Concentrations	(On the Vials Lot Specific)
Linearity	10 µg FEU*/ml

Procedure :

Reagent	Calibrator	Sample/Control
D Dimer R1	375µl	375 µl
Calibrator	50 µl	----
Plasma Sample	—	50 µl
Mix and incubate for 5 Minutes at 37 °C		
D Dimer R2	125 µl	125 µl

1) Read absorbance A1 after 5 Seconds. (Delay)
2) Incubate and Read the absorbance A2 after 240 Seconds (Measuring)
3) Calculate the absorbance differences ΔA=A2–A1 for each point of the calibration curve, controls and all unknown samples.
4) The concentration of D-Dimer in the unknown sample can be calculated from ΔA=A2–A1
5) Using a 3rd order polynomial mathematical model where abscissa (X) is the ΔA=A2–A1 and ordinate (Y) is the concentration of D Dimer or plotting the values of ΔA=A2–A1 obtained for every concentration level of the calibrator against the D- Dimer concentration and interpolating the individual ΔA=A2–A1 of every sample in the calibration curve.

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:
The concentration of D Dimer in unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with 5 calibrators at different levels. Stability of calibration: 6 weeks

Reference Range:
Reference cut off is derived after studying the plasmas of healthy individuals without DVT and PE and after the comparative data collected at a third party laboratory.
There is no internationally accepted standard for the determination of D-Dimer

D-Dimer: < 0.80 µg FEU/mL (D- Dimer is expressed as FEU)
(FEU = Fibrinogen Equivalent Units)

Important Note:
Some samples may not have quantifiable levels of D Dimer and may show 0.00 and those samples can be reported as less than < 0.80 µg FEU/mL
Some samples may show the D Dimer values below the baseline and may give negative results and those samples can be reported as less than < 0.80 µg FEU/mL

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Precision and Performance:

Dynamic Range and Linearity:

The D-Dimer procedure is linear from 0.00 – 10.00 µg FEU/mL.
Samples exceeding the upper limit of linearity should not be diluted, but instead should be reported as > 10.0 µg FEU/mL.

Samples with very elevated D-Dimer concentrations (> 50 µg FEU/mL) can generate false low results without appropriate "Z" flags due to excess antigen in the sample, such as can occur during lysis therapy.

Samples containing Heterophilic Antibodies may cause falsely elevated results. Samples with extremely abnormal optical characteristics, especially turbidity, may produce atypical results.

Precision:

Level µg FEU /ml	Within Run CV%	Between Run CV%
0.55	4.10	4.40
2.06	0.76	1.53

Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Method Comparison
A comparison was performed between this reagent and another commercially available product.
Y = 0.9562X + 0.0008 R=0.9801 N=86 Sample range: 0.0 – 10.0 µg FEU/ml

Bibliography:

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

Cat No:	Pack Size	Presentation
	40 ml	Two Liquid Reagents and Lyophilized Calibrator

Product Features

- **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**
- **Excellent correlations compared to existing commercial**
- **D Dimer Assays**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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SCAN TO EXPLORE MORE

Manufactured in India by :
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