TurbiMAX D-Dimer

Latex Enhanced Turbidimetric Immuno Assay

ORDERING INFORMATION

Ref. No:	Pack Size	Presentation
AVDDIMT- 16	16 ml	Two Liquid Reagents and 4
AVDDIMT- 24	24 ml	Level Calibrator Set
AVDDIMT- 48	48 ml	

INTENDED USE

TurbiMAX D-DIMER is an in-vitro diagnostic kit for the Quantitative Determination of **D-Dimer** in Human Plasma.

PRODUCT FEATURES:

1. Latex Enhanced Turbidimetric Immuno Assay
2. Ready to use liquid table two reagents
3. 4 Point Liquid Stable Calibrator Set provided
4. 2 Level Controls provided (Optional)
5. Measurement at 630 nms (600-630 nms)
6. 9 minutes Test Procedure at 37°C
7. Linearity : 0.00 to 10.00 µg FEU /ml
8. High Prozone Security up to 50 µg FEU/mL
9. Excellent Precision
10. Excellent correlations compared to existing commercial D Dimer Assays

CLINICAL SIGNIFICANCE

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).

Avecon''s Latex Enhanced Turbidimetric Immuno Assay method offers excellent analytical performance,laboratory efficiency and workflow.
Avecon's 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 600 to 630 nms.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8ºC and the contaminations is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Buffer Reagent R1
2. Turbi Latex Reagent R2
3. D-Dimer Calibrators (4) : Concentration as stated on the label

COMPOSITION:

Reagent 1 : Glycine Buffer-125 mMol/L
Reagent 2: Latex particles coated with mouse anti-human D-Dimer Monoclonal and Rabbit Polyclonal antibodies with preservatives.
D Dimer Calibrators and Controls: Different concentrations of D Dimer spiked in human plasma matrix with preservatives

SPECIMEN COLLECTION & STORAGE

Use vaccutainers for blood collection.Blood collected in plastic vaccutainers with citrate as anti coagulant. 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.

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.
When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard reagent if blank reagent absorbance exceeds 1.4 at 630 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SYSTEM PARAMETERS:

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

TEST 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.

CALCULATION

Calculation with calibrator/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 four calibrators at different levels.

EXPECTED VALUE

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: < 0.8 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 < 0.8 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 < 0.8 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.

QUALITY CONTROL & CALIBRATION

D-Dimer Controls are recommended for daily quality control. The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits

PERFORMANCE CHARACTERESTICS:

1. Linearity

Linearity : 10.00 µg FEU/mL

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.2 µg FEU/mL

3.Interferences:

Lipemic:	insignificant up to 900 mg/dL Intrapalid®
Hemoglobin:	insignificant up to 600 mg/dL
Non Conj. Bilirubin:	insignificant up to 25 mg/dL
Conj. Bilirubin:	insignificant up to 25 mg/dL
RF:	insignificant up to 1000 IU/mL

Cross-reactivity towards fibrinogen is negligible for fibrinogen concentration up to 600 mg/dl

4. Precision: 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).

Intra-Assay

N=20	Mean (µg FEU/mL)	SD (µg FEU/mL)	CV%
Control serum 1	2.15	0.1	4.65
Control serum 2	6.31	0.2	3.16

Inter-Assay

N=20	Mean (µg FEU/mL)	SD (µg FEU/mL)	CV%
Control serum 1	2.16	0.14	6.48
Control serum 2	6.38	0.24	3.76

5. 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

LIMITATIONS 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 > 20.0 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.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTES :

1) Applications and Programming should be derived for various analyzers whichever is best suited as per the mathematical models fed in their Software.
2) Very deep attention must be given to interfering substances. Certain drugs and other febrile substances are able to influence levels of D Dimer which lead to false non specific reactions
3) The clinical diagnosis cannot be done correctly using the result of only one test, but have to be done integrating critically the results of different laboratory tests and clinical data.
4) 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
5) The calibration curve has to be always repeated at each change of the lot of the Reagent and/or calibrator.

REFERENCE

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

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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GMP 5th Schedule MDR 2017

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