PATHOZYME DIAGNOSTICS

D DIMER

(TURBIDIMETRY METHOD)

CAT NO.: DDM

Reagent kit for quantitative estimation of D Dimer in Serum or Citrated Plasma.

DIAGNOSTIC SIGNIFICANCE:

D-Dimer is a degradation product of fibrin. After the initial formation of the fibrin clot, Factor XIII links two D-domains and generates a solid fibrin clot. Plasmin degrades the crosslinked fibrin and these degradation products contain the D-Dimer domain. The D-Dimer is a measure of fibrinolytic activity of plasmin in the bloodstream. Its determination is becoming a tool for diagnosing thrombosis and monitoring thrombolytic therapy for the Disseminated Intravascular Coagulation (DIC). Increased levels of D-Dimer are found in clinical conditions of Venous Thromboembolism (VTE) such as Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT) and also in DIC.

PRINCIPLE:

The D-Dimer contained in the sample reacts with the latex sensitized with anti-human D-Dimer monoclonal antibody (mouse) and forms aggregates, which are determined optically for calculation of D-Dimer concentration.

SPECIMEN COLLECTION:

For specimen collection and preparation, collect it in citrate.
Serum/Plasma, separated by centrifugation as soon as possible after collection, may be stored for up to 1 week at 4°C, or 4 months at –20°C. Samples may be frozen and thawed one time with no detrimental effect.
Serum tube dedicated to FDP containing thrombin and aprotinin may have stability similar to that of citrated plasma.

KIT PRESENTATION:

Pack Size	1 X 16 ml
R1 - D Dimer (Buffer Reagent)	1 X 12 ml
R2 - D Dimer (Latex Reagent)	1 X 04 ml
D DIMER Calibrator	1 Vial

WORKING REAGENT PREPARATION:

R1 – D Dimer (Buffer Reagent) & R2 – D Dimer (Latex Reagent) are Ready To Use.
D-Dimer Calibrator: Reconstitute the calibrator with Distilled water / Deionized Water with the volume specified on Calibrator Vial.

REAGENT STORAGE AND STABILITY:

All reagents are stable at 2-8^{0}C until the expiry date stated on the label.
On-board, in use and refrigerated on the analyzer: 4 weeks.
Stability of Calibrator: Reconstituted calibrator is stable for 1 month if stored at -20°C and 7 days stable if stored at 2 – 8°C.

ASSAY PARAMETERS:

Reaction	**: Fix Time**	**Sample Volume**	**: 20 µl**
Wavelength	**: 578 nm**	**R1 + R2 Volume**	**: 300 µl + 100 µl**
Flow Cell Temp.	**: 37^{0}C**	**Calibrator Conc.**	**: As On Vial**
Initial Delay	**: 10 Sec**	**Reaction Slope**	**: Increasing**
Interval Time	**: 240 Sec**	**Zero Setting**	**: Dist. Water**
Read Time	**: 240 Sec**	**Linearity**	**: 30,000**
No. of Reading	**: 01**	**Unit**	**: ng/ml**

PROCEDURE:

Pipette into TT	Calibrator	Test
R1 - D Dimer (Buffer Reagent)	300 µl	300 µl
D Dimer Calibrator	20 µl	--
Sample (Test)	--	20 µl
R2 - D Dimer (Latex Reagent)	100 µl	100 µl

Mix & aspirate immediately and read difference in absorbance between 10 seconds (AT_1) and 240 seconds (AT_2) for Calibrator and Test at 578 nm.

CALCULATION:

$$\text{D DIMER (ng/ml)} = \frac{\Delta\text{Abs of Test X Calibrator Concentration}}{\Delta\text{Abs of Calibrator}}$$

Where $\Delta Abs = (AT_1) - (AT_2)$

Unit Conversion: 1 ng/ml = 1/1000 µg/ml
(Divide the observed value with 1000 to convert into µg/ml)

NORMAL VALUES:

< 500 ng/ml

The reference value range will possibly be different depending on various conditions of individual laboratories, so set the reference value range suitable to each laboratory.
1) Some samples may consist of substances which cause non-specific reaction or interfering reaction. When assay values and results are questionable, validate it through re-testing by dilution or assaying by other test kit.
2) Note that Prozone (PZ) remark may be indicated for samples with target substance of beyond calibration range. However, samples with extremely high-level substance may show low values.
3) Note that samples with high-level (beyond calibration range) substance may affect the assay results of succeeding samples by carryover.
4) Note that serum separating agents in blood collection tubes may affect the assay result.
5) The responsible physician should make a clinical diagnosis comprehensively based on the assay results, clinical symptoms, and other results.

INTERFERENCES:

Bilirubin (18 mg/dL), Hemolysis (500 mg/dl) and Lipemia (20 g/L) and Rheumatoid Factor (800 IU/ml) do not interfere.

LINEARITY:

This method is linear up to **30,000 ng/ml**.

REFERENCES:

1. Sowako Kazuko, Fujimaki Michio. Fibrin/Fibrin Degradation Products (FDP) [J]. Japanese Clinical Medicine, 1989, (598): 892.
2. Rylatt DB. et al. An immunoassay for human D dimmer using monoclonal antibodies [J]. Thromb. Res, 1983, 31(6): 767-778.
3. Sowako Hezi, Fujimaki Michio. Determination of stabilized fibrin degradation products[J]. Journal of Thrombosis and Hemostasis, 1991, 2(1):

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Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

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