Block 5, Street 9 inside The Ismailia free zone. Ismailia- Egypt
Post Code-41511
Tel.-Fax: +202 21813500/ +202 21813600
Mob.: +2 01211550941/ +2 01119225860
E-mail: sales@arenabioscientific.com
Website: www.arenabioscien.com

# D-DIMER (TURBI-LATEX)

Diagnostic reagent set for the in-vitro quantitative determination of circulating derivatives of cross-linked fibrin degradative products (XL-FDP) in human plasma.

| | |
|---|---|
| REF: BS.1/DIM1.015.0015 | REF: BS.1/DIM1.020.0020 |
| REF: BS.1/DIM1.050.0050 | REF: BS.1/DIM1.100.0100 |

## CLINICAL SIGNIFICANCE

D-Dimer (DD) is the smallest fibrinolysis-specific degradation product found in the circulation. DD testing is involved in all clinical conditions in which there is hyper fibrinolysis alone or hyper fibrinolysis associated to hypercoagulation, with or without associated vascular thrombosis. For this reason, DD testing is present in several flowcharts to diagnose thrombotic disorders in particular venous thromboembolism (VTE), deep vein thrombosis (DVT), pulmonary embolism (PE), disseminated intravascular coagulation (DIC).

## METHOD PRINCIPLE

Anti-D-dimer antibody labeled solid-phase carrier latex particles. When D-dimer is present in the tested sample, the latex particles will agglutinate and produce turbidity in the liquid phase. The amount of antigen-antibody binding is the same as that of D-dimer in the sample. The content of aggregates is proportional.

## REAGENT COMPOSITION

| Reagents: | Composition | | |
|---|---|---|---|
| **R1:Buffer Reagent** | PBS<br>PEG<br>NaN3 | 0.1<br>4.0<br>1.0 | mol/L<br>%<br>g/L |
| **R2:Latex Reagent** | PBS<br>D-Dimer latex<br>NaN3 | 0.1<br>0.1<br>1.0 | mol/L<br>%<br>g/L |
| **Calibrator** | Lyophilized plasma enriched with D-Dimer.Concentration as stated on the vial label | | |

## PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  ***S56:*** dispose of this material and its container at hazardous or special waste collection point.
  ***S57:*** use appropriate container to avoid environmental contamination.
  ***S61:*** avoid release in environment.

For further information, refer to the D-DIMER reagent material safety data sheet.

## REAGENT PREPARATION, STORAGE AND STABILITY

***BioScien*** D-DIMER reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

D-D IMER Calibrator: Reconstitute with 1 ml distilled water. Mix gently and incubate at room temperature for 10 minutes before use.
Stability: 1 month deep freezed.

***Deterioration***
The ***BioScien*** D-DIMER reagent can be damaged due to microbial or chemical contamination or on exposure to extremetemperatures.

## SPECIMEN COLLECTION AND PRESERVATION

Citrated, platelet-poor plasma is prepared from venous blood collected into 3.2 % trisodium citrate at a ratio of 9 : 1. The citrate concentration must be adjusted in patients with a HCT >55%. Plasma should be separated as soon as possible after the specimen is obtained.
D-dimers are stable for 8 hours in citrated plasma maintained at room temperature, 7days at 2 - 8 ºC or 2 months at at -20 ºC.

## SYSTEM PARAMETERS

| | |
|---|---|
| Wavelength | 630 nm |
| Optical path | 1 cm |
| Reaction time | 10 min |
| Reaction direction | Positive |
| Assay type | Turbidimetric end point |
| Temperature | 37 ˚C |

## EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes

## ASSAY PROCEDURE

| | Blank | Calibrator | Sample |
|---|---|---|---|
| R1: Buffer Reagent | 300 µl | 300 µl | 300 µl |
| Normal Saline | 25 µl | | |
| Calibrator | | 25 µl | |
| Sample | | | 25 µl |
| Mix well and incubate at 37°C for 5 minutes. | | | |
| R2: Latex Reagent | 100 µl | 100 µl | 100 µl |
| Mix well and incubate at 37°C for 5 minutes. Read at 630. | | | |

## CALCULATION

D dimer concentration ( mg/l ) = $\frac{\text{A sample}}{\text{A calibrator}}$ X calibrator value

## QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances. For more information please contact ***BioScien*** technical support.

## PERFORMANCE CHARACTERISTICS

***Precision (reproducibility and repeatability):*** when a control sample is assayed 5 times consecutively, CV is 10% or less.

***Sensitivity:*** when the calibrator containing D-dimer at a concentration of 0 µg/ml and 0.5 µg/ml are assayed 10 times each consecutively, mean ± 2SD of the assayed absorbance of each sample is not overlapped.

***Specificity:*** when assaying control samples of known concentration, the assay values are within ± 15 % of the known concentration.

## LIMITATIONS OF PROCEDURE

1. The results of this test ***should not*** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.

## EXPECTED VALUES

Up to 0.5 mg/l

## REFERENCES


1. Gaffney, P.J. Distinction between Fibrinogen and Fibrin Degradation Products in Plasma. Clin. Chim. Acta. 65 (1): 109-115; 1975.
2. Elms, M.J. et al. Rapid Detection of Cross-Linked Fibrin Degradation Products in Plasma using Monoclonal Antibody-Coated Latex Particles. Am. J. Clin. Pathol. 85 (3): 360-364; 1986.
3. Whitaker, A.N. et al. Measurement of Cross-Linked Fibrin Derivatives in Plasma: an Immunoassay using Monoclonal Antibodies. J. Clin. Pathol. 37 (8): 882-887; 1984.
4. Hunt, F.A. et al. Serum Crosslinked Fibrin (XDP) and Fibrinogen/Fibrin Degradation Products (FDP) in Disorders Associated with Activation of the Coagulation or Fibrinolytic Systems. Br. J. Haematol. 60 (4): 715-722; 1985.


**SYMBOLS IN PRODUCT LABELLING**

| | | | |
|---|---|---|---|
| IVD | For in-vitro diagnostic use | Σ | Number of <n> test in the pack |
| LOT | Batch Code/Lot number | | Caution |
| REF | Catalogue Number | | Do not use if package is damaged |
| | Temperature Limitation | | Consult Instruction for use |
| | Expiration Date | | |
| | Manufactured by | | |

EC REP

**Medical Device Safety Service**
**MDSS GmbH**
Schiffgr aben 41
30175 Hannover, Germany

CE