D-DIMER

LATEX - TURBIDIMETRY

Intended use:
Quantitative Determination of D-Dimer
Only for in vitro use in clinical laboratory

Summary:
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.

Test 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.

Reagent Component

R1 – Buffer Reagent

R2 – Latex coated with anti-human D-dimer monoclonal antibody

Preparation and stability:
Reagent is ready for use.
If stored at 2-8°C and handled properly, component is stable until expiry date

stated on the label.

On-board, in use and refrigerated on the analyser: 4 weeks.

- Store the reagents according to the specified storage method, and do not use a batch passing the expiry date.
- Never freeze latex solution.
- Be sure not to mix reagents of different lots. Use the same lot of reagents when creating a calibration curve and assaying a sample.
- Avoid mixing the remaining reagents into new one, as this may cause contamination or deterioration of the reagents.
- Upon completion of assay, the reagents should be capped and then stored according to the specified storage method.
- After removing from a refrigerator, Latex reagents should be fully mixed prior to use.
- Do not allow dust or foreign substances to get mixed into reagents or cuvettes.

Specimen:
For specimen collection and preparation, collect it in citrate.
The plasma, separated by centrifugation as soon as possible after collection, may be stored for up to 1 week at 4°C, or 2 months at –80°C.
Samples may be frozen and thawed three times with no detrimental effect.
Serum separated by centrifugation as soon as possible after collection with collecting tube dedicated to FDP containing thrombin and aprotinin may have stability similar to that of citrated plasma.

Measuring range:
From 0.5 to 30 µg/ml

Limitation interference:
Bilirubin: No significant interference up to 18 mg/dl.
Lipemia (Intralipid): No significant interference up to 2000 mg/dl.
Hemolysis: No significant interference up to 500 mg/dl.

Testing procedure:
Applications for automated systems are available on request.
Materials required but not supplied:
D-Dimer Controls
D-Dimer Calibrator
General Laboratory Equipment

Manual procedure	
Wavelength:	700 nm.
Temperature:	+37°C
Cuvette:	1 cm light path
Zero adjustment:	Reagent blank/each series needs one reagent
	Sample / Calibrator
Sample / Calibrator	4 µl
R1	180 µl
Warm the mixture to 37 °C for 5 minutes.	
R2	60 µl
Proceed similarly with the calibrator, and compare the absorbance values for calculation of the D-dimer concentration in the sample.	

Quality Control

All clinical laboratories should establish an internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the laboratory's QC program.

Reference value:
Normal values: < 0.5 µg/ml
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range.

Analytical sensitivity (lower detection limit):
When the calibrator containing D-dimer at a concentration of 0 ug/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.

Reproducibility:
When a control sample is assayed 5 times consecutively, CV is 10% or less.

Notes:
For in vitro diagnostic use.
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.

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Literature:

1. Wells, P.S., Anderson, D.R., Rodger, M., et al. Evaluation of D-dimer in the diagnosis of suspected deep-vein thrombosis. New England Journal of Medicine 349: 1227-1235, 2003.

2. CLSI Document H21-A5: Collection, Transport, and processing of Blood Specimens for Testing Plasma-based Coagulation assays; Approved Guideline FIth Edition.

3. Gaffney PJ, et al. Monoclonal antibodies to crosslinked fibrin degradation products. British J. of Haematology. 1988;68:83-90.

4. Wells, P.S., Anderson, D.R., Rodger, M., et al. Excluding pulmonary embolism at the bedside without diagnostic imaging: management of patients with suspected pulmonary embolism presenting to ED by using a simple clinical model and D-dimer. Annals of Internal Medicine 135: 98-107, 2001.

Manufacturer

Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti
Adress : İkitelli O.S.B Mutsan San.Sit. M4 Blok No:17-19 Başakşehir/İSTANBUL
Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50
Web :www.diaclinica.com

SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions