D-Dimer
Turbilatex

INTENDED USE

Vitro D-dimer is intended for the quantitative detection of D-dimer in human plasma.

METHOD

Highly sensitive immunoturbidimetric assay.

CLINICAL SIGNIFICANCE

D-dimer is a type of fibrin degradation products (FDP) composed of stable fibrin degraded by plasmin. Stable fibrin is crosslinked by the action of coagulation factor XIII in the blood coagulation and fibrinolysis system. Various types of D-dimer molecules exist in the blood, including YY/DXD, YD/DY, DD/E and DD complex. Increasing in the level of D-dimer in the blood proves thrombus production, as well as the efficacy of fibrinolysis. Increasing in the level of D-dimer is also known to be associated with various diseases, including malignant tumors, obstetric diseases, vascular lesions, and DIC (disseminated intravascular coagulation syndrome). A negative D-Dimer test result has a high negative predictive value for patient with a suspected thrombotic disorder. This test should be used with other clinical and diagnostic information in order to diagnose and manage patients.

ASSAY PRINCIPLE

D-dimer in the sample reacts with the anti-human D-dimer mouse monoclonal antibody-coated latex, resulting in agglutination and elevation of turbidity. The resulting turbidity changes are then measured using a spectrophotometer, allowing quantitative measurement of the D-dimer concentration in the sample using multi-point calibration.

EXPECTED VALUES

Normal Range 1.0 µg/mL or lower There may be non-specific reaction or interfering reactions. When a plasma sample is inappropriately collected, false values which are higher than the actual values may be obtained. If measurement results appear unreliable, repeat the measurement (if necessary after dilution) or try another analytical measurement.

SPECIMEN

Mix 9 vol. of freshly venous blood in 1 vol. of trisodium citrate. Sample collection must be in conformity with the recommendations for haemostasis tests.
Citrated plasma is stable 4 days at 2-8°C, 1 month at -20°C. Do not freeze more than once! Thaw frozen samples at 37°C and then allow at room temperature before use. Thawed samples must be assayed within 2 hours.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.5. Preservative.
Latex (R2)	Anti-human D-dimer mouse monoclonal antibody coated latex (2.8 mg/mL). Preservative.
D-Dimer Calibrator	Optional. D-Dimer concentration is stated on the vial label.

Preparation of Calibrator

Reconstitute the calibrator with the volume stated on calibrator label. Mix gently and incubate at room temperature for about 20 minutes before testing. Do not shake.

Calibration curve (6 points): Prepare two-fold serial dilutions of the Calibrator with NaCl 9 g/L. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the D-Dimer concentration of each point of the curve.

Calibration curve

Prepare the following dilutions of the D-dimer Calibrator using NaCl 9 g/L. To obtain the concentration of each dilution, multiply using the dilution factor shown in the next table:

	1:1	1:2	1:4	1:8	1:16
NaCl 8 g/l (µl)	--	200	200	200	200
D-Dimer CAL (µl)	400	200	200	200	200
	Mix and transfer				
Factor	1.0	0.5	0.25	0.125	0.0625

Calibrator: 0 µg/l: Perpare a tube with NaCl 9 g/l

The sensitivity of the assay and the target value of the calibrator have been standardized against the 3rd International Standard of Ferritin (94/572, 2008 WHO).
Re-calibrate when control results are out of specified values; when using a different lot of reagent and when the instrument is adjusted.

Storage & Stability

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

D-Dimer Calibrator: Stable for 15 days at 2-8°C or 2 months at –20°C. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

PROCEDURE

Wavelength: 540 nm (530-550)
Temperature: 37°C
Cuvette light path: 1 cm
Zero adjustment against distilled water.

Pipette into a cuvette

Diluent R1	180 µl
Latex R2	60 µl
Calibrator or sample	4 µl

Mix and read the absorbance immediately (A1) and after 5 minutes (A2) of the sample addition.

CALCULATION

Calculate the absorbance difference (A2-A1) of each point of the calibration curve and plot the values obtained against the D-dimer concentration of each calibrator dilution. D-dimer concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve.

QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established D-Dimer values may be routinely used for quality control.
Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

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EC REP **Medical Device Safety Services**
MDSS GmbH, Burckhardtstr. 1
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PERFORMANCE CHARACTERISTICS

Measurement range:

Up to 30 µg/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit and measurement range depends on the sample to reagent / ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Limit detection: Values less than 0,5 µg/mL give non-reproducible results.

Sensitivity: Δ 0.01-0.05/min per 10 µg/mL of D-Dimer.

Accuracy: Results obtained using this reagents (y) were compared to those obtained using a Latex turbidimetric method (x). 120 samples were assayed by both methods. The correlation coefficient (r) was 0.99 and the regression line equation y = 0.97x + 0.81.

The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

Bilirubin (21 mg/dL), hemoglobin (5 g/L) and rheumatoid factor (500 UI/mL), do not interfere. Lipids (=2,5 g/L) do interfere.
Other substances may interfere[5]

NOTES

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However, handle the material as if infectious.
3. Reagent contains 0.1% Sodium azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures.
5. Shake the Vitro D-dimer latex reagent well before use to disperse the latex particles uniformly and improve test readability.

BIBLIOGRAPHY

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SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
70501	50 TEST

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ISO 13485:2016 CE

EC REP **Medical Device Safety Services**
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