SPECTRUM

The Creative Approach to Bioscience

D-Dimer Turbi Latex

REF: 585 001	50 Test	REF: 585 002	100 Test
R1 Diluent	1 X 20 ml	R1 Diluent	2 X 20 ml
R2 Latex	1 X 5 ml	R2 Latex	1 X 10 ml
Calibrator	1 X 1 ml	Calibrator	1 X 1 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

Intended Use

In vitro diagnostic reagents for the quantitative determination of D-Dimer in human Plasma by means of particle-enhanced turbidimetric immunoassay.

Background

The D-dimer assay is specific for fibrin derivatives. In this assay, the presence of cross linked D-dimer domain is diagnostic for lysis of a fibrin clot, and confirm that thrombin was formed and factor XIII was activated with reactive fibrinolysis. Since fibrinogen derivatives do not contain the cross-linked D-dimer domain, they are not recognized by the D-dimer assay, even when presence in high concentration. In other words, Fibrin derivatives in plasma containing D-Dimer (XDP) are specific markers for fibrinolysis, as opposed to fibrinogenolysis. D-dimers are detected by immunoassays using monoclonal antibodies specific for the cross-linked D-dimer domain in fibrinogen.

Test Principle

This D-dimer test is based upon reinforced immunoturbidimetry. Monoclonal anti D-dimer antibodies in the reagent react with the D-dimer antigen in the sample, forming antigen/antibody complexes that increase the work solution turbidity.

Reagents

R1 Reagent1
Tris-HCl 125 mM

R2 Latex reagent
Latex particles coated with mouse anti-human D-Dimer monoclonal antibodies.
Preservatives.

Calibrator
Human serum.D-Dimer concentration is stated on the vial label.

All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

Precautions and Warnings

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

Disposal of all waste material should be in accordance with local guidelines.

As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC). Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Do not freeze reagents.The D-Dimer latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarted.

The reagent1 should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

Specimen Collection and Preparation

Citrated, platelet-poor plasma is used for the d-dimer assay. 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.

Reagent Preparation and Stability

Spectrum D-dimer reagents (**R1** & **R2**) are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 ºC.

D-dimer Calibrator: Reconstitute with 1 ml distelled water. mix gently and incubate at room temperature for 10 minutes before use.

Stability: 1 month at at -20 ºC.

Calibration curve

Cal. 5: Calibrator
Cal. 4: 250 µl Cal. 5 + 250 µl saline
Cal. 3: 250 µl Cal. 4 + 250 µl saline
Cal. 2: 250 µl Cal. 3 + 250 µl saline
Cal. 1: 250 µl saline

Concentration (for example: the undiluted C = 5.7 µg FEU/ml)	Cal. 1	Cal. 2	Cal. 3	Cal. 4	Cal. 5
	0	0.71	1.42	2.85	5.7

Quality Control

Control sera are recommended to monitor the perfomance 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.

Materials required but not provided

D-Dimer control (Ref : 405 001)

Procedure

1 - Bring the reagents and the photometer to 37ºC

2 - Assay conditions:
Wavelength 630 nm (600 -630 nm)
Temperature 37ºC
Cuvette 1cm light path

3 - Adjust the instrument to zero with distilled water .
4 - Pipette into a cuvette :

Reagent1 (R1)	400 µl
Latex (R2)	100 µl
Calibrator or Sample	20 µl

5.Mix and read absorbance immediately (A_1) and after 2 min (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 calibrator dilution. D -dimer concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve.

Sensitivity

Up to 0.08 µg FEU/ml .

Linearity

Up to 7.5 µg FEU/ml .

specimens showing higher concentration should be diluted 1+2 using physiological saline and repeat the assay (result×3).

Expected Values

The determination of reference ranges for D-dimer concentrations of clinically healthy individuals is very difficult.

Suggested value in plasma with this method < 0.5 µ**g FEU/ml**.

These data are to be interpreted as a guide. Each laboratory should establish its own reference intervals.

References

Bick R.L. et al. thromb res 1992;65:785-90

Gaffney PJ. Fibrinolysis supplement 2.1993;7:2-8

Bover, P. et al. int J Epidemiol 1994;23:2027

Janssen M.G. et al. Thromb Haemost 1997;77:262-6

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
585 001	50 test
585 002	100 test

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CE

ISO 13485