Spectrum For Diagnostic Industries

D-Dimer Turbi Latex

IVD

REF.	Pack size
428 01 020	50 test R1 Buffer 1 X 20 ml R2 Latex 1 X 5 ml Calibrator 1 vial

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 present 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.

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 working 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 are stable to the expiration date stated on the vial label when capped and stored at (2 - 8 ºC). Do not freeze reagents.Open vial is stable for 3 months when stored at (2 - 8 ºC).

Deterioration

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 discarded.

The ***Reagent1*** should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

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 -20 ºC.

Reagent Preparation and Stability

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 ^{o}C.

D-dimer Calibrator: Reconstitute with distilled water; exact volume is stated on vial label . Mix gently and incubate at room temperature for 10 minutes before use.

Stability: 1 month at -20 ºC.

Calibration curve

Cal. 6: Calibrator
Cal. 5: 200 µl Cal. 6 + 200 µl saline
Cal. 4: 200 µl Cal. 5 + 200 µl saline
Cal. 3: 200 µl Cal. 4 + 200 µl saline
Cal. 2: 200 µl Cal. 3 + 200 µl saline
Cal. 1: 200 µl saline

Concentration (for example: the undiluted C = 5.7 µg /ml)	Cal. 1	Cal. 2	Cal. 3	Cal. 4	Cal. 5	Cal.6
	0	0.37	0.74	1.48	2.95	5.9

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

Procedure

1 - Bring the reagents and the photometer to 37ºC

2 - Assay conditions:

Wavelength	578 nm
Temperature	37ºC
Cuvette	1cm light path
zero adjustment	distilled water

4 - Pipette into a cuvette :

Reagent 1 (R1)	400 µl
Latex (R2)	100 µl
Calibrator or Sample	40 µl

4.Mix and read absorbance immediately (A_1). After 3 minutes of the sample addition, read (A2).

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

0.08 µg /ml

Linearity

7.5 µg /ml .

specimens showing higher concentration should be diluted 1+2 using physiological saline and the assay is repeated.Results are multiplied by 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** µg /ml .

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

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct 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. refer to special instructions/safety data sheets.

References

1- Bick R.L. et al. thromb res 1992;65:785-90
2- Gaffney PJ. Fibrinolysis supplement 2.1993;7:2-8
3- Bover, P. et al. int J Epidemiol 1994;23:2027
4- Janssen M.G. et al. Thromb Haemost 1997;77:262-6

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