DIAGON
Solutions beyond imagination

INSTRUCTIONS FOR USE

Dia-D-DIMER

Diagnostic reagent for quantitative in vitro determination of D-dimer in plasma on photometric systems

Cat. No.: 32075 Dia-D-DIMER
3 x 6.5 ml R1 buffer
3 x 2.5 ml R2 latex reagent;
Cat. No.: 32120 Dia-D-DIMER
3 x 12.0 ml R1 buffer
3 x 4.0 ml R2 latex reagent;

Summary[1,2,3]

During plasma coagulation soluble fibrin is generated by the influence of thrombin on fibrinogen. The soluble fibrin is cross-linked to the vessel walls by factor XIIIa. When splitting this cross-linked fibrin, characteristic products called D-dimers are released.Increased D-dimer concentrations are found in thrombotic diseases and microthrombotic events (e.g. in case of disseminated intravascular coagulation, DIC). D-dimer determination is mainly used to rule out deep vein thrombosis of the leg and pulmonary embolism.

Method

Particle enhanced immunoturbidimetric test.

Principle

Fixed time determination of the D-dimer concentration by photometric measurement of antigen-antibody-reaction between antibodies against D-dimer bound to particles and D-dimer present in the sample.

Reagents

Components and Concentrations

Rl: Buffer
R2: Particle suspension
Latex particle coated with monoclonal anti-human D-dimer antibody (mouse)

Storing Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 - 8 °C. Opened bottles of reagents are stable for 14 days, when stored on board at 15-19 °C, contamination has to be avoided after opening the vials. Do not freeze the reagents!

Warnings and Precautions

The reagents contain sodium azide (<0.1%) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
Take the necessary precautions for the use of laboratory reagents.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The reagent R2 has to be stirred before the first use avoiding formation of foam.

Materials required but not provided

General laboratory equipment

Specimen

Citrated plasma

Stability:	8 hours at 20-25 °C
	4 days at 4-8 °C
	6 months at -20 °C

Freeze only once! Discard contaminated specimens!

Assay Procedure for Analyzers

Application for Diagon Coag XL and Coag 4D coagulometers.
Wavelength 570 nm; Temperature 37 °C.

Sample	20 µl
Reagent 1 (R1)	115 µl
Incubate for 120 sec., then add:	
Reagent 2 (R2)	45 µl
Mix, (COAG XL: 20 cycles) read absorbance (A1) at 20 sec., then read absorbance (A2) at 150 sec. again	

Calculation
The D-dimer concentration of a given patient sample is calculated using instrument and batch dependent master curve. Find your muster curve data on the insert sheet of your Dia-D-DIMER reagent.

Quality Control
At least two levels of Diagon D-Dimer control should be assayed a minimum of once a day. In addition, these controls should be tested with each new batch of reagent and after specific maintenance or troubleshooting steps described in the appropriate User's Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.
Cat. No.: 93010 Dia-CONT Ddi I-II 2x5x1.0ml
Cat. No.: 93020 Dia-CONT Ddi I-II 2x10x1.0ml

Performance Characteristics [4,5]
Measuring Range
The test has been developed to determine D-dimer concentrations within a measuring range of 0.22-5.0 µg FEU/ml. If values exceed this range, samples should not be diluted but released with > 5.0 µg FEU/ml.

Specificity/Interferences
Due to its antibodies, Dia-D-Dimer is a specific immunoassay for human D-dimer. No interference was observed by rheumatoid factor up to 50 IU/ml. The antibody does not cross-react with fibrinogen and E fragment. A low cross-reactivity is observed with the D fragment and the high molecular weight fragments, fibrin X and Y.

Sensitivity/Limit of Detection
The lower limit of detection is 0.22 µg FEU/ml.

Within-run Reproducibility
Coefficient of variation ≤ 7.5%

Method comparison
A comparison between Dia-D-Dimer (y) and an immunoturbidimetric test (x) with 67 samples gave the following results:
y= 1.138 x - 0.330 r = 0.955

Reference Range
Cut-off value: 0.5 ug FEU/ml
Each laboratory should check if the cut-off value is transferable to its own patient population and instruments and determine its own cut-off value if necessary.

Literature
1. Wells, P.S., Anderson, D.R., Rodger, M., et al. Evaluation of D-dimer in the diagnosis of suspected deep-vein thrombosis N. Engl. J. Med. 2003; 349(13):1227-1235
2. Dempfle, C.E Use of D-dimer assays in the diagnosis of venous thrombosis. SeminThrombHemost. 2000;26(6):631-641
3. Pinczés, I. A D-dimer-szintmeghatározásánakjelentősége. LAM 2009;19(12):761-767
4. CLSI. Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline. CLSI Document H59-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.
5. Dempfle, C.E., Validation, calibration, and specificity of quantitative D-dimer assays. SeminVasc Med. 2005; 5:315-320

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Symbols			
IVD	In vitro diagnostics devices		Check in user manual
	Biohazard		Temperature range
	Manufacturer		Expiry date
LOT	LOT number	CE	CE conformity sign
REF	Catalogue number		