

DIA-D-DIMER

QUANTITATIVE D-DIMER TEST



Cat. No.: 32075 **3 x 6,5 mL Buffer**
3 x 2,5 mL Latex
Cat. No.: 32120 **3 x 12,0 mL Buffer**
3 x 4,0 mL Latex

- Do not use the reagent beyond the expiration date printed on the label!

PRODUCT NAME

Dia-D-DIMER quantitative D-dimer test.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-D-DIMER is a diagnostic test used for quantitative determination of D-dimer in plasma on photometric systems.

PREPARATION

Dia-D-DIMER reagents are ready to use. Swirl gently the vial of Latex reagent (R2) with horizontal movements more times (5-10) before using it, but do not shake. Wait until the reagents reach the working temperature!

SUMMARY AND PRINCIPLE

Dia-D-DIMER is a particle enhanced immunoturbidimetric test.

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 micro thrombotic events (e.g. in case of disseminated intravascular coagulation, DIC). D-dimer determination is mainly used to rule out Deep Vein Thrombosis (DVT) of the leg and Pulmonary Embolism (PE).

SPECIMENS

Dia-D-DIMER test requires freshly decalcified plasma. To obtain it, mix nine parts of freshly drawn venous blood with one part trisodium citrate (3,2%; 109mmol/L). The use of higher concentration of trisodium citrate (3,8%; 129mmol/L) is not recommended. Mix the blood carefully and centrifuge plasma before testing. The measurement must be performed within 24 hours. The plasma samples may be stored for up to 24 months at -24°C to -74°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5; H59.

PRINCIPLE

Dia-D-DIMER test is based on 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.

TEST PROCEDURE

For Dia-D-DIMER, two steps immunoturbidimetric test's application on DIAGON semi-automated coagulation analysers (Coag 4D, Coag 2D) follow the protocol detailed below. The duplicated measurement is recommended.

ACTIVE INGREDIENTS

Dia-D-DIMER Buffer (R1) is buffer.
 Dia-D-DIMER Latex (R2) is a latex particle coated with monoclonal anti-human D-dimer antibody. It contains preservative also.

1.	Reagents warming up to 20-25°C	~15min
2.	Adding sample into cuvette	10µl
3.	Adding Buffer (R1) into cuvette	130µl
4.	Sample and Buffer incubation	2min
5.	Adding Latex (R2) into cuvette Mix it three times!	30µl
6.	First reading time at 570nm	20sec
7.	Second reading time at 570nm	180sec

PRECAUTIONS

- Person installing the Dia-D-DIMER reagents must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-D-DIMER reagents, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Reagents coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the reagent otherwise erroneous results may occur!
- All reagents, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.

Normal and pathological controls are recommended for verified measuring. Each laboratory should establish its own quality control program. In case of determination by any other coagulometer, for instance DIAGON automated coagulation analysers (Coag XL, Coag L, Coag M) please follow the instructions of the manual.

STORAGE AND STABILITY

Dia-D-DIMER reagents in intact vial are stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in below table:

T (°C)	15-19	2-8
Day	14	14

Do not freeze it!

EXPECTED RESULTS

Dia-D-DIMER test results can be reported in fibrinogen equivalent units (FEU), lot specific value sheet in the box will help in the calculation. Cut-off value is 0,5 µg FEU/mL, but every 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.

LIMITATIONS

The result of D-dimer test with Dia-D-DIMER reagents may be influenced by drugs and other pre-analytical interfering agents. The potential limits of these parameters were tested on DIAGON analysers (Coag Line) with the following result:

Rheumatoid factor	Hemoglobin	Triglyceride	Bilirubin
90 IU/mL	9,6 g/L	6,14 mmol/L	811 µmol/L

Due to its antibodies, Dia-D-DIMER is a specific immunoassay for human D-dimer.

PERFORMANCE CHARACTERISTICS

• Limit of Detection (LoD):

The LoD of Dia-D-DIMER test is 0,22 µg FEU/mL tested on DIAGON analysers.

• Measuring Range:

The test has been developed to determine D-dimer concentrations within a measuring range of 0,22-5,00 µg FEU/mL without sample dilution. If values exceed this range, samples should be diluted with dilution buffer.

• High dose Hook Effect:

No high dose Hook effect was observed up to concentration of 25 µg FEU/mL.

• Negative Predictive Value (NPV):

The diagnostic utility of Dia-D-DIMER is validated by independent institutes to meet specific performance characteristic values required by CLSI in a multi-center study:

	NPV	Sensitivity	Sample
Coag L	96%	97%	135
Coag XL	96%	96%	115

• Precision:

The precision of Dia-D-DIMER test on automated coagulometers gives the following results:

Sample	Intra-Assay		Inter-Assay	
	1	2	3	4
n	20	20	25	25
Mean (µg FEU/mL)	0,446	1,852	0,487	1,921
CV (%)	2,713	2,469	7,481	2,437

MATERIALS REQUIRED BUT NOT PROVIDED
















- Different levels of control for quality control (Dia-CONT Ddi I-II; Cat. No.: 93020, 93010).
- Dilution buffer (Dia-IMIDAZOL; Cat. No.: 21180).
- Optical analyser for measuring, DIAGON analysers (Coag Line) are recommended.

BIBLIOGRAPHY

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2. CLSI. Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline. CLSI Document: H59-A; 2011.
3. Wells PS et al: Evaluation of D-dimer in the diagnosis of suspected deep-vein thrombosis. N Engl J Med; 349(13): 1227-1235; 2003.
4. Dempfle CE: Use of D-dimer assays in the diagnosis of venous thrombosis. Semin Thromb Hemost; 26(6): 631-641; 2000.
5. Pinczés I: A D-dimer-szint meghatározásának jelentősége. LAM; 19(12): 761-767; 2009.
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SYMBOLS			
	Manufacturer		Use-by date
	Batch code		Catalogue number
	Do not use if package is damaged		Fragile, handle with care
	Keep dry		Temperature limit
	Biological risks		Consult instruction for use
	Caution		In vitro diagnostic medical device
	Contains sufficient for <n> tests		This side up
	CE mark		