D-Dimer Assay Kit (D-D)

Method: Latex Enhanced IT

INTENDED USE

For the *in vitro* quantitative determination of D-Dimer in serum or plasma.

CLINICAL SIGNIFICANCE

D-Dimer containing moieties are formed by plasmin degradation of factor XIIIa cross linked fibrin. Elevated levels of D-Dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC). D-Dimer levels rise during pregnancy and high levels are associated with complications.

ASSAY PRINCIPLE

D-Dimer in serum or plasma reacts with antibody specific for human D-Dimer, which is coated with latex partical.The formation of antibody-antigen complex results in a increase of absorbance at 630nm.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris buffer	100mmol/L
Reagent 2 (R2)	
Latex coated with anti D-dimer monoclonal antibody	0.15%

SAMPLE COLLECTION AND PREPARATION

Fresh serum or sodium citrate anticoagulant plasma, pay attention to avoid hemolysis.

Serum samples are stable for 7 days at 2-8℃, or 4 weeks at -20℃ (A single freeze-thaw cycle does not affect the assay response.) Serum separated by centrifugation as soon as possible after collection with collecting tube dedicated to FDP containing thrombin and aprotinin may have stability similar to that of citrated plasma.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8℃.

Once opened the reagent is stable for 1 month on-board the analyzer at 2-8℃, and should be careful to avoid contamination.

ASSAY PROCEDURE

Method : Kinetic
Wave length : 630 nm
Delay time : 30 sec
Read time : 270 sec
Method of calibration : Multi standard non-linear
Number of calibrator : 5 calibrator

Test Procedure

Add the sample and reagents into colorimetric cup	
Sample（S）	5L
Reagent（R1）	180L
Mix and then incubate for 300 seconds at 37℃	
Reagent（R2）	60L
Mix and incubate for 30 seconds at37℃; Measure the absorbance continuously in 270 seconds; Calculate（△A/min).	

CALIBRATION

BIOMED D-Dimer calibrator

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of D-Dimer in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

Using BIOMED D-Dimer control as daily quality control which can be purchased separately. Control values should fall within a specific target range. If these values fall outside the range, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL RANGES

Serum/Plasma: < 1.0 µg/mL

It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Bilirubin	up to 20 mg/dL
Triglycerides	up to 2000 mg/dL
Hemoglobin	up to 500 mg/dL

SENSITIVITY

The LOD of BIOMED D-D is 0.21 ug/ml.

LINEARITY

The BIOMED D-Dimer linearity is up to 30 µg/mL..

PRECISION

Repeatability		
N=20	Level1	Level 2
Mean	1.08	13.68
SD	0.06	0.1
CV%	5.2	0.7
Total precision		
N=20	Level1	Level 2
S_T^2	0.00	0.10
S_T	0.06	0.31
CV%$_T$	5.10	2.28

BATCH DIFFERENCE

Three batches of kit samples were randomly selected for (1± 0.5) µg/mL, and the relative (R) of the results should not be more than 8.6%. In the sample of (15±5) µg/mL, the relative (R) of the results should not be more than 0.4%.

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

$y = 0.7988x + 0.3035$, $R^2 = 0.972$

120 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains preservatives. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Preservatives reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

References

1. Shisou, K, Fujimaki, M: Fibrin/Fibrinogen degradation products (FDP) , Japanese Society of Laboratory Medicine (598): 892, 1989
2. Rylatt D.B.,et al: An immunoassay for human D dimer using monoclonal antibodies. Thromb. Res., 31(6):767,1983.
3. Shisou, K, Fujimaki, M: Assay of Stabilized FDP, Japan Society on Thrombosis and Homeostasis, 2(1): 82, 1991

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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