D-Dimer

Diagnostic reagent for determination of D-Dimer concentration.

Liquid. Dual Reagents. Store at +2°C/+ 8°C. For in Vitro Diagnostic Use. Do not freeze.

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
8A11D	240 mL	L2164	80 mL	M4D162	200 mL	ZA108	60 mL
AT2297	125,2 mL	LB163	80 mL	RC2604	58,3 mL	ZA17	100 mL
BB095	80 mL	LM245	80 mL	RD193	180 mL	PL2248	64 mL
DM2162	1020 Tests	M2163	120 mL	TAB230	1302 Tests		
HN154	240 mL	M3161	40 mL	TAB231	600 Tests		

INTENDED USE

Thrombin converts fibrinogen to soluble fibrin by cleaving the fibrinopeptides A and B. The fibrin monomers polymerize spontaneously. Active factor XIII links two D-domains and generates a solid fibrin clot. A new plasmin-resistant antigenic determinant ("D-Dimer") is produced. Fragments containing D-Dimer are accordingly formed during the degradation of a fibrin clot by plasmin.
A large proportion of the fibrin degradation products consist of high molecular weight X-oligomers.
D-Dimer has a strong affinity for these high molecular weight degradation products. Only in vitro or during lysis therapy does complete degradation to D-Dimer molecules take place.
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.

TEST PRINCIPLE

D-Dimer in 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 600nm.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 600 nm
Temperature : 37°C
Sample : Plasma
Linearity : 10 µg FEU/mL

REAGENT COMPOSITION

Reagent 1:
Tris buffer 100 mmol/L
Reagent 2:
Latex coated with anti D-dimer monoclonal antibody: 0.15%

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

REAGENT STABILITY AND STORAGE

Store at +2/+8ºC.
Once opened vials are stable minimum 30 days at +2/+8°C at optimum conditions. On board stability is strongly related to autoanalyzers cooling specification and carry-over values.

SAMPLE

Use plasma samples.
Plasma samples are stable for 4 days at +2/+8°C, or 6 months at -20 °C (A single freeze-thaw cycle does not affect the assay response). Plasma 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.)

REFERENCE INTERVAL (NORMAL VALUES)*

Plasma: < 0.5 µg FEU/mL

UNIT CONVERSIONS

µg FEU/mL= mg FEU/L

µg FEU/mL x 1000 = ng FEU/mL

QUALITY CONTROL AND CALIBRATION

*Calibration Stability: Calibration stability is 30 days.
*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Sensitivity (LoD): 0.08 µg FEU/mL

Low Linearity (LoQ) (Values are based CLSI Standard EP17A2 and LoQ CV% values ≤ 20%): 0.15 µg FEU/mL D- Dimer.
High Linearity: 10 µg FEU/mL for higher values dilute sample 1/3 with 0.9% NaCl and repeat measurement. Linearity may considerably vary depending on the instrument used.

Precision Studies:

Repeatibility (Within run) (Intra-assay)

Mean concentration	CV	n
1.2 µg FEU/mL	3.7%	40
14.2 µg FEU/mL	1.3%	40

Reproducibility (Run to run) (Inter-assay)

Mean concentration	CV	n
1.2 µg FEU/mL	4.5%	40
14.2 µg FEU/mL	3.3%	40

Correlation: Correlation with a reference reagent is:
r=0,988 (Range 0.15 µg FEU/mL to 7.8 µg FEU/mL)
According to Passing-Bablok Fit:
Slope: 0.92
Intercept: 0.02

Interferences:

Bilirubin	up to 60 mg/dL
Triglycerides	up to 700 mg/ dL
Hemoglobin	up to 350 mg/ dL

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at +2/+8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 :When using, do not eat, drink or smoke.
S26 :In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 :After contact with skin wash immediately with plenty of water.
S36/37/39:Wear suitable protective clothing, gloves and eye/face protection.
S45 :In case of accident or if you feel unwell, seek medical advice immediately.
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.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
mL : Mililiter
µg FEU/mL: Microgram Fibrinogen-Equivalent Units / Mililiter
QC : Quality Control

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies products to be used together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration date
	Temperature limitation
	Consult instructions for use
	Caution
	Sufficient for

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