TRUEchemie D-DIMER Test Kit

(Immunoturbidimetric assay)

for the direct quantitative determination of D-DIMER in Human Plasma

INTENDED USE

The TRUEchemie D-Dimer liquid reagent test kit is used for the quantitative determination of D-Dimer in Plasma.

INTRODUCTION

D-Dimer is a protein fragment (small piece) that's made when a blood clot dissolves in your body. Blood clotting is an important process that prevents you from losing too much blood when you are injured. Normally, your body will dissolve the clot once your injury has healed.

PRINCIPLE

The concentration of D-Dimer in human plasma can be directly determined by utilizing the interaction of antigen and antibody. When we add sample to the latex particles coated with rabbit anti-human D-dimer antibody, insoluble complex is formed. The agglutination causes an absorbance change, dependent upon the D-Dimer contents of the patient sample that can be quantified by comparison from a calibrator of known D-Dimer concentration.

PACK SIZE

Kit Size	20 mL	40 mL
Cat No.	ADX 961	ADX962
Kit contents		
1) D-DIMER Reagent-1 (R1)	1 x 15 mL	2 x 15 mL
2) D-DIMER Reagent-2 (R2)	1 x 5 mL	2 x 5 mL
3) D-DIMER Calibrators	3 x 1 mL	3 x 1 mL

REAGENTS COMPOSITION

Reagent 1 (R1) Latex Reagent: Latex 0.13%, Buffer, stabilizer Sodium azide (0.95 g/L)

Reagent 2 (R2) Antibody: Buffer, D-Dimer monoclonal antibody: 0.05 mg/mL, Stabilizers

Calibrator: Human Plasma D-Dimer concentration is stated on the vial label

STORAGE AND STABILITY

All the kit compounds are stable until the expiry date stated on the label. Do not use reagents over the expiration date. Store the Bottle tightly closed, protected from light and prevent contaminations during the use.

Calibrator - 1: Ready to use, Calibrator 2 & 3 : Reconstitute the calibrator with 1ml DI water. Unopened Calibrator is stable untill the expiration date when stored at 2-8 °C.
After reconstitution, calibrator is stable for 3 days at 2-8 °C and 30 days at -20°C.

SAMPLE STORAGE AND STABILITY

1. Human citrated plasma is the recommended specimen type
2. Do not use samples that are obvious microbial contamination, serious hemolysis or icteric.
3. 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).

REAGENT PREPARATION

Ready-to-use reagents.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. Volume of reagents and samples can be adjusted as per the instrument but the ratio of the reagents should remain the same with proportional sample volume.
5. If the reagents became turbid or the absorbance of blank reagent is ≥ 2.000, it means that the reagent is invalid and you should discard it.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 600 nm

TEST PROCEDURE FOR PREPARATION OF CALIBRATION CURVE

Wavelength: 600 nm

Temperature: 37 ºC

Reagent	Cal - 1	Cal - 2	Cal - 3
D-DIMER Reagent (R1) (µl)	300	300	300
D-DIMER Reagent-2 (R2) (µl)	100	100	100
Calibrator (µl)	10	10	10

Blank the Photometer with Distilled water.
Mix well and read absorbance of calibrator against distilled water at 600 nm as follows:

Initial absorbance A_0 – Exactly after 45 sec.
Final absorbance A1 – Exactly after 150 sec. after A_0
Determine Δ A for Calibrator(C)
$\Delta AC = \Delta AC_1 - \Delta AC_0$

TEST PROCEDURE FOR PREPARATION OF SPECIMEN

Wavelength: 600 nm

Temperature: 37 ºC

Prewarm the Reagent to reaction temperature.

Reagent	Sample
D-Dimer Reagent-1 (R1) (µl)	300
D-Dimer Reagent-2 (R2) (µl)	100
Sample (µl)	10

Blank the Photometer with Distilled water.
Mix well and read absorbance of sample against distilled water at 600 nm as follows:

Initial absorbance A_0 – Exactly after 45 sec.
Final absorbance A1 – Exactly after 150 sec. after A_0
Determine Δ A for Sample(S)
$\Delta AS = \Delta AS_1 - \Delta AS_0$

Calculations:

$$\text{Plasma D-Dimer (µg FEU/mL)} = \frac{\Delta AS}{\Delta AC} \times \text{Calibrator concentration (µg FEU/mL)}$$

UNIT CONVERSIONS
µg FEU/mL= mg FEU/L
µg FEU/mL x 1000 = ng FEU/mL

QUALITY CONTROLS

Control Sera are recommended to monitor the performance 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.

NORMAL VALUES

Plasma: < 0.5 µg FEU/mL

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

CALIBRATION

Calibration stability is 30 days. Re-calibration is required when reagent batch is changed.

LIMITATIONS

Sensitivity is 0.08 µg FEU/mL

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.

INTERFERENCES

No interferences noted upto Bilirubin 60 mg/dL Triglycerides 700 mg/dL and Hemoglobin 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.

SYSTEMS PARAMETERS

Mode	:	Fixed Kinetic (Calibration - Multipoint)
Calibrator concentration	:	Stated on vial
Primary Wave length	:	600 nm
Linearity	:	10 µg FEU/mL
Units	:	µg FEU/mL
Flow cell Temp	:	37 °C
Reagent volume	:	300 µl (R1) + 100 µl (R2)
Sample volume	:	10 µl
Lag time	:	45 sec
Read time	:	150 sec
Normal Range	:	< 0.5 µg FEU/mL
Reaction slope	:	Increasing

REFERENCES

1. Trivelli, L.A., Ranney, H.M., and Lai, H.T., New Eng. J. Med. 284, 353 (1971).
2. Gonen, B., and Rubenstein, A.H., Diabetologia 15, 1 (1978).
3. Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., and Gallop, P.M., J. Clin. Endocrinol. Metab. 44, 859 (1977).
4. Bates, H. M., Lab. Mang., Vol 16 (Jan. 1978)

Index of symbols

Consult instructions for use		Catalogue number	REF	Use-by date	
For *in vitro* diagnostic use only	IVD	Batch code	LOT	Do not use if package is damaged	
Temperature limit 2-8 °C	2 °C 8 °C	Keep away from sunlight		Keep dry	
Manufacturer		Date of manufacture			
If device is non-sterile	NON STERILE	Warnings / Precautions	!		

Athenese-Dx Pvt. Ltd.
Module No. 407 & 408, 4th Floor,
TICEL Bio Park II, No. 5, CSIR Road.
Taramani, Chennai-600113, India
Tel: +91-44-22541131
E-mail: info@athenesedx.com
Website: www.athenesedx.com

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