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ACCUTURB-100

D-Dimer -Turbilatex

Latex Turbidimetry

INTENDED USE

For the Quantitative determination of D Dimer in Citrate Plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	CONT
TDR 25T	1 x 7.5 ML
TDR 50T	1 x 15 ML

CLINICAL SIGNIFICANCE

Increase of D-Dimer in blood testifies the blood clot is formed and fiberinolytic activity has functioned. It is known that high value of D-Dimer is indicated in diseases such as malignant tumor, vascular disease.

PRINCIPLE

The D-Dimer contained in the sample reacts with the latex sensitized with anti-human D-dimer monoclonal antibody (mouse) and forms aggregates, which are determined optically for calculation of D-Dimer concentration.

KIT CONTENT

Reagent	25 tests/kit	50 tests/kit	Major ingredients
Reaction buffer (R1 reagent)	1×5.5 ml	1×11 ml	Phosphate Reaction buffer
D Dimer antibody latex combo (R2 reagent)	1×2 ml	1×4 ml	Latex particles coated with anti-human D-Dimer monoclonal antibody
Cuvette & Bead	25 no's	50 no's	/
Specification	1 copy	1 copy	/
Magnetic card	1 piece	1 piece	/

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the D-Dimer Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.
5. Components from human origin have been tested and found to be negative for the presence of HBsAg,HCV and antibody to HIV(1/2).However handle the calibrator cautiously as potentially infectious material.

SAMPLE COLLECTION AND PRESERVATION

Only the specimens listed below were tested and found acceptable. For specimen collection and preparation, only use suitable tubes or collection containers.
Specimen: Citrate Plasma samples on an empty stomach are the recommended specimens.
Citrate Plasma : Collect fresh Citrate Plasma using sampling tubes. When processing samples in primary tubes, follow the instructions of the tube manufacturer.
For samples with Absorbance interference, including samples of hemolysis and turbidity, may affect the test results. Sample recollection is recommended.
Stability : Store Citrate Plasma less than 7 days at 2 ～ 8℃, 1 month at -20℃ ～ -15℃. Protected from light and avoid repeated freeze thaw cycles. Centrifuge samples containing precipitate before performing the assay.

REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8°C and contaminants prevented during there use, Do not use expired reagents.

ASSAY PROCEDURE

1.THE REAGENT DOSE DISPENSING IN THE CUVETTE

Reagent	Dose
Reaction Buffer (R1 Reagent)	220µl
Sample	20 µl
Mix and incubate for 3 minutes at 37°C in incubator slot (A,B,C,D).	
D-Dimer antibody latex combo (R2 Reagent)	80 µl

2. OPERATING STEP

(1). When starting it shows "Read card", Put the corresponding lot magnetic card in the reader slot, reading the card correctly, the screening displays the reagent name and lot number, the instrument status indication light is working (yellow-green). Please check carefully.
(2). After confirm the lot number, dispense 220µl reaction buffer (R1) to a colorimetric cuvette and 20µl sample and mixing sticker. Do not produce bubbles when dispensing the sample. Mix and incubate for 3 minutes at 37°C in incubator slot (A,B,C,D).
(3). Put the colorimetric cuvette in the detection well, gently press the cuvette until it contacts the bottom. The status indication light will be off when the analyzer detects the colorimetric cuvette successfully.
(4). When the analyzer shows "Add [R2]", dispense 80µl D-Dimer antibody latex combo (R2) in the cuvette. The analyzer will mix automatically and start to detect, it shows: "Testing…" it shows the result automatically and record the value.
(5). After detecting, move the cuvette. The status indication light will be working (yellow- green). Return to step (2) to detect next sample.
(6). If moving the cuvette out in the process of detecting, the screen shows "Give up testing".
(7). If the result shows >9999 ng/ml, may use Normal saline to dilute the sample 1:5 (add 400µl Normal saline in 100µl sample), input dilution multiply 5, the analyzer can calculate the sample concentration automatically.

LINEARITY

The method is linear to a concentration of 0 - 9999 ng/ml.
If the concentration exceeds this value, the sample should be diluted 1:5 with 0.9% saline solution and re-assayed.

REFERENCE INTERVAL

Citrate Plasma	up to 500 ng/ml

Detection Limit: Values ≤ 200 ng /ml may give Non- reproducible results.

QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

INTERFERENCES

Hemoglobin 10 g/dL, Bilirubin 20 mg/dL and Lipemia 10 g/dL do not interfere. Other substances may interfere.

BIBLIOGRAPHY

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
4. Himizu M, evaluation of D-dimer assay on LPIA-100, JJCLA, 16(1): 59, 1991
5. Matsuda M, New detection method of DD/E complex, KENSA, 18(2): 15, 1988

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