D-DIMER (TURBIDIMETRY)

INTENDED USE

BIOLINE D-DIMER reagent is for the Quantitative determination of D-DIMER in human plasma.

CLINICAL SIGNIFICANCE

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

METHOD AND 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.

REAGENT COMPOSITION

Contents	components	Concentration
R1	Tris buffer NaN3	0.01mol/L 0.1%
R2	Latex particles coated with mouse anti-Human mono-clone antibody	2mg/ml

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Avoid skin and eye contact. Avoid ingestion.
3. Disposal of the used material in accordance with local guidelines. Avoid pollution and reuse.
4. Do not use the product if interior package is damaged during shipment.
5. The possibility of reagent instability or deterioration may be considered if there is precipitation, visible exudate, turbidity, microorganism growth, calibration results do not meet the appropriate standard specification, or control values out of range.
6. Exercise the normal precautions required for handling all laboratory reagents.
7. Wear protective clothing and disposable gloves while handling the kit reagents.
8. Wash hands thoroughly after performing the test.
9. Use in ventilated area.
10. For acids, include appropriate warnings for spills such as "wipe up spills immediately and flush with water" and "should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician".
11. For biological spills, indicate appropriate disinfectants and disinfection procedure.
12. Dispose of all specimens and components of the kit as potentially infectious agents.
13. Do not use the kit or any kit component past the indicated expiry date.
14. Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit.
15. Avoid microbial contamination of reagents.
16. The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

REAGENT PREPARATION

Reagent R1 and R2 are ready to use.

REAGENT STORAGE AND STABILITY

1. Unopened reagent: stable for 18 months at 2～8℃, protect from light.
2. Opened reagent: stable up to 30 days at 2～8℃, protect from light.

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REAGENT DETERIORATION

Presence of particles and turbidity in R1 and if control results are not accurate..

SPECIMEN COLLECTION AND STABILITY

In order to obtain a plasma sample for measurement, mix 1 part of citric acid (0.11mol/L) with 9 parts of venous whole blood to avoid air bubbles. Centrifuge immediately, not less than 3000 rpm (1500*g), centrifuge for 10 minutes, and collect the upper plasma.

Sample stability: It can be stored for 4 hours (fresh) under +15-25℃; it can be stored for 1 month under -18℃.

INTERFERENCES

1. Lipemia (Intralipid): no interference up to 250mg/dl of intralipid.
2. hemoglobin: no interference up to 500mg/ dl.
3. Bilirubin: no interference up to 40mg/ dl.

The result may vary with different analyzers or calibrations.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ASSAY PROCEDURE FOR SEMIAUTO ANALYZER.

Reagent preparation: R1: Ready for use; R2: Ready for use.

Wavelength: 630 nm **Temperature:** 37℃

Cuvette: 1cm

	Blank Tube	Calibration Tube	Sample Tube
Sample	—	—	18ul
Calibrator	—	18ul	—
Deionized water	18ul	—	—
R1	225ul	225ul	225ul
Mix, incubate at 37℃ for 5 minutes.			
R2	75ul	75ul	75ul
Mix, incubate at 37℃ for 5 minutes, zero setting for blank tube, read the absorbance ΔA calibrator and ΔA sample			

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CALIBRATION : It is recommended to use Bioline Calibrators

Dissolve the lyophilized D-D calibrator with 1ml distilled water, balance 10 minutes in room temperature, then dilute to 6 levels calibrators as follows,

Calibrator	S6	S5	S4	S3	S2	S1
Cal. Vol. (μl)	200	100	50	50	25	0
Calibrator Diluent Vol.(μl)	0	100	150	350	375	200
ratio	1	1/2	1/4	1/8	1/16	0

Calibration frequency Recalibration is recommended:

- as a blank calibration after 24 hours
- as a blank calibration after reagent bottle change
- as a two point calibration every 30 days if the reagent always on-board
- as a two point calibration after reagent lot change
- as a two point calibration if required following quality control procedures

Calibration verification: Not necessary

CALCULATIONS

The D-dimer concentration of unknown samples is derived from a calibration curve generated in the semiauto analyzer.

QUALITY CONTROL

It is recommended to use Bioline D-D Quality Control or BioRad level 1 and level 2 for daily quality control.

Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

EXPECTED VALUES

<0.5μg/mL

The reference range should be determined by each hospital to confirm with the characteristics of the region being tested.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

1μg/mL

The lower detection limit represents the lowest measurable total uric acid concentration that can be distinguished from zero. It is calculated as three standard deviations of 20 replicates of the lowest standard.

Accuracy :≤±15%

Precision: ≤10%

Batch Error R≤15%

REFERENCES

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5) Matsuda M, New detection method of DD/E complex, KENSA, 18(2): 15, 1988