D-Dimer

Liquid Reagent

CE

Quantitative measurement of D-dimer in human plasma or serum.
Store at 2-8 °C.

REF: DDM-010

Summary:

D-dimer is a type of fibrin degradation products composed of stable fibrin degraded by plasmin. Stable fibrin is crosslinked by the action of coagulation factor XIII in the blood coagulation and fibrinolysis system. Increasing in the level of D-dimer in the blood are linked to thrombus production, as well as the efficacy of fibrinolysis. Increasing in the level of D-dimer is also known to be associated with various diseases, including malignant tumors, obstetric diseases, vascular lesions, and DIC (disseminated intravascular coagulation syndrome).

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.

Composition:

R1: Buffer Reagent
R2: Latex coated with anti-human D-dimer monoclonal antibody

Instruments:

Instrument applications are available upon request.

Preparation:

Reagent is ready for use.
If stored at 2-8°C and handled properly, component is stable until expiry date stated on the label.

On-board, in use and refrigerated on the analyser: 4 weeks.

- Store the reagents according to the specified storage method, and do not use a batch passing the expiry date.
- Never freeze latex solution.
- Be sure not to mix reagents of different lots. Use the same lot of reagents when creating a calibration curve and assaying a sample.
- Avoid mixing the remaining reagents into new one, as this may cause contamination or deterioration of the reagents.
- Upon completion of assay, the reagents should be capped and then stored according to the specified storage method.
- After removing from a refrigerator, Latex reagents should be fully mixed prior to use.
- Do not allow dust or foreign substances to get mixed into reagents or cuvettes.

Samples:

For specimen collection and preparation, collect it in citrate. The plasma, separated by centrifugation as soon as possible after collection, may be stored for up to a week at 4°C, or 2 months at –80°C. Samples may be frozen and thawed three times with no detrimental effect. 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.

Equipment:

- D-Dimer Controls
- D-Dimer Calibrator
- General Laboratory Equipment

Procedure:

The operating methods are different depending on the type of automatic analyser. The detailed operating methods and the parameters for each type of automatic analyser are available.
[Hitachi 7100 as an example]

1. Reagent Preparation
- R1: ready to use
- R2: ready to use
- Calibrator: prepare according to the instruction manual
- Diluent: ready to use

2. Supplemental remarks
- Calibrator (optional)

3. Assay procedure
Add 180uL of R1 to 4uL of the sample, warm the mixture to 37°C for 5 minutes, and then add 60uL of R2. Determine the absorbance of the mixture while warming to 37°C, 5 minutes after mixing at 700 nm of main-wavelength. Proceed similarly with the calibrator, and compare the absorbance values for calculation of the D-dimer concentration in the sample.

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Reference values:

Measuring range: 1.0 ug/mL or less

Performance characteristics:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Specificity:

When assaying control samples of known concentration, the assay values are within ± 15% of the known concentration.

Interfering substances:

Bilirubin: No significant interference up to 18mg/dl.
Lipemia (Intralipid): No significant interference up to 2000 mg/dl.
Hemolysis: No significant interference up to 500mg/dl.

Sensitivity:

When the calibrator containing D-dimer at a concentration of 0 ug/mL and 0.5 ug/mL are assayed 10 times each consecutively, MEAN ± 2SD of the assayed absorbance of each sample is not overlapped.

Reproducibility:

When a control sample is assayed 5 times consecutively, CV is 10% or less.

Assay Range:

From 0.5 to 30ug/Ml (on Hitachi).

Measuring Ranges:

1.0ug/mL or less

The reference value range will possibly be different depending on various conditions of individual laboratories, so set the reference value range suitable to each laboratory.

1. Some samples may consist of substances which cause non-specific reaction or interfering reaction. When assay values and results are questionable, validate it through re-testing by dilution or assaying by other test kit.
2. Note that Prozone (PZ) remark may be indicated for samples with target substance of beyond calibration range. However, samples with extremely high-level substance may show low values.
3. Note that samples with high-level (beyond calibration range) substance may affect the assay results of succeeding samples by carryover.
4. Note that serum separating agents in blood collection tubes may affect the assay result.
5. The responsible physician should make a clinical diagnosis comprehensively based on the assay results, clinical symptoms, and other results.

References:

1. Rylatt D.B.,et al: An immunoassay for human D dimmer using monoclonal antibodies. Thromb. Res., 31(6):767,1983.

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