D-Dimer – Latex Turbidimetry Ref.:DDM-010
Quantitative Determination of D-Dimer
Only for *in vitro* use in clinical laboratory
Store at 2-8ºC Ratio 3:1

D-Dimer

CE

CLINICAL SIGNIFICANCE

D-Dimer is a degradation product of fibrin. After the initial formation of the fibrin clot, Factor XIII links two D-domains and generates a solid fibrin clot. Plasmin degrades the crosslinked fibrin and these degradation products contain the D-Dimer domain. The D-Dimer is a measure of fibrinolytic activity of plasmin in the bloodstream. Its determination is becoming a tool for diagnosing thrombosis and monitoring thrombolytic therapy for the Disseminated Intravascular Coagulation (DIC). Increased levels of D-Dimer are found in clinical conditions of Venous Thromboembolism (VTE) such as Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT) and also in DIC.

PRINCIPLE OF THE TEST:

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.

WARNINGS AND PRECAUTIONS:

- When handling samples, take great care to prevent infection by HBV, HIV, and HCV, wear rubber gloves.
- Be sure not to allow foreign substances including dust, fungi, bacteria, and detergent to get mixed into samples. In addition, take care to prevent contamination of reagents and cuvettes.
- On testing, wear disposable gloves and avoid oral pipetting to prevent infection.
- Dispose of the reagent under a large amount of running water, as each component reagent contains sodium azide. If they get into the eyes or mouth or adhere to skin, first aid measures such as thorough flushing with water should be taken. Consult a physician if necessary.

INSTRUMENTS:

Instrument applications are available upon request.

COMPONENT COMPOSITION:

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

REAGENT PREPARATION AND STABILITY:

Reagent is ready for use.

If stored at 2-8℃ 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.

TYPE OF SPECIMEN:

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 1 week at 4℃, or 2 months at –80℃.
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.

TEST PROCEDURE:

Materials required but not supplied:
D-Dimer Controls
D-Dimer Calibrator
General Laboratory Equipment

Assay 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]

Add 180uL of R1 to 4uL of the sample.
Warm the mixture to 37 °C for 5 minutes.
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. Verify 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.

EXPECTED VALUES:

Normal values: < 0.5 µg/ml

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

Sensitivity:

When the calibrator containing D-dimer at a concentration of 0 ug/mL and 0.5 µg/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.

Measuring Range:
From 0.5 to 30 µg/ml (on Hitachi).

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.

BIBLIOGRAPHY:

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