

Please use the reagent after reading this package insert

D-Dimer

Quantitative turbidimetric latex assay for the measurement of D-Dimer

【General attention】

1. This reagent is for in vitro diagnostic use, and do not use for other purpose.
2. The doctor in charge along with clinical conditions and other laboratory results, etc. must judge the clinical diagnosis based on the result of a measurement overall.
3. Please use it according to use and the dosage regimen described in the package insert. The reliability of the result of a measurement cannot be guaranteed when use excluding described use and dosage regimen.

【Reagent Composition】

1. Buffer (R1) Liquid
2. Latex reagent (R2) Liquid

(Anti-human D-Dimer (mouse) monoclonal antibody sensitized latex)

【Intended use】

Measurement of D-Dimer in serum or plasma sample

【Principle】

1. Principle of measurement
Antibody adsorbed latex particles and D-Dimer in the sample react immunologically, and causing the latex particles to agglutinate. This agglutination results in a change of turbidity, and the change in absorbance is a measure of the amount of D-Dimer in the sample.
2. Feature
 1. Measurement principle is latex immuno turbidimetric assay.
 2. It is possible to adjust to various general-purpose automatic analyzers.
 3. unnecessary for preparation of reagent
 4. The preprocessing of the sample (dilution of the sample) is unnecessary.

【Handling Precautions】

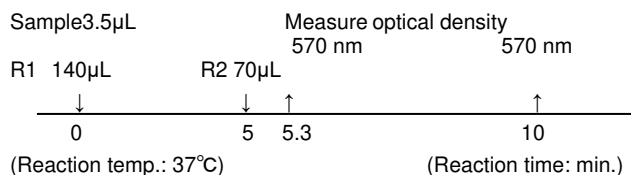
1. Measurement sample
Please use the fresh serum or plasma as a specimen for measurement. Please be careful to not cause hemolysis at the specimen collection.
2. Interfering substance etc.
The following components hardly interfered with the test result: chyle (up to formazin turbidity 2100), bilirubin F $\leq 18\text{mg/dL}$, bilirubin C $\leq 21.2\text{mg/dL}$, Hemoglobin 500mg/dL and RF $\leq 520\text{IU/mL}$.
3. Others
 - a. Storage reagents at (2-10°C), and the freezing preservation must be avoid
 - b. Please request material separately about the adaptation example to various automated analyzers.

【Procedure】

1. Preparation of the reagents
Buffer solution (R1) and Latex reagent (R2) are used as it is.
2. Stability
The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-10 °C and contaminations are prevented during their use.

3. Procedure

[Standard procedure]



4. Calibration

Using optional D-Dimer calibrator and measure them as sample based on the above-mentioned procedure, and made the calibration line.

【Judgment method of result】

- (1) Normal reference values
1.0μg/mL
※Please set the normal range in each institution
- (2) The nonspecific reaction can happen in various infectious diseases and autoimmune disease patients' serums. Please judge the diagnosis based on the result of a measurement overall in consideration of other inspections and clinical conditions.

【CLINICAL SIGNIFICANCE】

During fibrinolysis, plasmin breaks down fibrin and fibrinogen. When insoluble fibrin is degraded, a variety of cross-linked fibrin degradation products (XL-FDP) are produced. The smallest cross-linked fibrin degradation product is D-dimer, a fragment that contains one intermolecular cross-link between the gamma chains of two fibrin monomers. This cross-linkage only occurs in fibrin, but not in fibrinogen, so D-dimer is a specific degradation product of fibrin. Quantitative D-dimer determination aids in detecting the presence and degree of intravascular coagulation and Fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring the therapy for disseminated intravascular coagulation (non localized clotting in the blood vessels.) D-dimer is also routinely used for excluding deep venous thrombosis. The blood D-Dimer levels are used for a diagnosis of diabetes, condition of a patient grasp.

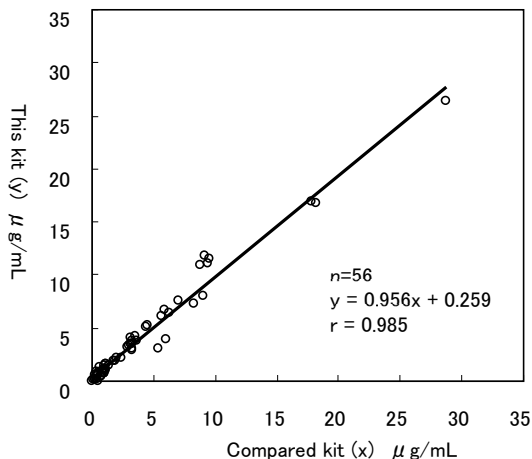
【PERFORMANCE】

1. ANALYTICAL PERFORMANCE

1. Sensitivity
 - (a) When measured saline liquid as the sample, absorbance change (ΔOD) is below 0.003/min.
 - (b) When measure known concentration sample, absorbance change of D-Dimer concentration $10\mu\text{g/mL}$ is between 0.005 to 0.045/min.
2. Accuracy
When measured the control serum of known concentration is measured, measurement value is within $\pm 15\%$ of the known value.
3. Reproducibility
When measure the same sample five times at the same time, the C.V of the absorbance value is 10% or less.
4. Measurement range
Measurement range of the D-Dimer in the sample is 0.5-30 $\mu\text{g/mL}$.

2. Correlation

Correlation performance study were conducted with commercially available LIA reagents (x) and obtained good correlation as below.



【Attention in handling for use】

1. Attention in handling (dangerous prevention)

- (1) An infectious microorganism such as hepatitis B viruses might exist in the sample, please handle it assuming that there is a risk for infection.
- (2) Sodium azide of 0.09w/v% is contained in the reagents as preservative. When entering eyes and mouths or adhering to the skin by mistake, flushing enough them with water as a stop-gap measure. If there is a necessity receive the doctor's treatment.

2. Directions

- (1) Do not use the reagents after the expiration date.
- (2) After open the reagents, use them as early as possible. When preserve them, please close the lid and preserve on a specified condition.
- (3) Please do not use the bottle and the accessory in this kit for other purposes.
- (4) Please set the buffer and the latex reagent at the position correctly after gently mixing by invert the bottle before measure. Please remove the bubble when bubbling.
- (5) When the measurement value exceeds the measure range, please dilute with saline liquid, and measure the specimen material. Those obtained by multiplying the dilution factor in value is the measured value.
- (6) Please do not use the reagent with different lot.
- (7) Please make the working curve at each measurement. Moreover, please measure the calibration sample for two times or more respectively.
- (8) Please use the calibrator sold separately, and refers to the manual of the goods before use.
- (9) Preserve the reagent at refrigerated condition (2-10°C) and avoid the freezing.

3. Attention for Disposal

- (1) Sodium azide of 0.09w/v% is contained in the reagents as preservative. The sodium azide might generate the metallic azide that it reacts with the lead pipe and the copper pipe and explosiveness is strong, and flush it in volumes of water, please when you abandon it.
- (2) An infectious microorganism such as hepatitis B viruses might exist in the sample, and process a used sample, the reagent container, and apparatus, etc. by sterilization, disinfection (0.5% solution of sodium hypochlorite), and incineration, etc.
- (3) Please process it according to regulations of Wastes Disposal and Public Cleaning Law and Water Pollution Control Law, etc. when you abandon and apparatus, etc.

【Storage and validity period】

1. Storage : 2~10°C
2. Validity period : 1 year after production
Expiration date is displayed on the outer box and bottle labels.

【Package】

Product Name	Contents
D-Dimer reagent	
Buffer (R1)	16mL × 1
Latex reagent (R2)	8.5mL × 1

〔Optional goods〕

(Product Name) (Contents)

D-Dimer Calibrator 6conc. x 1mL each (Lyophilized)

D-Dimer Control 2 concentrations × 2mL each (Lyophilized)

The indicated value is displayed on the label

【References】

- 1) Sano Masaya: Rinsyokensakiki • Shiyaku, 20-2-301 ~ 308 (1997)
- 2) Mitsuhashi Hiroyuki: Nihonrinsyou, 57-2, 569-572 (1999)

【Inquiries】

SHIMA Laboratories Co., Ltd.

Maeno-cho 3-36-3, Itabashi-ku, 174-0063 Tokyo, Japan

Tel: +81-3-3967-7277 Fax: +81-3-3967-3241

【Manufacturing and distribution】

SHIMA Laboratories Co., Ltd.

Maeno-cho 3-36-3, Itabashi-ku, 174-0063 Tokyo, Japan