



Instructions of D-Dimer Test Kit

【Product Name】

Generic Name: D-Dimer Test Kit (immunoturbidimetry)

English Name: D-Dimer

【Specification】

Reagent 1: 12×5ml, Reagent 2: 4×5ml;

Reagent 1: 12×2ml, Reagent 2: 4×2ml;

Reagent 1: 2×60ml, Reagent 2: 8×5ml;

Reagent 1: 4×6ml, Reagent 2: 4×2ml;

Specifics please see the kit outer package and bottle label

【Intend Use】

The product is supporting the use of coagulation analyzer produced by our company, suitable for in vitro quantitative determination of the content of D-dimer of human plasma. D-dimer is a specific degradation product of crosslinked fibrin, which generating or increasing reflects the dual activation of coagulation and fibrinolysis systems, used as an important indicator of in vivo thrombus formation, as well as the very valuable point for detecting primary and secondary fibrinolysis, monitoring thrombolytic therapy and so on. In clinical practice, it shows an important diagnostic value for testing thrombotic diseases, such as disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), pulmonary embolism (PE), cerebrovascular disease, myocardial infarction, severe hepatitis and so on.

【Principle of the Test】

D-Dimer assay adopts the principle of latex immunoturbidimetry; samples of D-Dimer generate antigen-antibody reaction with monoclonal antibody latex particles of anti-human D-Dimer, and result in agglutination and turbidity increase. By detection the variation of turbidity of samples, obtain D-Dimer content.

【Main Components】

Latex agglutination reagents: monoclonal antibody (mouse) latex particles of anti-human D-Dimer 30mol / L

Reaction buffer: trihydroxymethyl aminomethane 0.3%

【Storage Conditions and Validity】

Unopened kits should be stored at 2 °C ~ 8 °C, valid for 24 months and used within the validity period.

【Applicable Instruments】

It applies to full-automatic coagulation analyzers, such as XL1000/XL1000C/XL1000P/XL3600i/3600c/3600t/3600p/3200i/3200

c/3200t/3200p/1800i/1800c/1000e/1000s, produced by Beijing ZONCI Technology Development Co.,Ltd.

【Specimen Requirements】

Fresh venous whole blood, should be placed in a test tube containing 1/10 volume 0.109mol / L sodium citrate solution, and centrifuged at 3000 rpm/minute for 10 minutes to collect supernatant (plasma).

【Test Methods】

Reagent Preparation

This reagent is liquid, and can be directly used when it reaches to room temperature.

The test conditions must be met

For automatic coagulation analyzer, set as form below.

Reaction Temperature	37°C	Sample Volume	3ul	
Reaction Time	180s	Reagent	R1	150ul
	300s	Volume	R2	50ul

According to the operating steps of full-automatic coagulation analyzer to assay, plasma and reagent consumption can refer to the table above.

1. Calibration Procedure

Use D-Dimer calibrators produced by Beijing ZONCI Technology Development Co.,Ltd, to calibrate by reference to instructions.

4. Quality Control Procedure

When each measurement, should use quality control material produced by Beijing ZONCI Technology Development Co.,Ltd to evaluate the operating technique, instruments and reagents. If the result of control material is not within the allowable range, the batch measurements of the patients will be considered ineffectively and not be reported.

5. Sample Analysis

Test samples should be placed in the appropriate position of the instrument and then make a test. The instrument automatically calculates and outputs the measurement result.

【Reference Interval 参考区间】

D-Dimer < 1.0ug/ml. Verified by 240 clinical plasma tests, the results show the range of reference value is reasonable.

Each laboratory should establish its own range of reference value.

【Explanation for Test Results】

Factors that may affect the test results:

1. When the sample concentration exceeds the detection range, the sample should be re-measured after dilution.
2. When the measurement result is abnormal, should check each component of system, such as reagents, samples, etc., if necessary,



re-determination, and also apply other measurement methods to confirm.

【Limitations of Test Methods】

It is affected by many factors before the test, including sample collection and storage, technician proficiency, interfering substances, etc. All these factors must be carefully controlled.

【Performance Indicators】

1. Appearance

The appearance should meet the following requirements:

- a) The reagent kit should look neat, clear identification of text symbols;
- b) latex agglutination reagent should show as a even milky suspension;
- c) buffer of a colorless clear liquid.

2. Packing: the capacity of each reagent kit is less than the indicated volume.

3. Accuracy: when the concentration reaches to the range of 0.5ug / ml-4ug / ml, absolute deviation of each concentration point does not exceed $\pm 0.4\text{ug / ml}$; when the concentration reaches to the range of 4ug / ml-40ug / ml, absolute deviation of each concentration point does not exceed $\pm 10\%$;

4. Repeatability: $\text{CV} \leq 10\%$;

5. The linear range: 0.5-40ug / ml;

6. Inter variations: $\text{CV} \leq 10\%$.

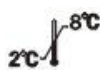
【Notes】

1. This product is only used for in vitro diagnosis
2. Diagnosis and treatment cannot rely on the test results only, and should consider clinical history and test results of other laboratories.
3. Before testing, make it reach to home temperature.

【Description of Symbols】



Reference Description



Storage temperature 2 °C ~ 8 °C



Only for in Vitro Diagnosis



Batch Number



Validity

【References】

1. WolfgangK, Walter, Latex-enhanced immunoturbidimetry

allows D-Dimer determination in plasma and serum samples. Clinical Chemistry, 2000,46(6):871-872

2. Brown M, Lau J, Nelson RD, et al, Turbidimetric D-dimer test in the diagnosis of pulmonary embolism; a metaanalysis. Clin Chem. 2003,49:1846-4853.
3. Di Nisio M, Squizzato A, Rutjes AW, et al. Diagnostic accuracy of D-Dimer test for exclusion of venous thromboembolism: a systematic review. J Thromb Haemost 2007.5(2):296-304
4. RC Gosselin, JT Owings, RC Jacoby, et al. Evaluation of a new automated quantitative D-Dimer, Advanced D-Dimer, in patients suspected of venous thromboembolism. Blood Coagulation and Fibrinolysis, 2002,123(4):323-330

【Information】

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Manufacturing License No.: Producing Certificate No.20070099 of Jing Drug Instrument Administration

【Registration Certificate Number for Medical Device/Technical Requirements Number】

Permission No.20152400424 of Jing Instrument Administration

【Instructions of Approval Date and Modified Date】

Instructions of Approval Date and Modified Date: Oct.15, 2014