D-Dimer Rapid Quantitative Test

CE IVD

INTENDED USE

The Biotime D-Dimer Rapid Quantitative Test is intended to quantify the concentration of D-Dimer in human whole blood or plasma on Biotime FIA Analyzers (Semi-automatic / Automatic) by fluorescent immunoassay. It is used as an aid detection of PE and DVT.
-Fluorescent immunoassay
-PE and DVT
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

D-Dimer is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. D-Dimer doesn't normally present in human blood plasma, except when the coagulation system has been activated, for instance because of the presence of thrombosis or disseminated intravascular coagulation. It is regarded as a specific fibrinolytic process marker. D-Dimer concentration is used to suspected thrombotic disorders. While a negative result practically rules out thrombosis, a positive result can indicate thrombosis but does not rule out other potential causes. Its main use, therefore, is to exclude thromboembolic disease where the probability is low. In addition, it is used in the diagnosis of the blood disorder disseminated intravascular coagulation. Myocardial infarction, cerebral infarction, pulmonary embolism, venous thrombosis, surgery, cancer, disseminated intravascular coagulation, infection and tissue necrosis may lead to elevated concentration of D-Dimer. Increased concentration of D-Dimer may also be observed in elderly and hospitalized patients with abnormal coagulation caused by bacteremia [1-3].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the D-Dimer in the sample and the mouse anti-D-Dimer monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with D-Dimer specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of D-Dimer in human blood.

The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of D-Dimer in human whole blood or plasma.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for single time use.
4. Once opening, the reagent should be used within the specified time to avoid detection failure due to moisture absorption.
5. While using the test cartridge and instruments, vibration and strong electromagnetic environment should be avoided.
6. Lot number of buffers and test cartridges must be matched.
7. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. Otherwise, it may cause damages to the instrument.

MATERIAL

Material Provided
The following components are included in the D-Dimer Rapid Quantitative Test.
Specification and Component

1. For type A reagent

Packing specification				
Catalog No.	Test cartridge	Detection buffer	SD card	Instructions for Use
BT2105	25 tests/kit	25 tubes/kit	1 piece/kit	1 copy/kit

2. For type B reagent

Packing specification				
Catalog No.	Test cartridge	Detection buffer	SD card	Instructions for Use
BT0203801	25 tests/kit	1 panel/25 tests	1 piece/kit	1 copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer

Applied information	Biotime FIA Analyzer	Applicable model
For type A reagent	Semi-automatic	BIOT-YG-I, FLI-100, FLI-600, FLI-1200
For type B reagent	Automatic	FLI-4000

2. Transfer Pipette Set (range 5~50μL and 10~100μL size)
3. Specimen Collection Containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. For Type A reagent: Test cartridge should be used within 30 min after opening the pouch. For Type B reagent: After opening the kit, it should be exposed to the air for no more than 24 hours under the conditions of 10-30℃ and 30%-90% relative humidity. It is recommended to use the original self-sealing pouch to seal the unused test cartridge and use it within 7 days. And the sample buffer should be ready for use.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with whole blood or plasma.
2. The specimen collection container should be citric acid tube for plasma or whole blood.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, plasma can be stored in refrigerator at 2-8℃ for no more than 7 days, or at -20℃ for no more than 6 months and whole blood can only be stored at 2~8℃ for no more than 48 hours. Samples must be recovered to the room temperature before test.
4. Separate the plasma from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to operation manual of Biotime FIA analyzers for details. The test should be operated at room temperature (~25℃).

For Type A reagent

Step 1: Preparation
Check/insert SD card into the equipment. Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
Take 50μL of plasma or 80μL of whole blood with a transfer pipette and add it into the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.
Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 3 minutes.

For Type B reagent

Step 1: Preparation

Check the lot number. Tear the aluminum foil bag, take out the test cartridge and buffer, and put it into the analyzer card slot.

Step 2: Sampling

For plasma samples, after put the samples to be tested into the analyzer, the analyzer automatically absorbs 50μL sample.

For whole blood sample, after put the sample to be tested into the analyzer, the analyzer automatically absorbs 80μL sample;

Step 3: Mixing

The instrument automatically adds the sample into the sample buffer, and then fully mixed.

Step 4: Loading

The instrument automatically absorbs 80μL of the above mixed solution into the detection hole of the test cartridge, and moves it to the incubator;

Step 5: Testing

After sample mixture addition, the test cartridge reacts in the incubation tank for 3min, and the analyzer reads the result;

NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal reference interval: <0.5mg/L
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be whole blood or plasma.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies[4-5].
3. Other factors also can induce the false results, including the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
D-Dimer control materials with two different concentrations were tested by every batch of Test Cartridges, and the deviations were within ±15%.
Assay Range: 0.1-10.0 mg/L
The Lowest Detection Limit: 0.1 mg/L
Linearity
A serial concentrations of D-Dimer reference materials at 0.1-10.0mg/L were tested, and the correlation coefficient (R) is ≥ 0.9900.
Precision
Intra-lot Precision
Intra-lot precision was determined by testing of D-Dimer reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.
Inter-lot Precision
Inter-lot precision was determined by testing of D-Dimer reference materials using 30 test cartridges from 3 consecutive lots randomly (10 test cartridges from each lot). The C.V. is ≤ 15%.
Specificity
The concentration of D-Dimer is not greater than 0.1mg/L when the concentration of FDP is 120mg/L.
The concentration of D-Dimer is not greater than 0.1mg/L when the concentration of VC is 2000mg/L.
The concentration of D-Dimer is not greater than 0.1mg/L when the concentration of barbituric acid is 100mg/L.

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use
	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer	2℃ 30℃	Store at 2-30°C
	Do not re-use	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		

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Version: A/06
Issuing date: 2024-08-15