D-Dimer Quantitative Test Kit (Quantum Dot Fluorescence Immunochromatography) Instruction for Use

CE IVD REF

In Vitro Diagnosis
For Professional Use

【Product Name】

D-Dimer Quantitative Test Kit (Quantum Dot Fluorescence Immunochromatography)

【Package Specification】

25 tests/kit

【Intended Use】

D-Dimer Quantitative Test Kit (Quantum Dot Fluorescence Immunoassay) is used to detect the content of D-dimer in human whole blood and plasma, clinically mainly used to differentiate primary and secondary fibrinolysis hyperfunction syndromes, can be used as an observation index for the effectiveness of thrombolytic therapy, and is of great significance for the diagnosis, efficacy evaluation, and prognosis judgment of thrombotic diseases. For in vitro diagnostic use only.

【Test Principle】

This kit adopts the principle of fluorescent immunochromatography, and quantitatively detects the concentration of D-dimer in human whole blood and plasma using the sandwich method with double antibodies. D-Dimer antibody is coated on the nitrocellulose membrane (NC membrane) detection line (T area), and chicken IgY antibody is coated on the control line (C area), supplemented with a probe pad fixed with quantum dot-labeled D-Dimer antibody and sheep anti-chicken IgY. The sample to be tested is added to the sampling hole of the test cassette. As the liquid flows, the sample to be tested first passes through the sample pad, forms a fluorescent complex with the probe pad fixed with quantum dot-labeled antibody, the complex passes through the detection line and the control line, respectively, and specifically binds to the antibody in the detection line and the control line. The captured by the coated antibody on the nitrocellulose membrane shows a fluorescent color band.

The fluorescence signal intensity reflects the amount of captured D-dimer. The higher the concentration of D-dimer in the sample, the more complexes accumulated on the detection line, the higher the signal intensity. The instrument analyzes the photometric values of the control line and the detection line using a fluorescence immunoassay analyzer, and then calculates and displays the concentration of D-dimer based on the calibration curve preset in the instrument, in units of mg/L.

【Main Material】

Main Material as below:

25 Test Cassette
25 Deliver Pipette
1 Bottle of diluent
25 Empty centrifuge tube
1 ID Card
1 User Manual

Material Required but not Provided:

1. Timer, thermometer, hygrometer;

Note: Components of different batches of reagent kits cannot be used interchangeably to avoid incorrect results

【Storage Conditions and Validity Period】

1. The test kit should be stored at 2~30°C, protected from light, and has a shelf life of 18 months.
2. The test cassette should be used within 1 hour after opening at a temperature of 10°C to 30°C and a humidity of 35% to 65%.

【Applicable Analyzer】

Dry fluorescence immunoassay analyzer GKYG-500 produced by Dezhou Guoke Medical Technology Co.,ltd.

【Specimen Requirement】

1. Collect and separate whole blood and plasma by conventional methods, and try to avoid hemolysis during the processing. Hemolyzed specimens cannot be used. All specimens should be treated as infectious agents.
2. Sodium citrate anticoagulant treatment is allowed for whole blood and plasma specimens.
3. Specimens should be tested in a timely manner. After adding the anticoagulant, the specimen should not be placed at a temperature of 18~28°C for more than 4 hours. Prolonged time may cause blood coagulation or fibrinogen precipitation, leading to inability to detect.
4. Whole blood and plasma specimens should be stored at a temperature of 18~28°C for no more than 1 day. If the specimen is free of contamination such as bacteria, it should not be stored at 28°C for more than 3 days, or at -20°C for more than 1 month. The specimen should not undergo more than 3 freeze-thaw cycles. Thawed frozen specimens should be thoroughly mixed.
5. Particulate matter in the sample will affect the test results. Specimens containing visible particles should be centrifuged to obtain the supernatant for experimentation.
6. Do not test samples from patients with severe hemolysis, lipemia, or jaundice. Samples containing hemoglobin (concentration exceeding 5mg/mL), bilirubin (concentration exceeding 0.2mg/mL), or triglycerides (concentration exceeding 15mg/mL) should not be used for testing.
7. The sample must be equilibrated to a temperature of 10°C~30°C before testing. Frozen stored samples should be completely thawed, rewarmed, and thoroughly mixed before use.

【Test Procedure】

1. When stored at low temperatures, the test cassette and sample dilution should be equilibrated to 10°C~30°C before use.
2. Follow the instructions for use of the instrument to turn on the instrument.
3. Remove the ID card from the reagent box and read the ID card information at the reading position of the fluorescent immunoassay analyzer.
4. Tear open the outer packaging, take out the test cassette, place it flat on the operating table, and use the test cassette within 1 hour after taking it out.
5. Pipette 20μL of the sample and add it to a tube of sample diluent, mixing thoroughly, then take 100μL of the mixed solution and drip it vertically into the sample well of the test card.
6. Immediately insert the test cassette into the fluorescent immunoassay analyzer at 15 minutes, click the "Test" button, and the test result will be automatically displayed on the instrument screen, and can be saved and printed.
7. Used test cassettes should be disposed of as potentially biohazardous materials.
8. Quality control:

1) C line is used as an indicator of the effectiveness of the test cassette, C line should appear in any cases.

2) The company's internal quality control products or other approved and applicable quality control products can be used to conduct quality control on the product. The test results should be within the specified quality control range.

Note: Test should be completed under the conditions of temperature 10°C to 30°C and humidity 35% to 65%.

【Reference Range】

The normal reference value of D-dimer corresponding to the 95th percentile of 189 normal human samples is <0.5mg/L;

The reference value is validated based on similar products already on the market. Due to differences in race and region, each laboratory can establish its own reference range according to actual conditions.

【Interpretation of Test Results】

1. If the test result is <0.5mg/L, the sample is negative;
2. If the test result is ≥0.5mg/L, the sample is positive;
3. If the whole blood and plasma sample is turbid, it will affect the flow rate

of the sample, leading to prolonged or undetectable test time, which may result in incorrect test results. Please centrifuge and discard the precipitate before use.

4. The accuracy of the sampling volume directly affects the accuracy of the test results.

5. Before use, check the integrity and expiration date of the reagent kit packaging, and then open the packaging. When stored at low temperatures, the reagent should be restored to 10°C~30°C before opening the packaging. Using it directly at low temperatures will affect the test results.

【Limitations of Detection Method】

This test kit belongs to the fluorescent immunoassay diagnostic reagent kit, and has inherent limitations in methodology:

1. The test result can only be used as an auxiliary diagnosis for doctors or other diagnoses, and needs to be combined with other clinical and laboratory data.

2. If the test result does not match the clinical assessment, further examination is needed.

3. For bilirubin ≤0.5mg/mL, triglycerides ≤10mg/mL, and hemoglobin ≤5mg/mL, the deviation of the test result is within ±10%.

4. When the D-dimer concentration in the sample is ≤50mg/L, no HOOK effect will occur.

5. If the sample test result shows greater than 10mg/L, it is recommended to dilute the sample with physiological saline (the maximum dilution factor should not exceed 1:5), and the concentration value of the sample after dilution multiplied by the dilution factor to obtain the sample concentration value.

【Product Performance Indicator】

1. Appearance inspection: The product and outer packaging should be clean, flat, with clear markings, complete components, and materials adhered firmly.

2. Migration speed: The liquid migration speed should not be less than 10mm/minute.

3. Linear range: In the range of 0.1mg/L～10mg/L, the Liner Correlation Coefficient(R) value should be ≥0.990.

4. Accuracy:

Use the enterprise internal control accuracy reference material (C1, C2) for detection. The test result should be within the following range:

1) Detection range of 0.5mg/L ± 15% by using the enterprise internal control accuracy reference material C1 at 15 minutes;

2) Detection range of 2.5mg/L ± 15% by using the enterprise internal control accuracy reference material C2 at 15 minutes;

5. Intra-lot precision

Use the enterprise internal control precision reference material (C9, C10) for parallel detection 10 times, and instrument determination at 15 minutes, with a coefficient of variation CV≤15%.

6. Inter-lot precision

For three lots of reagent kits, use the enterprise internal control precision reference material (C9, C10) for parallel detection 10 times, and instrument determination at 15 minutes, with a coefficient of variation CV≤15%.

7. Detection limit

Use the enterprise internal control detection limit reference material L1 for detection. The result should be 0.1mg/L at 15 minutes.

【Precautions】

1. This reagent kit is for in vitro diagnostic use only, and should be used once and not reused.

2. The reagent kit should be treated as containing infectious materials.

3. Before use, check the integrity and expiration date of the reagent kit packaging.

4. Please read the instructions for use of the reagent and instrument carefully before all operations.

5. Please strictly follow the instructions for use. Once the test starts, it cannot be stopped halfway. If stopped halfway, this test cannot be resumed. If retesting is needed, the reagent must be updated and retested.

6. Each batch of reagents has corresponding parameters in the matching instrument, and the manufacturer regularly updates the parameters in the instrument. If the new batch of product reagents is not recognized by the instrument, please contact the manufacturer to update the parameters in time.

7. The test cassette should not be used after opening for more than 1 hour.

8. Reagents of different lot numbers cannot be mixed, and ID cards and test cassettes cannot be mixed and used with different batch numbers.

9. The experimental environment should not be too high. The test cassette stored at low temperature needs to be restored to room temperature before opening to avoid moisture absorption.

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【Index of Symbols】

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:

Dezhou Guoke Medical Technology Co., Ltd

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