Instruction for D-Dimer test kit (Immunofluorescence)

1. Product Name

Generic name: D-Dimer Test Kit (Immunofluorescence)

Trade name: D-Dimer

2. Package

Specification 1: 25T/kit REF: 52026017

Specification 2: 50T/kit REF: 52027017

Quality Control (optional):

Specification: 0.5mL × 1 REF: 52105018

3. Intended Use& Indication

For *in vitro* quantitative determination of D-dimer content in human plasma or whole blood.

Clinically used for the diagnosis of disseminated intravascular coagulation (DIC), cerebral infarction, ACS, liver disease, malignant tumors, etc. Clinically, it is mainly used to exclude venous thrombosis, assisted diagnosis of disseminated intravascular coagulation, and monitoring of thrombolytic therapy.

Products for professional use only.

4. Test Principle

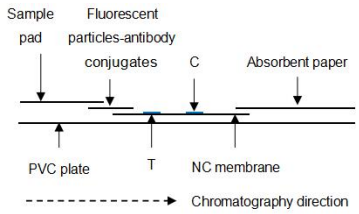
When the test sample is added to the sample port on the test card, D-dimer in the sample combines with mouse anti-D-dimer monoclonal antibody which is coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T) along the nitrocellulose membrane and combines with the pre-coated mouse anti-D-dimer monoclonal antibody, its fluorescence intensity is proportional to the D-dimer content in the sample. The remaining fluorescent antibody particle reaches the quality control area (C), the fluorescent particles-rabbit IgG was combined with the pre-coated goat anti-rabbit IgG to present a quality control line, if the sample does not contain D-dimer, the test area (T) will not appear fluorescence.

5. Main components & Additional Required Equipment

The test kit consists of test card, magcard, whole blood buffer and the instruction.

(1) The test card consists of the card housing and test strip. Test strip contains a sample pad, glass fiber (coated with fluorescent particles-D-dimer antibody conjugates and rabbit IgG conjugate), nitrocellulose (NC) membrane (test area (T) is coated with D-dimer monoclonal antibody, quality control area (C) is coated with goat anti-rabbit IgG), absorbent paper and PVC plate）.

Diagram is as follows:



Schematic diagram of test strip

(2) Magcard: loaded with calibration curve information for reagents with this batch.

(3) Whole blood buffer: the main component is phosphate buffer (PBS).

(4) Equipment: applicable to FA50/FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

6. Accessories Required But Not Provided

(1) Pipettes and pipette tips: 100 μL.

(2) Timer.

7. Special Storage & Transport Conditions

(1) The test kit is kept in sealed aluminum foil bag and can be stored at 2-30℃. The unopened pack is valid for 18 months from the date of manufactured. Once opened, it is valid for 1 hour.

(2) Transport at 2-30℃.

8. Sample Requirements

(1) The optimal sample is fresh non-hemolyzed plasma or whole blood. Recommended to use venous blood, results of other body fluids and samples may not be accurate.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep plasma refrigerated at 2-8℃ for not more than 1 day and frozen below -18℃ for not more than 1 month. Whole blood sample should not be frozen, or stored at 2-8℃ for more than 1 day.

(3) Bring the samples to room temperature before the test. Frozen samples need to be melted completely, re-warmed and mixed before use, avoid repeated freezing and thawing.

(4) Human plasma is recommended to be used for testing. Sodium citrate is recommended to be used as the anticoagulant.

9. Test Procedure

Carefully read the reagent instruction before using the test kit and strictly follow the instruction to ensure reliable results. Bring all reagents to room temperature (18-25℃) before use.

(1) Startup: Click “STD Mode” in the main menu to enter the measurement interface, click “Item” to select the desired test item and click “Type” to select the sample type.

(2) Click “Lot No.” to enter the card swiping interface, place magcard of the corresponding item to the magnetic induction zone, when hearing a “di” sound, the magcard is swiped successfully. Make sure the magcard and the test card are from the same batch (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.).

(3) Sampling:

a) Plasma: Take 100μL plasma, drop vertically to the sample port of the test card directly and start timing.

b) Whole blood: Take 100μL whole blood, drop vertically to the sample port on the test card directly, then add one drop of whole blood buffer to the sample port and start timing.

(4) Insert it into the analyzer’s test slot (the sample port end toward the inside). Click “Measure”, the instrument will automatically detect and print out the results after 15 minutes (If using “Fast Mode”, keep it for 15 minutes and quickly insert into the analyzer’s test slot).

10. Reference Interval

Reference range: <0.5mg/ L.

11. Explanation for Test Results

(1) When fluorescent strips the control area (C) appears on, the analyzer will automatically detect the fluorescence and analyze the test card, and then provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer cannot detect the fluorescence and alarm automatically, indicating that the operation is incorrect or the test card is damaged, in this case, carefully read the instructions again and re-test with a new test card. If the problem still exists, immediately stop using products of this batch and contact your

supplier.

(3) When the sample test results are greater than 10mg/L, the instrument displays > 10mg/L, when the test results are less than 0.1mg/L, the instrument displays < 0.1mg/L. If the result exceeds the linear range, the instrument displays greater than the linear upper limit or less than the linear low limit. The former can be diluted with saline water by an integer multiple before testing, multiply the result by the dilution ratio.

(4) This test kit does not produce Hook Effect within 50mg/L.

12. Detection Limit

(1) This test kit is for *in vitro* diagnostic use only.

(2) Sensitivity of this method is 0.1mg/L, not recommended for the early diagnosis of indications.

(3) Diagnosis and treatment can not only rely on this test result, it should be taken into account the patients' clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the detected patient population.

13. Interfering Substance

Hemoglobin, bilirubin, cholesterol, triglycerides, HAMA antibody and rheumatoid factor in samples can interfere with the test results, the maximum allowable concentrations of hemoglobin is 5g/L, bilirubin is 2mg/mL, cholesterol is 15mg/mL, triglycerides is 30mg/mL, HAMA antibody is 40ng/mL, rheumatoid factor is 525IU/mL.

14. Product Performance Indicators

(1) Analysis sensitivity: ≤ 0.1mg/ L.

(2) Linearity range: 0.2-10mg/ L (Linear correlation coefficient: r ≥ 0.990).

(3) Measurement precision: Within run repeatability: CV ≤ 10%,

Between run repeatability: CV ≤ 15%.

(4) Accuracy: -10%≤ Bias% ≤+10%.

(5) The Interference test: -10%≤ Bias% ≤+10%.

15. Precautions

(1) Once opened, use the test cards as soon as possible, otherwise it may cause moisture. Do not re-use the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wear gloves when handling sample or reagent for disinfection.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

16. Explanation of graphic symbol

	Consult Instructions for use		Temperature Limitation
LOT	Lot No.		Expiry Date
IVD	*In Vitro* Diagnostic Reagent	CE	CONFORMITE EUROPEENNE
	Production Date		Biohazard
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Dark dry preservation
EC REP	Authorized representative in the European community	REF	Catalogue number

17. Reference

(1) Evaluation of a quantitative D-Dimer latex immunoassay for acute pulmonary embolism diagnosed by computed tomographic angiography. David A, Feb 2007, 5: 556-60.

18. Metrological Traceability

The kit was traced to the D-Dimer Test Kit, produced by Stago Co., Ltd.

19. Help Information

If you need help please contact after sales.

20. Manufacturer

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

Web: www.genrui-bio.com

21. Instruments & Applications

Genrui's Immunofluorescence products, designed to work in automated lab environment, which are compatible with the FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for you particular instrument, please visit the instrument section of our website.

IVD CE EC REP

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