Finecare™ D-Dimer Rapid Quantitative Test

Catalog No. W211

INTENDED USE

The Finecare™ D-Dimer Rapid Quantitative Test along with Finecare™ FIA Meters (Model No.: FS-112, FS-113, FS-114, FS-205) is a fluorescence immunoassay for quantitative measurement of D-Dimer in human whole blood and plasma. The test is used as an aid in the diagnosis of thrombosis and thrombotic diseases.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

Fibrinogen, the main protein of the blood coagulation system, becomes activated into Fibrin by Thrombin and Fibrin polymerization during the process of blood coagulation. Plasmin then digests the Fibrin clot and Fibrin degradation products of different molecular weights are released into the bloodstream. D-Dimer is the main and smallest product of Fibrin degradation, comprising of 111~197 amino acids in α chain, 134~461 amino acids in the β chain, and 88~406 amino acids in the γ chain of Fibrinogen. All chains are cross-linked by disulfide bonds and the dimeric structure is held by two isopeptide bonds between C-terminal parts of γ chains. D-Dimer fragments can be measured easily in plasma and whole blood, and the presence or absence of D-Dimer may be useful in the diagnostic evaluation of venous thromboembolism.

PRINCIPLE

The Finecare™ D-Dimer Rapid Quantitative Test is based on fluorescence immunoassay technology, specifically the sandwich immunodetection method. Add the specimen to detection buffer and mix well. When the sample mixture is added into the sample well of the Test Cartridge, the fluorescence-labeled detector antibody on the conjugate pad will bind to antigen in specimen and form immune complexes. As the sample mixture migrates on the nitrocellulose membrane of test strip by capillary action, the complexes of detector antibody and antigen are captured to the other antibody that has been immobilized on membrane. Thus the more antigen in specimen, the more complexes are accumulated on membrane.

Signal intensity of detector D-Dimer antibodies reflect the amount of antigens and Finecare ™ FIA Meters show D-Dimer concentrations in blood specimen. The default results unit of Finecare™ D-Dimer Rapid Quantitative Test is displayed as XXX.XX mg/L from Finecare™ FIA Meters.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date printed on the package.
4. Do not use Test Cartridge if its Lot No. does not match with Lot No. of ID Chip that is inserted into the Finecare™ FIA Meters.
5. The desiccant is for storage purpose only, is not used in the test procedures.
6. The Finecare™ D-Dimer Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meters. Tests should be applied by well-trained healthcare professionals, and conducted in laboratories, GP offices, clinics, pharmacies, etc.
7. The Test Cartridge should remain in its original sealed pouch until ready to use. Do not use the Test Cartridge if the pouch is punctured or not well sealed. Discard after single use.
8. There is a blue line on the test membrane, it will disappear after sample adding. This indicates that Test Cartridge has been used. Do not reuse the Test Cartridge.
9. Do not use damaged or stained materials provided in the test kit.
10. The test kit and instrument should be used away from vibration and magnetic field. During normal usage, the instrument may introduce minute vibration, which should be regarded normal.
11. The Pipette Tips and Detection Buffer Tubes should be used for one specimen only. Discard after single use.
12. Do not use whole blood specimen when hemolysis or blood clot appears.
13. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
14. The blood specimens and used materials, such as Test Cartridges, Detection Buffer Tubes and Pipette Tips, are potentially infectious. Proper safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed for biological hazard materials.
15. The Finecare™ D-Dimer Rapid Quantitative Test should not be used as absolute evidence for acute myocardial infarction. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
16. If you have any questions or need help, please contact the local distributor to solve problems timely.
17. Notice to the users: Any serious incident that has occurred in relation to the Finecare™ D-Dimer Rapid Quantitative Test shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

MATERIAL

Material Provided

1. 25 individual sealed pouches, each containing:
   - 1 Test Cartridge
   - 1 Desiccant Pouch
2. 1 ID Chip
3. 1 Leaflet with Instructions For Use
4. 25 Pipette Tips
5. 25 Detection Buffer Tubes

Material Required But Not Provided

Function	Material Name	Note
Test instrument	Finecare™ FIA Meter	Model No.: FS-112
	Finecare™ FIA Meter Plus	Model No.: FS-113
	Finecare™ FIA Meter II Plus SE	Model No.: FS-114
	Finecare™ FIA Meter III Plus	Model No.: FS-205
Quality control	Finecare™ D-Dimer Control	Catalog No. W812
Separate the plasma	Centrifuge	For plasma specimen only
Blood sampling	Vacuum blood collection tube	For venous whole blood or plasma specimen
	Transfer pipette sets	100 µL specification
	Medical gloves	Well-fitting
Timekeeping for specific test step	Timer	/

STORAGE AND STABILITY

1. Store test kit for 24 months at 4 ~ 30°C.
2. Do not remove the Test Cartridge from the pouch until ready to use. The Test Cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

For Venous Whole Blood:
Collect blood with a suitable vacuum blood collection tube (containing EDTA, Heparin or Sodium Citrate). It is recommended that specimens should be tested immediately. If the specimen is not tested within 8 hours after collecting, it can be stored at 2 ~ 8 °C for 2 days.

For Plasma:
Separate the plasma from blood as soon as possible to avoid hemolysis. It is recommended that specimens should be tested immediately. If the specimen is not tested within 8 hours after collecting, it can be stored at 2 ~ 8 °C up to 7 days. For long-term storage, it can be kept below -20°C up to 12 months.

Note: *Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.*

TEST PROCEDURE

For complete information and operating procedures, please refer to Finecare™ FIA Meters Operation Manual. Bring all materials to room temperature before use. Tests should be performed at room temperature.

Step 1: Preparation
Ensure that the lot number of Test Cartridge matches the lot number of ID Chip as well as the Buffers. Insert ID Chip into Finecare™ FIA Meters. Be aware not to touch the insertion tip of the ID chip.

Step 2: Sampling
Draw 15 µL whole blood or 10 µL plasma with a transfer pipette and add it to the Detection Buffer Tube.

Step 3: Mixing
Close the lid of Detection Buffer Tube and mix the sample mixture thoroughly by shaking it about 10 times.

Step 4: Loading
Draw 75 µL sample mixture and load it into the sample well of Test Cartridge.

Step5: Testing

There are two test modes for Finecare™ FIA Meters, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA Meters for details.

a) **For Standard Test Mode:** For FS-112, FS-113, FS-114, insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well. Press "Test" to start test (Apply to FS-112). Press "Start Test" to start test (Apply to FS-113, FS-114). For FS-205, press "Test" then input the specimen types, press "Start" then insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well to start test. The test result will be displayed on the screen after 5 minutes.

b) **For Quick Test Mode:** Set the timer and count down right after adding sample mixture into the sample well and leave the Test Cartridge at room temperature for 15 minutes. Then immediately insert the Test Cartridge into the holder of Finecare™ FIA Meters. Press "Test" to start test (Apply to FS-112). Press "Start Test" to start test (Apply to FS-113, FS-114). The instrument will automatically start to scan the Test Cartridge immediately. Read the results on the display screen of Finecare™ FIA Meters.

Step 6: Printing

If needed, test result can be printed by clicking "Print".

INTERPRETATION OF RESULTS

The Finecare™ FIA Meters calculates D-Dimer Rapid Quantitative Test results automatically and displays the exact concentrations of D-Dimer on the screen as form of XXX.XX mg/L, while the unit of Finecare™ D-Dimer Rapid Quantitative Test results is XXX.XX mg/L (FEU).

Concentration	Clinical Reference
0 ~ 0.5 mg/L	Coagulation and Fibrinolysis in steady state
＞0.5 mg/L	Secondary fibrinolysis function hyperfunction occur, thrombolytic therapy is recommended

Note: *Each laboratory should establish a reference interval that is representative of the population to be evaluated. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.*

Invalid: When the Finecare™ FIA Meters flag that no sample or sample volume is insufficient, it indicates an invalid test (the signal on the scan strip is below the preset minimum signal). Please retest.

QUALITY CONTROL

Each Finecare™ D-Dimer Rapid Quantitative Test contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cartridge was inserted and read properly by Finecare™ FIA Meters. An invalid result from the internal control causes an error message on Finecare™ FIA Meters indicating that the test should be repeated.

Finecare™ D-Dimer Control (Catalog No. W812) is recommended for Finecare™ D-Dimer Rapid Quantitative Test and can be used in the following cases:

- When a box of a new lot is opened;
- In case the Finecare™ FIA Meters or Finecare™ D-Dimer Rapid Quantitative Test are not working properly;
- In case the result and the symptoms are not consistent or if there are doubts about their accuracy.

Note: *Please refer to the Instructions For Use of Finecare™ D-Dimer Control for detailed operation.*

TRACEABILITY

Finecare™ D-Dimer Rapid Quantitative Test has been standardized against the internal reference material.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood and plasma specimen only.
2. This test has been verified for healthcare professionals use. Refer to point 6 of the PRECAUTIONS in this instruction for requirements of training and qualifications required by the users. Note that this test is not used for self-testing.
3. The results of Finecare™ D-Dimer Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If the test results do not agree with the clinical evaluation, additional tests should be performed.
4. The false positive results include non-specific adhesion of some components in specimen that have similar epitopes to bind captured and detector antibodies.
5. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of D-Dimer, resulting in degradation with time or temperature, such that they become no longer recognizable by antibodies.
6. Whole blood using anticoagulants other than EDTA, Heparin or Sodium Citrate has not been evaluated in Finecare™ D-Dimer Rapid Quantitative Test and thus should not be used.
7. Other factors may interfere with Finecare™ D-Dimer Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparative study tested 94 clinical samples in using Finecare™ D-Dimer Rapid Quantitative Test and the SIEMENS D-Dimer assay. The Correlation Coefficient (r^2) was 0.9343.

Measuring Range and Detection Capability

- Measuring Range: 0.1~10 mg/L
- Limit of Detection (LoD): 0.1 mg/L

Precision

Intra-Lot Precision:

Within-lot precision has been determined by using D-Dimer precision controls with one lot of test, the CV was ≤ 15%.

Inter-Lot Precision:

Between-lot precision has been determined by using D-Dimer precision controls with three lots of tests, the CV was ≤ 15%.

Linearity

A serial concentration of D-Dimer linear controls were each tested for three times, the Correlation Coefficient (r) was ≥ 0.9900.

Analytical Specificity

The following substances do not interfere with the test results at the indicated concentrations:

Substance	Concentration
bilirubin	≤ 0.2 mg/mL
cholesterol	≤ 15 mg/mL
triglyceride	≤ 30 mg/mL

BIBLIOGRAPHY OF SUGGESTED READING

1. Naess H, Waje‐Andreassen U. Review of long‐term mortality and vascular morbidity amongst young adults with cerebral infarction[J]. European journal of neurology, 2010, 17(1): 17-22.
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3. Heit J A. Venous thromboembolism: disease burden, outcomes and risk factors[J]. Journal of Thrombosis and Haemostasis, 2005, 3(8): 1611-1617.
4. Meng R, Ji X, Li B, et al. Dynamical levels of plasma F1+ 2 and D-dimer in patients with acute cerebral infarction during intravenous urokinase thrombolysis[J]. Neurological research, 2009, 31(4): 367-370.
5. Lowe GD. How to search for the role and prevalence of defective fibrinolytic states as triggers of myocardial infarction? The haemostasis epidemiologist's view[J]. Italian Heart Journal Official Journal of the Italian Federation of Cardiology, 2001, 2(9):656-657.

INDEX OF SYMBOLS

Consult instructions for use	Contains sufficient for <n> tests	Date of manufacture
In vitro diagnostic medical device	Use-by date	Do not re-use
Temperature limit	Batch code	Catalogue number
Keep away from sunlight	Keep dry	Manufacturer
CE marking	Authorized representative in the European Community/ European Union	

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Huangpu District,
510663, Guangzhou, P.R.China
Tel: (+86) 400-830-8768
Email: Finecare@wondfo.com.cn
Website: en.wondfo.com

Qarad BV
Cipalstraat 3
2440 Geel
Belgium

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Wondfo®	文件编号 Document No.：IFU-W211(1)-01-01	版本Version: 01	项目名称：Leaflet with Instructions For Use	
	尺寸(长*宽*高)：350x125mm	颜色: K100 K60 K20	材质：双胶	工艺：/
	折页方式：对折再对折	修改内容：□文字 □颜色 □尺寸 □工艺 □材质 □其他 √无 修改内容截图		
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