Finecare™

# D-Dimer Rapid Quantitative Test

Catalog No. W211

## INTENDED USE

The Finecare™ D-Dimer Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of D-Dimer in human whole blood or plasma.
-Fluorescence immunoassay
-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 the 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.
Normal Reference Value:

| Concentrations | Clinical Reference |
|---|---|
| ＜0.5 mg/L | Coagulation and Fibrilolysis in steady state |
| ≥0.5 mg/L | Secondary fibrinolysis function hyperfunction occur, thrombolytic therapy is recommended |

## PRINCIPLE

The Finecare™ D-Dimer Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ D-Dimer Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the test, the fluorescence-labeled detector anti-D-Dimer on the membrane binds to D-Dimer antigen in whole blood/plasma specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and D-Dimer are captured by D-Dimer antibody that has been immobilized on test strip. Thus the more D-Dimer antigen is in whole blood/plasma specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of D-Dimer captured and Finecare™ FIA Meter shows D-Dimer concentrations in whole blood/plasma specimen. The default results unit of Finecare™ D-Dimer Rapid Quantitative Testis displayed as XXXmg/L from Finecare™ FIA Meter. The working range and the detection limit of the D-Dimer Test system are 0.1～10mg/L and 0.1mg/L, respectively.

## 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.
4. Do not use Test Cartridge if its lot # does not match with ID Chip # that is inserted onto the equipment.
5. The Finecare™ D-Dimer Rapid Test kit is only operational in the Finecare™ FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector buffer vials should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

## MATERIAL

### Material Provided

1. Test Cartridge 25
2. Test Cartridge ID Chip 1
3. Detector buffer 25
4. Leaflet of instruction

### Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (10μL100μL size)
3. Specimen Collection Containers
4. Alcohol Pads
5. Centrifuge (for Plasma only)
6. Timer

## STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 24 months.
2. Store Finecare™ D-Dimer Rapid Quantitative Test Cartridge at 4～30℃ in its sealed pouch up to the expiration date.
3. If stored in a refrigerator, allow a minimum of 30 minutes for the Test Cartridge to reach room temperature while it is in the sealed pouch.
4. Do not remove the device from the pouch until ready to use. The Test Cartridge should be used immediately once opened.

## SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either plasma or whole blood, do not use serum as specimen.

**For Whole Blood Collected by Venipuncture:**
1. Following standard phlebotomy procedure to collect a venipuncture whole blood specimen with a blood collection tube consisting suitable anticoagulant (Sodium citrate recommended)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3. It's not suitable to test the whole blood samples which have been stored at 2℃～8℃ for more than 2 days.

**For Plasma:**
1. Following standard phlebotomy procedure to collect a venipuncture whole blood specimen with a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant(Sodium citrate recommended).
2. Separate the plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 2 days. For long-term storage, specimens should be kept below -20℃.

## TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should beoperated in room temperature.
**Step1: Preparation**
Check/insert ID Chip into the instrument.
**Step2: Sampling**
Draw 15μL of whole blood or 10μL plasma with a transfer pipette and add it to the buffer tube.
**Step3: Mixing**
Mix well the specimen with buffer for 1minute by tapping or inverting the tube.
**Step4: Loading**
Take 75μL of sample mixture and load it onto the sample well of the Test Cartridge.
**Step5:Testing**
1. Finecare™ FIA meter:
Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. 5 minutes later, the result will show in the display and print out when click “Print”.
Quick test: Put the Test Cartridge on the operation platform. 5 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. The result will show in the display and print out when click “Print”.

2. Finecare™ multi-channel FIA meter:
Insert the Test Cartridge onto the Test Cartridge Holder. 5 minutes later, the result will show in the display and print out when click “Print”.

Please refer to the **Operationin** user manual of Finecare™ FIA Meter for details.

## QUALITY CONTROL

Each Finecare™ D-Dimer Rapid Quantitative Test Cartridge 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 Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

## LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, and plasma specimen only.
2. The results of Finecare™ D-Dimer Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If D-Dimer test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated D-Dimer that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
5. 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 comparison study of 202 human blood samples demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ D-Dimer Rapid Quantitative Test and the SYSMEX D-Dimer Test for 202 clinical samples, the Correlation Coefficient is 0.987

### Assay Range and Detection Limit

- **Assay Range**: 0.1～10 mg/L
- **Detection Limit:** 0.1 mg/L

### Linearity

A serial concentration of D-Dimer controls at 0.2mg/L, 0.5mg/L,1.0mg/L, 2.0mg/L, 5.0mg/L, 10mg/L were each tested for three times, the Correlation Coefficient (R) is ≥0.98.

### Precision

**Intra-Lot Precision**
Within-run precision has been determined by using 10 replicates of specimen of 1.0mg/L D-Dimer. C.V. is ≤15%.

**Inter-Lot Precision**
Between-run precision has been determined by using 3 replicates for each of three lots using D-Dimerspecimen levels at 1.0mg/L. C.V. is≤15%.

## BIBLIOGRAPHY OF SUGGESTED READING


1. NaessH,Waje-AndreassenU.Review of long-term mortality and vascular morbidity amongst young adults with cerebral infarction. European Journal of Neurology . 2010
2. Zhu YC,CuiLY,HuaBL,etal.Correlation between fibrinogen leveland cerebral infarction. Chinese Medical Sciences Journal .2006
3. JA Heit.Venous thromboembolism: disease burden, outcomes and risk factors. Journal of Thrombosis and Haemostasis . 2005
4. MengR,JiX,LiB,etal.Dynamical levels of plasma F (1+2)and D-dimer in patients with acute cerebral infarction during intrave-nous urokinase thrombolysis. Neurological Research .2009
5. Lowe GD.How to search for the role and prevalence of defective fibrinolytic states as triggers of myocardial infarction? The haemostasis epidemiologists view. Italian Heart Journal . 2001


| | | | |
|---|---|---|---|
| IVD In Vitro Diagnostic Use | See Instruction for Use | Expiry Date | |
| Tests per Kit | Manufacturing Date | Keep Dry | |
| LOT Batch Number | EC REP Authorized Representative | Keep away from Sunlight | |
| 4℃ 30℃ Store between 4～30℃ | | | |


Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District,510663,
Guangzhou, P.R.China

EC REP
Qarad b.v.b.a.
Cipalstraat 3
B-2440 Geel, Belgium


Version: 01/04/2015