

INTENDED USE

The Finecare™ cTn I 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 cardiac troponin I (cTn I) in human whole blood, serum and plasma. This test is used as an aid in the diagnosis of acute myocardial infarction (AMI).

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

SUMMARY

Cardiac Troponin I (cTn I) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with Troponin T (Tn T) and Troponin C (Tn C), Tn I forms a Troponin complex in heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTn I has an additional amino acid residues on its N-terminal that are not exist on the skeletal forms thus making cTn I a specific marker to indicate cardiac infraction. cTn I is released rapidly into blood after the onset of acute myocardial infarction (AMI). It shares a similar released pattern with CK-MB (4~6 hours after the onset of AMI). However, CK-MB level returns to normal after 36~48 hours, while the level of cTn I remains elevated for up to 6~10 days. The level of cTn I is very low in normal healthy people, and not detected in patients with skeletal muscle injury. Therefore, cTn I is a specific marker for diagnosis of AMI.

PRINCIPLE

The Finecare™ cTn I 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 is in specimen, the more complexes are accumulated on membrane.

Signal intensity of detector cTn I antibodies reflect the amount of antigens and

Finecare™ FIA Meters show cTn I concentrations in blood specimen. The default results unit of Finecare™ cTn I Rapid Quantitative Test is displayed as XXX.XX ng/mL 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™ cTn I 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™ cTn I 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™ cTn I 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™ cTn I Control	Catalog No. W808
	Finecare™ cTnI/CK-MB/Myo	Catalog No. W817
Separate the serum/plasm	Centrifuge	For serum or plasma specimen only
Blood sampling	Vacuum blood collection tube	For venous whole blood, serum 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). It is recommended that specimens should be tested immediately. If the specimen is not tested within 8 hours, it can be stored at 2 ~ 8 °C for 2 days.

For Serum or Plasma:

Separate the serum or 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, it can be stored at 2 ~ 8 °C for 7 days. For long-term storage, it should 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 75 µL serum, plasma or whole blood 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 15 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 cTn I test results automatically and displays the exact concentrations of cTn I on the screen as form of XXX.XX ng/mL.

Concentration	Clinical Reference
0 ~ 0.3 ng/mL	Normal Levels
> 0.3 ng/mL	Indicating risk of acute myocardial infarction. The levels may rise in 3~6 hours and reach the peak levels in 14~20 hours. The concentrations will return to normal levels in 5~7 days. Other cardiac markers assay may be necessary when chest pain occurs.

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™ cTn I 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™ cTn I Control (Catalog No. W808) or Finecare™ cTnI/CK-MB/Myo Multi-Control (Catalog No. W817) is recommended for Finecare™ cTn I 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™ cTn I 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™ cTn I Control or Finecare™ cTnI/CK-MB/Myo Multi-Control for detailed operation.

TRACEABILITY

Finecare™ cTn I 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, serum 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™ cTn I 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 cTn I, resulting in degradation with time or temperature, such that they become no longer recognizable by antibodies.

6. Whole blood using anticoagulants other than EDTA or heparin has not been evaluated in Finecare™ cTn I Rapid Quantitative Test and thus should not be used.
7. Other factors may interfere with Finecare™ cTn I 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 95 clinical samples in using Finecare™ cTn I Rapid Quantitative Test and the Roche Elecsys Troponin I assay. The Correlation Coefficient (r^2) was 0.972.

Measuring Range and Detection Capability

- Measuring Range: 0.1 ~ 50 ng/mL
- Limit of Detection (LoD): 0.1 ng/mL

Precision

Intra-Lot Precision:
Within-lot precision has been determined by using cTn I precision controls with one lot of test, the CV was $\leq 15\%$.

Inter-Lot Precision:
Between-lot precision has been determined by using cTn I precision controls with three lots of tests, the CV was $\leq 15\%$.

Linearity

A serial concentration of cTn I 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
cholesterol	≤ 60 mg/mL
triglyceride	≤ 40 mg/mL
bilirubin	≤ 2 mg/mL

BIBLIOGRAPHY OF SUGGESTED READING

1. Bhayana V, Henderson A R. Biochemical markers of myocardial damage[J]. Clinical biochemistry, 1995, 28(1): 1-29.
2. Wilkinson J M, Grand R J A. Comparison of amino acid sequence of troponin I from different striated muscles[J]. Nature, 1978, 271(5640): 31-35.
3. Wade R, Eddy R, Shows T B, et al. cDNA sequence, tissue-specific expression, and chromosomal mapping of the human slow-twitch skeletal muscle isoform of troponin I[J]. Genomics, 1990, 7(3): 346-357.
4. Cummins B, Auckland M L, Cummins P. Cardiac-specific troponin-I radioimmunoassay in the diagnosis of acute myocardial infarction[J]. American heart journal, 1987, 113(6): 1333-1344.
5. Fred S. Apple, Cardiac Troponin I. Cardiac Markers Humana Press Inc., Totowa, NJ 1998, pg. 229-243.
6. Bodor G S, Porter S, Landt Y, et al. Development of monoclonal antibodies for an assay of cardiac troponin-I and preliminary results in suspected cases of myocardial infarction[J]. Clinical chemistry, 1992, 38(11): 2203-2214.

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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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

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