Finecare™ cTn I Rapid Quantitative Test

Catalog No. W203

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 to 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, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by 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. The test will be applied on a routine basis and not in emergency situations.
17. If you have any questions or need help, please contact the local distributor to solve problems timely.
18. 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:
   - Test Cartridge
   - Desiccant Pouch
2. ID Chip
3. Leaflet with Instructions For Use
4. 25 Pipette Tips (for 100 µL transfer pipette set)
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/plasma	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 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 t
Heparin). It is recommended that specimens should be
the specimen is not tested within 8 hours after collecting
8 °C for 2 days.

For Serum or Plasma:
Separate the serum or plasma from blood as soon
hemolysis. It is recommended that specimens should be
the specimen is not tested within 8 hours after collecting
8 °C for 7 days. For long-term storage, it can be kept
months.

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

TEST PROCEDURE

For complete information and operating procedures, ple
FIA Meters Operation Manual. Bring all materials to roo
use. Tests should be performed at room temperature.

Step 1: Preparation
Ensure that the lot number of Test Cartridge matches th
as well as the Buffers. Insert ID Chip into Finecare™ FI
to touch the insertion tip of the ID chip.

Step 2: Sampling
Draw 75 µL serum, plasma or whole blood with a transf
the Detection Buffer Tube.

Step 3: Mixing
Close the lid of Detection Buffer Tube and mix the sampl
shaking it about 10 times.

Step 4: Loading
Draw 75 µL sample mixture and load it into the sample w

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 "Start Test" to start test. 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 "Start Test" to start testing (Apply to FS-112, 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 reminds 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

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, 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 was tested for 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 ≤ 15%.

Inter-Lot Precision:
Between-lot precision has been determined by using cTn I precision controls with three lots of tests, the CV was ≤ 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	≤ 60mg/mL
triglyceride	≤ 40mg/mL
bilirubin	≤ 2 mg/mL

BIBLIOGRAPHY OF SUGGESTED READING

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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 se expression, and chromosomal mapping of the hum muscle isoform of troponin I[J]. Genomics, 1990, 7(3
4. Cummins B, Auckland M L, Cummins P. Car radioimmunoassay in the diagnosis of acute m American heart journal, 1987, 113(6): 1333-1344.
5. Fred S. Apple, Cardiac Troponin I. Cardiac Marke Totowa, NJ 1998, pg. 229-243.
6. Bodor G S, Porter S, Landt Y, et al. Development o for an assay of cardiac troponin-I and preliminary re of myocardial infarction[J]. Clinical chemistry, 1992

INDEX OF SYMBOLS

See Instructions for Use		Tests per kit	
IVD	For *in vitro* diagnostic use only	Expiration date	
4°C 25°C	Store between 4 ~ 30°C	LOT	Batch number
Keep away from sunlight		Keep dry	
Manufacturer			

Guangzhou Wondfo Biotech Co., Ltd.
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