Finecare™ cTn I Rapid Quantitative Test

Catalog No. W203

INTENDED USE

The Finecare™ cTn I Rapid Quantitative Test along with Finecare™ FIA Meter is intended for vitro quantitative determination of cardiac troponin I (cTnI) in human whole blood, serum or plasma.
- Fluorescence immunoassay
- Diagnosis of myocardial infarction.

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

SUMMARY

Cardiac Troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with Troponin T (TnT) and Troponin C (TnC), TnI forms a Troponin complex in heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. cTnI is released rapidly into blood after the onset of acute myocardial infarction (AMI). It releases 4-6 hours after AMI and remains elevated for up to 6-10 days. The level of cTnI is very low in normal healthy people, and not detected in patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of AMI.

Normal reference values: < 0.3 ng/ml
Notice: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE

The Finecare™ cTn I Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ cTn I Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the test cartridge, the fluorescence-labeled detector cTnI antibody binds to cTnI antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and cTnI are captured to cTnI antibody that has been immobilized on test strip. Thus the more cTnI antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of cTnI captured and Finecare™ FIA Meter shows cTnI concentrations in blood specimen. The default results unit of Finecare™ cTn I Rapid Quantitative Test is displayed as XXX ng/ml from Finecare™ FIA Meter. The working range and the detection limit of the cTnI Test system are 0.1~50 ng/ml and 0.1 ng/ml.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Don't use Test Cartridge if its lot # does not match with ID Chip # that is inserted onto the equipment.
5. The Finecare™ cTn I Rapid Quantitative 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 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 handed and disposaled in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

MATERIAL

Material Provided

Test Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25
Leaflet with instructions for use	

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (100μL size)
3. Specimen Collection Containers
4. Alcohol Pads
5. Centrifuge (for Plasma/serum 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™ cTn I Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 24 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.

For Whole Blood Collected by Venipuncture:
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA 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 Serum and Plasma:
1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. 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 3 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 be operated in room temperature.

Step1:Preparation
Before testing, activate "use" in setting then save it.
Check/insert ID Chip onto the equipment.

Step2: Sampling
Draw 75μL of whole blood, serum or plasma with a transfer pipette and add it to the buffer tube.

Step3: Mixing
Mix well the specimen with buffer for 1 minute 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". 15 minutes later, choose the sample type, then the result will show in the display and print out when click "Print".
Quick test: Put the Test Cartridge on the operation platform. 15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Test". Choose the sample type, then 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. 15 minutes later, choose the sample type, then the result will show in the display and print out when click "Print".

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

QUALITY CONTROL

Each Finecare™ cTn I 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, serum, plasma specimen only.
2. The results of Finecare™ cTn I Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If cTnI 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 cTnI that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
5. 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

Test cartridges from same batch were tested with cTnI control of 0.1ng/mL, 5.0 ng/mL and 10ng/mL, mean and Bias% were calculated. When the concentration of cTnI<1.0ng/ml, Bias% was within 15%; When the concentration of cTnI≥ 1.0ng/ml, Bias% was within 10%

Assay Range and Detection Limit

- **Assay Range**: 0.1~50 ng/ml
- **Detection Limit:** 0.1ng/ml

Linearity

A serial concentration of cTnI controls at 0.1ng/mL, 0.5ng/mL and 1.5ng/mL, 5.0 ng/mL, 15ng/mL, 25ng/mL were tested, the Correlation Coefficient (R) is ≥ 0.995

Precision

Intra-Lot Precision

Within-run precision has been determined by using 10 replicates from same batch to test with 0.3ng/mL cTnI control. C.V. is ≤ 10%.

Inter-Lot Precision

Between-run precision has been determined by using 3 replicates from random 3 continuous batches to test with 0.3ng/mL cTnI control. C.V. is ≤ 15%.

BIBLIOGRAPHY OF SUGGESTED READING

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3. Wade R, Eddy R, Shows TB, Kedes L. cDNA Sequences, Tissue-Specific Expression and Chromosomal Mapping of the Human Slow-Twitch Muscle Isoform of Troponin I. Genomics 1990; 7:346-357.
4. Cummins B, Auckland ML, Cummins P. Cardiac-specific troponin-I radioimmunoassay in the diagnosis of acute myocardial infarction. Am Heart J 1987; 113:1333-1344.
5. Fred S. Apple, Cardiac Troponin I. Cardiac Markers Humana Press Inc., Totowa, NJ 1998, pg. 229-243.
6. Bodor GS, Porter S, Landt Y, Landenson JH. Development of Monoclonal Antibodies for an Assay of Cardiac Troponin-I and Preliminary Results in Suspected Cases of Myocardial Infarction. Clin Chem 1992; 38(11):2203-2214.

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

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