Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test

Catalog No. 216

INTENDED USE

The Finecare™ cTnI/CK-MB/Myoglobin Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of cardiac troponin I (cTnI), MB Isoenzyme of Creatine Kinase (CK-MB) and Myoglobin in human whole blood, serum or plasma.
-Fluorescence immunoassay
-Diagnosis for 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. The human cTnI has a additional amino acid residues on its N-terminal that are not exist on the skeletal forms thus making cTnI a specific marker for indicating cardiac infraction. cTnI is released rapidly into blood after the onset of acute myocardial infarction (AMI).
MB Isoenzyme of Creatine Kinase (CK-MB) is an 84,000 molecular weight enzyme that represents a significant fraction of the creatine kinase present in myocardial tissue. CK-MB is also present in a variety of other tissues, albeit at much lower levels. The appearance of CK-MB in serum, in the absence of major muscle trauma, may be indicative of cardiac damage and thus, myocardial infarction. Furthermore, the temporal pattern of CK-MB release following an infarction is important. Thus, a CK-MB value which shows no significant change over time is not confirmatory of myocardial infarction. Assessment of CK-MB has been reported to be useful in determining the efficacy of reperfusion after acute coronary thrombosis.
Myoglobin(Myo) is a tightly folded, globular heme-protein located in the cytoplasm of both skeletal and cardiac muscle cells. Its function is to store and supply oxygen to muscle cells serum levels of myoglobin have been shown to elevate under the following conditions: skeletal muscle damage, skeletal muscle or neuromuscular disorders, cardiac bypass surgery, renal failure, strenuous exercise, etc. Therefore, the utilization of an increase in serum myoglobin has to be used in conjunction with other aspects of the patient assessment in order to aid in the diagnosis of an Acute Myocardial Infarction (AMI).

Normal Reference Value:

	Concentrations	Clinical Reference
cTnI	＜0.30ng/mL	Normal Levels
	≥0.30ng/mL	Indicating risk of acute myocardial infarction.
CK-MB	0.0～5.00ng/mL	Did not suffer from myocardial infarction
	＞5.00ng/mL	Probably suffered from myocardial infarction.
Myo	0.0~58.0ng/mL	Normal Levels
	＞58.0ng/mL	Indicating risk of acute myocardial infarction

PRINCIPLE

The cTnI/CK-MB/Myo Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ cTnI/CK-MB/Myo Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the test, the fluorescence-labeled detector anti-cTnI/CK-MB/Myo antibody on the membrane binds to cTnI/CK-MB/Myo 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/CK-MB/Myo are captured to anti-cTnI/CK-MB/Myo antibody that has been immobilized on test strip.Thus the more cTnI/CK-MB/Myo antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of cTnI/CK-MB/Myo captured and Finecare™ FIA Meter shows cTnI/CK-MB/Myo concentrations in blood specimen. The default results unit of Finecare™ cTnI/CK-MB/Myo Rapid Test is displayed as XXXng/mL from Finecare™ FIA Meter.

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 instrument.
5. The Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meter. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.
6. 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.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may introduce minute vibration, which should be regarded normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens. The pipette tips and detector buffer vials should be used for one specimen only. Discard after single use.
9. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
10. Blood specimens, used test cartridges, pipette tips and detector buffer vials are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
11. The Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test should not be used as absolute evidence for myocardial infarction. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test will be applied on a routine basis and not in emergency situations.

MATERIAL

Material Provided

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

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™ cTnI/CK-MB/Myo Rapid Quantitative Test Cartridge at 4～30℃ in its sealed pouch up to the expiration date.
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. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
2. Separate the serum/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 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 into 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™ cTnI/CK-MB/Myo 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™ cTnI/CK-MB/Myo Rapid Test should be evaluated with all clinical and laboratory data available. If cTnI/CK-MB/Myo Rapid Quantitative Test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies. 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 cTnI/CK-MB/Myo antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
4. Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test and thus should not be used.
5. Other factors may interfere with Finecare™ cTnI/CK-MB/Myo 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 using 208 human blood samples, demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test and the Roche Diagnostics GmbH Troponin I STAT, CK-MB STAT and Myoglobin STAT for the 208 clinical samples, the Correlation Coefficient is 0.969, 0.964 and 0.956.

Assay Range and Detection Limit

• Assay Range:

For cTn I: 0.1～50ng/mL

For CK-MB: 0.3～100ng/mL

For Myo: 2～400ng/mL

• Detection Limit:

For cTn I: 0.1ng/mL For CK-MB: 0.3ng/mL For Myo: 2ng/mL

Linearity

For cTn I: A serial concentration of Cardiac troponin I (cTnI) controls at 0.1ng/mL, 0.5ng/mL 1.5ng/mL, 5.0ng/mL, 15.0ng/mL, 25.0ng/mLwere each tested for three times, the Correlation Coefficient (R) is ≥0.995.

For CK-MB: A serial concentration of CK-MB controls at 2.5 ng/mL, 5.0ng/mL 10.0 ng/mL, 20.0ng/mL, 40.0ng/mL, 60.0ng/mL were each tested for three times, the Correlation Coefficient (R) is ≥ 0.995.

For Myo: A serial concentration of Myoglobin controls at 20.0ng/mL, 50.0ng/mL 75.0ng/mL, 100.0ng/mL, 250.0ng/mL, 350.0ng/mLwere each tested for three times, the Correlation Coefficient (R) is ≥0.995.

Precision

Intra-Lot Precision

For cTn I: Within-run precision has been determined by using 10 replicates of specimen of 0.3ng/mL Cardiac troponin I (cTnI). C.V. is ≤10%.

For CK-MB: Within-run precision has been determined by using 10 replicates of specimenof 10.0ng/mL CK-MB. C.V. is≤ 15%.

For Myo: Within-run precision has been determined by using 10 replicates of specimenof 100.0ng/mL Myoglobin. C.V. is ≤ 15%.

Inter-Lot Precision

For cTn I: Between-run precision has been determined by using 3 replicates for each of three lots using Cardiac troponin I (cTnI) specimen levels at 0.3ng/mL. C.V. is≤15%.

For CK-MB: Between-run precision has been determined by using 3 replicates for each of three lots using CK-MB specimen levels at 10.0ng/mL. C.V. is ≤15%.

For Myo: Between-run precision has been determined by using 3 replicates for each of three lots using Myoglobin specimen levels at 100.0ng/mL. C.V. is ≤ 15%.

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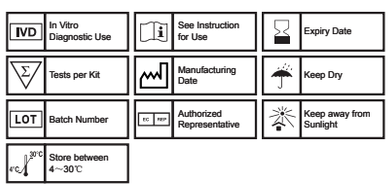

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