



Myoglobin Rapid Test

Catalog No. W204

INTENDED USE

The Finecare™ Myoglobin Rapid Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of Myoglobin in human whole blood, serum or plasma.

- Fluorescence immunoassay
- Diagnosis of myocardial infarction.

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

SUMMARY

Myoglobin 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. The molecular weight of myoglobin is approximately 17,800 daltons. The relatively low molecular weight and the location of storage accounts for the rapid release from damaged muscle cells and earlier rises in concentration measured above baseline in blood as compared to other cardiac markers. Since myoglobin is present in both cardiac and skeletal muscle, any damage to either of these muscle types results in its release into the blood stream. 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). Myoglobin may also rise moderately above the reference range in chronic ischemic heart disease (i.e. unstable angina).

Normal reference values: <58.0ng/mL

PRINCIPLE

The Finecare™ Myoglobin Rapid Test is based on fluorescence immunoassay

technology. The Finecare™ Myoglobin Rapid Test uses a sandwich immunodetection method, when sample is added to the sample well of the test, the fluorescence-labeled detector anti-Myoglobin antibody on the membrane binds to Myoglobin 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 Myoglobin are captured to anti-Myoglobin antibody that has been immobilized on test strip. Thus the more Myoglobin antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of Myoglobin captured and Finecare™ FIA Meter shows Myoglobin concentrations in blood specimen. The default results unit of Finecare™ Myoglobin Rapid Test is displayed as XXX ng/mL from Finecare™ FIA Meter. The working range and the detection limit of the Myoglobin Test system are 2.0 ~ 400ng/mL and 2.0ng/mL, 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. Don't use Test if its lot # does not match with ID Chip # that is inserted onto the instrument.
5. The Finecare™ Myoglobin Rapid 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, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
11. The Finecare™ Myoglobin Rapid 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 °C. The buffer is stable up to 24 months.
2. Store Finecare™ Myoglobin Rapid Test Cartridge at 4 ~ 30 °C, 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 °C ~ 8 °C.
3. It's not suitable to test the whole blood samples which have been stored at 2 °C ~ 8 °C 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 °C ~ 8 °C for up to 3 days. For long-term storage, specimens should be kept below -20 °C.

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.

Take out one tube of Buffer from refrigerator and balance it at room temperature for a couple of minutes.

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™ Myoglobin Rapid 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™ Myoglobin Rapid Test should be evaluated with all clinical and laboratory data available. If Myoglobin 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 Myoglobin 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™ Myoglobin Rapid Test and thus should not be used.
5. Other factors may interfere with Finecare™ Myoglobin Rapid 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™ Myoglobin Rapid Test and the Roche Diagnostics GmbH Myoglobin STAT for the 208 clinical samples, the Correlation Coefficient is 0.956

Assay Range and Detection Limit

- **Assay Range:** 2.0~400ng/mL
- **Detection Limit:** 2.0ng/mL

Linearity

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

Precision

Intra-Lot Precision














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


Inter-Lot Precision

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%.


BIBLIOGRAPHY OF SUGGESTED READING

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3. Rozenman Y, Gotsman M. The Earliest Diagnosis of Acute Myocardial Infarction. Annu Rev Med 1994;45:31–44.
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 IVD	In Vitro Diagnostic Use	 See Instruction for Use	 Expiry Date
 Tests per Kit	 Manufacturing Date	 Keep Dry	
 LOT	Batch Number	 Authorized Representative	 Keep away from Sunlight
 Manufacturer	 Do not reuse	 REF	Catalog #
 Store between 4~30 C			



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