

CK-MB Rapid Quantitative Test



Catalog No.: BT2103

INTENDED USE

The Biotime CK-MB (Creatine Kinase MB) Rapid Quantitative Test is intended to quantify the concentration of CK-MB in human serum or plasma on Biotime FIA Analyzer by fluorescent immunoassay. It is used as an aid detection of acute myocardial infarction.

- Fluorescent immunoassay
- Myocardial infarction

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

INTRODUCTION

This product is used to detect the concentration of Creatine Kinase MB(CK-MB) in serum or plasma. Creatine kinase (CK) is an enzyme of two subunits M and/or B with three different pairs of subunits combine to give rise to three different isoenzymes CK-MB, CK-BB, and CK-MM. Those isoenzymes normally present in the cytosol, depending on the tissue: while CK-MB is expressed in cardiac muscle, CK-MM is expressed in sarcomeric muscle (both skeletal and cardiac muscle) and CK-BB is expressed in smooth muscle and most non-muscle tissues. Upon body injury, they are released into blood and result in abnormal increased concentrations in serum or plasma.

As a heart specific isoenzyme, CK-MB can be used to assist diagnoses of an acute myocardial infarction. The level of CK- MB in blood elevates in fourth hour to the sixth hour after acute myocardial infarction and reaches the peak in 18th-24th hours.

Diseases rather than acute myocardial infarction may also cause elevated blood CK-MB. Other test or diagnosis should be performed for comprehensive evaluations^[1-3].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the CK-MB in the sample and the mouse anti-CK-MB monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with CK-MB specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of CK-MB in human blood.

The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of CK-MB in human serum or plasma.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste shall be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. Otherwise, it may cause damages to the instrument.

MATERIAL

Material Provided

1. Test cartridge 25 tests/kit
2. Detector buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1 copy/kit

Material Required But Not Provided

1. Biotime FIA Analyzer
2. Transfer Pipette Set and pipette tips(range 10~100μL)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30°C, the shelf life is 24 months.
2. Store the test cartridge at 2-30°C, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum or plasma.
2. The specimen collection container should be EDTA tube for plasma, heparin anticoagulant tube for plasma or pro-coagulant tube for serum.
3. The collecting of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, it can be stored in refrigerator at 2-8°C for no more than 7 days, or at -20°C no more than for 6 months. Samples must be recovered to the room temperature before tests.
4. Separate the serum or plasma as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the operation manual of Biotime FIA analyzers for details.

The test should be operated at room temperature(~25°C).

Step 1: Preparation

Check/insert SD card into the equipment.

Take out one tube of buffer from refrigerator and balance it to room temperature.

Step 2: Sampling

Take 40μL of serum or plasma with a transfer pipette and add it into the buffer tube.

Step 3: Mixing

Mix well the specimen with buffer by tapping or inverting the tube several times.

Step 4: Loading

Take 80μL of sample mixture and load it into the well of the test cartridge.

Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.

Step 5: Testing

Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 15 minutes.

NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal reference interval: <5.0 ng/mL

Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum or plasma specimen.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result should be carefully evaluated when patients are known to have these antibodies^[4-5].
3. Other factors also can induce the false results, including the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy

CK-MB control materials with two different concentrations were tested by every batch of Test Cartridges, and the deviations were within ±15%.

Assay Range: 1.0-80.0ng/mL

The Lowest Detection Limit: 1.0ng/mL.

Linearity

A serial concentrations of CK-MB reference materials at 2.5-80.0ng/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.

Precision

Intra-lot Precision

Intra-lot precision was determined by testing of CK-MB reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.

Inter-lot Precision

Inter-lot precision was determined by testing of CK-MB reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot).The C.V. is ≤ 15%.

Specificity

The concentration of CK-MB is not greater than 1.0ng/mL when the concentration of CK-MM is 10000ng/mL.

The concentration of CK-MB is not greater than 1.0ng/mL when the concentration of CK-BB is 10000ng/mL.

SYMBOLS

| Symbol | Description | Symbol | Description |
|--------|------------------|--------|------------------------------------|
| | Catalogue number | | In vitro diagnostic medical device |

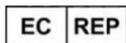
| | | | |
|--|------------------------------------|--|------------------------------|
| | Lot number | | Consult instructions for use |
| | Date of manufacture | | Keep dry |
| | Expiry date | | Keep away from sunlight |
| | Manufacturer | | Store at 2-30°C |
| | Do not re-use | | CE mark |
| | European authorized representative | | |

BIBLIOGRAPHY OF SUGGESTED READING

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