# CK-MB FIA Rapid Test Device

## (Whole Blood/Serum/Plasma)

## FI2-CKMB-001

*A rapid test for the diagnosis of Creatine Kinase MB (CK-MB) by measuring Creatine Kinase MB in whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).*
*For professional in vitro diagnostic use only.*

### INTENDED USE

The CK-MB FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of human CK-MB in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

### SUMMARY

Creatine Kinase MB (CK-MB) is an enzyme present in the cardiac muscle with a molecular weight of 87.0 kDa.[1] Creatine Kinase is a dimeric molecule formed from two subunits designated as "M" and "B" which combine to form three different isoenzymes, CK-MM, CK-BB, and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue.[2] The release of CK-MB into the blood following MI can be detected within 3-8 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours.[3] CK-MB is one of the most important cardiac markers and is widely recognized as the traditional marker for the diagnosis of MI.
The CK-MB FIA Rapid Test Device is a simple test that utilizes a combination of antibody coated particles and capture reagents to quantitatively detect CK-MB in whole blood, serum or plasma.

### PRINCIPLE

The CK-MB FIA Rapid Test Device detects CK-MB based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains CK-MB, it attaches to the CK-MB antibody which is conjugated with fluorescent microspheres. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of CK-MB in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of CK-MB in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) to show CK-MB concentration in specimen.

### REAGENTS

The test includes anti-CK-MB antibody conjugated fluorophores and CK-MB antibody coated on the membrane.

### PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda CK-MB FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by approved medical professionals.

### STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

### KIT COMPONENTS

- 25 x foil wrapped CK-MB rapid test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (CK-MB)
- Package Insert

### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

### SPECIMEN COLLECTION AND PREPARATION

### PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

### BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

### SAMPLE DILUTION / SAMPLE STABILITY

1. The specimen **(100 ul of whole blood or 75 ul serum / plasma)** can be added directly with a micro pipette into the buffer tube.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately **1 minute**.

### DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. **Serum/plasma:** Transfer **75 µl of serum/plasma** into the buffer tube, mix the specimen and the buffer well.
4. **Whole Blood:** Transfer **100 µl of whole blood** into the buffer tube, mix the specimen and the buffer well.
5. **Add diluted specimen with a Pipette**: Pipette 85 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
6. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

"Quick test" mode: Insert the test cassette into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.
"Standard test" mode: Insert the test cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

## INTERPRETATION OF RESULTS

The result of tests for CK-MB is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

Linearity range of the Biopanda CK-MB FIA Rapid Test Device is 0.2-75 ng/mL.

## QUALITY CONTROL

Each Biopanda CK-MB FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## LIMITATIONS

1. The Biopanda CK-MB FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of CK-MB.
2. The Biopanda CK-MB FIA Rapid Test Device will only indicate the presence of CK-MB in the specimen and should not be used as the sole criterion for evaluating MI.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of CK-MB may produce a dose hook effect, resulting in incorrect interpretation of CK-MB levels. High dose hook effect has not been observed with this test up to 75 ng/mL of CK-MB.
5. The haematocrit level of the whole blood should be between 25% and 65%.
6. The results of the Biopanda CK-MB FIA Rapid Tests are based on measuring the levels of CK-MB in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

## EXPECTED RESULTS

| Concentrations | Clinical Reference |
|---|---|
| <5 ng/mL | Not indicative of Acute Creatine Kinase MB infarction |
| >5 ng/mL | Indicative of Acute Creatine Kinase MB infarction |

## PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda CK-MB FIA Rapid Test Device can detect levels of CK-MB as low as 0.2 ng/mL in whole blood, serum or plasma.
3. **DETECTION RANGE**: 0.2-75 ng/mL
4. **LINEARITY RANGE**: 0.2-75 ng/mL, R≥0.990
5. **PRECISION**

**INTRA-LOT PRECISION**

Within-run precision has been determined by using 10 replicates of 5 specimens containing 0 ng/ml, 5 ng/ml, 10 ng/ml, 20 ng/ml and 40 ng/ml of CK-MB. C.V. is ≤ 15%.

**INTER-LOT PRECISION**

Between-run precision has been determined by using 10 replicates for each of three lots using 5 specimens containing 0 ng/ml, 5 ng/ml, 10 ng/ml, 20 ng/ml and 40 ng/ml of CK-MB. C.V. is ≤15%.

6**. CROSS-REACTIVITY**

Cross-reactivity studies were carried out with following analytes.
HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

7. **INTERFERING SUBSTANCES**

The following potentially interfering substances were added to CK-MB negative and positive specimens, respectively.

| | |
|---|---|
| Acetaminophen: 20 mg/dL | Caffeine:20 mg/dL |
| Acetylsalicylic Acid:20 mg/dL | Gentisic Acid:20 mg/dL |
| Ascorbic Acid:20mg/dL | Albumin:10,500mg/dL |
| Creatin:200 mg/dL | Hemoglobin:1,000 mg/dL |
| Bilirubin:1,000mg/dL | Oxalic Acid:600mg/dL |
| Cholesterol:800mg/dL | Triglycerides:1,600mg/dL |

None of the substances at the concentration tested interfered in the assay.

## REFERENCES


1. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. J Clin Immunoassay, 17:24-9, 1994.
2. Lee, T.H., Goldman, L. Serum enzyme assays in the diagnosis of acute myocardial infarction. Ann Intern Med, 105:221-233, 1986.
3. Kallner A,Sylven C,Brodin.U,etal. Early diagnosis of acute myocardial infarction;a comparison between chemical predictors. Scand J Clin Lab Invest, 49:633-9, 1989.


**Index of Symbols**

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|---|---|---|---|---|---|
| | Attention, see instructions for use | | Tests per kit | | Do not reuse |
| IVD | For in vitro diagnostic use only | | Use by | REF | Catalogue # |
| | Store between 4-30°C | LOT | Lot Number | | Consult instructions |
| | Do not use if package is damaged | | Manufacturer | | |

*Thank you for purchasing Biopanda's CK-MB FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.*


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