Myoglobin FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-MYO-001

A rapid test for the diagnosis of myocardial infarction (MI) by measuring Myoglobin 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 Myoglobin FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Myoglobin in whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

SUMMARY

Myoglobin (MYO) is a heme-protein normally found in skeletal and cardiac muscle with a molecular weight of 17.8 kDa. It constitutes about 2 percent of total muscle protein and is responsible for transporting oxygen within the muscle cells[1]. When the muscle cells are damaged, Myoglobin is released to the blood rapidly due to its relatively small size. Following the death of tissue associated with MI, Myoglobin is one of the first markers to rise above normal levels. The level of Myoglobin increases measurably above baseline within 2-4 hours post-infarct, peaking at 9-12 hours and returning to baseline within 24-36 hours[2,3]. A number of reports suggest the measurement of Myoglobin as a diagnostic aid in confirming the absence of myocardial infarction with negative predictive values of up to 100% reported at certain time periods after onset of symptoms[4].

PRINCIPLE

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

REAGENTS

The test kit includes anti-Myoglobin antibody coated fluorophores and anti-Myoglobin 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. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. 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.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda Myoglobin FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device 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 Myoglobin Rapid Test Device
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (Myoglobin)
- 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 1 day, 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 run within half-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 and Heparin sodium, Citrate sodium, and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. The specimen **(50 ul of serum / plasma / 75 ul of whole blood)** can be added directly with the micro pipette into the buffer.
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**.
4. It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

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 50 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
   Whole blood: Transfer 75 µl of whole blood into the buffer tube with pipette; mix the specimen and the buffer thoroughly.
4. **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.
5. 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 device 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 device 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 Myoglobin 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 Myoglobin FIA Rapid Test is 5-200 ng/mL.

QUALITY CONTROL

Each Biopanda Myoglobin 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 Myoglobin FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Myoglobin.
2. The Biopanda Myoglobin FIA Rapid Test Ca Device ssette will only indicate the presence of Myoglobin in the specimen and should not be used as the sole criterion for evaluating AMI.
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 Myoglobin may produce a dose hook effect, resulting in incorrect interpretation of Myoglobin levels. High dose hook effect has not been observed with this test up to 200 mg/L of Myoglobin.
5. The results of the Biopanda Myoglobin FIA Rapid Tests are based on measuring the levels of Myoglobin 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
<90 mg/L	Not indicative of Acute Myocardial Infarction
>90 mg/L	Indicative of Acute Myocardial Infarction

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda Myoglobin FIA Rapid Test Device can detect levels of Myoglobin as low as 5 ng/mL in whole blood, serum or plasma.
3. **DETECTION RANGE**: 5-200 ng/mL
4. **LINEARITY RANGE**: 5-200 ng/mL, R≥0.990
5. **PRECISION**

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 50 ng/mL and 100 ng/mL of Myoglobin. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 2 specimens containing 50ng/mL and 100ng/mL of Myoglobin. 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 Myoglobin negative and positive specimens, respectively.

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

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

8**. METHOD COMPARISON**

The Myoglobin FIA Rapid Test Device was compared with the results obtained with Cobas E602 for 112 samples. The correlation coefficient(r) is 0.990.

REFERENCES

1. Wong SS. Strategic utilization of cardiac markers for diagnosis of acute myocardial infarction. Ann Clin Lab Sci, 26:301-12, 1996.
2. Kagen LJ.Myoglobin methods and diagnostic uses.CRC Crit.Rev. Clin.Lab.Sci., 2:273,1978.
3. Chapelle JP.et al.Serum Myoglobin determinations in the assessment of acute myocardial infarction. Eur. Heart Journal, 3:122, 1982.
4. Hamfelt A. et al.Use of biochemical tests for myocardial infarction in the county of Vasternorrland, a clinical chemistry routine for the diagnosis of myocardial infarction. Scand. J. Clin. Lab. Invest. Suppl., 200:20, 1990.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

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

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