H-FABP FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-FABP-001

A rapid test for the detection of Heart Type Fatty Acid-Binding protein (H-FABP) by measuring H-FABP in whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

FABP is a plasma marker of acute myocardial infarction (AMI). The plasma kinetics of FABP (15 kD) closely resemble those of myoglobin in that elevated plasma concentrations are found within 2 hours after AMI and return to normal generally within 18 to 24 hours. But the concentration of FABP in the skeletal muscle is 20 times lower than in cardiac tissue (for myoglobin the same content for cardiac and skeletal tissue), that makes FABP to be more cardiac specific than myoglobin. This makes FABP a useful biochemical marker for the early assessment or exclusion of AMI. FABP also appears to be a useful plasma marker for the estimation of myocardial infarct size. FABP is suitable for use as a standard in immunoassay for early detection of acute myocardial infarction, immunogen for antisera production, mass FABP standard, FABP biochemical and immunochemical studies, tracer for iodination.

PRINCIPLE

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

REAGENTS

The test includes anti-H-FABP antibody conjugated fluorophores and anti-H-FABP 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 H-FABP FIA Rapid Test 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 H-FABP Rapid Test Device
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (H-FABP)
- 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^{o}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 1 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.

SAMPLE DILUTION / SAMPLE STABILITY

1. The specimen **(75 ul of whole blood or 50 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**.
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.
4. **Whole Blood:** Transfer **75 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 device. 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 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 H-FABP 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 H-FABP FIA Rapid Test Device is 1–120 ng/mL.

QUALITY CONTROL

Each Biopanda H-FABP 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 H-FABP FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of H-FABP.
2. The Biopanda H-FABP FIA Rapid Test Device will only indicate the presence of H-FABP 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 H-FABP may produce a dose hook effect, resulting in incorrect interpretation of H-FABP levels. High dose hook effect has not been observed with this test up to 120 ng/mL of H-FABP.
5. The haematocrit level of the whole blood should be between 25% and 65%.
6. The results of the Biopanda H-FABP FIA Rapid Test Device are based on measuring the levels of H-FABP 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
<6 ng/mL	Healthy
>6 ng/mL	AMI risk

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda H-FABP FIA Rapid Test Device can detect levels of H-FABP as low as 1 ng/mL in whole blood, serum or plasma.
3. **DETECTION RANGE**: 1-120 ng/mL
4. **LINEARITY RANGE**: 1-120 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, 8 ng/ml, 20 ng/ml, 60 ng/ml and 120 ng/ml of H-FABP. 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, 8 ng/ml, 20 ng/ml, 60 ng/ml and 120 ng/ml of H-FABP. C.V. is ≤15%.

6. **CROSS-REACTIVITY**

Cross-reactivity studies were carried out with following analytes.

10,000 ng/mL Skeletal Troponin I, 2,000 ng/mL Troponin T, 20,000 ng/mL Cardiac Myosin, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis. The results showed no cross-reactivity.

7. **INTERFERING SUBSTANCES**

The following potentially interfering substances were added to H-FABP 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

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2. Lescuyer P, et al. (2005) Heart-fatty acid-binding protein as a marker for early detection of acute myocardial infarction and stroke. Mol Diagn 9(1), 1-7.
3. Akbal E, et al. (2009) Serum heart type fatty acid binding protein levels in metabolic syndrome. Endocrine 36(3), 433-437, doi: 10.1007/s12020-009-9243-6
4. Petzold T, et al. (2001) Heart-type fatty acid binding protein (hFABP) in the diagnosis of myocardial damage in coronary artery bypass grafting. Eur J Cardiothorac Surg 19(6), 859-864.
5. Storch J and Thumser AE, (2000) The fatty acid transport function of fatty acid-binding proteins. Biochim Biophys Acta 1486, 28–44.

Index of Symbols

	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 H-FABP FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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Effective date: 31/03/2025