H-FABP

Fast Test Kit

(Immunofluorescence Assay)

CE IVD

Cat.# IF1014
Cat.# IF2014

User Manual

INTENDED USE

H-FABP Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of Heart-type Fatty Acid Binding Protein (H-FABP) in serum, plasma or whole blood. This test is used in the early diagnosis of AMI and pulmonary embolism, and monitoring of chronic heart failure.

SUMMARY

H-FABP (Heart-type Fatty Acid Binding Protein) that finds in abundance in cardiomyocytes is one of the Fatty acid-binding proteins (FABPs). The molecular weight of H-FABP is about 15 kDa, the combination of their low molecular weight and cytoplasmic location means that H-FABP proteins are released very rapidly following Acute Myocardial Infarction (AMI). H-FABP has been repeatedly shown to a highly sensitive early rise biomarker across the full spectrum of ACS, detectable as early as 30 minutes following the onset of an ischemic episode.

PRINCIPLE

The test uses an anti-human H-FABP monoclonal antibody conjugated with fluorescence latex and another anti-human H-FABP monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human H-FABP monoclonal antibody binds with the H-FABP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human H-FABP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of H-FABP in sample.

Insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/ Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentration of H-FABP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:

Getein H-FABP test card in a sealed pouch with desiccant.....25
Disposable pipet.....25
User manual 1
SD card/RFID card 1
Whole blood buffer.....1

2. A kit for Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein H-FABP test cards....2
User manual 1
Sample diluent.....1
Box with pipette tips.....1
Mixing plate.....1

3. Sample diluent/Whole blood buffer composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human H-FABP monoclonal antibody, the test line is coated with another anti-human H-FABP monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8℃ for better results.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma, whole blood. EDTA or sodium citrate*** can be used as the anticoagulant for plasma and whole blood sample. Samples should be free of hemolysis.
2. Serum or plasma are suggested for better result.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before test (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature (15~30℃) and be homogeneous before test. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated or hemolysis samples.
7. SAMPLE VOLUME ***(for Getein1100): 100 µl.***

TEST PROCEDURE

1. Collect specimens according to user manual.

2.Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3.Confirm SD card or RFID card lot No. in accordance with test kit lot No.. Perform “SD card or RFID card” calibration when necessary.

4.Enter testing interface of Getein1100.

5.Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

6.Put the test card on a clean table, horizontally placed.

7.Using sample transfer pipette, deliver ***100 µl*** of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).

8.***Reaction time: 3 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9.Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.

10.Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1.It is required to perform “SD card or RFID card” calibration when using a new batch of kits.

2.It is suggested to calibrate once for one batch of kits for Getein1100.

3.Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/ Getein1600.

Others: Measuring range of the test kit is1.0 ng/ml~120.0 ng/ml, dilute the sample which concentration is higher than the upper limit, the dilution ratio should be less than 4 times with fetal bovine serum or negative sample.

EXPECTED VALUE

The expected normal value for H-FABP was determined by testing samples from serum of 391 apparently healthy individuals. The 95th percentile of the concentration for H-FABP is 3.49 ng/ml, the 99th percentile of the concentration for H-FABP is 6.36 ng/ml, results higher than or equal to 6.36 ng/ml are considered positive. The reference range of H-FABP in plasma and whole blood sample is the same.

It is recommended that each laboratory should establish its expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	1.0 ng/ml~120.0 ng/ml
Lower Detection Limit	1.0 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1.As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

2.Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

1.Viswanathan K, Kilcullen N, Morrell C, et al. Heart-type fatty acid-binding protein predicts long-term mortality and re-infarction in consecutive patients with suspected acute coronary syndrome who are troponin-negative. J Am Coll Cardiol. 2010, 55(23): 2590-2598.

2.Puls M, Dellas C, Lankeit M, et al. Heart-type fatty acid-binding protein permits early risk stratification of pulmonary embolism. Eur Heart J. 2007, 28(2):224-229.

3.Kleine AH, Glatz JF, van Nieuwenhoven FA. et al. Release of heart type fatty acid binding protein into plasma after acute myocardial infarction in man. Mol Cell Biochem.1992, 116(1-2): 155-162.

4.Body R, McDowell G, Carley S, et al. A FABP-ulous 'rule out' strategy? Heart fatty acid binding protein and troponin for rapid exclusion of acute myocardial infarction. Resuscitation. 2011, 82(8): 1041-1046.

5.EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.

6.EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO18113-2:2011).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on H-FABP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2012.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing H-FABP Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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