Chuangxingwell

H-FABP Rapid Test Kit
Package Insert

A rapid test for the diagnosis of acute myocardial infarction (AMI) to detect Heart Type Fatty Acid-Binding protein (H-FABP) qualitatively in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

IVD

【INTENDED USE】
The H-FABP Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection 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 newly introduced 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 Rapid Test Kit is a qualitative, membrane based immunoassay for the detection of Heart-type Fatty Acid-Binding Protein (H-FABP) in whole blood, serum or plasma. In this test procedure, capture reagent is immobilized in the test line region of the test. After specimen is added to the specimen area of the Kit, it reacts with anti-H-FABP antibody coated colloid gold particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized capture reagent. The test format can detect H-FABP in specimens. If the specimen contains Heart-type Fatty Acid-Binding Protein (H-FABP), a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain Heart-type Fatty Acid-Binding Protein (H-FABP), a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】
The test contains anti-H-FABP antibody coated colloid gold particles and capture reagent coated on the membrane.

【PRECAUTIONS】
- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】
Store as packaged at room temperature or refrigerated (2-30°C) with a valid period of 24 months. The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch until use. Use the test kit within 1 hour once the foil pouch is opened. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】
The H-FABP Rapid Test Kit can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 50μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test Kit.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test Kit.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test Kit, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the 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 run within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】
Materials provided
- Test Cassettes
- Droppers
- Buffer
- Package insert

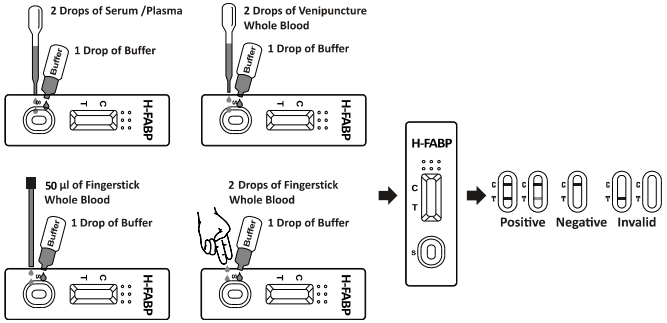
Materials required but not provided
- Specimen collection Containers
- Centrifuge
- Timer

For fingerstick whole blood
- Lancets
- Heparinized capillary tubes and dispensing bulb

【DIRECTIONS FOR USE】
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen:
   - Hold the dropper vertically and transfer **2 drops of serum or plasma (approximately 50μL)** to the specimen area, then **add 1 drops of buffer** (approximately **40 μL**), and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **2 drops of whole blood** (approximately **50μL**) to the specimen area, then **add 1 drops of buffer** (approximately **40 μL**), and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 50μL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 1 drop of buffer** (approximately 40 μL) and start the timer. See illustration below.
   - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50μL) to fall into the specimen area of test cassette, then **add 1 drop of buffer** (approximately 40 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】
(Please refer to the illustration above)

POSITIVE:*Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Fatty Acid-Binding Protein (H-FABP) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line 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.

【QUALITY CONTROL】
A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】
1. The H-FABP Test Kit is for in vitro diagnostic use only. This test should be used for the detection of Fatty Acid-Binding Protein (H-FABP) in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in H-FABP can be determined by this qualitative test.
2. The H-FABP Rapid Test Kit will only indicate presence/ absence of H-FABP above a particular level in the specimen and should not be used as the sole criteria for the diagnosis of acute myocardial infarction.
3. The H-FABP Rapid Test Kit cannot detect H-FABP at a concentration less than 8ng/mL in specimens. A negative result at any time does not preclude the possibility of acute myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Some specimens containing unusually high levels of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
6. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 1 day may not run properly on the test Kit. Repeat the test with a serum or plasma specimen from the same patient using a new test Kit.

【EXPECTED VALUES】
The H-FABP Rapid Test Kit has been compared with a leading commercial H-FABP EIA test, demonstrating an overall accuracy of 90.7%.

【PERFORMANCE CHARACTERISTICS】
Sensitivity and Specificity
The H-FABP Rapid Test Kit has been evaluated with a leading commercial H-FABP EIA test using clinical specimens. The results show that the sensitivity of the H-FABP Rapid Test Kit is 89.9% and the specificity is 91.0% relative to the leading EIA test.

Method		EIA		Total Result
H-FABP Rapid Test Kit	Results	Positive	Negative	
	Positive	62	19	81
	Negative	7	193	200
Total Result		69	212	281

Relative sensitivity: 62/69=89.9% (95%CI*: 80.2%~95.8%);
Relative specificity: 193/212=91.0% (95%CI*: 86.4%~94.5%);
Accuracy: (62+193)/(62+7+19+193)=90.7%(95%CI*: 86.7%~93.9%). *Confidence Intervals

Precision
Intra-Assay
Within-run precision has been determined by using 15 replicates of five specimens: H-FABP negative, H-FABP 8.0 ng/mL positive, H-FABP 10 ng/mL positive, H-FABP 20 ng/mL positive and H-FABP 50 ng/mL positive. H-FABP negative, H-FABP 8.0ng/mL positive, H-FABP 10ng/mL positive, H-FABP20ng/mL positive and H-FABP 50ng/mL positive values were correctly identified >99% of the time.

Inter-Assay
Between-run precision has been determined by 15 independent assays on the same five specimens: H-FABP negative, H-FABP 8.0 ng/mL positive, H-FABP 10 ng/mL positive, H-FABP 20 ng/mL positive and H-FABP50 ng/mL positive specimens. Three different lots of the H-FABP Rapid Test Kit have been tested over a 3-day period using H-FABP negative, H-FABP 8.0ng/mL positive, H-FABP 10ng/mL positive, H-FABP 20ng/mL positive and H-FABP 50 ng/mL positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity
The H-FABP Rapid Test Kit has been tested by specimens containing 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.

Interfering Substances
The following potentially interfering substances were added to H-FABP negative and positive specimens.

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.

【BIBLIOGRAPHY】

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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.
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Index of Symbols

	Caution	IVD	In Vitro Diagnostic Medical Device		Do Not Use if Package is Damaged
	Manufacturer	LOT	Batch Code	Σ	Contains Sufficient for <n> Tests
CE	CE Marking	REF	Catalogue Numbe	EC REP	Authorized representative in the European Community
	Keep Dry		Use-By Date		Keep Away From Sunlight
	Temperature Limit		Do Not Re-use		Date of Manufacture

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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