H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood /Serum/Plasma) Package Insert

For professional in vitro diagnostic use only.
A rapid test for the diagnosis of myocardial infarction (MI) to detect H-FABP and cardiac Troponin I (cTnI) qualitatively in whole blood, serum or plasma.

【INTENDED USE】

The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human H-FABP and cardiac Troponin I (cTnI) in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

【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 thanmyoglobin. 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.

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.[1]Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.

The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of antibody coated particles and capture reagents to qualitatively detect H-FABP and cardiac Troponin I (cTnI) in whole blood, serum or plasma. The minimum detection level is 8ng/mL H-FABP and 0.5 ng/mL Troponin I.

【PRINCIPLE】

The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of H-FABP and cardiac Troponin I (cTnI) in whole blood, serum or plasma. The membrane is pre-coated with specific capture antibodies in each of the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with specific antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with specific capture reagents on the membrane and generate a colored line. The presence of this colored line in the specific test line region indicates a positive result, while its absence indicates a negative result. Toserveasaproceduralcontrol,acoloredlinewillalwaysappearinthecontrollineregion indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-FABP antibody conjugated colloid gold particles, anti-Troponin I antibody conjugated colloid gold particles, and capture reagents 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 in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.**Do not use after the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 cassette.
  - 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 cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, 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 2 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 2 days 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

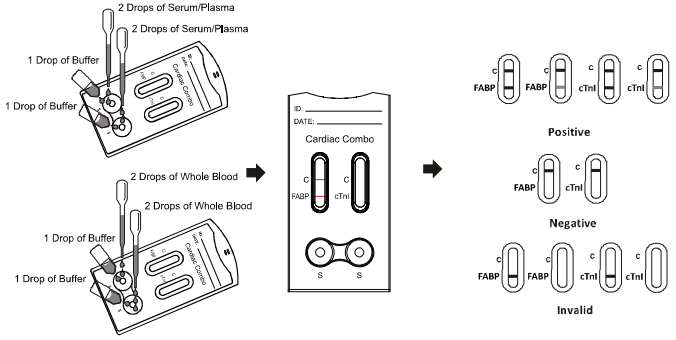
【DIRECTIONS FOR USE】

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 as soon as possible. Twist off the tab of the buffer vial without squeezing.
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 50 μL)** to the specimen area, then **add 1 drop 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 drop 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:* A colored line in the control line region (C) and the presence of one or more colored lines in the test line regions indicates a positive result. This indicates that the concentration of H-FABP and/or cardiac Troponin I is above the minimum detection level.

***NOTE:** The intensity of the color in the test line region(s) will vary depending on the concentration of H-FABP and/orcardiac Troponin I present in the specimen. Therefore, any shade of color in the test line regions should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).This indicates that the concentration of H-FABP andcardiac Troponin I are below the minimum detection levels.

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/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/ Plasma) is for in vitro diagnostic use only. This test should be used for the detection of H-FABP, and cardiac Troponin I (cTnI) in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in H-FABP and cardiac Troponin I can be determined by this qualitative test.
2. The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/ Plasma) will only indicate the qualitative level of H-FABP and Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 8ng/mL H-FABP and 0.5ng/mL cardiac Troponin I (cTnI) in specimens. A negative result at any time does not preclude the possibility of 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 titers 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 2 days may not run properly on the test cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.

【EXPECTED VALUES】

The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/ Plasma) has been compared with a leading commercial H-FABP/cTnI EIA test, demonstrating an overall accuracy of 90.7% with H-FABP, 99.1% with cardiac Troponin I (cTnI).

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/ Plasma) has been evaluated with a leading commercial H-FABP/cTnI EIA test using clinical specimens. The results show that relative to leading EIA tests, the H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/ Plasma) shows 89.9% sensitivity and 91.0% specificity for H-FABP, and 99.4% sensitivity and 99.0% specificity for cardiac Troponin I (cTnI).

H-FABP

Method		EIA		Total Result
H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)	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

Cardiac Troponin I

Method		EIA		Total Result
H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	172	5	177
	Negative	1	472	473
Total Result		173	477	650

Relative sensitivity: 172/173=99.4% (95%CI*: 96.8%~99.9%);
Relative specificity: 472/477=99.0% (95%CI*: 97.6%~99.7%);
Accuracy: (172+472)/(172+1+5+472)=99.1%(95%CI*: 98.0%~99.7%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of below fifteen specimens: H-FABP 8.0ng/mL positive, H-FABP 10ng/mL positive,H-FABP 20ng/mL positive and H-FABP 50ng/mL positive, and cardiac Troponin I (cTnI) specimen levels at 0ng/mL, 1.0ng/mL, 5.0ng/mL, 10ng/mL and 40ng/mL. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same fifteen specimens: H-FABP8.0ng/mL positive, H-FABP 10ng/mL positive, H-FABP20ng/mL positiveand 0ng/mL, 1.0ng/mL,5ng/mL, 10ng/mL and 40ng/mL of cardiac Troponin I (cTnI). Three different lots of the H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by 10,000ng/mL Skeletal Troponin I, 2,000ng/mL Troponin T, 20,000ng/mL Cardiac Myosin, 1,800 ng/mL CK-MM, 1,200ng/mL CK-BB, 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.

Interfering Substances

The following potentially interfering substances were added to H-FABP and/or cardiac Troponin I (cTnI) negative and positive specimens, respectively.

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

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

【BIBLIOGRAPHY】

1. Wong SS. Strategic utilization of cardiac markers for diagnosis of acute myocardial infarction. *Ann Clin Lab Sci*, 26:301-12, 1996..
2. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarctionand monitoring reperfusion. *J Clin Immunoassay*, 17:24-9, 1994.
3. Lee TH, Goldman L. Serum enzyme assays in the diagnosis of acute myocardial infarction. *Ann Intern Med*, 105:221-233, 1986.
4. Kallner A, Sylven C, Brodin. U, et al. Early diagnosis of acute myocardial infarction; a comparison between chemical predictors. *Scand J Clin Lab Invest*, 49:633-9, 1989.
5. Adams, et al. Biochemical markers of myocardial injury, *Immunoassay Circulation* 88: 750-763, 1993.
6. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. *J.Biol.Chem*. 266:966, 1991.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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