New Diagnostic Product to Acute Myocardial Infarction (AMI) Diagnosis
- FABP Cardiac Infarction Rapid Test Kit

**Introduction**

Heart diseases, including acute myocardial infarction (AMI), are the second leading cause of death all over the world. Among patients with heart diseases, the number of cases of AMI and angina pectoris has increased sharply in recent years: it accounts for 40% of the death caused by heart disease. In fact, AMI is the leading cause of death in the United States: 500,000 people die of AMI each year.

AMI occurs when coronary artery is obstructed by blood clot and fails to supply blood to the heart. This obstruction results in inadequate flow of oxygen-and nutrient-rich blood, and consequently the rapid onset of damage or even death to the portion of the heart muscle. The normal function of heart muscle requires high level of oxygen supply, so even brief interruption of blood flow can cause tissue death.

Several studies worldwide have shown that life-saving therapies are most beneficial in the early course of AMI. According to previous investigation, about 1.1 million Americans encounter AMI annually, of which 50% occasions are fatal. Moreover, approximately 20% of the death occurs before patients can reach the emergency room in hospitals for the treatment. Therefore, early detection and early treatment of AMI have become the most critical and effective steps of lifesaving.

We develop a new diagnostic product, FABP (Fatty Acid Binding Protein) Cardiac Infarction Rapid Test Kit to meet the challenges of health care and needs of diagnosis market,

**Areas of Application**

1. New Biomarker for early detection: This product is used for rapid detection if the occurrence of acute myocardial infarction (AMI) is suspected (major symptoms of AMI are pain and constriction in the chest area, and difficulty in breathing).
2. Fast and Safe: This product can be used by a doctor for AMI diagnosis, or by a person for self-testing.
3. Easy to use: This product is suitable for hospitals, family doctors as well as emergency units such as ambulances, emergency rooms, and rescue units. It is also suitable for institutions such as cardiology departments, rehabilitation centers, and nursing homes.

**Principle**

This product is based on the detection of heart-specific fatty acid-binding protein (h-FABP). h-FABP is a protein with molecular weight of 15 kDa in the plasma of myocardium cells. Its main function is to regulate the transportation of free fatty acids within myocardium cells. In addition, it also helps to provide energy to myocardium cells. When myocardium is damaged, h-FABP immediately leaks into the bloodstream, causing rapid elevation on the concentration of h-FABP. This makes h-FABP a very powerful biochemical marker for early assessment of AMI.
For the detection of h-FABP, monoclonal antibodies are used to target specifically on human h-FABP. Furthermore, the rapid test technology has been used for this product. When the gold-labeled antibodies react to h-FABP, immunoreactions can be visualized by color change. This technique allows fast detection of AMI.

As the procedures of a diagnostic test, three drops of blood are applied on the sample well at one end of the test strip. Due to capillary action, the blood moves towards the other end of the strip. The gold-labeled antibodies are placed on a defined position of the strip. When the blood containing h-FABP passes this position the antibodies will bind to the h-FABP molecules and move together with the h-FABP molecules, until h-FABP is captured by a line of the capture antibodies. As a consequence, the reaction will result in the occurrence of a red line that indicates positive result or the absence of red line that gives negative result (for details, see “Instructions for Use” on this product).

**Characteristics & Technical Data**

**High Sensitivity**

Currently similar products for in vitro AMI diagnosis are based on the detection of index molecules, such as Troponin T, Troponin I, and CK-MB. Their detectable timing is 6-8 hours after the onset of AMI, which is very late in the sense of life saving. Furthermore, within the first 3 hours of AMI occurrence, the concentrations of these index molecules rises slowly, and are too low to be detected in blood sample.

In contrast, the level of h-FABP is sharply elevated immediately after the onset of AMI, and it peaks at 4-6 hours (see Diagram 1 below). This feature enables h-FABP to become a new specific biomarker for early diagnosis of AMI. In fact, this product can be used as early as 30 minutes after AMI occurs.

The sensitivity of this product is 6.5ng/ml of h-FABP in blood. A value higher than 6.5ng/ml is recognized as AMI positive.
Diagram 1: Concentration curves of FABP, TnI, CPK during the period of AMI occurrence

(TnI: Troponin I. CPK: Creatine phosphokinase. CPK is an index for determining whether heart, brain, and skeletal muscle is damaged.)

As shown in Diagram 2 below, 86.2% of the cases could be detected by h-FABP within 3 hours of AMI occurrence. In contrast, only 8.8% of the cases could be detected by CK-MB within 3 hours or between 3-6 hours upon AMI occurrence (see Diagram 3). Obviously, h-FABP is a better index for early detection of AMI.
Diagram 2: The sensitivity of h-FABP tests
Diagram 3: The sensitivity of CK-MB tests

(each circle in the diagrams represents one case. The short bars represent the average concentrations of h-FABP in blood. The dash line is the cutoff value differentiating healthy people from AMI positive persons.)

High Specificity

As shown in Diagram 4, there is a comparatively great amount of h-FABP in human body, and it mainly resides in cardiac muscle (myocardium). The concentration of h-FABP in skeleton muscle is very low. On the opposite, there is only a tiny amount of myoglobin in human body, and myoglobin can be found mainly in skeleton muscle instead of myocardium (see Diagram 5). Therefore, although myoglobin can be used for the detection of AMI, its specificity is not high enough due to its disadvantageous tissue distribution. For instance, if skeleton muscle is damaged, more myoglobin will be released to the blood than that if myocardium is damaged, which would lead to false diagnosis of AMI. In contrast, damage to skeleton muscle does not affect on h-FABP so much as on myoglobin, i.e. h-FABP offers higher specificity in the diagnosis of AMI.
Diagram 4: Concentration of h-FABP in different tissues

Diagram 5: Concentration of myoglobin in different tissues

(Cardiac muscle: 1- left ventricle, 2- right ventricle, 3- left atrium, 4- right atrium muscle
Skeleton muscle: 5-intercostals, 6-diaphragm, 7-musculus iliopsoas, 8-pectoralis major, 9-rectus abdominis)

It is demonstrated in Diagram 6 that h-FABP is better than either Troponin I or CPK in both sensitivity and specificity.
High Reliability

As shown in Diagram 7, the accuracy of the h-FABP test is higher than either myoglobin or CK-MB during the whole time course: 89.7% for the first 3 hours, 97% for the 3-6 hours, and 86% for the 6-12 hours of AMI occurrence. In comparison, the accuracy of myoglobin is a little lower in addition to its lower specificity as discussed above. Among the three indexes, the least accurate index is CK-MB: only 3.5% for the first 3 hours of AMI occurrence, 23.9% for the 3-6 hours, and 53% for the 6-12 hours. Therefore, h-FABP is a very effective and reliable biomarker for the detection of AMI within at least the first 6 hours of AMI occurrence.
Control

Instruction of Use Procedure
1. The red line by the letter C in the result window is the internal control. It confirms sufficient specimen volume, correct procedural performance, and good product quality.
2. Control standards are not supplied with this product. However, it is recommended to a doctor that positive and negative specimen controls be tested as a good practice.
3. This product is for in vitro assay only, and not for quantitative analysis.
4. Diagnosis of AMI can not be based solely on the results with this product. Physicians should take a combination of other diagnostic measures.
5. Although the test is very reliable, it may produce a false result in a special case. People at risk of incorrect detection are athletes, individuals with renal insufficiency, and individuals with angina pectoris.

Storage and Expiration

Storage and Expiration
1. **Storage**: store at room temperature or refrigerated. Do not freeze.
2. **Expiration Date**: 12 months from the production date (printed on the pouch or transport box). Do not use beyond the expiration date.

Reference
4. Toshio Watanabe. Clinical Biochemistry, 2001; 34:257
6. Published technical and clinical data from rennesens GmbH, Germany.
7. Published technical and clinical data from Dainippon Pharmaceutical Co., Ltd., Japan.

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