Windsor, Canada, www.bioassayplus.com

One step Fatty Acid Binding Protein Rapid Test Cassete

Specimen : serum / Plasma

Introduction

Heart type fatty-acid binding proteins (h-FABPs) are members of cytosolic protein family. The name FABP originates from their ability to adhere fatty acids noncovalently in a high-affinity manner. FABP is relatively tissue specific; and liver, heart and intestinal FABPs are named L-FABP, H-FABP and I-FABP, respectively. They are most abundantly found in heart and liver tissue. h-FABP is the principle extracellular fatty-acid transporter to transport fatty acids into heart cells. h-FABP distribution in the heart is 0.57 mg/g, whereas myoglobin's distribution is 2.7 mg/g. Skeletal tissue also contains FABP in an amount of 0.04-0.14 mg/g. The monoclonal antibody to h-FABP can specifically recognize heart type fatty acid binding protein. h-FABP is mainly in cytosole with low molecular weight. It appears in blood early within two hours after myocardial infarction. Compared to tropnin, h-FABP is used for the early diagnosis of myocardial infarction.

Principle of The Test:

This assay is a double antibody chromatographic lateral flow immunoassay. The test strip in the device consists of (1) a red-colored conjugate pad containing colloidal gold coupled with anti-h-FABP antibody, and (2) a nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with anti-h-FABP antibody, and the C line is coated with goat anti-mouse antibodies. When h-FABP is present in the specimen, the T line will become a red-colored band. If h-FABP is not present or present below the detectable level, no T line will develop. The C line should always appear as a red-colored band regardless of the presence of h-FABP. The C line serves as an internal qualitative control of the test system to indicatevthat an adequate volume of specimen has been applied and the liquid migration occurred.

Materials Provided

1. 25 test devices, each pouched with a disposable pipette and a desiccant.

2. One package insert

Materals Required (But not provided)

1. Controls: h-FABP positive and h-FABP negative
2. Specimen collection containers
3. Timer

Storage

Store kit at 15-30^{o}C (59-86°F). Kit contents are stable for 2 years or until the expirationdate printed on the label, whichever comes first. Exposing the kit to the temperatures over 30^{o}C (86°F) may reduce the shelf life ordamage the device.

Specimen collection and storage

1. Use human serum sample only.
2. Follow standard laboratory procedures to collect serum specimens.
3. Since cardiac proteins are relatively unstable, it is recommended that fresh samples be tested as soon as possible.
4. Heat activation of samples may lead to hemolysis or protein denaturation and therefore should be avoided.
5. If samples are to be stored for more than 24 hours, they should be stored at –20°C or below, and brought to room temperature before testing. Repeatedly frozen and thawed specimens are not recommended for this assay.
6. Any sediment in serum specimens should be removed by centrifugation. Avoid using any turbid specimens, which may be contaminated by microorganisms.

Warning and Precautions

1. For in vitro diagnostic use only.
2. CAUTION: All human blood products, including serum samples, should be considered potentially infectious. It is recommended that the reagents and patient samples be handled according to the OSHA Standard on Blood borne Pathogens or other appropriate national biohazard safety guidelines or regulations.
3. Do not use kit beyond the expiration date indicated on the product.
4. The test should remain in its sealed pouch until ready for use.

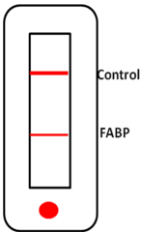
5. Wear disposable gloves while handling specimens and thoroughly wash hands afterwards.
6. Use separate clean tips for different specimens. Do not pipette by mouth.
7. Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
8. Observe established procedures for proper disposal of specimens and used test devices.

Procedures

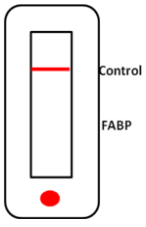
1. Refrigerated specimens or other test materials, including devices, must be equilibrated to room temperature before testing to avoid invalid results.
2. Remove the device from the pouch and place it on a flat surface. Label the device with specimen identification.
3. Add three drops of serum (about 80-100 ml) into the sample well.
4. Strong positive results may be observed within 15 minutes. Weak positive results may take a longer time. The results should be read within 15-20 minutes.

Interpretationof Results

1. POSITIVE: If both the C line and T line appear, the result indicates that the h-FABP is detected and the result is positive. Note: The color intensities of C line and T line may not be the same. A faint T line indicates a borderline specimen, which should be re-tested using an alternative method for confirmation.

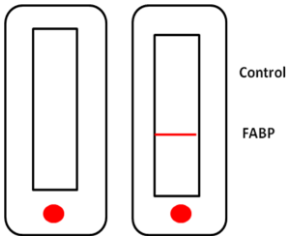


2. NEGATIVE: If only the C line appears, the test indicates that no h-FABP is detected or its level is below the detectable and the result is negative.



When the test result is negative or is in conflict with other results, it is imperative to perform a new test approximately one hour later. If the second result is negative and if the last sample was taken more than 6 hours after a suspected AMI case, then the patient has likely not suffered from AMI.

3. INVALID: When no control line appears within 5 minutes, the results should be considered invalid. In this case, repeat the test with a new test device.



Quality Control

◎ Built-in control features: This test contains a built-in quality control feature, the C line. The appearance of the red C line indicates that that an adequate volume of specimen has been applied and the flow occurred.

◎ External quality Control: External controls are recommended, positive and negative, to monitor the performance of the assay. Quality controls should be run bimonthly, when the lot is changed, or if the result is suspect.

Limitations of Test

1. The test provides a qualitative test result. The qualitative nature of this assay does not provide information about actual concentration of h-FABP, at a given time. Interpretation of any test result using the test should be made together with other clinical information available to physicians using appropriate professional judgment.

2. Human serum samples containing unusually high titers of certain antibodies, such as human anti-mouse or human anti-rabbit antibodies (HAMA or HARA), may influence the test results. The test has been optimized to minimize interference from HAMA-containing specimens; but complete elimination of this interference from all patient specimens cannot be guaranteed. Patient samples may contain human anti-mouse antibodies (HAMA) which are capable of giving falsely elevated or depressed results with assays that utilize mouse monoclonal antibodies.

3. Serum samples demonstrating gross lipemia, gross hemolysis, or turbidity should not be used with this test.
4. If the test result is inconsistent with the clinical symptom and patient history, it should be interpreted with caution.

Expected Values

1. The test is designed to yield a positive result for free cardiac h-FABP concentrations > 10 ng/ml;

2. The time required for blood cardiac FABP levels to reach the upper limit of normal has been found to be 2 hours following the onset of symptoms. Negative test result less than 2 hours after the onset of symptoms does not indicate no myocardial infarction, a continuous test is necessary after 2 hours.