One-Step c-FABP
Blood/Serum/Plasma Test
Cat. H-017/H-018

Immuoassay for the Qualitative Determination of cFatty acid binding protein

An assay for early detection of myocardial infarction

INTENDED USE

cFABP can be used as an early marker of myocardial infarction. cFABP is more sensitive and reliable early marker of AMI. FABP can be use-ful also for the early detection of minor myocardial events such as unstable angina too. Switching clinical studies from myoglobin to cFABP can be helpful for the improvement of early AMI diagnosis.

SUMMARY AND EXPLANATION

Fatty Acid Binding Protein (cFABP) is a small cyto-solic protein responsible for the transport and deposition of fatty acids inside the cell. Several different isoforms of FABP are expressed in different tissue types. Cardiac isoform of FABP (cFABP) is expressed mainly in cardiac muscle tissue and in significantly lower concentration in skeletal muscles. Cardiac isoform of FABP consists of 132 amino acid residues with molecular weight 14727 Da and theo-retical pl 6.34. Recently it was demonstrated that cFABP can be used as an early marker of myocardial infarction. cFABP has the same kinetics of liberation into patients blood as myoglobin. Because cFABP concentration is significantly lower in skeletal muscle (com-paring with myoglobin) the concentration of cFABP in the blood of healthy donors is also significantly lower (6 - 10 ng/ml for cFABP and 40 - 60 ng/ml for myoglobin). This fact makes cFABP more sensitive and reliable early marker of myocardial cell death. Recent studies demonstrated that FABP can be use-ful also for the early detection of minor myocardial events such as unstable angina. Switching clinical studies from myoglobin to cFABP can be helpful for the improvement of early AMI diagnosis.

PRINCIPLE OF THE PROCEDURE

The quick one-step test utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay. If cFABP is present in the sample in concentration above the detection level-10 ng/ml, a labeled specific monoclonal antibody-dye complex. This complex is then captured by another specific monoclonal antibody immobilized in the Test Zone (“T”) of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of cFABP in the sample. On the other hand, a color band will always appear at the control zone (“C”).

MATERIALS PROVIDED

1. Test Device
2. Dropper
3. Instruction manual

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timing device.
2. Specimen collection container.

SAMPLE COLLECTION AND STORAGE

1. Fresh blood samples are preferred. While drawing the blood, the anti-coagulant reagent, such as EDTA, must be added. The blood samples kept at refrigerator for overnight might be suitable for test.
2. Plasma and serum stored in refrigerator for a few days usually are suitable for test.

QUALITY CONTROL

Although the Kit contains an internal quality control function (pink/rose color band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper kit performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

ASSAY PROCEDURE

Prior to use, bring all test components and patient samples to room temperature.

FOR SERUM/PLASMA TEST:

1. Remove the cassette from the foil pouch and place it on a clean, dry, level surface.
2. Hold the disposable dropper in a vertical position and Add 2 drops of sample (one by one) into the sample well of the test device. Allow each drop to soak in before adding the next one.
3. As soon as the sample reaches the view window, start timing.
4. Read result within 10 minutes.

FOR BLOOD TEST:

1. Remove the cassette from the foil pouch and place it on a clean, dry, level surface.
2. Hold the disposable dropper in a vertical position and Add 1 drop of blood into the Sample well of the test device.
3. And then after 30 seconds add 1 drop of coating buffer. Add 1 more drop; if there is no liquid flow through shown up on the membrane.
4. As soon as the sample reaches the view window, start timing.
5. Read result at 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

If both the Control band (C line) and the Test band (T line) appear, the result is positive.

NEGATIVE RESULT:

The test is negative if a colored line appears only in the Control band (C line area) and with no Test band (T line area).

INVALID RESULT:

If a color band does not appear in the Control band (C line). The sample may have been added to the wrong window, or the test device may have deteriorated. The specimen should be re-tested using a new test device.

WARNINGS AND PRECAUTIONS

1. Wear disposable gloves while handling Specimens. Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high level disinfectant.
3. Decontaminate and dispose of all specimens, reaction Kits and potentially contaminated materials, as if they were infectious, in a biohazard container.
4. Avoid splashing or aerosol formation.
5. Do not use the Kit after the expiration date.
6. For in vitro diagnostic use only.

LIMITATIONS OF THE TEST

1. The test is for in vitro diagnostic use only.
2. The test is limited to the detection of cFABP in plasma/serum.
3. Although the test is very accurate in detecting elevated cFABP, a low incidence of false positive results can occur, especially lysis samples.
4. The test is a qualitative screening assay and is not suggested for use in determining the quantitative levels.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

**SENSITIVITY AND PRECISION**

The cut-off of the Qiktech one-step cFABP Test is **10.0 ng/ml**. The precision of the Qiktech one-step cFABP test was determined using replicate assays of samples from three different patients' pools, with kits from three different production lots. Each specimen sample was run through ten parallel assays. The data demonstrated 100% precision for the duplicates of each sample and 100% precision using the test kits from different lots.

**BIBLIOGRAPHY**