INSTRUCTIONS FOR USE
ONE STEP TEST
h-FABP Cardiac Marker
Detection in Whole Blood / Serum / Plasma

TOYO DIAGNOSTICS

Only for professional *in vitro* diagnostic use

Product Code : THFP01

Heart Type Fatty Acid Binding Protein (h-FABP) Cardiac Infarction Test Device detects cardiac marker h-FABP in human whole blood, serum and plasma sample.

BACKROUND INFORMATION

Heart diseases, including myocardial infarction (AMI) are the second leading cause of death all over the world. 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 investigations about 1.1 million Americans encounter 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.
h-FABP is a protein that consists of 132 amino acid residues with molecular weight of 15 kDa in the plasma of myocardium cells and theoretical pI value of hFABP is 6,34. 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. h-FABP concentration is significantly lower in skeletal muscle (comparing with myoglobin). The concentration of h-FABP in blood of healthy donors is also significantly lower (4 - 10 ng/ml for h-FABP and 40 - 60 ng/ml for myoglobin). This fact makes h-FABP more sensitive and reliable early marker of myocardial cell death. 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.

INTENDED USE

h-FABP Cardiac Infarction Test Device is a rapid immunochromatographic assay for qualitative detection of human cardiac marker h-FABP in human whole blood / serum / plasma to aid diagnosis of myocardial infarction (MI).

REAGENTS

This test device contains anti-h-FABP antibodies coated particles and capture reagent immobilized on the membrane.

METHOD

h-FABP Cardiac Infarction Test Device is a rapid, qualitative, immunochromatographic assay for the detection of h-FABP in human whole blood / serum / plasma samples. There is capture reagent immobilized to "T" test area of the test. While performing the test; whole blood / serum / plasma sample dropped to the sample well reacts with the particles coated with anti-h-FABP antibodies. This complex migrates to the other end of the membrane by capillary action. If there is h-FABP in the sample, it binds to capture reagent in the "T" test area and create a visible, colored signal that means the test result is positive. If the sample does not contain h-FABP, colored line does not appear in the "T" test area. This means the test result is negative. As a procedural control, a colored line always appears in the "C" control area indicating that proper volume of sample has been introduced and membrane wicking has occurred.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
7. Test can give false positive results in the individual who suffers from renal insufficiency, angina pectoris and in the individuals who performs serious sports for long periods of time, like athletes.
8. This test will indicate only the presence or absence of h-FABP in the sample, and should not be used as the only basis for the diagnosis of myocardial infarction. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
9. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of myocardial infarction.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources.
Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.

For Whole Blood Samples: Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.

For Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum.

For Plasma Samples: Collect blood into a collection tube with anticoagulants (heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.

Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Do not freeze whole blood sample. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris. EDTA shouldn't be used as anticoagulant.

Kit components: Test devices, droppers, diluent (for whole blood samples only) and instructions for use.

Additional materials required but not provided: Sample collection tube, centrifuge and timer, lancet, heparinized dispensing bulbs and capillary tubes (for only fingerstick whole blood).

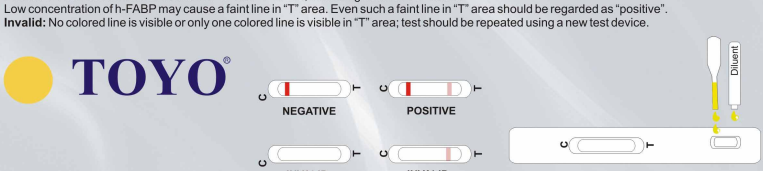
Additional materials recommended but not provided: Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

TEST PROCEDURE

1. Take the test device out of its pouch. Bring the tests and whole blood / serum /plasma samples to room temperature.
2. **For Whole Blood Samples:** Draw whole blood sample into dropper and put 1 drop (30 µl) into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.
3. **For Serum / Plasma Samples:** Draw serum / plasma into dropper and put 2 drops (60 µl) into the sample well of the cassette. Allow first drop to soak in before adding the next drop. Do not use diluent for serum / plasma samples.
Avoid the formation of any air bubbles.
4. Depending on the h-FABP concentration in the sample, after sample reach the view window, the test can react even in 5 minutes. Results should be read at 15 minutes as shown below. Results forming after 15 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area, indicating that h-FABP does not exist.
Positive: Two colored lines are visible in "C" and "T" areas, indicating that h-FABP exists.
Low concentration of h-FABP may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Cut off: 6,5 ng/ml
h-FABP Cardiac InfarctionTest Device has been evaluated using clinical samples. Clinical studies show that 3 hours after the onset of AMI, h-FABP Cardiac Infarction Test Device's accuracy is 90 %, between 3 and 6 hours 98 % and 12 hours later 87 %.

INTERFERENCES

h-FABP Cardiac Infarction Test Device has been tested with potential interfere substances such as; 110 mg/ml human albumin, 6 mg/ml bilirubin, 10 mg/ml hemoglobin, 5 mg/ml cholesterol and 15 mg/ml triglycerids and no interference was observed.
h-FABP Cardiac Infarction Test Device has also been tested with following compounds and no interference was observed at a concentration of 50 µg/ml.

Acetominophen	Captopprill	Flunarizine Hydrochloridine	Oxazepam
Acetylsalicylic acid	Chloramphanicol	Furosemide	Pentoxifyline
Anisodamine	Chlordiazepoxide	Hydrochlorothiazide	Phenobarbital
Asorbic acid	Cilazapril	Isosorbide Mononitrate	Quinine
Atenolol	Diclofenac	Labetalol	Ramipril
Atorvastatin Calcium	Digoxin	Metoprolol Tartrate	DL-Tyrosine
Bisoproplol Fumarate	Erythromycin	Moracizine Hydrochloride	Trimethoprim
Caffeine	Felodipine	Nifedipine	Verapamill

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SYMBOLS USED

CE

Manufacturer

EC REP Authorized European Representative

Attention, see instruction for use

Consult instruction for use

IVD *In vitro* diagnostic medical device

Σ n Number of test

For single use only

Storage temperature

LOT Lot number

REF Catalog number

Expiry date