TOYO DIAGNOSTICS

INSTRUCTIONS FOR USE
ONE STEP TEST
CK-MB (Creatine kinase MB)
Detection in Whole Blood / Serum / Plasma

Only for professional *in vitro* diagnostic use

Product Code : TCM01
CK-MB (Creatine kinase MB) Test Device detects CK-MB in human whole blood / serum / plasma.

BACKGROUND INFORMATION

Creatine Kinase MB (CK-MB) is an enzyme present in the cardiac muscle with a molecular weight of 87.0 kDa. Creatine Kinase is a dimeric molecule formed from two subunits designated as "M" and "B" which combine to form three different isoenzymes, CK-MM, CK BB, and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue. The release of CK-MB into the blood following MI can be detected within 3-8 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours. CK-MB is one of the most important cardiac markers and is widely recognized as the traditional marker for the diagnosis of MI.

INTENDED USE

CK-MB (Creatine kinase MB) Test Device is a rapid chromatographic immunoassay for the qualitative detection of CK-MB in human whole blood / serum / plasma samples to aid diagnosis of myocardial infarction (AMI).

REAGENTS

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

METHOD

CK-MB Test Device is a rapid, qualitative, immunochromatographic assay for the detection of CK-MB 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-CK-MB antibodies. This complex migrates to the other end of the membrane by capillary action. If there is CK-MB 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 CK-MB, 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.Unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
8.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 device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.
9.The test result should be used in conjunction with other clinical information such as clinical signs/ symptoms and other test results to diagnose AMI. A negative result obtained from a patient whose sample was taken at 2 - 16 hours after onset of chest pain may help in ruling out AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis and requires further confirmation. Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of CK-MB into the blood stream.
10.This test will indicate only the presence or absence of CK-MB 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.

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 (EDTA, 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 (EDTA, 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.

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

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

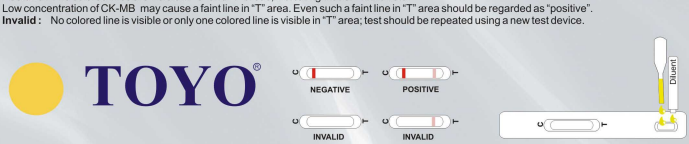
Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

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 into dropper and put 2 drops (60 µl) into the sample well of the cassette. Immediately after, 1 drop (~40µL) of diluent is added into the sample well and allowed to soak in.
For Serum / Plasma Samples: Draw serum / plasma into dropper and put 2 drops (60 µl) into the sample well of the cassette. Do not use diluent for serum / plasma samples.
Avoid the formation of any air bubbles.
3. Depending on the CK-MB concentration in the sample, the test can react even in 5 minutes. Results should be read at 10 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative : Only one colored line is visible in "C" area, indicating that CK-MB does not exist.
Positive : Two colored lines are visible in "C" and "T" areas, indicating that CK-MB exists.
Low concentration of CK-MB 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

Sensitivity and Specificity

The One Step CK-MB Test Device (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial CK-MB EIA test using clinical specimens. The results are as below;

Method		EIA		Total Results
CK-MB Test Device	Results	Positive	Negative	
	Positive	69	1	70
	Negative	0	350	350
Total Results		69	351	420

Sensitivity: 100%
+ Predictive V: 98,6 %
Cut off: 5 ng/mL
Specificity: 99,8%
- Predictive V: 100%

Intra-Assay

Within-run precision has been determined by using replicates of 15 tests for each of three lots using CK-MB specimen levels at 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL and 40 ng/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 five specimens: 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL and 40 ng/mL of CK-MB. Three different lots of the One Step CK-MB Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

CROSS REACTIVITY

Sera containing known amounts of CK-MB have been tested with 1,390 ng/mL CK-MM and 1,000 ng/mL CK-BB. No cross-reactivity was observed, indicating that the One Step CK-MB Test Device (Whole Blood/Serum/Plasma) has a high degree of specificity for CK-MB.

INTERFERING SUBSTANCES

The One Step CK-MB Test Device (Whole Blood/Serum/Plasma) has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 6 mg/mL bilirubin, 10 mg/mL hemoglobin, 5 mg/mL cholesterol and 15 mg/mL triglycerides. The following compounds have also been tested using the One Step CK-MB Test Device (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen
Acetoacetic Acid
Acetylsalicylic acid
Anisodamine
Ascorbic Acid
Atenolol
Atorvastatin Calcium
Caffeine
Captopril
Chloramphanicol
Chlordiazepoxide
Cilazapril
Creatine
Diclofenac
Digoxin
DL-Tyrosine
Ethanol
Felodipine
Flunarizine Hydrochloride
Furosemide
Gentisic Acid
Hydrochlorothiazide
Isosorbide Mononitrate
Labetalol
Metoprolol Tartrate
Moracizine Hydrochloride
Nifedipine
Oxalic Acid
Oxazepam
Pentoxifyline
Phenobarbital
Quinine
Ramipril
Verapamil

REFERANCES

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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
Σn Number of test
For single use only
Storage temperature
LOT Lot number
REF Catalog number
Expiry date