BoatBIO

IVD

CK-MB Rapid Test Kit (Colloidal Gold)

A rapid test for the diagnosis of myocardial infarction (MI) to detect CK-MB qualitatively in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

PRODUCT NAME

CK-MB Rapid Test Kit(Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The CK-MB Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human CK-MB in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

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.
The CK-MB Rapid Test (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of antibody coated particles and capture reagents to qualitatively detect CK-MB in whole blood, serum or plasma. The minimum detection level is 5 ng/mL CK-MB.

PRINCIPLE

The CK-MB Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of CK-MB in whole blood, serum or plasma. The membrane is pre-coated with specific capture antibodies in the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with specific antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with specific capture reagents on the membrane and generate a colored line. The presence of this colored line in the specific test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control,a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided
• Test devices • Package insert • Buffer • Droppers
Materials Required but Not Provided
• Timer • Specimen collection containers •Centrifuge •Lancets (for fingerstick whole blood only) •Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

WARNINGS AND PRECAUTIONS

1 For professional in vitro diagnostic use only. Do not use after the expiration date.
2 Do not eat, drink or smoke in the area where the specimen or kits are handled.
3 Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4 Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5 Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

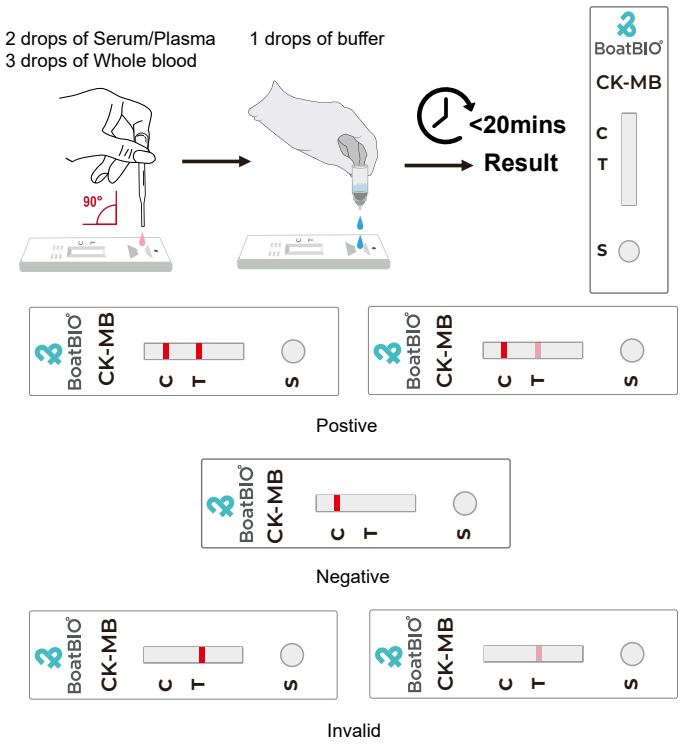
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

• The CK-MB Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
• To collect Fingerstick Whole Blood specimens:
• Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
• Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
• Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
• Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
• Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
• Touch the end of the capillary tube to the blood until filled to approximately 75j.iL. Avoid air bubbles.
• Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
• Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
• Position the patient’s finger so that the drop of blood is just above the specimen area of the test cassette.
• Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient’s finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
• Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clearnon-hemolyzed specimens.
• Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
• Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
• If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

Allow test devices, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
For Serum or Plasma specimen:
• Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 μ L) to the specimen well, then add 1 drop of buffer (approximately 40 μL), and start the timer. See illustration below.
For Venipuncture Whole Blood specimen:
• Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 μL) to the specimen well, then add 1 drop of buffer (approximately 40 μL), and start the timer. See illustration below.
For Fingerstick Whole Blood specimen:
• To use a capillary tube: Fill the capillary tube and transfer approximately 75 μL of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 μ L) and start the timer. See illustration below.
• To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 μL) to fall into the specimen well of test cassette, then add 1 drop of buffer (approximately 40 μ L) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE:* A colored line in the control line region (C) and the presence of another colored line in the test line regions indicates a positive result. This indicates that the concentration of CK-MB is above the minimum detection level.
***NOTE**: The intensity of the color in the test line region(s) will vary depending on the concentration of CK-MB present in the specimen. Therefore, any shade of color in the test line regions should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).This indicates that the concentration of CK-MB are below the minimum detection levels.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

I .The CK-MB Rapid Test (Whole Blood/Serum/ Plasma) is for in vitro diagnostic use only. This test should be used for the detection of CK-MB in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in CK-MB can be determined by this qualitative test.
2. The CK-MB Rapid Test (Whole Blood/Serum/ Plasma) will only indicate the qualitative level of CK-MB in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The CK-MB Rapid Test (Whole Blood/Serum/Plasma) cannot detect less than

5ng/mL CK-MB in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
6. 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 cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.

EXPECT VALUE

The CK-MB Rapid Test (Whole Blood/Serum/ Plasma) has been compared with a leading commercial CK-MB ELISA test, demonstrating an overall accuracy of 99.4% with CK-MB.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The CK-MB Rapid Test (Whole Blood/Serum/ Plasma) has been evaluated with a leading commercial CK-MB ELISA test using clinical specimens. The results show that relative to leading ELISA tests, the CK-MB Rapid Test (Whole Blood/Serum/Plasma) shows >99.9% sensitivity and xx% specificity for CK-MB.

Method		ELISA		Total Results
CK-MB Rapid Test (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	62	3	65
	Negative	0	468	468
Total Results		62	471	533

Relative sensitivity:
62/62=>99.9% (95%CI*: 95.3%~100.0%);
Relative specificity: 468/471=99.4% (95%CI*: 98.1%~99.9%);
Accuracy: (62+468)/(62+3+468)=99.4%(95%CI*: 98.4%~99.9%).
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of below five specimens: CKMB 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: Ong/mL, 5ng/mL, 10ng/mL, 20ng/mL, and 40ng/mL of CK-MB. Three different lots of the CK-MB Rapid Test (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The CK-MB Rapid Test (Whole Blood/Serum/Plasma) has been tested by 3,200 ng/mL CKMM, 1,700ng/mL CK-BB, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to CK-MB negative and positive specimens respectively.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL	Bilirubin: 1,000mg/dL
Acetylsalicylic Acid: 20 mg/dL	Creatin: 200 mg/dL	Oxalic Acid: 600mg/dL
Gentisic Acid: 20 mg/dL	Ascorbic Acid: 20mg/dL	Cholesterol: 800mg/dL
Hemoglobin: 1,000 mg/dL	Albumin: 10,500mg/dL	Triglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay.

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

CMC MEDICAL DEVICES & DRUGS S.L
Address: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054
Email - info@cmcmedicaldevices.com