Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep CK-MB (Serum/Plasma) RapiCard™ InstaTest

REF 166776-1-44

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.

IVD See external Label 20°C 30°C Σ 1 Test

INTENDED USE

The CK-MB RapiCard InstaTest (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 AND EXPLANATION

Creatine Kinase MB (CK-MB) is an enzyme present in the cardiac muscle with a molecular weight of 87.0 kDa.[1]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. [3] 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 RapiCard InstaTest (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.

TEST PRINCIPLE

The CK-MB RapiCard InstaTest (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 each of 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.

SPECIMEN COLLECTION AND PREPARATION

- The CK-MB RapiCard InstaTest (Serum/Plasma) can be performed usingserum or plasma.
- 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.

MATERIALS AND COMPONENTS

Materials provided with the test kit

- Test Cassettes
- Droppers
- Buffer
- Package insert

Materials required but not provided

- Specimen collection Containers
- Centrifuge
- Timer

For fingerstick whole blood

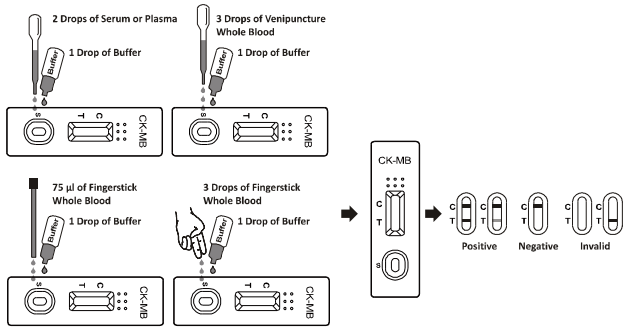
- Lancets
- Heparinized capillary tubes and dispensing bulb

ASSAY PROCEDURE

Allow the test, specimen, buffer and/or controls to reach 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 within one hour.
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 50µL)** to the specimen area, then **add 1 drops of buffer** (approximately **40 µL**), 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.



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RESULTS

POSITIVE:*A colored line in the control line region (C) and the presence of one or more colored lines 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The CK-MB RapiCard InstaTest (Serum/ Plasma) has been evaluated with a leading commercial CK-MB EIA test using clinical specimens. The results show that relative to leading EIA tests, the CK-MB RapiCard InstaTest (Serum/Plasma) shows >99.9% sensitivity and 99.4% specificity for CK-MB.

CK-MB Rapid Test vs. EIA

Method		EIA		Total Result
CK-MB RapiCard InstaTest (WholeBlood/Serum/Plasma)	Results	Positive	Negative	
	Positive	62	3	65
	Negative	0	468	468
Total Result		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: 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: 0ng/mL, 5ng/mL, 10ng/mL, 20ng/mL, and 40ng/mL of CK-MB. Three different lots of the CK-MB RapiCard InstaTest (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The CK-MB RapiCard InstaTest (Whole Blood/Serum/Plasma) has been tested by 3,200 ng/mL CK-MM, 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.

REAGENTS

The test contains anti-CK-MB antibody conjugated colloid gold particles and capture reagents coated on the membrane.

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 OF PROCEDURE

1. The CK-MB RapiCard InstaTest (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 RapiCard InstaTest (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 RapiCard InstaTest (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.

EXPECTED VALUES

The CK-MB RapiCard InstaTest (Serum/ Plasma) has been compared with a leading commercial Myoglobin/CK-MB/cTnI EIA test, demonstrating an overall accuracy of 99.4% with CK-MB.

PRECAUTION

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards

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throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE

Store as packaged in the sealed pouch either 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 after the expiration date.

REFERENCES

1. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. *J Clin Immunoassay*, 17:24-9, 1994.
2. Lee, T.H., Goldman, L. Serum enzyme assays in the diagnosis of acute myocardial infarction. *Ann Intern Med*, 105:221-233, 1986.
3. Kallner A,Sylven C,Brodin.U,etal.Early diagnosis of acute myocardial infarction;a comparison between chemical predictors. *Scand J Clin Lab Invest*, 49:633-9, 1989.

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