CK-MB TEST CARD
004A302

A rapid test for the qualitative detection of CK-MB in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE
The **CK-MB test card** 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 infarct (MI).

SUMMARY
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.[2] 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 test card** is a simple test that utilizes a combination of anti-CK-MB antibody coated particles and capture reagent to detect CK-MB in whole blood, serum or plasma. The minimum detection level is 5 ng/mL.

PRINCIPLE
The **CK-MB test card** is a qualitative, membrane based immunoassay for the detection of CK-MB in whole blood, serum or plasma. The membrane is pre-coated with capture reagent on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-CK-MB antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture reagent on the membrane and generate a colored line. The presence of this colored line in the 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.

REAGENTS
The **CK-MB test card** contains anti-CK-MB antibody coated particles and capture reagent coated on the membrane.

PRECAUTIONS
- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not use if pouch is damaged.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Humidity and temperature can adversely affect results.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.

STORAGE AND STABILITY
The kit can be stored at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

MATERIALS
MATERIALS PROVIDED
- Test devices
- Disposable specimen droppers
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Specimen collection container
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Timer

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SPECIMEN COLLECTION AND PREPARATION

- The **CK-MB test card** 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 device by using **a capillary tube**:
  - Touch the end of the capillary tube to the blood until filled to approximately 100 µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
- Add the Fingerstick Whole Blood specimen to the test device by using **hanging drops**:
  - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
  - Allow 4 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. 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

1 Allow the test device, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

2 Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.

3 Place the test device on a clean and level surface.

4a For **Serum or Plasma** specimens: Hold the dropper vertically and **transfer 2 drops of serum or plasma** (approximately 50 µL) to the specimen well (S) of the test device, then start the timer. See illustration below.

4b For **Venipuncture Whole Blood** specimens: Hold the dropper vertically and **transfer 4 drops of venipuncture whole blood** (approximately 100 µL) to the specimen well (S) of the test device, then start the timer. See illustration below.

4c For **Fingerstick Whole Blood** specimens:
- To use a capillary tube: Fill the capillary tube and **transfer approximately 100 µL of fingerstick whole blood** specimen to the specimen well (S) of the test device, then start the timer. See illustration below.
- To use hanging drops: Allow **4 hanging drops of fingerstick whole blood specimen** (approximately 100 µL) to fall into the center of the specimen well (S) on the test device, then start the timer. See illustration below.

5 Wait for the coloured line(s) to appear. **Read results at 10 minutes.** Do not interpret results after more than 20 minutes.

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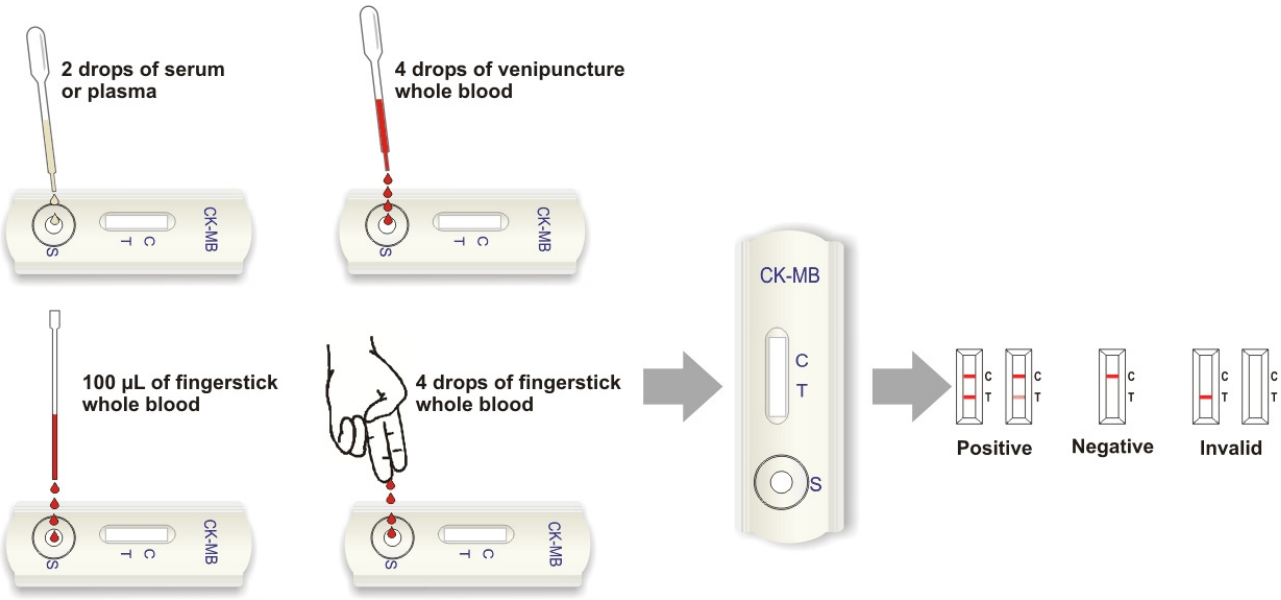

INTERPRETATION OF RESULTS

Negative: **One colored line appears in the control line region (C).** No apparent colored line appears in the test line region. This indicates that the concentration of CK-MB is below the minimum detection level.

Positive:* **Two distinct colored lines appear.** One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Invalid: **Control line (C) 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 card. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

***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.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is 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

1. The **CK-MB test card** 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 test card** 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 test card** cannot detect less than 5 ng/mL of 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. 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.

EXPECTED VALUES

The **CK-MB test card** has been compared with a leading commercial CK-MB EIA test, demonstrating an overall accuracy of 99.8%.

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PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The **CK-MB test card** has been evaluated with a leading commercial CK-MB EIA test using clinical specimens. The results show that the sensitivity of the **CK-MB test card** is 100% and the specificity is 99.8% relative to the leading EIA test.

CK-MB test card vs. EIA

Method		EIA		Total Results
	Results	**Positive**	**Negative**	
CK-MB test card	**Positive**	54	1	55
	Negative	0	422	422
Total Results		54	423	477

Relative Sensitivity: 100% (93.4%-100.0%) *
Relative Specificity: 99.8% (98.7%-99.9%)*
Accuracy: 99.8% (98.8% to 99.9%)*
* 95% Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using replicates of 10 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 **CK-MB test card** have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Sera containing known amounts of antibodies to 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 **CK-MB test card** has a high degree of specificity for CK-MB.

Interfering Substances

The **CK-MB test card** 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 **CK-MB test card** and no interference was observed.

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

BIBLIOGRAPHY

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, et al. *Early diagnosis of acute myocardial infarction; a comparison between chemical predictors.* Scand J Clin Lab Invest, 49:633-9, 1989.

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	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Use by
	Read instructions for use		Store at

ulti med Products (Deutschland) GmbH
Reeshoop 1 • 22926 Ahrensburg
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