



# Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)

## Package Insert

English

REF: CMA-435

A rapid test for the diagnosis of myocardial infarction (MI) to detect Myoglobin, CK-MB and cardiac Troponin I (cTnI) qualitatively in whole blood, serum or plasma.

For professional *in vitro* diagnostic use only.

**[INTENDED USE]**

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

**[SUMMARY]**

Myoglobin (MbO), creatine kinase MB (CK-MB) and cardiac Troponin I (cTnI) are proteins released into the bloodstream after cardiac injury. Myoglobin is a heme-protein normally found in skeletal and cardiac muscle with a molecular weight of 17.8 kDa. When muscle cells are damaged, Myoglobin is released into the blood rapidly due to its relatively small size. The level of Myoglobin increases measurably above baseline within 4-6 hours after onset of cardiac injury, and returning to baseline within 24-36 hours. CK-MB is an enzyme also released in cardiac injury, and returning to baseline within 20-24 hours. Creatine kinase is a dimeric molecule formed from two subunits designated as "M" and "B". Creatine kinase most involved in the metabolism of cardiac muscle tissue. The release of CK-MB into the blood following an MI can be detected within 3-6 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours. Cardiac Troponin I is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is part of a three subunit complex comprised of Troponin T and Troponin C. Along with Troponin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of Troponin I is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury.

Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a simple test that uses conjugated anti-Myoglobin, anti-CK-MB and anti-cTnI antibodies to qualitatively detect Myoglobin, CK-MB and cardiac Troponin I (cTnI) in whole blood, serum or plasma. The minimum detection level is 50ng/mL Myoglobin, 5ng/mL CK-MB and 0.5ng/mL Troponin I.

**[PRINCIPLE]**

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of Myoglobin, CK-MB and cardiac Troponin I (cTnI) 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 wetting has occurred.

**[REAGENTS]**

The kit uses anti-Myoglobin antibody conjugated colloid gold particles, anti-CK-MB antibody conjugated colloid gold particles, anti-Troponin I antibody conjugated colloid gold particles, and capture reagents coated on the membrane.

**[PRECAUTIONS]**

- 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 the test cassette if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards 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 materials should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Storage and stability can adversely affect results.

Store the packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test result is stable in the sealed pouch. **DO NOT FREEZE.** Do not use after the expiration date.

**[SPECIMEN COLLECTION AND PREPARATION]**

- The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (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 cassette by using a **capillary tube**:
  - Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles both on the top and of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Add the **Fingerstick Whole Blood Specimen** to the test cassette by using **handing drogs**:
  - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
- Allow 2 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 clear non-hemolyzed specimens.

Testing should be performed immediately after the specimens have been collected. Do not place the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 2 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C (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.

Use 3 specimens to run temperature prior to testing. Frozen specimens must be completely thawed and 3 specimens to run temperature. Do not refreeze 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]

Materials provided

- Test Cassettes
- Specimen collection Containers
- For fingerstick whole blood
- Lancets
- Capillary Tubes
- Heparinized capillary tubes and dispensing bulb

Materials required but not provided

- Butter
- Centrifuge
- Timer

## [DIRECTIONS FOR USE]

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
- 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 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL), and start the timer. See illustration below.

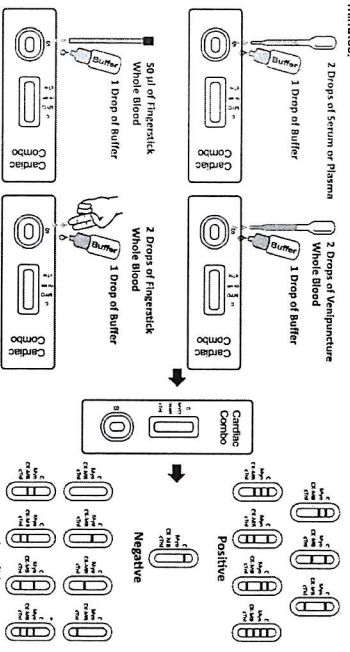
**For Venipuncture Whole Blood Specimen:**

- Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 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 50 µL of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
- To use handing drogs: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50 µL) to fall into the specimen area of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. Read result at 10 minutes. Do not interpret the result after 20 minutes.



## [INTERPRETATION OF RESULTS]

(Please refer to the illustration above)

**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 Myoglobin, CK-MB and/or cardiac Troponin I 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 Myoglobin, CK-MB and/or cardiac Troponin I 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 Myoglobin, CK-MB and cardiac Troponin I are below the minimum detection levels.

**INVALID:** No line appears in the control line region (C) and no line appears in the test line region (T). This indicates that the specimen volume or incorrect procedural techniques are the most likely reason 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.

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

- The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of Myoglobin, CK-MB, and cardiac Troponin I (cTnI) in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of the Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) will only be used as the sole criteria for the diagnosis of myocardial infarction.
- The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 50ng/mL Myoglobin, 5ng/mL CK-MB and 0.5ng/mL cardiac Troponin I (cTnI) in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
- 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 levels 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 Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a commercial Myoglobin, CK-MB, cTnI ELISA test, demonstrating an overall sensitivity of 97.5% with Myoglobin, 95.1% with cardiac Troponin I (cTnI), 99.4% with CK-MB.

## [PERFORMANCE CHARACTERISTICS]

Sensitivity and Specificity

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) was evaluated with a leading commercial Myoglobin ELISA, CK-MB ELISA, cTnI ELISA test using clinical specimens. The results show that relative to leading ELISA tests, the Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) shows 99.9% sensitivity and 97.2% specificity for Myoglobin, 99.4% sensitivity and 99.0% specificity for cardiac Troponin I (cTnI), and 99.9% sensitivity and 99.4% specificity for CK-MB.

Method	Results	Positive	Negative	Total Results
Myoglobin Rapid Test Cassette (Whole Blood/Serum/Plasma)	Positive	94	319	379
	Negative	54	390	444
<b>Total Results</b>				
	Positive	94	319	379
	Negative	54	390	444
<b>Confidence Intervals</b>				
Relative sensitivity: 97.5% (95%CI: 94.6%-100.0%)				
Relative specificity: 99.4% (95%CI: 97.6%-99.9%)				
Accuracy: (54+319)/(54+1+319+390)=99.9%				
<b>Confidence Intervals</b>				
Relative sensitivity: 99.9% (95%CI: 98.0%-99.9%)				
Relative specificity: 97.2% (95%CI: 94.6%-99.9%)				
Accuracy: (172+417)/(172+5+417)=99.1%				
<b>Confidence Intervals</b>				
Relative sensitivity: 99.4% (95%CI: 98.0%-99.9%)				
Relative specificity: 99.4% (95%CI: 98.0%-99.9%)				
Accuracy: (62+468)/(62+3+468)=99.4%				

Method	Results	Positive	Negative	Total Results
CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma)	Positive	62	468	533
	Negative	6	471	533
<b>Total Results</b>				
	Positive	62	468	533
	Negative	6	471	533

Method	Results	Positive	Negative	Total Results
Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	Positive	172	417	650
	Negative	1	477	650
<b>Total Results</b>				
	Positive	172	417	650
	Negative	1	477	650

Relative sensitivity: 99.9% (95%CI: 98.0%-99.9%)  
Relative specificity: 97.2% (95%CI: 94.6%-99.9%)  
Accuracy: (172+417)/(172+5+417)=99.1%

Relative sensitivity: 99.4% (95%CI: 98.0%-99.9%)  
Relative specificity: 99.4% (95%CI: 98.0%-99.9%)  
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Attention, see instructions for use For *in vitro* diagnostic use only

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