Rapid Response™

Cardiac Markers Combo Test Cassette
(Whole Blood/Serum/Plasma)

REF MCT-13C40 Product Insert

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ Cardiac Markers Combo Test Cassette is a rapid visual immunoassay for the qualitative, presumptive detection of human Myoglobin, CK MB and cardiac Troponin I in whole blood, serum or plasma. This kit is intended for use as an aid in the diagnosis of myocardial infarction (MI).

Introduction

Myoglobin (MYO), 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. It constitutes about 2 percent of total muscle protein and is responsible for transporting oxygen within muscle cells. 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 2-4 hours post-infarct, peaking at 9-12 hours, and returning to baseline within 24-36 hours. CK-MB is an enzyme also 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 an 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. 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 tropomyosin, 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.

Principle

The Rapid Response™ Cardiac Markers Combo Test Cassette detects Myoglobin, CK-MB and Troponin I through visual interpretation of color development on the internal strip. Anti-myoglobin, anti-CK-MB, and anti-cTnI antibodies are immobilized on the respective test regions of the membrane. During testing, the specimen reacts with anti-myoglobin, anti-CK-MB, and anti-cTnI antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are certain sufficient markers in the specimen, a colored band will form at the corresponding test region of the membrane. The presence of this colored band indicates a positive result for that marker, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

Materials

Materials provided

- Individually packed test devices
- Buffer
- Disposable pipettes
- Product insert

Materials required but not provided

- Specimen collection container
- Timer
- Centrifuge

Storage and Stability

- The kit should be stored at 35.6-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Collection and Storage of Specimens

- The Rapid Response™ Cardiac Markers Combo Test Cassette is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6-46.4°F (2-8°C) for up to 3 days. For long term storage, specimens should be kept below -4°F (-20°C). Whole blood collected by venipuncture should be stored at 35.6-46.4°F (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.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.
- 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.

Test Procedure

Bring tests, specimens, buffer and/or controls to room temperature (59-86°F; 15-30°C) before use.

1. Remove the test from its sealed pouch and use it as soon as possible. For best results, the assay should be performed within one hour.
2. Place the test device on a clean and level surface.

For Serum or Plasma specimens:

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

For Whole Blood specimen:

b) Transfer **3 drops of whole blood specimen** (approximately 75 µL) to the specimen well of the device with the provided disposable pipette, then add **1 drop of buffer** and start the timer.

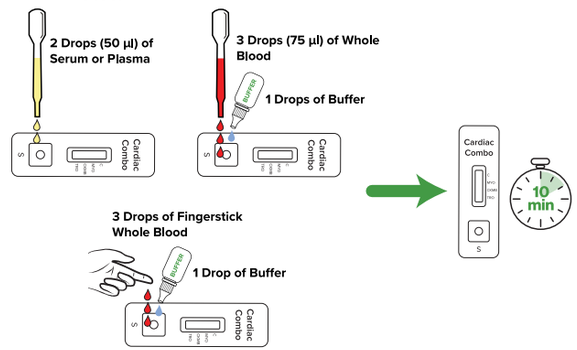
OR

c) Allow **3 hanging drops of fingerstick whole blood specimen** to fall into the center of the specimen well (S) on the device, then add **1 drop of buffer** and start the timer.

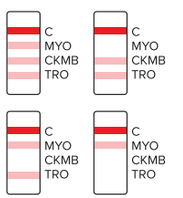
Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.

As the test begins to work, color will migrate across the membrane.

3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

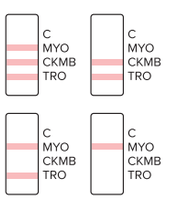


Results Interpretation



POSITIVE: One band appears in the control region (C) and another one, two, or three band(s) appear(s) in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Rapid Response™ Cardiac Markers Combo Test Cassette is for professional in vitro diagnostic use, and should be used for the detection of Myoglobin, CK MB, and Troponin I. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The Rapid Response™ Cardiac Markers Combo Test Cassette will only indicate the presence of Myoglobin, CK-MB and Troponin I in the specimen, and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 50 ng/mL Myoglobin, 5 ng/mL CK-MB or 0.5 ng/mL Troponin I in specimens. Thus, a negative result does not at any time rule out the existence of those cardiac markers in blood, because they may be absent or below the minimum detection level of the test.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
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.

Performance Characteristics

Table: Myoglobin Rapid Test vs. EIA

Relative Sensitivity:
>99.9% (94.0%-100.0%)*
Relative Specificity:
97.7% (95.6%-98.8%)*
Overall Agreement:
98.0% (96.2%-98.9%)*
***95% Confidence Interval**

		Myoglobin Rapid Test +	-	Total
EIA	+	60	0	60
	-	9	374	383
		69	374	443

Table: CK-MB Rapid Test vs. EIA

Relative Sensitivity:
>99.9% (93.4%-100.0%)*
Relative Specificity:
99.8% (98.7%-100.0%)*
Overall Agreement:
99.8% (98.8%-100.0%)*
***95% Confidence Interval**

		CK-MB Rapid Test +	-	Total
EIA	+	54	0	54
	-	1	422	423
		55	422	477

Table: Troponin I Rapid Test vs. EIA

Relative Sensitivity:
98.7% (96.2%-99.6%)*
Relative Specificity:
98.4% (97.0%-99.2%)*
Overall Agreement:
98.5% (97.4%-99.2%)*
***95% Confidence Interval**

		CK-MB Rapid Test +	-	Total
EIA	+	225	3	228
	-	8	505	513
		233	508	741

Bibliography

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8. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.

Glossary of Symbols

Consult instructions for use
Test per Kit
Authorized Representative
Store between 35.6°F to 86°F (2-30°C)
Use by
Do Not Reuse
LOT Lot Number
IVD For *in vitro* diagnostic use only
REF Catalogue #

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