HOMEMED CARDIAC COMBO 3-in-1 (Myo/CK-MB/Trop I) TEST KIT (Whole Blood/Serum/Plasma)

HOMEMED

For in vitro diagnostic use by healthcare professionals only.

INTENDED USE

The HOMEMED Cardiac Combo 3-in-1 (Myo/CK-MB/Trop I) Test Kit (Whole Blood/Serum/Plasma) 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 a SCREENING test only to aid in the diagnosis of myocardial infarction (MI). Positive and negative results should be confirmed by a laboratory.

INTRODUCTION

Myoglobin (Myo), Creatine Kinase MB (CK-MB) and cardiac Troponin I (cTn I) 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 a longer window of detection for cardiac injury.

PRINCIPLE

The HOMEMED Cardiac Combo 3-in-1 (Myo/CK-MB/Trop I) Test Kit (Whole Blood/Serum/Plasma) detects Myoglobin, CK-MB and Troponin I through visual interpretation of colour development on the internal strip. Anti-myoglobin, anti-CK-MB, and anti-cTnI antibodies are immobilised 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 coloured 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 coloured line will form at the corresponding test line region of the membrane. The presence of this coloured line indicates a positive result for that marker, while its absence indicates a negative result. The appearance of a coloured line at the control line region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS REQUIRED

Materials Provided	**Materials Required but not provided**
Individually packed test	Timer
Disposable pipette	
Safety lancet	
Buffer	
Package insert	

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.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch 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.

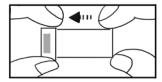
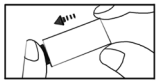
SPECIMEN COLLECTION AND STORAGE

- The HOMEMED Cardiac Combo 3-in-1 (Myo/CK-MB/Trop I) Test Kit (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum or plasma specimens only.
- Only clear, non-hemolysed 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 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 performed 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.

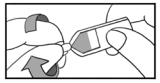
PROCEDURE

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

1. Remove the test, safety lancet, alcohol swab and buffer from the sealed pouch and place it on a clean, level surface. The test should be performed immediately after opening.
2. Clean the puncture site with the alcohol swab provided.
3. Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the finger.

4. Twist off the cap of the buffer ampule.



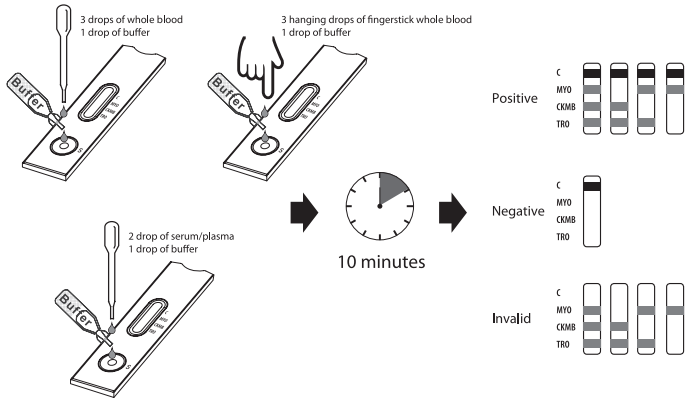
5. Using whole blood: Transfer 3 drops of whole blood (± 75µl) to the specimen well (S) of the device with the provided disposable pipette, then add 1 drop of buffer and start the timer.
   OR
   Allow 3 drops of hanging fingerstick whole blood to fall into the center of the specimen well (S) of the test device, then add 1 drop of buffer

and start the timer.

Using serum/plasma:

Transfer 2 drops of serum/plasma (± 50µl) to the specimen well (S) of the device with the provided disposable pipette, then start the timer.

6. 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, colour will migrate across the membrane.
7. Wait for the coloured line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes .



INTERPRETATION OF RESULTS

(Refer to the illustration above)

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

- A test line at the MYO test line indicates a Myoglobin concentration of ≥ 50 ng/ml
- A test line at the CKMB test line indicates a CK-MB concentration of ≥ 5 ng/ml
- A test line at the TRO test line indicates a Troponin I concentration of ≥ 0.5 ng/ml

Negative: Only one coloured line appears, in the control line region (C). No coloured lines appear in the test line region (T).

Invalid: Control line fails to appear. Results from any test which has not produced a control line 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 colour in the test line region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test line region should be considered positive. Note that this is a qualitative test only, and the concentration of analytes in the specimen can not be determined by the test.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured line appearing in the control line 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 OF THE TEST

1. The HOMEMED Cardiac Combo 3-in-1 (Myo/CK-MB/Trop I) Test Kit (Whole Blood/Serum/Plasma) 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 colour intensity or width of any apparent lines.
2. The HOMEMED Cardiac Combo 3-in-1 (Myo/CK-MB/Trop I) Test Kit (Whole Blood/Serum/Plasma) 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 Myoglobin below 50 ng/ml, CK-MB below 5 ng/ml or Troponin I below 0.5 ng/ml. Thus, a negative result does not at anytime 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 Test vs. ELA

Relative Sensitivity: >100.0% (94.0%-100.0%)*	**Myoglobin Test**				
			+	-	**Total**
Relative Specificity: >97.7% (95.6%-98.9%)*	**ELA**	+	60	0	**60**
Overall Agreement: >98.0% (99.7%-99.9%)*		-	9	374	**383**
***95% Confidence Interval**			69	374	443

Table: CK-MB Rapid Test vs. ELA

Relative Sensitivity: >100.0% (93.4%-100.0%)*	**CK-MB Rapid Test**				
			+	-	**Total**
Relative Specificity: >99.8% (98.7%-99.9%)*	**ELA**	+	54	0	**54**
Overall Agreement: >99.8% (98.8%-99.9%)*		-	1	422	**423**
***95% Confidence Interval**			55	422	477

Table: Troponin I Rapid Test vs. ELA

Relative Sensitivity: >98.7% (96.2%-99.7%)*	**CK-MB Rapid Test**				
			+	-	**Total**
Relative Specificity: >98.4% (97.0%-99.3%)*	**ELA**	+	225	3	**228**
Overall Agreement: >98.5% (97.4%-99.3%)*		-	8	505	**513**
***95% Confidence Interval**			233	508	741

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

	Catalog number	2°C 30°C	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

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Material reference number - TBC.
effective date