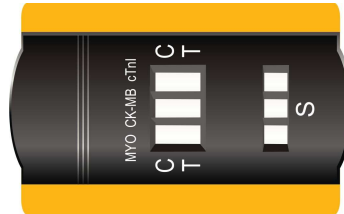


## CARDIAC COMBO TEST 004A313

### ulti med Cardiac Combo 3S Test Cassette for Whole blood, Serum or Plasma



#### INTENDED USE

The **Cardiac Combo 3S Test Cassette** is a rapid chromatographic immunoassay for the qualitative detection of human Myoglobin, CK-MB and cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

#### SUMMARY

Myoglobin (MYO), Creatine Kinase MB (CK-MB) and cardiac Troponin I (cTnI) are proteins released into the bloodstream after cardiac injury. Myoglobin is a haeme 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.<sup>7</sup> 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.

The **Cardiac Combo 3S Test Cassette** utilizes a combination of antibody coated particles and capture reagents to qualitatively detect Myoglobin, CK-MB and Troponin I in whole blood, serum or plasma. The minimum detection level is 50 ng/ml Myoglobin, 5 ng/ml CK-MB and 1.0 ng/ml Troponin I.

#### PRECAUTIONS

The **Cardiac Combo 3S Test Cassette** should be stored at 4-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

#### SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection: Collect an anticoagulated blood sample by using heparin as the anti-coagulant. All three proteins, Troponin I, CK-MB or Myoglobin are very unstable in serum or whole blood specimen. Especially whole blood or serum specimens must be tested as soon as possible.

Plasma/Serum specimen collection:

1. Centrifuge whole blood to obtain plasma/serum specimen.
2. If specimens are not immediately tested, they should be refrigerated at 2-8°C. Specimens should be at room temperature before running a test.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

#### WARNINGS

- The same lancet needle should be used for one person only and should not be shared with another person, because the used needle is a biohazard.
- Decontaminate and dispose of all specimens, reaction kits, lancet needles and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
- Do not use the kit after the expiration date.
- Do not use if pouch is torn or damaged.
- Do not eat or smoke while handling specimens.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- For in vitro diagnostic use only.

#### MATERIALS PROVIDED

- 20 Test cassettes
- 60 disposable sample droppers
- 1 Package insert

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Heparinised tubes (for whole blood only)
- Timer

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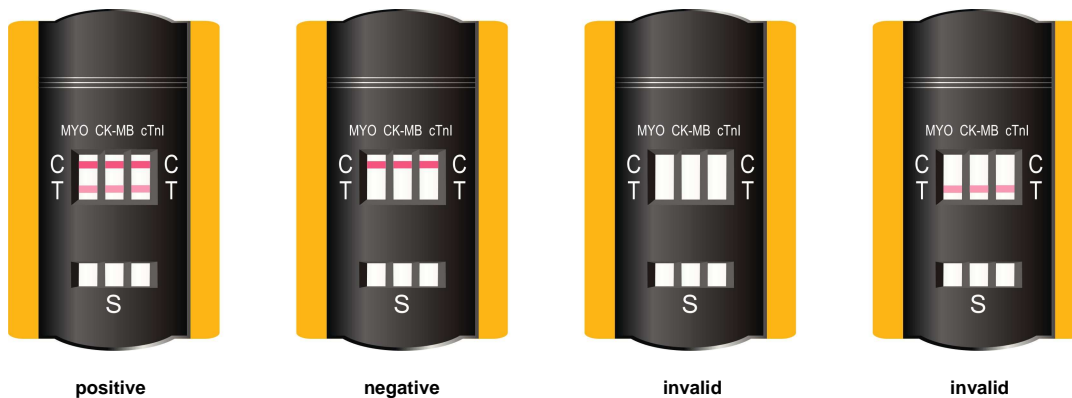
### PROCEDURE

1. Remove the test cassette from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test cassette and add 2 hanging drops of specimen into each of the Sample Wells. Repeat until a total of 5 drops are added into each of the sample wells. The subsequent addition of specimen should be done after the previous drops of specimen have been absorbed into the specimen well. If specimen drops are added too quickly, especially for blood specimen, it may cause clogging of the Sample Well.
3. As the test begins to work, you will see a reddish coloured front move across the respective Result Windows in the centre of the test cassette.  
**Note:** If the chromatography does not start 2 minutes after application of the sample, add one more drop of specimen into the respective sample well.
4. Interpret test results after 10 minutes. Do not interpret results after more than 20 minutes.

**Caution:** The above interpretation time is based on reading the test results at ambient temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

### INTERPRETATION OF THE TEST

1. A reddish line will appear at the section of each Result Window marked with "C". These lines are the Control Lines, which indicate that the tests are working properly.
2. There is a Test Line for each of the respective result window, MYO as Myoglobin, CK-MB as CK-MB, and cTnI as Troponin I.



**Positive Result:** The presence of a reddish coloured "C" control line together with any reddish colour of in the respective "MYO", "CKMB" or "cTnI" test line area, regardless of which line appears first, indicates a positive result of the respective parameter.

**Important Note:** Generally, the higher the analyte level in the specimen, the stronger the Test Line colour will be. When the analyte level is close to but still within the sensitivity limit of the test, the colour of the Test Line will be very faint. **Nonetheless, this is still a positive result.**

**Note:** Specimens containing very low levels of Myoglobin may develop a coloured "MYO" test line at more than 20 minutes.

**Negative Result:** The presence of only a reddish coloured "C" control line in the respective window indicates a negative result for this parameter.

**Invalid Result:** If after performing the test no reddish coloured control line is visible in the Result Window, this result is considered invalid for the respective parameter. Not following the procedures correctly or using a test kit that has deteriorated can cause invalid results. It is recommended that the specimen be re-tested.

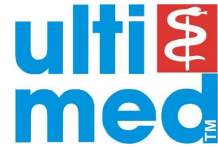
**Note:** A positive result will not change once you have established your answer at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 20 minutes. Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.

### LIMITATIONS OF THE TEST

Although the **Cardiac Combo 3S Test Cassette** is accurate in detecting cTnI, CK-MB and MYO, a low incidence of false results can occur. Not all patients suffering from acute heart diseases are supposed to release Troponin I in concentrations  $\geq 1$  ng/ml (see bibliography "Antman... et al."). Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. **From a fundamental point of view, rapid tests are not suited as a final criterion for the judgement of the status of a patient.**







# CARDIAC COMBO TEST

## 004A313



**References**

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 Manufacturer	 Contents sufficient for <n> tests
 For in vitro diagnostic use only	 Lot. no.
 For single use only	 Expiration date
 Read instructions for use	 Store at



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