



Cardiac Markers Combo(cTnl/Myo/CK-MB) Rapid Test

Catalog No.: BGW1501C

INTRODUCTION

The Cardiac Markers Combo Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of human Myoglobin, CKMB 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).

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 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. CKMB 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, CKMM, CKBB and CKMB. CKMB 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.

REAGENTS AND MATERIALS SUPPLIED

Cardiac Markers Combo Rapid Test kit contains the following components to perform the assay

1. Test device cassette
2. Assay Buffer
3. Instructions for use
4. Specimen Collection Straw/Capillary

SPECIMEN COLLECTION

Serum/plasma samples:

Fresh serum or plasma samples can be used. No special patient preparation required. Care should be taken to ensure blood full clotting and any visible particulate matter in the sample should be removed by centrifugation or filtration. Avoid the use of highly hemolytic, turbid, microorganism contaminated samples or samples stored for over 30days at 2-8°C. Store samples at 2-8°C.



Samples not required for assay within 3 days should be stored frozen (-20°C or lower). Avoid sample deterioration by multiple freeze-thaw cycles.

-Plasma: Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.

-Serum: Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.

The original samples cannot be tested directly, must be diluted with sample diluents before testing!

TEST PROCEDURE

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

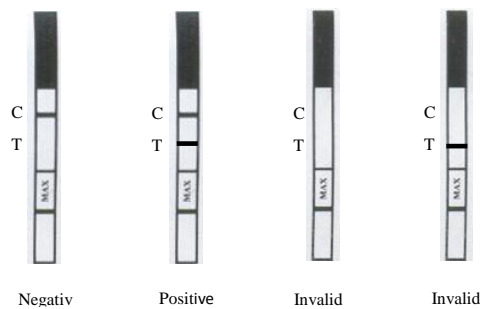
- (1) Remove the test device from the sealed pouch and use it as soon as possible.
- (2) With arrows pointing toward the urine specimen, immerse the strip test vertically in the urine specimen, for at least 5 seconds. Do not pass the maximum line (max) on the strip test when immersing the strip.
- (3) Lay the strip flatly on a non-absorbent clean surface. Start the timer and wait for the red line(s) to appear. Read result within 5 minutes but no longer than 15 minutes.

INTERPRETATION OF RESULTS

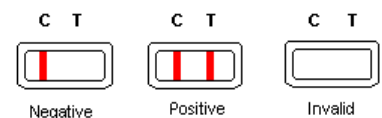
Negative: Only one colored band appears on the control (C) region. No apparent band on the test (T) region.

Positive: in addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region. Invalid: A total absence of color in both regions is an indication of procedure error and/or the test reagent has deteriorated.

Strip:



Cassette:



STORAGE AND STABILITY

The test kit can be stored at room temperature (4 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.