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See external label



2°C-30°C



Σ=25 or 50 tests



Cat. #166779-1

Troponin I/CKMB/Myoglobin Panel test One-Step Blood/plasma/serum Test

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A Panel of Assay for Acute Myocardial Infarction (AMI)

Immunoassay for the Qualitative Determination of Troponin I and Troponin I/T/C Complex and CKMB as well as Myoglobin

Intended Use

Cardiac Troponin I (cTni), CKMB and Myoglobin are three specific protein marker found in cardiac muscle. They and their complex are released to blood circulation soon after onset of acute myocardial infarction (AMI). The elevated level could be detected approximately 6-8 hours until 10-15 days after onset of AMI.

The Cortez Diagnostics, Inc. one-step Troponin I /CKMB/Myoglobin test is a panel of rapid immunoassay for qualitatively determination of Tni or CKMB or myoglobin.

Summary and Explanation

Tni is a molecular weight of 23,000. Together with troponin T and C, it forms a structure complex. The cTni and its complex are released to blood circulation soon after onset of acute myocardial infarction (AMI). The elevated level could be detected approximately 10-20 hours until 10-15 days after onset of AMI.

Two-form cTni, free cTni and cTn I-T-C complex, are released to bloodstream after cardiac damage. Tn I is found in skeletal muscles (sTni) as well, but it differs in its amino acid composition from cardiac Tni so that these two Tni can be distinguished immunologically. The elevated level could be detected approximately 10-12 hours after onset of AMI. Not only Tni is specific protein marker for AMI, it also remains the elevated level varied from 6 - 50 ng/ml for 60-80 hrs after AMI. The Cortez Diagnostics, Inc. cTni test is an easy, fast and visually read method that does not require instrumentation, such like ECG. The test system employs unique antibodies, one pair selectively identifies free cTni, and one pair selectively identifies cTni-T-C complex with a high degree of sensitivity.

CKMB is an isoform of enzyme Creatine kinase with MW 85,745. When the heart cells are damaged, it released to the blood rapidly. The elevated level could be detected approximately as early as 6 hour after onset of AMI. The CKMB range of normal serum is less than 5 ng/ml. The mean peak level of CKMB is 21 ng/ml or even higher after the onset of AMI.

The Cortez Diagnostics, Inc. CKMB test is an easy, fast and visually read method that does not require instrumentation, such like ECG. The test system employs unique antibodies, one pair selectively identifies CKMB with a high degree of sensitivity. The sensitivity and diagnostic efficacy of CKMB combined with myoglobin is a statistically significantly higher compared to the combination of cTni and myoglobin for the early diagnosis of AMI.

Myoglobin is a low molecular weight cytoplasm protein. When the muscle cells are damaged, it released to the blood rapidly than any other myocardial markers. The elevated level could be detected approximately as early as 1 hour after onset of AMI. The peak level appears at 4-8 hours after AMI. The myoglobin range of normal serum is 30-90 ng/ml. The level of myoglobin can elevate to 200 ng/ml or even higher after 1 hour of onset of AMI. During the peak hour, the level can be as high as 900 ng/ml. The level usually returned to normal 12 hrs after the onset of AMI.

The Cortez Diagnostics, Inc. myoglobin test is an easy, fast and visually read method that does not require instrumentation, such like ECG. The test system employs unique antibodies, one pair selectively identifies myoglobin with a high degree of sensitivity. Myoglobin is a better suited for the early diagnosis of AMI.

Principle of the Procedure

The Cortez Diagnostics, Inc. OneStep test utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay. If any one of cTni/cTni-T-C or CKMB or Myoglobin is present in the sample in concentration above the detection level, a labeled specific monoclonal antibody-dye complex. This complex is then captured by another specific monoclonal antibody immobilized in the Test Zone (“T”) of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of analyte in the sample. On the other hand, a color band will always appear at the control zone (“C”).

Materials Provided

1. Test Device
2. Dropper
3. Instruction manual

Materials Required But Not Provided

1. Timing device.
2. Specimen collection container.

Sample collection and Storage

1. Fresh blood samples are preferred. **While drawing** the blood, the anti-coagulant reagent, such as EDTA, must be added. The blood samples kept at refrigerate for overnight might be suitable for test.
2. Plasma and serum stored in refrigerate for a few days usually are suitable for test.

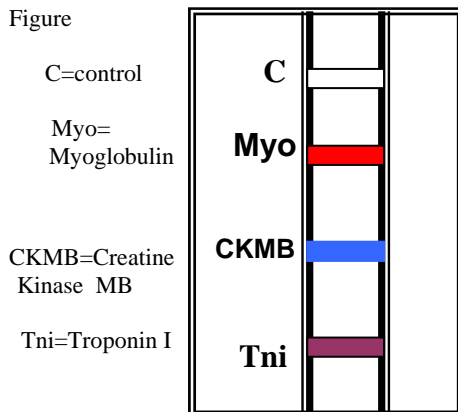
Quality Control

Although the Kit contains an internal quality control function (pink/rose color band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper kit performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

Assay Procedure

- Prior to use, bring test all components and patient samples to room temperature .
1. Remove the “test Device” from the foil wrapper by tearing along the “splice”, and place it on a clean level surface. Discard the desiccant. Bring all samples to room temperature.
 2. Add 10 **drops** of blood or 9 drops of serum into the Sample well (S) as shown in picture.
 3. Read the results within 20 minutes after the serum/plasma shown in the window.

Figure



INTERPRETATION OF RESULTS

POSITIVE Result: If the Test band (marked with a “T”) is shown up. Usually T band is shown up within 20 minutes if it is positive.

Negative Result: If there is no color line shown up within 20 minutes after the plasma shown up in the test window.

Invalid result: If a color band does not appear in the Control zone “C”, the test results are invalid. The sample may have been added to the wrong window, or the test device may have deteriorated. The specimen should be re-tested using a new test device.

WARNINGS AND PRECAUTIONS

1. Wear disposable gloves while handling Specimens. Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high-level disinfectant.
3. Decontaminate and dispose of all specimens, reaction Kits and potentially contaminated materials, as if they were infectious, in a biohazard container.
4. Avoid splashing or aerosol formation.
5. Do not use the Kit after the expiration date.
6. For in vitro diagnostic use only.

Limitations of the Test

1. The test is for in vitro diagnostic use only.
2. Although the test is very accurate in detecting elevated of analytes, a low incidence of false positive results can occur, especially lysis samples.
3. The test is a qualitative screening assay and is not suggested for use in determining the quantitative levels.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

Unique feature: As a matter of fact, for almost all one-step diagnostics kits with testing blood/serum samples, the strong false positive will be shown if the specimen come out of patients with Auto-immuno disease (such as RF+) or containing human anti-mouse antibodies (HAMA). Cortez Daignostics, Inc. Panel of AMI kit do not show any false positive mentioned above for the test of CKMB and Myoglobin -- that will help to exclude the false positive results.

Sensitivity and Precision

The sensitivity and cut-off of the one-step Test is

for Tni : 1 ng/ml

for CKMB: 5 ng/ml

for Myoglobin: 70 ng/ml

(The unit defined by Stratus II assay)

The precision of the one-step cTni test was determined using replicate assays of samples from three different patients' pools, with kits from three different production lots. Each specimen sample was run through ten parallel assays. The data demonstrated 100% precision for the duplicates of each sample and 100% precision using the test kits from different lots.

Specificity & Interfering Substances

The following substances were tested for cross reactivity in cTni free serum and in normal serum containing cTni. None of the substances showed interference or cross-reactivity with the test.

<u>Substance Added</u>	<u>Concentration</u>
Skeletal troponin I	1,000ng/ml
Cardiac troponin T	1,000ng/ml
Cardiac troponin C	1,000ng/ml
CKMM	4,000 ng/ml
Bilirubin	10 mg/ml

Cholesterol	800 mg/dl
Hemoglobin	250 mg/ml
Triglyceride	1,250 mg/ml

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