



**Rapid One-Step Assay for
Cardiac CK-MB+Myoglobin+Troponin I**
(Serum/Plasma/Whole blood)

**For professional in vitro diagnostic use only
Not for sale in USA**

INTENDED USE

For the rapid qualitative determination of cardiac myoglobin, CK-MB, and troponin I in human whole blood, serum and plasma as an aid in the diagnosis of myocardial infarction.

SUMMARY

The cardiac markers CK-MB, myoglobin, and troponin I have been established as useful tools in the diagnosis of acute myocardial infarction (AMI). Since the temporal release patterns of the three markers have significant differences, all three are useful tools in the determination of the source of chest pain. Cell injury from AMI has been shown to result in a level of blood myoglobin above the upper limit of normal in approximately 2-3 hours after the onset of chest pain. Maximum concentrations are generally observed after 9-12 hours. CK-MB and troponin I are found in blood at elevated concentrations approximately 4- 6 hours after the onset of chest pain and peak at 12-24 hours. However, whereas CK-MB levels return to normal values in about 72 hours, troponin I levels remain elevated for up to 14 days¹. The use of these three markers is therefore complementary as an aid in the diagnosis of AMI given the different release times and half-lives after myocardial infarction.

PRINCIPLE

The *ABI* Cardiac Myoglobin/Troponin/CK-MB Rapid Test employs a solid-phase chromatographic immunoassay technology to qualitatively detect the elevation of myoglobin, troponin I and creatine kinase MB in human blood samples. When a sample of blood is dispensed into the sample well, red blood cells are removed by the built in separation system. Myoglobin, troponin and CK-MB present in the sample bind to specific antibody-dye conjugates and migrate through the test area containing immobilized cardiac markers. The cardiac marker-antibody-dye complexes bind to the corresponding immobilized antibodies in the Test area. Cardiac marker proteins present in the specimen form complexes with the specific dye conjugates and biotinylated marker proteins. These complexes migrate through the test line area containing immobilized streptavidin. The antibody dye-protein-biotinylated antibody complex binds to immobilized streptavidin in the test area. Unbound dye complexes migrate out of the test area and are later captured in the control area.

REAGENTS AND MATERIALS PROVIDED

Each Cardiac 3 in 1 test kit contains 30 test devices in separate sealed pouches.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Vacutainer™ (Becton Dickinson, Rutherford, NJ, USA) tube, or equivalent, containing heparin as an anticoagulant
2. Timer
3. Positive and Negative Controls
4. Micropipetter and disposable pipette tips

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.

- Do not use beyond the expiration date.
- Use separate syringe or clean pipette tips for different specimens. Do not pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kits are handled.
- Wear disposable gloves while handling specimens and running the tests, and thoroughly wash hands afterwards.
- All patient samples should be handled as if they are capable of transmitting diseases. Observe established good laboratory procedures for proper disposal of specimens, used pipette tips or syringes, and used test devices.
- The Cardiac Troponin test device should remain in its sealed pouch until ready for use.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30 °C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

Whole blood, plasma or serum may be used as samples for this procedure. Collect blood in a tube containing heparin as the anticoagulant. Guidelines recommended by the National Committee for Clinical Laboratory Standards (NCCLS) should be followed when collecting, transporting and processing patient samples. Since cTnI is relatively unstable, it is recommended that fresh samples be used as soon as possible to collect critical patient information. Heat inactivation of samples may lead to hemolysis or protein denaturation and therefore should be avoided.

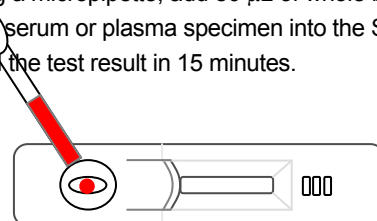
Whole blood samples should be tested within 2 hours of collection. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

PROCEDURAL NOTES

- If the Cardiac 3 in 1 test has been stored in the refrigerator, allow it to return to room temperature before testing. Do not open the foil pouch until you are ready to perform the test.
- Several tests may be run at one time.
- To avoid cross-contamination, use a clean pipette tip for each specimen.
- When the specimen is dispensed, do not position the pipette tip too high from the device's Sample area, in order to prevent the samples from splashing.

Test procedure

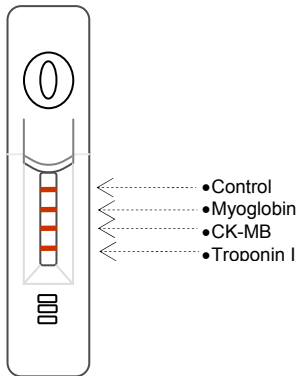
1. Open the foil pouch, remove the Cardiac test cassette, and lay the device on a level surface. Label the device with the patient's name or control number.
2. Using a micropipette, add 80 µL of whole blood or 60 µL of serum or plasma specimen into the Sample well.
3. Read the test result in 15 minutes.



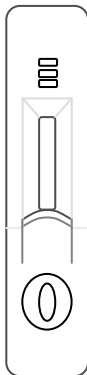
INTERPRETATION OF RESULTS

Positive result, CK-MB, Myoglobin and Troponin I

Red violet bands appear in the control and test window, as shown below.



Invalid Result



If no pink band is present in the Control window within 15 minutes, the test is invalid, and the sample should be run again with a new test device.

Notes for Result Interpretation:

- The color intensity of the Test and Control bands may increase beyond 15 minutes. As the membrane in the reading window dries up, the color intensity of the bands and background change and thus may interfere with reading the test results.
- For best results, the test result should be read at 15 minutes. The result, particularly a result which is negative before 15 minutes, should not be read beyond 15 minutes.
- The test bands will appear before the control band in most strong positive cases. The test bands may be darker than the control band.
- The test bands may appear after the control band in weak positive cases, and the test band may be weaker than the control band.

EXPECTED VALUES

The Cardiac Myo/CKMB/TnI Assay has been calibrated against the Dade Behring Stratus CS. The myoglobin assay is designed to yield a positive result for myoglobin concentrations at or more than 50.0 ng/mL. The CK-MB Assay is designed to yield a positive result for CK-MB concentrations at or more than 5.0 ng/mL. The Cardiac Troponin I Assay is designed to yield a positive result for cTnI concentrations at or more than 0.6 ng/mL.

LIMITATIONS

The results of the Cardiac Myo/CKMB/TnI Assay are to be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose myocardial infarction. A negative result obtained from a patient's sample 16

hours after the onset of chest pain may help in ruling out AMI. A positive assay result from a patient suspected of AMI may be used as an indicative of myocardial damage and requires further confirmation. Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of protein markers into the bloodstream.

Samples containing an unusually high titer of certain antibodies, such as human anti-mouse or human anti-goat antibodies, may affect the performance of the test.

INTERFERING SUBSTANCES

Levels of the following substances do not appear to interfere with the Cardiac Troponin I Assay.

Human Albumin	16 g/dL
Bilirubin (unconjugated)	60 mg/dL
Free Hemoglobin	4 g/dL
Triglycerides	1,300 mg/dL

METHOD COMPARISON

Serum samples (n=121) collected from individuals after being admitted to a hospital emergency department with chest pain. The samples were tested with the ABI Myoglobin/Troponin I test and with FDA approved cardiac troponin I test kit. The correlation between the tests is shown below:

FDA approved CK-MB test	ABI Positive	ABI Negative	Total
Reference method Positive	74	4	78
Reference method Negative	3	143	146
Total	77	147	224

Comparative Sensitivity: 96.1% (74/78)
 Comparative Specificity: 97.2% (143/146)
 Overall Agreement: 96.9% (216/224)

FDA approved Myoglobin test	ABI Positive	ABI Negative	Total
Reference method Positive	54	2	56
Reference method Negative	0	78	78
Total	54	80	134

Comparative Sensitivity: 100.0% (54/54)
 Comparative Specificity: 97.5% (78/80)
 Overall Agreement: 98.5% (132/134)



FDA approved Troponin I test	ABI Positive	ABI Negative	Total
Reference method Positive	31	1	32
Reference method Negative	1	88	89
Total	32	89	121

Comparative Sensitivity: 96.9% (31/32)
 Comparative Specificity: 98.9% (88/89)
 Overall Agreement: 98.35% (119/121)

REFERENCES

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