ACCUCARE™®
ONE STEP TROPONIN I RAPID TEST
(Whole Blood/Serum/Plasma)

One step rapid Card Test for detection of Troponin I in human Whole Blood/Serum/Plasma

Store at 2-30̊C. DO NOT FREEZE.
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
10 Tests	TPI 10
25 Tests	TPI 25

CLINICAL SIGNIFICANCE

Troponin I (TnI) is part of troponin complex, which together with tropomyosin, forms the main component that regulates the Ca^{+2} –sensitive ATP-ase activity of actomyosin is striated muscle (skeletal and cardiac). The troponin complex consists of three subunit has a distinct function with TnC as the site of Ca^{+2} binding, TnT the tropomyosin binding, and TnI as the inhibitory subunit. Different isoforms of TnI exists in the skeletal and cardiac muscles (sTnI and cTnI, respectively) with distinct immunologic epitopes that allow the production of cardiac-specific TnI antibodies. The cardiac marker, troponin I has been established as useful tools in the diagnosis of acute myocardial infraction (AMI). Troponin I is found in blood at elevated concentrations approximately 4-6 hours after the onset of chest pain and peak at 12-24 hours. Troponin I levels remain elevated for up to 14 days. The use if this marker is an aid in the diagnosis of AMI after myocardial function.

PRINCIPLE

The ACCUCARE® ONE STEP TROPONIN I RAPID TEST employs a solid-phase chromatographic immunoassay technology to qualitatively detect the elevation of Troponin I 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. Troponin I in the specimen makes a complex with the specific dye conjugate and biotinylated anti-troponin I antibody. This complex migrates through the test area containing immobilized streptavidin. The antibody dye-troponin I-biotinylated antibody complex bind to the immobilized streptavidin in the test area. Unbound dye complexes migrate out of Test area and are later captured in the Control area. Visible pinkish-purple bands will appear in the test and Control areas if the concentrations of troponin I is above established cutoff values. If the troponin I concentration in the specimen is 0.6 ng/ml or greater, a band is present in the troponin I area. If a band is present only in the Control area, the test result is read as negative, indicating that the Troponin I concentrations are all below the cutoff values. If no band is present in the Control area, the test is invalid and another test must be run, regardless of the presence or absence of band(s) in the Test Area.

CONTENTS

Test Device, Desiccant
Instruction for Use (IFU)
Disposable (Dropper) 20 µl sampling device
Assay Buffer Vial

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. The result of the Cardiac TnI Assay is to be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose myocardial infarction.
2. A negative result obtained from a patient's sample 16 hours after the onset of chest pain may help in ruling out AMI.
3. A positive assay result from a patient suspected of AMI may be used as an indicative of myocardial damage and requires further confirmation.
4. 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.
5. 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.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP TROPONIN I RAPID TEST can be performed using Whole Blood or Serum or Plasma.
2. Collect Whole Blood into an appropriate blood collection tube with or without anticoagulant (EDTA, citrate or heparin). If you want use serum or plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens must be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days.
4. Bring specimens to room temperature prior to testing.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

1. Allow test device and specimen equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 2 drops (40 µl) of Whole Blood/Serum/Plasma in the sample well "S" using the dropper provided.
4. After that add 1 drops (appx. 40 µl) of Assay Buffer in the sample well "S".
5. Allow reaction to occur and read the results at 20 minutes. Do not interpret the results after 20 minutes.

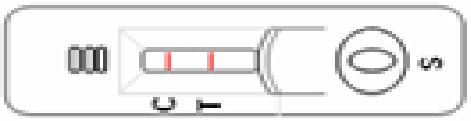
ISO 13485:2016

CE

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 ▪Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com

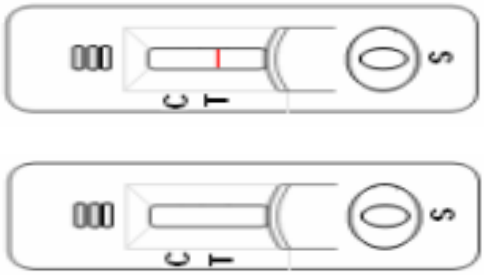
INTERPRETATION OF RESULTS

1. POSITIVE
If two color bands appear, one at control line 'C' and other at test line 'T', the specimen is positive for Troponin I.



2. NEGATIVE
If only one color band appear at control line 'C' as the specimen is Negative for Troponin I.

3. INVALID
If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.



EXPECTED VALUE

The cardiac Troponin I assay is designed to yield a positive result for cTnI concentrations at or more than 0.6 ng/mL.

PERFORMANCE CHARACTERISTICS

The ACCUCARE™ ONE STEP TROPONIN I RAPID TEST has been evaluated with positive and negative samples and data are as below:

Specimen	Positive	Negative	Sensitivity
Positive	300	00	100 %

Specimen	Positive	Negative	Specificity
Negative	23	1420	98.41 %

BIBLIOGRAPHY

1. Troponin testing:An audit in three metropolitan hospitals, Richard X Davey, JMA, Vol.179, 81-83, 21st July 2003.
2. Clinical laboratory in emergency medicine, cardiac Troponins, John Sarko, Charles V.Pollack, The journal of emergency medicine, Vol.23, 57-65, 2002.
3. A systematic review of Troponin T and I for diagnosing Acute Myocardial Infarction, Mark H.Ebell, Cheryl A. Flynn, The Journal of Family Practice,April 16, 2000.
4. Analytical performance and clinical application of a new rapid bedside assay for the detection of serum cardiac Troponin I, Christopher Heeschen, Brita U. Goldmann, Robert. H. Moeller, Christian W. Hamm, Clinical Chemistry, 44:9, 1925-1930, 1998.
5. National Academy of Clinical Biochemistry Standards of Laboratory Practice: Recommendations for the use of cardiac markers in coronary artery diseases, Alan H. B. Wu, Fred S. Apple, W. Brian Gibler, Robert L. Jesse, Myron M. Warshaw, Roland Valdes, Jr., Clinical Chemistry 45:7, 1104-1121, 1999.
6. Cardiac specific Troponin I levels to predict the risk of mortality in patients with acute coronary syndromes, Elliott M. Antman, Milenko J. Tanasijevic, Bruce Thompson, Mark Schactmann, The New England Journal of Medicine, 1342-1349, October 31, 1996.
7. IFCC Committee on Standardization of markers of cardiac damage: Premises and Project Presentation, Abstract, Vol.11 No.2, 19-22, JIFCC, 1999.
8. Clinical Laboratory Diagnostics, Use and Assessment of Clinical laboratory results, Edited by Lothar Thomas, First Edition, TH Books Verlagsgesellschaft mbH, Frankfurt, Germany, 1998.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

ISO 13485:2016

CE

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 ▪Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com