PATHKITS

SIMPLE TROPONIN-I

Product Code: **PKRK011**
Kit Contents (**25 Kits**)
Shelf Life: **24 Months**

Kit Components	Quantity (Units)
Test Strips	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa(1). Troponin I is part of a three subunit complex comprising 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(2). After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI 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 high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma(3). cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery(4) Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction

Intended Use

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of *myocardial infarction* (MI) A rapid visual Immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. For professional *in vitro* diagnostic use only.

Test Principle

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with *anti-cTnI* antibodies on the test region. During the test, the specimen is allowed to react with colored *anti-cTnI* antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interacts with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

Warnings and Precautions

1. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not use it if the pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Do not open the sealed pouch, unless ready to conduct the assay.
7. Do not use expired devices.
8. Bring all reagents to room temperature (15-30°C) before use.
9. Do not use the components in any other type of test kit as a substitute for the components in this kit.
10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
12. Handle the negative and positive controls in the same manner as the patient specimens

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

Mfg By: PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198
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SIMPLE TROPONIN-I

Specimen Collection and Handling

1. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.
2. The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
3. Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated with as early as possible an opportunity to avoid hemolysis.

Materials Required but not provided

1. Timer or Stopwatch
2. PPE and other consumables for collection and disposal of samples

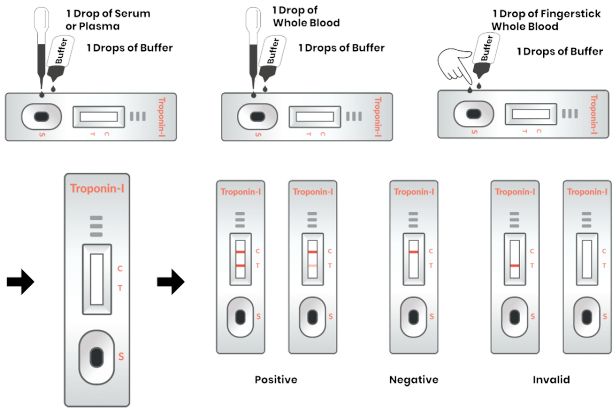
Limitations of Test

1. The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
2. The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at any time rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

Procedure

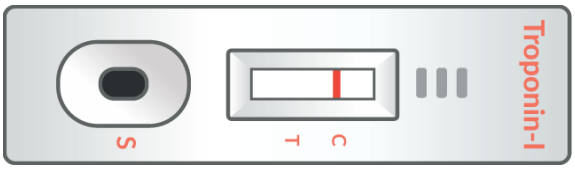
Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain the best result, the assay should be performed within one hour.
2. Transfer 1 drop (approximately 25µl) of serum or plasma to the specimen well of the device with a disposable dropper provided in the kit, and then add 1 drop of buffer to start the timer.
3. Transfer 1 drop (approximately 25µl) of whole blood specimen to the specimen well of the device with a disposable dropper provided in the kit, then add 1 drop of buffer, and start the timer.
4. Allow 1 hanging drop (approximately 25µl) of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer, and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in the observation window. As the test begins to work, you will see color move across the membrane.
5. Wait for the colored band(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.



Interpretation of results

NEGATIVE RESULT: Only one colored band appears in the control region (C). No apparent colored band appears in the test region(T).



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T)

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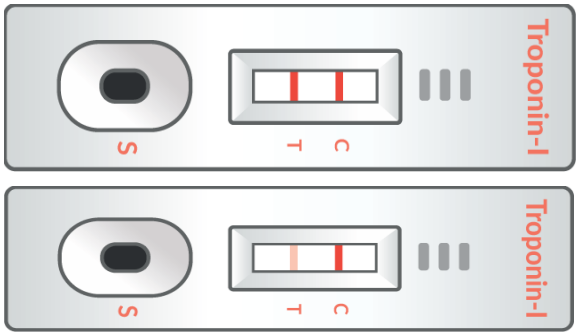
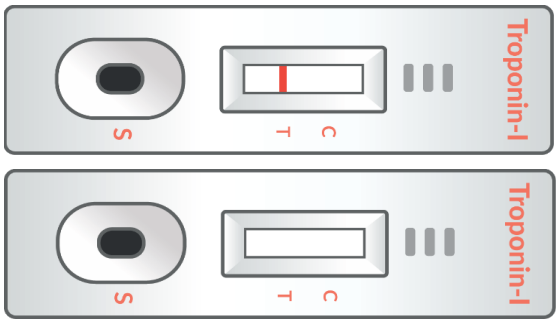


INVALID: If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device.



Quality Control

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

References:

1. Adams 3rd, J.E., Abendschein, D.R. and Jaffe, A.S., 1993. Biochemical markers of myocardial injury. Is MB creatine kinase the choice for the 1990s?. *Circulation*, *88*(2), pp.750-763.
2. Mehegan, J.P. and Tobacman, L.S., 1991. Cooperative interactions between troponin molecules bound to the cardiac thin filament. *Journal of Biological Chemistry*, *266*(2), pp.966-972.
3. Adams, J.E., Sicard, G.A., Allen, B.T., Bridwell, K.H., Lenke, L.G., Davila-Roman, V.G., Bodor, G.S., Ladenson, J.H. and Jaffe, A.S., 1994. Diagnosis of perioperative myocardial infarction with measurement of cardiac troponin I. *New England Journal of Medicine*, *330*(10), pp.670-674.
4. Hossein-Nia, M., Holt, D.W., Anderson, J.R. and Murday, A.J., 1996. Cardiac troponin I release in heart transplantation. *The Annals of thoracic surgery*, *61*(1), pp.277-278.
5. Alpert, J., 2000. Myocardial Infarction Redefined. Joint European Society on Cardyology. *J. Amm. Coll. Cardio*, *36*(3).

Technical Assistance

For customer support, please contact our Technical Support:
Pathkits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P),
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Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

(Medical Device & Diagnostic Division)

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File No. : NZ/IVD/2022/000028

Dated : 21-MAR-2022

M/s PATHKITS HEALTHCARE PRIVATE LIMITED,
Plot No-28-29, Sector-18
Gurgaon, Gurgaon, Haryana (India) - 122001
Telephone No.: 8802872273 FAX: 8802872273

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/IVD/2021/000068 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

6. The licence holder shall, on being informed by the Central Licensing Authority that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;
7. The licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;
8. The licence holder shall maintain at least one unit of sample from each batch of invasive medical device and in vitro diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;
9. The licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;
10. The medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;
11. The manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;
12. If the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority.

13. This licence is being issued with the condition that the firm shall submit real time stability data for three lots for all the proposed product up to claimed shelf life i.e 24 months as on when the studies completed.

Yours faithfully

VENUGOPAL G SOMANI

Licensing Authority

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), [illegible]
3113c, postalCode=110002, st=DELHI, [illegible]
af5d, cn=VENUGOPAL G SOMANI
Date: 2022.03.21 16:13:19 +05'30'

सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2021/000068

Endorsement No. 6

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Troponin-I Test Kit Model No.:NIL Intended Use:The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin- I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI) A rapid visual Immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. Class of medical device:Class C Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Troponin-I Test Kit

Place:

Date21-Mar-22

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3118c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.03.21 15:06:31 +05'30'

Central Licensing Authority