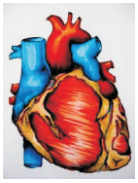


TROPONIN-I CARD TEST
HEARTSCAN®

For Professional Use

A rapid test for the qualitative detection of Human cardiac Troponin I in Serum or Plasma. IVD

Read the pack Insert before use provided along with the kit

REF HTC

INTENDED USE : The Heart Scan® One Step Troponin I Card Test is a rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY : 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, comprising of Troponin T and Troponin C. Along with Tropomyosin, this structural protein 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 cardiac 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. The high specificity of Troponin I measurements for the identification of myocardial damage has been demonstrated in conditions such as the preoperative period, after marathon runs, and blunt chest trauma.

Troponin I 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. Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred bio marker for myocardial infarction.

The HeartScan® One Step Troponin I Card Test is a simple test that utilizes a combination of anti-Troponin I antibody particles and capture reagent to detect Troponin I in serum or plasma. The minimum detection level is 0.5 ng/mL.

PRINCIPLE : The HeartScan® One Step Troponin I Card Test (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of Troponin I in serum or plasma. The membrane is pre-coated with capture reagent on the test line region of the test. During testing, the serum or plasma specimen reacts with the particle coated with anti-Troponin I antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture reagent on the membrane and generates a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY :

STORAGE: Store as packaged in the sealed pouch either at room temperature or refrigerated (2 to 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. Do not use beyond the expiration date.

PACK SIZE : Available in pack of 5 & 10 Test.

KIT CONTENTS :

Pack Size	5 Test	10 Test
Troponin I Test Device	5 Nos.	10 Nos.
2ml Dropper	5 Nos.	10 Nos.
1g Silicagel	5 Nos.	10 Nos.
Pack Insert	1 No.	1 No.

MATERIALS REQUIRED BUT NOT PROVIDED :

1. Sterilised Vial
2. Disposable Gloves
3. Presession Pipette
4. Sodium hypochloite Solution (Free available chlorine 50-500 mg/L)

PRECAUTIONS :

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. The test device must remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves
7. Humidity and temperature can adversely affect results.
8. The used test should be discarded according to local regulations.

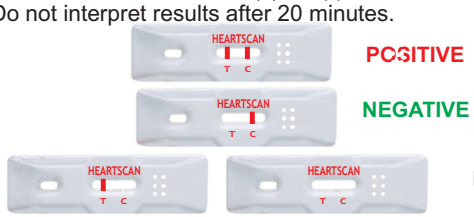
SPECIMEN : Fresh serum or plasma.

SPECIMEN COLLECTION AND PREPARATION :

1. The Heart Scan® One Step Troponin I Card Test (Serum/Plasma) can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolongedperiods. Serum and plasma specimens may be stored at 2 to 8° C for up to 3days. For long-term storage, specimens should be kept below -20° C.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE :

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Add 2 drops of serum or plasma in to the sample window.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS :

(Please refer to the illustration above)

POSITIVE : Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

NOTE : The intensity of the color in the test line region (T) will vary depending on the concentration of cardiac Troponin I present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE : One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID : Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS :

1. The HeartScan® One Step Troponin I Card Test (Serum/Plasma) is for in-vitro diagnostics only. This test should be used for the detection of Troponin I in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Tropoinin I can be determined by this qualitative test.
2. The HeartScan® One Step Troponin- I Card Test (Serum/Plasma) will only indicate the qualitative level of Cardiac Troponin-I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.

3. The HeartScan®One Step Troponin I Card Test (Serum/Plasma) cannot detect less than 0.5 ng/mL of Cardiac Troponin I in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
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.

EXPECTED VALUES : The HeartScan®One Step Troponin I Card Test has been compared with a leading commercial Cardiac Troponin I EIA test, demonstrating an overall accuracy of 98.5%.

PERFORMANCE CHARACTERISTICS : The HeartScan®One Step Troponin I Card Test has been evaluated with a leading commercial Cardiac Troponin-I EIA test using clinical specimens. The results show that the sensitivity of the HeartScan®One Step Troponin I Card Test is 98.5% and the specificity is 98.4% relative to the leading EIA test.

HeartScan®One Step Troponin I Card Test VS EIA.

Method		EIA		Total Results
HearScanOne Step Troponin I Card Test	Results	Positive	Negative	
	Positive	197	8	205
	Negative	3	505	508
Total Results		200	513	713

Relative Sensitivity : 98.5% (95.7% - 99.7%) Relative Specificity : 98.4% (97.0%-99.3%) Accuracy : 98.5% (97.3%-99.2%)

INTERFERING SUBSTANCES : The HeartScan® One Step Troponin I Card Test has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 6 mg/mL bilirubin, 10 mg/mL hemoglobin, 5 mg/mL cholesterol and 15 mg/mL triglycerides. The following compounds have also been tested using the HeartScan®One Step Troponin I Card Test and no interference was observed at a concentration of 50 µg/mL.

Acetaminophen
Acetylsalicylic acid
Anisodamine
Ascorbic Acid
Atenolol
Atorvastatin Calcium
Bisoprolol Fumarate
Caffeine
Captopril
Chloramphanicol
Chloridizepoxide
Cilazapril
Diclofenac
Digoxin
DL-Tyrosine
Erythromycin
Felodipine
Flunarizine Hydrochloride
Furosemide
Hydrochlorothiazide
Isosorbide Mononitrate
Labetalol
Metoporolol Tartrate
Moracizine Hydrochloride
Nifedipine
Oxazepam
Pentoxifyline
Phenobarbital
Quinine
Remipril
Trimethoprim
Verapamil

TROUBLE SHOOTING

FLOODING OF SAMPLE	
Cause/Error	Remedy
Addition of more than 2 drops of Serum / Plasma	Add only 2 drops of Serum / Plasma

WEAK INTENSITY OF CONTROL LINE	
Cause/Error	**Remedy**
Very cold reagent	Bring the sample to room temperature before testing (25±5°C) if stored at lower temperature

POOR SENSITIVITY OR WEAK INTENSITY OF TEST AND CONTROL LINES	
Cause/Error	**Remedy**
Frozen sample not mixed properly after thawing Hooks Effect, due to too high concen -tration of the antibodies	Mix the sample well and centrifuge to remove particulate mater before pipetting. Dilute the serum 10 times with negative serum and test again.

GHOST LINE APPEARANCE	
Cause/Error	**Remedy**
Backflow	Read the result within the prescribed time.

REFERENCE :1. Adams, et al. *Biochemical markers of myocardial injury,* Immunoassay Circulation 88:750-763, 1993.
2. Mehegan JP, Tobacman LS. *Cooperative interaction, between troponin molecules bound to the cardiac thin filament.* H.Biol. Chem. 266:966, 1991.
3. Adams, et al. *Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I.* N. Eng.J. Med 330:670, 1994.
4. Hossein-Nia M, et al. *Cardiac troponin I release in heart transplantation.* Ann.Thorac. Surg. 61:227, 1996.
5. Alpert JS, et al. Myocardial Infarction redefined, Joint European Society of Cardiology American College of cardiology: J. Am. Coll. Cardio, 36(3):959, 2000.

NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
2C 8C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL −	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

R-5, 2013-05-05

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