CARDIAC TROPONIN I (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADTNI1	20 Tests
RADTNI2	10 Tests

Intended Use:
The Cardiac Troponin I Device is a rapid visual immunoassay for the qualitative detection of cardiac Troponin I in human whole blood, serum or plasma samples. This kit is intended for use as an aid in the diagnosis of myocardial infarction (MI). For in vitro diagnostic use by trained personnel only.

Summary:
Cardiac Troponin I (cTnI) 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 complex 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 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. cTnI release has also been documented in cardiac conditions other than myocardial infarction 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 preferred biomarker for myocardial infarction.

Test Principle:
Anti-cTnI antibody is immobilized on the test line region of the device. During testing, the sample reacts with anti-cTnI antibody conjugated to particles which are precoated near the sample well of the test. The mixture migrates up the membrane by capillary action and interacts with reagents at the test line. If there is sufficient cTnI in the sample, a coloured band will form at the test line region of the device. The presence of this coloured band indicates a positive result, while absence of test line band indicates a negative result. The appearance of a coloured band at the control region serves as a procedural control, indicating that the proper volume of sample has been added and correct membrane wicking has occurred.

Materials Provided
Individually pouched test devices
Buffer
Disposable pipettes
Instructions For Use sheet

Materials not provided: Timer, specimen collection container, centrifuge, lancets, Heparinized capillary tubes and dispensing bulb.

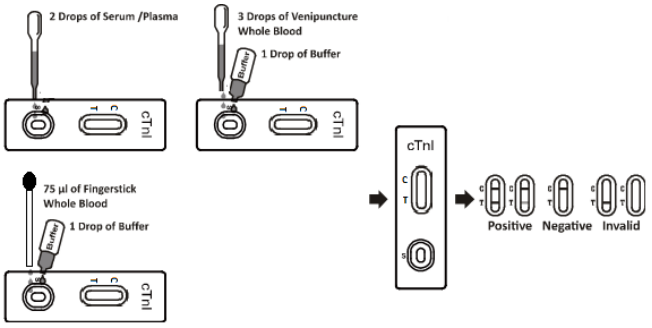
Precautions:
- Do not use after expiry date.
- Do not use the test device if the foil pouch has been punctured or damaged.
- Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
- Wear protective clothing including laboratory coat, disposable gloves and safety glasses when conducting the test.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

Reagent Preparation and Stability:
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze devices. Do not use after the expiry date. The buffer is stable for 6 months after opening.

Sample Collection and Storage:
The Cardiac Troponin I Device is intended for use with human whole blood, serum, or plasma samples.
To collect finger prick whole blood samples: Clean the finger tip with an alcohol swab. Allow to dry. Massage the hand without touching the puncture site from the hand to the fingertip. Puncture the skin with a sterile lancet and wipe away the first sign of blood. Squeeze the finger to form a rounded drop of blood at the puncture site.
Using a capillary tube: Touch the end of a capillary tube to the blood until filled to approximately 75µl. Avoid air bubbles. Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the sample well of the test device.
Using a disposable dropper: Take up whole blood into the dropper and dispense drops as required.
Whole blood samples collected by finger prick must be used immediately. Whole blood samples collected by venepuncture can be used in the test for up to 24 hours if stored at 2 – 8°C. Do not freeze whole blood samples.
Separate serum or plasma from red blood cells as soon as possible to avoid haemolysis. Use only clear non-haemolysed samples.
Serum and plasma samples may be stored at 2 - 8°C for up to 3 days or for longer term storage freeze at -20°C or below.
Before testing equilibrate samples completely to room temperature. Frozen samples must be fully thawed and mixed well prior to testing. Avoid repeated freeze-thaw cycles.
If samples are to be transported, pack them in compliance with all applicable regulations for transportation of etiological agents.

Assay Procedure:
1. Bring the device, samples and controls fully to room temperature (15 - 30°C) before starting any testing. Remove the test device from the sealed pouch, place it on a clean and level surface and use it immediately.
2. For Serum or Plasma samples: Take up serum or plasma into a dropper and transfer 3 drops (approximately 75 µL) to the sample well and start the timer. See illustration below.

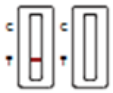
   For Venipuncture whole blood samples: Transfer 3 drops of whole blood (approximately 75 µl) using a dropper or 75 µl whole blood using a pipette to the sample well, then add 1 drop of buffer (approximately 40 µL) and start the timer. For finger prick whole blood samples: Fill the capillary tube and transfer approximately 75 µl whole blood to the sample well. Add 1 drop of buffer (approximately 40 µL) and start the timer.
3. Wait for coloured band(s) to appear. The result should be read at 10 minutes. Do not interpret any result after 20 minutes.



Interpretation of Results:

POSITIVE: Two coloured lines appear. One line develops at the control line (C) and another band appears at the test line (T).

NEGATIVE: Only one coloured line appears, in the control region. No colour development at the test line.



INVALID: Control band fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
1. The intensity of colour at the test line may vary depending on the concentration of analytes present in the sample. Therefore, any shade of colour at the test line should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the sample.
2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Quality Controls:
Internal procedural controls are included in the test. A coloured band appearing in the control zone is considered an internal positive procedural control, confirming sufficient sample volume and correct procedural technique.
External controls are not supplied with this kit. It is recommended that positive and negative quality controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test:
1. The Cardiac Troponin I Device is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of cardiac Troponin I. Neither the quantitative value nor the rate of increase in cTnI can be determined by this test.
2. The Cardiac Troponin I Device will only indicate the presence of Troponin I in the sample and should not be used as the sole criteria for the diagnosis of myocardial infarction.
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 samples. Therefore, a negative result does not at anytime rule out the presence of Troponin I in blood, the analyte may be present at a concentration below the sensitivity level of the test.
4. The results obtained with this test should not be used as the sole criterion for diagnosis of heart conditions but be used in conjunction with other diagnostic procedures and clinical findings.
5. Some samples containing unusually high titres of heterophile antibodies or rheumatoid factor 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.
6. There is a slight possibility that some whole blood samples with very high viscosity or which have been stored for more than 1 day may not run properly on the test device. Repeat the test with a serum or plasma sample from the same patient using a new test device.

Expected Values:
The Cardiac Troponin I Device has been compared with a leading commercial cTnI EIA test, demonstrating an overall accuracy of 99.1%.

Performance Characteristics:

Sensitivity and Specificity:
The Cardiac Troponin I Device has been evaluated against a predicate chemiluminescence immunoassay test using clinical samples. The results show that the sensitivity of the Cardiac Troponin I Device is 97.6% and the specificity is 99.4% relative to the leading EIA test.

Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V5: rev Jan 2021

Method		Chemiluminescence IA		Total Result
Cardiac Troponin I Device	Results	Positive	Negative	
	Positive	83	2	85
	Negative	2	358	360
Total Result		85	360	445

Relative sensitivity: 97.6% (95%CI*:91.8% - 99.7%);
Relative specificity: 99.4% (95%CI*:98.0% - 99.9%);
Accuracy: 99.1% (95%CI*:97.7% - 99.8%). *Confidence Interval

Precision:
Intra-Assay precision was determined using 3 replicates of 5 samples: a negative sample and Troponin I positive samples at 1.0, 5, 10 and 40 ng/ml. The negative and positive 1.0 ng/ml, 5.0 ng/ml, 10 ng/ml and 40 ng/ml samples were correctly identified >99% of the time.

Inter-Assay precision was determined by 3 separate assays using the same five samples as above. Three different lots of the Cardiac Troponin I Device were tested over a 3-day period. The negative and positive 1.0 ng/ml, 5.0 ng/ml, 10 ng/ml and 40 ng/ml samples were correctly identified >99% of the time.

Cross-Reactivity
The Cardiac Troponin I Device has been tested using 10,000 ng/ml Skeletal Troponin I, 2,000ng/ml Troponin T, 20,000ng/ml Cardiac Myosin, HBsAg, HBsAb, HBeAg, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive samples. The results showed no cross-reactivity in the Cardiac Troponin I Device by these analytes.

Interfering Substances
The following substances were added to Troponin I negative and positive samples.

Acetaminophen	20mg/dl	Caffeine	20mg/dl
Acetylsalicylic Acid	20mg/dl	Gentisic Acid	20mg/dl
Ascorbic Acid	20mg/dl	Albumin	10.5g/dl
Creatine	200mg/dl	Haemoglobin	1000mg/dl
Bilirubin	1000mg/dl	Oxalic Acid	600mg/dl
Cholesterol	800mg/dl	Triglycerides	1600mg/dl

None of the substances interfered in the Cardiac Troponin I Device assay at the concentration tested.

References:

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. J.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.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

CE

Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V5: rev Jan 2021