

The Troponin-T Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Troponin-T (cTnT) in human whole blood specimens.

For *In-Vitro Diagnostic Use only*

#### ORDER INFORMATION

Pack Size	REF
01 Test	PTWB 01
05 Tests	PTWB 05
10 Tests	PTWB 10
25 Tests	PTWB 25
50 Tests	PTWB 50

#### CLINICAL SIGNIFICANCE

Troponin T together with troponin I (cTnI) and troponin C (cTnC) forms a complex that plays a fundamental role in transmission of intracellular calcium signal of actin-myosin interaction. Troponin T is almost exclusive to the myocardium, with small amounts expressed in skeletal muscle not detectable in current Troponin T assays. Insufficient blood flow and oxygen supply to the heart muscle causes necrosis of the myocardium and subsequent release of Troponin T & I into the bloodstream. Troponin T in the bloodstream rises to detectable levels after 4-6 hours, peaks at 10-12 hours and can be detected for up to 14 days post infarction. Troponin I is released from necrotic cardiac myocytes into the bloodstream within hours (~4-8 hours) after the onset of chest pain. The peak TnI concentration is generally reached in 12-48 hours. Troponin I serum levels can remain elevated for up to 4-7 days. The diagnostic utility of Troponin T & I to detect myocardial necrosis and to enable risk stratification in patients with Acute Coronary Syndrome (ACS) is well established. Furthermore, the use of Troponin T as a prognostic indicator for recurrence of ischemic events and death in ACS patients is increasing. The concentration of cardiac troponin T can be detected in patients with UAP and patients without ST segment elevation, which is related to the incidence of death. Therefore, the determination of cardiac troponin I can also be used to grade patients for risk level. Results from PoCT devices detecting Troponin T & I should always be used in conjunction with clinical presentation, history and other diagnostic information

#### PRINCIPLE

The Troponin T (cTnT) Rapid Test Cassette (Whole Blood) is a qualitative, lateral flow immunoassay for the detection of Troponin T (cTnT) in whole blood specimens. In this test, monoclonal Trop-T antibody is coated in the test line region of the test. During testing, cTnT present in whole blood specimen reacts with Trop-T antibody coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the monoclonal Trop-T antibody on the membrane in the test line region. The presence of a colored line in the test line region indicates a positive result for cTnT, while its absence indicates a negative result for that infection. To serve as a procedural control, a colored line will always appear in the control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.

#### KIT COMPONENTS

- Test Cassettes • Droppers • Package Insert • Alcohol Swab
- Lancet (for fingerstick whole blood only)

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen Collection Containers
- Timer

#### PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance with GLP.
6. Follow the testing procedure exactly as mention in the insert.

#### STORAGE AND STABILITY

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

#### SPECIMEN COLLECTION & PREPARATION

The Troponin-T Rapid Test Cassette (Whole Blood) performed using whole blood specimen.

- **Whole Blood (WB):** For Whole blood do not use anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate and anticoagulants.

#### To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the sample well of the test cassette by using a sample dropper. Avoid air bubbles.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

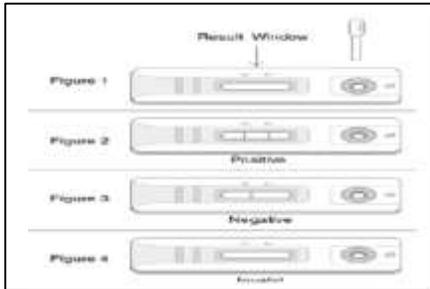
#### DIRECTIONS FOR USE

**Allow the test device, specimen to equilibrate at room temperature before testing.**

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Whole Blood specimen:** Hold the dropper vertically and transfer 3 drop of whole blood (approximately 60-70 µL)

- to the specimen well, and start the timer. See illustration below.
- Wait for the colored line(s) to appear. Read results at 15 minutes.  
**Note:** Do not interpret the result after 20 minutes.

### INTERPRETATION OF RESULTS



#### 1) Positive

The control line (C) and test line (T) lines are visible on the test device. This is positive for cTnT antigen. This is indicative of presence of Troponin T

#### 2) Negative

The control line is the only visible line on the test device. No cTnT antigen were detected

#### 3) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

### Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume 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.

### Limitations of the Test

- The Troponin T Rapid Test Kit (Whole Blood) is for in vitro diagnostic use only. This test should be used for detection of Troponin-T (cTnT) in whole blood specimens. Neither the quantitative value nor the rate of increase in the concentration of cTnT can be determined by this qualitative test.
- A negative result can occur if the level of cTnT present in the specimen is below the detection limits of the assay or cTnT that is detected is not present during the stage of AMI in which a sample is collected. However, a negative test result does not preclude the possibility of AMI.
- AMI progresses rapidly. If symptoms are suspicious or persist while the result from the Troponin T Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method, such as ECG.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician

### Detection Limitation

The Troponin T Rapid Test Kit (Whole Blood) can detect cTnT antigen as low as 0.3 ng/ml.

### Sensitivity and Specificity

A total of 305 specimens were collected from susceptible subjects and tested by Troponin T Rapid Test and a commercial Troponin-T Rapid

test as reference. Comparison for all subjects is showed in the following table.

Troponin T Rapid Card Test	Method	Other Rapid Test		Total Test
	Result	Positive	Negative	
	Positive	75	0	75
	Negative	0	230	230
<b>Total Results</b>		<b>75</b>	<b>230</b>	<b>305</b>

Sensitivity: >98% (95% CI\*: 94.4%-99.8%) \*Confidence Interval  
 Specificity: >98% (95%CI\*: 96.7%-99.6%)

### Cross-reactivity

The Troponin T Rapid Test Kit (Whole Blood) has been tested for sTnI (Skeletal muscle TnI-10µg/mL), cardiac myosin (20 µg/mL), HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross- reactivity.

### Interfering Substances

The following compounds have also been tested using the Troponin T Rapid Test Kit (Whole Blood) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Genticic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/d.l

### BIBLIOGRAPHY

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### GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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