Troponin I (cTnI) Rapid Test Kit (Serum/Plasma/Whole blood)

The Troponin-I (cTnI) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Troponin-I (cTnI) in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

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

CLINICAL SIGNIFICANCE

Troponin I together with troponin T (cTnT) and troponin C (cTnC) forms a complex that plays a fundamental role in transmission of intracellular calcium signal of actin-myosin interaction. The physiological effect of troponin I is to inhibit the activity of ATP enzyme in actin-myosin complex in the absence of calcium ion to prevent muscle contraction. The integrity of myocardial cell membrane is destroyed during myocardial necrosis, which is often accompanied by the release of structural proteins and other intracellular macromolecules into myocardial stroma. These biomarkers of myocardial necrosis include cardiac troponin I and T (cTnI and cTnT), creatine kinase isoenzyme MB (CM-MB), myoglobin (MYO) and so on. Compared with other available myocardial markers, cardiac troponin has good sensitivity and tissue specificity for myocardial injury, and is the first choice for the detection of myocardial injury.[1] It can assist in the diagnosis of myocardial infarction (MI) and risk stratification of (ACS) in acute coronary syndrome.[2] MI can be diagnosed when the concentration of cardiac troponin I in blood is higher than the 99th percentile of the normal control group (the precision of cTnI test at 99th percentile is less than or equal to 10%).[3] In patients with acute myocardial infarction (AMI), the concentration of serum cTnI increased at 3-6 hours after chest pain, reached the highest level at 12-16 hours, and lasted for 4 to 9 days.[4] It has been reported that the concentration of cTnI is also increased in unstable angina pectoris (UAP) and congestive heart failure (CHF). The concentration of cardiac troponin I can be detected in patients with UAP and patients without ST segment elevation, which is related to the incidence of death.[5] Therefore, the determination of cardiac troponin I can also be used to grade patients for risk level

PRINCIPLE

The Troponin I (cTnI) Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of Troponin I (cTnI) in whole blood, serum or plasma specimens. In this test, monoclonal Trop-I antibody is coated in the test line region of the test. During testing, cTnI present in whole blood, serum or plasma specimen reacts with Trop-I antibody coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the monoclonal Trop-I 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 cTnI, 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 • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only)
• 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 in 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-I (cTnI) Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

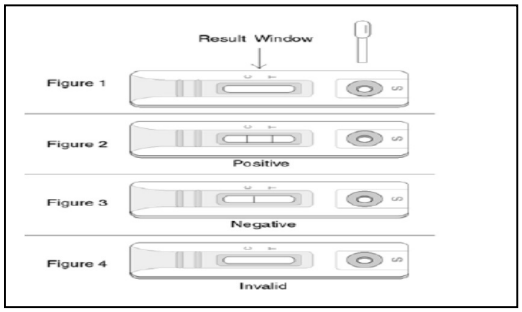
- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by veinpuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by veinpuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) 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 Serum or Plasma specimen**: Hold the dropper vertically and transfer 2 drop (40-50 µL) drops of serum or plasma and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer. See illustration below.
   For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 1 drop (25 µL) drops of whole blood and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer. See illustration below.
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 (1 drops) of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
4. 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 cTnI antigen. This is indicative of presence of Troponin I
2) Negative
The control line is the only visible line on the test device. No cTnI 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

1. The cTnI Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of Troponin-I (cTnI) in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of cTnI can be determined by this qualitative test.
2. A negative result can occur if the level of cTnI present in the specimen is below the detection limits of the assay or cTnI 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.
3. AMI progresses rapidly. If symptoms are suspicious or persist while the result from the Troponin I Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method, such as ECG.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician

Detection Limitation
The cTnI Rapid Test Cassette (Whole Blood/Serum/Plasma) can detect cTnI 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 I Rapid Test and a commercial Troponin-I Rapid test as reference. Comparison for all subjects is showed in the following table.

Method		Other Rapid Test		Total Test
Troponin I Rapid Card Test	Result	Positive	Negative	
	Positive	75	0	**75**
	Negative	0	230	**230**
Total Results		**75**	**230**	**305**

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

Cross-reactivity
The cTnI Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested for sTnI (Skeletal muscle TnI-10µg/mL), cardiac mysosin (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 IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic 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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2. Adams JE, Sicard GA, Allen BT, et al. Diagnosis of perioperative myocardial infarction with measurement of cardiac troponin I. N. Eng. J. Med. 1994;330, 670-4.
3. Bodor GS, Porterfield D, Voss EM, et al. Cardiac troponin-I is not expressed in fetal and healthy or diseased adult human skeletal muscle tissue. Clin. Chem. 1995;41,1710-5.
4. Brogan GX Jr, Hollander JE, McCuskey CF, et al. Evaluation of a new assay for cardiac troponin I vs creatine kinase-MB for the diagnosis of acute myocardial infarction. Biochemical Markers for Acute Myocardial Ischemia (BAMI) Study Group. Academic Emerg. Med. 1997;4, 6-12.
5. Tucker JF, Collins RA, Anderson AJ, et al. Early diagnostic efficiency of cardiac troponin I and Troponin T for acute myocardial infarction. Acad Emerg Med. 1997;4, 13-21.

GLOSSARY OF SYMBOL

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

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged			Cont.	Content

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