Cardiac Troponin I Rapid Test Cassette (WB/S/P)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The Cardiac Troponin I Rapid Test Cassette is a lateral flow immunoassay for the qualitative detection of cardiac Troponin I (cTnI) and its complex in human whole blood, serum or plasma. It provides an aid in the diagnosis of acute myocardial infarction (AMI).

[SUMMARY]

Cardiac Troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with Troponin T (TnT) and Troponin C (TnC), TnI forms a troponin complex in the heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTnI has additional amino acid residues inits N-terminal that does not exist in the skeletal forms thus making cTnI a specific cardiac marker. Normally the level of cTnI in the blood is very low. cTnI is released into the bloodstream in forms of free cTnI and cTnI-C-T complex at 4-6 hours after myocardial cell damage. The elevated level of cTnI could be as high as 50 ng/mL during 60-80 hours after AMI and remains detectable for up to 10 -14 days post AMI. Therefore, circulating cTnI is a specific and sensitive marker for AMI. The Cardiac Troponin I Rapid Test is a simple, visual qualitative test that detects cardiac Troponin I in human whole blood, serum or plasma. It is a noninvasive method and does not use radioactive isotopes. The test is easy to perform and requires no specialized equipment. Visual interpretation provides an accurate qualitative result. It is a useful on-site aid in the diagnosis of acute myocardial infarction (AMI).

[PRINCIPLE]

The Cardiac Troponin I Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of cTnI in human whole blood, serum or plasma. In this test procedure, anti-cTnI antibody is immobilized in the test line region of the device. After a whole blood, serum or plasma specimen is placed in the specimen well, it reacts with anti-cTnI antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-cTnI antibody. If the specimen contains cTnI, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain cTnI, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For *in vitro* diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with anti-cTnI antibody on the test line, goat anti-mouse on the control line, and a dye pad which contains colloidal gold coupled with anti-cTnI antibody.
The quantity of tests was printed on the labeling.

Materials Provided

- Test cassette
- Package insert
- Buffer
- Dropper

Materials Required But Not Provided

- Specimen collection container
- Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

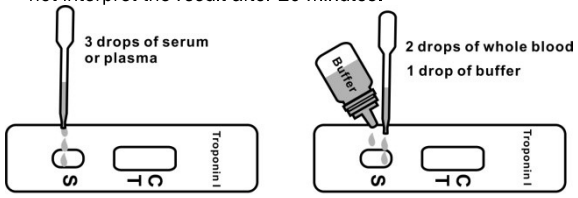
[SPECIMEN]

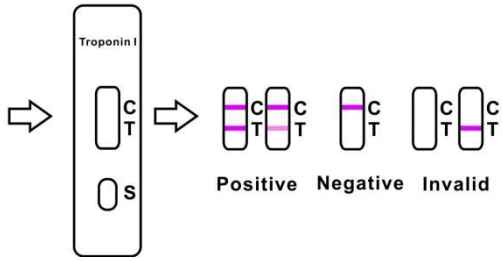
- The test can be used to test whole blood, serum or plasma specimens.
- Collect blood specimen (containing EDTA, citrate or heparin) by vein puncture following standard laboratory procedures.
- Separate the serum or plasma as soon as possible by centrifugation after collecting, if needed.
- Store specimens at 2-8℃(36-46℉) if not testing immediately. Store specimens at 2-8℃ up to 7 days. The serum and plasma specimens should be frozen at -20℃(-4℉) for longer storage. Do not freeze whole blood specimens.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
3. For serum or plasma specimen: Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 100 µL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
4. For whole blood specimens: Hold the dropper vertically and transfer 2 drops of whole blood (approximately 70 µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 35 µL) and start the timer. See illustration below.
5. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.





(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive:*Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This positive result indicates the presence of cTnI.
Negative: One colored line appears in the control region (C). No line appears in the test region (T). This negative result indicates the absence of cTnI.
Invalid: Control line 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 using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control 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 good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The Cardiac Troponin I Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the cTnI in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that cTnI is either not present or at levels undetectable by the test.

[PERFORMANCE CHARACTERISTICS]

The Cardiac Troponin I Rapid Test will detect the concentration of Troponin I is equal to or greater than 0.5 ng/mL.

Accuracy

A side-by-side comparison was conducted using the Cardiac Troponin I Rapid Test and commercially available Cardiac Troponin I Rapid Tests. 600 clinical specimens from three Professional Point of Care sites were evaluated with the Cardiac Troponin I Rapid Test and the commercial kit. The specimens were checked with a commercially available ELISA to confirm the presence of cTnI in the specimens. The following results are tabulated from these clinical studies:

Agreement with Commercial Cardiac Troponin I Rapid Test

		Commercial Cardiac Troponin I Rapid Test		Total
		Positive	Negative	
	Positive	219	1	220
	Negative	0	380	380
Total		219	381	600

The agreement between these two devices is 100% for positive specimens, and 99.74% for negative specimens. This study demonstrated that the Cardiac Troponin I Rapid Test is substantially equivalent to the commercial device.

Agreement with ELISA

		ELISA		Total
		Positive	Negative	
	Positive	216	4	220
	Negative	2	378	380
Total		218	382	600

A statistical comparison was made between the results yielding a clinical sensitivity of 99.08%, a clinical specificity of 98.95% and an accuracy of 99%.

Cross-Reactivity and Interference

1. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin and bilirubin, were spiked at high concentrations into the cTnI positive and negative specimens and tested, separately. No cross-reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20 mg/mL	+	-
Bilirubin	10 µg/mL	+	-
Hemoglobin	15 mg/mL	+	-
Glucose	20 mg/mL	+	-
Uric Acid	200 µg/mL	+	-
Lipids	20 mg/mL	+	-

2. Some other common biological analytes were spiked into the cTnI positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

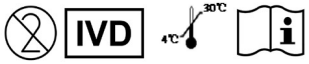
Analytes	Conc.	Specimens	
		Positive	Negative
Acetaminophen	200 µg/mL	+	-
Acetoacetic Acid	200 µg/mL	+	-
Acetylsalicylic Acid	200 µg/mL	+	-
Benzoylecgonine	100 µg/mL	+	-
Caffeine	200 µg/mL	+	-
EDTA	800 µg/mL	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200 µg/mL	+	-
β - Hydroxybutyrate	20,000 µg/mL	+	-
Methanol	10.0%	+	-
Phenothiazine	200 µg/mL	+	-
Phenylpropanolamine	200 µg/mL	+	-
Salicylic Acid	200 µg/mL	+	-

Reproducibility

Reproducibility studies were performed for Cardiac Troponin I Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100% at two sites, and 99.4% at one site. The inter-site agreement was 99.8%.

[BIBLIOGRAPHY]

1. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
2. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
3. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology/American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.



Index of Symbol

Do not reuse	*In vitro* diagnostic medical device
Store between 4-30℃	Consult instructions for use
Caution	Lot number
Use by	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged

Version No.: 2.0
Effective Date: Jul. 30, 2018