Cardiac troponin-I (cTnI) Rapid Test

REF: ABH-IC06-cTnI

INTENDED USE:

The Cardiac troponin-I (cTnI) Rapid Test is an in vitro immunochromatographic assay for qualitative detection of cTnI in whole blood, serum or plasma with the cut-off of 0.5 ng/mL. This test is used as an aid for diagnosis of myocardial injury such as acute myocardial infarction (AMI).

TEST PRINCIPLE:

The cTnI Rapid Test is a lateral flow chromatographic immunoassay that uses highly sensitive monoclonal antibodies to detect cTnI in whole blood, serum or plasma specimens. Anti-cTnI antibody is pre-coated in test (T) line region. During testing, the specimen reacts with cTnI antibody conjugates in the conjugated pad. The immune complex of Ag and conjugates then move upward on the membrane chromatographically and reacts with the anti-cTnI antibody in T line region. If the specimen contains cTnI, a colored line will appear in T line region. If the specimen does not contain cTnI, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control (C) line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

COMPONENTS:

The kit component configurations are provided below:
Test Cassette (20 Pcs), Buffer (1×1 mL), and IFU.

STORAGE AND STABILITY:

-Store the kit at 2-30˚C. If stored at 2-8˚C, ensure that the test device is brought to 15-30˚C before opening. Test kit is valid for 18 months.
- Do not freeze the kit or store the kit over 30˚C.

SPECIMEN COLLECTION AND PREPARATION:

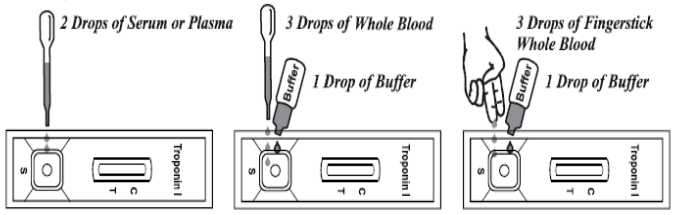
- This test is intended for using whole blood (from venipuncture or fingerstick), serum or plasma.
- To avoid hemolysis, serum or plasma should be separated as soon as possible.

SPECIMENT STORAG:

- Sample should be tested immediately after collection. If testing will be delayed, serum and plasma samples may be stored up to 3 days at 2~8°C or stored at -20°C for long-term storage. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Refrigerated or frozen specimens should reach 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.

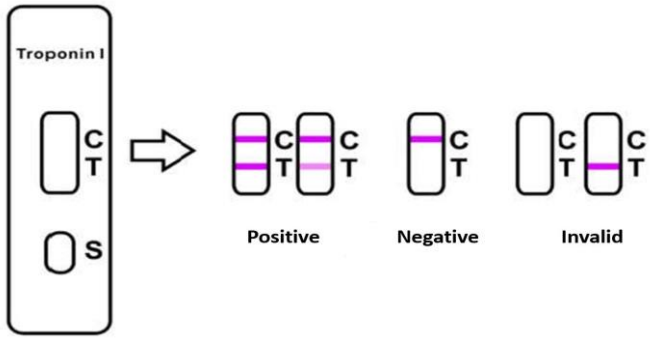
TEST PROCEDURE:

1. Allow the test device and specimens to equilibrate to temperature prior to testing.
2. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
3. For serum or plasma specimens: Transfer 2 drops of samples (70 µL) to the sample well (S) of the test results.
4. For Whole blood specimens: Transfer 3 drops of samples (100 µL) to the sample well (S) of the test results. Then, add 1 drop of buffer.
5. Wait for the colored band(s) to appear. The result should be read in 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF ASSAY RESULTS:

- Negative: When only the C line develop. No apparent colored line appears in T line.
- Positive: When both the C and T line develop.
- Invalid: If the C Line does not appear, the assay is invalid regardless of whether the color of T line is present. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS:

Clinical Sensitivity and Specificity

The cTnI Rapid Test has been valuated with specimens obtained from patients. A commercialized ELFA assay was used as the reference method. The results show that the cTnI Rapid Test has a high overall accuracy.
Relative Sensitivity: 98.2%
Relative Specificity: 98.7%
Accuracy: 98.5%

Table 1: The cTnI Rapid Test vs RT-PCR

Method		ELFA		Total
cTnI Rapid Test	Results	Positive	Negative	
	Positive	108	2	110
	Negative	2	155	157
Total Results		110	157	267

Cross-reactivity and Interference

*Interferences: Human albumin (110 mg/mL), Bilirubin (6 mg/mL), Hemoglobin (10 mg/ml), cholesterol (5 mg/ml), triglycerides (15mg/mL).
*Cross-reactivity: Pregnancy serum (3 mIU/mL), CEA (3 ng/mL), AFP (3 ng/mL), PSA (3 ng/mL), HBsAg (3 IU/mL), RF (3 IU/ml), Skeletal Troponin I (10,000 ng/mL), Troponin T (2,000 ng/mL).

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Version: 01 Revision Date: 2022.07.22

WARNINGS:

1. This instruction of use (IFU) must be read completely before performing the test. Failure to follow directions in IFU may yield inaccurate test results.
2. Test results should be read in 10 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.
3. Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the cassettes should be used within 30 min.
4. Do not use expired devices.
5. Bring all reagents and samples to room temperature (15-30°C) before use.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.

LIMITATIONS OF THE PROCEDURE:

1. This test is for health care professional use.
2. There is no meaning of lines color intensity.
3. This test should not be used as a only criteria for the diagnosis of AMI. The results should be confirmed with other valid tests.
4. The final diagnosis should be made by the physician's clinical findings and test results

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.

Index of CE Symbols:

	Use by date		Consult instructions for use
	Contains sufficient for tests		Caution
	Date of Manufacture		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limit
LOT	Batch Code		Do not re use
REF	Catalog Number		Do not use if package is damaged
	Keep dry		Keep away from sunlight

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