Cardiac Troponin I (cTnI) Rapid Test Kit (Colloidal Gold)

CE IVD

A rapid test for the diagnosis of myocardial infarction (MI) to detect cardiac Troponin I (cTnI) qualitatively in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

PRODUCT NAME
Cardiac Troponin I (cTnI) Rapid Test Kit (Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The Cardiac Troponin I (cTnI) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

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 acute myocardial infarction (AMI) 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 most preferred biomarker for myocardial infarction.
The Cardiac Troponin I (cTnI) Rapid Test is a simple test that utilizes a combination of anti-cTnI antibody coated particles and capture reagent to detect cTnI in whole blood, serum or plasma. The minimum detection level is 0.5ng/mL.

PRINCIPLE
The Cardiac Troponin I (cTnI) Rapid Test is a qualitative, membrane based immunoassay for the detection of cardiac Troponin I (cTnI) in whole blood, serum or plasma. In this test procedure, capture reagent is immobilized in the test line region of the test. After specimen is added to the specimen well of the cassette, it reacts with anti-cTnI antibody coated colloid gold particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized capture reagent. The test format can detect cardiac Troponin I (cTnI) in specimens. If the specimen contains cardiac Troponin I (cTnI), a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain cardiac Troponin I (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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

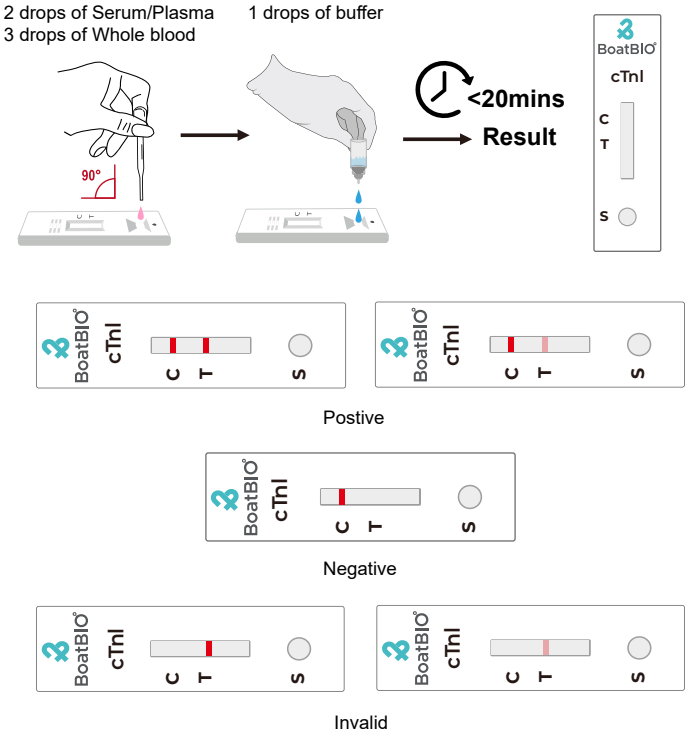
MATERIALS
Materials provided
• Test devices • Package insert • Buffer • Droppers
Materials Required but Not Provided
• Timer • Specimen collection containers •Centrifuge •Lancets (for fingerstick whole blood only) •Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

WARNINGS AND PRECAUTIONS
1 For professional in vitro diagnostic use only. Do not use after the expiration date.
2 Do not eat, drink or smoke in the area where the specimen or kits are handled.
3 Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4 Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5 Humidity and temperature can adversely affect results.

STORAGE AND STABILITY
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
• The Cardiac Troponin I (cTnI) Rapid Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.• Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
• 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 test by using a capillary tube:
• Touch the end of the capillary tube to the blood until filled to approximately 75 pL. 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 specimen well of the test cassette.
• Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
• Position the patient's finger so that the drop of blood is just above the specimen well of the test cassette.
• Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen well on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well. Avoid touching the finger directly to the specimen well.
• Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
•Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 1 day of collection. Do not freeze whole blood specimens. 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.
• If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE
Allow test devices, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) 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 cassette on a clean and level surface.
For Serum or Plasma specimen:
• Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 μ L) to the specimen well, then add 1 drop of buffer (approximately 40 μL), and start the timer. See illustration below.
For Venipuncture Whole Blood specimen:
• Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 μL) to the specimen well, then add 1 drop of buffer (approximately 40 μL), and start the timer. See illustration below.
For Fingerstick Whole Blood specimen:
• To use a capillary tube: Fill the capillary tube and transfer approximately 75 μL of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 μ L) and start the timer. See illustration below.
• To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 μL) to fall into the specimen well of test cassette, then add 1 drop of buffer (approximately 40 μ L) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of cardiac Troponin I (cTnI) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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

LIMITATIONS
1. The Cardiac Troponin I (cTnI) Rapid Test is for in vitro diagnostic use only. This test should be used for the detection of Troponin I in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in cTnI can be determined by this qualitative test.
2. The Cardiac Troponin I (cTnI) Rapid Test will only indicate the qualitative level of cTnI in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The Cardiac Troponin I (cTnI) Rapid Test cannot detect less than 0.5ng/mL of cTnI in specimens. A negative result at any time does not preclude the possibility of

myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) 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. High levels of Biotin (Such as supplements marketed for hair, skin, and nail growth) may interfere with the test result. Please consider Biotin interference as a possible error when a test result doesn't match the clinical presentation.6
7. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 1 day may not run properly on the test cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.

EXPECT VALUE

The Cardiac Troponin I (cTnI) Rapid Test has been compared with a leading commercial cTnI ELISA test, demonstrating an overall accuracy of 99.1%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The Cardiac Troponin I (cTnI) Rapid Test has been evaluated with a leading commercial cTnI ELISA test using clinical specimens. The results show that the sensitivity of the Cardiac Troponin I (cTnI) Rapid Test is 99.4% and the specificity is 99.0% relative to the leading ELISA test.

Method		ELISA		Total Results
Cardiac Troponin I (cTnI) Rapid Test	Results	Positive	Negative	
	Positive	172	5	177
	Negative	1	472	473
Total Results		173	477	650

Relative sensitivity: 172/173=99.4% (95%CI*: 96.8%~99.9%);
Relative specificity: 472/477=99.0% (95%CI*: 97.6%~99.7%);
Accuracy: (172+472)/(172+1+5+472)=99.1%(95%CI*: 98.0%~99.7%).
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of five specimens: a negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive. The negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same five specimens: a negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive specimens. Three different lots of the Cardiac Troponin I (cTnI) Rapid Test have been tested over a 3-day period using negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Cardiac Troponin I (cTnI) Rapid Test has been tested by 10,000ng/mL Skeletal Troponin I, 2,000ng/mL Troponin T, 20,000ng/mL Cardiac Myosin, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no crossreactivity.

Interfering Substances

The following potentially interfering substances were added to cTnI negative and positive specimens.
Acetaminophen: 20 mg/dL Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL Albumin: 10,500mg/dL
Creatin: 200 mg/dL Hemoglobin 1,000 mg/dL
Bilirubin: 1,000mg/dL Oxalic Acid: 600mg/dL
Cholesterol: 800mg/dL Triglycerides: 1,600mg/dL
None of the substances at the concentration tested interfered in the assay.

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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EC REP

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