Firstep Bioresearch, Inc.

Cardiac Troponin-I RapidTest
cTnI Cassette (0.5 ng/mL)
FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

The cardiac Troponin-I Rapid Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of cardiac Troponin-I (cTnI) in human Whole Blood/Plasma/Serum specimens as an aid in the diagnosis of myocardial infarction.

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 heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTnI has an additional amino acid residues on its N-terminal that are not exist on the skeletal forms thus making cTnI a specific marker for indicating cardiac infarction. cTnI is released into blood after the onset of acute myocardial infarction (AMI). Its release pattern is similar to CK-MB (4-6 hours after the onset of AMI). However, CK-MB level returns to normal after 36-48 hours, while levels of cTnI remain elevated for up to 6-10 days. The level of cTnI is very low in normal healthy people, and not detected in patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of AMI.

PRINCIPLE

Cardiac Troponin-I Rapid Test is a sandwich immunoassay. When sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-cTnI conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-cTnI antibody that is coated on the test region. If cTnI is present at levels of 1.0 ng/mL or greater in whole blood and 0.5 ng/mL or greater in plasma/serum, the result is the formation of a colored band in the test region. If there is no cTnI in the sample, the area will remain colorless. The sample continues to move to the control area and forms a pink to purple color, indicating the test is working and the result is valid.

MATERIALS PROVIDED

Each Cardiac Troponin-I Rapid Test contains:

1. User instruction sheet.
2. Test Device in a desiccated pouch: 1 test cassette, 1 dropper, and 1 desiccant.
3. Buffer

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Timer.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Blood specimens may be potentially infectious. Proper handling and disposal methods should be established.
3. Avoid cross-contamination of samples by using a new specimen collection container for each sample.
4. Test device should remain sealed until ready for use.
5. Do not use the test kit after the expiration date.

STORAGE AND STABILITY

The Cardiac Troponin-I Rapid Test should be stored at 8-35°C in the original sealed pouch. Do not freeze. Avoid direct sunlight.

SPECIMEN COLLECTION AND PREPARATION

1. **Fingerstick Whole Blood**
   a. Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   b. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   c. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
   d. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
   e. Add the fingerstick whole blood specimen to the test by using hanging drops.
   f. Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
   g. Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area in the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
2. **Venipuncutre Blood specimens**
   a. Plasma
   Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
   b. Serum
   Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
3. **Test specimens as soon as possible after collecting.**
   Storage: Whole Blood can not be frozen. A specimen should be refrigerated if not used the same day of collection. Serum and Plasma Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before using. Store specimens are at 2-8°C if not tested immediately. The specimens should be frozen at -20°C for longer storage. 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.

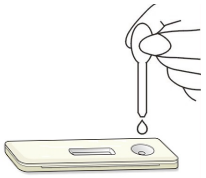
PROCEDURE

Preparation

1. If specimen, control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2. Do not open pouches until ready to perform the test.

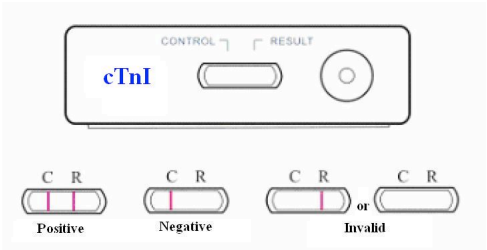
Testing

1. Remove the test device from the foil pouch, and place it on a flat, dry surface,
2. Adding specimen to the sample well.
   2.1 For **Fingerstick Whole Blood** specimen, allowing 3 hanging drops of fingerstick whole blood (about 100~120 μL) falls into the sample well and adds 1 drops of buffer to the sample well.
   2.2 For **Venipuncture Whole Blood** specimen, using the disposable dropper, adds 3 drops (about 100~120 μL) of specimen and 1 drop of buffer to the sample well.
   2.3 For **Serum or Plasma** specimen, using the disposable dropper, adds 2 drops (about 80 μL) of specimen to the sample well.
3. As the test begins to work, you will see purple color move across the result window in the center of the test device.
4. Interpret test results at 15 minutes. Do not read test results after 15 minutes.



INTERPRETATION OF RESULTS

Positive (+): If two colored bands are visible within 15 minutes, the test result is positive and valid. The test result can be read as soon as a distinct colored band appears in the test area.
Note: Specimens containing very low levels of cTnI may develop two color bands over 15 minutes.
Negative (-): If test area has no color band and the control area displays a colored band, the result is negative and valid.
Invalid: The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.



QUALITY CONTROL

An internal procedural control is included in the test device. A line must form in the Control region regardless of the presence of cTnI. The presence of the line in the Control region indicates that the proper sample volume has been used and that the reagents are migrating properly. If the line in the Control region does not form, the test is considered invalid.

LIMITATIONS

1. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. A negative result obtained from a patient whose sample was taken at 2-16 hours after the onset of chest pain may help in ruling out AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis and requires further confirmation. Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of the cTnI in to the bloodstream.
2. The test only provides qualitative result. A quantitative assay method must be used to determine the cTnI concentration.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity:

This Rapid Test (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial assay system (Abbott ARCHITECH i SYSTEM) using clinical specimens. The results show that the sensitivity of this Test Kit (Whole Blood/Serum/Plasma) is 99.1% and the specificity is 99.5% relative to the leading commercial assay system.

Cardiac Troponin-I Rapid Test **vs.** Abbott ARCHITECH i SYSTEM in Serum & Plasma

cTnI Cut-Off Value (0.5 ng/mL)		Abbott ARCHITECH i SYSTEM	
		positive	negative
cardiac Troponin-I Rapid Test	positive	106	2
	negative	1	413

Cardiac Troponin-I Rapid Test **vs.** Abbott ARCHITECH i SYSTEM in Whole Blood

cTnI Cut-Off Value (1.0 ng/mL)		Abbott ARCHITECH i SYSTEM	
		positive	negative
cardiac Troponin-I Rapid Test	positive	106	2
	negative	1	413

Precision:

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using cardiac Troponin-I specimen levels at 0, 0.25, 0.5, 0.75, 1.0, 1.5 and 2.0 ng/mL. The specimens were correctly identified > 99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same fourteen specimens; 0, 0.25, 0.5, 0.75, 1.0, 1.5 and 2 ng/mL of cardiac Troponin-I. Three different lots of the Test Kit have been tested using these specimens. The specimens were correctly identified > 99% of the time.

Cross Reactivity.

Testing Sample containing known amounts of antibodies to cardiac Troponin-I has been tested with 10,000ng/mL Skeletal Troponin I, and 2,000ng/mL, Troponin T. No cross-reactivity was observed, indicating that this Test Kit (Whole Blood/Serum/Plasma) has a high degree of specificity for cardiac Troponin-I.

Interference testing:

The following substances were added to cTnI negative and 0.5 ng/mL cTnI spiked Serum/Plasma samples. The following substances were added to cTnI negative and 1.0 ng/mL cTnI spiked Whole Blood samples. No interference was found with any of the substances at the following concentrations:

Bilirubin 10 mg/dL
Cholesterol 800 mg/dL
Hemoglobin 250 mg/dL
Triglyceride 500 mg/ dL

REFERENCES

1. Adams JE, et al. Circulation, Vol. 88, 101-106(1993)
2. Adams JE, et al. N. Eng. J. Med. Vol. 330,670-674(1994)
3. Bodor GS, et al. Clin. Chem. Vol. 41, 1710-1715 (1995)
4. Brogan GX, et al. Academic Emerg. Med.Vol. 4, 6-12 (1997)
5. Tucker JF, et al. Academic Emerg. Med.Vol.4, 13-21(1997)

INDEX OF SYMBOLS

	DO NOT REUSE
	USE BY
LOT	BATCH CODE
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
REF	CATALOG NUMBER
IVD	IN VITRI DIAGNOSTIC MEDICAL DEVICE
	TEMPERATURE LIMITATION
	CONSULT INSTRUCTIONS FOR USE
	KEEP AWAY FROM SUNLIGHT
	KEEP DRY

CE

EC REP

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