CE CTK BIOTECH SIMPLIFYING DIAGNOSTICS

REF

Catalog Number R3001C

IVD

In vitro Diagnostic

INTENDED USE

The *OnSite* Troponin I Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of cardiac Tropnin I (cTnI) and its complex in human serum or plasma at a level equal to or higher than 1 ng/mL. It is intended to be used as a screening test and as an aid in the diagnosis of acute myocardial infarction (AMI). Any reactive specimen with the *OnSite* Troponin I Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

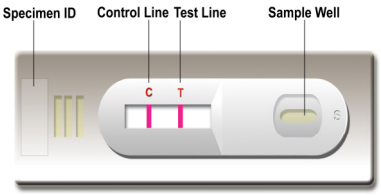
Cardiac Troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with troponin T (TnT) and troponin C (TnC), TnI forms a troponin complex in the heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTnI has additional amino acid residues in its N-terminus that do 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 blood stream 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 *OnSite* Troponin I Rapid Test is intended to detect elevated troponin I and its complex in human serum or plasma in less than 10 minutes by untrained or minimally skilled personnel without laboratory equipment requirement.

TEST PRINCIPLE

The *OnSite* Troponin I Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-cTnI antibody conjugated with colloidal gold (antibody conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with polyclonal anti-cTnI antibody, and the C line is pre-coated with goat anti-mouse IgG antibody.



When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Elevated cTnI if present in the specimen will bind to the antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-cTnI antibodies, forming a burgundy colored T line, indicating a cTnI positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of goat anti-mouse IgG/mouse IgG-gold conjugate immunocomplex regardless of the presence of cTnI in the specimen. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C -30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. Handle the negative and positive Controls in the same manner as patient specimens.
12. The test result should be read within 10 minutes after a specimen is applied to the sample well or sample pad of the device. Reading result after 10 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C - 30°C. The positive and negative controls should be kept at 2°C - 8°C. If stored at 2°C - 8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by veinpuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the serum by centrifugation.
Step 4: Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C - 8°C if not tested immediately.

Store specimens at 2°C - 8°C for up to 5 days. 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.

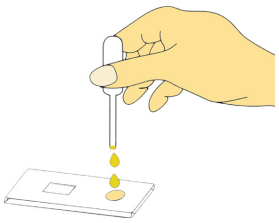
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60- 90 µL) of specimen into the sample well making sure that there are no air bubbles.



Note: Add 1 drop of Saline or Phosphate-Saline buffer (common buffers used in clinic not provided in the kit) into the sample well if flow migration is not observed within 30 seconds in the result window which could occur with a highly viscous specimen.

Step 5: Set up the timer.

Step 6: Results can be read in 10 minutes. Positive results can be visible in as soon as 1 minute.

Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. If the C line does not develop, review the whole procedure and repeat the test with a new device.

2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kit falls outside of 2°C - 30°C.
   e. The temperature of the test area falls outside of 15°C - 30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. NEGATIVE RESULT: If only the C line is developed, the test indicates that no detectable cTnI is present in the specimen. The result is negative.

2. POSITIVE RESULT: If both C and T lines are developed, the test indicates that the level of cTnI is equal or higher than 1 ng /mL. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

3. INVALID: If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The *OnSite* Troponin I Rapid Test can detect cTnI in serum or plasma at a concentration of 1.0 ng /mL or greater.

Interference testing:

The following substances were added to troponin I negative and 1.0 ng/mL troponin I spiked serum 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	1250 mg/dL

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of elevated Troponin I in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The *OnSite* Troponin I Rapid Test is limited to the qualitative detection of Troponin I at a level equal to or higher than 1 ng/mL in human serum or plasma. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates the level of cTnI is not detectable. However, a negative test result does not preclude the possibility of AMI.
4. A negative result can occur if the level of cTnI present in the specimen is below the detection limits of the assay or the cTnI that are detected are not present during the stage of AMI in which a sample is collected.
5. 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.
4. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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 CE Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
2°C 30°C	Store between 2-30°C	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
10110 Mesa Rim Road
San Diego, CA 92121, USA
Tel: 858-457-8698
Fax: 858-535-1739
E-mail: info@ctkbiotech.com

EC REP **MDSS GmbH**
Schiffgraben 41, 30175 Hannover, Germany

PI-R3001C Rev. F
Effective date: 2013-07-08
English Version

For Export Only, Not For Re-sale In the USA