

Health-Chem Diagnostics, LLC

3341 S.W. 15th Street – Pompano Beach, FL 33069 - USA – Phone: (954) 979-3845 – Fax: (954) 979-7997
Website: www.healthchemdiagnostics.com

ONE STEP CARDIAC TROPONIN I - TEST

(Whole Blood/Serum/Plasma)

FOR *IN VITRO* DIAGNOSTIC USE

INTENDED USE

The **One Step Troponin I Test** is an Immunochromatography based *IVD* test. It is designed for qualitative determination of Cardiac Troponin I (cTnI) in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

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 that plays a fundamental role in the regulation of intracellular calcium. Although Troponin I is also found in skeletal muscle, Cardiac Troponin I (cTnI) has an additional amino acid residue on its N-Terminal which distinguishes it from its skeletal muscle form making cTnI a specific marker for indicating cardiac infarction. cTnI is released rapidly into the blood stream soon after the onset of Acute Myocardial Infarction (AMI). Its release pattern is similar to Creatinine Kinase-Muscle and Brain, CK-MB, (4-6 hours after the onset of AMI). However, CK-MB levels returns to normal after 36-48 hours, where as levels of cTnI remains elevated for up to 6-10 days. The level of cTnI is below 0.06ng/ml in average, healthy people, and is also not detected in patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of AMI patients. The level of cTnI may reach 100-1300ng/ml in some AMI patients.

Principle of the Procedure

The **One-Step Troponin I Test** is a Chromatographic Immunoassay for the qualitative determination of cTnI in human whole blood, serum or plasma. When specimen is added to the sample pad, it contacts a colloidal gold anti-cTnI conjugate that is embedded on the pad. If cTnI is present in the specimen it forms a colloidal gold anti-cTnI-cTnI complex. As the mixture moves along to the test region it contacts a second anti-cTnI antibody that is immobilized on the membrane resulting in the formation of a reddish line if the complex is present. The sample continues to move to the control area where it forms a reddish colored band, indicating that the test results are valid.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at 2-30°C.
2. The test device must remain in the sealed pouch until time of use.
3. DO NOT FREEZE.
4. Do not use beyond the expiration date.

PRECAUTIONS

1. For professional *In Vitro* Diagnostic use only.
2. The test device should remain in the sealed pouch until time of use. Do not use after the expiration date.
3. All serum or plasma specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The test device should be discarded in a proper biohazard container after testing.
5. Avoid cross-contamination of serum samples by using a new specimen pipette for each sample.

INSTRUCTIONS: SPECIMEN COLLECTION

1. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

2. 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.

MATERIALS PROVIDED

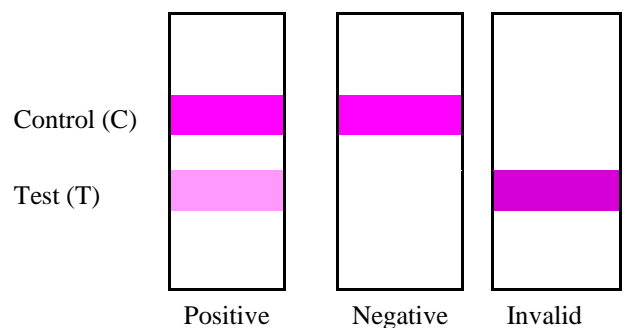
1. Test cards individually foil pouched with a desiccant
2. Plastic dropper
3. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer/clock
2. Pipette
3. Controls

ASSAY PROCEDURE

1. Read package insert carefully before testing. Allow the test devices, whole blood, serum or plasma to equilibrate to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.
2. Remove the test device from the foil pouch and use it as soon as possible.
3. Place the test device on a clean and level surface. Hold the dropper provided vertically and transfer 3 drops of specimen (100µl) to the specimen well (S) in the test device.
4. Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not read the result after 15 minutes.



INTERPRETATION OF RESULTS

(Whole Blood)

1. **Positive:**

Two colored lines should be observed in the viewing window. The line in the test region (T) is the probe line; the line in the control region (C) is the control line, which is used to validate the test results. The color intensity of the test line may be weaker or stronger than that of the control line.

2. **Negative:**

The control line appears in the test window, but the test line is not visible.

3. **Invalid:**

No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test is invalid and the assay should be repeated.

LIMITATIONS OF PROCEDURE

1. The test result should be used in conjunction with other clinical information such as clinical signs/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 useful in confirming the diagnosis but additional testing is required. 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 into the blood stream.
2. The Troponin I test only provides qualitative result. A quantitative 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.

EXPECTED VALUES

The **One-Step Troponin I Test** designed to yield a positive result for cTnI concentrations at 0.5ng/ml or greater. The time required for blood cTnI level to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. cTnI level reaches the maximum concentration after 12-24 hours of the

onset, and then remains elevated for 6-10 days in some cases. Therefore, a negative result within the first hours of the onset of symptoms does not rule out AMI with certainty. If suspected, repeat the test at appropriate intervals.

PERFORMANCE CHARACTERISTICS

Sensitivity

The One-Step Troponin I Test can detect cTnI in whole blood, serum or plasma with concentration of 0.5ng/ml or greater.

Accuracy

| Cut off | Special |
|----------|---------|
| 0.5ng/ml | 99.9% |
| 0.2ng/ml | 97% |
| 0.1ng/ml | 93% |

Interference testing

The following substances were added to the negative control and 0.5ng/ml Troponin I spiked serum samples. No interference was found with any of the substances at the following concentrations;

| Substance | Concentration |
|--------------|---------------|
| Bilirubin | 10 mg/ml |
| Cholesterol | 800 mg/ml |
| Hemoglobin | 250 mg/ml |
| Triglyceride | 250 mg/ml |
| sTnI | 1000ng/ml |
| cTnT | 1000ng/ml |
| cTnC | 1000ng/ml |

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
US FDA & ISO Certified Facilities
3341 SW 15th STREET, POMPANO BEACH, FL - USA
www.healthchemdiagnostics.com
Certified ISO CMDCAS 13485:2003



FM77504 - Quality Award
FDA Registration No.: 1048532