

RAMP® Troponin I

INTENDED USE

The RAMP® Troponin I Assay is a quantitative immunochemical test indicated for use as an *in vitro* diagnostic product used to measure cardiac troponin I levels in EDTA whole blood. Measurement of cardiac troponin I aids in the rapid diagnosis of acute myocardial infarction (AMI). The RAMP® Troponin I Assay is intended to be used only to prioritize patient management for those suspected of AMI.



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WARNING!
For *in vitro* diagnostic use only
Failure to follow RAMP® test procedures may result in invalid and/or erroneous results. Read the entire instructions for use prior to performing test.

SUMMARY AND EXPLANATION

Troponin is the contractile regulatory protein of striated muscles. This protein complex is comprised of three distinct polypeptides that are involved in calcium regulation: troponin C, I and T. Troponin I (TnI) is the subunit that inhibits actomyosin ATPase activity [1,2]. The cardiac isoform of TnI is not expressed in any type of skeletal muscle and is tissue-specific for the myocardium, making it an excellent biochemical marker for detection of myocardial injury [2-5]. Studies of patients with AMI have demonstrated early release of TnI into the blood stream after the onset of chest pain, reaching peak concentrations at 14 to 36 hours. The levels remain elevated for 3 to 7 days after infarction [5,6]. Measurement of TnI levels therefore provides a sensitive and specific determination of myocardial injury over a wide time window.

Elevated levels of cardiac-specific troponins convey prognostic information beyond that supplied by the patient's clinical signs and symptoms, the electrocardiogram (ECG) at presentation, and the pre-discharge exercise test [7]. Antman, et al. reported that patients with elevated levels of TnI had a statistically significant increase in mortality (p<0.001) when compared to patients without TnI elevations [8]. Further, the study provided data supporting a quantitative relationship between the TnI level and the risk of death in acute coronary syndrome (ACS) patients (p<0.001). Additional work has demonstrated increases in other non-fatal cardiac events such as non-fatal myocardial infarction, congestive heart failure, and urgent revascularization with increasing levels of TnI [9-11].

The ability of TnI to be measured at the low-end of the concentration range allows therapeutic intervention to be considered at any elevation above the normal range. Patients that present with no ST-elevation on their ECG but who have even a slight elevation in TnI or TnT may receive a greater treatment benefit from certain drugs such as GP IIb/IIIa inhibitors or low molecular weight heparins [12-14].

Other conditions such as blunt trauma or myocarditis that is not secondary to ischemic coronary artery disease can also lead to myocardial injury and result in increased TnI blood levels. These clinical factors should be considered when interpreting test results, and the TnI levels should be used in conjunction with clinical signs and symptoms and ECG changes [7].

TEST PRINCIPLE

The RAMP® Troponin I test is a quantitative immunochemical test for the determination of TnI in EDTA whole blood. The EDTA whole blood is mixed with buffer and antibody-coated, labeled particles, and applied into the sample well of the test cartridge. The red blood cells are retained in the sample pad, and the separated plasma migrates along the strip. Fluorescent-dyed particles coated with anti-TnI antibodies bind to TnI, if present in the sample. As the sample migrates along the strip, TnI-bound particles are captured at the detection zone, and excess fluorescent-dyed particles are captured at the control zone.

The RAMP® instrument then measures the amount of fluorescence emitted by the complexes bound at the detection zone and at the control zone. Using a ratio between the two fluorescence values, a quantitative reading is calculated. For further information on the use of the instrument, refer to the RAMP® Operator's Manual.

REAGENTS

- The RAMP® test kit contains all the reagents necessary for the quantification of Troponin I in EDTA whole blood.
- The sample buffer contains phosphate buffer, animal protein, surfactant, and ProClin® 300 / ProClin® 950 as preservatives.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use. For US customers, the RAMP® Troponin I test must be operated in a laboratory setting when used with the RAMP® 200.
- For use by qualified personnel per local, state, or Federal regulations or accrediting agency requirements.
- Read the entire instructions for use (IFU) prior to use. Directions should be read and followed carefully, or invalid or erroneous results may occur.
- Do not interchange or mix components of different RAMP® tests, RAMP® lots or components from other manufacturers.
- Do not use the kit or any kit component beyond the stated expiry date.
- Do not use any visibly damaged components.
- Do not insert a cartridge on which blood or any other fluid is spilled into the instrument.
- Disposal of all waste materials should be in accordance with local guidelines.
- Exercise standard precautions required for handling all laboratory reagents and patient samples.
- The device contains material of animal origin and should be handled as a potential biohazard.
- The sample buffer provided contains ProClin®, a potential skin sensitizer. Avoid spilling or splashing reagents containing ProClin® on skin or clothing. In case of contact, thoroughly flush with water.

STORAGE AND STABILITY

Store at 2 to 8°C (35 to 46°F). Do not freeze.

Stability

Unopened at 2 to 8°C (35 to 46°F)	Up to the stated expiration date
When stored at 15 to 25°C (59 to 77°F)	14 days

SAMPLE COLLECTION & PREPARATION

- Use ONLY EDTA Whole Blood (Plastic K₂EDTA tubes are recommended). Other sample types and anticoagulants have not been evaluated.
- Avoid blood samples that show gross hemolysis as these may interfere with the test and cause erroneous results. If this occurs, another blood sample should be obtained and tested.
- Testing must be completed within 2 hours of phlebotomy. However, if this is not possible, the EDTA whole blood can be stored for up to 2 days at 2 to 8°C. If stored, allow blood samples to equilibrate to 18 to 25°C for at least 15 minutes prior to use.

MATERIALS PROVIDED

- 25 pouches, each containing 1 RAMP® test cartridge and 1 test tip
- 25 RAMP® buffer vials
- 1 transfer device for 75 µL
- 1 lot card
- 1 instructions for use (IFU)

MATERIALS REQUIRED (BUT NOT PROVIDED)

- REF: C1100 RAMP® Reader instrument; or
- REF: C2100 RAMP® 200 instrument control module, and
- REF: C3100 RAMP® 200 instrument test module
- REF: C2003 RAMP® Cardiac Controls (optional)
- Optional accessories such as RAMP® printer and/or barcode scanner
- Specimen collection tubes: EDTA (Venous Whole Blood)

Use only the listed RAMP® instruments with this test.

LOT CARD CALIBRATION

Each RAMP® test kit includes a lot card that is individually packaged in an anti-static pouch. The lot card provides information specific to the kit test cartridge lot, including lot number, expiration date, and standard curve information. For further details on loading lot-specific information, see the RAMP® instrument Operator's Manual. No additional calibration beyond insertion of the lot card is necessary. This operation is required only once per test kit lot.

For each new lot, remove the lot card from its pouch and insert it into the lot card slot on the instrument. Once the lot card has been uploaded, return to its pouch and do not discard. Avoid touching the contacts at the end of the lot card.

PROCEDURE

Prior to sample preparation allow all components to come to room temperature for at least 15 minutes.

- Keep the test cartridge and test tip in the sealed foil pouch until ready for use. Once opened, test cartridges and test tips must be used or discarded within 60 minutes.
 - The test cartridge, test tip, and buffer vial should be discarded after a single-use. Do not reuse.
- Prepare RAMP® instrument for test cartridge. Refer to the RAMP® Operator's Manual for detailed instructions on Starting a Test.
 - Ensure that the EDTA whole blood sample is well mixed by gentle inversion.
 - Uncap the buffer vial and place upright on a clean, dry level surface, or in a holder.
 - Open a test pouch and remove the test cartridge and tip. Place the test cartridge on a clean, level surface. Firmly attach the test tip to the supplied transfer device.
 - Before inserting the test tip into the sample, fully depress the transfer device plunger.
 - Insert tip into sample and fully release plunger. The test tip should fill with 75 µL of blood.
 - Immediately transfer the filled test tip into the buffer vial close to, but not touching, the bottom.
 - Mix sample slowly by fully pressing and releasing the plunger 10 times; while keeping the tip submerged in the buffer for optimal mixing and to minimize air bubbles.
 - Once mixing is complete, draw 75 µL of sample into the test tip by releasing the plunger one final time and immediately dispense liquid into the sample well of the test cartridge. Small droplets may remain in the tip; this is expected.
 - Immediately insert the test cartridge fully into the instrument and press until firm resistance is felt.
 - The instrument will draw the cartridge in and test development will begin.
 - The instrument will analyze the cartridge and report the result in approximately 19 minutes.
 - Record the result, if required. For additional information on printing and/or uploading results, please refer to the Operator's Manual.

Running a test

1

Collect EDTA whole blood sample for testing. Prepare instrument to run test.

2

Place buffer vial upright on level surface and remove cap.

3

Open foil pouch and firmly attach test tip to the transfer device.

4

Depress plunger and insert test tip into EDTA whole blood sample. Gently release plunger to draw blood into test tip.

5

Insert filled test tip into buffer and slowly depress plunger 10 times to fully mix.

6

Transfer 75 µL of mixed sample into test cartridge well.

7

Immediately insert cartridge into RAMP® instrument port. When test is finished, read result.

8

Discard all used components.

