



REF M101-091003

mLabs® Troponin I

Rapid quantitative microfluidic assay for detection of troponin I

For Health Care Professional Use Only

INTRODUCTION

For years, physicians have relied upon serum markers to assist with the diagnosis of myocardial injury. Troponin I has been known as a reliable marker of myocardial tissue injury and used as a test of several different heart disorders, including myocardial infarction. The major advantage of troponin I involves its greater specificity for myocardial injury than traditional CK or myoglobin. The troponin I test is used to help diagnose a heart attack, to detect and evaluate mild to severe heart injury, and to distinguish chest pain/shortness-of-breath patient that may be due to other causes.

TEST PRINCIPLE

The mLabs® Troponin I test is based on the fluorescent immunoassay technology in a microfluidic cartridge. The immunoassay technology relies on the inherent ability of binding to the specific structure of

a molecule. In the mLabs® Troponin I microfluidic cartridge, one antibody pair is carefully chosen so to have excellent specificity and sensitivity for troponin I. The reporter antibody with a fluorescent dye attached is pre-coated in the reaction zone of the cartridge, while the capture antibody is immobilized in the detection zone. As the sample flows through, the analyte troponin I in the sample first encounters and binds to the reporter antibody. As the sample continues to flow through the detection zone, the capture antibody captures the troponin I-reporter complex by forming a sandwich structure and remains in the detection zone, while the reporter antibody without troponin I is washed away. The fluorescent signal in the detection zone is proportional to the troponin I concentration in the sample.

CONTENT OF THE KIT

- 25 test cartridges
- 30 pipette tips
- 1 mLabs® Data Drive (USB-disk or SIM card)
- 1 Package insert

SAMPLE COLLECTION & STORAGE

- Always wear protective gloves and lab coats when handling patient samples as they may potentially be infectious.
- All samples should be regarded as potentially hazardous and/or contaminated.
- Collect venous blood samples using K2 EDTA collection tubes.
- Ensure that the collection tube is completely filled to maintain the correct anti-coagulant to blood ratio.
- Thoroughly mix the whole blood sample through gentle inversion (> 8 times) of the tube.
- Perform the whole blood test within 60 minutes of sample collection.
- Refrigerate whole blood samples if the test cannot be performed within 60 minutes after sample collection..
- Do not use syringes to collect test samples.

TEST SAMPLE STABILITY

Whole blood samples are stable at room temperature for a maximum of 60 minutes. Severely hemolyzed samples should be avoided.

TEST KIT STORAGE

Refrigerate the troponin I test kit at 2-8 °C immediately upon receipt.

Only remove the number of tests required from refrigeration.

The troponin I test kit is stable at 2-8 °C until its expiration date.

TEST PROCEDURE

1. Sample Preparation

- The mLabs® Troponin I cartridge is only to be used together with mLabs® Immunometer.
- Equilibrate the pouched test cartridge to room temperature (~20-30 minutes) before use.
- Thoroughly mix the collected whole blood sample through gentle inversion (~2-3 times) of the tube before test.

2. mLabs® ImmunoMeter Preparation

- A single mLabs® Data Drive (USB-disk or SIM card) is provided along with each kit of cartridges. Either a USB-disk (U-disk) or a SIM card can be used.
- For U-disk, please insert it into the USB port at the rear of the ImmunoMeter prior

to performing test. For SIM card, please remove the SIM card from the holder and insert it into the SIM reader while the SIM reader is connected to the meter.

- From the main screen of the Immuno Meter, as for U-disk, press “DATA DRIVES” > “UDISK”; as for SIM card, press “DATA DRIVES > ”SIM”.
 - Once the data has been uploaded into the ImmunoMeter, the Data Drive can be removed for all subsequent related measurements.
 - Store the Data Drive in a clean, dry location for future use.
- #### 3. Sample Addition
- Remove test cartridge from pouch and label it with the patient’s ID on the front with a permanent marker.
 - Using the provided pipette, transfer 250 µL of sample into the inlet of the cartridge, dropwise.
 - Do not place the pipette tip into the inlet during sample transfer as air bubbles may be generated. For inside mode, test the cartridge right after sample addition. For outside mode, allow at least 8 (no more than 15) minutes for the sample to interact with the reagents in the cartridge before reading.

4. Performing Test and Reading Results

- Insert the test cartridge to the cartridge holder of the mLabs® ImmunoMeter.
- Press “PATIENT TEST” from the main screen of the ImmunoMeter.
- Select the assay and sample type.
- Press “START” to start testing.
- The results will be displayed on the screen after test is complete.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity
Troponin I = 0.02 ng/ml
2. Measurable Range
Troponin I = 0.02 to 50 ng/ml
3. Cutoff
Troponin I = 0.3 ng/ml

INTERFERENCE TESTING

Hemoglobin (up to 5 mg/mL), lipids (triolein up to 30 mg/mL), bilirubin (up to 0.15 mg/mL) added to plasma containing troponin I did not interfere with the recovery of troponin I. These substances also did not generate a positive response in the absence of troponin I. It is noted that severely hemolyzed specimens should be avoided.

Hematocrit in between 30% and 55% has no significant effect on the recovery of troponin I.

EXPECTED VALUES

In a study carried out using apparently healthy individuals' samples, the 95th percentile values were below 0.1 ng/mL. It is recommended that each laboratory should establish its own reference range.

LIMITATIONS

Carefully inspect the mLabs® Troponin I test pouch's integrity before use. If the pouch is found to be tampered with, i.e. torn or punctured, do NOT proceed to use the test cartridge. Contact your local technical support immediately.

The mLabs® Troponin I test kit is strictly for in-vitro usage only. Instructions and procedures provided in this insert should be carefully adhered to.

The mLabs® Troponin I test kit is not intended to be used as absolute evidence for myocardial injury. Obtained test results are only a reference for a physician.

All the provided items in the test kit are for single usage application and should be properly discarded after usage.

REFERENCES

S.Z. Goldhaber. Pulmonary embolism. New England Journal of Medicine. 1998. 339: pg 93-104.

P.S. Wells, D.R. Anderson, M. Rogers et al. Evaluation of D-dimer in the diagnosis of suspected deep-vein thrombosis. New England Journal of Medicine. 2003. 349. pgs 1227-1235.

P.F. Fedullo and V.F. Tapson. The evaluation of suspected pulmonary embolism. New England Journal of Medicine. 2003. 349. pgs 1247- 1256.

| Symbols | Explanation |
|---|------------------------------------|
|  | In vitro diagnostics |
|  | Name and address of manufacturer |
|  | European Authorized Representative |
|  | CE Mark |
|  | Temperature limitation |
|  | Lot number |
|  | Expiry date |
|  | Do not reuse |
|  | Catalogue number |
|  | Contents sufficient for n tests |
|  | Caution. Read carefully. |

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