CE IVD

MICROPOINT

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mLabs® Cardiac Panel 3

Rapid quantitatiave microfluidic assay for the detection of Cardiac Panel 3

For Health Care Professional Use Only

INTRODUCTION

The mLabs® Cardiac Panel is a fluorescence immunoassay to be used with the mLabs® Immunometers for the rapid quantitative determination of creatine kinase MB (CK-MB), troponin I (TnI), and myoglobin in whole blood. The mLabs® Cardiac Panel is to be used as an aid in the diagnosis of myocardial infarction (injury), as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure), as an aid in the ranking of risk of patients with heart failure, and as an aid in the ranking of risk of patients with acute coronary syndromes. Blood protein markers are important to the differential diagnosis of acute myocardial infarction (AMI). Markers used in the diagnosis of AMI include: myoglobin, troponin I, creatine kinase (CK), and the MB isoenzyme of creatine kinase (CK-MB). The diagnosis of AMI in a patient presented with chest pain is difficult in many cases. The World Health Organization (WHO) developed three major criteria for differentiating chest pain from non-cardiac reasons and chest pain in patients with AMI. These criteria are: 1) Physical examination along with patient history, 2) electrocardiographic data, and 3) changes in blood protein biomarkers associated with AMI. Blood myoglobin concentrations may be elevated as a result of conditions that produce muscle damage such as trauma, exercise, surgery, ischemia, and several degenerative muscle diseases. Blood levels of CK-MB can be elevated as a result of chronic or accute muscle damage including trauma and strenuous exercise. Cardiac troponin I is primarily elevated as a result of AMI, but can also be elevated as a result of minor cardiac injury such as unstable angina, congestive heart failure (CHF), cardiac transplant, and several conditions that can damage the myocardium. The mLabs® Cardiac Panel offers a specific, minimally invasive measurement for evaluating patients for CHF and to evaluate risk in patients with acute coronary syndrome (ACS).

TEST PRINCIPLE

The assay principle combines a two-step immunoassay sandwich method with a final fluorescent detection. The mLabs® Cardiac Panel 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® Cardiac Panel microfluidic cartridge, three antibody pairs are carefully chosen so to have excellent specificity and sensitivity for Troponin I, Myoglobin, and CK-MB. The reporter antibody for each analyte has a fluorescent dye attached and pre-coated in a separate reaction zone of the cartridge, while the capture antibody specific to the analyte is immobilized in the detection zone. As the sample flows through, the analytes in the sample first encounter and bind to the reporter antibody. As the sample continues its flow through the detection zone, the capture antibody captures the analyte-reporter complex by forming a sandwich structure and remains in the detection zone, while the reporter antibody without analyte is washed away. The fluorescent signal in the detection zone is proportional to the analyte concentration in the sample.

MATERIALS PROVIDED

- 25 test cartridges
- 30 pipette tips
- 1 mLabs® Data Drive (USB-disk or SIM card)
- Instructions for use

SAMPLE COLLECTION & STORAGE

Always wear protective gloves and suitable 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 samples using a K2 EDTA collecton 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 after sample collection.
- Refrigerate whole blood samples after collection.
- Do not use syringes to collect test samples.

TEST SAMPLE STABILITY

Whole blood samples are stable at room temperature for a maximum of 6 hours.

TEST KIT STORAGE

Refrigerate the Cardiac Panel 3 test kit at 2-8 °C immediately upon receipt.

Only remove the number of tests required from refrigeration.

The Cardiac Panel 3 test kit is stable at 2-8 °C until its expiration date.

TEST PROCEDURE

1. Sample Preparation

- The mLabs® Cardiac Panel 3 cartridge is only to be used together with mLabs® immunometer.
- Equilibrate the pouched test cartridge to room temperature (~20-30 minutes) before using.
- Thoroughly mix the collected whole blood sample by gently inverting (~2-3 times) the tube before test.

2. mLabs® ImmunoMeter Preparation

- A single mLabs® Data Drive (USB-disk or SIM card) is provide 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 ImmunoMeter, 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, allow at least 2 (no more than 15) minutes for the sample to interact with the reagents in the cartridge before reading. 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
   CK-MB = 1 ng/ml
   Myoglobin = 5 ng/ml
2. Measurable Range
   Troponin I: 0.02 to 50 ng/ml
   CK-MB: 1 to 80 ng/ml
   Myoglobin: 5 to 500 ng/ml
3. Cutoff

   Troponin I: 0.5 ng/ml
   CK-MB: 5 ng/ml
   Myoglobin: 100 ng/ml

INTERFERENCE TESTING

Hemoglobin (up to 1,000 mg/dl), Lipids (cholesterol up to 1,000 mg/dl and triglycerides to 1,000 mg/dl) or bilirubin (up to 20 mg/dl) added to anticoagulated plasma samples containing the three analytes did not interfere with the recovery of the analytes. These substances also did not generate a positive response in the absence of Cardiac Panel 3. It is noted that severely hemolyzed specimens should be avoided. Hematocrit in between 30% and 55% has no significant effect on the recovery of Cardiac Panel 3. No high dose hook effect was observed with the mLabs® Cardiac Panel 3 up to the following concentrations:

CK-MB: 1,050 ng/ml
Troponin I: 2,100 ng/ml
Myoglobin: 2,625 ng/ml

EXPECTED VALUES

In a study carried out using apparently healthy individuals’ samples, the 95th percentile values were below 4.3 ng/ml for CK-MB, 0.1 ng/ml for Troponin I, 107 ng/ml for Myoglobin. It is recommended that each laboratory should establish its own reference range.

LIMITATIONS

Carefully inspect the mLabs® Cardiac Panel 3 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® Cardiac Panel 3 test kit is strictly for In Vitro Usage only. Instructions and procedures provided in this insert should be carefully adhered to.

The mLabs® Cardiac Panel 3 test kit is not intended to be used as absolute evidence for acute myocardial infarction or congestive hear failure. Obtained test results should be consulted with physician in addition with other test results.

All the provided items in the test kit are for single usage application and should be properly discarded after usage as inserted test samples may potentially be infectious.

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

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