INTENDED USE

Quick AMI Test is a rapid visual immunoassay for the qualitative presumptive detection of human Myoglobin, CK-MB and cardiac Troponin I in whole blood, serum or plasma. This kit is intended for use as an aid in the diagnosis of acute myocardial infarction (AMI).

Quick AMI Test is an in vitro diagnostic device intended only for professional use.

PERFORMANCE CHARACTERISTICS

- **Troponin I (cTnI)**
  - Accuracy: > 98%.
  - Sensitivity: 0.5 ng/ml.

- **Myoglobin (MYO)**
  - Accuracy: > 97%.
  - Sensitivity: 50 ng/ml.

- **Creatine Kinase-MB (CK-MB)**
  - Accuracy: > 99%.
  - Sensitivity: 5 ng/ml.

INTRODUCTION

Myoglobin (MYO), Creatine Kinase MB (CK-MB) and cardiac Troponin I (cTnI) are proteins released into the bloodstream after cardiac injury.

Myoglobin is a heme-protein normally found in skeletal and cardiac muscle; it constitutes about 2% of total muscle protein and is responsible for transporting oxygen within muscle cells. When muscle cells are damaged, Myoglobin is released into the blood rapidly due to its relatively small size. The level of Myoglobin increases measurably above baseline within 2-4 hours post-infarct, peaking at 9-12 hours, and returning to baseline within 24-36 hours.

The Creatine Kinase is a dimeric molecule composed of two subunits designated as "M" and "B", which combine to form three different isoenzymes, CK-MM, CK-BB and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue. The release of CK-MB into the blood following an MI can be detected within 3-8 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours.

Cardiac Troponin I is a protein found in cardiac muscle; it is part of a three subunit complex comprised of Troponin T, Troponin I and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain and it could remain elevated for 6-10 days, after the cardiac injury.

PRINCIPLE

Quick AMI Test detects Myoglobin, CK-MB and Troponin I through visual interpretation of color development on the internal strip. Anti-myoglobin, anti-CK-MB, and anti-cTnI antibodies are immobilized on the respective test regions of the membrane. During testing, the specimen reacts with anti-myoglobin, anti-CK-MB, and anti-cTnI antibodies conjugated to colored particles and pre-coated on the sample pad of the test. If there are certain sufficient markers in the specimen, a colored band will form at the corresponding test region of the membrane. The presence of this colored band indicates a positive result for that marker, while its absence indicates a negative result. The appearance
of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

**MATERIALS PROVIDED**

- Quick AMI Test cassette device, individually packed.
- Package insert.
- Buffer.
- Lancing device (finger-stick) for whole blood sample collection.
- Disposable pipettes.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Specimen collection container.
- Centrifuge.
- Timer.

**SPECIMEN COLLECTION**

- Quick AMI Test is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger-stick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

**PROCEDURE**

1. Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.
2. Remove the test from its sealed pouch and use it as soon as possible. For best results, the assay should be performed within one hour.
3. Place the test device on a clean and level surface.
4. For Serum or Plasma specimens: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 mL) to the specimen well (S) of the test device, then start the timer.
   OR
   Transfer 3 drops of whole blood specimen (approximately 75 μL) to the specimen well of the device with the provided disposable pipette, then add 1 drop of buffer and start the timer.
   OR
   Allow 3 hanging drops of finger-stick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer and start the timer.
5. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area. As the test begins to work, color will migrate across the membrane.
6. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.
INTERPRETATION OF RESULTS

Positive
One band appears in the control region (C) and another one, two, or three band(s) appear(s) in the test region (T).

Negative
Only one colored band appears, in the control region (C). No colored band appears in the test region (T).

Invalid
Absence of a colored band at the control region: repeat the test using a new device.

Note
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

STORAGE AND STABILITY

• The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
• The test must remain in the sealed pouch or closed canister until use.
• Do not freeze.
• The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

• For professional in vitro diagnostic use only.
• Do not reuse tests.
Quick AMI Test

- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

LIMITATIONS OF THE TEST

1. Quick AMI test only indicates the presence of Myoglobin, CK-MB and Troponin I in the sample, and it should not be considered as the only criteria for the diagnosis of acute myocardial infarction.
2. If the test is negative and the symptoms persist it is recommended to conduct further research using other types of clinical tests. The test can not detect lower concentrations than those indicated in the SPECIFICATIONS section under the heading Sensitivity, a negative result only indicates that the sample has not reached the level of the cut-off and it can not exclude the presence of the markers in lower concentrations.
3. The final diagnosis must be confirmed by a physician, who also considers other clinical parameters.

REFERENCES