Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay intended for the qualitative detection of Myoglobin, CK-MB, and cardiac Troponin I (cTnI) in whole blood, serum, or plasma as an aid in the diagnosis of myocardial infarction.

### INTENDED USE

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid, membrane-based immunoassay used in vitro for the qualitative detection of Myoglobin, CK-MB, and cardiac Troponin I (cTnI) in whole blood, serum, or plasma to aid in the diagnosis of myocardial infarction. The results obtained should be correlated with clinical observations and other diagnostic tests. This test is not intended for use in immunocompromised patients.

### SPECIMEN COLLECTION AND PREPARATION

- **Whole Blood**: Collect whole blood in a sodium citrate tube. Centrifuge the blood at 2,000xg for 5 minutes to obtain serum. Store at 2-8°C and use within 72 hours.
- **Serum**: Collect serum into a sodium citrate tube. Allow to clot at room temperature for 30 minutes and centrifuge at 2,000xg for 5 minutes. Store at 2-8°C and use within 2 days.
- **Plasma**: Collect plasma into a sodium citrate tube. Remove the clot and allow to remain at room temperature for 30 minutes. Centrifuge at 2,000xg for 5 minutes. Store at 2-8°C and use within 2 days.

### STORAGE AND STABILITY

- **Whole Blood**: Store at 2-8°C until use.
- **Serum/Plasma**: Store at 2-8°C until use.

### PRECAUTIONS

- **For professional in vitro diagnostic use only.** Do not use after expiration date.
- **Avoid repeated freeze/thaw cycles.**
- **Do not use if package is damaged.**
- **May cause a false positive result when used on patients with a history of autoimmune diseases, chronic infections, or malignancies.**

### PROCEDURE

1. **Wash the patient’s hand with soap and warm water or clean with an alcohol swab.** Allow to dry.
2. **Place the bulb onto the top end of the capillary tube,** then squeeze the bulb to dispense the contents of the plastic bag onto the test area of the test cassette. Allow to air dry for 1 minute.
3. **Wait for the colored line(s) to appear.** Read results at 10 minutes. Do not interpret the results after 20 minutes.

### INTERPRETATION OF RESULTS

- **POSITIVE:** A colored line in the control line region (C) and the presence of one or more colored lines in the test line region(s) (T) indicates a positive result. This result may indicate the presence of Myoglobin, CK-MB, and/or cardic Troponin I in the specimen and should be correlated with clinical observations and other diagnostic tests. Further diagnostic testing is recommended.
- **NEGATIVE:** No line appears in the test line regions. This result may indicate the absence of Myoglobin, CK-MB, and/or cardiac Troponin I in the specimen and should be correlated with clinical observations and other diagnostic tests.

### QUALITY CONTROL

- **Control standards are not supplied with this kit; however, it is recommended that positive and negative control standards be used as a good laboratory practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- **The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only.** This test should be used for the detection of Myoglobin, CK-MB, and cardiac Troponin I (cTnI) in whole blood, serum, or plasma specimens only. Only the quantitative values observed are the rate of increase in Myoglobin, CK-MB, and cardiac Troponin I that can be determined by this qualitative test.

### PERFORMANCE CHARACTERISTICS

**Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)** has been evaluated with leading commercial assays. The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been shown to have 99.9% sensitivity and 97.2% specificity for cardiac Troponin I (cTnI) test, demonstrating an overall accuracy of 97.9% with Myoglobin, 99.1% with cardiac Troponin I (cTnI), and 99.4% with CK-MB.

### IMPORTANT INFORMATION

- **For professional in vitro diagnostic use only.** Do not use after expiration date.
- **Avoid repeated freeze/thaw cycles.**
- **Do not use if package is damaged.**

### CONCLUSION

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been used in conjunction with a leading commercial test to test for the presence of cardiac markers. The results obtained should be correlated with clinical observations and other diagnostic tests. Further diagnostic testing is recommended.