EXPLANATION OF THE TEST

Myoglobin has long been recognized as the earliest biochemical marker for the diagnosis of MI. Myoglobin (approximately 17,500 MW) is small enough to pass easily into circulation upon cardiac injury, elevated levels are often present within 2 hours post MI. Serum myoglobin peaks at approximately 6-9 hours, but is cleared from circulation rapidly and returns to normal within 24-36 hours. Myoglobin is highly sensitive for myocardial injury but because it is abundant in both cardiac and skeletal muscle, it lacks adequate specificity. In order to increase cardiac specificity, myoglobin has been used in conjunction with Troponin I test. The test is packaged as disposable, single-use kits designed for bedside use, as well as in the Emergency Department or in the Central Laboratory. The analytical sensitivity of the test is 50ng/ml Myoglobin. This test is intended for professional uses as an aid in the diagnosis of Myoglobin protein.

MATERIALS PROVIDED

1. Test device
2. Instruction manual

PRECAUTIONS

The One Step Myoglobin Test kit should be stored at room temperature 4-30°C (40-86°F). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.
1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection: Collect an anticoagulated blood sample by using sodium citrate or heparin as the anti-coagulant. Note: Myoglobin is very unstable in serum or whole blood specimens. Whole blood or serum specimen must be tested as soon as possible.

Plasma/Serum specimen collection:
1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested, they should be refrigerated at 2-8 °C. Specimens should be at room temperature before running a test.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

PROCEDURE OF THE TEST

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk (Figure 1) and add 1 hanging drop into the Sample Well. After the drop is absorbed into the Sample Well, add another hanging drop, repeat the procedure until a total of 4 hanging drops have been added to the Sample Well. If specimen drops (total about 110 to 120 µl of blood) are added too quickly, specially for blood specimen, it may cause clogging of the Sample Well.
3. If flow is seen in the result window after 30 seconds, add 5th hanging drop of blood into sample well.

As the test begins to work, you will see purple color move across the Result Window in the center of the test disk. Note: If purple color dye does not begin to flow through the “Result Window” within 2 minutes, add one more drop of sample.
5. Interpret test results at 10 to 15 minutes. Do not interpret test results after 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

1. A purple band will appear at the left section of the Result Window. This shows that the test is working properly. This band is the Control Band.
2. The right section of the Result Window indicates the test results. If another color band appears at the right section of the Result Window, this band is the Test Band.

Positive Result: The presence of two color bands (“T” band and “C” band) within the result window regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the “T” band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the “T” band will be very faint.
**Negative Result** The presence of only one purple color band within the Result Window indicates a negative result (Figure 3).

**Invalid Result**: If after performing the test no purple color band is visible within the Result Window, this result is considered invalid. (Figure 4). Not following the procedures correctly or using a test kit that has deteriorated can cause invalid results. It is recommended that the specimen be re-tested.

**Note**: A positive result will not change once you have established your answer at 20 minutes. Interpreting test results after 20 minutes, the sensitivity of the test will be higher than 50 ng/ml. Some specimens with a high rheumatoid factor concentration may yield a nonspecific positive result. Specimens containing very low levels of Myoglobin may develop “T” band color over 15 minutes.

**LIMITATIONS OF THE TEST**
Although the One Step Myoglobin Test is accurate in detecting Myoglobin, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

**REFERENCES**

**GRAPHICAL SYMBOLS USED**

![Storage temperature](image1)
![Lot number](image2)
![In vitro diagnostic device](image3)
![Expiry date](image4)
![Catalogue number](image5)
![Determination number for kit](image6)
![Read instruction before use](image7)
![Manufacturer](image8)

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