

“See Now” Myoglobin test Serum/Plasma/Whole blood



For in vitro Diagnosis Use
Product Code: SN 6.2

Intended Use

The “See Now” Myoglobin Test (Serum/Plasma/Whole blood) is a rapid chromatographic immunoassay for the qualitative detection of Myoglobin in human serum, plasma or whole blood to aid in the diagnosis of acute myocardial infarction(AMI).

Principle

Myoglobin is a low molecular weight cytoplasmic protein. When the muscle cells are damaged it release to the blood rapidly than any other marker. The elevated level could be detected approximately as early as 2 hours after onset of AMI. The peak level appears at 4-8 hours after AMI. The myoglobin normal serum is 30-90ng/ml. The level of myoglobin can elevate to 200 ng/ml or greater. Human Myoglobin test is an immunochromatographic assay. When sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-myoglobin conjugate that are coated on the conjugate pad. The mixture moves along to the membrane by capillary action and reacts with anti-myoglobin antibody that is coated on the test region. If myoglobin is present at a level of 50 ng/ml or greater a color line is appeared in the test region. If myoglobin is present at level/levels is not present in the sample, the test region will remain colorless. The sample continues to move the control region and forms a colored line, indicating the test is working and its results is valid.

Precautions

- **FOR IN VITRO DIAGNOSTIC USE ONLY.**
- Do not use it after the expiration date.
- 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 all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

Materials Provided

- Test devices, Desiccant
- An instruction insert

Storage and Stability

The kit can be stored at room temperature (15-25°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.**

Specimen Collection and Preparation

- The “See Now” Myoglobin Test can be performed using either

serum, plasma or whole blood.

- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used. Remove the serum or plasma from the clot or red cells, respectively, as soon as possible to avoid hemolysis. Lipemic, icteric, or hemolyzed specimens may give inconsistent test result. Specimens, of containing precipitate, should be clarified prior to testing.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 4-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

Test Procedure

Allow the test device, buffer, specimen to equilibrate to room temperature (15-25°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops (**100 µL**) of serum, plasma or whole blood. Avoid air bubbles.
3. Wait for the red line to appear. The result should be read at 15 minutes. **Do not interpret the result after 30 minutes.**

Interpretation of Results

Positive

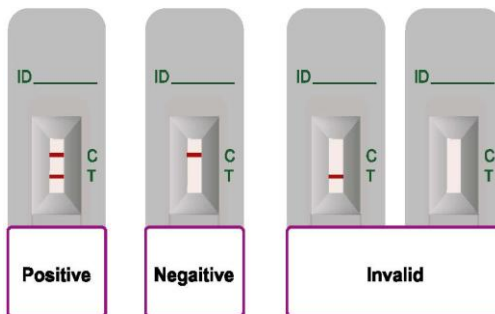
Distinct pink colored bands appear at the control and test line regions.

Negative

Only one pink colored band appears at the control region.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.



Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Detection Limit

“SeeNow” Myoglobin test can detect myoglobin with concentration of 100 ng/mL or greater.