Atlas Medical

Myoglobin Test Device (Whole Blood/Serum/Plasma)

A rapid, one step test for the qualitative detection of Myoglobin in whole blood, serum or plasma.

IVD *For In-Vitro diagnostic and professional use only*

2 30°C Store at 2-30 °C CE

INTENDED USE

Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human Myoglobin in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

INTRODUCTION

Myoglobin (MYO) is a heme-protein normally found in skeletal and cardiac muscle with a molecular weight of 17.8 kDa. It constitutes about 2 percent of total muscle protein and is responsible for transporting oxygen within the muscle cells.[1] When the muscle cells are damaged, Myoglobin is released to the blood rapidly due to its relatively small size. Following the death of tissue associated with MI, Myoglobin is one of the first markers to rise above normal levels. 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. A number of reports suggest the measurement of Myoglobin as a diagnostic aid in confirming the absence of myocardial infarction with negative predictive values of up to 100% reported at certain time periods after onset of symptoms.

Atlas One Step Myoglobin Rapid Test Device (Whole Blood/Serum/Plasma) is a simple test utilizing a combination of anti-Myoglobin antibody coated particles and capture reagent to detect Myoglobin in whole blood, serum or plasma. The minimum detection level is 50 ng/mL.

PRINCIPLE

Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of Myoglobin in whole blood, serum or plasma. The membrane is pre-coated with capture reagent on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-Myoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture reagent on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

MATERIALS PROVIDED

- Test devices (contain anti-Myoglobin antibody coated particles and capture reagent coated on the membrane).
- Droppers.
- Buffer.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container.
- Lancets (for finger stick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only).
- Centrifuge.
- Timer.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The Used test should be discarded according to local regulations.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C).
- The test is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

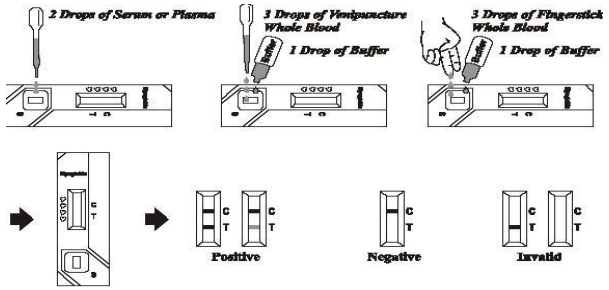
SPECIMEN COLLECTION AND PREPARATION

- Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
- Allow 3 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the 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 fingerstick should be tested immediately.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

PROCEDURE

Allow the test, specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the test device on a clean and level surface.
   For Serum or Plasma specimens: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 μL) to the specimen well (S) of the test device, then start the timer. See illustration below.
   For Venipuncture Whole Blood specimens: Hold the dropper vertically and transfer 3 drops of venipuncture whole blood (approximately 75 μL) to the specimen well (S) of the test device, then add 1 drop of buffer and start the timer. See illustration below.
   For Fingerstick Whole Blood specimens: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75μL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:*

Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE:**

The intensity of the color in the test line region (T) will vary depending on the concentration of Myoglobin present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE:

One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID:

Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

EXPECTED VALUES

Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial Myoglobin EIA test, demonstrating an overall accuracy of 98.0%.

QUALITY CONTROL

- An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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.

LIMITATIONS

Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of Myoglobin in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Myoglobin can be determined by this qualitative test.

1. Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) will only indicate the qualitative level of Myoglobin in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
2. Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) cannot detect less than 50 ng/mL of Myoglobin in the specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect results. Even if test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
5. 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial Myoglobin EIA test using clinical specimens. The results show that the sensitivity of Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) is 100% and the specificity is 97.7% relative to the leading EIA test.

Method		EIA		Total Results
One StepMyoglobin Test	Results	Positive	Negative	
	Positive	60	9	69
	Negative	0	374	374
Total Results		60	383	443

One Step Myoglobin Test vs. EIA

Relative Sensitivity: 100% (94.0%-100%)*

Relative Specificity: 97.7% (95.6%-98.9%)*

Accuracy: 98.0% (96.2%-99.1%)*

*** 95% Confidence Interval**

Precision

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using Myoglobin specimen levels at 0 ng/mL, 50 ng/mL, 100 ng/mL, 200 ng/mL, and 400 ng/mL. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: 0 ng/mL, 50 ng/mL, 100 ng/mL, 200 ng/mL, and 400 ng/mL of Myoglobin. Three different lots of Atlas One Step Myoglobin Test Device (Whole Blood/Serum/ Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Interfering Substances

Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 6 mg/mL bilirubin, 10 mg/mL hemoglobin, 5 mg/mL cholesterol and 15 mg/mL triglycerides.

The following compounds have also been tested using Atlas One Step Myoglobin Test Device (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen	Chloramphanicol	Flunarizine Hydrochloride	Nifedipine
Acetoacetic Acid	Chlordiazepoxide	Furosemide	Oxalic Acid
Acetylsalicylic acid	Cilazapril	Gentisic Acid	Oxazepam
Anisodamine	Creatine	Hydrochlorothiazide	Pentoxifyline
Ascorbic Acid	Diclofenac	Isosorbide Mononitrate	Phenobarbital
Atenolol	Digoxin	Labetalol	Quinine
Atorvastatin Calcium	DL-Tyrosine	Metoprolol Tartrate	Ramipril
Caffeine	Ethanol	Moracizine Hydrochloride	Verapamil
Captopril	Felodipine		

REFERENCES

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry