

One Step Rapid Test for Troponin I

MaxLINE Troponin I Rapid Test

Serum/Plasma Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVTRO-10	10 Tests
AVTRO-20	20 Tests
AVTRO-25	25 Tests
AVTRO-30	30 Tests
AVTRO-50	50 Tests

INTENDED USE:

MaxLINE Troponin I is an rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in human serum/plasma.

PRODUCT FEATURES

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen Sandwich Principle.
3. Detects human cardiac Troponin I
4. Sensitivity: 99.5%
5. Specificity: 99.8%
6. Cut off Sensitivity : 1.5ng/ml

INTRODUCTION

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is part of a three subunit complex comprising of Troponin T 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. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remain elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma. cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery. Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.

The cTnI One Step Troponin I Test Device (Serum/Plasma) is a simple test that utilizes a combination of anti-cTnI antibody coated particles and capture reagent to selectively detect cTnI in serum or plasma. The minimum detection level is 1.5 ng/mL

PRINCIPLE :-

MaxLINE Troponin I is an rapid chromatographic immunoassay for the qualitative detection) of human cardiac Troponin I in human serum /plasma. Troponin I device contains two lines; "C" (Control Line) & "T" (Test line). The test membrane is pre-coated with a anti-human cTnI antibody on the Test line region and utilizes a separate control to assure assay flow and performance. During testing, the test sample is added directly to the sample well. The sample interact with monoclonal cTnI antibodies conjugated to gold nano particles. The solution migrates upward on the membrane (via capillary action) to react with the cTnI s antibody on the membrane. If Troponin I is present, a purple/pink line will appear at the test line. The purple/pink line at the control region should always appear if the assay is performed correctly.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°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. Do not use beyond the expiration date.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Product Insert
AVTRO-10	10 Tests	10Nos.	1 No.
AVTRO-20	20Tests	20 Nos.	1 No.
AVTRO-25	25 Tests	25 Nos.	1 No.
AVTRO-30	30 Tests	30 Nos.	1 No.
AVTRO-50	50 Tests	50 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

- a) Individually packed test strip
- b) Sample Dropper
- c) Product insert

2. Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for serum/ plasma separation only)
- Stop Watch

PRECAUTIONS

1. Do not use test kit components after the expiration date.
2. Dispose of all used test components in a properly labeled container.
3. Read the package insert care fully before testing.

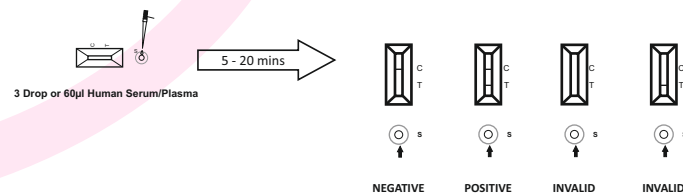
SPECIMEN COLLECTION AND STORAGE

1. Human Serum /Plasma must be used with this assay and usual precautions for venipuncture s hould be observed.
2. Collect blood in a clean, dry, sterilized vial and allow it to clot. Separate the serum by centrifugation a t 5000 r.p.m for 15 minutes at room temperature.
3. Testing should be performed as soon as possible after collection. Do not leave serum/Plasma at r oom temperature for prolonged periods.

TEST PROCEDURE

1. Remove the cassette from the foil pouch by tearing at the "notch" and place it on a flat surface.
2. Holding a sample dropper vertically, add exactly 3 drops of 60µl of serum /plasma to the sample port.
3. Read results between 5-20 minutes and discard the cassette after 20 minutes.
4. Do not read the results after 20 minutes.

INTERPRETATION OF RESULT



1. **Negative** : One coloured band appears in the control region c
2. **Positive** : Two coloured bands appear: one in the test region (T) and the other in the control region c.
3. **Invalid** : Non appearance of any coloured bands indicates inconclusive result.

Note : In the case of invalid test should be repeated with fresh cassette.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is considered 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.

EXPECTED VALUE:

The cTnI One Step Troponin I Test Device (Serum/Plasma) has been compared with a leading commercial cTnI EIA test, demonstrating an overall accuracy of 99.7%.

PERFORMANCE CHARACTERISTICS

800 Samples whose result were earlier confirmed by leading commercial cTnI EIA test were tested with MaxLINE Troponin I The Result are Given below :-

Method		EIA Test		Total Results
	Results	Positive	Negative	
MaxLINE cTnI Test device	Positive	199	1	200
	Negative	1	599	600

sensitivity :99.5 %

specificity: 99.8%

PRECISION

Intra-Assay

Within-run precision has been determined by testing 15 replicates of three specimens : a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by testing 15 replicates on the same three specimens : a negative, a low positive and a high positive. Three different lots of the Troponin I Rapid Test Device (Serum/Plasma) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to Troponin I negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin:	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATIONS OF THE TEST

1. The cTnI One Step Troponin I Test Device (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of Troponin I in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in cTnI can be determined by this qualitative test.
2. The cTnI One Step Troponin I Test Device (Serum/Plasma) will only indicate the qualitative level of cardiac Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The cTnI One Step Troponin I Test Device (Serum/Plasma) cannot detect less than 1.0 ng/mL of cTnI in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

DISCLAIMER:

The manufacturer has taken every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.















WARNING:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

REFERENCE

1. Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
3. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
4. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology/American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test



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