ImmunoScience INDIA

ImmunoQuick

TROP I

Rapid Test for Troponin I - Device/Cassette

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

INTENDED USE

"Rapid test for Troponin I - Device/Cassette" is an immunoassay for the rapid and visual detection of Troponin I (CTnI) in human serum/plasma/ whole blood for the diagnosis of myocardial Infarction.

PRINCIPLE

After addition of the serum/plasma/whole Blood sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with Troponin I specific Antibodies and Rabbit IgG. If the sample contains detectable levels of the Troponin I, it reacts with the gold conjugated Troponin I specific Antibodies to form a complex. This complex moves further and reacts with Troponin I specific Antibodies coated as a test line on the nitrocellulose membrane to form colored band (Test line). The unbound complex and the Rabbit IgG conjugated colloidal gold particles move further to the goat anti-Rabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

CONTENTS OF KIT

1. Pouches of Test device With Desiccant
2. Plastic Dropper
3. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Stop Watch
2. Sample Container
3. Disposable gloves

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all information in the pack insert carefully before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use expired test, Expiry date is printed on the foil pouch and kit.
3. Store kit in a dry place at temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipments.
4. Dispose off hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat used samples and tests as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product

SPECIMEN COLLECTION

1. This test can be performed using serum/plasma/whole blood.
2. Testing should be performed immediately after the Collection of samples. Do not leave the specimen at room temperature for prolonged periods.
3. For whole blood, Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin can be used as suitable anticoagulants.
4. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to maximum three days.
5. Do not use hemolyzed, turbid or contaminated samples. Turbid samples should be centrifuged and only clear supernatant must be used for testing.

TEST PROCEDURE

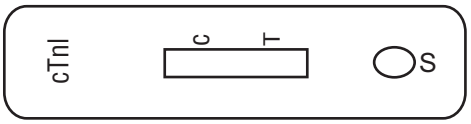
1. Allow the kit components and sample to reach room temperature (20°C to 30°C).
2. Remove the test device, plastic dropper and desiccant pouch from the pouch. Check the color of desiccant it should be blue, if it has turned colorless or pink, discard the test and use another test.
3. Place the device on flat surface & add 2 drops (Approx. 90 µl) of serum or plasma or whole blood sample in well "S".
4. Start the timer.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative: If colored line appears at the control region 'C' only.

Positive: A distinct colored lines appears at the control region 'C' and at the test region 'T'.

Invalid: The test should be considered invalid if,
A) No line appears at 'C' and 'T' region.



B) No line appears at 'C' region and line appear only at 'T' region.

NOTE :
The intensity of the colored line in the test region (T) will vary depending on the levels of troponin I in the specimen. However, neither the quantitative value nor the rate of increase in level of Troponin I in the specimen can be determined by this qualitative test. Positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 260 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 60/60) and the relative specificity was 100 % (i. e. 200/200).

The results are summarized in the following table:

Sample Type	Total Number of Samples Tested	ImmunoQuick Troponin I Test Device		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Troponin I Positive Serum Samples	25	25	0	100	-
Troponin I Positive Plasma Samples	25	25	0	100	-
Troponin I Positive Blood Samples	10	10	0	100	-
Negative Human Serum Samples	150	0	150	-	100
Negative Human Plasma Samples	25	0	25	-	100
Negative Human Blood Samples	25	0	25	-	100

External Evaluation:

In an external study, total 200 samples were evaluated for sensitivity and specificity. Relative sensitivity was found 100 % (i. e. 50/50) and the relative specificity was found 100 % (i. e. 150/150). Positive Predictive Value (PPV) and NegativePredictive Value (NPV) for the test was found 100%.

The results are summarized in the following table:

Sample	Total Number of Samples Tested	ImmunoQuick Troponin I Test Device		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
Troponin I Positive Samples	50	50	0	100	-	100	-
Troponin I Negative Samples	150	0	150	-	100	-	100

The lowest detection limit observed for the product is 0.5 ng/ml.

LIMITATIONS

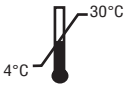
This test provides presumptive diagnosis of Troponin I. A confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. Hence, positive test needs to be confirmed by confirmatory tests.

REFERENCES

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. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation.Ann. Thorac. Surg. 61: 227, 1996.
5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology/American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.
6. Brogan GX Jr, Hollander JE, McCuskey CF, et al. Evaluation of a new assay for cardiac troponin I vs creatine kinase-MB for the diagnosis of acute myocardial infarction. Biochemical Markers for Acute Myocardial Ischemia (BAMI) Study Group. Academic Emerg. Med. 1997;4, 6-12.
7. Tucker JF, Collins RA, Anderson AJ, et al. Early diagnostic efficiency of cardiac troponin I and Troponin T for acute myocardial infarction. Acad Emerg Med. 1997;4, 13-21.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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