

One step rapid Card Test for detection of Troponin T in human Whole Blood/Serum/Plasma

Store at 2-30°C. DO NOT FREEZE.
For In-Vitro Diagnostic Use only

ORDER INFORMATION

Pack Size	REF
1 Tests	TPTC 1
10 Tests	TPTC 10
25 Tests	TPTC 25

CLINICAL SIGNIFICANCE

Troponin T (TnT) is part of troponin complex, which together with tropomyosin, forms the main component that regulates the Ca⁺² –sensitive ATP-ase activity of actomyosin in striated muscle (skeletal and cardiac). The troponin complex consists of three subunit has a distinct function with TnC as the site of Ca⁺² binding, TnT the tropomyosin binding, and TnI as the inhibitory subunit. Different isoforms of TnI exists in the skeletal and cardiac muscles (sTnI and cTnI, respectively) with distinct immunologic epitopes that allow the production of cardiac-specific TnI antibodies. The cardiac marker, Troponin T has been established as useful tools in the diagnosis of acute myocardial infarction (AMI). Troponin T is found in blood at elevated concentrations approximately 4-6 hours after the onset of chest pain and peak at 12-24 hours. Troponin T levels remain elevated for up to 14 days. The use of this marker is an aid in the diagnosis of AMI after myocardial function.

PRINCIPLE

The ACCUCARE® ONE STEP TROPONIN T RAPID TEST employs a solid-phase chromatographic immunoassay technology to qualitatively detect the elevation of Troponin T in human blood samples. When a sample of blood is dispensed into the sample well, red blood cells are removed by the built in separation system. Troponin T in the specimen makes a complex with the specific gold Nano particle conjugate and anti-Troponin T antibody. This complex migrates through the test area containing immobilized anti-Troponin T antibody. The antigen Gold Nano Particle-Troponin T- antibody complex bind to the immobilized anti-Troponin T antibody in the test area. Unbound dye complexes migrate out of Test area and are later captured in the Control area. Visible pinkish-purple bands will appear in the test and Control areas if the concentrations of Troponin T is above established cutoff values. If the Troponin T concentration in the specimen is 0.3 ng/ml or greater, a band is present in the Troponin T area. If a band is present only in the Control area, the test result is read as negative, indicating that the Troponin T concentrations are all below the cutoff values. If no band is present in the Control area, the test is invalid and another test must be run, regardless of the presence or absence of band(s) in the Test Area.

CONTENTS

Test Device
Instruction for Use (IFU)
Disposable (Dropper) 20 µl sampling device
Desiccant

STORAGE & STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. **DO NOT FREEZE.**
- Do not use beyond the expiration date.
- Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

- For professional *In-vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Read the Instruction for use carefully before performing the test.

LIMITATIONS

- The result of the Cardiac TnT Assay is to be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose myocardial infarction.
- A negative result obtained from a patient's sample 16 hours after the onset of chest pain may help in ruling out AMI.
- A positive assay result from a patient suspected of AMI may be used as an indicative of myocardial damage and requires further confirmation.
- Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of protein markers into the bloodstream.
- Samples containing an unusually high titer of certain antibodies, such as human anti-mouse or human anti-goat antibodies, may affect the performance of the test.

SPECIMEN COLLECTION & PREPARATION

- The ACCUCARE® ONE STEP TROPONIN T RAPID TEST can be performed using Whole Blood or Serum or Plasma.
- Collect Whole Blood into an appropriate blood collection tube with or without anticoagulant (EDTA, citrate or heparin). If you want use serum or plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens must be used.
- 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 2-8°C for up to 3 days.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

- Allow test device and specimen equilibrate to room temperature (15-30°C) prior to testing.
- Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
- Place the test device on a clean and flat surface. Carefully dispense 2 drops (40 µl) of Whole Blood/Serum/Plasma in the sample well "S" using the dropper provided.
- After that add 1 drops (appx. 40 µl) of Assay Buffer in the sample well "S".
- Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF RESULTS

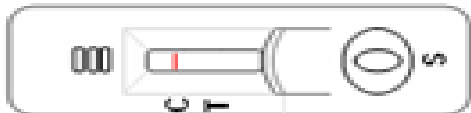
1. POSITIVE

If two color bands appear, one at control line 'C' and other at test line 'T', the specimen is positive for Troponin T.



2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Troponin T.



3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.



EXPECTED VALUE

The cardiac Troponin T assay is designed to yield a positive result for cTnT concentrations at or more than 0.3 ng/mL.

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP TROPONIN T RAPID TEST has been evaluated with positive and negative samples and data are as below:

Specimen	Positive	Negative	Sensitivity
Positive	40	00	100 %

Specimen	Positive	Negative	Specificity
Negative	04	246	98.4 %

BIBLIOGRAPHY

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GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For <i>in vitro</i> Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit
	Tests per Kit		Do Not Use if Damaged
	Do not reuse		Keep Dry



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