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"See Now" Troponin I Cassette Test

For in vitro Diagnosis Use
Product Code: SN 6.1

CE

Intended Use

The Troponin I rapid test (Serum/Plasma/Whole blood) is a rapid chromatographic immunoassay for the qualitative detection of cardiac *Troponin I)* in serum, plasma or whole blood to aid in the diagnosis of acute myocardical infarction(AMI).

Principle

Cardic Troponin it is a cardic protein with a molecular weith of 22.5 KDal. Together Troponin T and Troponin C forms a troponin complex in heart to pivotal role in the transmission of intracellular calcium signal actin-myosin interaction. There are some advantages that troponinI I has more specificity and sensibility to AMI then troponin T. The human cTnI has an additional amine and residues on N-terminal that do not exist on the skeletal forms thus making cTnI a specific marker for indicating cardiac infection cTnI is released into blood after the onset of AMI. Its released pattern is similar to CK-MB. Therefore cTnI is a specific marker for diagnosis of AMI, cTnT level may be falsely increased when the specimen is collected from renal failure patient. The Troponin I (TnI) rapid test is a sandwich immunoassay. When sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-cTnI conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-cTnI antibody that is coated on the test region. If cTnI is present at levels of **0,5 ng/mL** or greater, the result is the formation of a colored band in the test region. If there is no cTnI in the sample, the area will remain colorless. The sample continues to move to the control area and forms a pink to purple color, indicating the test is working and the result 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 (cassette format)
- Pipette
- An instruction insert

Materials Required But Not Provided

Specimen collection container Centrifuge (for plasma only); Timer

Storage and Stability

The kit can be stored at room temperature (4-30ºC). 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

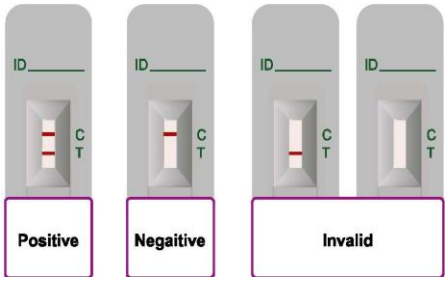
- The Troponin I rapid test can be performed using either serum, plasma or whole blood.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used. Remove the serum or plasma from the clot or red cells, respectively, as soon as possible 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.
- If specimens are to be shipped, they should be packed in compliance with national regulations covering the transportation of etiologic agents.

Test Procedure

Allow the test device, buffer, specimen to equilibrate to room temperature 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 2 drops **(around 80-100 µL)** of sample.
3. Wait for the red line to appear. The result should be read at **15 minutes**. **Do not interpret the result after 20 minutes.**

Interpretation of Results



Positive
Distinct pink colored bands appear at the control and test line regions (C & T).

Negative
Only one pink colored band appears at the control region (C).

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
The Troponin I rapid test, can detect cTnI with concentration of **0.5 ng/mL**.

Accuracy:
One hundred specimens were tested. The Troponin I concentration was determined by Simens system. The test showed more than 99% of the specificity at cTn I negative samples and more than 99% of sensitivity at samples that had Tn I concentration higher than **0,5 ng/mL.**

Table 2. Result analysis of clinical contrast trial

See Now cTnI	Siemens Troponin I		Total
	Positive	Negative	
Positive	42	0	42
Negative	0	58	58
Total	42	58	100

Diagnostic coincidence rate= 42+58/(42+58)×100%=100%

Positive coincidence rate=42/(42+0)×100% =100%

Negative coincidence rate=58/(0+58)×100%=100%

False positive rate=0/(0+58)×100%=0

False negative rate=0/(42+0)×100%=0

Color Intensity related to Reference Concentration

Results	cTnI reference concentration (ng/mL)
++++	> 50
++++	30 – 50
+++	15 – 30
++	5 – 15
+	1 – 5
+	0,5 – 1
-	< 0,5

Interference testing:
The following substances were added to troponin I negative and 0,5 ng/mL troponin I spiked serum samples. No interference was found with any of the substances at the following concentrations

Albumin	10,500 mg/dL
Acetaminophen	20 mg/dL
Acetylsalicylic	20 mg/dL
Bilirubin	10 mg/dL
Caffeine	20 mg/dL
Creatinin	200 mg/dL
Cholesterol	800 mg/dL
Hemoglobin	250 mg/dL
Triglyceride	500 mg/dL

LIMITATIONS
1. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. A negative result obtained from a patient whose sample was taken at 2-16 hours after the onset of chest pain may help in ruling out AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis 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 the cTnI in to the bloodstream.
2 The cTnI rapid test only provides qualitative result. A quantitative assay method must be used to determine the cTnI concentration.
3.As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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