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"See Now" Troponin I test Serum/Plasma/Whole blood

CE

For in vitro Diagnosis Use
Product Code: SN 6.1

Intended Use

The "*See Now*" Troponin 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 Troponinit 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.

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
- Desiccant
- 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 (15-25°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.

Specimen Collection and Preparation

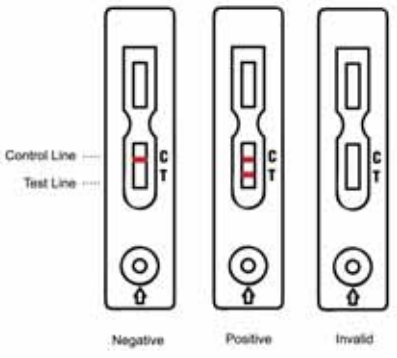
- The "*See Now*" Troponin I Test can be performed using either serum, plasma or whole blood.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used. Remove the serum or plasma from the clot or red cells, respectively, as soon 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 (15-25°C) 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 3 full drops (100 µL) of serum, plasma or whole blood. Avoid air bubbles.
3. Wait for the red line to appear. The result should be read at 15minutes. Do not interpret the result after 30 minutes.

Interpretation of Results



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

Positive
Distinct pink colored bands appear at the control and test line regions.

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

"SeeNow" Troponin I, can detect cTnI with concentration of 0,5 ng/mL or greater.