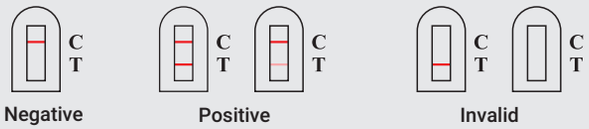

Quality control

- A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
- External controls are not supplied with this kit. 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

Limitations

- This test is for in vitro diagnostic use only.
- This test is designed for the qualitative detection of cTnI (cardiac Troponin I) in whole blood, serum, or plasma. No interpretation should be made regarding the quantitative measurement or the level of cTnI increase based on the intensity of color in the test lines
- A positive test result indicates the presence of cTnI in the sample. It should be interpreted in conjunction with clinical findings, the patient's medical history, and other diagnostic information to accurately diagnose acute myocardial infarction (AMI).
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.2 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of AMI.
- Some specimens containing unusually high levels of heterophile antibodies or rheumatoid factor (RF) may affect the expected results. Therefore, even if the test result is positive, it is important to consider further clinical evaluation in conjunction with other available clinical information.
- In whole blood samples with high viscosity or samples stored for more than one day, it is possible that the sample may not flow properly through the test cassette. In such cases, the test should be repeated using a new cassette and another serum or plasma sample from the same individual.
- High levels of biotin may interfere with the test results.

Performance Evaluation (Sensitivity and Specificity)

The performance of the test was assessed by analyzing 183 clinical samples using the Troponin I Rapid Test kit and and the ELISA method (to determine the precise level of cTnI in the samples).

cTnI Rapid Test (Whole blood/Serum/Plasma)			
Sanje test results	Test results (0.2 ng/ml)		Total
	Negative	Positive	
Positive	1	102	103
Negative	78	2	80
Total	79	104	183
Quality Control			
Sensitivity 98.07%	Specificity 98.7%		Accuracy 98.36%

Limit of detection

Limit of detection (LOD) of the test is 0/2 ng/ml (200 pg/ml).

Limit of detection

To evaluate intra-assay and inter-assay precision, studies were performed by 5 standard control samples, including: 1 negative sample and 4 positive samples (0/5 ng/ml, 1 ng/ml,2 ng/ml, 5 ng/ml of cTnI). Three different lots of the Troponin I Rapid Test were evaluated on three replicates of the above 5 samples, over three consecutive days. The samples were correctly identified in 99% of cases.

Cross-Reactivity and Interference

This test does not cross-react with the following substances:
Skeletal Troponin I (10,000ng/mL), Troponin T (2,000ng/mL), Cardiac Myosin (20,000ng/mL), HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Anti-Syphilis, Anti-Rheumatoid factor, Anti-HIV, Anti-H.pylori, Anti-MONO IgM, Anti-CMV IgG, Anti-Rubella IgG and Anti-Toxoplasmosis IgG

Interfering substances

This test does not interfere with the following drugs:
Acetaminophen: 200 µg/ml, Caffeine: 200 µg/ml, Acetylsalicylic Acid: 200 µg/ml, Gentisic Acid: 200 µg/ml, Ascorbic Acid: 200 µg/ml, Albumin: 10500 mg/dl, Creatin: 200 mg/ml, Hemoglobin 1000 mg/dl, Bilirubin: 1000 mg/dl, Oxalic Acid: 600mg/dL, Cholesterol: 800mg/dL, Triglycerides: 1,600mg/dL

Symbols Guide

Σ	Number of tests per kit	2°C 30°C	Temperature limit
	Do not use if the foil pouch is damaged	IVD	In vitro diagnosis
	Instruction manual	LOT	Lot number
	Single use only	REF	Catalog number
	Factory		Keep away from direct sunlight
	Keep away from moisture		

Contact Information

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Phone: +98 21 88032342 Telegram: +98 9104014711
www.sanjebio.com info@sanjebio.com

Sanje

ISO 13485 ISO 9001

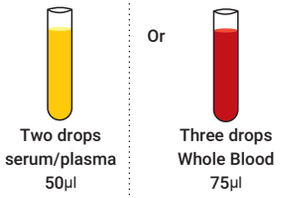
Catalogue Number
C1TR340

Sanje

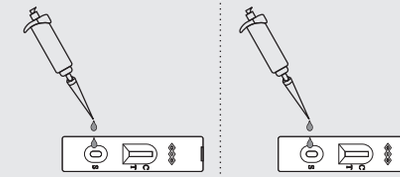
Troponin I Rapid Test (Whole Blood/Serum/Plasma)

Instructions for Use

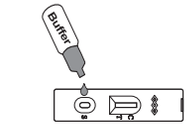
1. Take 2 drops (50µl) of serum/plasma or 3 drops (75µl) of whole blood sample.



2. Transfer sample to the sample well (S Area) of the cassette

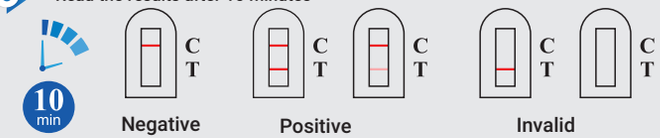


Only for whole blood sample add 1 drop (40µl) of buffer to the sample well.



No buffer

3. Read the results after 10 minutes



Do not interpret the result after 20 minutes.

Rapid Test Device

Troponin I Rapid Test (cTnI) (Whole Blood/Serum/Plasma)

Cut-off: 0/2 ng/ml

Intended Use

The Troponin I Rapid Test is a immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma samples. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

Summary

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. In association with the proteins, Troponin T (TnT) and Troponin C (TnC), cTnI forms a three-subunit complex. This complex, along with tropomyosin, plays a vital role in transmitting contraction signals in skeletal and cardiac muscles. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain and its concentration remains elevated for 6-10 days. Therefore, compared to CK-MB, cTnI provides a longer diagnostic window for detecting MI. Additionally, cTnI levels are very low in the blood of healthy individuals and are not found in patients with skeletal muscle injuries. The high specificity and sensitivity of cTnI for cardiac tissue, make it the preferred marker for diagnosing heart attacks. This test uses a simple and rapid method to evaluate the presence of cTnI levels above normal in whole blood, serum, and plasma samples, and qualitatively identifies positive samples with visible results.

Principle

Troponin I Rapid Test (Whole Blood/Serum/Plasma) is an immunochromatographic test designed for the qualitative detection of Troponin I in a patient's sample. It utilizes a monoclonal antibody specific to Troponin, conjugated to gold nanoparticles on the conjugate pad, and another specific monoclonal antibody on the test line to accurately identify the Troponin I protein.

WARNINGS AND PRECAUTIONS

- Do not use the test after the expiry date.
- Carefully read the instruction manual before use.
- Keep the test cassette in the aluminum pouch until use. Perform the test within one hour after opening; otherwise, it becomes unusable.
- Do not use the test if the aluminum foil pouch is damaged
- Avoid contact of the buffer with skin, eyes, and mouth. In case of contact, rinse thoroughly with water.
- Wear appropriate gloves and a mask while using the kit.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Wash hands before and after after using the kit and do not eat, drink or smoke in the area where the specimens and kits are handled.

Composition

- 40 Test Cassette
- One Disposable dropper contains 2 ml of Buffer
- 1 Instruction Manual

Storage Conditions

- Store the cassette and kit components in their original packaging sealed within an aluminum foil pouch at room temperature (12-30°C).
- Do not refrigerate the kit.
- Do not freeze the test cassette or buffer.
- Prolonged exposure to high temperatures or humidity may degrade the test components.

Sample Collection and Preparation

- The Troponin I Rapid Test can be performed on whole blood, plasma, or serum. Sample collection must be conducted under standard laboratory conditions.
- To prevent hemolysis, separate serum or plasma from blood promptly using centrifugation. Only use clear, non-hemolyzed samples.
- The test should be performed immediately after sample collection, and the sample should not be left at room temperature for an extended period. If necessary, serum and plasma samples can be stored for 3-7 days at 2-8°C and for longer periods at -20°C.
- Whole blood collected from a vein can be stored for up to one day at 2-8°C. Whole blood should not be frozen.
- Samples must reach room temperature before testing. Frozen samples must be completely thawed and mixed. Repeated freezing and thawing of samples is not allowed.
- Laboratory tubes containing EDTA, citrate, or heparin can be used for sample collection following standard laboratory protocols.

Instructions for Use

- The sample, cassette, and kit components should reach room temperature (15-30 °C) before starting the test.
- Remove the test from its sealed pouch, and place it on a clean, level surface. To obtain a best result, the assay should be performed within one hour.
- For serum/plasma sample:

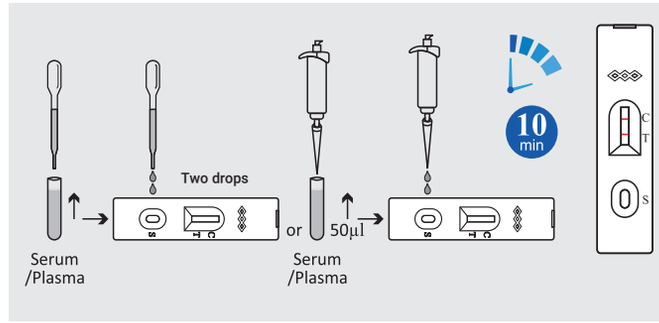
Transfer 2 drops (50µl) of serum or plasma to the sample well (S Area).

- For whole blood sample:

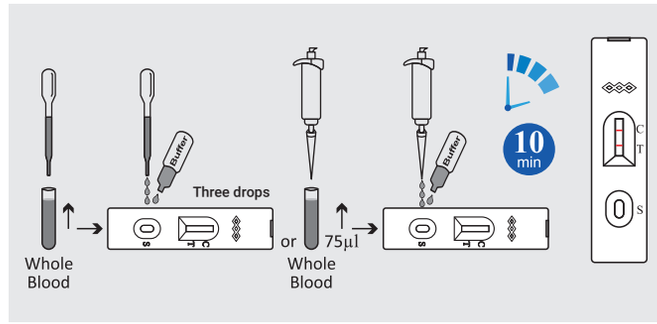
Transfer 3 drops (75µl) of whole blood specimen to the sample well and then add 1 drop (40µl) of buffer (S Area).

- Wait 10 minutes for the colored band(s) to appear. Do not interpret the result after 20 minutes.

Serum / Plasma



Whole blood



Interpretation of Results

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).

Invalid: No colored line appears at the control line (C). This may be due to insufficient sample volume or technical error. Repeat the test using a new kit. If the issue persists, contact the manufacturer.

Rapid Test Device