IVD

Asan Easy Test® Cardiac TnI

ASAN

Point-of-care cardiac test for the qualitative detection of cardiac Troponin I in whole blood, plasma and serum

Immunochromatography

INTENDED USE

For the qualitative detection of cardiac Troponin I (cTnI) in human whole blood, plasma or serum as an aid in the diagnosis of acute myocardial infarction in emergency room, critical care, point-of-care and hospital settings. The Asan Easy Test® Cardiac TnI Test provides a qualitative analytical test result. The qualitative nature of this assay does not provide information about change - either the rise or fall - in the concentration of cardiac troponin I with single testing. A quantitative method should be used, if desired, to quantitate the concentration of cardiac troponin I (cTnI) at any given time. Clinical consideration and professional judgment should be applied when interpreting the results of the Asan Easy Test® Cardiac TnI, especially when a single test result is used.

EXPLANATION OF THE TEST

The Asan Easy Test® Cardiac TnI employs a solid-phase chromatographic immunoassay technology to qualitatively detect the elevation of cardiac troponin I (cTnI) in human blood samples. When a sample of blood is pre-coated into the sample well, red blood cells are removed by the separation filter and the plasma migrates into the test membrane. Cardiac Troponin I present in the sample bind to specific antibody-gold conjugate and migrate through the test area containing immobilized anti-troponin I. The cardiac marker-antibody-gold complexes bind to the corresponding immobilized antibodies. unbound dye complexes migrate out of the Test area and are later captured in the control area.

MATERIALS PROVIDED

Asan Easy Test® Cardiac TnI contains following item to perform the assay.

1. Test device in aluminum pouch with a desiccant.
2. Disposable dropper.
3. Instruction manual for use

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND PREPARATION

1.Specimen Collection and Storage

[Whole blood] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture.

If blood specimens are not immediately tested, they should be refrigerated at 2~8℃ and should be used within 3days or at -20℃ for longer period.

[Serum] Collect the whole blood into the collection tube(NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.

[Plasma] Collect the whole blood into the collection tube(containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

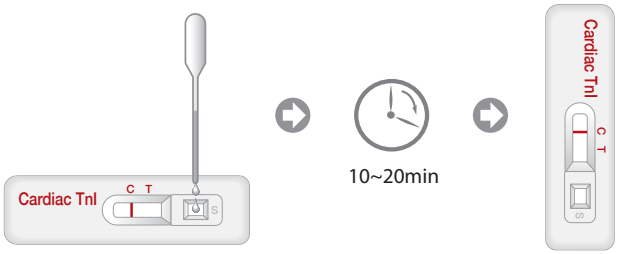
If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8℃ or -20℃ for longer period.

2.Precaution

1) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
2) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
3) Use separately disposable capillay pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
3. Add 3 drops (about 120㎕) of specimens into the sample well(S) of the test device.
4. Interpret test results at 10 minutes. Do not interpret after 20 minutes.



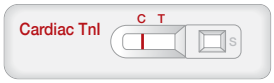
Add 3drops of sample — Reading

INTERPRETATION OF THE TEST

1. A color band will appear in the upper section ("C" zone) of the window to show that the test is working properly. This band is a control band.
2. The down section ("T" zone) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is a test band.

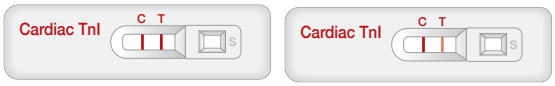
A. NEGATIVE RESULTS:

The presence of only one purple color band ("C" band) within the result window indicates a negative result.



B. POSITIVE RESULTS:

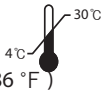
The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result .



C. INVALID RESULTS:

If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

STORAGE & EXPIRATION



1. Asan Easy Test® Cardiac TnI should be store at 4~30℃ (39.2~86 ℉)
2. Expiration date of this kit is 24 months after its manufacture date

PERFORMANCE CHARACTERISTICS

Multi-site studies were performed using a total of 222 specimens. Each specimen was tested with Asan Easy Test® Cardiac TnI and commercial quantitative TroponinI Assay. The results are summarized in the following tables.

n= 222		Commercial quantitative TroponinI Assay		Total
		Positive	Negative	
Asan Easy Test® Cardiac TnI	Positive	105	0	105
	Negative	1	116	117
Total		106	116	222

※ Relative Sensitivity : 99.1%, Relative Specificity : 100%
※ Detection limit : 1.5 ng/ml

LIMITATIONS OF THE TEST

1. The result of the Asan Easy Test® Cardiac TnI is to be used in conjunction with other clinical information such as clinical signs and electrocardiographic test results to diagnose cardiac ischemia. A positive test result from a patient suspected of AMI may be used as an indicator of myocardial damage and requires further confirmation. Sampling of patients suspected of AMI at multiple time points is recommended due to the delay between onset of symptoms and the release of cardiac protein markers into the blood stream.
2. Samples containing unusually high titers of certain antibodies, such as human anti-mouse or human anti-goat antibodies, may affect the performance of the test.

ASAN
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