Troponin- I card

One Step Detection Kit for Cardiac Troponin I

ANGSTROM BIOTECH PVT. LTD

EXPLANATION OF THE TEST

Cardiac Troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kDa. In the heart it forms a protein complex together with Troponin T and C. The troponin complex is broken up following myocardial damage, and the individual protein components are released into the bloodstream. Although Troponin I is also found in skeletal muscles, this form differs from cTnI in its amino acid composition. This distinction allows the two forms of Troponin I to be distinguished immunologically and thereby ensures an accurate test assay. cTnI is released to blood circulation soon after the onset of cardiac damage. Approximately 4 to 6 hours following an acute myocardial infarction (AMI), a detectable level of cTnI can be detected with our immunochromatographic test. While the normal serum level of cTnI is below 0.06ng/ml, levels as high as 100-1300ng/ml in some AMI patients.

PRINCIPLE OF THE TEST

Angcard cTnI rapid test is a colloidal gold/antibody complex based immunoassay designed for the qualitative determination of cTnI in whole blood, serum or plasma samples. To perform the Angcard cTnI rapid test, the specimen is dispensed into the sample well of the cassette. cTnI that is present in the specimen is bound by antibody-gold conjugate forming an antibody-antigen complex. This complex migrates to the test line(T) of the window where it is captured by another anti-cTnI antibody immobilized the membrane, forming a purple-colored line. The rest of the particles migrate to the control line(C) of the window, where dye conjugate is captured by an immobilized antibody, producing a purple-colored control line even in the absence of cTnI. Angcard cTnI rapid test has 0.25ng/ml of the detection limit and it's for professional use as aid on the diagnosis of acute myocardial infarction(AMI). If the specimen contains an elevated level of cTnI, the test line(T) will appear colored. Both the intensity of the test line and the speed of its appearance will increase with an increased concentration of cTnI in the sample. A slightly elevated level of cTnI (0.25ng/ml) gives a marginally detectable test line(T). The higher the cTnI concentration, the more intensive the test line(T) is and the faster it appears.

MATERIALS PROVIDED

Angcard cTnI kit contains the following components:

1. Test device individually & desiccant dropper.
2. Instruction manual for use

PRECAUTIONS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date and do not freeze the kit.
3. For in vitro diagnostic use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the specimens and kits properly after test, in accordance with GLP.

SPECIMEN COLLECTION AND STORAGE

1. Specimen to be tested should be obtained and handled by standard methods for their collections. Since cardiac proteins are relatively unstable, it is recommended that fresh samples be used as soon as possible to collect critical patient information.

A. Serum: allow the blood to clot, then centrifuge to separate the serum.

B. Plasma: collect the whole blood into the tube contained anti-coagulants such as heparin, citrate or EDTA. Centrifuge the blood and separate the plasma.

C. Whole blood: whole blood should be collected over heparin, citrate or EDTA. Mix the blood by inversion and use it to the test.

2. All specimens should be tested as soon early they are prepared. If necessary, they may be stored at 2-8 ℃ for up to 24 hours or at -20℃ for longer periods.

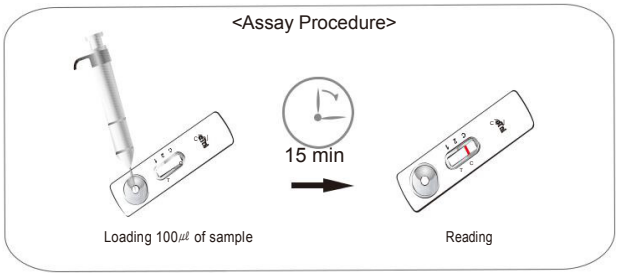
TEST PROCEDURE

Read the instruction for use with care before running a test.

(1) Open the foil pouch and lay the test device on a level surface.
(2) Add 100㎕ of the specimen into the sample well(S).
(3) Read the test result after 15 minutes.

STORAGE & EXPIRATION

1. Angcard cTnI rapid kit should be stored between 4 to 30℃(34 - 86˚F).
2. Expiration date of this kit is 24 months after its manufacture date.

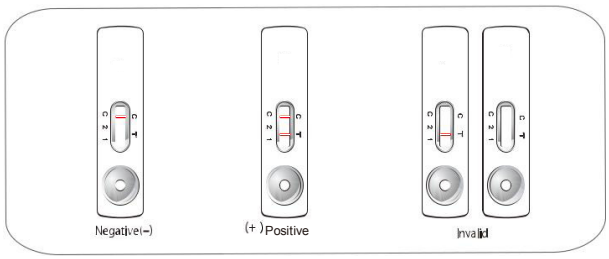


INTERPRETATION OF THE RESULTS

Read the result 15 minutes after application of the specimen. The test line(T) may become more intensive after this time but the risk of a weak false positive result will increase simultaneously. Some samples may be very viscous and in those cases the result can be read when background of the reaction window has cleared up.

1. Negative result (concentration of cTnI is below the cut-off level of Angcard test) is indicated by the presence of a colored control line(C) and the absence of a test line (T). cTnI has not been released into the blood circulation or it is under the detection limit.
2. Positive result (cTnI > 0.25ng/ml) is indicated by a colored test line(T) and a colored control line(C).
3. An invalid test result is indicated by the absence of a control line(C). If no colored control line is formed in the control indicator window, the test device is damaged and so the test result shall be rejected. In such a case repeat the test with a new test unit.

When judging the test result, it is important to remember the intensity of the test line increases with increased concentration on cTnI in the patient's bloodstream. If the result given by the Angcard cTnI rapid test agrees with other diagnostic methods and clinical symptoms, the AMI diagnosis can be considered probable. When the test result is negative or is in conflict with other results, it is imperative to perform a new test approximately one hour later. If the second result is negative and if the last sample was taken more than 6 hours after a suspected AMI case, then the patient has likely not suffered from AMI.



LIMITATIONS OF THE TEST

Angcard cTnI rapid test is designed for primary screening test. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view,

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⚠	Attention,see instructions for use		Consult Instructions For Use
IVD	For in vitro diagnostic use only	REF	Catalog #
4°C~30°C	Store between 4-30°C	LOT	Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by