Cardiac Troponin I Rapid Test

For detection of Cardiac Troponin I in Human Serum, Plasma or Whole Blood.

IVD *In-vitro diagnostic use only* *Not reuse*

Introduction

Troponin, a molecule that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three subunits: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium. Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reach peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

The current guidelines of The Joint European Society of Cardiology/American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

Intended Use

Cardiac Troponin I Fast Test Kit applies colloidal gold immunochromatography to detect cardiac Troponin I (cTnI) in serum, plasma or whole blood samples qualitatively or semi-quantitatively with standard colorimetric card. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction, Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome.

Principle

The test uses a monoclonal anti-human cTnI antibody conjugated with colloidal gold and a monoclonal anti-human cTnI antibody coated on the test line. After the sample (serum, plasma or whole blood) has been applied to the test stripe, the gold-labelled monoclonal anti-human cTnI antibody binds to the cTnI in the sample and a marked antigen-antibody complex forms. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the monoclonal anti-human cTnI antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the cTnI concentration.

Kit Precautions and Storage Instructions

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
9) Store kit at room temperature (2 -30 ^{o}C). Do not expose the kit to temperature over 30 ^{o}C.

Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

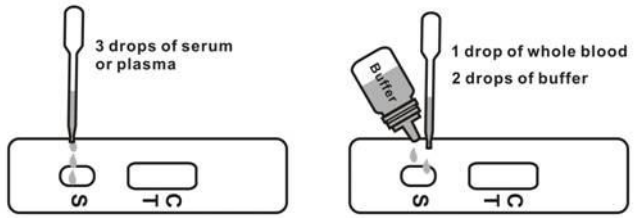
Specimen Collection, Storage and Precautions

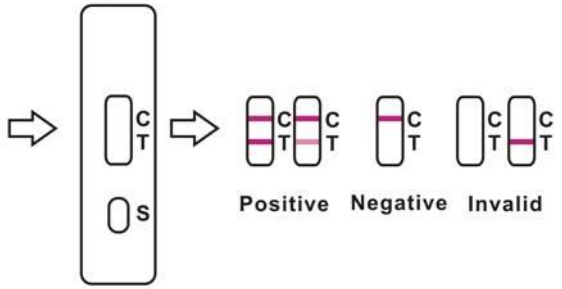
1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant .
2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card. It is suggested that the heparin needs to be used as anticoagulant for the WB sample.
4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8 °C . For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30 °C) prior to use.
5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.
9) Suggest choosing serum or plasma as the test sample. If choose whole blood as the test sample, it should be used together with blood sample diluent.

Test Procedure

1) Allow all test components and specimen to come to room temperature prior to testing
2) Remove the test device from the foil pouch, and place it on a flat, dry surface
3) For serum or plasma specimen: With a micropipette (not provided) or a disposable dropper, add about 100 µL of serum/ plasma specimen into the sample well marked "S".
4) For whole blood specimens: : Hold the dropper vertically and transfer 1 drop of whole blood(approximately 35 µL) to the specimen well (S) of the test device. **Allow about 30 seconds for the specimen to be absorbed totally**. Then add 2 drops of buffer (approximately 70 µl) and start the timer. See illustration below.
5) As the test begins to work, you will see red color move across the result window in the center of the test device.
6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)





Positive (+): Two purplish red streaks appear, one is located on the test line (T), and the other is located on the control line(C).

Negative (-): Only one purplish red streak appears, just located on the control line(C).

Invalid: No purplish red streak appears on the control line (C). This means that some performances must be wrong or the test card has already been invalid. At this situation, please read the manual carefully again, and try again with a new test card. If the same situation happened again, you should stop using this batch of products immediately, and contact your supplier.

Limitations of the Test

The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

Suggested Reading List

1.Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36: 887~893.

2.Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).