HEXAGON TROPONIN

Immunochromatographic 1-Step Test for the Detection of Human Cardiac Troponin I in Serum, Plasma or Whole Blood

Package Size

REF 27032P 20 Tests

IVD

Intended Use

HEXAGON TROPONIN is intended for the rapid, qualitative detection of troponin I (human cardiac troponin I, cTnI) in human serum, EDTA- and Heparin plasma or whole blood as an aid in the specific confirmation of a suspected acute myocardial infarction (AMI) or its diagnosis. This assay is intended for professional use and the analysis should be performed by trained laboratory personnel only.

Test Principle

The test employs a monoclonal anti-cTnI antibody gold conjugate (mouse) in the mobile phase, monoclonal anti-cTnI antibodies (mouse), fixed in the test line, and polyclonal anti-mouse IgG antibodies (goat) in the control line.

As the sample flows through the absorbent pad, human troponin I is bound by the anti-cTnI-gold conjugate to form an immunocomplex, which binds to the anti-cTnI antibodies in the test line and produces a red-violet test line **(T)**. Excess conjugate reacts in the control line with the anti-mouse IgG antibodies, forming a second red-violet line **(C)** to demonstrate the correct function of the reagents.

Clinical Value

Cardiac troponin I (cTnI) is a cardiac muscle protein with molecular weight of 22.5 kilodaltons. cTnI forms a troponin complex with cardiac troponin T(cTnT) and cardiac troponin C(cTnC) in the heart tissue playing a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. cTnI is released into the blood stream after the onset of AMI. cTnI is more specific and sensitive to AMI than cTnT.

Human cTnI has additional amino acid residues on its N-terminal that do not exist on the skeletal forms. cTnI is therefore a specific marker for AMI. Similarly to CK-MB, cTnI is released 4- 6 hours after the onset of AMI. However, CK-MB level returns to normal after 36-48 hours, while level of cTnI remains elevated for up to 6- 10 days. The level of cTnI is very low in normal healthy people and is not detected in patients with skeletal muscle injury. cTnT level may be falsely increased when the specimen is collected from renal failure patient.

Contents

TEST **20 Test devices** with a conjugate of monoclonal anti-cTnI antibodies (mouse) and gold, anti-cTnI (mouse) and anti- mouse IgG antibodies (goat)

PIP **20 disposable dropper pipettes**

Storage and Stability

The test kit is stable up to the given expiration date if stored at 2...25°C. Do not use beyond the expiration date-Do not freeze.

Specimen

Serum, EDTA or Heparin plasma or whole blood.

Whole blood and plasma specimen collection :

Collect whole blood in a tube containing anticoagulant such as heparin or EDTA and centrifuge the blood to obtain plasma. Fresh whole blood without anticoagulant can be used. Use immediately before clotting.

Serum specimen collection :

Collect whole blood in a tube without anticoagulant and allow clotting.

cTnI is relatively unstable, it is recommended to use fresh samples as soon as possible. Whole blood sample should be tested within 3 hours after collection. If specimen must be stored, red blood cells should be removed. Serum samples may be refrigerated for 24 hours at 2...8°C.

If serum or plasma samples must be stored for more than 24 hours, store at -20°C or below.

Heat inactivation of specimens should be avoided to prevent causes hemolysis and protein denaturation.

Each specimen should be handled with care and treated as if potentially infectious.

Procedure

1. Allow specimen and TEST to reach room temperature prior to testing.
2. Remove TEST from its pouch and use it as soon as possible.
3. Label TEST for patient identification.
4. By holding PIP vertically, dispense **3 free falling drops (approximately 100 µl)** of sample into the round **sample** window **(S)** at the lower end of TEST. Always ensure that blood is properly homogenized before you transfer it to the test device.
5. Read results at 15 minutes at a well lit place. To avoid incorrect readings or invalid results, do not read after 15 minutes.

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Interpretation of Results

Negative (Fig. 1)

Only one red-violet Control line **(C)** appears in the upper part of the rectangular result window showing that the test has been carried out correctly.

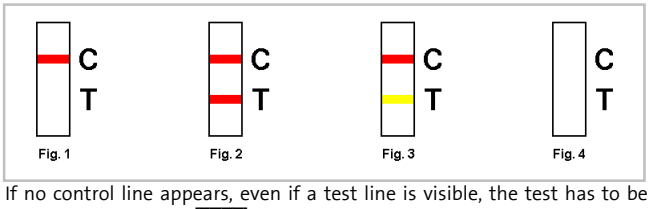
Positive (Fig. 2 and 3)

A second red-violet Test line **(T)** appearing in the lower part of the rectangular result window, indicates a positive result for cardiac Troponin I in the sample.

Even a weak line indicates a positive result (Fig. 3).

Different intensities between Test **(T)** and Control **(C)** lines may occur but are irrelevant for the interpretation of the results.

Invalid (Fig. 4)



If no control line appears, even if a test line is visible, the test has to be repeated with a fresh TEST.

Performance Characteristics

The test detects troponin I with a sensitivity limit of about 0.5 ng/ml.

No cross-reactivity has been observed with other troponins (troponin T, skeletal troponin I).

Typical performance data can be found in the Verification Report, accessible via

www.human.de/data/gb/vr/1c-tropi.pdf or

www.human-de.com/data/gb/vr/1c-tropi.pdf

If the performance data are not accessible via internet, they can be obtained free of charge from your local distributor.

Notes

1. For in vitro diagnostic use only.
2. The test result should be used together with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI.
3. Do not use the test device after expiry date.
4. The test cannot detect less than 0.5 ng/ml troponin I in a specimen. A negative result does not preclude the possibility of myocardial infarction. If AMI is suspected the test should be repeated at appropriate intervals within the first 12 hours after onset of symptoms. Test results must always be evaluated with other data and information available to the physician. Other clinically available tests are required if questionable results are obtained.
5. A negative result obtained from a patient whose sample was taken at 2-16 hours after the onset of chest pain may help in ruling out AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis and requires further confirmation.
6. Specimens with a high rheumatoid factor concentration may yield a nonspecific positive result.
7. Handle all specimens as potentially infectious.
8. All materials contaminated with patient specimens should be inactivated by validated procedures (autoclaving or chemical treatment) according to applicable regulations.

References

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