HCV CARD

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC09

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for detection of Hepatitis C virus in human serum and plasma samples.

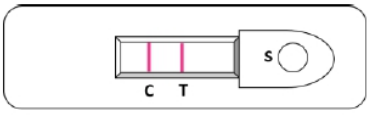
CLINICAL SIGNIFICANCE

Hepatitis C Virus (HCV) is a small, enveloped positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. On the basis of Phylogenetic analysis, HCV has been grouped into six major genotypes each of which contains one or more subtypes.

The first generation HCV antibody test became in early 1990s and was widely used more recombinant antigen. Third generation assays were introduced recombinant NS5 antigen in the late 1990s. The first, second and third generation HCV antibodies assays still lack sensitivity in seroconversion or show inexplicable discrepancies with confirmatory assay. To solve this problem, fourth generation assays using antigen from multiple HCV genotype that includes genotypes 2 & 3 apart from Genotype 1 containing universal conserved epitopes, are been developed ad evaluated.

PRINCIPLE

One step card test for HCV ab. utilizes the principle of immunochromatography. The method uses multiple epitope HCV recombinant peptide conjugated to colloidal gold and immobilized on nitrocellulose strip in thin line.



As the test sample flows through the membrane assembly of the test device, the coloured multiple epitope HCV recombinant peptide gold conjugate complexes with the HCV Ab in the sample. This complex moves further on the membrane to the test region where it is immobilized by a multiple epitope HCV recombinant peptide coated on the membrane leading to formation of a pink-purple coloured band. The formation of first purple band (T zone) confirms a positive test result. Absence of this coloured band in the test region indicates a negative test result. To serve as a procedural control, a coloured line will always appear at the control line region if the test has been performed properly.

KIT COMPONENTS

Test Device, Sample Dropper, Assay Buffer and Instructions for use.

PRECAUTIONS

1. Handle all specimens as if they contain infectious agents.
2. Wear protective disposable gloves when specimens are being tested.
3. Dispose all the samples and kit properly as per the instruction after test in accordance in GLP
4. Read the instructions carefully before performing the test.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Collect whole blood into an appropriate blood collection tube with or without anticoagulant (EDTA, citrate or heparin) for plasma or serum respectively.
2. Separate plasma or serum by centrifugation.
3. Carefully withdraw the plasma or serum, label and store in at 2-8°C for upto two weeks. Those may be stable upto one year, if store at -20 °C.

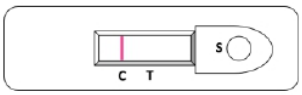
TEST PROCEDURE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Place the test device on a clean and level surface. Add 1 drop (25 µl) of serum or plasma to the sample well "S" of the test device.
2. Add 1 drop of assay buffer in sample well "S".
3. Immediately start the timer.
4. Wait for the coloured line(s) to appear. The test line should be read at 15-20 minutes. It is important that the background is clear before the result is read.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:
Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative



POSITIVE RESULT:
Two distinct purple lines appear. One line should be in the control region (C) and another line should be in the test region (T).

INVALID TEST:
Control line fails to appear. In sufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributors.

LIMITATIONS

1. The One-step HCV test device (Serum/Plasma) is for in vitro use only. The test should be used for the detection of antibodies to HCV in serum or plasma specimen.

2. The One-step HCV test device (Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C Viral infection.

3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

BIBLIOGRAPHY

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3. Van der Poel, C.L., H.T.M. Cuypers, H.W. Reesink, and P.N. Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunobiot assay. Lancet 1991: 337:317

4. Wiber, J.Decelopment and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204.

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

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ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE