HCV CARD

Serum/Plasma

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Ref. RDT-HCC.105, 50 Test

INTENDED USE

HCV Card Test is a rapid Chromatographic Immunoassay for the Qualitative detection of antibodies generated against proteins that are encoded by conserved sequence of core,NS3, NS4, NS5 parts of HCV genome in human serum/plasma.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods failed to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.

PRINCIPLE

HCV Rapid Test (Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HCV antigen (core, NS3, NS4, NS5) on the test region of the device.

During testing, the serum or plasma specimen reacts with the HCV antigen (core, NS3, NS4, NS5) gold conjugate. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a pink-purple line at test region. Presence of this pink-purple line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with the conjugate as a control line.

PRESENTATION

	50 Tests
HCV Test Cards	50 Cards
Assay Buffer	1 Vail

PRECAUTION

- HCV CARD is for in-vitro diagnostic use only.
- Handle all specimens as if they contain infectious agents. After the completion of assay procedure, treat the glasswares with 0.5% to 1% solution of sodium hypochlorite for 1 hour before disposal.
- Avoid any contact between hands and eyes or nose during (specimen) collection and testing.

STORAGE AND STABILITY

HCV test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND STORAGE

HCV CARD TEST is performed on human serum or plasma. It is recommended that the test should be carried out immediately after the collection of blood and separation of serum. Serum specimen can be stored at 2°C-8°C following collection upto 3 days or for longer storage the specimen should be frozen (-20°C).

Specimen containing precipitates, can cause a problem, is well known in chromatography procedures, and hence should be clarified either by centrifugation or by filtration.

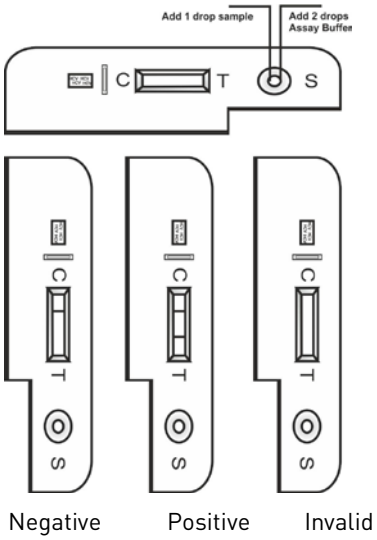
If your card test is showing stagnant flow on chromatography it is most likely due to problem in the sample. Retest with a fresh fasting sample or a diluted sample.

TEST PROCEDURE

1. Bring the test, specimen and /or control to room temperature prior to testing.
2. Remove one test card from the pouch and place it on a clean flat surface.
3. **Using the dropper provided add one drop of serum/plasma sample (Approx. 30µl) then two drops of buffer (Approx. 60µl) immediately into the sample well. Avoid overflowing.**
4. Read results within 15 minutes. Strong positive reaction may visible within 5 minutes. Do not read result after 20 minutes.
5. If negative or questionable results are obtained, and HCV infection is suspected, the test should be repeated on a fresh serum specimen.

INTERPRETATION OF RESULTS

- **Negative:** If a distinct pink-purple line is formed only at the control region marked 'C' (control line) the test result is negative.
- **Positive:** If a distinct pink-purple line is formed at the test region marked 'T' (test line) and the control region marked 'C' (control line) the test result is positive, indicating that the sample contains Hepatitis C Antibody.
  The interpretation of test result (+ve for hepatitis) remains unchanged even if there is a difference in intensity of colour in positive line and control line which is found many times.
- **Invalid:** A total absence of pink-purple line in both regions or no pink-purple line appears on the control (C) region is an indication of procedure error and / or the test reagent deterioration. Repeat the test with a new test cassette.



Negative Positive Invalid

LIMITATIONS

The test will only indicate the presence or absence of Hepatitis C antibody in the specimen and other consideration like clinical symptoms should be noted before making final diagnosis. Additional followup testing, using available clinical methods (along with repeating HCV CARD) is required, if the HCV CARD test is negative with persisting clinical symptoms.

REFERENCES

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