HCV CARD (WB)

(Whole Blood/Serum/Plasma)

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Ref. RDT-HCC.105W, 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 **Whole blood, Serum or 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 fail 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. HCV Card Test is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in whole blood, serum or plasma.

PRINCIPLE

HCV Rapid Test (Whole blood, Serum or 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 line region of the device.

During testing, the 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 bottle

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 & 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 whole blood, serum or plasma.

• Whole blood as specimen

Collect the whole blood in to test tube with anticoagulant; EDTA, heparin or oxalate can be used as a suitable anticoagulant. the specimen should be collected in test tube, if immediate testing is not possible, then the specimen may be stored at 2°C-8ºC for upto 72 hours before testing.

• Serum / plasma as specimen

For Serum, collect blood into a test tube without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing. 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.

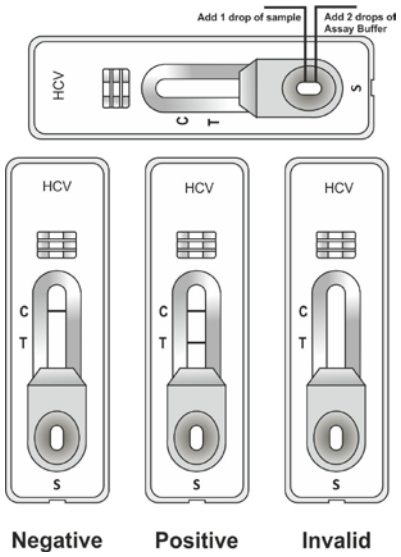
If your card test is *showing stagnant flow on chromatography* it is most likely due to problem in the sample. *Retest with a fresh fasting sample or a diluted sample.*

TEST PROCEDURE

1. Allow 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 one drops of whole blood / serum / plasma sample (about 30µl) then two drop 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 15 minutes.
5. If negative or questionable results are obtained, and HCV infection is suspected, the test should be repeated on a fresh serum specimen.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but such result should be interpreted only after all clinical and laboratory findings have been evaluated.

INTERPRETATION OF RESULTS

- **Negative:** If a distinct pink-purple line is formed only at the control zone marked 'C' (control line) the test result is negative.
- **Positive:** If a distinct pink-purple line is formed at the test zone marked 'T' (test line) and the control zone 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 as is many a time found.
- **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.



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 repeat HCV CARD) is required, if the HCV CARD test is negative with persisting clinical symptoms.

REFERENCES

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