

## 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. HCV Rapid Hepatitis C Virus Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in serum or plasma.

## PRINCIPLE:

HCV Rapid Hepatitis C Virus 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 line 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 colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that the correct volume of specimen has been added and membrane wicking has occurred.

## PRESENTATION:

	25 Tests	50 Tests
Disposable Test Cards	25 Cards	50 Cards
Assay Diluent	1 Bottles	2 Bottles

The shelf life or expiry of the card is printed on the pouch.

## 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 CARD should be stored at 4-30°C. However, the card may be stored at room temperature not exceeding 30°C in the original sealed pouch.

## SAMPLE 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 2-8°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.

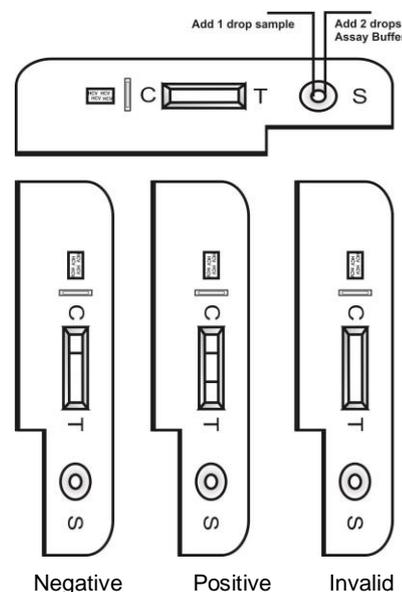
If your card test is showing *stagnant flow on chromatography* it is most likely due to problem in the sample. *Retest with a fresh fasting sample or a diluted sample.*

## 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 (about 30µl) then two drops of buffer (about 80µl) 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:

- **Positive:** If a distinct 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 which is found many times.
- **Negative:** If a distinct purple line is formed only at the control zone marked 'C' (control line) the test result is negative.
- **Invalid:** A total absence of color in both (C) and (T) regions or no colored band appears on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit.



## 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.

## REFERENCE:

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, Non-B viral hepatitis genome. *Science* 1989; 244:359.
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non- A, non-B hepatitis. *Science* 1989; 244:362.
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 immunoblot assay. *Lancet* 1991; 337:317.

