HCV STRIP TEST
(Serum/Plasma)

IMMUNOPAK
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INTENDED USE
The HCV Test Strip (Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- Hepatitis C virus (HCV) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Strip must be confirmed with alternative testing method(s) and clinical findings.

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. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in serum or plasma.

PRINCIPLE
HCV Test Strip (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 strip. 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

	25 Tests	50 Tests
HCV Test Strip	25 Strips	50 Strips
Assay Buffer	1 Bottle	1 Bottle

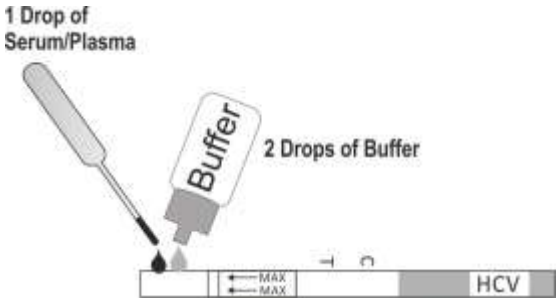
PRECAUTIONS
1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Do not use if the pouch is damaged or broken.
3. Test is for single use only. Do not re-use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Humidity and temperature can adversely affect results.

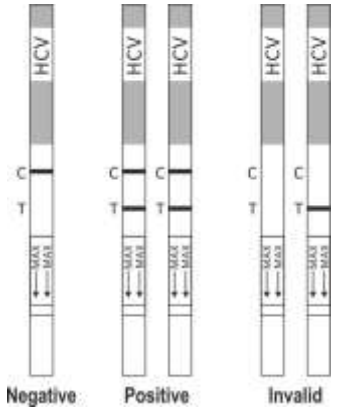
STORAGE AND STABILITY
HCV strip test should be stored at 4-40°C. The strip may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the strip is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND STORAGE
HCV STRIP 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 strip 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 strip, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.
2. Remove the test strip from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test strip on a clean and level surface. Hold the dropper vertically and transfer one drop of serum or plasma (about 30µl) to the sample pad then add two drops (about 75µl) of assay buffer immediately. Avoid air bubbles. See illustration below.
4. Read results in 15 minutes. Do not interpret the result after 20 minutes.

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 strip.





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LIMITATIONS

1. The HCV Test Strip (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HCV in serum or plasma specimen.
2. The HCV Test Strip (Serum/Plasma) will only indicate the presence of antibodies to HCV in 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 considered with other clinical information available to the physician. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
4. A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titre of heterophile antibodies or rheumatoid factor may affect expected results.

REFERRENCES

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