PATHKITS

SIMPLE HCV

Product Code: **PKRK013**
Kit Contents (**25 Kits**)
Shelf Life: **24 Months**

Kit Components	Quantity (Units)
Test Strips	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

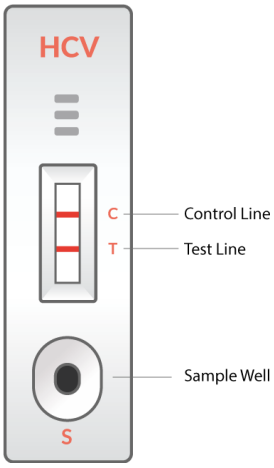
Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope (1). Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first generation HCV ELISA 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 (2). The HCV One Step Rapid Test is a rapid test to qualitatively detect the presence of antibodies to HCV in a serum or plasma specimen. The test utilises a combination of protein A Coated particles and recombinant HCV proteins to selectively detect antibodies to HCV in serum or plasma. The recombinant HCV proteins used in the test are encoded by the genes for both structural (nucleocapsid) and non-structural proteins (NS3, NS4 & NS5) (3).

Intended Use

The HCV One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma.

Test Principle

The Simple HCV Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma specimen reacts with the HCV antigen coated particles. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a coloured line. Presence of this coloured line (T zone) indicates a positive result, while its absence indicates a negative result.



To serve as a procedural control, a coloured line will always appear at the control line region, indicating that the correct volume of specimen has been added and membrane wicking has occurred.

Warnings and Precautions

1. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
2. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
3. Do not use it if the pouch is damaged or broken.
4. Test is for single use only. Do not reuse under any circumstances.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Bring all reagents to room temperature (15-30°C) before use.
7. Do not use the components in any other type of test kit as a substitute for the components in this kit.
8. Do not open the sealed pouch, unless ready to conduct the assay.
9. Do not use expired devices.
10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
12. Handle the negative and positive controls in the same manner as the patient specimens.

M/s PATHKITS HEALTHCARE PRIVATE LIMITED.
4th Floor,28-29, Electronic City, Sector 18, Gurgaon,
Haryana (India) -12001
India Customer care No.: +91-7303429198
Email: info@pathkits.com

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Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

Specimen Collection and Handling

Specimens to be tested should be obtained and handled by standard methods for their collections.

1. **Serum:** Allow the blood to clot, then centrifuge to separate the serum.
2. **Plasma:** Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
4. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Materials Required but not provided

1. Timer or Stopwatch
2. Centrifuge
3. PPE and other consumables for collection and disposal of samples

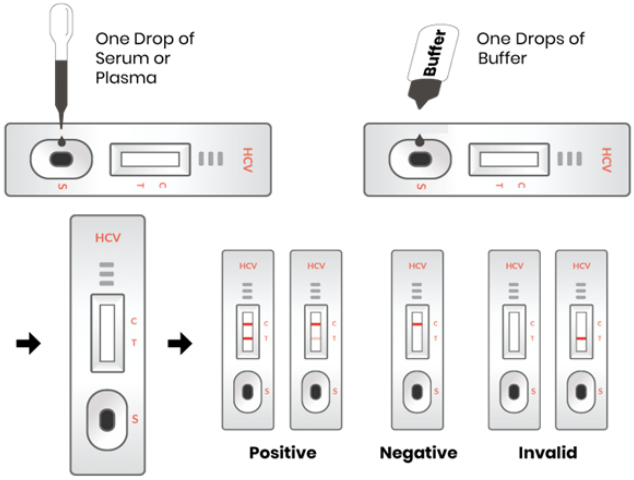
Limitations of Test

1. The Test is for *in vitro* diagnostic use only.
2. The test is an aid to clinical diagnosis of HCV infection.
3. The test result should be interpreted together with all other clinical and laboratory findings by a physician before a definite diagnosis can be reached.
4. This is a screening test, confirmation to be done by other tests like ELISA/ Western blot.
5. In cases where the test result is negative while clinical symptoms persist, further consultation with a physician and additional tests of other methods should be followed.
6. A negative result at any time does not preclude the possibility of HCV infection.

Procedure

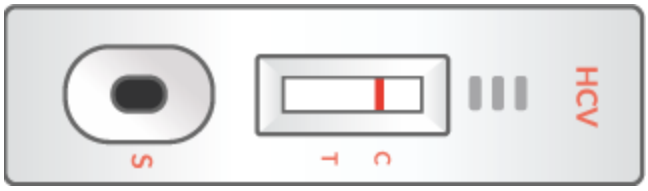
Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it as soon as possible. Place the test on a clean and level surface.
2. With the help of a dropper provided, put 1 drop (approx.25µl) of serum/plasma sample and then add one drop (approx.40µl) of buffer immediately into the sample well. Avoid overflowing.
3. Wait for the colored line to appear. Read results in 15 minutes. Do not interpret the result after 20 minutes.



Interpretation of results

NEGATIVE RESULT: One colored line appears in the control line region(C). No line appears in the test line region (T).



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

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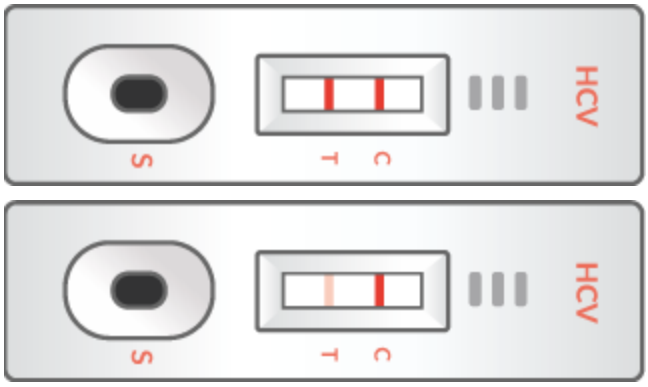
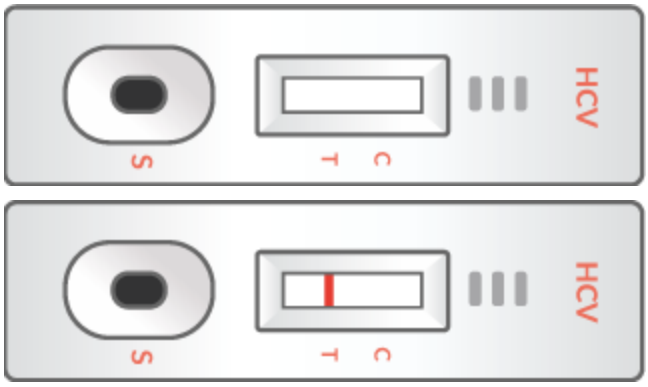


INVALID: If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device.



Quality Control

Internal procedural controls are included in the test. A Colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume.

References

1. Cuthbert, J.A., 1994. Hepatitis C: progress and problems. *Clinical Microbiology Reviews*, *7*(4), pp.505-532.
2. Busch, M.P., Tobler, L., Quan, S., Wilber, J.C., Johnson, P., Polito, A., Steane, E., Zola, A., Bahl, C., Nelles, M. and Lee, S.R., 1993. A pattern of 5-1-1 and c100-3 only on hepatitis C virus (HCV) recombinant immunoblot assay does not reflect HCV infection in blood donors. *Transfusion*, *33*(1), pp.84-88.
3. Badr, R.S., Korah, T.E., Tawfeek, A.R. and Mohamed, K.A., 2016. A study on how patients catch hepatitis C virus. Menoufia Medical Journal, 29(2), p.215.

Technical Assistance

For customer support, please contact our Technical Support:

Pathkits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P),
Gurgaon -122001, India Customer care No.: +91-7303429198
Email: info@pathkits.com

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