ImmunoScience INDIA

ImmunoQuick

HCV Ab

Rapid Test for Detection of Antibodies to HCV - Device/Cassette (From Human Serum / Plasma / Whole Blood)

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

INTENDED USE

"Rapid test for detection of antibodies to HCV - Device/Cassette" is an immunoassay for the rapid and visual detection of antibodies to HCV in human serum/ plasma/whole blood for the diagnosis of Hepatitis C virus infection.

PRINCIPLE

After addition of the serum/plasma/whole Blood and assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant HCV specific antigens and Mouse IgG Antibody. If the sample contains detectable levels of the antibodies against recombinant HCV specific antigens, it reacts with the gold conjugated recombinant HCV specific antigens to form a complex. This complex moves further and reacts with recombinant HCV specific antigens coated as a test line on the nitrocellulose membrane to form colored band. The unbound complex and the Mouse IgG conjugated colloidal gold particles move further to the goat anti-Mouse IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

CONTENTS OF KIT

1. Pouches of Test device With Desiccant
2. Assay Buffer Bottle
3. Plastic Dropper
4. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Stop Watch
2. Sample Container
3. Disposable gloves

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all information in the pack insert carefully before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use expired test, Expiry date is printed on the foil pouch and kit.
3. Store kit in a dry place at temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of reach of children

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose off hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat used samples and tests as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the different specimen samples or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION

1. This test can be performed using serum/plasma/whole blood.
2. Testing should be performed immediately after the Collection of samples. Do not leave the specimen at room temperature for prolonged periods.
3. For whole blood, Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants.
4. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to maximum three days.
5. Do not use hemolyzed, turbid or contaminated samples. Turbid samples should be centrifuged and only clear supernatant must be used for testing.

TEST PROCEDURE

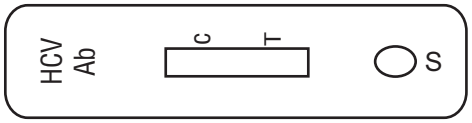
1. Allow the kit components and sample to reach room temperature (20°C to 30°C).
2. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
3. Open the pouch and remove the test device, plastic dropper and desiccant pouch from the pouch. Check the color of desiccant it should be blue, if it has turned colorless or pink, discard the test and use another test.
4. Label the test with patient's identity
5. Place the device on plane surface & add 1 drop (Approx. 30 µl) of serum/plasma or 2 drops of whole blood (Approx. 60 µl) sample in well "S".
6. Immediately dispense one drop (Approx. 30 µl) of assay buffer into well "S", by holding the plastic dropper bottle vertically.
7. Start the timer.
8. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative: If colored line appears at the control region 'C' only

Positive: A distinct colored lines appears at the control region 'C' and at the test region 'T'.

Invalid: The test should be considered invalid if,
A) No line appears at 'C' and 'T' region



B) No line appears at 'C' region and line appear only at 'T' region

NOTE: The intensity of the color in the test line region (T) will vary depending on the levels of antibody in the specimen. However, neither the quantitative value nor the rate of increase in level of antibody in the specimen can be determined by this qualitative test. Positive results may appear as early as five minutes. Negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 247 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 47/47) and the relative specificity was 100 % (i. e. 200/200).

The results are summarized in the following table:

Sample	Total Number of Samples Tested	ImmunoQuick HCV Ab Test Device		Sensitivity (%)	Specificity (%)
		Positive	Negative		
HCV Positive Serum Samples	27	27	0	100	-
HCV Positive Plasma Samples	10	10	0	100	-
HCV Positive Blood Samples	10	10	0	100	-
Negative Human Serum Samples	150	0	150	-	100
Negative Human Plasma Samples	25	0	25	-	100
Negative Human Blood Samples	25	0	25	-	100

Cross reactivity was studied with HIV 1 positive, HIV 2 positive and HBsAg positive samples. No cross reactivity was observed.

External Evaluation:

ImmunoQuick HCV Ab test device were evaluated at NIB (National Institute of Biologicals) Ministry of Health and Family welfare, Government of India. Sensitivity was found 100 % and the specificity was found 100 %.

LIMITATIONS

This test provides presumptive diagnosis of HCV. A confirmed HCV diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. Hence, positive test needs to be confirmed by confirmatory tests.

REFERENCES

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.
4. Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
30°C 4°C	Store at 4°C to 30°C
2	Single Use
Σ	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
i	Read package insert before use

MANUFACTURED BY

ImmunoScience India Private Limited
Gat No. 41, Kusgaon, Shivapur-Velhe Road,
Tal- Bhor, Pune, Maharashtra (India) -412205.