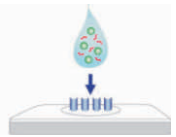
RAPITEST™ HCV

INTRODUCTION:

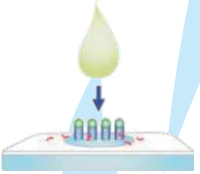
Rapitest™ HCV Test is a direct binding screening test for the detection of antibodies to Hepatitis C viruses, which causes chronic liver diseases. Recombinant HCV [NS3, NS4 & NS5] and structural core protein antigens are employed to identify HCV antibodies specifically. This test is very sensitive and rapid, results are interpreted in less than 5 minutes. Test results are read visually without any instrumentation.

HOW IT WORKS:

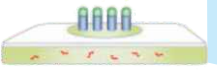


Serum sample is dropped on the surface of the membrane.

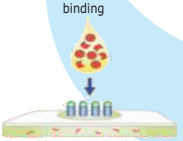
While sample flow through the membrane the analyte is captured on the analyte capture molecule



The membrane is washed to get rid of non specific background binding



Wash buffer flow through the membrane washing away the material that not bound by the analyte capture molecule.



The gold conjugate is dropped on the membrane and it flows through the membrane, the detection molecule binds to the captured molecule and gives visual detection

Wash buffer is added to remove the unbound conjugate and gives the clear visual reaction

PRINCIPLE:

Rapitest™ HCV Flow – Through Test is a membrane based test, which is coated with recombinant antigen [NS3, NS4, NS5 and Core] specific to HCV antibodies at test region "T". The control Region "C" is coated with Protein A. The reaction well is initially washed with a wash buffer in order to make the membrane ready for testing, then the serum / plasma specimen is added. The antigens coated in the membrane captures respective antibodies to HCV in the serum / plasma, if the specimen has antibodies to HCV. The membrane is again washed to remove excess and un-reacted antibodies in the membrane. Prior washing, Protein A conjugated gold reagent is added to visualize the presence of bound antigen & antibody complex. A final wash is done to clear the back ground left with pink dot. dot at test region "T" and control region "C" is a positive result and absence of dot at test region "T" is a negative result. No dot at region "C" indicates the test is "INVALID".

KIT CONTENTS:

Rapitest™ HCV Flow - Through Test is supplied with

1. Rapitest™ HCV Flow Through Test cassettes – pouched with a sample dropper and a silica gel as drying agent.
2. Wash buffer
3. Protein A conjugate
4. Instruction Manual

STORAGE AND STABILITY:

The test kit can be stored at temperatures between 2°C to 8°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION:

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Do not intermix reagents from different lot.
5. Do not change the sequence of addition of reagents.
6. Follow standard guidelines for personal safety , handling and disposal of potentially infectious materials.
7. Do not use Whole blood / turbid serum sample.
8. Do not use the kit if the pouch is damaged or the seal is broken.
9. The instructions should be followed exactly to get accurate results.
10. Do not eat or smoke while handling samples.
11. Do not use hemolysed samples.

YUVRAJ BIOBIZ INCUBATOR INDIA [P] LTD., E4, CMDA INDUSTRIAL ESTATE, MARAIMALAI NAGAR, CHENNAI - 603 209, INDIA EMAIL : info@ybio.in

SPECIMEN COLLECTION & PREPARATION:

Rapitest™ HCV Serum (Flow - Through) Test can be run on serum and plasma samples. The test works best on fresh samples. For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing. For plasma samples, separate the plasma from centrifugation. If the specimen cannot be tested on the day of collection, store the specimen in a refrigerator (at 2 to 4°C) for up to 3 days. If testing cannot be done within 3 days, specimens should be stored in a freezer (at -20°C or colder). Make sure to stir and bring the specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE:

When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test device from the pouch and use it as soon as possible.

1.Add **5** drops of the wash buffer to the reaction well, allow it to be absorbed.

2.Using the disposable dropper provided, add **1 drop (50 µL)** of serum/plasma to the reaction well of the test device, and let it to be absorbed.

3.Add **5** drops of the wash buffer to the reaction well, allow it to be absorbed.

4.Use the Protein-A conjugate dropper bottle provided, add **5** drops into the sample well.

5.Add **5** drops of the wash buffer to the reaction well, allow it to be absorbed.

READ RESULTS IMMEDIATELY
READING TOO LATE CAN GIVE FALSE RESULTS.

INTERPRETATION OF RESULTS:

NEGATIVE :

Only one colored dot appears on the control (C) region. No dot on the test (T) region.

HCV POSITIVE:

In addition to a pink colored control(C) dot, a distinct pink colored dot will also appear in the test region T.

INVALID :

A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. Test dot either dark or light in pink color should be considered reactive .
2. All initially reacted samples should be subjected to centrifugation at 10000 rpm for 10 min. The test should be repeated with supernatant collected after centrifugation. If no dot appears on repetition it indicates a falsely reactive sample. A truly reactive sample will not show much change in its color intensity after centrifugation.
3. The false reactivity of the sample is generally due to the presence of suspended particulate matter in the serum which may or may not be visible to the naked eye.
4. If the sample dose not soak- in 60 seconds, the sample should be observed for any suspended particulate matter. If it present, centrifuge the sample at 10000 rpm for 15 min. Use a fresh device to re- run the test.
5. Sample found to be reactive by the above screening test must be confirmed by standard supplemental assay, like Western Blot.
6. If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of HCV infections.

PERFORMANCE AND CHARACTERISTICS:

In an in-house trial, one thousand and fifty samples were tested in parallel with a licensed commercially available CE Marked Device and Rapitest HCV. The results obtained as follows.

Sample	No. of Samples	CE Marked Device	Rapitest HCV
Negative for HCV antibodies	950	950	950
Positive for Ab. to HCV	100	100	99

Based on this evaluation the sensitivity of RAPITEST HCV is 99% and specificity of Rapitest HCV is 100%

BIBLIOGRAPHY

1. Young Gyu Cho, Min Kyung Yi, Kyung Lib jang, Chang Min Kim and Young Chul Sung: Cloning and Overexpression of the Highly Immunogenic Region of HCV Genome fromKorean Patients. Mol. Cells, Vol. 3, 4-7 - 416
2. S. Osborne, E. Cecconato, S. Griva, F. Garetto, R. Calogero, C. Rosa and F. Bonelli : Expressionin E. coli and purification of a chimeric p22-NS3 recombinant antigen of Hepatitis C Virus (HCV). Federation of European Biochemical Societies, Volume 324, number 3, 253-257
3. A.Yoshikawa, K. Takahashi, S. Kishimoto : Serodiagnosis of hepatitis C virus infection by ELISA for antibodies against the putative core protein (p20C) expressed in Escherichiacoli. Journal of Immunological Methods, 148 (1992) 143-150

IVD

YUVRAJ BIOBIZ INCUBATOR INDIA [P] LTD., E4, CMDA INDUSTRIAL ESTATE, MARAIMALAI NAGAR, CHENNAI - 603 209, INDIA EMAIL : info@ybio.in