Sensit HCV Ab Rapid Test

Cat No.: S026-01

In vitro Diagnostics

INTENDED USE

Sensit HCV Ab Rapid Test Kit is a qualitative immunochromatographic assay for the detection of antibodies against Hepatitis C virus (HCV) in whole blood, Serum or Plasma from Human. Sensit HCV Ab Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA.

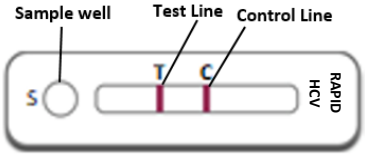
SUMMARY &TEST DESCRIPTION

Hepatitis C virus (HCV) is a small, enveloped, positive sense, single stranded RNA virus. The worldwide prevalence of HCV is 0.2 to 2% on Blood donors and up to 80% in Intravenous drug users. Transmission of HCV is by transfusion and other parenteral means such as sharing of needles, occupational exposure to blood and haemodialysis. Chronic infection can lead to Cirrhosis and hepatocellular carcinoma.

Sensit HCV Ab Rapid Test device contains HCV recombinant antigen as the capture molecule and HCV recombinant antigen colloidal gold conjugate as detection molecule. Sensit HCV Ab Rapid Test captures the antibody developed during the infection. The captured antibody is detected using colloidal gold conjugate.

TEST PRINCIPLE

Sensit HCV Ab Rapid Test works on chromatographic immunoassay. Basic components of test strip include: a) Conjugate pad which includes HCV recombinant antigen, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines T: HCV recombinant antigen and C: Goat Anti Mouse.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where HCV antibodies present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex will bind to the immobilized HCV recombinant antigen (on test line) producing a visible line on the membrane. If the respective antibodies are not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each sealed in a foil pouch containing following items:
   a. One Test card
   b. Dropper
   c. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Do not reuse the test device; each test can be used ONLY SINGLE TIME.
6. Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

Whole Blood:

- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

Serum:

- Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

Note:

- *If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20^{0}C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

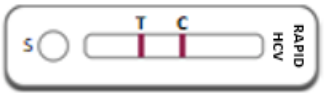
TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 1 drop of specimen without air bubble to the Sample well "S".
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
4. Wait for 10-15 minutes and interpret results. Do not read the result after 15 minutes. All results where control band does not appear are considered invalid.

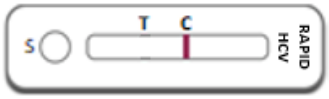
INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS 'C' & 'T' ON THE DEVICE AS SHOWN BELOW.

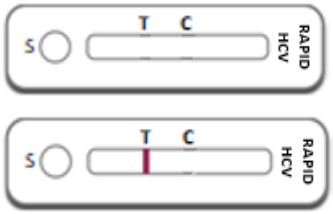
Positive: Color bands at position C and T. HCV Antibody is present in the sample



Negative: Color band at position C. HCV Antibody is not present in the sample



Invalid: Color band at C does not appear



Reference:

1. 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
2. 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 antighen recombinant immunoblot assay.Lanncet 1991; 337: 317

Manufactured by:

ubio Biotechnology Systems Pvt Ltd,
Plot #15A, Biotechnology Zone,
KINFRA Hi-Tech Park,
Kalamassery, Cochin, Kerala, India 683503,
Ph: +91-484-2970043

UBD/QA/IFU/S026-01
Rev. No: A1.1/13.09.2021