Hepatitis C Virus (HCV) antibody Test Cassette (WB/S/P)

Cat. No.: HC V273

INTENDED USE

The Hepatitis C Virus (HCV) Antibody Test Kit is a rapid and convenient immunochromatographic *in vitro* assay for detection of antibodies to Hepatitis C virus in human whole blood, serum or plasma. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Hepatitis C virus (HCV) is a leading cause of hepatitis. The worldwide prevalence of HCV is 0.2% to 2% in 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 cirrhoses and hepatocellular carcinoma. However, chronic infection is often asymptomatic even in the presence of liver damage discernible on biopsy.

The principle of the HCV Antibody Test Kit is a double antigen sandwiched, immunochromatographic assay. The purified HCV recombinant antigens are conjugated to colloidal gold and dry-immobilized on the nitrocellulose membrane. When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate to form antigen-antibody-gold complex if HCV antibody is present in the sample. These complexes will continue to migrate along the strip until the Test Zone (T) of the membrane where they are captured by the HCV antigens to form a visible red line. The un-bound gold conjugate will continue to move to the Control Zone (C) forming a visible red line. To serve as an internal process control, a control band should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Cassette, sample dropper, desiccant
- Sample buffer
- Test instructions

MATERIALS REQUIRED BUT NOT PROVIDED

- Lancet or other blood collection device
- Alcohol swab
- Clock or timer

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not use after the expiration date shown on the pouch.
- Wear gloves while handling specimens. Wash hands thoroughly afterwards.
- Dispose all specimens and used devices in a proper biohazard container.
- Keep out of children's reach.

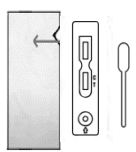
SPECIMEN PREPARATION

- [Whole blood] Collect the whole blood using the suitable anti-coagulant by venipuncture or using a lancet.
- [Serum or plasma] Centrifuge whole blood to get plasma or serum specimen.
- If serum is not tested immediately, it should be refrigerated at 2-8 degrees Centigrade. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.
- Serum containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- The whole blood may be used for testing immediately or may be stored at 2-8 degrees Centigrade up to three days.

TEST PROCEDURES

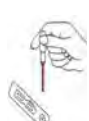
1

Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface.



2

Use the dropper or pipette to withdraw specimen from the specimen collection container and dispense 1 drop (20µl) into the sample well, and then dispense 2 drops (approximately 90µl), sample buffer into the sample well. For each sample or control, use a separate container, dropper or pipette and device.

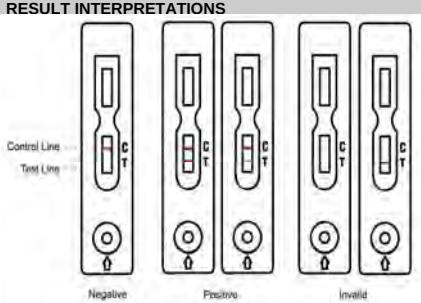


3

Observe the result within 20 minutes. Ensure that the background of the test area is white before interpreting the result.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region.

Positive
A clear pink control band and a detectable test band appear.

Invalid
No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is designed for *in vitro* diagnostic use only.
- There is always a possibility that false results will occur due to factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

MANUFACTURER

ATLAS LINK TECHNOLOGY CO., LTD
Road Xing Min, Guan South Industry Zone, 065500 Langfang City, Hebei Province, CHINA
Web: https://www.invitro-test.com

Revision: 20180525BJ