Hepatitis C Virus Antibody Test

Instructions For Use

Format: Strip
Specimen: Serum/Plasma
Catalog Number: A02-06-213

* Please read the instructions carefully before use

INTENDED USE

Hepatitis C Virus (HCV) Antibody Test is a rapid and convenient immunochromatographic assay for the qualitative detection of antibodies against HCV in human serum or plasma samples. It is intended for professional use as an aid in diagnosis of HCV infection. 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. Hepatitis C virus is a single-stranded RNA virus that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes without prompt medical intervention, including cirrhosis and liver cancer (heptatocellular carcinoma). Diagnosis of HCV infections could be based on serological tests.

Artron Hepatitis C Virus (HCV) Antibody Test is an antibody-capture immunochromatographic assay, detecting the presence of HCV antibodies in either serum or plasma . Specific HCV antigens are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test line of the nitrocellulose membrane. When a serum or plasma sample is added, it rehydrates the gold-antigen conjugate and the HCV antibodies, if present in the sample, interacts with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the test region (T) where they are captured by the immobilized antigens, forming a visible pink line (test line), indicating a positive result). If HCV antibodies are absent in the sample, no pink line will appear in the test region.

To serve as an internal process control, a control line should always appear in the control region (C) after the test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch (contains: test strip and desiccant).
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Glove.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
  Keep out of children's reach.

SPECIMEN PREPARATION

- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

1. Remove the testing device from the foil pouch by tearing at the notch. Hold the strip at the colored end. (Do not touch the arrow end; do not touch the test window, the middle part of the strip)

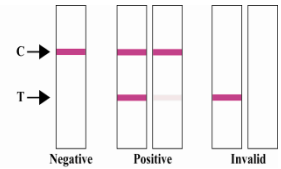
2. Holding the strip vertically, immerse the strip into the specimen with the arrow end pointing towards the specimen. Do not immerse past the MAX line.

3. Take the strip out when the sample has migrated to the test window (about 10 seconds). Lay the strip (MAX side facing up) flat on a clean, dry, non- absorbent surface.

4. Read the result in 10 minutes, following instructions under the “Results Interpretation” section
NOTE: Specimens with high concentrations of HCV antibodies may produce positive results in as little as 1 minute. Confirm negatives in 20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS



Negative
A pink colored line appears only in the control region (C), indicating a negative result for HCV infections.

Positive
A clear pink control line (C) and a detectable test line (T) appear, indicating a positive result for HCV infections.

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

QUALITY CONTROL

Although the testing device contains an internal control (pink colored line in the control region), good laboratory practice recommends the 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 should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting HCV infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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 CONTACT INFORMATION

Artron Laboratories Inc.
3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

Ph: 604.415.9757
Fax: 604.415.9795
www.artronlab.com
info@artronlab.com

EC REP

Wellkang Ltd
Suite B
29 Harley Street LONDON,
W1G 9QR
United Kingdom