HAV CARD (Hepatitis A Virus Antibody Test)

IMMUNOPAK

(Serum/Plasma)

Last update 10-2020

Ref. RDT-HAV.112, 10 Test

INTENDED USE

The HAV Rapid Test kit is a Chromatographic immunoassay (CIA) for direct qualitative detection of antibodies to Hepatitis A type virus (HAV) in human serum/ plasma.

PRINCIPLE

HAV is a chromatographic immunoassay (CIA) for the detection of antibodies to HAV in human serum/plasma. Mouse anti human-IgM μ strands are precoated onto membrane as a capture reagent on the test region. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with HAV recombinant antigens. If antibodies to HAV are present, a pink colored band will develop on the membrane in proportion to the amount of HAV antibodies present in the specimen. Absence of this pink colored band in the test region suggests a negative result. To serve as a procedural control, a pink colored band in the control region will always appear regardless the presence of antibodies to HAV.

PRESENTATION:

	10 Tests
HAV Test Card	10 Cards
Assay buffer	1 Bottle

The shelf life or expiry of the card is printed on the pouch.

PRECAUTION

- For in vitro diagnostic uses only.
- All patient samples should be treated as if capable of transmitting diseases.
- Do not interchange reagents from different lots. Do not use test kit beyond expiration date.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

STORAGE & STABILITY

Store HAV Rapid Test at temperature ranges 2°C-40°C in the sealed pouch. Refer to the expiration date for stability. Do not freeze.

SAMPLE COLLECTION AND STORAGE

Plasma

- Have a certified phlebotomist collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by veinpuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma for testing, or label and store it at 2°C-8°C for up to two weeks. Plasma may be frozen at -20°C for up to one year.

Serum

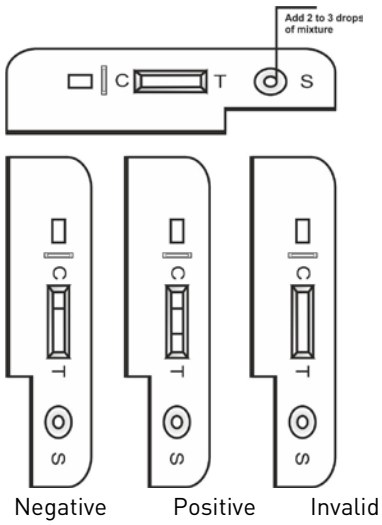
- Have a certified phlebotomist collect whole blood into a red top collection tube (containing no anticoagulants) by veinpuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum for testing or label and store it at 2°C-8°C for up to two weeks. Serum may be frozen at -20°C for up to one year.

TEST PROCEDURE

- Using a micropipette, pipette out 5μl of the specimen and dispense into a test tube. Then pipette out 250μl of the assay buffer and dispense to the test tube (1:50 dilution). Mix well. This is the test specimen.
- Remove the test cassette from pouch by tearing.
- Holding the sample dropper vertically, add 50-80μl or 2-3 drops of mixture into sample well.
- Observe the result in 20 minutes.

INTERPRETATION OF RESULTS

- **Negative:** No apparent band in the test region (T), a pink-colored band appears in the control region (C). This indicates that no HAV antibody has been detected.
- **Positive:** In addition to a pink-colored band in the control region (C), a pink-colored band will appear in the test region (T). This indicates that the specimen contains HAV antibodies.
- **Invalid:** If no band appears in the control region (C), regardless of the presence or absence of line in the test region (T). It indicates a possible error in performing the test. The test should be repeated using a new device.



LIMITATIONS

- The test is to be used for the qualitative detection of antibodies to HAV.
- A negative result does not rule out infection by HAV because the antibodies to HAV may be absent or may not be present in sufficient quantity to be detected at early stage of infection.

REFERENCE

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.

Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91-265-2281631
Email: mail@reckondiagnostics.com
An ISO 13485:2016 Certified Company

RECKON DIAGNOSTICS P. LTD.
THE TEST OF CONFIDENCE - SINCE 1989