

# Hepatitis E Virus Antibody Test

**IMMUNOPAK**

## INTENDED USE:-

The HEV Gold Rapid Screen Test (RST) is a Chromatographic immunoassay (CIA) for direct qualitative detection of antibodies to Hepatitis E type virus (HEV) in human serum/ plasma.

## PRINCIPLE:

HEV RST is a chromatographic immunoassay (CIA) for the detection of antibodies to HEV in human serum/plasma. Mouse anti human-IgM  $\mu$  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 HEV recombinant antigens. If antibodies to HEV are present, a pink colored band will develop on the membrane in proportion to the amount of HEV 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 HEV.

## PRESENTATION:

	25 Tests	50 Tests
Disposable Test Cards	25 Cards	50 Cards
Assay Diluent	1 Bottles	1 Bottles

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 HEV Rapid Screen Test at temperature ranges 4-30 °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 2-8°C for up to two weeks. Plasma may be frozen at -20°C for up to one year.

### Serum

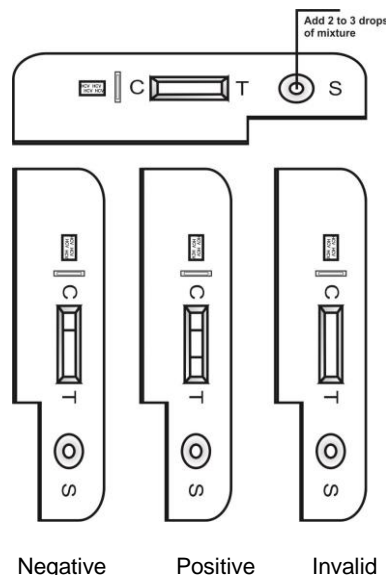
- Have a certified phlebotomist collect whole blood into a red top collection tube (containing no anticoagulants) by veinpuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum for testing or label and store it at 2-8°C for up to two weeks. Serum may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

## TEST PROCEDURE:

- Using a micropipette, pipette out 3 $\mu$ l of the specimen and dispense into a test tube. Then pipette out 150 $\mu$ l 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.
- Add 50-80 $\mu$ l 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 HEV 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 HEV 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 HEV.
- A negative result does not rule out infection by HEV because the antibodies to HEV 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.

