Assay+ Hepatitis B Virus Surface Antigen Rapid Test User Instruction

REF Catalog No. HBV-Test (Cassette)

IVD In Vitro Diagnostic

Intended Use

Hepatitis B Surface Antigen (HBsAg) Test is a rapid and convenient immunochromatographic assay for the qualitative detection of HBsAg in human serum or plasma at or above the concentration of 1 ng/ml. It is intended for professional use as an aid in the diagnosis of Hepatitis B virus (HBV) 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 B virus (HBV) is partially double-stranded DNA that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids or blood, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes, including cirrhosis and liver cancer (hepatocellular carcinoma). The virus is divided into four major serotypes (adr, adw, ayr, ayw) based on antigenic epitopes presented on its envelope proteins.

Hepatitis B surface antigen (HBsAg) is the first marker to appear in the blood in acute hepatitis B, being detected 1 week to 2 months after exposure and 2 weeks to 2 months before the onset of symptoms. Three weeks after the onset of acute hepatitis almost half of all patients will still test positive for HBsAg. In the chronic carrier state, the HBsAg virus persists for long periods with no seroconversion to the corresponding antibodies. The most commonly used diagnostic and blood screening markers sought is HBsAg. An individual positive for HBsAg is considered to be infected with HBV and is therefore potentially infectious.

One Step HBsAg test is an antigen-capture immunochromatographic assay, detecting the presence of HBsAg in blood samples. Monoclonal antibodies specifically against HBsAg are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test line on the nitrocellulose membrane. When the blood sample is added, it rehydrates the gold-antibody conjugate and the HBsAg, if any in the sample, interacts with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antibodies, forming a visible pink line (Test band, indicates positive results). If HBsAg is absent in the sample, no pink line will appear in the Test Zone (T).

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

This HBsAg Test detects HBsAg for major serotypes (adr, adw, ayr and ayw) at concentrations of 1.0 ng/ml or greater.

Package Contents

Each box contains 25 test devices
Each pouch has a desiccant and test strip

Material Required But Not Provided

1. Gloves
2. Timer or clock

Storage

Store kit at 15-30ºC (59-86°F). Kit contents are stable for 2 years or until the expiration date printed on the label, whichever comes first. Exposing the kit to the temperatures over 30ºC (86°F) may reduce the shelf life or damage the device.

Warning And Pprecautions

- 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 or 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 of time.
- 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 have reached room temperature prior to testing.

Test Procedures

1. To begin testing, open the sealed pouch by tearing along the notch. Remove the cassette from the pouch and use it as soon as possible.
2. Add 30-40ul serum/plasma to the well over the test card using included pipette.
3. Follow adding sample, add two drops assay buffer from the dropper bottle.
4. Results are then read 15 to 30 minutes, make sure control line is always positive.

NOTE: Specimens with high concentrations of HBsAg may produce positive results in as little time as 1 minute.

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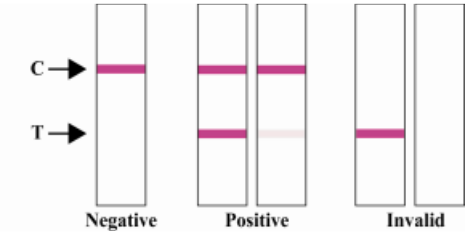
Confirm negatives in 20 minutes**. DO NOT INTERPRET RESULTS AFTER 30 MINUTES.**

Result Interpretations

Negative
A pink colored line appears only at the control region (C), indicating a negative result for HBV infection.

Positive
A distinct pink control line (C) and a detectable test line (T) appears, indicating a positive result for HBV infection.

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



Quality Control

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

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.
● 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 HBsAg, a low incidence of false results may still occur. Therefore, other clinically available tests should also be done 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.

Inquires And General Information

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