HBsAg Rapid Test Kit

INTENDED USE

The Hepatitis B Surface Antigen (HBsAg) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B antigen in blood serum or plasma to aid in the diagnosis of Hepatitis B virus.

INTRODUCTION

Hepatitis is a viral disease that primarily infects the liver. It is categorized into three types, Hepatitis A, Hepatitis B, and Hepatitis C. Hepatitis B is caused by the hepatitis B virus, leading to short-term or chronic illness. A complex antigen found on the surface of the Hepatitis B Virus (HBV) known as HBsAg is detected for the diagnosis of the disease. Presence of the surface antigen is indicative of either short-term or chronic Hepatitis B infection. HBsAg is typically found in HBV infections two to four weeks before unusual transaminase levels and three to five weeks before the onset of symptoms or jaundice. The four main subtypes of HBsAg are adw, adr, ayw, and ayr. Ten main serotypes of HBV exist because of the antigenic variability of the viral determinant. The CDC released guidelines for hepatitis B testing and screening in March 2023, suggesting screening for the hepatitis B virus (HBV) for all adults, as well as risk-based and repeat testing for specific groups. A three-test panel consisting of the hepatitis B surface antigen (HBsAg), antibody to hepatitis B surface antigen (anti-HBs), and total antibody to hepatitis B core antigen (anti-HBc) should be used for testing.
All pregnant people are recommended to have a history of HBV screening, preferably in the first trimester, regardless of their prior vaccination status or screening records.

PRINCIPLE

The Hepatitis B Surface Antigen (HBsAg) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B antigen in blood serum or plasma to aid in the diagnosis of Hepatitis B virus. This test procedure is bases on the principle of double antibody-sandwich technique. After a Whole Blood/Serum/ Plasma specimen is placed in the specimen well, if HBsAg is present in sample, it reacts to the labelled HBsAb antibody-dye conjugate. If the specimen contains dengue virus NS1 antigen, a colored line will appear in the test line region indicating a positive result. The pre-coated HBsAb then binds the immune complex on the membrane, and a visible colorful line appears in the test line region, signifying a positive result. A colored line signifying a negative result won't form in the test line region if HBsAg isn't present. A colorful line that indicates appropriate specimen volume addition and membrane wicking will always show at the control line region, acting as a procedural control.

MATERIALS AND METHOD

1. Individual sealed pouches, each pouch contains:
    a. 1×Test Card
    b. 1×Desiccant Pouch
2. Extraction kit
3. Sampling Tubes

STORAGE AND STABILITY

- Keep the test kit between (4 - 30°C) in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for the use.

SPECIMEN COLLECTION

1. The Hepatitis B surface antigen test can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolyzed specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20 °C.
5. Bring specimens to room temperature prior to testing.
6. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow the test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.
3. For the serum or plasma specimen: Hold the dropper vertically and add three drops (about 100µl) to the test device's specimen well (S). Then, set the timer.
4. For whole blood specimens: Hold the dropper vertically and transfer 1 drop of whole blood (approx. 35 µL) to the specimen area, then add 2 drops of buffer (approx. 70 µL), and start the timer.
5. Wait for the colored line(s) to appear. Read the results in 10 minutes. Do not interpret the result after 20 minutes.

RESULT:

1. Two Pink Lines - (POSITIVE)
2. One Pink Line at (C) - (NEGATIVE)
3. No Pink Line - (INVALID)

LIMITATIONS

1. Only a qualitative detection can be made with the HBsAg Rapid Test. There is no assurance that the blood levels of HBsAg and test line intensity are correlated.
2. To ensure an appropriate diagnosis, the test results, like any other diagnostic technique, should be analysed in conjunction with the patient's clinical findings, medical history, and results from additional diagnostic procedures.
3. It's possible that this test won't reveal the HBV serotype that's infected.