Instructions for HBsAg Serum/Plasma Test Cassette (Colloidal Gold)

[Product Name]
HBsAg Serum/Plasma Test Cassette (Colloidal Gold)

[Intended Use]
The HBsAg Serum/Plasma Test is a lateral flow chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum or plasma at a level equal to or higher than 1 ng/mL. It is intended to be used as a screening test and as an aid in the diagnosis of infection with hepatitis B virus (HBV). Any reactive specimen with the HBsAg Serum/Plasma Test must be confirmed with alternative testing method(s) and clinical findings.

[Principle]
The HBsAg Serum/Plasma Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-HBsAg antibody conjugated with colloidal gold (HBsAg Ab conjugates) and a control antibody conjugated with colloidal gold, and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with non-conjugated HBsAg antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. HBsAg, if present in the specimen, will bind to the HBsAg Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated non-conjugated HBsAg antibody forming a burgundy colored T line, indicating a HBsAg positive test result. Absence of the T line suggests a negative result.

The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies, regardless of color any color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

[Storage and Stability]
Store at 4 to 30 ℃in a dry place and avoid direct sunlight. Do not freeze. It is valid for 24 months from date of manufacturing.

[Specimen Requirements]
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma
1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into a new pre-labeled tube.

Serum
1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C if not tested immediately. Specimens can be stored at 2-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

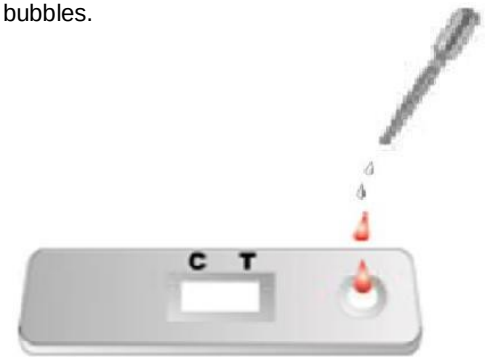
Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

[Assay Procedure]
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2 drops (about 60-90 µL) of specimen into the sample well making sure that there are no air bubbles.



Step 5: Set up timer.
Step 6: Read the test result within 15 minutes. Positive results could be visible in as soon as 1 minute.

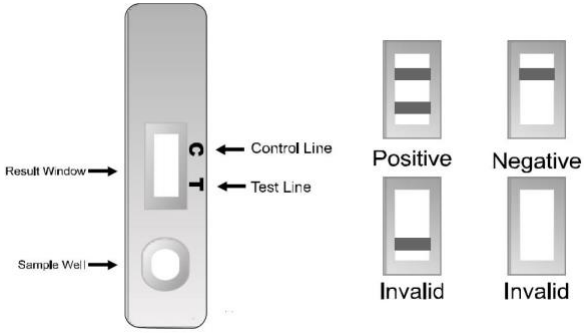
Do not read the result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

[Interpretation of Results]

1. **NEGATIVE RESULT:** If only the C line is developed, the test indicates that the level of HBsAg in the specimen is undetectable (lower than 1 ng/mL). The result is negative or non-reactive.

2. **POSITIVE RESULT:** If both the C and the T lines are developed, the test indicates that the specimen contains HBsAg at a level equal to or higher than 1 ng/mL. The result is positive or reactive.
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



[Limitations]

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of HBsAg in serum or plasma from individual subjects. Failure to follow the procedure may lead to inaccurate results.
2. HBsAg Serum/Plasma Test is limited to the qualitative detection of HBsAg in human serum or plasma. The intensity of the test line does not have a linear correlation with the HBsAg titer in the specimen.
3. A non-reactive test result does not preclude the possibility of exposure to or infection with HBV.
4. A non-reactive result can occur if the quantity of HBsAg present in the specimen is below the detection limits of the assay (lower than 1 ng/ml) or the HBsAg that is detected was not present during the stage of disease in which a sample is collected.
5. If the symptoms persist when the result from HBsAg Serum/Plasma Test is non-reactive, it is recommended to re-sample the patient a few days later or to test with an alternative test method.
6. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

[References]

1. Emanuel Rubin and John Farber. The liver and biliary system. Acute viral hepatitis P 721-729. Rubin E, Farber JL ed. Pathology 2nd ed. 1994. J.B. Lippincott, Philadelphia.
2. Kaplan PM, Greenman RL, Gerin JL, Purcell RH, Robinson WS. DNA polymerase associated with human hepatitis B antigen. J Virol. 1973 12(5):995-1005.
3. Dane DS, Cameron CH, Briggs M. Virus-like particles in serum of patients with Australia-antigen-associated hepatitis. Lancet. 1970;1(7649):695-8.
4. Magnius LO, Espmark A. A new antigen complex co-occurring with Australia antigen. Acta Pathol Microbiol Scand [B] Microbiol Immunol. 1972;80(2):335-7.

[Manufacturer]

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