HBsAg cassette

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<td>4255240</td>
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For professional in vitro diagnostic use only

HBsAg
A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in serum or plasma.

ONE STEP

PRINCIPLE

The LINEAR HBsAg Cassette Test is a rapid one step membrane-based immunodiagnostic assay designed for qualitative determination of hepatitis B surface antigen (HBsAg) in human serum. The assay can detect the concentration of HBsAg in serum as low as 2 ng/ml in 30 minutes without the use of any equipment.

Hepatitis B virus (HBV) is the prototypic member of the hepadnaviruses. In the lipid envelope of this small DNA virus the hepatitis B surface antigen (HBsAg) is located. During the replicative phase of the virus this surface antigen is produced in excess and detectable in the blood of infected person. So the detection of Hepatitis B Antigen (HBsAg) is an indication of an existing acute or chronic Hepatitis B infection.

It can be used to (a) monitor the prognosis of patients recovering from the hepatitis B viral infection, (b) indicate the patient that have prior immunological exposure to Hepatitis B surface antigen.

In addition Anti-HBsAb (Hepatitis B surface antibody) determination is a sign for healing or for a successful vaccination against Hepatitis B virus (HBV). The LINEAR HBsAb rapid test can delivered on demand. The incubation period of HBV is 6 weeks to 6 months.

The LINEAR Hepatitis B Antigen (HBsAg) Cassette Test is an immunoassay enhanced with red particles for the determination of human HBV surface antigen (HBsAg) in serum.

The membrane was precoated with goat anti HBsAg antibody in the test region. During the test, the sample is allowed to react with a red particles labelled second HBsAg antibody. This mixture moves upward on the membrane by capillary action. For a positive result, the complex composed of HBsAg of the sample and red particles labelled second HBsAg antibody binds to the membrane immobilized HBsAg antibody and a red colored line appears at the test region (T). Absence of this colored line in the test region suggests a negative result. To serve as procedural control, a colored line at the control region (C) always appears in the test area.

SPECIMEN COLLECTION AND PREPARATION

- Serum is obtained following regular clinical procedure.
- If the specimen is not tested the same day as collected, it should be stored refrigerated.
- If storage periods greater than 3 days, serum should be frozen. It should be avoided to thaw and refreeze specimens.
- Samples that have been stored over a longer period or had been frozen should be mixed before use.

MATERIAL REQUIRED
- Timer.
- Specimen collection container.
- Centrifuge and pipettes.

PROCEDURE

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

1. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 drops of sample (approx. 120 μL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.

3. Wait for the red line(s) to appear. Depending on the concentration of HBsAg, positive results may be observed in as short as 60 seconds. However, to confirm negative results, the complete reaction time, 30 minutes, is required.

PACKAGING CONTENTS

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<tr>
<td>4255240</td>
<td>HBsAg test device</td>
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<tr>
<td></td>
<td>Disposable specimen droppers</td>
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STORAGE AND STABILITY

Store at 2-30°C.

The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A red test result line in the T region indicates that sample contains hepatitis B surface antigen (HBsAg). The appearance of a line in the test result line region (T) indicates that no hepatitis B surface antigen (HBsAg) are detected.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). The absence of a line in the test result line region (T) indicates that no hepatitis B surface antigen (HBsAg) are detected.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL
A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control (containing 10 ng/mL HBsAg) and a negative control (containing 0 ng/mL HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

CLINICAL SIGNIFICANCE
Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen.

LINEAR HBsAg is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma. See: Limitations of the procedure.

ANALYTICAL PERFORMANCE
Sensitivity
The LINEAR Hepatitis B Antigen (HBsAg) Cassette Test detects HBsAg concentration greater than 2 ng/mL (including any subtypes) in human serum by the development of a colored line in the test region of the test device.

Specificity
The LINEAR Hepatitis B Antigen (HBsAg) Cassette Test uses an antibody that is highly specific for Hepatitis B Antigen (HBsAg) in serum. A result of 99.5% concordance to ELISA test was determined by a clinical study of 1208 samples.

LIMITATIONS OF THE PROCEDURE
1. LINEAR HbsAg is a screening test, for professional in vitro diagnostic use only. This screening test should be used for the detection of HBsAg in serum or plasma specimen. Neither the quantitative value nor the rate of HBsAg concentration can be determined by this qualitative test.
2. LINEAR HBsAg will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. LINEAR HBsAg cannot detect less than 1 ng/mL of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

WARNING AND PRECAUTIONS
• Do not open the sealed pouch, unless ready to start the test procedure, because the test is humidity-sensitive.
• Do not smoke or eat where antigen containing materials is being handled.
• Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards.
• Decontaminate and dispose specimens and all potentially contaminated materials as if they contain infectious agent.
• 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 physici an after all clinical and laboratory findings have been evaluated.

REFERENCES