**INTRODUCTION**

CORE-HBsAg is a one step, rapid, self performing, qualitative, two site sandwich immunoassay for the determination of the Hepatitis B surface antigen infection, in serum/plasma specimens.

**SUMMARY**

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B Surface Antigen (HBsAg), earlier known as Australia Antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter.

Detection of HBV using HBsAg as the marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infections.

CORE- HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml within 15 minutes.

**PRINCIPLE**

CORE- HBsAg one step test for HBsAg utilizes the principle of Immunochromatography, a unique two site immunoassay on a membrane. As the test sample flows through the membrane assembly within the test device, the colored anti-HBsAg-colloidal gold conjugate complexes with HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-HBsAg coated on the membrane leading to formation of a pink colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-mouse antibodies coated on the membrane at the control region, forming a pink colored band. This control band serves to validate the test results.

**REAGENT AND MATERIALS SUPPLIED**

Each individual pouch contains:
1. Test Device: Comprising of membrane assembly predispensed with anti HBsAg antiserum and anti-mouse antiserum coated at the respective regions.
2. Disposable Plastic Dropper.
3. Desiccant Pouch.

**SPECIMEN COLLECTION AND PREPARATION**

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma is preferable, serum/plasma specimen may be stored at 2-8°C to up to 24 hours in case of delay in testing. Do not use haemolysed specimen.

**TESTING PROCEDURE AND INTERPRETATION OF RESULTS**

1. Bring the sealed pouch to room temperature, open the pouch and remove the device. Once opened, the device must be used immediately.
2. Dispense two drops of serum/plasma specimen into the sample well ‘S’ using the dropper provided. Refrigerated specimens must be brought to room temperature prior to testing.
3. At the end of fifteen minutes, read the results as follows:

   **Negative**: Only one colored band appears on the controls region “C”.

   **Positive**: In addition to the control band, a distinct colored band also appears on the test region “T”.

4. The test should be considered invalid if neither the test band nor the control band appear. Repeat the test with a new device.
5. Although, depending on the concentration of HBsAg in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.

![Testing Procedure Diagram](image-url)
LIMITATIONS OF THE TEST
1. Presence of elevated levels of other antigens such as RF and cross reacting auto antibodies such as antibodies to HLA DR4 may yield false positive results. This may occur in less than 1% of the specimens. For confirmation of results, a confirmatory test must be used.
2. This test detects the presence of HBsAg in the specimen and hence should not be used as the sole criterion for the diagnosis of Hepatitis infection.
3. As with all diagnostic tests, the result must be correlated with clinical finds.

STORAGE AND STABILITY:
The sealed pouches in the test kit may be stored between 4-30°C for the duration of the shelf life as indicated on the pouch.

NOTE
1. For in vitro diagnostic use only.
2. NOT FOR MEDICINAL USE
3. Do not use beyond expire date.
4. Read the instructions carefully before performing the test.
5. Handle all specimens as potentially infectious.
6. Follow standard biosafety guidelines for handling and disposable of potentially infective material.

PERFORMANCE CHARACTERISTICS
In an in-house study, the performance of CORE-HBsAg, one step test for HBsAg was evaluated using a panel of 250 samples of positive (of varying reactivity) and negative sera in comparison with two commercially available ELISA kits. The results of evaluation are as follows:

<table>
<thead>
<tr>
<th></th>
<th>Core-HBsAg</th>
<th>ELISA I</th>
<th>ELISA II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Samples Tested.</td>
<td>250</td>
<td>250</td>
<td>250</td>
</tr>
<tr>
<td>Number of Positive results.</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Number of Negative result.</td>
<td>200</td>
<td>200</td>
<td>200</td>
</tr>
</tbody>
</table>

In another independent study, the performance of CORE-HBsAg, one step test for HBsAg was evaluated using a panel of 50 samples (20 positive samples and 30 negative samples) in comparison with another rapid immunochromatography method (IC) as well as Enzyme Immunoassay (EIA) and a Microparticle Enzyme Immunoassay (MEIA). From the above studies, CORE-HBsAg, one step test for HBsAg correlated very well with HBsAg ELISA in terms of sensitivity, specificity and accuracy. CORE-HBsAg, one step test for HBsAg showed positive results with serum/plasma samples having HBsAg concentrations under 0.5ng/ml and above from a HBsAg low titre performance panel (PHA 104) of Boston Biomedica Inc., USA.

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