HBsAg
Hepatitis B Surface Antigen Test Device (Serum/Plasma)

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

INTENDED USE
The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in serum or plasma.

SUMMARY
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.

SPECIMEN COLLECTION AND PREPARATION

Materials Provided
- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided
- Specimen collection containers
- Centrifuge
- Timer

DIRECTIONS FOR USE

1. Bring the pouch to room temperature before opening it. 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 full drops of serum or plasma (approx. 100μl) to the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 15 minutes. Note: A low HBsAg concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.
**INTERPRETATION OF RESULTS**
*(Please refer to the illustration above)*

**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).

**NEGATIVE:** One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

**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**

**Internal Quality Control**
A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**External Quality Control**
It is recommended that a positive and negative external control be run every 20 tests, and as deemed necessary by internal laboratory procedures. Some commercial controls may contain interfering preservatives; therefore, interpretation of results with external quality controls should be done with caution.

**Procedure for External Quality Control Testing**
1. Hold the Control vial vertically and add 2 full drops of Control to the Specimen well (S) as in procedure Step 2.
2. Continue with Step 3 of Directions For Use. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

**LIMITATION**
1. The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of HBsAg in serum or plasma specimen.
2. The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) 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. The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) 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.

**EXPECTED VALUES**
The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is over 98%.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity**
The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma).

**Specificity**
Antibodies used for the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

**HBsAg Reference Method**

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<thead>
<tr>
<th>Method</th>
<th>Results</th>
<th>Positive</th>
<th>Negative</th>
<th>Total Results</th>
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<tbody>
<tr>
<td>HBsAg Test Device</td>
<td>Results</td>
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<tr>
<td>Positive</td>
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<tr>
<td>Total Results</td>
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<td>155</td>
<td></td>
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</table>

Relative Sensitivity: > 99.0%
Relative Specificity: 96.7%
Accuracy: 98.3%

**Intra-Assay**
Within-run precision has been determined by using 15 replicates of three specimens containing 0 ng/mL, 1 ng/mL and 5 ng/mL of HBsAg. The negative and positive values were correctly identified 98% of the time.

**Inter-Assay**
Between-run precision has been determined by using the same three specimens of 0 ng/mL, 1 ng/mL and 5 ng/mL of HBsAg in 15 independent assays. Three different lots of the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 98% of the time.

**BIBLIOGRAPHY**

**ORDERING INFORMATION**

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<th>CATALOG NO.</th>
<th>QUANTITY</th>
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<tr>
<td>1160 002</td>
<td>50 test</td>
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E-mail: info@spectrum-diagnostics.com
Tel: +2 02 4665 1848 - Fax: +2 02 4665 1847
Obour city industrial area. block 2008 piece 19 A. Cairo, Egypt.
www.spectrum-diagnostics.com

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