**HBsAg Rapid Test Cassette**

(Serum/Plasma)

**Package Insert**

**INTENDED USE**

The HBsAg Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) 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. 1 The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adr, ayr, adw and ayw. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

The HBsAg Rapid Test Cassette 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.

**PRECAUTIONS**

The HBsAg Rapid Test Cassette is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**EXPECTED VALUES**

The HBsAg Rapid Test Cassette has been compared with a leading commercial HBsAg ELSA test. The correlation between these two systems is over 99%.

**PERFORMANCE CHARACTERISTICS**

<table>
<thead>
<tr>
<th>Method</th>
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</tr>
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<tbody>
<tr>
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<td>Results</td>
</tr>
<tr>
<td>Positive</td>
<td>200</td>
</tr>
<tr>
<td>Negative</td>
<td>350</td>
</tr>
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Relative Sensitivity: >99.9% (95% CI: 98.3%-100%)
Relative Specificity: 99.5% (95% CI: 98.4%-100%)

**QUALITY CONTROL**

A procedural control is included in the test. A colored 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 10ng/mL HBsAg) and a negative control (containing 0ng/mL HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS**

1. The HBsAg Rapid Test Cassette is for professional in vitro diagnostic use only. The 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. The HBsAg Rapid Test Cassette 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 virus infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. The HBsAg Rapid Test Cassette cannot detect less than 1 PEI 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.

**PRECAUTIONS**

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 2000ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg Rapid Test Cassette (Serum/Plasma). The test can detect 1 PEI ng/mL of HBsAg in serum/plasma.

**SPECIFICITY**

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

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