First Response® HBsAg Card Test
Rapid HBsAg Card test

One-Step Hepatitis B Card Test
Detection of Hepatitis B Surface Antigen in Human Serum or Plasma

Intended Use
The First Response® HBsAg card test is an In vitro, qualitative, one - step immune - chromatographic assay for the detection of Hepatitis B virus Surface Antigen in serum or plasma.

Summary and Principle of Procedure
Viral Hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis seen in children and adults are caused by Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV). Hepatitis B Virus was discovered by Blumberg, et al. A complex antigen known as the Hepatitis B Surface Antigen (HBsAg) found on the surface of HBV is the first to be detected. The presence of HBsAg in a serum sample is indicative of an active HBV infection, either acute or chronic. In a typical HBV infection, HBsAg will be detected 2 to 4 weeks before the transaminase level becomes abnormal and 3 to 5 weeks before the patient develops symptoms or becomes jaundiced. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the viral determinant, there are 10 major serotypes of HBV.

The First Response® HBsAg card test uses solid phase immunochromatographic technology for the qualitative detection of HBsAg in serum or plasma. The test is a two-site immunometric assay in which a combination of monoclonal and polyclonal antibodies is used to selectively detect HBsAg in serum or plasma with a high degree of sensitivity. Each device has a Reading Window with an upper Control area and a lower Test area, and a sample well. In the test procedure, 2 drops (25 ul each) of serum or plasma sample is added to the sample well (S). The test device is stable at room temperature before opening the foil pouch. Perform the test immediately after removing the Test Device from the foil pouch. Do not use it beyond the expiration.

Storage and Stability
The First Response® HBsAg card test kit should be stored at 4-30°C (39-86°F) in the sealed pouch. The storage conditions and stability dating given were established under normal laboratory conditions.

Specimen Collection and Storage
• The First Response® HBsAg card test can be performed on serum or plasma only. Sodium citrate, heparin or EDTA may be used as an anticoagulant. Use of other anticoagulants has not been established.
Remove the serum or plasma from the clot of Red Blood Cells (RBC) as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens should be used. Specimens containing any particulate matter may give inconsistent test results. Such specimens should be clarified by centrifugation before testing. Testing should be performed as soon as possible after sample collection. Do not leave samples at room temperatures for prolonged periods.
• If specimens are to be stored, they should be refrigerated at 2-8°C or frozen. For prolonged storage, samples should be frozen and stored below - 20°C. Specimens should not be repeatedly frozen or thawed.
• Bring specimens to room temperature prior to testing. The frozen specimens must be completely thawed, thoroughly mixed and brought to room temperature prior to testing.
• If specimens are to be shipped, they should be packed in compliance with Federal regulations covering the transportation of etiologic agents.

History
First Response® HBsAg Card Test was discovered by Blumberg, et al. A complex antigen known as the Hepatitis B Surface Antigen (HBsAg) found on the surface of HBV is the first to be detected. The presence of HBsAg in a serum sample is indicative of an active HBV infection, either acute or chronic. In a typical HBV infection, HBsAg will be detected 2 to 4 weeks before the transaminase level becomes abnormal and 3 to 5 weeks before the patient develops symptoms or becomes jaundiced. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the viral determinant, there are 10 major serotypes of HBV.

Materials Provided
1) First Response® HBsAg Card Test Device with dropper.
2) Instructions for use.

Precautions
• For In vitro diagnostic use only.

Warning
1) For In vitro diagnostic use only.
2) Do not eat or smoke while handling specimens.
3) Wear protective gloves while handling specimens, Wash hands thoroughly afterwards.
4) Avoid splashing or aerosol formation.
5) Clean up spills thoroughly using an appropriate disinfectant.
6) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a bio-hazardous waste container.
7) Do not use the test kit if the pouch is damaged or the seal is broken.
8) Procedure

1) Slowly add 2-3 drops (25ul each) of serum or plasma in the sample well (S).
2) As the test begins to work, you will see purple colour move across the Result Window in the center of the Test Device.
3) Interpret test results at 5-10 minutes.

5) Do not interpret after 10 minutes.

Interpretation of the test
1) A colour band will appear at section ‘C’ of the Result Window to show that the test is working properly. This band is the Control Band.
2) The test results appear in the section ‘T’ of the Result Window.

Caution: The above interpreting time is based on reading the test results at room temperature of 15-30°C, if the room temperature is significantly lower than 15°C, then the interpreting time should be increased appropriately.
Negative result
The presence of only one band within the result window at the control line 'C' region indicates a negative result.

Positive result
Two coloured lines, one at the control window 'C' and one at the test window 'T' indicate that antibodies against Hepatitis B virus have been detected.

Invalid
A distinctive coloured line at the control window 'C' should always appear. The test is invalid and should be repeated if no line forms at the control window 'C'.

Limitations and Interferences
The assay must be performed in strict accordance with these instructions to obtain accurate, reproducible results. The First Response® HBsAg card test is for In vitro diagnostic use only. This test is designed for use with serum or plasma samples only. Use of other body fluids, including whole blood, urine, or saliva, has not been established. This test will indicate only the presence or absence of HBsAg in the specimen, and should not be used as the only basis for the diagnosis of hepatitis viral infection. As with all diagnostic tests, results must be considered with other clinical information available to the physician.

First Response® HBsAg card test cannot detect extremely low concentrations of HBsAg in specimens. If the test result is negative and clinical First Response HBsAg symptoms persist, additional follow-up testing using other clinical methods is required. A negative result at any point does not preclude the possibility of Hepatitis B infection.

User Quality Control
A Quality control check should be made before using a new kit of First Response HBsAg card test using commercially available control sera. A quality control test using positive and negative control standards should be performed as part of good testing practice and to confirm the expected Q.C. results. The positive control will yield a moderate positive result. The negative control will yield a negative result (control line only). Upon confirmation of the expected results, the kit is ready for use with patient specimens. For information about the commercial controls and other assistance, contact PMC technical services.

A coloured line in the control window 'C' can be considered an internal procedural control. If the test has been performed correctly and the device is working properly, a distinct coloured line will always appear. If a test result is not clear, a new test should be performed. If the problem persists, contact PMC technical services.

Performance Characteristics
Card test detects all 10 major sero types of HBV. Cross reactivity with Hepatitis A & Hepatitis C viruses was not observed up to 0.5 ng/ml.

A multi-site studies were performed using a total of 200 patients including 98 hepatitis B virus infection patients. Each specimen was tested with the First Response® HBsAg test and a commercially available test (ELISA). The results obtained agreed 100% with the expected results. The results obtained agreed 100% with the expected results.

Expected Values
First Response® HBsAg Card test can detect HBsAg levels of 5 ng/ml in serum in 5 minutes. Levels as low as 0.5 - 1 ng/ml were visible in 10 minutes.

First Response® HBsAg card test using commercially available control sera. A quality control test using positive and negative control standards should be performed as part of good testing practice and to confirm the expected Q.C. results. The positive control will yield a moderate positive result. The negative control will yield a negative result (control line only). Upon confirmation of the expected results, the kit is ready for use with patient specimens. For information about the commercial controls and other assistance, contact PMC technical services.

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Commercially available enzyme immunoassays (EIA) and radioimmuno-assays (RIA) are most commonly used to detect HBsAg. The correlation between these two systems is generally 99%. HBsAg levels below 5 ng/ml, and as low as 0.5-1 ng/ml, need to be detected for best clinical utility.

Proficiency Evaluation
An Intra - laboratory reproducibility study or test proficiency evaluation was performed using 3 lots of devices at 3 locations for a total of 90 tests. At each location, 5 positive and 5 negative samples were used for testing of the 3 lots. The results obtained at each site agreed 100% with the expected results. An intra assay study was conducted using 3 lots in 3 - day testing for both negative and positive results. The results obtained agreed 100% with the expected results.

References

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ISO 9001-2008 Certified Company
ISO 13485 - 2003 Certified Company
Rev. B 05/11/2007
Note: Instructions for Use will be printed in local language of the Country using the Test, if required.