HBsAg

One step Hepatitis B Surface Antigen Test Cassette (Serum/Plasma)

IVD For *in-vitro* diagnostic and professional use only

2 ~ 30°C **Store at 2-30°C**

INTENDED USE

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

INTRODUCTION

Hepatitis is inflammation of the liver tissue . The most common cause worldwide is viruses. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. Hepatitis B is transmitted through contact with infectious body fluids, such as blood, vaginal secretions, or semen, containing the hepatitis B virus (HBV). Injection drug use, having sex with an infected partner, or sharing razors with an infected person increase your risk of getting hepatitis B. Hepatitis B surface antigens can be found in your blood within several weeks (2 to 4 weeks) after the infection starts. They are one of the earliest signs of a hepatitis B infection. The presence of HBsAg in (S/P) is an indication of an active Hepatitis B infection, either acute or chronic. HBsAg has four principal subtypes: adw, ayw, adr and ayr. 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.

PRINCIPLE

HBsAg One Step Hepatitis B Surface Antigen Test Cassette (Serum/Plasma) is a qualitative, lateral flow 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 test. During the test, the serum or plasma on the sample (S) 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. If the present antibodies in specimen, forming a colored line, indicating a positive test result. Absence of any T line indicates a negative result. A colored control line (C) should always appear in case of a positive or a negative result. Its absence indicates invalid test results.

MATERIALS

MATERIALS PROVIDED

- Test Cassette (Contain anti-HBsAg coated on the membrane).
- Plastic dropper.
- Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container.
- Centrifuge (for plasma only)
- Timer.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- This package insert must be read completely before performing the test. Failure to follow directions in the package insert may give rise to inaccurate test results.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Never smoke, drink, or eat in the assay laboratory.
- The test cassette should remain in the sealed pouch until use.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after performing the test.
- Handle specimens as though they contain infectious agents.
- Do not use buffers and test cassettes from different lots interchangeably.
- Used tests, specimens and potentially contaminated materials should be discarded off according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not use the test if printing is unclear and/or expiry date is missing.
- Please ensure that precise amount of sample is used to avoid incorrect results.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Cassette is stable through the expiration dated printed on the sealed pouch.
- The test Cassette must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Don't use beyond the expiration date.

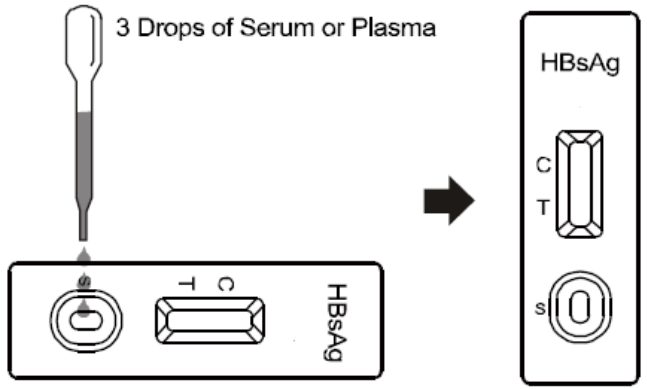
SPECIMEN COLLECTION AND PREPARATION

- HBsAg One Step Hepatitis B Surface Antigen Test cassette (Serum/Plasma) can be performed using either serum or plasma.
- Only clear, non-hemolyzed specimens can be used. Separate the serum or plasma from blood as soon as possible to avoid haemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept at below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in transportation of etiologic agents.

PROCEDURE

Allow to the test cassette, serum or plasma specimens, and/or controls to equilibrate at room temperature (15-30°C) prior for testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Transfer **3 drops of serum or plasma (approximately 120 µL)** to the specimen well of test device and start the timer. See illustration below.
3. Wait for the colored line to appear. Read the result at **15 minutes**, if the result was negative wait and read again at **30 minutes.** Do not read the result after **30 minutes.**



INTERPRETATION OF RESULTS

POSITIVE:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

Positive

NOTE:

The intensity of the red color in the test line region will vary depending on the concentration of HBsAg present in the specimen. Therefore, any shade of red in the test region should be considered positive.

NEGATIVE:

Only one colored band appears in the control region (C), and no band appears in the test region (T).

Negative

INVALID:

No band appears in the control region (C), whether a test band(s) is present or not. 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Invalid

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms adequate membrane wicking.
- 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.

LIMITATION

- The HBsAg One Step Hepatitis B Surface Antigen Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of HBsAg in serum or plasma specimen.
- The HBsAg One Step Hepatitis B Surface Antigen test Cassette (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.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- The HBsAg One Step hepatitis B Surface Antigen Test Cassette (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.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HBsAg Rapid Test Cassette (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 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.

	HBsAg Rapid Test			
ELISA		Positive	Negative	Total
	Positive	241	2	243
	Negative	0	359	359
	Total	241	361	602

Relative Sensitivity: >99.9% (95%CI:* 98.8%-100.0%).
Relative Specificity: 99.4% (95%CI:*98%-100%).
Accuracy 99.7% (95%CI:* 98.8%-100%)
***95% Confidence Interval**

Precision

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 >99% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of 0 ng/mL, ng/mL and 5 ng/mL of HBsAg in 15 independent assays. Three different lots of Atlas HBsAg Rapid Test Device (serum/ plasma) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross Reactivity

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering substances

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed. In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

REFERENCES

- Blumberg, B.S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7:223
- World Health Organization. (2003). *Report of a collaborative study to 1) assess the suitability of a candidate replacement International Standard for HBsAg and a reference panel for HBsAg and 2) to calibrate the candidate standard in IU*. WHO Working Group on Hepatitis and HIV Diagnostic Kits. [WHO/BS/03.1987]. https://www.who.int/biologicals/publications/meetings/areas/vaccines/hepatitis/BS03.1987.pdf

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry