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

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

Store at 2-30 ºC

INTENDED USE

Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood/serum/plasma) is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in whole blood , serum and 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 (WB/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 Bvirus.

Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device is a rapid test to qualitatively detect the presence of HBsAg in Whole Blood/serum/plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum and plasma.

PRINCIPLE

Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in whole blood/serum /plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the Device. During testing, the 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.

MATERIALS

Materials Provided

- Test device (contain anti-HBsAg particles and anti- HBsAg coated on themembrane).
- Disposable specimendroppers.
- Package insert.
- Buffer (for whole bloodonly).

Materials Required But Not Provided

- Specimen collectioncontainers.
- Lancets (for finger stick whole blood).
- Timer.
- Centrifuge.
- Disposable heparinized capillary tubes and dispensing bulb (for finger stick whole blood only).

Packaging Contents

REF **8.16.24.0.0001 (1 Test Cassette, Buffer)**

REF **8.16.24.0.0020 (20 Test Cassette, 1x3ml Buffer)**

REF **8.16.24.0.0025 (25 Test Cassette, 1x3ml Buffer)**

REF **8.16.24.0.0030 (30 Test Cassette, 1x3ml Buffer)**

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits arehandled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens aree being tested.
- Humidity and temperature can adversely affect results.

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.

SPECIMEN COLLECTION AND PREPARATION

- Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood/serum/plasma) can be performed using whole blood (from venipuncture or fingerstick).
- To collect Fingerstick Whole Blood specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingersitck Whole Blood specimen to the test device by using a capillarytube:
- Touch the end of the capillary tube to the blood until filled to approximately 100 µL. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.
- Add the Fingersitck Whole Blood specimen to the test device by using hanging drop:
- Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
- Allow 2 hanging drop of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 compliance with federal regulations covering the transportation of etiologicagents.

PROCEDURE

Allow to the test device, specimen, buffer, and/or controls to equilibrate at room temperature (15-30°C) prior for testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

For Serum or Plasma specimen:

Hold the dropper vertically and transfer **3 drops of serum or plasma (approximately 75 µl)** to the specimen well of test Cassette and start the timer. See illustration below.

For Venipuncture Whole Blood specimen:

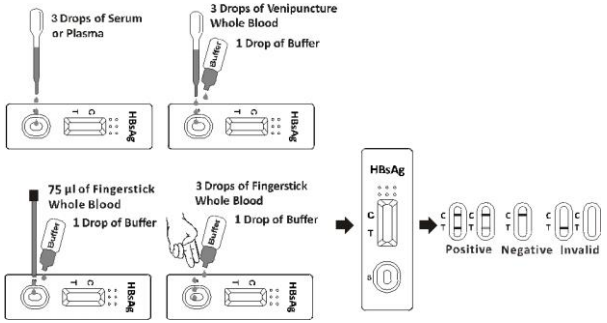
Hold the dropper vertically and transfer **3 drops of whole blood (approximately 75 µl)** to the specimen area, then add **1 drop of buffer (approximately 40 µl)**, and start the timer. See illustration below.

For Fingerstick Whole Blood specimen:

To use a capillary tube: Fill the capillary tube and transfer **approximately 75 µl** of fingerstick whole blood specimen to the specimen area of test cassette, then add **1 drop of buffer (approximately 40 µl)** and start the timer. See illustration below.

- To use hanging drops: Allow **3 hanging drops of fingerstick whole blood specimen (approximately 75 µl)** to fall into the specimen area of test cassette, then add **1 drop of buffer (approximately 40 µl**) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read results at 15 ~30 minutes**. Do not interpret the result after 30 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE

Two distinct colored lines appear.
One line should be in the control region (C) and another line should be in the test region (T).

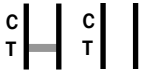
NOTE:

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

NEGATIVE

One colored line appears in the control region (C). No apparent colored 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

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 control (containing 0 ng/mL HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

EXPECTED VALUES

Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is over 99%.

LIMITATION

- Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) is for *in vitro* diagnostic use only. The test should be used for the detection of HBsAg in whole blood, specimen. Neither the quantitative value nor the rate of HBsAg concentration can be determined by this qualitative test.
- Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) 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.
- Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) 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

Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) was tested against a sensitivity panel including both ad and ay subtypes with concentrations ranging from 0 to 300ng/mL. All
10 HBsAg subtypes produced positive results on Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood). The test can detect 1 ng/mL of HBsAg in whole blood in 15 minutes.

Specificity

Antibodies used for Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results

Method		EIA		Total Results
HBsAg Test Device	Results	Positive	Negative	
	Positive	180	1	181
	Negative	0	200	200
Total Results		180	201	381

Relative Sensitivity: >99.9%(95% CI:*98.3%-100%)

Relative Specificity: 99.5%(95% CI:*97.3%-99.9%)

Accuracy:99.7%(95% CI:*98.5%-99.9%)

**** 95% Confidence Interval***

Precision

1. Intra-Assay:
   Within-run precision has been determined by using 10 replicates of six specimens containing 0 ng/mL, 1 ng/mL, 2 ng/mL 5 ng/mL and 12 ng/mL, 20 ng/mL of HBsAg. The negative and positive values were correctly identified > 99% of the time.
2. Inter-Assay:
   Between-run precision has been determined by using the same six specimens of 0 ng/mL, 1 ng/mL, 2 ng/mL 5 ng/mL and 12 ng/mL, 20 ng/m of HBsAg in 15 independent assays. Three different lots of Atlas HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood) 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.

REFERENCES

1. Blumberg, B.S. *The Discovery of Australian Antigen and its relation to viral hepatitis.* Vitro. 1971; 7: 223

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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