One Step Rapid Test for HBsAg

MaxLINE HBsAg Rapid Test

Serum/Plasma/Whole Blood Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVHBVWB-10	10 Tests
AVHBVWB-20	20 Tests
AVHBVWB-25	25 Tests
AVHBVWB-30	30 Tests
AVHBVWB-50	50 Tests

NOTE : 10T, 20T, 25T, 30T Pack Sizes are not available for domestic trade.

INTENDED USE

A rapid, one step test device is used for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in Serum/Plasma/Whole blood.

PRODUCT FEATURES:

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antibody Sandwich Principle.
3. Detects all 10 HBsAg Serotypes.
4. Detects 0.5 ng/ml HBsAg in 20 minutes .
5. Relative Sensitivity : 100% (0.5ng/ml).
6. Relative Specificity : 99.8%.
7. Has been compared with a leading commercial HBsAg EIA test and the correlation between the systems is over 99.8%.

INTRODUCTION

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. The presence of HBsAg in Serum/Plasma/Whole Blood 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 developed. 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 One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma/Whole Blood) is a rapid test to qualitatively detect the presence of HBsAg in Serum/Plasma/Whole Blood specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in Serum/Plasma/Whole Blood.

PRINCIPLE

The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma/Whole Blood) is a qualitative, lateral flow immunoassay for the detection of HBsAg in Serum/Plasma/Whole Blood. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, the Serum/Plasma/Whole Blood specimen reacts with the particle coated with anti-HBsAg antibody. 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 negatives 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.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (4-30°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.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Buffer Vial	Product Insert
AVHBVWB-10	10 Tests	10 Nos.	1 No.	1 No.
AVHBVWB-20	20 Tests	20 Nos.	1 No.	1 No.
AVHBVWB-25	25 Tests	25 Nos.	1 No.	1 No.
AVHBVWB-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVHBVWB-50	50 Tests	50 Nos.	3 Nos.	1 No.

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 and kits are handled.
- Handle all specimens as if they contain infectious agents . Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

MATERIALS

1. Materials Provided

Each kit contains :

a) Individually packed test device
b) Buffer
c) Sample Dropper
d) Product insert

2. Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (For serum/plasma separation)
- Stop Watch

SPECIMEN COLLECTION AND PREPARATION

1. The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma/Whole blood) can be performed using either serum/plasma/Whole blood .
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected . Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation of etiologic agents.

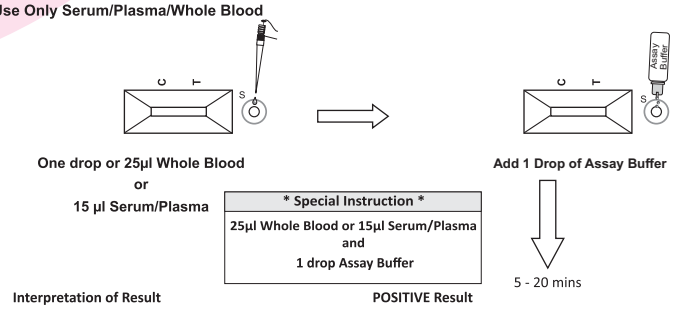
TEST PROCEDURE

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

1. Remove the test device from the foil 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.
   - **I) For Whole Blood specimens:** Hold the dropper vertically and **transfer 1 drop or 25 µl of whole blood** to the specimen well (S) of the test device, and then **add 1 drop of assay buffer** (approximately 35 µL) and start the timer.
   - **ii) For Plasma or Serum:** Use the pipette and add 15 µl Serum or Plasma to the specimen well (S) of the test device, and after absorbing the sample then add 1 drop of assay buffer (approximately 35 µL) and start the timer. See illustration below.

INTERPRETATION OF RESULTS

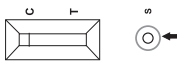
Use Only Serum/Plasma/Whole Blood



Interpretation of Result

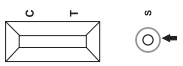
Negative

One bands appears in Window "C" Region



INVALID

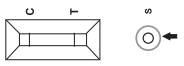
No bands appears in Window Region. The Result is considered invalid



POSITIVE Result

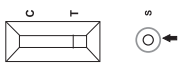
Positive

Two bands appears in Window "C" and "T" Region



INVALID

The result should also be considered invalid if only test band appears and no control band appears in window region.



Wait for the line to appear. The result should be read at 5-20 minutes.

Note: A low HBsAg concentration might result in a weak line appearing in the test region (T) after an extended period of time;
Interpret results up to 20 Minutes to take care of low positive samples. Do not Interpret results after 20 Minutes.

NOTE:
The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAg present in 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.

QUALITY CONTROL
A procedural control is included in the test. A color 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 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.

EXPECTED VALUES
The HBsAg Rapid Test (Serum/Plasma/Whole blood) has been compareds with a leading commercial HBsAg test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS
Sensitivity
The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma/Whole Blood) 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/Whole Blood). The test can detect 0.5ng/ ml of HBsAg in 20 minutes.

Specificity
Antibodies used for the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma/Whole Blood) 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/Whole Blood) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

HBsAg Reference Method

Type of Specimen	Observation				
	MaxLINE HBsAg Test		HBsAg ELISA		Total Results
	Positive	Negative	Positive	Negative	
Positive	150	0	150	0	150
Negative	01	754	0	755	755

On the basic of above internal Evalutions:
Relative Sensitivity: 100% Relative Specificity: 99.8%

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 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/ Whole Blood) 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.

INTERFERING SUBSTANCES
The following potentially interfering substances were added to HBsAg negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

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

DISCLAIMER:
The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.

WARNING:
The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

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

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test

MAKE IN INDIA
ISO 13485 Certified Company
GMP 5th Schedule MDR 2017

Manufactured in India by :
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