

TMDA/DMD/MDA/F/014
Rev #:00



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

**PUBLIC ASSESSMENT REPORT FOR MAXLINE HEPATITIS B VIRUS SURFACE ANTIGEN
(HBSAg) RAPID TEST**

Version number 2.0, 18.05.2026

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1. Introduction

Maxline is a class D in-vitro diagnostic device belonging to the immunology specialty category. It is approved in Tanzania as a kit for use in adults, children, elderly etc. by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 26 MDR 0011
Brand Name (if relevant)	MAXLINE
Common name	HBsAg Rapid Test
Class of the device and rule applied	Class D as per Rule 1 for classification of In Vitro Diagnostic Devices
GMDN code and term	48322, Hepatitis B virus surface antigen IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Malulu Company Limited, P. O. Box 850, NSSF Uchumi Complex, Agakhan Road, Kilimanjaro, Tanzania. Contact name: Juhi Desai Tel No: +255 742710732 Email: malulucompanylimited@gmail.com
Name and address(es) of local responsible person (LRP).	Malulu Company Limited, P. O. Box 850, NSSF Uchumi Complex, Agakhan Road, Kilimanjaro, Tanzania. Contact name: Juhi Desai Tel No: +255 742710732 Email: malulucompanylimited@gmail.com

1.2. Assessment Procedure

The application for registration of Maxline was submitted on 20.05.2024. The product underwent full assessment. Assessment was completed in 6 rounds of evaluation. Maxline was registered on 16.02.2026

2. Technical information

2.1. Intended use

The intended use of Maxline as declared by the manufacturer and approved by TMDA is qualitative detection of Hepatitis B Surface Antigen (HBsAg) in serum / plasma/Whole blood. Maxline is approved for use in healthcare settings by trained professionals only.

2.2. Device details and features

Maxline has been registered as a kit which consists of 50 test devices, 3 buffer vials, sample dropper, product insert.

Maxline is a manually operated kit. It is used for detection of Hepatitis B Surface Antigen (HBsAg). Maxline operates by lateral flow immunoassay. The test out-put is qualitative.

The type of specimen used is Serum/ Plasma/Whole Blood and is collected by capillary or venous method.

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 or plasma.

Commercial presentation

There are 2 approved commercial presentations as follows: 1 unit in aluminum foil, 25 and 50 units in secondary pack are placed in box.

Additional contents include 3 buffer vials, dropper, 1 package insert

2.3. Items required but not submitted

Specimen collection containers, centrifuge, stopwatch.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions is 4-30°C, avoid freezing and exposing test kits to high temperatures.

3.1.3. Shipping conditions

The recommended shipping conditions is 5°C ± 3°C, 40°C ± 1°C and 55°C ± 1°C.

4. Manufacturing site audit

The manufacturer of the device is Avecon Healthcare Pvt. Ltd.

Plant: 338, Sector-2, Industrial Growth Centre, Saha (Haryana), India-133104

Quality audit of the manufacturing facility was conducted through site visit on date 10th - 11th October 2024. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: repeatability and reproducibility, limit of detection and interference, analytical sensitivity and analytical specificity

5.2. Clinical Performance

Clinical performance was conducted at Kilimanjaro Clinical Research Institute. The following parameters were tested; clinical sensitivity and clinical specificity.

Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that Maxline is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The package insert includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2. Secondary pack



6.3 Instructions for use/Package insert

See the IFU in the last page

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. Maxline is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date



One Step Rapid Test for HBsAg MaxLINE HBsAg Rapid Test

Serum/Plasma/Whole Blood Test Protocol

Ref. No.	Pack Size
AV/HBVBW-10	10 Tests
AV/HBVBW-20	20 Tests
AV/HBVBW-25	25 Tests
AV/HBVBW-30	30 Tests
AV/HBVBW-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% (0.5 ng/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 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 of jaundice develop. 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 or plasma.

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 or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, the serum or plasma 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 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.

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
AV/HBVBW-10	10 Tests	10 Nos.	1 No.	1 No.
AV/HBVBW-20	20 Tests	20 Nos.	1 No.	1 No.
AV/HBVBW-25	25 Tests	25 Nos.	1 No.	1 No.
AV/HBVBW-30	30 Tests	30 Nos.	2 Nos.	1 No.
AV/HBVBW-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 or plasma
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.

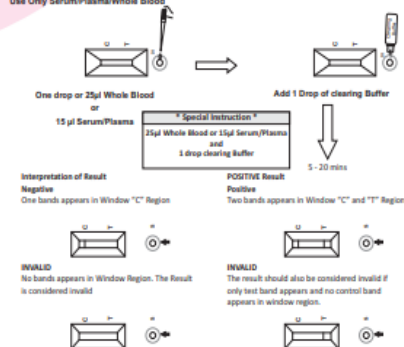
TEST PROCEDURE

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 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 buffer (approximately 35 µl) and start the timer. See illustration below.

INTERPRETATION OF RESULTS

Use Only Serum/Plasma/Whole Blood



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 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 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) has been compared 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 0.5 ng/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 who is 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.

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

On the basis of above internal Evaluations:

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	Gentamicin:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatinine:	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 or plasma specimen.
2. The HBsAg One Step Hepatitis B Surface Antigen Test Device (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.
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 taken 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. *Virology*, 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



Manufactured in India by:
AVECON Healthcare Pvt. Ltd.
Transforming Research into Innovations

Plot No.: 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India-133104.
E-mail: helpdesk@aveconhealthcare.com, Website: www.aveconhealthcare.com
Customer Care No.: +91 93065 12576

Ver.: 4/04-23

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.
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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 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 of jaundice develop. 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 or plasma.

PRINCIPLE

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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.

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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 or plasma
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non hemolyzed specimens can be used.
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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.

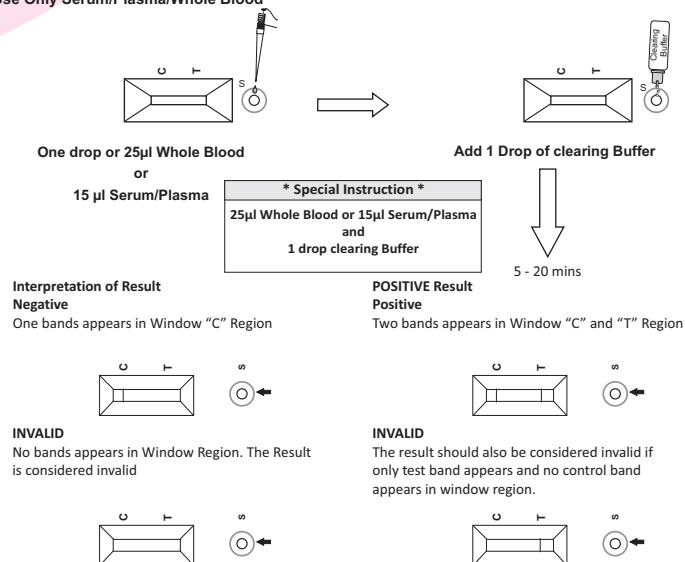
TEST PROCEDURE

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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 buffer** (approximately 35 µL) and start the timer.
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INTERPRETATION OF RESULTS

Use Only Serum/Plasma/Whole Blood



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;

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NOTE:

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EXPECTED VALUES

The HBsAg Rapid Test (Serum/ Plasma) has been compared 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.

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HBsAg Reference Method

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

On the basis of above internal Evaluations:

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.

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INTERFERING SUBSTANCES

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

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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

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2. The HBsAg One Step Hepatitis B Surface Antigen Test Device (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.
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 taken 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

	Catalogue Number		Warning/Caution
	Batch No.		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



Manufactured in India by :
AVECON Healthcare Pvt. Ltd.
 Transforming Research into Innovations

Plot No.: 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India-133104.

E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

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