One Step test for HBsAg
MERISCREEN™ HBsAg Advance

Meril Diagnostics

For in vitro diagnostic use
Read this pack insert thoroughly before use

Product code RDHBWB-01 **Pack Size** 50T

INTENDED USE:
MERISCREEN™ HBsAg Advance is a qualitative, I*n-vitro* diagnostic immuno-chromatography assay for the detection of Hepatitis B surface antigen (HBsAg) a marker for Hepatitis B infection in human serum, plasma, capillary and/or venous whole blood. The test is intended for use by the trained competent person and healthcare professionals as an aid to the diagnosis in either laboratory or point of-care settings.

INTRODUCTION:
Hepatitis B Virus (HBV) is the most common cause of persistent viremia and the most important cause of chronic liver disease and hepatocellular carcinoma. Clinically apparent HBV infections may have been extent for several millennia. It is estimated that there are 300 million chronic carriers of HBV in the world. The carrier rates vary from as little as 0.3% (Western countries) to 20% (Asia, Africa). HBV is a hepatotropic DNA virus. The core of the virus contains a DNA polymerase, the core antigen (HBcAg) and the "e" antigen (HBeAg). The core of HBV is enclosed in a coat that contains lipid, proteins and carbohydrate and expresses an antigen terms Hepatitis B surface antigen (HBsAg).
HBsAg is the first marker to appear in the blood in acute hepatitis B, being detected 1 week to 2 months after exposure and 2 weeks to 2 months before the onset of symptoms. Three weeks after the onset of acute hepatitis almost half of the patients will still be positive for HBsAg. In the chronic carrier state, the HBsAg persists for long periods (6-12 months) with no sero-conversion to the corresponding antibodies. Therefore, screening for HBsAg is highly desirable for all donors, pregnant women and people in high risk groups.

PRINCIPLE:
MERISCREEN™ HBsAg Advance is a rapid test based on immunochromatography principle. HBsAg specific antibody is immobilized on to the test region of nitrocellulose membrane. The sample is dispensed into the sample well. HBsAg if present in the test sample binds to monoclonal anti-HBsAg coupled with colloidal gold. The antigen – antibody complex moves along the membrane and gets captured by anti-HBsAg antibody immobilized on nitrocellulose membrane, which is visualize by reddish purple band on the test region. At control region Goat anti-Chicken IgY is immobilized and it binds to un-reacted colloidal gold conjugate to give reddish purple coloured band at Control region. Control band will appear irrespective to the sample status. Control band is the procedural control and it has nothing to do with the intensity of test band.

REAGENTS AND MATERIALS PROVIDED:

KIT CONTAINS	RDHBWB-01
Individually Packed Test Devices	50 Nos.
Assay Buffer bottle	2.5 mL
Sample Droppers	50 Nos.
Alcohol Swab	50 Nos.
Lancet	50 Nos.
Pack Insert	1 No.

STORAGE AND STABILITY:
The sealed pouches in the test kit may be stored between 2-30ºC till the duration of the shelf life as indicated on the pouch. DO NOT FREEZE.
In case, the desiccant pouch changes from blue to light pink or colourless, the test device should not be used.

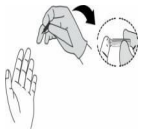
PRECAUTIONS:
1. For *in vitro* diagnostics and professional use only.
2. Allow all reagents and sample(s) to attain room temperature (18ºC to 30ºC) before use.
3. Test Device is sensitive to humidity; hence use the Test Device immediately once pouch is opened.
4. Do not use the kit contents beyond the expiry date.
5. Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
6. Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
7. Do not use haemolysed specimen for testing.
8. Use sufficient volume of sample for testing.
9. Do not re-use the Test Devices; sample dropper from the procedure may lead to aberrant results.
10. Do not pipette reagents by mouth and do not smoke, eat or drink while handling specimens and performing a test.
11. Avoid contact of reagents with eyes and skin.
12. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. Avoid re-using gloves or use of washed gloves.
13. Handle sample(s) and used materials as if it is capable of transmitting infection.
14. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. All remnants of sample(s), used materials, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121ºC for 30 minutes or dipped in 10% hypochlorite solution for 30 minutes prior to disposal.
15. Clean up spills thoroughly using an appropriate disinfectant.

SPECIMEN COLLECTION AND HANDLING:

A. Venous Whole Blood Collection by venipuncture:

1. Using venipuncture, draw whole blood into the collection tube (containing anticoagulants including heparin, EDTA or Sodium Citrate).
2. Whole blood specimens should be tested as soon as possible after collection. If whole blood specimens cannot be tested immediately, it must be refrigerated at 2-8°C and tested within 3 days of collection.
3. Do not use a blood specimen stored for more than 3 days (72 hrs); it can cause a nonspecific reaction.
4. Bring blood specimens to room temperature (15-30°C) prior to use.

B. Capillary Whole Blood Collection through finger prick:



1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the fingertip then prick the lateral side of the finger with the sterile lancet provided. Immediately, Safely dispose of the lancet.
3. Wipe away the first drop of blood with sterile gauze.
4. Using a dropper, take 20uL whole blood upto mark and transfer on sample well by two times.
5. The specimen collected must be used immediately. The specimen collected cannot be stored.

C. PLASMA:
1. Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
2. Separate the plasma by centrifugation at 1500 RPM for 10 minutes.
3. Carefully withdraw the plasma into new pre-labelled tube.

D. SERUM:
1. Collect blood specimen into a collection tube containing no anticoagulants.
2. Allow the blood to clot.
3. Separate the serum by centrifugation at 1500 RPM for 10 minutes.
4. Carefully withdraw the serum into a new pre-labelled tube. Test the specimens as soon as possible after collection. Stored serum/plasma/whole blood specimens kept at 2-8ºC can be used for testing upto 3 days. Serum/Plasma specimens should be frozen at -20ºC for longer storage.

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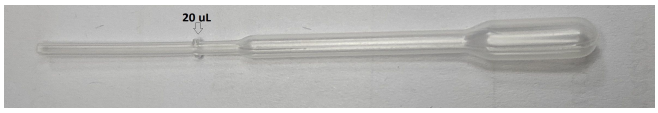
TEST PROCEDURE:

1. Bring the sealed pouch to room temperature, open the pouch and remove the device. Once opened, the device must be used immediately.
2. Take a Serum/Plasma and Whole Blood up to the mark and Dispense two drop of specimen into the sample port.

[Refrigerated specimens must be brought to room temperature prior to testing.]



3. Add one drops of the Assay Buffer to the Sample well (S).

4. At the end of 15 minutes read the results as follows.

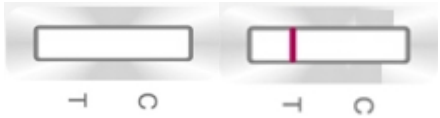
Note: Do not read the results after 20 minutes.

INTERPRETATION OF RESULTS:

NEGATIVE: If only the Control (C) band is developed, the test indicates that no detectable Hepatitis B surface antigens are present in the specimen. The result is negative.

POSITIVE: If Control(C) and HBsAg test band are developed, the test indicates for the presence of Hepatitis B surface antigen in the specimen. The result is HBsAg positive.

INVALID: If no Control(C) band is developed, the assay is invalid regardless of colour development on 'Test' band as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS:

MERISCREEN™ HBsAg Advance has been tested using an in-house panel of positive and negative clinical samples confirmed by HBsAg ELISA for HBsAg. The result shows that MERISCREEN™ HBsAg Advance is suitable for screening of HBsAg samples. Based on the following evaluation:

HBsAg Sensitivity and Specificity:

	Positive	**Negative**	**Total**
Positive Sample	**100**	**0**	**100**
Negative Sample	**0**	**1000**	**1000**
Sensitivity: 100%		**Specificity: 100%**	

ANALYTICAL SENSITIVITY:

MERISCREEN™ HBsAg Advance can detect Hepatitis B surface antigen in Serum, Plasma or Whole Blood at a concentration of as low as 0.5 ng/mL at 15 minutes.

Symbols used on Meril Diagnostics labels:

LIMITATIONS OF THE TEST:

1. This is only a screening test. All reactive test samples should be confirmed by confirmatory test like NAAT/Neutralization test.
2. As with all diagnostic tests, the test result must always be co-related with clinical findings.
3. Presence of heterophile antibodies in patient's sample with Rheumatic diseases and autoimmune disorder may lead to false results.
4. A negative result can occur if the quantity of the analyte of interest present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.
5. A negative result at any time does not preclude the possibility of exposure or infection.
6. Repeat the test in case of very faint band or if have any doubt for test band.
7. False negative results may arise because of hook effect due to very high concentration of analyte of interest in sample. Repeat the test by using different dilution of same sample.
8. Other clinically available tests should be used if questionable results are obtained.
9. This test is only intended for human's serum, plasma and whole blood samples.
10. This is the qualitative test and should not be used for measurement of HBsAg concentration.
11. Test results should be interpreted in conjunction with clinical findings.

REFERENCES:

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2. Chandler, J., Gurmin, T., Robinson, N., (2000) The place of gold in rapid tests. IVD Technology, 7(2):37-49.
3. Weiss, A., (1999) Concurrent engineering for lateral flow diagnostics. IVD Technology, 5(7):48-57.
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5. Kao, J.H., (2008) Diagnosis of hepatitis B virus infection through serological and virological markers Expert Rev. Gastroenterol. Hepatol. 2(4) : 553-562.
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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.

NOTICE:

Every effort is made to supply ordered consignment as per the sample submitted but due to continuous development, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer.