Size 137 x 218 mm

VioTUBE™ HBsAg

ONE STEP TEST FOR HBsAg

DIPSTICK

INTRODUCTION

VioTUBE™ HBsAg, is one step test for HBsAg is a rapid, qualitative, two site sandwich immunoassay for the detection of Hepatitis B surface antigen, a marker for Hepatitis B infections, in serum/plasma specimen. For professional use.

SUMMARY

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B surface Antigen (HBsAg), earlier known as Australia antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter.

Detection of HBV using HBsAg as the marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infection.

VioTUBE™ HBsAg one step test for HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml.

PRINCIPLE

VioTUBE™ HBsAg one step test for HBsAg utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly within the test dipstick, the colored Agglutinating sera for HBsAg-colloidal gold conjugate complexes with the HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by the Agglutinating sera for HBsAg coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

VioTUBE™ HBsAg kit contains:

1. DIPSTICK : Contains membrane assembly predispensed with Agglutinating sera for HBsAg -colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for HBsAg and Agglutinating sera for rabbit globulin at the respective regions.
2. Desiccant pouch.
3. TUBE : Test tube with result reading zones.
4. CAP : Test tube caps.
5. Package insert.

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Σ	10

OPTIONAL MATERIAL REQUIRED BUT NOT PROVIDED

Disinfectant, Disposable gloves, Biohazard waste container, Micropipette.

STORAGE AND STABILITY

VioTUBE™ HBsAg is stable up to the expiry date mentioned on the label when stored at 4°C To 30°C. Once the pouch is opened, the dipstick must be used immediately. DO NOT FREEZE.

NOTES

1. Read the instructions carefully before performing the test.
2. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
3. Do not use beyond expiry date. Do not intermix the reagents from different lots.
4. The dipstick is for single use only.
5. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

Colour	C	M	Y	K
Mauve	30	100	0	0
Black	0	0	0	100

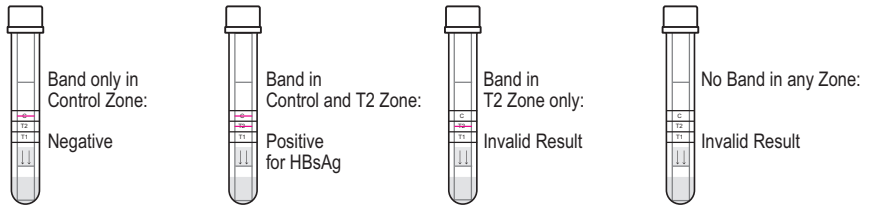
SPECIMEN COLLECTION AND PREPARATION

1. **VioTUBE™ HBsAg** uses human serum / plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Preferably use fresh sample. However, specimen may be stored refrigerated (2°C To 8°C) for short duration. For long storage, freeze at -20°C or below.
4. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not heat inactivate before use.
7. Do not use turbid, lipaemic and haemolysed serum/plasma.
8. Do not use haemolysed, clotted or contaminated specimens.
9. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
10. Refrigerated specimens must be brought to room temperature prior to testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed aluminium foil pouch of **VioTUBE™ HBsAg** dipstick to room temperature.
2. Open the pouch and retrieve the dipstick (taking care not to touch the membrane area), and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the dipstick and use another dipstick. ***Once opened, the dipstick must be used immediately.***
3. Take the result area marked test tube provided with the kit and label it with patient's identity and number.
4. Add 200µl of serum/plasma sample into the test tube using a micropipette.
5. Place the dipstick into the tube, with the arrows on the dipstick pointing downwards and close the test tube with the cap.
6. Put the test tube vertically straight in the test tube stand.
7. Read the results at the end of **30 minutes** as follows based on the marking of T1/T2/C on the test tube.
8. The test should be considered invalid if no colored band appears on the dipstick. The test should also be considered invalid if a colored band appears only at the test zone 'T2' and not at the control zone 'C'. In such cases, repeat the test with a new **VioTUBE™ HBsAg** dipstick, ensuring that the test procedure has been followed accurately.

RESULT INTERPRETATION



PERFORMANCE CHARACTERISTICS

Internal Evaluation

VioTUBE ™ HBsAg was evaluated with a serial dilution of known concentration of HBsAg positive sample. It was observed that **VioTUBE™ HBsAg** was able to detect all the dilutions with HBsAg concentration of ≥ 0.5 ng/ml.
Therefore the detection limit of **VioTUBE™ HBsAg** is 0.5 ng/ml.
With a low titre performance panel (PHA 104) from BOSTON BIOMEDICA Inc., USA, **VioTUBE ™ HBsAg** showed (±) reactivity with a sample that contained as low as 0.3 ng/ml of HBsAg. In the same panel, with another sample of 0.6 ng/ml, **VioTUBE™ HBsAg** showed (+) reactivity.

Independent External Evaluation

In an in-house study, the performance of **VioTUBE ™ HBsAg** was evaluated using a panel of 398 samples - 100 positives & 298 negatives, in comparison with commercially available Immunochromatographic Test (IC), Enzyme Immunoassay (EIA) and the results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	VioTUBE™ HBsAg	IC	EIA
Number of specimens tested	398	397	398	398
Number of Positives	100	100	100	100
Number of Negatives	298	297	298	298

The above study indicates good correlation of the results of **VioTUBE™ HBsAg** with that of EIA.
Based on this evaluation: Sensitivity of **VioTUBE™ HBsAg** : 100%. Specificity of **VioTUBE™ HBsAg** : 99.6%.

LIMITATIONS OF THE TEST

1. Though **VioTUBE™ HBsAg** is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.

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2. Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies. Though **VioTUBE™ HBsAg** uses sufficient amounts of HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit the majority of this interference; nevertheless, some samples with high titers may still express clinically important assay interference. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
3. Do not compare the intensity of test lines and the control lines to judge the concentration of HBsAg in the test specimen.
4. Since various tests of HBsAg differ in their performance characteristics and antibody composition, their reactivity patterns may differ.
5. Testing of pooled samples is not recommended.
6. HBsAg is coded for by the S gene, and the common antigenic epitopes of all subtypes of HBsAg are found in the same 'a' determinant. The antibodies used in **VioTUBE™ HBsAg** are directed against this 'a' determinant so that all subtypes of HBsAg can be detected. However, a few patients infected with HBV may show negative for HBsAg inspite of a positive test for HBV-DNA or HBV polymerase chain reaction. These rare cases are due to antigenically divergent variants. Therefore, the existence of such variants should be considered before taking clinical decisions.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Kim, C. Y., Tillis, J. G. Purification of Biophysical Characterization of Hepatitis B antigen, J. Clin. Invest, 52, May 1973, pgs 1176-1186.
2. Kee Myung Lee et.al., Emergence of Vaccine- induced escape mutant of Hepatitis B Virus with Multiple surface gene mutations in a Korean child, J. Korean Med .Sci. 2001; 16, pgs 359-362.
3. Koyanagi T et al. Analysis of HBs antigen negative variant of hepatitis B virus: Unique Substitutions, Glu 129 to Asp and Gly 145 to Ala in the surface antigen gene. Med Sci Monit, 2000; 6(6): 1165-1169.
4. Data on file: Orchid Biomedical Systems.

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SYMBOL KEYS

	Temperature Limitation		Manufacturer		This side up		Contains sufficient for <n> tests
	Use by		Consult Instructions for use	DIPSTICK	Dipstick		Do not reuse
	Date of Manufacture	REF	Catalogue Number	TUBE	Test tubes	CAP	Test tube caps
LOT	Batch Number / Lot Number			IVD	In vitro Diagnostic Medical Device		

Manufactured by:

Orchid Biomedical Systems

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

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