ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HBSD

PRATHAM® HBsAg Test

For the qualitative and differential detection of Hepatitis B virus surface antigen in human serum/plasma/whole blood

INTENDED USE

PRATHAM® One Step Hepatitis B Surface Antigen (HBsAg) Test Device is an in vitro diagnostic rapid test based on the principle of immunochromatography test for qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum/plasma/whole blood at a level equal to or higher than 0.5 ng/mL. For professional use only.

INTRODUCTION

Hepatitis B is an infectious disease caused by the Hepatitis B virus (HBV) that affects the liver. It is a type of viral Hepatitis. It can cause both acute and chronic infection. Many people have no symptoms during the initial infection. In acute infection, some may develop a rapid onset of sickness with vomiting, yellowish skin, tiredness, dark urine, and abdominal pain. Often these symptoms last a few weeks and rarely does the initial infection result in death. 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. HBsAg test (Card/Device) for HBsAg detects the presence of HBsAg in human serum / plasma / whole blood.

TEST PRINCIPAL

PRATHAM® One Step Hepatitis B Surface Antigen (HBsAg) Test Device is a lateral flow test based on the principle of immunochromatography, the method uses monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose membrane. As the test sample flows laterally through nitrocellulose membrane it mixes with the gold conjugated antibodies. If the sample contains HBsAg, the colloidal gold-antibody conjugate binds to the antigen, forming an antigen, forming an antigen-antibody-colloidal gold complex. This complex then migrates through the nitrocellulose strip by capillary action. When the complex meets the line of immobilized antibody at (Test line) 'T', the complex is trapped forming an antibody antigen-antibody colloidal gold complex. This forms a pink/purple band indicating the sample is positive for HBsAg. To serve as a procedural control, an additional line of anti-rabbit IgG antibody (Control line) 'C' has been immobilized on the strip. If the test is performed correctly. If will result in the formation of a pink/purple band upon contact with the conjugate at the control line region.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micro Pipette, Tips & Centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of shelf life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

SPECIMEN COLLECTION AND STORAGE

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -20ºC or below. Do not freeze whole blood samples. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.

6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior to use.

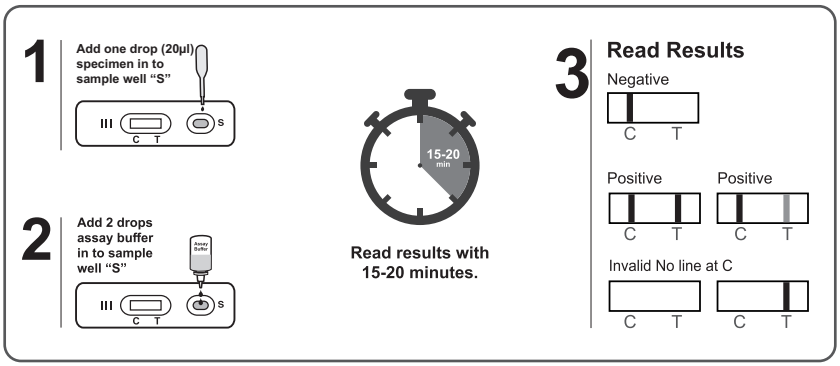
WARNING AND PRECAUTIONS

- Use product insert to perform the assay. Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micro pipette tips for each sample to avoid cross contamination.
- Do not use hemolized blood specimens for testing.
- Do not throw away used device, sample tube and tips any where discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The test shall be performed by competent person only.
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add one drop (20µl) of serum / plasma / whole blood into the sample well.
5. Add 2 drops of assay / running buffer into the sample well using provided buffer vial.
6. Interpret test results within 20 minutes. Don't interpret results after 20 minutes.

INTERPRETATION OF RESULTS



Negative:
A pink colored band appears only at the control region 'C', indication a negative result for HBsAg infections.

Positive:
Appearance of two pink/purple lines, one at the test line region 'T' and other at the control line region 'C', indicates that the specimens has surface protein antigens of Hepatitis B virus in the specimen and it should be considered as positive.

Invalid:
No visible band at the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not

supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

IN-HOUSE EVALUATION

In an in-house study, the performance of device was evaluated using a panel of thirty known positives (of varying reactivity) and one hundred fifty known negative specimens in comparison to licensed Competitor HBsAg rapid test. The results of the evaluation are as follows:

Results					
Types of specimens	**Numbers**	**Pratham Hepatitis B Surface Antigen Test**		**Competitor HBsAg test**	
		Positive	Negative	Positive	Negative
Positive	30	30	0	30	0
Negative	150	0	150	0	150
Sensitivity		100%			
Specificity		100%			

LIMITATION OF THE TEST

1. HBsAg Test Kit detects HBsAg in human serum or plasma and is only screening test. All reactive specimens should be confirmed by supplemental assays like PCR or ELISA. Therefore, for a definitive diagnosis, the patient's clinical history, symptom ology as well as serological data should be considered. The result should be reported only after complying with above procedure.
2. The assay is only validated for serum or plasma from individual bleeds and not for pools of serum or other body fluids.
3. This test is standardized to work best when the test procedure mentioned in the package insert is strictly followed. Any deviation from the test procedure may lead to erroneous results.
4. A non-reactive result does not exclude the possibility of exposure or infection with Hepatitis B virus.
5. It should be noted that repeated false reactive results may occur due to non-specific binding of specimen to the membrane.
6. Patients with auto-immune liver diseases may show false positive results.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

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.

BIBLOGRAPHY OF SUGGESTED READING

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SYMBOLS

 Read instructions for use	 Name of Manufacturer	 For single use only
 No. of test	 Expiry Date of Kit.	 Date of manufacturing of IVD Kit
 In-vitro diagnostic use	 Keep away from Sunlight	 Reference Catalogue Number
 Storage Condition		

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
Plot No. H-125, RIICO Indl. Area, Kaharani, Bhiwadi Extn.
Alwar, Rajasthan-301019 (INDIA)
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