HEPA™ CARD

WHOLE BLOOD / SERUM / PLASMA

IMMUNOPAK

Last update 02/2017

INTENDED USE

CARD test for detection of Hepatitis B (HBsAg) in whole blood, serum or plasma.

INTRODUCTION

Hepatitis B surface antigen ("Australia Antigen") consists of lipid, carbohydrate and protein elements; the protein moiety provides a marker for identification of chronic, infectious HBV infections. Hepatitis B is transmitted sexually or intravenously and has an incubation period of six months. If not diagnosed properly and in time, it can develop into acute or chronic infection, liver cirrhosis and fulminant hepatitis.

This test is very useful for screening blood donors, to find out whether they are HBsAg positive before collection of blood.

PRINCIPLE

HEPA™CARD is a qualitative test based on immunochromatography sandwich principle. The test card includes a combination of monoclonal anti-body gold conjugate (colloidal gold) and polyclonal solid phase antibodies which selectively binds Hepatitis B surface antigen with high degree of sensitivity.

The HBsAg test is a one-step immunochromatographic assay based on the antigen capture, or "Sandwich" principle. The method uses monoclonal antibody conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose strip in a thin line. The test sample is introduced into well and flows laterally through an absorbent pad where it mixes with the signal reagent. If the sample contains HBsAg, the colloidal gold-antibody (mouse) conjugate binds to the antigen, forming an antigen-antibody-colloidal gold complex. The complexes then migrate through the nitrocellulose strip by capillary action, which are stopped by an immobilized antibody zone forming a pink-purple line. The formation of the first pink-purple line (T zone) is indicative of hepatitis positive. To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with the conjugate as a control line.

PRESENTATION

	50 TESTS
Hepa (HBsAg) test cards	50 Cards
Assay Buffer	1 Bottle

PRECAUTION

- HEPA ™ CARD is for in vitro diagnostic use only.
- Handle all specimens as if they contain infectious agents. After the completion of assay procedure, treat the glasswares with 0.5% to 1% solution of sodium hypochlorite for 1 hour before disposal.
- Avoid any contact between hands and eyes or nose during (specimen) collection and testing.

STORAGE AND STABILITY

HEPA™ test card (HBsAg) should be stored at 4-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on Pouch as well as carton label. The test kit should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND STORAGE

• Whole blood as specimen

Fresh blood from finger prick/puncture may be used as a test specimen for collection of whole blood as a test specimen; EDTA, heparin or oxalate can be used as a suitable anticoagulant. the specimen should be collected in a clean glass or plastic test tube, if immediate testing is not possible, then the specimen may be stored at 2-8ºC for upto 72 hours before testing. Do not use hemolysed clotted or contaminated blood samples for performing the test.

• Serum / Plasma as specimen

For Serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

It the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Stir and bring the specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

1. Bring the specimen and pouch containing the HBsAg Card to room temperature prior to testing.
2. Remove one test card from the pouch and place it on a clean flat surface.

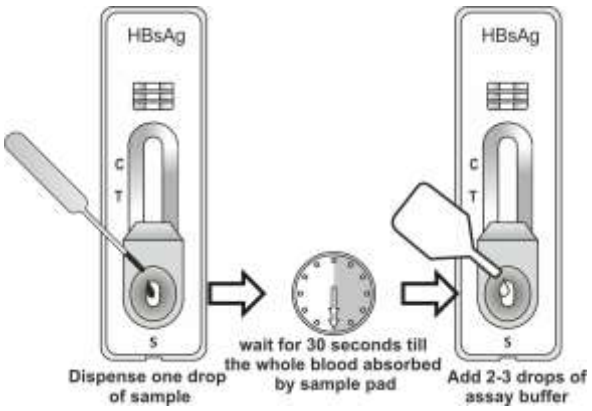
WHOLE BLOOD AS SPECIMEN:

3. With the help of the dropper provided add one drop (approx. 25µl) of anticoagulated or finger prick blood to the sample well, **Wait for few seconds till the Whole blood absorbed by sample pad (approx. 30 second),** alternatively 25 µl of whole blood specimen may be delivered in the sample well using a micropipette.(see the figure)
4. Add 2-3 drops (120 µl) of assay buffer (Diluent) into the sample well of the test device. **(If needed add one more drop of assay buffer).**

SERUM/PLASMA AS SPECIMEN:

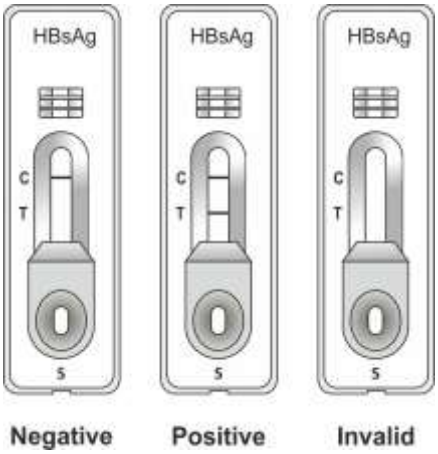
5. Using the dropper provided add 2 to 3 drops of serum sample into the sample well. Avoid overflowing.
6. Let the reaction to proceed until the appearance of positive line and control line or upto 20 minutes.
7. Read results within 20 minutes. Strong positive reaction may visible within 5 minutes.
8. If negative or questionable results are obtained, and HBV infection is suspected, the test should be repeated on a fresh specimen.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but such result should be interpreted only after all clinical and laboratory findings have been evaluated.



INTERPRETATION OF RESULTS

- **Negative:** If a distinct pink-purple line is formed only at the control zone marked 'C' (control line) the test result is negative.
- **Positive:** If a distinct pink-purple line is formed at the test zone marked 'T' (test line) and the control zone marked 'C' (control line) the test result is positive, indicating that the sample contains Hepatitis B Antigen. The interpretation of test result (+ve for hepatitis) remains unchanged even if there is a difference in intensity of colour in positive line and control line as is many a times found.
- **Invalid:** A total absence of pink-purple line in both regions or no pink-purple line appears on the control (C) region is an indication of procedure error and / or the test reagent deterioration. Repeat the test with a new test kit.



SENSITIVITY

HEPA™ CARD (20 min. test) can detect Hepatitis B antigen in whole blood / serum or plasma in a concentration as low as 0.5 ng/ml.

LIMITATIONS

The test will only indicate the presence or absence of Hepatitis B Surface Antigen in the specimen and other consideration like clinical symptoms should be noted before making final diagnosis. Additional followup testing, using available clinical methods (along with repeat HEPA™CARD) is required, if the HEPA™CARD test is negative with persisting clinical symptoms.

REFERENCES

1. MILICH D.R., Immune response to the hepatitis B Virus: infection, animal models, vaccination, VIRAL HEPATITIS, 1997, 3, 63-103
2. HOLLINGER F.B., Hepatitis B virus, in Fields Virology, Third Edition. Lippincott - Raven Publishers, Philadelphia. 1996, 2739-2807
3. BLUMBERG B.S., ALTER H.J., VISNICH S. JAMA. A “New” Antigen in Leukemia Sera, 1965, 191. 541-546.
4. PRINCE A.M., An antigen detected in blood during the incubation period of serum hepatitis. Proc Natl Acad Sci USA, 1968, 60. 814-821.

3/7, Industrial Estate, Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com
Phone: +91·265·2281631
Email: mail@reckondiagnostics.com

RECKON DIAGNOSTICS P. LTD.