

**INTENDED USE:**

**CARD test for detection of Hepatitis B (HBsAg) in 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 purple band. The formation of the first purple band (T zone) is indicative of hepatitis positive. To serve as a procedural control, an additional line of antibody antimouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of purple band upon contact with the conjugate as a control line.

**PRESENTATION:**

	50 Tests	100 Tests
Disposable Test Cards	50 Cards	100 Cards

The shelf life or expiry of the card is printed on the pouch.

**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 & STABILITY:**

HEPA™ CARD HBsAg should be stored at 4-30°C. However, the card may be stored at room temperature not exceeding 30°C in the original sealed pouch.

**SAMPLE COLLECTION AND STORAGE:**

HEPA™CARD TEST is performed on human serum or plasma. It is recommended that the test should be carried out immediately after the collection of blood and separation of serum. The antigen HBsAg is thermolabile. Serum specimen can be stored at 2-8°C following collection upto 3 days or for longer storage the specimen should be frozen (-20°C). Specimen containing precipitates, can cause a problem, is well known in chromatography procedures, and hence should be clarified either by centrifugation or by filtration.

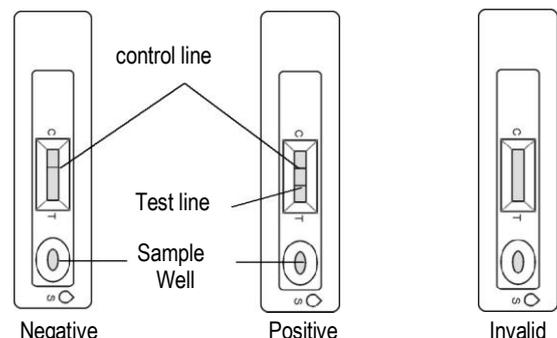
If your card test is showing *stagnant flow on chromatography* it is most likely due to problem in the sample. *Retest with a fresh fasting sample or a diluted sample.*

**TEST PROCEDURE:**

1. Bring the specimen and pouch containing the HEPA™ CARD to room temperature prior to testing.
2. Remove one test card from the pouch and place it on a clean flat surface.
3. Using the dropper provided put 2-3 drops of serum sample into the sample well. Avoid overflowing.
4. Let the reaction to proceed until the appearance of positive line and control line or upto 20 minutes.
5. Read results after 20 minutes. Strong positive reaction may visible within 5 minutes.
6. If negative or questionable results are obtained, and HBV infection is suspected, the test should be repeated on a fresh serum specimen.
7. 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:**

- **Positive:** If a distinct 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.
- **Negative:** If a distinct purple line is formed only at the control zone marked 'C' (control line) the test result is negative.



**SENSITIVITY:**

HEPA™ CARD (20 min. test) can detect Hepatitis B antigen in 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).

**REFERENCE:**

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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.

