HEPA™ STRIP

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INTENDED USE:
Strip test for detection of (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- HEPATITIS B VIRUS 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™ STRIP is a qualitative test based on immunochromatography sandwich principle. The test strip includes a combination of monoclonal antibody 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 antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose strip in a thin line. The test sample 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 (Test line) is an indication of hepatitis positive. To serve as a procedural control, an additional line of antibody antimouse IgG has been immobilized on the strip. If the test is performed correctly, this will result in the formation of purple band on control line.

PRESENTATION:

	50 Tests	**100 Tests**
Disposable Test Strips	50 Strips	100 Strips

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

PRECAUTION:
- HEPA™ STRIP is for in vitro diagnostic use only.
- Handle all specimens as they may 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.

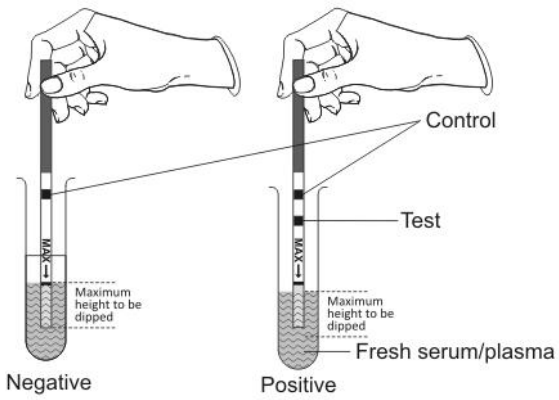
STORAGE & STABILITY:
HEPA™ STRIP HBsAg should be stored at 4-30^{0}C. However, the strip may be stored at room temperature not exceeding 30^{0}C in the original sealed pouch.

SAMPLE COLLECTION AND STORAGE:
HEPA™ STRIP 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 seperation of serum. The antigen HBsAg is thermolabile. Serum specimen can be stored at 2-8^{0}C following collection upto 3 days or for longer storage the specimen should be frozen (-20^{0}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 strip 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 HEPA™ STRIP to room temperature prior to testing.
2. Place a 8 x 75 mm test tube in a test tube stand, pipette approximately 200 µl of sample directly to the bottom of the test tube. Avoid wetting of the inside walls of the test tubes, as drops on the walls of the test tubes may risk the test by wetting the test stick above the filter area.
3. Take one test strip from the pouch and place it in the test tube till the mark (↓↓) on the strip with sample pad end down words.
4. Let the strip remain standing in the sample until you see that the control line (the upper part in the Reaction Zone) as fully formed. Allow the reaction to occur for 20 minutes.
5. Read the results within 10-20 minutes, strong positive reaction will be 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 the physician should interpret only after all clinical and laboratory findings have been evaluated.

INTERPRETATION OF RESULTS:



- **Positive:** If a distinct purple line is formed at the lower end (test line) and in the upper part (control line) of the Reaction Zone the test result is positive, indicating that the sample contains Hepatitis B surface Antigen. A difference of intensity in colour may occur between the test line and control line but this does not affect the interpretation of the result.
- **Negative:** If a distinct purple line is formed only at the upper end of the Reaction Zone (control line) the test result is negative.

SENSITIVITY:
HEPA™ STRIP can detect Hepatitis B surface Antigen in serum or plasma in a concentration of as low as 0.5 ng/ml. (after 20 minutes).

LIMITATIONS:

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

REFERENCE:

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