

HBsAg

(Hepatitis-B Card)

This rapid kit is for detection of HBsAg in serum or plasma.

INTRODUCTION:

Hepatitis refers to inflammation of liver. Chemicals, toxins and virus can cause hepatitis. Most common agent causing acute hepatitis is virus. Of these Hepatitis B virus leads to severe forms of disease.

After incubation period of 1-6 months surface antigen (HBsAg) of Hepatitis B virus appears in blood serving as first serological marker for detection & diagnosis of HBsAg in serum.

HBsAg surface antigen consists of lipid, carbohydrate & protein elements. This disease is transmitted sexually or intravenously, so it is important to screen blood donors before collection of blood.

PRINCIPLE:

This test is based on the principle of immune-chromatography. The HBsAg Card consists of four main regions i.e. the sample well, the conjugate pad, test window, and the sink pad. The conjugate pad is impregnated using the colloidal gold dye conjugated to the monoclonal antibodies. The polyclonal antibodies are immobilized selectively at the test zone. At the control zone the polyclonal antibodies conjugated with HBsAg are selectively immobilized. The sample when added into the sample well flows through absorbent pad by capillary action.

If HBsAg is present in the sample, the labeled monoclonal antibody binds to it and moves upward. HBsAg monoclonal antibody complex binds to polyclonal antibody at the test band area to form purple colored band. In the absence of HBsAg the labeled monoclonal antibody moves along with specimen and binds with Immobilized polyclonal - HBsAg complex to form purple colored band at control band zone.

SPECIMEN COLLECTION AND STORAGE:

Fresh clear non hemolyzed serum or plasma should be used.

PRECAUTION:

HBsAg card is for In-vitro diagnostic use only. Carefully handle all the specimen as infectious material. Autoclave the specimen & glassware before disposal.

PRESENTATION:

	No of pouches
	50 Test
Disposable HBsAg test card	50

STORAGE STABILITY & SENSITIVITY:

The HBsAg test cards are stable up to the expiry date printed on the label.

The HBsAg test cards must be stored at 4-30° C. Do not freeze.

The HBsAg test card has a sensitivity of 0.5 - 1.0 ng/ml.

Perform the test immediately after removing card from foil pouch.

PROCEDURE:

Allow the HBsAg test pouch to attain room temperature.

Carefully remove the card from the pouch & place it on flat clean surface.

Add 50µl or 2 drops of serum sample into the sample well using the micro pipette or dropper.

Read results within 20 minutes.

Do not read result after 20 minutes.

RESULT INTERPRETATION:

Appearance of two purple colored bands within 10 minutes confirms strong positive result & presence of HBsAg in the sample.

Appearance of only one purple band near the upper end of card confirms the negative result & indicates absence of HBsAg.

Negative result	: Single band in control zone
Positive result	: Two bands one in control zone and one in test zone
Invalid result	• No bands even after completion of test

LIMITATIONS:

Testing under fan may retard specimen flow, so avoid it.

The HBsAg card is 100% specific as no cross reaction with Hepatitis A.

A false positive result may sometimes be encountered in 1% of cases. The final diagnosis & conclusion should be derived from other criteria & clinical findings as HBsAg card indicates presence & absence of Hepatitis B surface antigen in the specimen.

The sensitivity of HBsAg is 0.5 - 1.0 ng/ml.

A negative result does not preclude the possibility of infection with HBV. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical laboratory findings have been evaluated. A false positive result may sometimes be encountered in 1% of cases.

BIBLIOGRAPHY

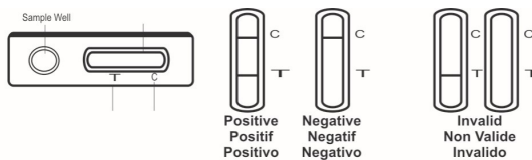
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While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

The manufacturers 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.

One Step Hepatitis Test Device

1. Add 50 µl of Sample
2. Read result within 20 min.



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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 4-30°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by