

## **HBsAg Rapid Test**

### **Diagnostic Test for Detecting Hepatitis B Surface Antigen**

#### **Name and Intended Use**

**HBsAg Rapid Test** is a visually read, qualitative immunoassay for *in vitro* detection of Hepatitis B Surface Antigen in serum or plasma. The test is intended as an aid to diagnosis of Hepatitis B infection.

#### **Summary and Explanation of the Test**

Viral hepatitis is a systemic disease primarily involving the liver, and in most cases is caused by one of three viruses: Hepatitis A (HAV), Hepatitis B (HBV) or Hepatitis C (HCV). The antigen found in the envelope of HBV is designated Hepatitis B Surface antigen (HBsAg) and its presence in serum or plasma indicates active HBV infection. **HBsAg Rapid Test** is a simple, one-step test that detects the presence of HBsAg.

#### **Biological Principles of the Procedure**

**HBsAg Rapid Test** is a lateral flow immunoassay. If HBsAg is present in the sample, it forms a complex with the colloidal gold anti-HBsAg conjugate that is dried onto the test strip. The liquid migrates through the nitrocellulose membrane, and if colloidal gold – antibody – HBsAg is present this binds to a second anti-HBsAg antibody immobilized on the membrane, forming a visible red line. The test strip contains an internal control line in the control region that should always show up as a red line regardless of the test line result.

#### **Materials Provided**

**HBsAg Rapid Test** contains the following components to perform the assay:

1. Test device (cassette)
2. Instruction manual

#### **Accessories (required but not provided):**

Timer                      Disposable dropper or micropipettor

#### **Storage and Stability**

The test devices are sealed in a moisture-proof foil laminate pouch, containing desiccant. These should be stored in the coolest and driest area available, preferably at 4-30°C. The kit has a shelf life of 24 months from the date of manufacture. The devices should not be frozen and must be protected from exposure to humidity; once a pouch is opened, the device should be used within one hour.

## Precautions

To obtain reproducible results, the following instructions must be followed:

1. For *in vitro* diagnostic use only with serum or plasma samples.
2. Use disposable gloves while handling potentially infectious material and performing the assay.
3. Do not use the kit beyond the expiration date.
4. Do not eat, smoke, or drink while handling specimens.
5. Do not combine reagents from different batch numbers as the components are optimized for individual batch to give best results.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Do not open the foil pouch until it attains room temperature to prevent formation of condensation.
8. For best results, strictly follow the test procedure and storage instructions.

## Specimen Collection and Storage

Collect whole blood in a clean container by venipuncture. Use either plain tubes for serum or tubes containing anti-coagulant (EDTA, citrate or heparin) for plasma. Separate the serum or plasma. If samples are not immediately tested, they should be stored at 4-8°C for not more than 2 weeks.

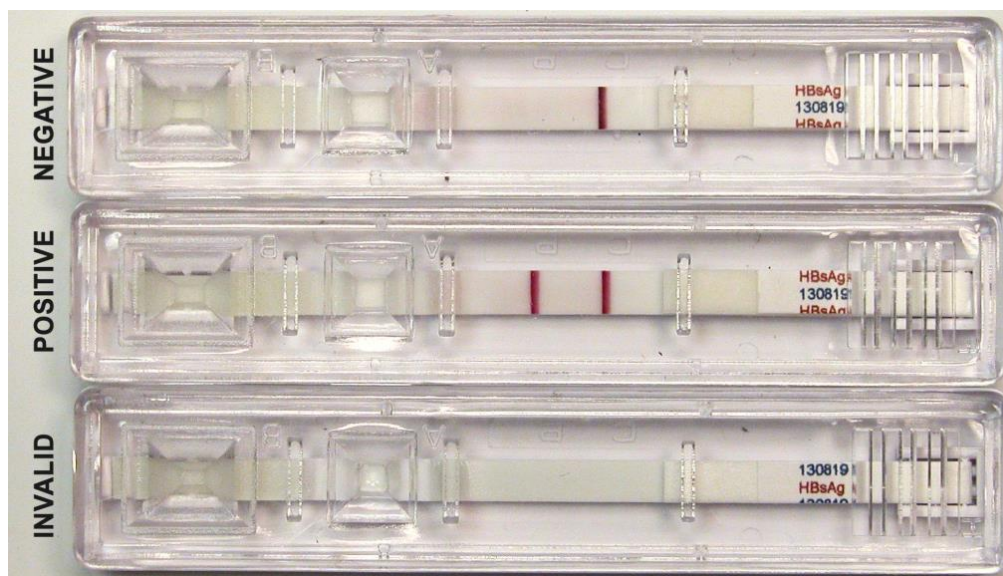
## Test Procedure

1. Bring the complete kit and sample to be tested to room temperature prior to testing. Once the device pouch is opened, it must be used within one hour.
2. Place 3 - 4 drops (~ 100 µL) of serum or plasma into the sample window of the device.
3. The sample will rehydrate and mix with the red colloidal gold conjugate, which flow into the membrane. After 10- 15 minutes all the pink color from the conjugate will clear from the membrane except for test and controls lines that form. The result of the test can then be read.



## Interpretation of Results

As shown below, a reactive test shows as two colored lines, one in the test area (P = Positive), one in the control area (C = Control). The test should be considered reactive if any visible line is evident in the test area, even if it is very faint. A non-reactive test shows only one colored line in the control area. If the control line is not visible, the test is invalid.



## Performance Characteristics

The test has been evaluated with positive and negative clinical samples with results as follows:

Sample	Total Number	Positive	Negative	Sensitivity (%)	Specificity (%)
HBsAg Negative	150	1	149	--	99.3%
HBsAg Positive	100	99	0	99%	--

## Limitations and Interferences

1. The test procedure, precautions and interpretation of results for the test must be followed strictly.
2. The test is a qualitative screening assay and is not for quantitative determination of antibodies to HCV. There is no meaning attributed to line color intensity or width.
3. **This is only a screening test.** The test does not rule out Hepatitis B infection because HBsAg may not be present in sufficient quantity to be detected at a very early stage of infection.
4. Positive results must be confirmed by other diagnostic procedures and clinical data.