

1. INTENDED USE

The Biokits HBsAg Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in **human serum or plasma**. This test is intended for **professional use only**.

2. INTRODUCTION

Hepatitis B virus (HBV) infection is a major global health problem affecting the liver. Hepatitis B surface antigen (HBsAg) is the earliest detectable marker of acute or chronic HBV infection and reflects active viral replication. Early identification of HBsAg-positive individuals is essential for clinical management, blood screening, antenatal care, and prevention of HBV transmission.

The Biokits HBsAg Rapid Test provides a simple, qualitative visual result to support screening for Hepatitis B infection using **serum or plasma specimens only**.

3. PRINCIPLE OF THE TEST

The Biokits HBsAg Rapid Test is a lateral-flow immunochromatographic assay employing a two-line detection system consisting of a test line (T) and a control line (C). When serum or plasma is applied to the device, HBsAg present in the specimen binds to gold-conjugated anti-HBsAg antibodies and migrates along the nitrocellulose membrane by capillary action. The resulting antigen-antibody complexes are captured by immobilized anti-HBsAg antibodies at the test line region, producing a visible colored line when HBsAg is present. The control line is coated with polyclonal antibodies that react with a colored control conjugate, generating a visible line independent of HBsAg concentration. The appearance of the control line confirms proper sample flow, reagent integrity, and validity of the test procedure.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched HBsAg Test Device with desiccant
2. Disposable sample dropper
3. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at **2–30°C**. Do not freeze.
2. Protect from sunlight and humidity.
3. Use immediately after opening the test pouch.
4. Do not use if the pouch is damaged or opened.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the label.

6. PRECAUTIONS

1. For **In-Vitro Diagnostic Use Only**.
2. This test is validated **only for serum or plasma**—do not use whole blood.
3. Do not reuse the test device.
4. Avoid using severely hemolytic, lipemic, or icteric specimens.
5. Use a fresh dropper or pipette tip for every specimen to prevent contamination.
6. Follow standard laboratory safety procedures and wear appropriate PPE.
7. Dispose of all materials as biomedical waste.
8. Ensure reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is a **qualitative screening assay** and does not measure the concentration of HBsAg.
2. Results should not be used as the sole basis for diagnosis; reactive samples must be confirmed using laboratory methods (ELISA, CLIA, PCR, etc.).
3. Very low HBsAg levels or specimens collected during the window period may produce false-negative results.
4. False positives may occur due to technical errors or interfering substances.
5. Only **serum and plasma** are acceptable samples; whole blood is not suitable for this device.
6. Improper handling, incorrect procedure, or expired/damaged kits may lead to invalid results.

8. SAFETY INFORMATION

1. Treat all specimens as potentially infectious.
2. Wear gloves, lab coat, and eye protection when handling samples and reagents.
3. Clean spills with appropriate disinfectants.
4. Do not pipette by mouth.
5. Dispose of test devices, droppers, and materials as per biomedical waste guidelines.
6. Follow institutional protocols in case of accidental exposure.

9. REFERENCES

1. World Health Organization (WHO). Guidelines for the prevention and clinical management of Hepatitis B infection.
2. Lok AS, McMahon BJ. "Chronic Hepatitis B: Update." *Hepatology*. 2009;50(3):661–662.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Collect blood into a tube without anticoagulant. Allow the blood to clot completely, then centrifuge to separate the serum. ✓ Collect blood into an anticoagulant tube (EDTA, citrate, or heparin) and centrifuge to obtain plasma.
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, freeze serum/plasma at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE

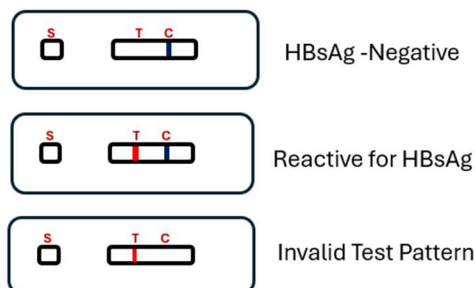


Add 2 Drops (50 ul) of Serum/Plasma into the Sample Well “S”

Read Results at 5-20 Minutes

Note: Do not read results after 20 min- it may give incorrect results !

RESULT INTERPRETATION



PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 100%
- ✓ Clinical Specificity: 99.7%
- ✓ Analytical Sensitivity (Limit of Detection): 0.5 ng/mL

M/s: **ubio Biotechnology Systems Pvt Ltd. Plot No: 15A, Biotechnology Zone, KINFRA Hitech Park, Kalamaserry, Cochin, Kerala - 683503, INDIA.**