

## Instructions for Use

Version: 1.1.1  
Revision date: 20-May-24

# Hepatitis B Virus Surface Antigen (HBsAg) Rapid Test Kit

**Catalog No.:** abx090708

**Size:** 100 tests

**Storage:** Store all reagents at 2-30°C. Keep dry.

**Application:** For qualitative detection of HBsAg in human serum, plasma, or whole blood.

### Introduction and assay principle

Abbexa's HBsAg Rapid Test Kit is based on the gold immuno-chromatography assay (GICA) principle. The sample pad inside the cassette contains gold nanoparticles coated with Mouse anti-HBsAg antibodies. HBsAg antibodies are coated in the test region on a nitrocellulose membrane, creating the test line, and Goat anti-Mouse IgG antibodies are coated on the control line. Any HBsAg present in the samples combines with the colloidal gold particle-conjugated HBsAg antibodies on the sample pad, forming a complex, which then binds to the HBsAg antibodies in the test region. When the concentration of HBsAg in the sample is more than the detection limit, there is a color change in the detection line and the result is positive. When the concentration of HBsAg in the sample solution is less than the detection limit, there is no color change in the detection line and the result is negative. The control region on the upper end of the cassette confirms if the test has been successful.

#### Kit Components (100 tests)

- Test cassettes: 100
- Pipettes: 100
- Sample diluent: 4 vials

#### Material Required But Not Provided

- Timer
- Centrifuge
- Blood collection tubes
- Paper towel (or similar)
- Soap and clean water

### Sample preparation

- **Serum:** Samples should be collected into a serum separator tube. Coagulate the serum by leaving the tube undisturbed in a vertical position overnight at 4°C or at room temperature for up to 1 hr. Centrifuge at approximately 1000 × g for 20 mins. If precipitate appears, centrifuge again. Assay immediately or aliquot and store between 2-8 °C for short-term storage (up to 5 days) or -20 °C for long-term storage.
- **Plasma:** Collect plasma using EDTA, citrate or heparin as an anticoagulant. Centrifuge for 15 mins at 1000 × g, within 30 mins of collection. If precipitate appears, centrifuge again. Avoid hemolytic samples. Assay immediately or aliquot and store between 2-8 °C for short-term storage (up to 5 days) or -20 °C for long-term storage.
- **Whole blood (venipuncture):** Collect whole blood using EDTA, citrate or heparin as an anticoagulant. Assay immediately or store between 2-8°C for up to 24 hours. Do not freeze whole blood samples.
- **Whole blood (fingerstick):** Wash hands thoroughly with soap and water. Ensure fingertips are clean and dry. Using a lancet, press against the fingertip to puncture. Use a clean paper towel or similar material to wipe off the first drop of blood. Gently massage the finger from knuckle to fingertip to allow a second drop of blood to form. Immediately collect 1 drop (approximately 40-50 µl) of blood and assay immediately.

### Assay procedure

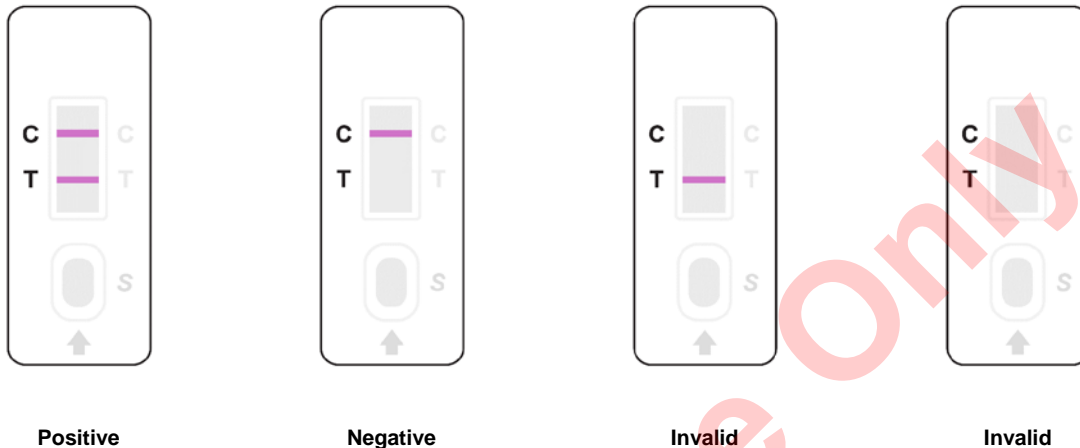
1. Take a test cassette and lay it flat on a clean table.
  - Whole blood samples: Add 1 drop (approximately 40-50 µl) of whole blood sample to the sample well on the test cassette.
  - Serum and plasma samples: Using the provided pipette, add 1 drop (approximately 35-45 µl) serum or plasma sample to the sample well on the test cassette.
2. Add 1 drop (approximately 40 µl) of sample diluent to the sample well on the test cassette. Start the timer.
3. Leave at room temperature for 15 min, then analyze the result. The result is invalid if read after 20 min.

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### Results analysis

- **Positive result:** A colored line is observed in both the control (C) section and the test (T) section.
- **Negative result:** A colored line is observed in the control (C) section but not the test (T) section.
- **Invalid result:** No colored line is observed in the control (C) section.



### Notes

1. The test cassettes should be brought to room temperature before use.
2. After opening the aluminum foil, use the test cassette as soon as possible.
3. Fresh samples are recommended. Frozen samples should be brought to room temperature slowly and mixed gently before use. Avoid repeated freeze/thaw cycles, bacterial pollution, visible particles; and avoid cloudy, hemolytic, turbid, or viscous samples.
4. Do not mix or re-use the disposable pipettes to avoid cross-contamination.
5. Avoid touching the cassette membrane through the sample well or test result window.
6. This kit is for qualitative detection of HBsAg in human serum, plasma, or whole blood samples. For other sample types, a preliminary experiment is recommended to determine compatibility with this kit.
7. A negative result does not preclude the possibility of exposure to or infection with Hepatitis B Virus (HBV).
8. This kit does not cross-react with serum positive for any of the following: Dengue Virus, HAV, HCV, HIV, Syphilis, TB, H. pylori, ANA, HAMA, RF ( $\leq 2500$  IU/ml).
9. The following substances at the stated concentrations do not interfere with the assay: Bilirubin (20 mg/dL), Creatine (442  $\mu\text{mol/L}$ ), Glucose (55 mmol/L), Albumin (50 g/L), Salicylic Acid (4.34 mmol/L), Heparin (3000 U/L), EDTA (3.4  $\mu\text{mol/L}$ ), Human IgG (1000 mg/dL), Sodium Citrate (3.8%).
10. This kit is for research use only and the results are for reference only. It is recommended to use this kit in conjunction with another detection method.
11. Use personal protective equipment (PPE) such as lab coats and disposable gloves when handling samples and kit reagents. Thoroughly wash hands after performing the assay.
12. All waste should be disposed appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.
13. Limit of detection: 0.5 ng/ml.