Hepatitis B Surface Antigen Cassette Rapid Test

(Serum/Plasma)

INTENDED USE

The HBsAg One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in serum or plasma. For professional in vitro diagnostic use only.

INTRODUCTION

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. revious designations included the Australia or Au antigen 1. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute orchronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus. The HBsAg One Step Rapid Test is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimens. The test utilises a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

PRINCIPLE

The HBsAg One Step Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a coloured line.

The presence of this coloured line in the test region indicates a positive result, while its absence indicates a negative result.

To serve as a procedural control, a coloured line will always appear in the control line region indicating that the proper volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The HBsAg One Step Rapid Test containing anti- HBsAg particles and anti-HBsAg coated on the membrane.

MATERIALS SUPPLIED

1.Test device 2 Pipette dropper 3.Desiccant 4.Buffer 5.Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C.

If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re- use under any circumstances.

SPECIMEN COLLECTION

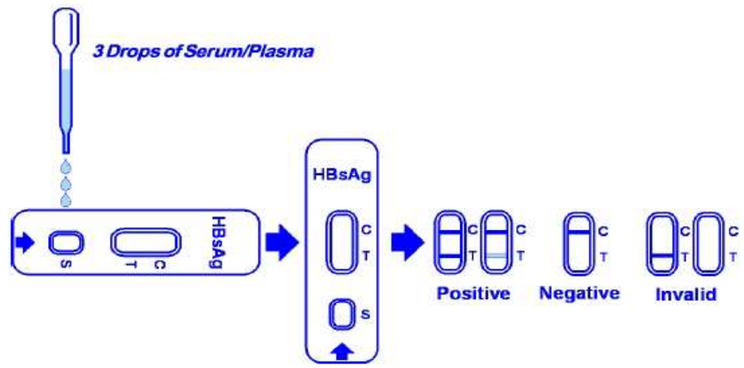
1. The HBsAg One Step Rapid Test can be performed using either serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non- haemolysed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below - 20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation of etiologic agents.

TEST PROCEDURE

Allow the test, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 75 µl) and start the timer. Avoid air bubbles. See illustration below.
3. Wait for the coloured line(s) to appear. Read results in 15 minutes. *Do not interpret the result after 15 minutes.*

INTERPRETATION OF RESULTS



Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

Negative: One coloured line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that a positive control (containing 10 ng/mL HBsAg) and a negative control (containing 0 ng/mL HBsAg) are sourced from a local competent authority and tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The HBsAg One Step Rapid Test is for in vitro diagnostic use only. This test should be used for the detection of HBsAg in serum or plasma specimen.

2. The HBsAg One Step Rapid Test will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.

3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

4. The HBsAg One Step Rapid Test cannot detect less than 1 ng/mL of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HBsAg One Step Rapid Test has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg One Step Rapid Test. The test can detect 5ng/mL of HBsAg in 15 minutes, and 1 ng/mL of HBsAg in 20 minutes.

Specificity

Antibodies used for The HBsAg One Step Rapid Tests were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg One Step Rapid Test was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

HBsAg Reference Method

Method		EIA		Total Results
HBsAg Test Device	Results	Positive	Negative	
	Positive	245	5	250
	Negative	2	240	242
Total Results		247	245	492

Relative sensitivity: ＞97.8%

Relative specificity: 98.0%

Accuracy: 98.6%

REFERRENCE

1. Blumberg, B. S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7: 223