

## HBsAg

### A rapid one step test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in serum or plasma.

**IVD** For In-Vitro diagnostic and professional use only



Store at 2-30 °C

#### INTENDED USE

The Atlas human Hepatitis B Virus Surface Antigen (HBsAg) is intended for the qualitative determination of HBsAg in human serum, plasma.

#### INTRODUCTION

Hepatitis B is a liver disease caused by the hepatitis B virus. Most infected persons develop chronic, long-term Hepatitis B and are at risk for cirrhosis (scarring of the liver) and liver failure. Hepatitis B is regarded as one of the most serious disease of the six detectable hepatitis disease.

#### PRINCIPLE OF THE ASSAY

The HBsAg Rapid Test Dipstick is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the Dipstick. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

#### MATERIALS

##### MATERIALS PROVIDED

1. Test Strips (Contain anti-HBsAg coated on the membrane).
2. Package insert.

##### MATERIALS NEEDED BUT NOT PROVIDED

The following materials are required but not provided in the kit:

1. Specimen collection container.
2. Timer.
3. Centrifuge to process a plasma specimen.
4. Protective gloves.

#### STORAGE OF ASSAY KIT AND INSTRUMENTATION

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Strip is stable through the expiration dated printed on the sealed pouch.
- The test Strip must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Don't use beyond the expiration date.

#### SPECIMEN COLLECTION AND PREPARATION

1. HBsAg One Step Hepatitis B Surface Antigen Test Strip (Serum/Plasma) can be performed using either serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Assay should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum, plasma Specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20°C. Collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection
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 or corresponding national regulations covering the transportation of etiologic agents.

#### PRECAUTIONS AND WARNINGS

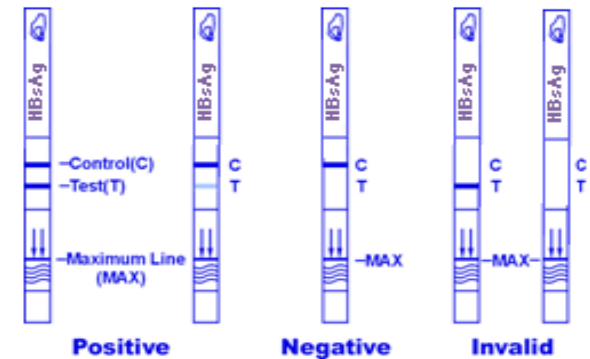
1. For in vitro diagnostic use only.
2. Handling of reagents, specimens should be in accordance with local safety procedures.
3. Do not smoke, drink, eat or apply cosmetics in the working area. Do not pipette by mouth. Use protective clothing and disposable gloves.
4. Wash hands after operations.
5. Wipe and wash the splashed specimen with highly effective disinfectant.
6. Used specimens, Test strips and materials that may

be contaminated should be disposed of Avoid splashing and the formation of smog.

7. Do not reuse expired assays.
8. Use unpacked Test strips as soon as possible to avoid being humidified.

#### ASSAY PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test Strip from the sealed pouch and use it as soon as possible.
2. Identify the test strip for each specimen or control.
3. With arrows pointing toward the specimen, immerse the test strip vertically in the serum or plasma specimen for at least 10-15 seconds. Occur. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
4. Place the test strips on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 15 minutes. It is important that the background is clear before the result is read.  
Do not interpret the results after 30 minutes.



#### INTERPRETATION OF RESULTS

**Positive:** Observe the two colored lines (bands), the control line in the control ("C") region of the test membrane, and the test line in the test ("T") region of the membrane.

**Negative:** Only one purplish red colored band appears on the control region.

**Invalid:** Neither purplish red test band nor purplish red control band appears. The specimen should be tested again using a new strip.

#### LIMITATIONS

1. The HBsAg Rapid Test Dipstick is for professional in

vitro diagnostic use only. The test should be used for the detection of HBsAg in serum or plasma specimen. Neither the quantitative value nor the rate of HbsAg concentration can be determined by this qualitative test.

2. The HBsAg Rapid Test Dipstick 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 Rapid Test Dipstick cannot detect less than 1ng/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. Result does not at any time preclude the possibility of HBV infection.

#### QUALITY CONTROL

A procedural control is included in the test. A colored 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 10ng/ml HBsAg) and a negative control (containing 0ng/ml HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

#### PERFORMANCE CHARACTERISTICS

##### Sensitivity

The HBsAg Rapid Test Dipstick (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300ng/ml. All 10 HBsAg subtypes produced positive results on The HBsAg Rapid Test Dipstick (Serum/Plasma). The test can detect 1 PEI ng/ml of HBsAg in serum/plasma.

##### Specificity

Antibodies used for the HBsAg Rapid Test Dipstick (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Dipstick (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

Method	ELISA		Total Results	
	Results	Positive		Negative
HBsAg Rapid Test Cassette(Serum/Plasma)	Positive	241	2	243
	Negative	0	359	359
Total Results		241	361	602

#### Precision

##### Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing 0ng/ml, 1ng/ml and 5ng/ml of HBsAg. The negative and positive values were correctly identified 98% of the time.

##### Inter-Assay

Between-run precision has been determined by using the same three specimens of 0ng/ml, 1ng/ml and 5ng/ml of HBsAg in 15 independent assays. Three different lots of the HBsAg Rapid Test Dipstick(Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 98% of the time.

#### Cross-reactivity

The HBsAg Rapid Test Dipstick (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity


#### Interfering Substances

















The HBsAg Rapid Test Dipstick (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.

In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

#### REFERENCES:

Blumberg, B.S. *The Discovery of Australian Antigen and its relation to viral hepatitis*. Vitro. 1971; 7: 22

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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry