

**One step rapid HBsAg strip Test for detection of Hepatitis B (HBsAg) in human Serum/Plasma**

**For In-Vitro Diagnostic Use only**

**ORDER INFORMATION**

Pack Size	REF
	Device
25 Tests	HBSS 25
50 Tests	HBSS 50

**CLINICAL SIGNIFICANCE**

Hepatitis B surface antigen ("Australis Antigen") consists of lipid, carbohydrate and protein elements. The protein moiety provides a marker for identification of chronic and infectious HBV infections. Hepatitis B is transmitted sexually or intravenously and has an incubation period of six months. If not diagnosed properly and in time, it can develop into acute or chronic infection, liver cirrhosis and fulminant Hepatitis. This test is very useful for screening blood donors, to find out whether they are HBsAg positive before collection of blood.

**PRINCIPLE**

ACCUCARE® ONE STEP HEPATITIS B Ag Strip Test utilizes the principle of immunochromatography, a unique assay based on antigen capture or sandwich principle. The method uses monoclonal antibody conjugated to colloidal gold and polyclonal antibodies immobilized on nitrocellulose membrane in thin line. The test sample flows through the membrane assembly of the test and formed the colored monoclonal anti-HBsAg colloidal gold conjugate complexes with the HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by a polyclonal anti-HBsAg coated on the membrane leading to formation of a pink-purple colored band. The formation of first purple band (T zone) confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-rabbit IgG coated on the membrane at the control region, forming a pink-purple band. This control band serves to validate the test results.

**CONTENTS**

Strip Test  
Instruction for Use (IFU)  
Desiccant

**STORAGE & STABILITY**

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. **DO NOT FREEZE.**
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

**PRECAUTIONS**

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.

4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

**LIMITATIONS**

1. Though ACCUCARE® ONE STEP HEPATITIS B Ag Strip Test is a reliable screening assay, it should not be used as a sole criterion for diagnosis of Hepatitis B infection.
2. The ACCUCARE® ONE STEP HEPATITIS B Ag Strip Test will only indicate the presence or absence of Hepatitis B surface antigen in the specimen and other consideration like clinical symptoms should be noted before making final diagnosis.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or CLIA analysis. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Interference due to heterophile antibodies, RF (Rheumatoid Factors) and other non-analyte substances in high titer in patient's serum express erroneous analyte detection in immunoassays interferences. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interferences.
5. Most positive results develop within 15 minutes. However, certain sera samples may take longer time to flow. Do not read results after 20 minutes.

**SPECIMEN COLLECTION & PREPARATION**

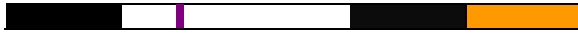
1. The ACCUCARE® ONE STEP HEPATITIS B Ag Strip Test can be performed using either serum or plasma.
2. Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have 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, it should be packed in compliance with federal regulations for transportation of etiologic agents.

**PROCEDURE FOR TEST DEVICE**

1. Collect serum/plasma in a clean test tube (approximately 0.5-1 ml may be required). Ensure that only sufficient quantity of the specimen is collected to allow submerging the colored area on the dipstick (about 1cm high).
2. Open the pouch, remove the dipstick and place it on a flat surface. (Once opened, the dipstick must be used immediately)
3. Dip the dipstick in serum/plasma specimen submerging only the colored area.
4. The dipstick should be left submerged for the entire duration of the test ensuring only the colored area is submerged in the specimen.
5. Read the results at the end of 15 minutes as follows.

### INTERPRETATION OF RESULTS

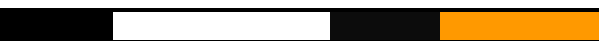
**NEGATIVE:** Only one pink to deep purple colored band appears on the dipstick.



**POSITIVE:** Two distinct pink to deep purple colored bands appear on the dipstick.



**INVALID:** The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new dipstick.



### SENSITIVITY

One Step HBsAg Strip Test can detect Hepatitis B antigen in serum or plasma in a concentration as low as 1.0 ng/ml

### INTERFERING SUBSTANCES

No interference in the ACCUCARE® ONE STEP HBsAg STRIP TEST was evident when the following substances were tested:

Sample Type	Number of Samples Tested	Positive	Negative
Clinical Specimens	100	01	99
Pregnant women	100	01	99
Other disease Samples*	100	00	100

\*Other disease Samples: These are the samples that potentially interfere with HBsAg immunoassays. Details of the samples are as follow:

Sample Type	No. of Sample Tested
HCV Positive	20
HIV Positive	20
Syphilis Positive	15
Anti-HAV Positive	15
Rubella Positive	15
Anti-HTLV Positive	15
<b>Total</b>	<b>100</b>

### PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP HEPATITIS B Ag Strip Test has been evaluated with positive and negative samples confirmed by ELISA examination.













Specimen	Positive	Negative	Sensitivity
Positive	300	00	100 %

Specimen	Positive	Negative	Specificity
Negative	09	1446	99.38 %

### BIBLIOGRAPHY

1. Ruben, E. (1979) Acute and chronic viral hepatitis. Federation Proceedings. 28:2665.
2. Magnus, L.O., et al. (1975) new antigen-antibody system. Clinical significance in long-term carriers of Hepatitis B surface antigen. J. American Medical Association. 231: 356.

### GLOSSARY OF SYMBOL

	Consult Instruction for Use		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged