ACCUCARE™

ONE STEP HBsAg STRIP TEST

(Serum/Plasma)

Strip Test for detection of Hepatitis B (HBsAg) in Serum or Plasma
Only for *In Vitro Diagnostic* Use

ORDER INFORMATION

REF	CONT
HBSS 50	50 Tests

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, 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.
This test is intended for professional use as an aid on the diagnosis of hepatitis B. HBsAg Test can identify HBsAg in plasma or serum specimens with a high degree of sensitivity. The sensitivity of the test is 1 ng/ml (ad/ay) by using laboratory control.

PRINCIPLE

One step test for HBsAg 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 strip in thin line. As the test sample flows through the membrane assembly of the test device, the colored polyclonal 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 monoclonal anti-HBsAg antiserum 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.

KIT COMPONENTS

Test Strips in sealed bottle and Product Insert.

STORAGE AND STABILITY

The sealed bottle can be stored 2-30°C till the expiration date printed on the sealed pouch. DO NOT FREEZE.

PRECAUTIONS

1. Handle all specimens as if they contain infectious agents.
2. Wear protective disposable gloves when specimens are being tested.
3. The Device is sensitive to Humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Dispose all the samples and kit properly as per the instruction after test in accordance in GLP
5. Read the instructions carefully before performing the test.

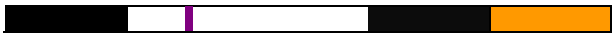
SPECIMEN COLLECTION & PREPARATION

1. Remove the "Strip" from its sealed bottle and recap immediately.
2. Dip the strip vertically till to sample flow on observation area
3. The strip should dip up to max level indicate on the strip
4. Remove the Strip from the tube & lay it on a flat surface.
5. Allow reaction to occur in next 15-20 minutes.
6. The test should be read between 15-20 minutes after dipping the specimen in the samples.

DIRECTION FOR USE

7. Remove the "Reaction Strip" from its foil wrapper by tearing along the "splice".
8. Dip the strip vertically till the max level indicated on the strip for 10 sec. in the serum/plasma tubes.
9. Remove the Strip from the tube & lay it on a flat surface.
10. Allow reaction to occur in next 15-20 minutes.
11. The test should be read between 15-20 minutes after dipping the specimen in the samples.

INTERPRETATION OF RESULTS



NEGATIVE: Only one pink to deep purple coloured 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

LIMITATION

1. Though One Step HBsAg Strip Test is a reliable screening assay, it should not be used as a sole criterion for diagnosis of Hepatitis B infection.
2. The 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. Interference due to heterophile antibodies, RF (Rehumatoid Factors) and other nonanalyte 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.
4. Most positive results develop within 15-20 minutes. However, certain sera samples may take longer time to flow. Do not read results after 30 minutes.

BIBLIOGRAPHY

1. Ruben, E. (1979) Acute and chronic viral hepatitis. Federation Proceedings. 28:2665.
2. Magnius, 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.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 .Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com