HBsAg CARD

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC08

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

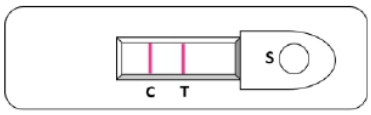
INTENDED USE: Test for detection of Hepatitis B (HBsAg) in human serum and plasma samples.

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.

PRINCIPLE

HBsAg card 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 strip in thin line. As the test sample flows through the membrane assembly of the test device, the coloured 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 antiserum coated on the membrane leading to formation of a pink-purple coloured band. The formation of first purple band (T zone) confirms a positive test result. Absence of this coloured 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 Device, Sample Dropper and Instructions for use.

PRECAUTIONS

1. Handle all specimens as if they contain infectious agents.
2. Wear protective disposable gloves when specimens are being tested.
3. Dispose all the samples and kit properly as per the instruction after test in accordance in GLP
4. Read the instructions carefully before performing the test.

STORAGE & STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

Fresh Serum or Plasma: If testing is not performed within 3 days of collection of specimen, the specimen should be refrigerated immediately at 2-8°C.

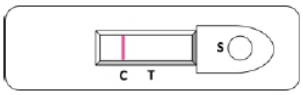
TEST PROCEDURE

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

1. Remove the test device from the foil pouch and use it as soon as possible.
2. Add 2-3 (50-60 µL) drops of serum in sample well "S" using the dropper provided.
3. Allow reaction to occur in next 15-20 minutes.
4. The test should be read between 15-20 minutes after addition of serum samples.
5. Do not interpret the results after 30 minutes.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:
Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative



POSITIVE RESULT:
In addition to the coloured line in the control region a clearly distinguishable pink purple coloured line also appears in the test region 'T' (Test line) indicating a positive result and that the sample contains Hepatitis B Antigen. A difference of intensity may occur between the lines in the test region and the test region but this does not affect the interpretation of the result.

INVALID TEST:
If no line appears in the control as well as the test region, the test should be repeated with fresh card.

SENSITIVITY

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

QUALITY CONTROL

Although the testing device contains an internal quality control (coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

LIMITATIONS

1. Though HBsAg Card 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 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.
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.

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

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ISO 13485 : 2003
GMP
CE