Ana-Chek® HEPATITIS B Ag RAPID 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/Plasma.

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

Ana-Chek® HBsAg Rapid Card 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.

KIT COMPONENTS

Test Device, Sample Dropper and Instructions for use.

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.

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

1. The Ana-Chek® HBsAg Rapid Card 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 hemolysed 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.

TEST PROCEDURE

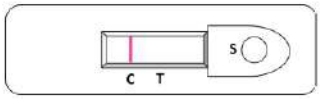
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing

1. Remove the test device from the aluminum 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 device on a clean and flat surface. Carefully dispense 2-3 drops (50-60 µl) of Serum/Plasma in the sample well "S" using the dropper provided.
3. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF THE RESULTS

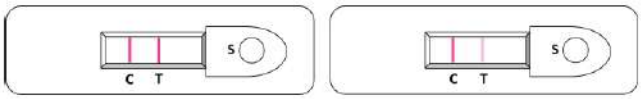
NEGATIVE RESULT:

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



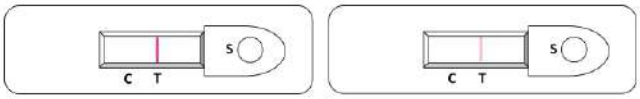
POSITIVE RESULT:

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.



INVALID TEST:

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



NOTE: The intensity of the color band in the test line region will vary depending on the concentration of Hepatitis B Antigen present in the specimen. However, neither the quantitative value nor the rate of increase in Hepatitis B Antigen can be determined by this qualitative test.

LIMITATION OF PROCEDURE

1. Though Ana-Chek® HBsAg Rapid Card is a reliable screening assay, it should not be used as a sole criterion for diagnosis of Hepatitis B infection.
2. The Ana-Chek® HBsAg Rapid Card 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 (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.
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. interpreted with caution.

INTERFERING SUBSTANCES

No interference in the Ana-Chek® HBsAg Rapid Card was evident when the following substances were tested:

Sample Type	Number of sample tested	Positive	Negative
Clinical Specimens	100	1	99
Pregnant Women	100	1	99
Other disease samples*	100	0	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
Total	100

PERFORMANCE CHARACTERISTICS

The Ana-Chek® HBsAg Rapid Card has been evaluated with positive and negative samples confirmed by ELISA examination.

Specimen	Positive	Negative	Sensitivity
Positive	300	0	100%

Specimen	Positive	Negative	Sensitivity
Positive	9	1446	99%

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.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care & WhatsApp: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

ISO 9001: 2015
ISO 13485: 2016
GMP
CE