PATHKITS

SIMPLE HBsAg

Product Code: **PKRK012**
Kit Contents (**25 Kits**)
Shelf Life: 24 Months

Kit Components	Quantity (Units)
Test cassettes	25
Sample Dropper	25
IFU	1

Introduction

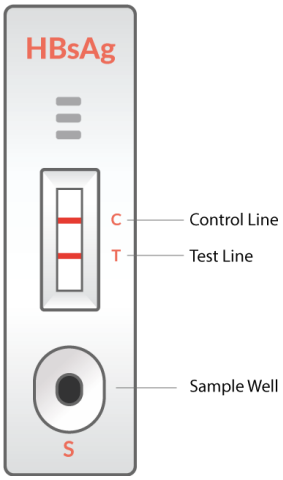
Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). Hepatitis B is a major global health problem that causes chronic infection and puts people at high risk of death from cirrhosis and liver cancer (1). Hepatitis B virus is a partially double stranded DNA virus which belongs to Genus *Orthohepadnavirus* of family *Hepadnaviridae* (2). According to WHO estimation 296 million people were living with chronic hepatitis B infection in 2019, with 1.5 million new infections each year while 820000 deaths due to Liver cirrhosis and hepatocellular carcinoma (primary liver cancer) caused by Hepatitis B virus [1]. The hepatitis B virus (HBV) is transmitted through blood and infected bodily fluids. It can be passed to others through direct contact with blood, unprotected sex, use of illegal drugs, unsterilized or contaminated needles, and from an infected woman to her new born during pregnancy or childbirth (3). Hepatitis B symptoms are Abdominal pain, Fever, joint pain, loss of appetite, Weakness fatigue, yellowing of skin and the whites of your eyes(4).

Intended Use

Simple HBsAg one step hepatitis B surface antigen test Device (Serum/Plasma) is a rapid chromatographic Immunoassay for the qualitative detection of Hepatitis B surface Antigen in serum or plasma.

Principle

Simple HBsAg Rapid test card is one step test for HBsAg utilizing the principle of agglutination of antibodies with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly of the device after addition of the sample, the colored colloidal gold conjugate of the Agglutinating antibodies for HBsAg complexes with the HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by another Agglutinating antibodies for HBsAg coated on the membrane leading to formation of a pink-purple colored band which 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 Agglutinating antibodies for Rabbit globulin coated on the membrane at the control region, forming a pink-purple band.



The control band formation is based on the 'Rabbit globulin / Agglutinating antibodies for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signals independent of the analyte concentration. This control band serves to validate the test performance.

Warnings and Precautions

1. Read these instructions for use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the negative and positive controls in the same manner as patient specimens.

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11. The test results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 15–20-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e., an electric fan or strong air-conditioning.
13. Specimen with extremely high concentrations of red blood cells, fibrin should be re-centrifuged before use

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

Specimen Collection and Handling

Specimens to be tested should be obtained and handled by standard methods for their collections.

1. **Serum:** Allow the blood to clot, then centrifuge to separate the serum.
2. **Plasma:** Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and 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.
4. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Materials Required but not provided

1. Timer or Stopwatch.
2. PPE and other consumables for collection and disposal of samples.

Limitations

1. Though Simple HBsAg Rapid test is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.
2. Interference due to heterophile antibodies, Rheumatoid factors and other nonanalytic substances in a patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies.
3. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
4. Do not compare the intensity of the test lines and the control lines to judge the concentration of HBsAg in the test specimen.
5. Since various tests of HBsAg differ in their performance characteristics and antibody composition, their reactivity patterns may differ.
6. Testing of pooled samples is not recommended.
7. If negative or questionable results are obtained and HBV infection is suspected, the test should be repeated on a fresh serum specimen.

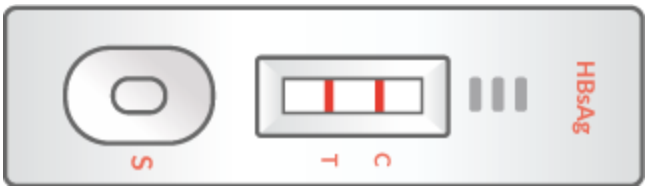
Test Procedure

1. Bring the kit components and specimen to be tested to room temperature before testing.
2. Open the test card from the pouch prior to use and place it on a flat and dry surface. The test should be performed immediately after removing the test card from the pouch.
3. With the help of a dropper provided, put 2 drops (Approx.50µl) of serum/plasma into the sample well. Avoid overflowing.
4. Let the reaction proceed until the appearance of the positive line and control line or up to 20 minutes.
5. Read results within 20 minutes. Strong positive reactions may be visible within 5 minutes.

Interpretation of results

Positive Results

If a distinct pink-purple line is formed at the test zone marked 'T' (test line) and the control zone marked 'C' (control line) the test result is positive, indicating that the sample contains Hepatitis B Antigen. The interpretation of test result (+ve for hepatitis) remains unchanged even if there is a difference in intensity of colour positive line as is many a times found.



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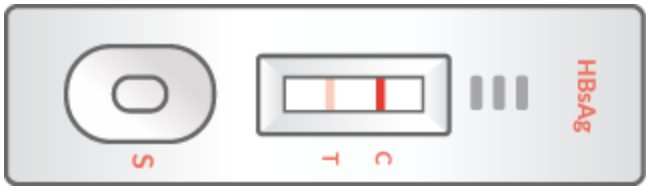
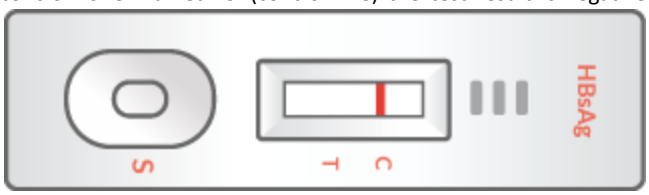
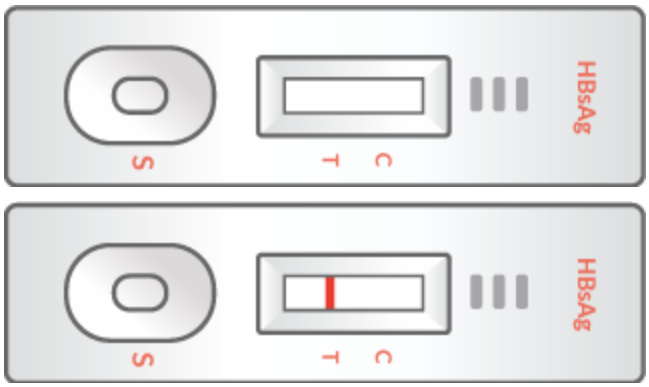


Negative Result: If a distinct pink-purple line is formed only at the control zone marked 'C' (control line) the test result is negative.



Invalid Results

Control line does not appear in the Control (C) region. If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Quality Control

Internal procedural controls are included in the test. A Colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume.

References

1. https://www.who.int/news-room/fact-sheets/detail/hepatitis-b
2. Ryu, W.S., 2016. *Molecular virology of human pathogenic viruses*. Academic Press.
3. Elhassen, K.E.H. and Elhag, W.I., Sero prevalence of Hepatitis B Virus among patients attending Dental Clinics in Khartoum state Sudan.
4. Bruss, V., 2007. Hepatitis B virus morphogenesis. *World journal of gastroenterology: WJG*, *13*(1), p.65.

Technical Assistance

For customer support, please contact our Technical Support:
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सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2021/000068

Endorsement No. 7

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 4th Floor, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:HBsAg test kit Model No.:NIL Intended Use:It is a visual, rapid, sensitive and accurate one step immunoassay for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in Human Serum or Plasma. The assay is intended to be used as an aid in the recognition and diagnosis of acute infections and chronic infectious carriers of the Hepatitis B Virus (HBV). Class of medical device:Class D Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE HBsAg test kit

Place:

Date28-Jun-22

VENUGOPAL G SOMANI

Central Licensing Authority

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb2557[illegible]ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.06.29 11:00:21 +05'30'