Laboquick HBsAg TEST

Laboquick HBsAg Test User's Manual
One step quick test aimed at to detect HBsAg in Serum or Plasma.
Hepatitis B surface antigen Cassette Test. Only for professional use.
Product Code: LBAG.01

Intended Use
Laboquick HBsAg test, is used as a diagnostic device aimed at qualitative detection of the hepatitis B antigen (HBsAg) on the immunochromatographic basis in the human blood serum/plasma.

Summary
The most common cause of the acute hepatitis is a virus. Like all the other viruses that cause hepatitis, the hepatitis B virus (HBV) constitutes the most serious type of this disease. Hepatitis B is an infection disease caused by hepatitis B virus (HBV). This virus which is a DNA virus has three antigenic structures. The hepatitis B surface antigen (HBsAg) that formerly known as Australian Antigen, presents on the outer part i.e. on the sheath of the virus. Furthermore there are two important antigenic structure in the center part of the virus that called nuclecapsid. These are the hepatitis B central antigen (HBcAg) an hepatitis B antigen (HBeAg). Incubation period the Hepatitis B virus varies between one to six months. In case of detecting HBsAg positive in the serum during at least for a six month period, it can be said that the chronic HBV infection exists. The Hepatitis B can cause various between slightly noticeable infections to the very severe liver diseases such as cirrhosis and primary hepatocellular carcinoma (liver cancer). Hepatitis B virus places it's own genetic material in to the liver cells thus provides fertility by the liver cells' routine schizogenetic mechanism. Human body immune system start to attack it's own liver cells those contain the genetic material of the virus. In other words the virus indirectly damages the liver. Constant attacks of the immune system result in damage and death of the liver cells. Hepatitis B can be transmitted by blood products, dental treatment, sexual intercourse, sharing the needle in intravenous drug use or tattooing, acupuncture and piercing with contaminated tools or from mother to the child in birth. Hepatitis B is the most common infection disease on the world and it is the ninth cause of that on entire globe. At least 350 million of people are the chronic vector of the disease. Geographic distribution of the disease varies very different regions with very different numbers on the world.

Test Principle
The HBsAg test device consists of a sample window including a sample ped that the serum/plasma is dripped on it. Sample ped is held by a permeable membrane. The membrane consists of three antibody areas. The first one of these areas is mobile and the others are stable. The mobile area includes monoclonal antibodies and color sensitive colloidal gold particles. The stable area that forms the test line forms the stable area on the membrane. The third area that forms the control line includes a anti-mouse immunoglo bulin. The serum/plasma sample starts to move on the membrane and If the sample includes enough HBsAg antigen in the sensitivity range of the device, anti HBsAg forms a compound with colloidal gold conjugate and moves towards to the test area that indicated by the letter "T". Then the compound enclosed in this area and thereupon a line is formed in the area "T". Since the line in this area is related to the HBsAg presence in the sample, it is evaluated with the line in the test area and the absence or the presence of this line shows a negative or a positive test result. The colloidal gold particles those are not enclosed in the test area move towards to the control line area and successfully enclosed in the section "C" in order to form control line regardless to the presence of HBsAg. Finally the line that formed in this area acts as a control device by showing that there is enough sample in the device and the sample followed the correct flow course.

Package Contents
HBsAg testing device, disposable plastic pipette, silica gel bag as humidifier.

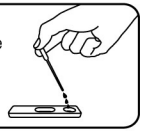
Storage Conditions
The HBsAg testing device must be stored between +2 to +30°C and must not be frost. Under these conditions, the device work stably until the expiry date that printed on the packaging unless the package is opened.

Warnings and Cautions
1. Read the instructions before use.
2. The device is for in diagnostic usage and it is disposable.
3. Do not ever freeze the tests. If the test was stored in a refrigerator, wait the product reaches to the room temperature before use. The test must be carried out in room temperature (between +15 ... +30°C).
4. Do not use a test after expiry date.
5. Only human blood serum or plasma can be used as a sample. Do not use navel cord blood because this blood prevents the movement of the colloidal gold and can cause messing up on the results.
6. Observe carefully the number of drops. Only 2-3 drops must be dropped on the test.
7. After removing the testing device from it's package, use it immidietaly.
8. If the package is torn, the device must not be used.
9. If the collected samples are frozen, they must not re-frozen after thawing.
10. The serum and plasma samples that contains high amounts of fibrin and erythrocyte must be centrifuged before use.
11. If both the test and control lines are very weak, dilute the sample about the rate 1:10 with PBS and retry the test with a new laboquick HBsAg test.
12. To prevent mixing between samples, use a different disposable sample pipette for each test.
13. To prevent the contamination possibility disposable gloves must be use while working with the material that potentially contains viruses during the test. Severe attention must be taken about not contacting the potentially infectious material with mouth, face, eyes and open wounds.
14. During the test, no cosmetic application must be done, no liquids or food must be consumed and do not smoke.
15. Spattering and evaporation of the samples must be prevented during test.
16. Getting the most successful results depends on fulfilling the test protocol. Dropping the sample with a pipette in appropriate dimensions, application temperature and timing are very important for the results.
17. All the steps must be taken after the start of the test procedure.
18. Do not use the samples containing hemolytic, lipaemic or bacteria. These kinds of samples can cause false results.

Test Usage Procedure

1. Test device must be on room temperature.
2. Remove the test from the package just before starting the test.
   Place the test on a flat surface.

3. Drop 2 - 3 drops of (75µl) serum/plasma sample in to the sample cavity.
   Any air bubble occurrence must be prevented.



4. The test results can be read after 10-20 minutes.
5. Any lines that occurs after 20 minutes do not have any quality for diagnosis and any lines that occurs after 20 minutes must be ignored.

Evaluating the results

6.

NEGATIVE

A single line that occurs on the section above the letter "C" in the result window indicates a negative result.

POSITIVE

Two lines that occur on the both sections above the letters "C" and "T" in the result window indicate a positive result.

INVALID

If there are no lines on the result window after the predetermined waiting period, the result is invalid. The test must be re-done with a new device.

Sample for Test
Fresh human serum or plasma sample will be used for this test.

Preparing The Sample For Test
In order to obtain the serum/plasma sample for the test, a blood sample is taken into a dry and clean vial and left for clotting. Then the serum is separated from the blood sample by centrifuging 15 minutes on 5000 RPM under room temperature. The separated serum must be stored between +2 to +8°C unless it will be used. If it is necessary to store the sample more than three days, the sample must be frozen under -20°C or below.

Sensitivity
The Laboquick HBsAg cassette test can detect the HBsAg virus in the sample with the ratio of 0.5ng/ml.

Specificity
The specificity of the Laboquick HBsAg test is defined as 99.9%.

Test Limitations
1. HBsAg tes can not be used alone for diagnosis. This test can only be used to display the HBsAg presence in the sample taken. Evaluation process of the results must be carried out by an expert with the support of other examinations.
2. The blood samples that taken must not be taken from any open wound or in another body fluid in order to make the test valid.
3. Test can give false reactive results in patients with an autoimmune liver disease.
4. The test device gives the best result in room temperature. Since the samples that frozen and thawed many times can include chunks, they may block the test device. As a result of this, the sample which can not move freely in the test device leaves a dark colored trail behind. Hence this makes the test results difficult to read.
5. Completing the test successfully depends on abiding to the user's manual, skipping any condition that written in the manual can cause faulty results.
6. Dropping more than 2 – 3 drops on to the sample cavity of the device can cause faulty results.

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