

Laboquick HBsAb TEST

Laboquick HBsAb Test User's Manual

One step quick test aimed at to qualitative detection of Hepatitis B surface antibody (HBsAb or anti - HBs) in serum or plasma. Only for professional use.
Product Code: LBAB.01

Intended Use

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

Summary
Viral hepatitis basically is a systematic disease that effects liver. Cause of many acute viral hepatitis diseases are hepatitis A, hepatitis B (HBV) and hepatitis C viruses. The grift antigen on the HBV surface called as HBsAg. HBsAg presence in the serum or plasma is the indicator of the effective acute or chronic hepatitis B disease. HBsAb which is the antibody of the HBsAg cannot be detected in 3 to 6 months after the patient infected with the virus. This antibody is accepted as the indicator of the HBV disease. According to the researches, it is understood that especially the newborn babies are infected with hepatitis B. It is determined that the immune systems of the 5 - 15% of the individuals who have strong immune systems either produce very low amounts of antibodies against the HBV virus or have no reaction against it.

Test Principle
The HBsAb 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 test line section of the membrane is coated with HBsAg. During the testing phase, serum or plasma sample interacts with the HBsAb coated particles and forms a colored line. The presence of a line on this section indicates a positive result as well as an absence of a line at the same places indicates a negative result. For control of the testing operation, on the control line section, a colored line always will be present to prove that sufficient amounts of sample have been used and the membrane has been absorbed that sample.

Package Contents
HbsAb (anti - HBs) Testing Device, Disposable plastic drip, Silica Gel bag as humidifier.

Storage Conditions
The HBsAb 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 just for outer body diagnosis.
 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 degrees).
 4. Do not use a test after expiry date.
 5. Only human blood serum or plasma can be used as a sample.
 6. After removing the testing device from it's package, use it immediatly.
 7. If the package is torn, the device must not be used.
 8. If the collected samples are frozen, they must not re-frozen after thawing.
 9. To prevent mixing between samples, use a different disposable sample dosimeter for each test.
 10. 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.
 11. During the test, no cosmetic application must be done, no liquids or food must be consumed and do not smoke.
 12. Getting the most successful results depends on fulfilling the test protocol. Dripping the sample with a dosimeter in appropriate dimensions, application temperature and timing are very important for the results.
 13. All the steps must be taken after the start of the test procedure.

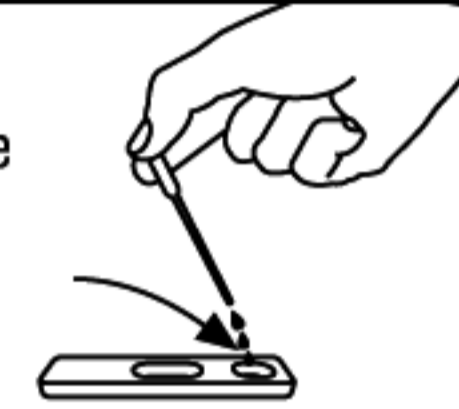
Test Usage Procedure

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 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 15 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. The line in the testing section can be weak according to the HBsAb concentrations.

Evaluating the results



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



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



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. To prevent the laking in the blood taken, the serum or plasma must be separated without delay. Only clean, bright and not laked samples must be used. 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 HBsAb cassette test can detect the HBsAb antibodies in the sample with the ratio of 10miu/ml. The relative precision is determined as 99%.

Specificity
The relative specificity of the Laboquick HBsAb test is defined as 98.7%.

Test Limitations

1. HBsAb test can not be used alone for diagnosis. This test can only be used to display the HBsAb 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. 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.
4. Completing the test successfully depends on abiding to the user's manual, skipping any condition that written in the manual can cause faulty results.

- References**
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