Laboquick ANTI- HIV 1/2 TEST

ANTI - HIV 1/2 test USER GUIDE Manual
One step rapid test for detection HIV 1/2 antibodies in serum or plasma.
Only for professional use.
Product Code: LBHV.01

Intended Use
Anti - HIV 1/2 Cassette Test is a 4th generation test which used as a diagnostic device aimed for qualitative detection of the Anti - HIV 1/2 antibodies on the immonochromatographic basis in the human serum / plasma.

Summary
Type 1 human immunodeficiency virus (HIV-1) and type 2 human immunodeficiency virus (HIV-2) are the etiologic agents of the acquired immunodeficiency syndrome (AIDS). According to the obtained data, HIV virus can be contaminated by sexual intercourse, exposing to the infected blood products (including infected syringes and needles) or to the baby from mother during pregnancy. Detecting the HIV 1 / 2 antibodies in the system means the system exposed to the HIV 1 / 2 viruses in a while.
This test is a device that aimed at to detect the HIV 1 / 2 antibodies in human blood serum or plasma. It is only aimed at revealing the antibodies that produced by the immune-system against the HIV 1 / 2. In case of getting a positive result, the result must be confirmed with other tests, such as western blot and Eliza. This fast test device is also highly specific against to the HIV1 and HIV2 antibodies. Since the HIV antigens are being used as gripper in the test device, it can detect any HIV antibody class.

Test Principle
The Anti-HIV 1 / 2 test is based on immunochromatographic principle. The test device includes a sample cavity which forms the material that makes the reagent move. Sample ped is held by a permeable membrane. The membrane consists of three areas. The first area includes colored colloidal gold composition which becomes more sensitive with HIV antigens and this area is the one that becomes mobile by interacting with the dropped sample. The second area is the one that contains recombinant HIV antigens. (Test line).The third area (control line) also includes stable control antibodies on the membrane. If there are HIV antibodies in the sample, the HIV antigen forms a compound with colloidal gold conjugant. Then this compound is held by the test line and a red line appears as a result. Uncombined colloidal gold particles continue their capillary movement until they come across with the control line on the membrane. They are held at this point to form the control line and as a result of this a red control line occurs which means the test result is valid.

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

Storage Conditions
The Anti - HIV testing device must be stored between +2 to +30°C and shouldn't frozen. Under these conditions, the device work stably until the expiry date that printed on the packaging unless the package is opened.

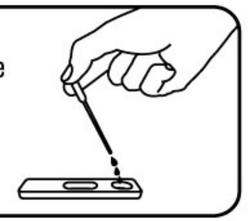
Warnings and Cautions
1. Read the instructions before use.
2. The device is just for in vitro diagnostic use and it is disposable.
3. Never freeze the tests. If the test was stored in a refrigerator, wait the product reaches to the room temperature before use. The test must be carried out in room temperature (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 drops of sample must be dropped on the test.
7. After removing the testing device from it's package, use it immediately.
8. If the package is torn, the device must not be used.
9. To prevent mixing between samples, use a different disposable sample pipette for each test.
10. Read the positive test results at the latest in 10 minutes and the negative results in 20 minutes. The results that taken after 20 minutes must be ignored.
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. Dropping the sample with a pipette 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.
14. 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 drops of (10µl) serum/plasma sample in to the sample cavity.
Any air bubble occurrence must be prevented.



4. Positive results can be read at least in 10 minutes and likewise the negative result in 20 minutes.

5. Do Not Interpret Result After 20 Minutes

Evaluating the results

NEGATIVE

A single line that occurs on the section above the letter "C" in the result window indicates a negative result. This indicates that the sample does not include antibodies against the HIV virus.

POSITIVE

6. Two lines that occur on the both sections above the letters "C" and "T" in the result window indicate a positive result. This indicates that the sample includes antibodies against the HIV virus.

INVALID

If there are no lines on the result window after the predetermined waiting period, the result is invalid. The test procedure could be carried out wrongly or the test can be malfunctioned. The test must be repeated with a new device.

Sample for Test
Fresh human serum or plasma sample must 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.

Precision
The precision of the Laboquick Anti – HIV cassette test was determined as 100%.

Specificity
The specificity of the Laboquick Anti – HIV cassette test was determined as 99%.

Test Limitations
1. Getting a negative test result, does not remove the possibility of being infected with HIV 1 / 2 or carrying the virus.
2. 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.
3. The aim of this device is never to make a certain diagnosis. The results of this device must certainly supported by the experts with additional diagnostic methods.

References

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