Laboquick ANTI SYPHILIS TEST

Laboquick Anti - Syphilis Test User's Manual

One step rapid test aimed at to detect the Syphilis (Treponema Pallidum) antibodies in serum or plasma.
Only for professional use.
Product Code: LBSY.01

Intended Use
Laboquick anti – syphilis cassette test, is used as a diagnostic device aimed at qualitative detection of the Treponema Pallidum antibodies on the immunochromatographic basis in the human serum or plasma.

Summary
Syphilis is a well know sexually transmitted disease ever since the early ages which caused by the bacteria named as Treponema Pallidum and it can effect many organs unless it is treated. It is known as pox among the public. The disease mainly transmitted by sexual intercourse. In the early stages of the disease the infection can be transmitted from an open wound by contacting with the geni tal or lip mucosa. Few and far between this disease can be transmitted from open wound of an infected person to an open wound of an health person. This shows that how contagious is the bacteria. Treponema Pallidum can also transmitted by blood transfusion. %70 percent of the pregnant women who has syphilis, transmit the bacteria to the baby and the %25 of these infected babies are born dead or die because of premature birth. Approximately after 3 weeks that the Treponema Pallidum enters the system, ulcerated lesions that called cankers occur. The antibodies that produced by the system against the bacteria that causes syphilis can be detected after 4 – 7 day of the occurrence of the cankers and they remain detectable unless the disease treated sufficiently. The anti - syphilis test qualitatively detects the Treponema Pallidum antibodies (IgG and IgM) by using the two pieces antigen combinations consisted of syphilis antigen coated particles and syphilis antigens that fixed on the membrane.

Test Principle
Laboquick Anti - Syphilis test device is a qualitative and membrane based product that aimed at to detect Treponema Pallidum antibodies (IgG and IgM) in the human serum or plasma. In the operation principle of this test, the recombinant syphilis antigen is stable in the test line section. After adding the sample from the device's sample cavity, the sample gets into the reaction with the syphilis antigen coated particles that exist in the device. This mixture continues it's movement and interacts with the syphilis antigen by moving chromatographically along the device. Two pieces antigen testing method can detect both IgG and IgM antibodies. If there are Treponema Pallidum antibodies in the sample, a colored line that indicates a positive result will be occurred in the test section. In case of the lack of the related antibodies in the sample, there will not be any line in this section and this results in the evaluation of 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
Anti – Syphilis testing device, disposable plastic pipette, silica gel bag as humidifier.

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

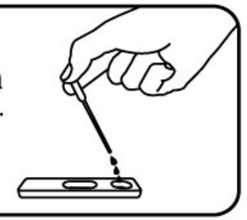
Warnings and Cautions
1. Read the instructions before use.
2. The device is just for in vitro diagnostic use.
3. Never freeze the tests. If the test was stored in a refrigerator, wait the product reaches to the room temperature before use. The test must be carried out in room temperature (between +15 – +30 degrees).
4. Do not use a test after expiry date.
5. Only human blood serum or plasma can be used as a sample.
6. Observe carefully the number of drops. Only 2 drops of serum or plasma must be dripped 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 dosimeter for each test.
10. Read the positive result at latest at 10 minutes. The results that taken after 30 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. 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. Drip 2 drops of serum/plasma sample in to the sample cavity.



4. The test results can be read after 10 minutes.

5. Any results that occurs after 30 must be ignored.

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 Syphilis 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 include antibodies against the Syphilis 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^{0}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^{0}C or below.

Sensitivity
The relative precision of the laboquick Anti – Syphilis test cassette is determined as %99.7

Specificity
The relative specificity of the Laboquick Anti – Syphilis test cassette is determined as %99.6

Test Limitations
1. This test is only for in-vitro use and it is used to detect the Treponema Pallidum antibodies in human serum or plasma. This test gives qualitative results and it can not be used to detect the increase in the levels of the related antibodies or quantitative detection of the antibody levels.
2. The aim of the anti – syphilis testing device is only to detect the Treponema Pallidum antibodies in the sample taken. It never has the aim to make a certain diagnosis or prognosis. The results of the device must be evaluated by the experts with additional diagnosis and prognosis methods.
3. If the symptoms are still present even the result is negative, other tests must be taken with different clinical methods. A negative result does not negate the risk of getting infected or carrying the bacteria.
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.

References

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