# Laboquick ANTI-HCV TEST

**Anti – HCV USER GUIDE manual**
One step test aimed to detect Hepatitis C Antibodies in the serum or plasma
Only for professional use.
Product Code: LBHC.01

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

**Summary**
Hepatitis C virus is a sheathed virus including single coil RNA and belongs to the Flaviviridae family. HCV is the primal agent of the non-A and non-B hepatitis which transmit parenterally and the main cause of the acute and chronic hepatitis all around the world. Generally it is transmitted parentally like as hepatitis B. Predominantly it is transmitted by the infected blood and blood products transfusion. Intravenous drug use and transmitting to the baby from infected mother during the pregnancy can be accepted as other ways of infection. HCV can also be transmitted with sexual intercourse. Since the viral load of the HCV is low, the period of the exposure is necessary to be longer than the other contamination ways. Sexual intercourse is essential with the chronic disease vectors and in these cases the saliva can be the main infection source. HCV - RNA is frequently detected in the semen of the infected. Therewithal it is easier to take the HCV by sexual intercourse from the HCV positive persons. In the end, the total virus amount and the presence of the HCV infection is essential for sexual transmission. Anti-HCV test is a 4th generation which consists envelope, NS3, NS4, NS5 antigen double sandwich immunoassay coating can detect HCV in 14 - 30 days after antibodies started to produced.Anti-HCV cassette test is a device that qualitatively detects the antibodies that produced against the HCV virus in the serum or plasma taken. This test is only a scanning test that is used to detect the HCV antibodies. A certain diagnosis can not be given by means of the results of this test. Additional diagnosis methods must be used.

**Test Principle**
The Anti-HCV 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 HCV antigens and this area is the one that becomes mobile by interacting with the dripped sample. The second area is the one that contains recombinant HCV antigens. (Test line). The third area (control line) also includes stable control antibodies on the membrane. If there are HCV antibodies in the sample, the HCV 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 HCV testing device, disposable plastic pipette, silica gel sachet as humidifier.

**Storage Conditions**
The Anti - HCV testing device must be stored between +2 to +30ºC and should not be frozen. Under these conditions, the device work stably until the expiry date that printed on the packaging unless the package is opened.

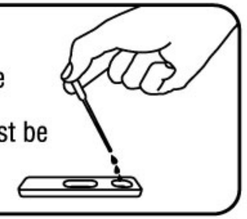
**Warnings and Cautions**
1. Read the instructions before use.
2. The device is for in vitro diagnostic usage and it is disposable.
3. Do not ever freeze the tests. If the test was stored in a refrigerator, wait the product reaches to the room temperature before use. The test must be carried out in room temperature (between +15 – +30 degrees).
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 of sample 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 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. Dripping the sample with 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.

## Usage of the test device

1. Test device must be at 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 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. Results that occurred after 20 minutes. Shouldn't taken into consideration.

**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 has no antibodies against the HCV virus.

6.


**POSITIVE**

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 has antibodies against the HCV 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 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 +8ºC unless it will be used. If it is necessary to store the sample more than three days, the sample must be frozen under -20ºC or below.

**Sensitivity**
The sensitivity of the Laboquick Anti – HCV cassette test was determined as 99,5%. Test also can detect HCV Antibodies as low as 1 NCU/ml level.

**Specificity**
The specificity of the Laboquick Anti – HCV cassette test was determined as 99,8%.

**Test Limitations**
1.Getting a negative test result, does not remove the possibility of being infected with HCV or carrying the virus.
2.The test device gives the best result in room temperature. Since the samples that are 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**

1. Di Bisceglie AM. Hepatitis C.Lancet 1998; 251: 351-355
2. Dienstag J. Sexual and perinatal transmission of hepatitis C.Hepatology 1997; 26 (suppl 1): 66-70
3. Doldur Ç. Genel cerrahi hastalarında anti-HCV prevalansı, Ankara: 1999
4. Nelson DR, Marousis CG, Davis GL, et al. The Role Of Hepatitis C Virus Specific Cytotoxic T Lymphocytes In Chronic Hepatitis C. J Immunol 1997; 158: 1473-1481
5. Wilson RA. Viral hepatitis. New York 1997: 239-259
6. Cayper, H.T.M Wiakel, I.N. Vander Poel (1971) J. Of hepatology 13, 5, 15
7. Halfon, Retal (1997) J. Medical Virology 52:391 – 395
8. Sarin, S.K. & Hess G.(1998) Transfusion associated Hepatitis
9. Sayers, M.H.& Gretch DR. (1993) J Transfusion 30, 809 - 13



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