

# Laboquick HELICOBACTER PYLORI ANTIBODY TEST

## Helicobacter Pylori Antibody Test Instructions

### Intended Use:

Laboquick Helicobacter pylori antibody (HP Ab) cassette test is used as a diagnostic tool to detect qualitative immunochromatographic helicobacter pylori antibody (HP Ab) in serum/plasma. One step, quick test to determine helicobacter pylori in serum/plasma. Helicobacter pylori antibody cassette test for professional use. Product Code: LHAB.01

### Introduction:

The gastritis and peptic ulcers are one of the most common infections seen in people. Once the helicobacter pylori bacterium was discovered, it was confirmed as the major reason of the ulcer and stomach cancers in many reports. Even if the certain role of h. pylori has not been determined yet, eliminating h. pylori is suggested to finalize the ulcer disease. The detection of certain IgG antibodies occurred against the h. pylori is accepted as a correct method to determine h. pylori infection of symptomatic patients. However it is also possible to observe h. pylori in some of asymptomatic patients.

### Test Principle:

Helicobacter pylori test is based on the immunochromatographic principle. The test device has a sample hole made of the material enabling the reagent to proceed. The sample pad is held by the permeable membrane. The membrane that constitutes the test device has been formed ultimately once the helicobacter pylori antigens are passed through the test band space as well as the monoclonal antibodies specific to helicobacter pylori passed through the front cover.

Helicobacter pylori antibody takes part in the end section of buffer membrane contenting the colloidal golden resultant. In case IgG antibodies specific to helicobacter pylori are present in the patient serum/plasma, the colloidal golden resultant proceeds together with the patients serum by using the mixture form of chromatographically antigen- antibody-antigen golden particles towards test space (T) in order to form a visible line. Thus, a visible line appearance in the T space confirms the positive result in the detection of IgG antibodies specific to helicobacter pylori. Otherwise, this visible line shall not appear. Unless this visible line is seen in T space, the result is negative related to the IgG antibodies specific to helicobacter pylori. However, there is a color line every time in the control space (C). This control line is a procedural indicator. It confirms that the sufficient sample solution is dropped, the sample expands in the test properly and reagent is under control.

### Package content:

Helicobacter pylori test device, disposable plastic pipette and silica gel bag as humidifier.

### Storage Conditions:

The test must be stored between +4° to +30°C and must not be frozen. The test kit will provide valid results under these conditions provided that it is used prior to the expiry date and the package has not been opened.

### Warnings and Cautions:

The following should be taken into consideration to get the correct results;

- 1-Before use, read the instructions carefully,
- 2-The device is just for in vitro diagnostic use.
- 3-Never freeze the tests. If the test is stored in the refrigerator, you should provide the test to have the room temperature before use. The test should definitely be done under room temperature ( between 15.....30°C degree)
- 4-Do not use the expired products.
- 5-Use only serum or plasma acquired from the human blood as the sample. Do not use the umbilical cord blood because it prevents the movement of colloidal golden structure thus leads to confusion in the test result.
- 6-Observe the number of drops to be added carefully. Remember to add only 3-4 drops in the test.
- 7-Use the test device immediately after unpackaged.
- 8-If the package of the test is damaged or torn, do not use the test device.
- 9-If the collected samples are frozen before, they should not be frozen again after dissolved.
- 10- The serum or plasma samples contenting high levels of fibrin and erythrocytes should be centrifuged before use.
- 11- In case both the test and control lines are appeared very slightly, dilute the sample in rate of 1:10 with PBS and repeat the test by using a new Laboquick H. pylori test.
- 12- In order to prevent any confusion between the samples, one disposable dropper should be used for each test.
- 13- To prevent any conterminous effect to people and environment, disposable gloves should be used while dealing with the material contenting the virus potentially during the test. The material having any infection possibility should be avoided from any contact to mouth, face, eye and any open scar on skin.
- 14- During the test, any cosmetics should not be used; any food or beverage should not be consumed and smoking should be avoided

15- Prevent the possibility of any leaping of samples or producing the steam during the test.

16- It should be remembered that the best results can only be obtained depending on the proper conformance to the instructions. Sample dropping should be done by the dropper in proper size, the test application temperature and timing are very important for the results.

17- Once the test procedure starts, every step should be taken uninterruptedly.

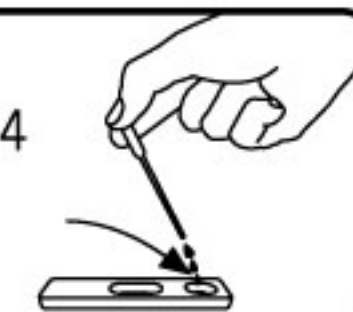
18- Do not use any sample contenting hemolytic, lipaemic and bacterium, otherwise the test results can be acquired incorrect.

### Instructions:

1 Test device should be provided at room temperature.

2 Remove the test from package and place it on a straight surface.

3 Drip the serum/plasma sample of 3-4 drops into the sample hole.



4 Test results can be read within 10-20 minutes.

5 Any result to be read after 20 minutes shall have no effectiveness thus should not be taken into consideration.

### Results Evaluation:



The indication line taking part at the section marked with "C" in the result display confirms the NEGATIVE result.



Two indication lines taking part at the sections both marked with "C" and "T" confirms the POSITIVE result.



If any line as not appeared in the result display until the end of the testing time, the test is invalid. The test should be repeated.

### Sample to be used for the test:

The human serum or plasma sample should be used for this test.

### Sample Collection:

The sample of the blood is taken on a clean, dry and sterilized vial to acquire the serum/plasma to be analyzed. Then, it is allowed to be clotted. The serum is separated from the blood sample in a centrifuge with the cycle of 5.000 RPM for 15 minutes under room temperature. If the serum is not used instantly, it should be kept under 2-8 C degree. For longer periods i.e. 3 days or more, it should be frozen under -20 C degree or below.

### Test Limits:

1- Only Laboquick Helicobacter pylori test can not be used to diagnose the disease. This test can only be used to detect the presence of helicobacter pylori in the sample. The test results should definitely be supported by the supplement diagnosis and diagnostic methods with the expert comments.

2- In order to deem the test valid, the blood samples should not be taken from any open wound or any other body fluid.

3- Test device gives the best result under room temperature. Since the samples which are frozen and dissolved for many times can content some granules inside, they can block up the test device thus the sample that can not have a free motion inside the test device shall leave a dark colored stain therefore the results shall not be read easily.

4- The most productive completion of the test is depending on full conformance to the instructions. Otherwise the results may lead to faults.

5- More than 3-4 drops is applied on the sample hole of the test device can lead to faulty results.

### References:

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