

Laboquick HELICOBACTER PYLORI ANTIGEN TEST

Helicobacter Pylori Antigen Test Instructions

Intended Use:

Laboquick Helicobacter pylori antigen cassette test is used as a diagnostic tool to detect qualitative immunochromatographic helicobacter pylori antigen (HP Ag) in stool.

One step, quick test to determine helicobacter pylori in stool.

Product Code: LHAG.01

Introduction:

Helicobacter pylori is a gram-negative bacterium that causes inflammation of the stomach lining. The results of affection by this bacterium may lead to the chronic gastritis and is strongly linked to the development of duodenal and gastric ulcers and stomach cancer. Unfortunately the helicobacter pylori disease is commonly observed and the infection has been founded in the population by 40-50% in the developed countries and 80-90% in developing countries. A number of techniques are also improved to detect the helicobacter pylori bacterium.

Urea breath test is one of these techniques. It can be numbered various different types of commonly used techniques to detect the helicobacter pylori infection. Some of them can be defined as the detection of the stains such as Giemsa staining procedures specific to Helicobacter pylori through the antral endoscopic biopsy, biopsy culture methods and rapid urea test. These methods can only be applied with the professional laboratory equipment by the qualified technical personnel in laboratory atmosphere. The culturing method is also requiring longer times to get the result. The serologic approaches detects the reaction of patient's immunologic system against the disease however these approaches prevent the specialist to distinguish an active infection or the passed infection. In addition, antibody titer does not change in the course of treatment. The antigen detection of helicobacter pylori infection in stool can determine all isotypes of existing organism in the stool sample.

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 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 golden resultant. In case the helicobacter antigens are present in the patient's stool, it dissolves in the solution included in the sampling bottle then proceeds 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 helicobacter pylori. Otherwise, this visible line shall not appear. Unless this visible line is seen in T space, the result is negative. 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, 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 5.....30°C degree)
- 4-Do not use the expired products.
- 5-Observe the number of drops to be added carefully. Remember to add only 3-4 drops in the test.
- 6-Use the test device immediately after unpackaged.
- 7-If the package of the test is damaged or torn, do not use the test device.
- 8- During the test, any cosmetics should not be used; any food or beverage should not be consumed and smoking should be avoided.
- 9-Prevent the possibility of any leaping of samples or producing the steam during the test.
- 10-It should be remembered that the best results can only be obtained depending on the proper conformance to the instructions.
- 11-Once the test procedure starts, every step should be taken uninterruptedly.

Instructions:

- 1 Unpackage the aluminum bag of test device by tearing as shown.

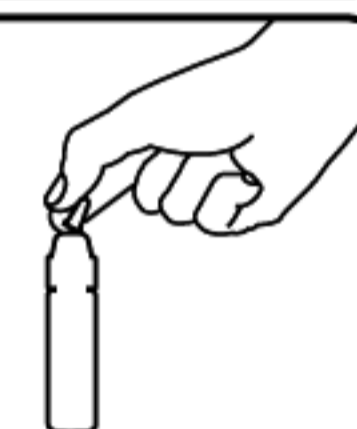


- 2 For sample collection check the sample collection part.

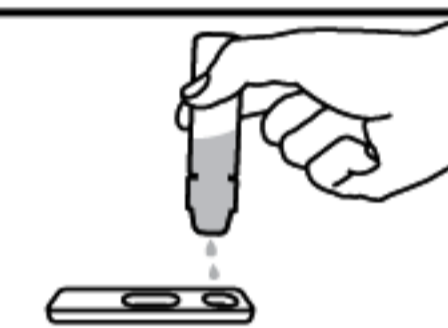
- 3 Shake the sampling bottle thoroughly.



- 4 Be sure that the sampling bottle is at the vertical direction in the manner that the top part is correctly positioned, then break off the plastic cover carefully.



- 5 Put 3-4 drops from the sample solution into the dropping hole as shown in the picture.



- 6 Read out the test results after 5-10 minutes. Do not take the results in to consideration after 15 minutes.

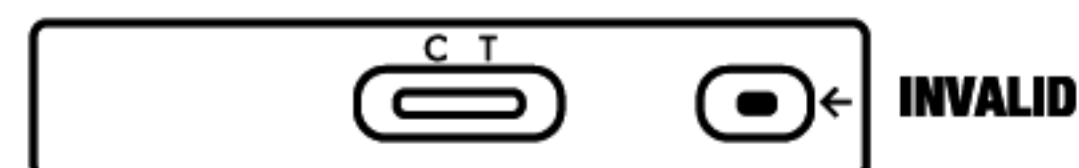
Results Evaluation:



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 Collection:

Collect the sample of stool into the sampling device in the package of the test. Loosen the top part of sampling device and take the test stick out and take the samples from three different parts of the stool. Then place the stick into the sampling bottle and fasten strictly. If the sample is not analyzed instantly, keep it under 4°C degree. At the time of the test to be done, the sample should be brought to the room temperature.

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 case the defects continue even if the test results are found negative, other various tests should be done by using the other clinical methods. Any result seen as negative does not remove the risk and possibility of helicobacter pylori infection. The sole using purpose of the
- 3- Test device gives the best result under room temperature
- 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 4-5 drops is applied on the sample hole of the test device can lead to faulty results.

References:

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