

BEFORE PERFORMING THE TEST, PLEASE READ THESE INSTRUCTION CAREFULLY

Helicobacter Antigen Fecal Test

Rapid test for the detection of Helicobacter pylori antigens (bacteria) in feces.
Medical device for self-testing

INTRODUCTION

Helicobacter Antigen Test is a rapid test for the detection of H. pylori antigens in the feces. The principle of this test is based on antigen-antibody reaction. Applied to the test membrane, in the production process, the monoclonal anti - H. pylori antibodies react with H. pylori bacteria present in the feces sample. The test result is read in the form of colored lines on a cassette after 10 minutes.

CONTENTS

The package includes equipment necessary to perform one test for the presence of Helicobacter pylori antigens in the feces:

- » 1 sealed aluminum bag, containing: 1 cassette test and 1 desiccant
- » 1 container with a diluent and applicator to collect feces samples
- » 1 instruction for use

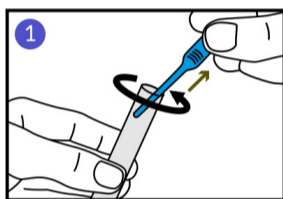
Prepare a watch that will be needed to measure the time of reading the test result, and hygienic tissue helpful in breaking off the tip of the container to collect feces samples.

IMPORTANT NOTES CONCERNING COLLECTION OF FECES SAMPLE FOR TESTING

- » Feces for testing can be collected at any time of the day to any container, previously thoroughly washed and dried
- » Feces sample should not be taken while taking antibiotics, proton pump inhibitors or bismuth preparations, as these measures inhibit the excretion of bacteria H. pylori.
- » Performed the test immediately after collection of feces. Do not leave the feces samples at room temperature for a long time.

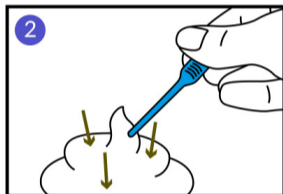
Test must be performed in strict compliance with the instructions below:

If the test was stored at 2 - 8°C, for half an hour before the test you should remove it from the refrigerator and bring its temperature to room temperature.



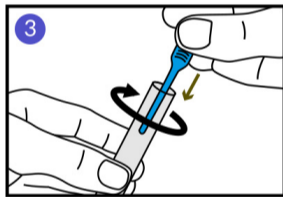
COLLECTION OF FECES SAMPLE FOR TESTING

» Pick up the feces sampling container so that the blue cap is on top and the white one at the bottom. Remove the blue cap and using the applicator placed in the cap collect feces sample. ❶

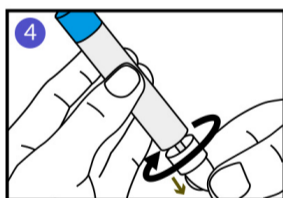


» To collect feces sample for testing "screw" the tip of the applicator at three different places of the tested feces, to a depth of approximately 1 cm. It should be noted that the feces must cover the surface of the applicator only a thin layer. ❷

Note: Too much feces on the applicator which is later introduced into the container with a diluent may give invalid test result.



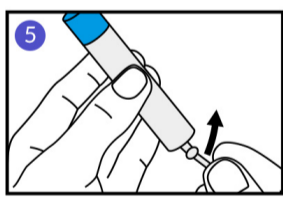
» Place the applicator with collected feces sample back into the container with a diluent, tightly screw the cap ❸ and shake vigorously to mix thoroughly.



TEST PERFORMANCE

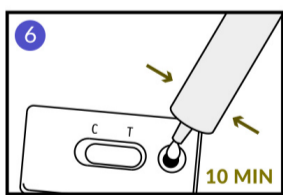
» Remove the cassette test from aluminum bag and place it on a level surface. In the bag there is also a desiccant, which must be thrown into household garbage.

The test should be completed within an hour.



» While holding the sampling container as before (blue cap at the top, white cap at the bottom) unscrew this time the white cap that secures the tip of the container against accidental breakage. ❹

» Shake the container vigorously to thoroughly mix the feces sample with diluent. Then, grab the tip of the container through the hygienic tissue and break it. ❺



» Squeezing the container wall place **3 full drops** of the solution on the round window of the test plate. During the dripping, do not touch the tip to the test plate. ❻ **Start time measurement.**

Read the test result after **10 minutes**. Strongly positive results can be read earlier.

Do not take into account the result obtained after a period longer than 20 minutes.

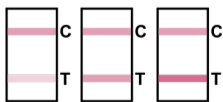
Pour the rest of the sample liquid from the container into the toilet and rinse it with water. After the reading of the test result, throw the test and empty container into the household garbage.

INTERPRETATION OF TEST RESULTS



Negative result

In the result window there appears only one line: control line C. The test line T does not appear.
 Helicobacter pylori bacteria was not detected in the test sample.

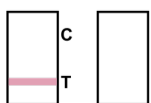


Positive result

In the resulting window, there are two stained pink lines: control C and test T.
 Helicobacter pylori bacteria was detected in the test sample.

The color intensity of the test line T does not matter. The test T line may be weaker, the same or stronger than the control line C.

Even a very weak T line should be interpreted as a positive test. In the tested sample occult blood was found



Invalid result

In the resulting window no line appears or only test line T. In this case, the interpretation of the test result is not possible and the test should be repeated with a new sample of feces and using a new test.

PRECAUTIONS

- » Test is for external use only.
- » Helicobacter Antygen Test package should be stored at 2-30°C. Do not freeze.
- » Do not use the test kit after the expiry date shown on the packaging.
- » Do not use the test if the bag is damaged, because the moisture from the air can damage the test.
- » The test is intended for single use only.
- » Dispose of the used test like any other household waste.
- » Keep the test out of the reach of children.

FREQUENTLY ASKED QUESTIONS

Who should perform the test to detect antigens of Helicobacter pylori?

This test should be performed by those who notice gastrointestinal ailments. Due to the nature of the sample, the test is particularly suitable for performing in children. Helicobacter Antygen Test is also recommended to assess the effectiveness of medical therapy conducted to remove bacteria from the body. In this case, the test should be made no earlier than 4-5 weeks after the end of treatment. To evaluate the effectiveness of the cure the antibody detection tests (e.g. Helicobacter Test) should not be used because detectable levels of these antibodies is maintained for at least a year after full recovery.

What does negative Helicobacter Antygen Test result mean?

A negative result means that the test has not detected the Helicobacter pylori bacterium in a feces sample. Taking antibiotics, proton pump inhibitors or bismuth preparations inhibits the excretion of H. pylori. Therefore, negative results obtained during or shortly after treatment can be unreliable. In such cases, the test should be performed at least 4-5 weeks after treatment completion.

If, in spite of a negative test result, complaints from the digestive system persist, you should see your family doctor.

What does positive Helicobacter Antygen Test result mean?

A positive test result means that in the sample of feces there are H. pylori antigens. The presence of these antigens indicates current infection with the Helicobacter pylori bacterium. However, in order to make a definitive diagnosis and begin possible treatment, see your family doctor.

Are the results of Helicobacter Antygen Test reliable?

The result obtained using the Helicobacter Antygen Test is reliable if the instruction for use and the time of reading the test result are carefully observed.

What does the line that appears at letter C on a test plate mean?

It is the control line. The appearance of a colored stripe at letter C indicates that the test is working properly, as well as the test is done properly.

Should the line that appears at the letter T be as strong as the control line C

The line that appears at the letter T does not have to be as strong as the control line C. Test line T can be stronger or weaker than the control line C. Even if the test line T is very weak, the test result should be interpreted as positive.

To summarize: if the result window shows two lines (control and test), regardless of their intensity, the test result should be interpreted as positive.

Will the test continue to be reliable after more than 20 minutes?

No. The test result should be read within 10 minutes from the addition of a diluent, and the result is reliably maintained up to 20 minutes.

What is the diagnostic sensitivity and specificity of the test?







Research carried out in comparison with the endoscopic method proves that the relative sensitivity and relative specificity of the test is above 99,9%. As good results obtained by using monoclonal antibodies specific for H. pylori.

Date of the last revision of the instruction: 20.06.2022

Version 8 BS_AT/EN

SYMBOLS

CE 1434

	Read the instructions carefully before performing the test		Only for in vitro diagnostics
	For single use only		Store at room temperature 2-30°C
	Lot number		Expiration date



Manufacturer:

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