

BEFORE PERFORMING THE TEST, PLEASE READ THESE INSTRUCTION CAREFULLY

Helicobacter blood Test

Test for the detection of specific antibodies against Helicobacter pylori bacterium in finger blood sample.

Medical device for self-testing.

INTRODUCTION

The Helicobacter Test detects specific antibodies that appear in human body in response to Helicobacter pylori infection. The test is performed with blood from a finger. The test result is read in the form of colored lines at the time of 5 minutes.

CONTENTS

Package contains the equipment necessary to perform one test:

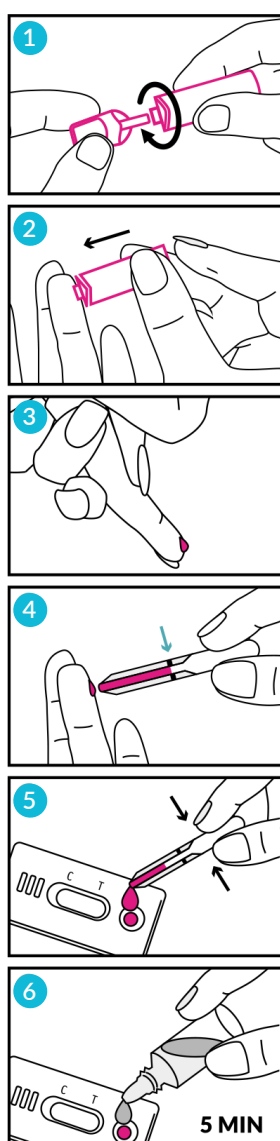
- » 1 sealed aluminum bag, containing: 1 cassette test and 1 desiccant
- » 1 dropper container with a diluent
- » 1 sterile lancet
- » 1 plastic pipette
- » 1 instruction for use

The test should be removed from the plastic bag immediately prior to testing. Desiccant present in the package should be discarded in household garbage.

Before the test, prepare a means to disinfect the fingertip (e.g. cotton swab with 70% alcohol), a piece of paper towel and watch that you will need to measure the time of reading the test result.

IMPORTANT NOTES PRIOR TO TESTING

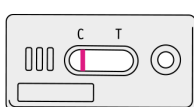
- » If the test was stored at 2 - 8°C, for half an hour before the test you should remove it from the refrigerator and bring its temperature to room temperature.
- » Wash your hands with soap and warm water (to increase the blood supply to the finger that will be pricked) and dry them thoroughly.
- » It is not required to perform the test on an empty stomach.
- » Test must be performed in strict compliance with the instructions below.



TEST PERFORMANCE

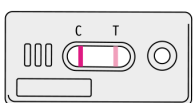
- » Remove the cassette test from the plastic bag and place it on an even clean surface. The bag also contains the desiccant which should be disposed of to the household garbage. Test must be performed within an hour.
- » Remove from the box the sterile lancet intended for pricking the finger and the small, plastic pipette intended for collection the blood.
- » **Gently massage the pricked finger for a minimum of 30 seconds (usually the middle or third finger are pricked).**
- » Disinfect the fingertip, which you will prick. After disinfection wait 30-60 seconds for complete drying of the skin.
- » Remove the cap by twisting it by 90°. ❶ Lancing device is ready for use.
- » Place the lancet by its open part to the lateral part of the fingertip so that it adhered to it and push it until you hear a distinctive "click". ❷ Finger was pricked.
- » Lower the hand with pricked finger to form a large and full drop of blood. You can also press the pricked finger several times on both sides as shown in the drawing. ❸
- » Holding pipette in a horizontal position, bring its tip to the drop of blood. **Do not squeeze the pipette, or fingertip.** Under the influence of capillary forces the blood will flow to the pipette. Hold the pipette close to the drop until blood fills it up to the black line. Avoid air bubbles. ❹
- » Squeezing the pipette, enter the entire contents into the round window of the test plate. ❺ Wait until the blood is completely absorbed.
- » Unscrew the cap of the bottle with the diluent and without hesitating, place 3 full drops of the diluent on the round window of the test plate. ❻
- » Read the test result 5 minutes after solution adding. Do not take into account the result obtained after a period longer than 10 minutes.
- » Pour the rest of the diluent from the container into the toilet and flush it. After the reading of the test result, throw the test and empty container into the household garbage.

INTERPRETATION OF TEST RESULTS



Negative result

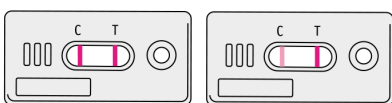
In the result window there appears only one line: control line C. The test line T does not appear. Helicobacter pylori was not detected in the test sample.



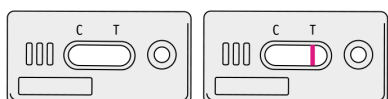
Positive result

In the resulting window, there are two stained pink stripes: Control C and test T. It means that in tested sample antibody H. pylori has been detected.

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



Even a very weak T stripe should be interpreted as a positive test.



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 faces and using a new test.

PRECAUTIONS

- » Test is for external use only
- » Helicobacter 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.
- » Do not use the lancet if it is incomplete or damaged.
- » The test and lancet are intended for single use only.
- » Dispose of the used test and lancet like any other household waste.
- » Keep the test out of the reach of children.

FREQUENTLY ASKED QUESTIONS

How does the Helicobacter Test from blood act?

Helicobacter Test detects IgG antibodies specific to Helicobacter pylori bacteria. These antibodies are present in the human infected with Helicobacter pylori.

Helicobacter Test is a screening test; result obtained by the test shows only if the anti-H. pylori antibodies are present or not in the blood, the test does not assess the level of these antibodies.

Helicobacter Test is useful in the diagnosis of gastro-intestinal problems caused by the presence of the Helicobacter pylori bacterium in the human body.

Is the test result reliable?

The test result is certain, but only if the test is performed exactly according to instructions. If the instructions are not observed, also if the test plate gets wet or when the amount of blood introduced into the round window is insufficient, the test may be invalid. Therefore, while collecting the blood you should pay attention it filled pipette into a black mark. A drop of blood placed on the round window of the test plate should be small, but full, no air bubbles.

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.

How to interpret the test result, if the intensity of the two lines in the result window is different?

The color and intensity of the lines T and C appearing in the result window are not relevant to the interpretation of the test result. 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.

Will the test continue to be reliable after more than 30 minutes?

No. The test result should be read within 5 minutes from the addition of the solution, and the result is reliably maintained up to 10 minutes.

What should I do in case of a positive test result?

A positive test result means that there are IgG anti-H.pylori antibodies in the tested blood. The presence of these antibodies indicates current or previous organism infection with the Helicobacter pylori bacterium. However, in order to make a definitive diagnosis it is recommended to take Helicobacter Antygen TEST from stool by Domowe Laboratorium or see your doctor.

What should I do in case of a negative test result?

A negative test result means that the IgG anti-H. pylori antibodies were not detected in the tested blood. However, if gastrointestinal symptoms repeat, you should seek medical help.

What result can I expect after the drug therapy?

Most likely, it will be positive. The level of IgG anti-H. pylori antibodies is maintained at detectable level for at least a year after the application of an effective drug therapy. Helicobacter Test from blood, like other high-speed detection antibody screening tests, is not intended to evaluate the effectiveness of cure.



Date of the last revision of the instruction: 20.06.2022

Version 12 AL_AT/EN

SYMBOLS

For lancet device :

CE 0197

	For single use only		Radiation sterilized
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Manufacturer:

NSP TECH PTE LTD
10 Admiralty Street,
Northlink Building #02-06,
Singapore 757695

For test :

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:

Hydrex Diagnostics Sp. z o.o.
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04-028 Warsaw, Poland
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 controly
medical devices