

HELICOBACTER PYLORI

Diago-HP

One-Step Whole Blood H.pylori Test

FOR IN-VITRO DIAGNOSTIC USE. NOT FOR INTERNAL USE. SELF-TESTING DEVICE.

PLEASE READ THE INSTRUCTION MANUAL CAREFULLY BEFORE PERFORMING THE TEST.

DO NOT TAKE ANY DECISION OF ANY MEDICAL RELEVANCE WITHOUT FIRST CONSULTING A MEDICAL PRACTITIONER AFTER PERFORMING THE TEST.

WARNING! DO NOT PRESS ORANGE PUSH-BUTTON BEFORE USING LANCET.

THE TEST SHOULD BE CARRIED OUT WITHIN 15 MINUTES FROM OPENING A FOIL PACKAGE

INSTRUCTIONS FOR USE

Helicobacter Pylori Test can be used to detect Helicobacter pylori (H.pylori) antibodies. Studies have shown that the presence of H.pylori antibodies in your blood may be related to gastritis, ulcers, or in some cases, it may indicate the possible presence of stomach cancer.

Helicobacter Pylori Test detects antibodies produced in your body in response to the H.pylori infection. If the antibodies are present, the test gives a positive result. The test is designed to demonstrate the presence of antibodies to H.pylori bacteria in blood. Clinical studies for HELICOBACTER PYLORI Diago-HP Test were performed using 186 samples with confirmed positive or negative results (results were confirmed by ELISA). HELICOBACTER PYLORI Diago-HP Test showed relative accuracy of 98.2%, relative specificity of 100.0%, and relative sensitivity of 96.2%.

HOW TO USE

1. Wash your hands. Tear open foil package by tearing along the slice on the package and remove the Test Device and Dropper.
2. Wipe the finger you intend to stick with the Alcohol Swab; and using the Lancet provided, remove protective cap, and stick your finger as follows (look at pictures aside):
 - Twist and remove The Protection Cap (Figure 1).
 - Place the Lancet against your finger and press firmly (Figure 2).
 - Squeeze your finger, making sure you get a large hanging drop of blood (Figure 3).
3. Hold the Dropper provided horizontally (flat) and touch the tip of the Dropper to the drop of blood (Figure 4).

NOTE: Do not squeeze the bulb. Blood will flow into the Dropper. You will need to squeeze your finger to get additional blood. Fill blood to the black line on the Dropper.

4. Place the filled Dropper against the Sample Well (round hole) marked with an "S" on the Test Device (Figure 5).
5. Squeeze the top of the Dropper, squeezing the entire blood sample into the Test Device.
6. Wait 90 seconds after adding the blood to the Sample Well.
7. Twist open the cap of the Test Solution vial.
8. Slowly add five (5) drops of Test Solution to the Diluent Well marked with a "D" (Figure 6).
9. Start the timer and read results at exactly 15 minutes.

BEFORE YOU BEGIN THE TEST:

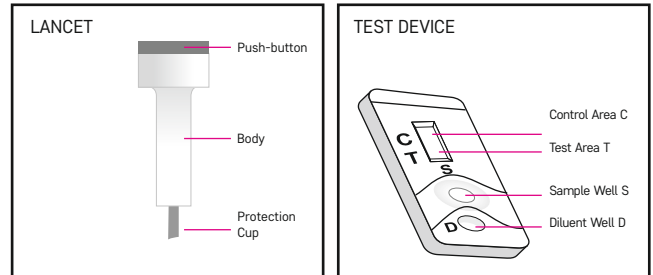
Store the test at room temperature 15 - 30°C (59 - 86°F).

Do not use the test after the expiration date printed on the package.

If you have any questions regarding the instructions or your results, please refer to the Question and Answer section on reverse side or call Infoline 800 70 30 11

MATERIALS REQUIRED BUT NOT PROVIDED:

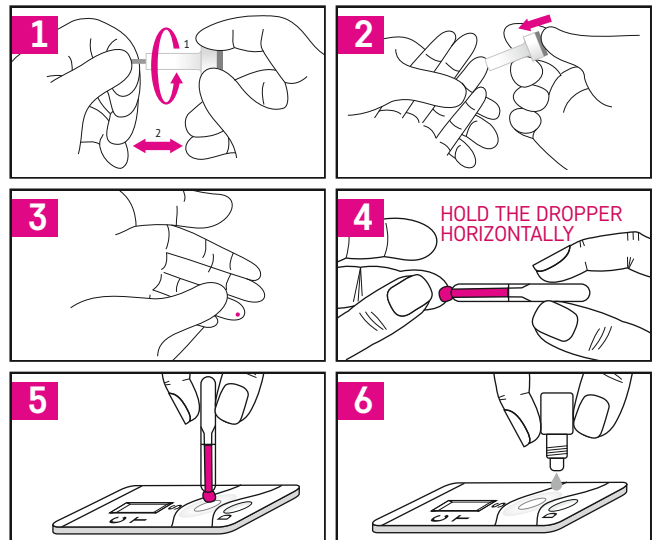
Clock with second hand or timer.



CONTENTS OF PACKAGE

Foil Package (Contains: Test Device and Dropper), Vial of Test Solution, Finger Stick Device (lancet), Alcohol Swab, Instruction for use.

NOTE: The foil Package contains desiccant sachet for moisture protection which should be discarded



HOW TO READ YOUR RESULT ?

In the Results Window there is a Control Area marked with a "C" and a Test Area marked with a "T".

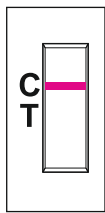


Figure 7

NEGATIVE RESULT

The result is negative if:

- One line appears in the Control Area C

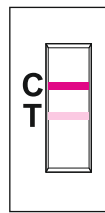


Figure 8

POSITIVE RESULT

The result is positive if:

- Two lines appear, one in the Control Area C and one in the Test Area T

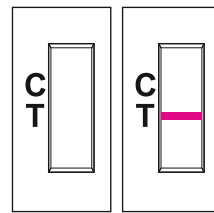


Figure 9

INVALID RESULT

The result is invalid if:

- No lines appear in the Control Area C and Test Area T
- One line appears in the Test Area T

Repeat the test using a new test kit.

CAUTION:

- If the test result is positive, then it means that the blood sample contains specific anti-Helicobacter pylori antibodies. This indicates an existing or recent infection with the Helicobacter pylori bacteria. You should contact your doctor to confirm the results and determine a method of treatment.
- If the test result is negative, then it means that the blood sample contains no specific anti-Helicobacter pylori antibodies. Infection with the Helicobacter pylori bacteria can be virtually ruled out. However, in case of abdominal discomfort and further overall discomfort or in case of symptoms indicating health deterioration you should also contact your doctor for further tests and a final diagnosis.
- The colour and intensity of lines do not matter. One line may be darker than the other one. If the line is visible and continuous, the test can be interpreted as described above.
- Do not read the test result after 15 minutes as the test continues to be subject to chemical reactions that may impact the test result. You should consult your doctor to discuss the test result.

TEST LIMITATIONS:

- Helicobacter Pylori Diago-HP test is a screening test limited to detect Helicobacter pylori in whole blood.
- The accuracy of the result depends on the proper conduct of the test. The test is accurate and effective in detecting antibodies, but occasionally erroneous results may occur.
- As with all tests intended for self-testing, the final diagnosis should not be based on a single test result. The diagnosis should be made by the doctor after evaluation of all clinical and laboratory tests results.
- All components of the test are in contact with blood, hence a care must be taken to avoid a potential infection.
- Do not use the test after the expiry date stated on the package. Keep away from children.

QUESTIONS AND ANSWERS

WHAT IS H.PYLORI?

Helicobacter pylori (H.pylori) is a bacterium that infects your stomach and may cause gastritis and stomach ulcers.

HOW DOES THIS TEST WORK?

This test detects antibodies produced in your body in response to the H.pylori infection. If the antibodies are present, the test gives a positive result. The test is designed to demonstrate the presence of antibodies to H.pylori bacteria in blood.

WHAT IS THE CLINICAL PERFORMANCE OF DIAGO-HP?

Diago-HP showed relative accuracy of 98.2%, relative specificity of 100.0%, and relative sensitivity of 96.2%.

WHAT DO I DO IF THE TEST INDICATES A POSITIVE RESULT?

This test is meant only as a screen. If you get a positive result, call your doctor and discuss the result.

HOW LONG DO I HAVE TO WAIT TO READ THE RESULTS?

The test results must be read at 15 minutes after adding the Test Solution. The results are not valid if they are read after 15 minutes.

WHAT IF THE LINES IN THE RESULTS WINDOW ARE NOT THE SAME COLOR OR INTENSITY?

The color or intensity of the lines in the Results Window do not have any significance. If the lines are visible and unbroken then they can be interpreted as explained above.

WHAT IS THE PURPOSE OF THE LINE IN THE CONTROL AREA?

The line in the Control Area assures you that the test was run correctly. If no line appears in the Control Area then the test is invalid and should be repeated.

ALL ELEMENTS OF THE USED TEST SHOULD BE INSERTED INTO THE ORIGINAL BOX AND TREATED AS A WASTE. DO NOT RE-USE ANY PIECE OF THE TEST KIT.

For Diago-HP test

DIAGNOSIS S.A.
ul. Gen. W. Andersa 38A
15-113 Białystok, POLAND

CE 0197

15°C / 59°F to 30°C / 86°F

STERILE R

HTL STREFA S.A.
Adamówek 7
95-035 Ozorków, POLAND

CE 0344

1,5 mm blade
Penetration depth - 1,5 mm.

	Temperature limit		Consult instruction for use
	Batch Code		Do not re-use
	Use-by date		In vitro diagnostic medical device
	Manufacturer		Catalogue number
	Contains sufficient for <n> tests		Last updated
	Sterilized using irradiation		Keep away from sunlight
	Do not use if package is damaged		Keep dry

Store at 15-30°C (59-86°F).

See the package and the label for the Batch code and expiration date.

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REF 0504-1H

Rev. 2016.06.23
ANGIELSKA - INSTRUKCJA na podstawie
polskiej wersji z dnia 2016.06.16