

Prevention at home.

PRECAUTIONS

- 1) Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.
- 2) Keep out of the reach of children.
- 3) Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
- 4) Follow strictly the indicated time, blood and diluent quantities.
- 5) Store between +4°C and +30°C. Do not freeze.
- 6) Do not re-use the Helicobacter Pylori test device and lancet.
- 7) External use only. DO NOT SWALLOW.
- 8) This test is exclusively intended to in vitro diagnostic self-testing use.

REF 17084R

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CONTENT

THE BOX CONTAINS ALL THE NECESSARY TO PERFORM 1 H. PYLORI TEST:



- * Not provided necessary material: absorbent cotton and alcohol 70°
- * Only open the protective pouch when you are ready to use the test.
- * The desiccant bag should not be used.

 **PRIMA**[®]
HOME TEST

HELICOBACTER PYLORI TEST

Easy to use rapid Self-Test for the determination of the anti-Helicobacter Pylori antibodies in blood

INSTRUCTIONS FOR USE

The presence of the bacterium Helicobacter Pylori (HP) on the internal wall of the stomach and of the duodenum can cause chronic gastritis which can lead towards ulcers.

It is proven that 90% of the people that suffers from ulcers, they have an infection caused by the HP bacterium. This infection can increase the risk of the stomach cancer. Therefore it is very important to detect as soon as possible the infection which can be easily treated by specific antibiotics.

The easiest way to detect the infection is through the presence of specific antibodies that the immune system produces after the contact with the bacterium to try to defend.

The Helicobacter Pylori test is an high specific rapid immunodiagnostic test that allows to detect the presence of the anti-HP antibodies through a single drop of blood.

PROCEDURE

- 1) Wash your hands with soap and rinse with clear warm water.
- 2) Tear the protective pouch (from the notch) and only get out the device and the pipette. Dispose of the small desiccant bag.

- 3) Push the orange small rod into the body of the lancet until hearing a **CLICK** indicating the device is activated. - **FIG. A**

Be careful not to push the trigger because the needle can come out too early.

- 4) Remove the orange rod by turning it on the left or on the right. - **FIG. B**

- 5) Clean the end of the forefinger or of the middle finger with a cotton pad damped with alcohol. Massage the end of the finger, from the base of the finger to the end, to enhance the blood flow.

- 6) **Strongly press** the extremity of the lancet on the part of the finger which is cleaned with alcohol in order to obtain a very good contact.

Press on the trigger button. - **FIG. C**

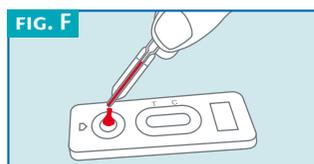
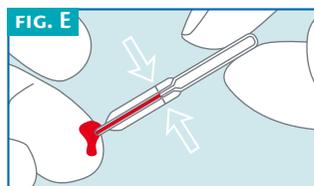
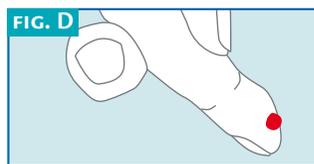
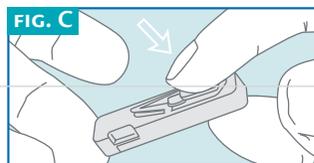
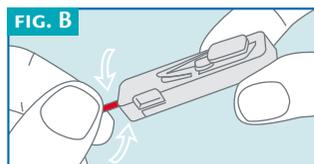
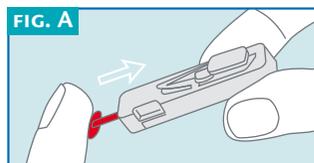
The tip retracts automatically and safely after use.

- 7) Keeping the hand down massage the end that was stung to obtain a blood drop. - **FIG. D**

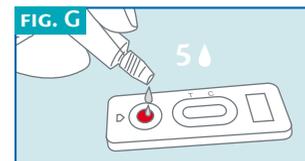
- 8) **Without pressing the pipette bulb**, put it in contact with the drop. - **FIG. E**

The blood migrates into the pipette through the capillarity to the line indicated on the pipette. You may massage again your finger to obtain more blood if the line is not reached. As far as possible, avoid of air bubbles.

- 9) Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb. - **FIG. F**



- 10) Wait for the blood totally being dispensed in the well. Using the dropper bottle, add **5 drops** of diluent into the sample well of the device - **FIG. G**



- 11) Read the result after **10 minutes**.

RESULT INTERPRETATION

READ THE RESULT AFTER 10 MINUTES. DO NOT READ THE RESULT AFTER 15 MINUTES.

The intensity of the line colour does not have any importance for the interpretation of the test result.



POSITIVE RESULT

Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be clearer than the intensity of the line C.

This result means that there is the presence of the antibodies anti-HP in blood and that you should consult a doctor.



NEGATIVE RESULT

Only one coloured line appears under the C mark (Control). This result means that the presence of the antibodies anti-HP in blood was not detectable.



NON VALID RESULT

No line appears or a coloured line appears under the mark T (Test) without any line under the mark C (Control). In this case, it is not possible to interpret the test, which must be considered as non valid. It is recommended to repeat the test with a new test device and a new blood sample.



F.A.Q. - QUESTIONS AND ANSWERS

HOW DOES THE TEST HELICOBACTER PYLORI WORK?

The presence of the HP bacterium on the gastric tissues causes the production of the specific antibodies by the immune system. There is a relation between the presence of specific circulating antibodies and the bacterium. The Helicobacter Pylori test detects specifically the antibodies in blood and allows to presume the presence of the bacterium.

WHEN SHOULD THE TEST BE USED ?

The test can be performed anytime of the day. The test can be performed in case of repeated stomach and intestinal troubles (GERD, gastritis, ...)

CAN THE RESULT BE INCORRECT?

The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if Helicobacter Pylori test gets wet before test performing or if the quantity of blood dispensed in the sample well is not sufficient, or if the number of diluent drops are less than 4 or more than 5.

The plastic pipette provided in the box allows making sure the collected blood volume is correct

HOW TO INTERPRET THE TEST IF THE COLOUR AND THE INTENSITY OF THE LINES ARE DIFFERENT?

The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the colour intensity of the test line is.

WHAT IS THE LINE THAT APPEARS UNDER THE MARK C (CONTROL) FOR?

When this line appears, it only means that the test was performing well.

IF I READ THE RESULT AFTER 15 MINUTES, WILL THE RESULT BE RELIABLE?

No.

The result should be read within 10 minutes after adding the diluent. The result is reliable up to 15 minutes.

WHAT DO I HAVE TO DO IF THE RESULT IS POSITIVE?

If the result is positive, it means that the antibodies anti-HP were detected in blood and that you should consult a doctor to show the test result. It might be possible that the antibodies come from a previous infection already treated. Then, the doctor will decide whether additional analysis should be performed.

WHAT DO I HAVE TO DO IF THE RESULT IS NEGATIVE?

If the result is negative, it means that it was not possible to detect the antibodies anti-HP. However, if the symptoms persist, it is recommended to consult a doctor.

WHAT IS THE ACCURACY OF HELICOBACTER PYLORI TEST?

The helicobacter pylori test is very accurate and has been used for more than 10 years by professionals in the field. Evaluation reports show an overall agreement of at least 90% with reference methods.

SYMBOLS

In vitro diagnostic device

Read the instructions before use

Store between +4°C and +30°C

Expiry date (last day of the months)

Do not reuse

List number

Lot number

Legal manufacturer

Lancet: **STERILE** **R**

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