

I have an H. pylori infection. What should I do?

Please visit your doctor, who will arrange for the appropriate examinations to be undertaken in order to confirm the diagnosis. Using treatment with antibiotics, your doctor will in most cases be able to completely destroy the bacteria and thus avoid any further associated intestinal symptoms. It might be helpful to take these instructions with you to show your doctor, so you can give him or her a better idea of the type of test carried out.

I have stomach pains, but I seem not to be infected by H. pylori. What should I do?

Consult your doctor for a detailed examination.

The test components can be disposed of with your normal household waste after use.

IMPORTANT NOTE:

Always consult your doctor before making any important medical decisions.

Product information:

- Not being infected with H. pylori does not necessarily mean that you cannot get a stomach ulcer for another reason.
- Although the test is very accurate, false results may arise in very rare cases.
- This is an immunological test for the detection of antibodies against H. pylori in blood.
- Test components of animal origin (such as antibodies) are potentially infectious material, but present no risk to health provided that all test components are used in accordance with instructions. The buffer solution contains harmless concentrations of sodium azide.



Read instructions carefully before use!

Keep out of reach of children.
Do not use the test after expiry date.
(See box flap).

Store at 4° - 30°C (39° - 86°F).
Use test and lancet only once.
Do not use a damaged lancet.
Do not take the test cassette apart.
Do not ingest buffer solution.
For external use only.

In-vitro diagnostic device for self-testing.
Copy Prepared by Pasante Healthcare Ltd., July 2006

Lancet: **STERILE**

Stomach Ulcer Test

Instructions for use



Please read both sides of these instructions carefully before performing the test.

General information:

The bacterium Helicobacter pylori ("H. pylori") causes conditions such as gastritis and stomach ulcers. There is as yet no immunisation available against the infection, which occurs in both children and adults. However, use of the appropriate medication (such as antibiotics) can eliminate the bacterium.

The stomach lining and duodenum are both protected against stomach acid by a protective coating. If this protective function is disturbed in any way, the mucous membrane of the stomach can be damaged, leading to ulcers. This typically happens due to H. pylori infection, which also increases the risk of developing stomach cancer.

According to estimates, today around half of the world's population are infected with Helicobacter pylori, although not every infection produces symptoms. On the one hand, the extent of infection present makes a difference, while on the other hand a person's general health and diet play a role in development of the condition. Using this diagnostic test, infection with H. pylori can be detected simply and reliably. All you need is one drop of blood, and the result can be read in just a few minutes.

In most cases, H. pylori infection can be treated very successfully using a combination of antibiotics and antacids. Once the bacteria have been eliminated, the gastritis is generally cured.

PLEASE NOTE:

If you have already been infected with H. pylori in the past and the infection was eliminated using antibiotics, this test may yield a positive reading even more than one year following treatment, although the infection is no longer present.

Test components:

- Sealed foil pack with test cassette and desiccant, buffer bottle with 0.5 ml buffer solution, plaster, lancet, instructions

Materials required, but not provided:

- A clean tissue and a watch with a second hand

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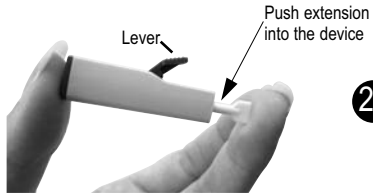
Instructions for use

1 Preparation

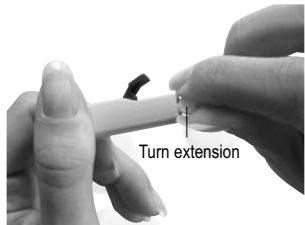
Do not open the sealed foil pack until you are ready to carry out the test. Have a clean tissue ready, plus a watch with a second hand. Then take the test cassette out of the foil pouch and place it on a flat surface. Discard the unopened desiccant (a small white package), which protects the test from humidity, with your regular household waste.

2 Using The Lancet

Please study the following illustrations and read the explanations carefully before taking a blood sample in order to ensure optimum test performance. Do not use the lancet if its extension has been removed or damaged. Wash your hands well with soap and warm water (in order to increase blood flow to your finger) and dry thoroughly. If you are using an alcohol swab, make sure that the site to be pricked is completely dry before using the lancet.



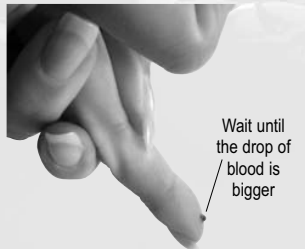
- 2a** Hold the lancet by placing your middle finger on the extension and your thumb at the other end. Load the lancet by pushing the yellow extension into the device as far as it will go using your middle finger.



- 2b** Next, turn the yellow extension clockwise or anti clockwise until it rotates freely. Then pull it out and put aside.



- 2c** Press the opening (the place from which you have removed the extension) against your middle fingertip, as illustrated, and fully depress the red lever until you hear a "click". The lancet inside will prick your finger. (The needle automatically retracts after usage. If the lancet has been released without pricking your finger, it can be reset by pushing the needle back using the extension. However, for sanitary reasons, do not use the lancet a second time on yourself or anybody else.)



- 2b** Now, with your whole arm hanging down and your pricked finger pointing downwards, wait until a big drop of blood has formed. It may be necessary to squeeze on both sides of your finger as shown in figure 2d, enabling blood to collect in your fingertip.

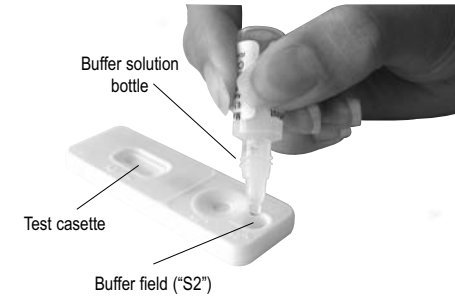
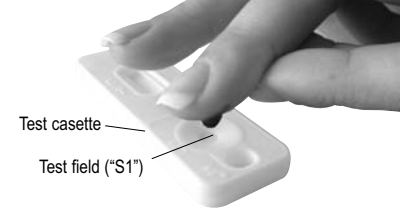
- 3** As shown in the illustration, move your finger close to the test cassette and allow one drop of blood, as illustrated, to fall onto the test field (S1). Make sure you do not touch the test field with your finger.

Wait 30 seconds.

While waiting, you may wish to cover the punctured area with the enclosed plaster.

- 4** Unscrew the cap of the buffer solution bottle and place exactly 7 drops of the solution onto the buffer field (S2), as shown in the illustration.

Wait 10 minutes, or until the background in the result field has turned white again, before reading the result as shown below.



5 Evaluating test results

POSITIVE RESULT
Two lines



NEGATIVE RESULT
One line



INVALID RESULT
No line



The test is **positive** if, within the 10-minute reaction time, **two purple lines appear in the result field of the test cassette at both "C" and "T"**, even if the line shown at "T" is very faint. This indicates an infection with *H. pylori*. Please consult your doctor for a more detailed examination.

The test is **negative** if only **one purple line appears in the result field of the test cassette at "C"**. This means that no *H. pylori* infection could be detected.

The test is **invalid** if, after 10 minutes, **no purple line appears at all**. Reasons for an invalid test result include a damaged foil pack, improper storage, or a mistake when performing the test. Please keep all test components and contact the manufacturer of the test.

After 20 minutes, the test results can no longer be interpreted reliably. Please therefore discard the test cassette once you have assessed your test result.