

Evaluating test result



Positive

Negative

Invalid

Further explanations on the test results may be found in the next coloured textblock.

After 15 minutes, the test results can no longer be interpreted reliably. Therefore please discard the test cassette once you have assessed your test result in time.

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** or if there is **a line at "T" but no line at "C"**. 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.

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. Not being infected with *H. pylori* does not necessarily mean that you cannot get a stomach ulcer for another reason.

 Read instructions carefully before use.
Keep out of reach of children.
Do not use test after expiration date.
 Store at 39° to 86°F (4° to 30°C).
Use test and lancet only once.
Do not use a damaged lancet.
Do not dismantle test cassette.
 For external use only.
0483 In-vitro-diagnostic test for self testing.

Contents: Instruction for use, foil pouch with test cassette and desiccant, buffer bottle, lancet, plaster

Lancet
VITREX Medical A/S
Vasekaer 6-8, 2730 Herlev, Denmark



CARE diagnostica®

Stomach Ulcer Health Care TEST



General information:

The bacterium *Helicobacter pylori* ("*H. pylori*") causes conditions such as gastritis and stomach ulcers. There is as yet no immunization 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 the world's population are infected with *Helicobacter pylori*, although not every infection produces any 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.

Performance data

In a clinical trial with 304 people, 132 individuals were diagnosed positive for *H. pylori*. Out of these, 118 people also received a positive result with the Stomach Ulcer Health Care Test. Stomach Ulcer Health Care Test can thus be considered as a useful method for the detection of *H. pylori* infections.

Product information

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 low concentrations of sodium azide as a preservative. The test components can be disposed of with your normal household waste after use.

NOTES:

Always consult your doctor before making any important medical decisions.

Limitations of this test

Although the test is very accurate, false results may arise in very rare cases. 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.

Preparations

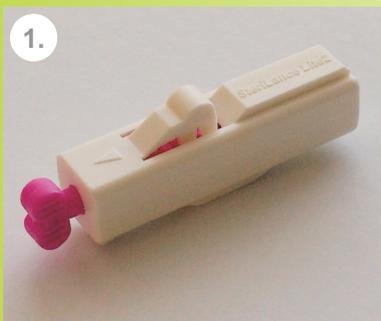
Do not open the sealed foil pack until you are ready to carry out the test.

Discard the attached desiccant, which protects the test from humidity, unopened with your regular household waste.

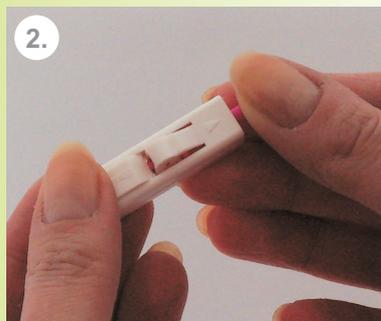
Prepare a clean paper tissue, plus a watch with a second hand.

Using the lancet

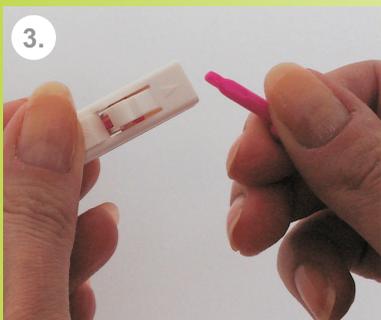
Do not use the lancet if its extension has been removed or damaged. Wash your hands well with soap and warm water in order to increase blood flow to your finger.



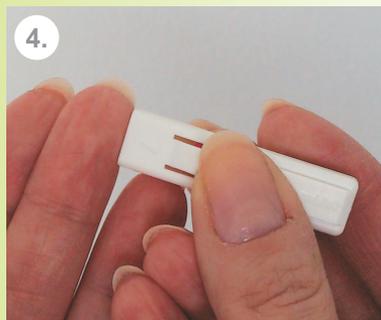
1. The lancet consists of a housing, containing the sting device. The trigger which looks like a lever is on the upper side of the lancet and releases the sting. The front end of the lancet is protected and hidden by a protective cap.



2. Separate the protective cap through a complete revolution. During the rotation, do not press on the lever, otherwise the sting will get released.



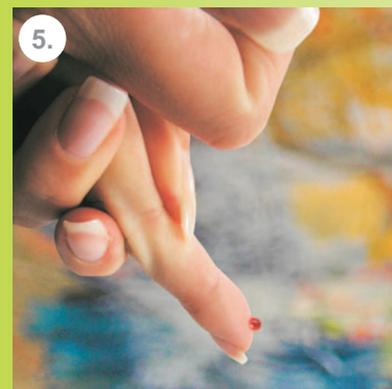
3. Now pull off the loose protective cap and pull it away from the housing. The lancet is ready for use now.



4. Press the opening of the lancet to the hill side of the middle finger and press the lever until you hear a click.

Performing the test

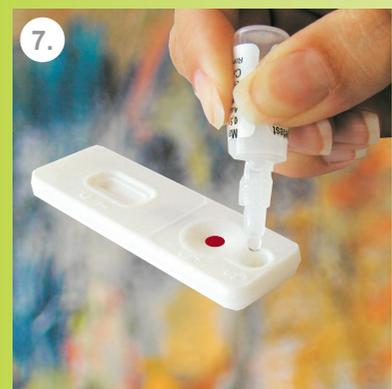
Within just 10 minutes you will get to know whether there are signs of a *H.pylori* infection.



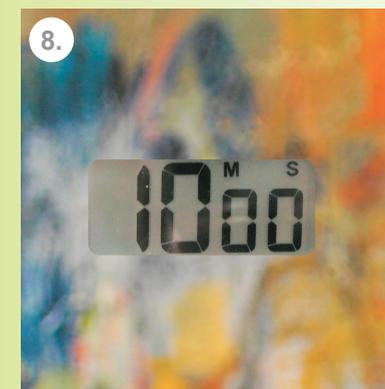
5. Now, with your whole arm hanging down and your pricked finger pointing downwards, wait patiently until a big drop of blood has formed. It may be necessary to squeeze on both sides of your finger as illustrated.



6. As shown in the illustration, move your pricked finger close to the test cassette and allow one drop of blood to fall onto the test field "S1". Make sure you do not touch the test field. Then wait 30 seconds.



7. Slowly place exactly 9 drops of the solution onto the buffer field "S2" to avoid an overflow.



8. Wait 10 minutes. The result might be less reliable if you wait longer or shorter.

Continue on next page.