

Heli-C-CHECK[®]

Healthy stomach? Find out now at home!

Early detection can protect...

INSTRUCTIONS FOR USE

For Self-testing

HELI-C-CHECK

Heli-C-CHECK is a simple and reliable immunochromatographic self test for the qualitative detection of *Helicobacter pylori* antibodies in a blood sample from the fingertip.

Carefully read the instructions for use before testing. To perform Heli-C-CHECK you will also need a watch or timer. Perform the test in a well illuminated place.

PRINCIPLE OF THE TEST

A *Helicobacter pylori* infection is defined as a colonization of the stomach with the bacterium *Helicobacter pylori*. People who are infected with this bacteria, often show no symptoms, however for many, an infection can cause damage to the stomach lining which can lead to stomach inflammation (gastritis) or a stomach ulcer (peptic ulcer). Furthermore *Helicobacter pylori* infection can also lead to diseases such as stomach cancer or lymphoma.

Helicobacter pylori infection in humans is often dependent on nationality: It has been observed that in developing countries approximately 70% of 20 to 35 year olds are infected with the pathogen. In developed countries such as Germany or the UK, the bacterium is less common. In addition, age plays a crucial role: the older the person is, the higher the probability a person will be a carrier of the bacterium.

Heli-C-CHECK is a rapid, sensitive, easy to use and evaluate home test for the detection of *Helicobacter pylori* antibodies in a small blood sample. The test is used as an aid in the diagnosis of a *Helicobacter pylori* infection, which may be connected to illnesses like peptic ulcer, inflammation of gastric or duodenal mucosa and other disorders in the upper gastrointestinal region. A final diagnosis of any of the above mentioned diseases cannot be based on a positive test result alone but should be confirmed by a doctor. The test requires only one drop of blood from the fingertip and it can be carried out and interpreted in only 5-10 minutes.

CONTENTS

- 1 aluminium sachet with test cassette and pipette
- 1 sterile automatic lancet
- 1 plastic vessel with a 10 microlitre glass capillary
- 1 tube containing buffer solution
- 1 plaster
- 1 alcohol soaked swab
- 1 instruction leaflet

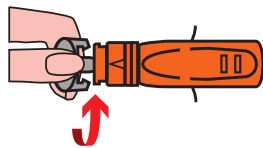
TEST PROCEDURE

Please read these entire instructions for use carefully before you start performing the test. All components required for the test should be at room temperature (2-27°C). Prepare all necessary components before obtaining the blood sample:

- The automatic lancet
- The alcohol soaked swab
- The plaster
- The glass capillary

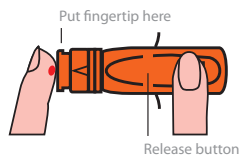
Open the tube containing the buffer solution by unscrewing the cap. Take the plastic pipette and the test cassette out of the aluminium sachet. Place the test cassette horizontally on a dry surface (with application fields up).

1. Twist the grey cap until it loosens. Continue to rotate the cap for at least 2 more times and then pull it out.



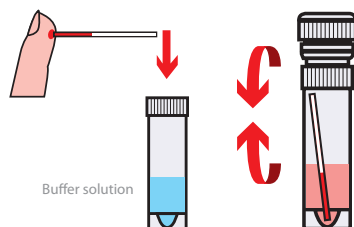
2. Gently massage the fingertip then clean it with the alcohol soaked swab. Leave until the finger has dried. Warming up your finger will make sample collection easier.

3. Press the automatic lancet with the round opening firmly against the clean fingertip and activate it with the button. The puncture is practically painless.

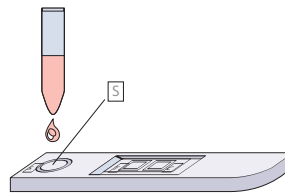


4. Press a drop of blood out of the fingertip. Open the plastic vessel and remove the glass capillary carefully. Hold the capillary horizontally in the drop of blood until it has filled completely.

5. Place the filled glass capillary in the tube containing the buffer solution and close the tube firmly with the screw cap. Shake the tube several times until the blood from the capillary has mixed with the solution.



6. Remove the screw cap of the buffer tube. Take a few drops from the diluted blood sample (mixture) by using the plastic pipette.
7. Hold the pipette containing the diluted blood sample vertically over the round application field (S) and give 3 drops onto it. After applying the drops do not touch or move the test cassette for 5 minutes. Do not read the result after more than 10 minutes.



Helicobacter pylori. Consult your doctor for a final diagnosis and treatment plan.

Negative: The test indicates that there are no IgG antibodies to *Helicobacter pylori* present in the tested blood. An existing infection with *Helicobacter pylori* can virtually be ruled out. If you suffer from gastrointestinal problems please consult your doctor, further medical investigation seems necessary.

STORAGE

Store the test kit and all components at room temperature (2-27°C). The shelf life of the test is 24 months, provided that all storage conditions are strictly followed. The expiration date is printed on the carton box and aluminium sachet.

INTERPRETATION OF RESULTS

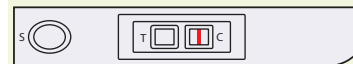
POSITIVE

The test result is positive if a red line forms in the control field C and a dark or light red line appears in the test field T.



NEGATIVE

The test result is negative if a red line forms in the control field C and no line becomes visible in the test field T.



INVALID

If no control line is formed you have likely not followed the instructions correctly or the test kit was damaged. Please repeat the test with a new test kit.

Positive: The test results show that there are IgG antibodies to *Helicobacter pylori* in the tested blood. If these antibodies are detected this indicates that there is a high probability of an existing or recent infection with *Helicobacter pylori*.

WARNINGS AND LIMITATIONS

If the instructions are not followed correctly as outlined, it may lead to inaccurate results. A final diagnosis should be made by a medical professional in conjunction with clinical symptoms and laboratory results.

- The accuracy of Heli-C-CHECK depends upon correct test performance.
- If the instructions are not followed in detail, outcome of the test may be incorrect. Do not reuse the test or components.
- A final diagnosis should be made in conjunction with clinical symptoms and further laboratory data.
- All components shall be disposed of in original packaging, together with normal household waste.
- Do not use the test after the expiration date.
- Do not use when test kit or components are damaged.
- You should perform the test within 20 minutes after opening the aluminium sachet.
- The solution contains 0.09% sodium azide. Avoid contact with skin. Do not swallow!
- Please keep Heli-C-CHECK out of reach of children!

www.helicheck.com

Follow instructions	For in-vitro diagnostics only (Use outside the body)	See imprint on package
Store in a dry place 2-27° DO NOT FREEZE!	Tests per package	Do not reuse
		See imprint on package



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For the love of life.