

# Heli-C-CHECK®

Early detection can save...

**Healthy stomach?** Test yourself at home now!

Rapid test for the detection of antibodies against the bacterium *Helicobacter pylori*

## INSTRUCTIONS FOR USE

For self-testing

### INTRODUCTION

The most common cause of painful inflammation of the stomach lining with nausea and abdominal discomfort is a bacterium called *Helicobacter pylori*. Chronic inflammation in the stomach (gastritis) or ulcer may have further consequences. Moreover, *Helicobacter pylori* can contribute to the development of diseases, such as ulcers in the stomach and lymphoma progress (a type of cancer).

**Heli-C-CHECK®** is a rapid test for use at home to detect the presence of *Helicobacter pylori* antibodies in whole blood. **Heli-C-CHECK®** is intended as an aid in the detection of *Helicobacter pylori* infection.

**Heli-C-CHECK®** as an immunochromatographic rapid test detects the presence of *Helicobacter pylori* specific anti-IgG antibodies in a whole blood sample which bind to colloidal gold-labeled antigens. This complex binds to the test line (T) and produces a visible red line. The test also includes a control system consisting of a control line (C). It confirms sufficient sample volume and a correct test procedure.

An explanation of how to read and interpret the test result is given in the instruction pamphlet. Therefore, it is important to fully understand the entire instruction pamphlet before performing the test.

### TEST CONTENTS

- 1 test cassette (H.pylori) in a sealed pouch
- 1 pipette
- 1 glass capillary tube in a protective container
- 1 solution bottle with sample dilution buffer
- 1 automatic sterile lancet for comfortable blood sampling

Owen Mumford Ltd.  
Brook Hill, Woodstock  
Oxfordshire, OX20 1TU, UK

CE 1639 STERILE R

EC REP Owen Mumford GmbH, Alte Häge 1, 63762 Großostheim

- 1 alcohol pad
- 1 plaster

Paul Hartmann AG  
89522 Heidenheim, Germany

CE

- 1 instructions for use

**Additionally required:**

- 1 timer

### TEST PREPARATION

Let test cassette and solution bottle stand at a room temperature (15°C to 27°C) before performing the test. Open the solution bottle with the sample dilution buffer by screwing the cap and let it stand upright on a table.

### TEST PERFORMANCE

Read the instructions for use **completely** before performing the test.

A **step-by-step instruction** is given on the **next page** and describes the test procedure.

### EVALUATION OF TEST RESULTS

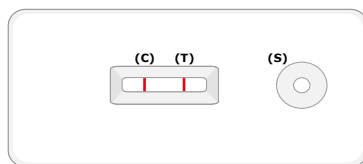
To read the test results simply determine whether a line is present or absent at the control (C) position. It does not matter how strong or weak a Control line (C) is.

### POSITIVE TEST RESULT

If a **faint red to dark red Control line (C)** is visible in the result window **along with a faint red to dark red Test line (T)**, the test result is positive.

The test result means that *Helicobacter pylori* antibodies are detectable in your blood sample. The detection of these antibodies indicates with a high probability an existing or recent infection with *Helicobacter pylori*. To receive

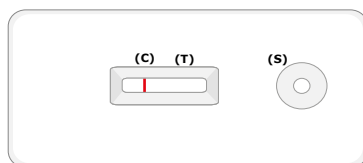
a final diagnosis, please consult a physician.



### NEGATIVE TEST RESULT

If **only a faint red to dark red Control line (C)** is visible in the result window with **no Test line (T)**, the test result is negative.

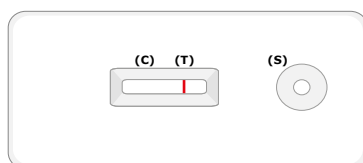
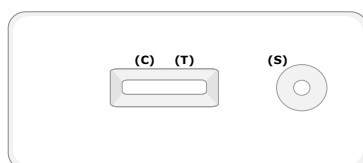
The test result indicates that *Helicobacter pylori* antibodies are not present in the blood sample. Preliminary, there is no existing infection with *Helicobacter pylori*. If there are any gastrointestinal symptoms, please visit a physician for further medical investigation.



### INVALID TEST RESULT

If there is **no Control line (C)** or **only a Test line (T)** in the result window, the test did not run correctly and the results are not valid.

It is important that you carefully followed the instructions for the test. You should test again with a new blood sample and a new test.



### PERFORMANCE EVALUATION

Heli-C-CHECK	Reference Test		
	Positive	Negative	Total
	63	2	65
	4	86	90
Total	67	88	155

Sensitivity: 94.03%

Accuracy: 96.92%

Specificity: 97.73%

### WARNINGS AND IMPORTANT INFORMATION

- The test is intended for use outside the body only.
- Not to be taken internally. Avoid sample buffer contact with skin and eyes.
- Keep out of the reach of children.
- Protect from sunlight, do not freeze. Store in a dry place between 10°C und 27°C.
- Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by a physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components.
- The test should be carried out immediately or within one hour after opening the foil pouch.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- All test components can be disposed in household waste.
- After successful *Helicobacter pylori* treatment, antibodies in the blood can remain detectable for months, sometimes years. **Heli-C-CHECK®** should therefore not be used for re-testing after a successful treatment.
- The test may only be performed by non-pregnant adult users.

### Explanation of symbols:

 Follow instructions	 In vitro diagnostic medical device (for external use)	 Best before (See imprint on package)
 Store at 10°C - 27°C Do not freeze.	 Content sufficient for 1 test	 Do not reuse
 Manufacturer	 Sterilization by irradiation	 Batchnumber (See imprint on package)
 Reference number	 Authorised Representative	

CE 0483

Instructions English  
Revision from 2021-03 (Rev. 05)



NanoRepro AG  
Untergasse 8  
D-35037 Marburg  
www.nanorepro.com

REF 920000



For the love of life.

# Heli-C-CHECK®

**Healthy stomach?** Test yourself at home now!

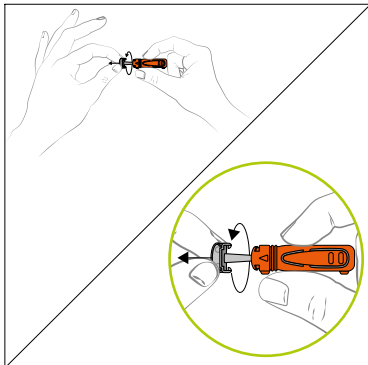
Rapid test for the detection of antibodies against the bacterium *Helicobacter pylori*

Early detection can save...

## STEP-BY-STEP INSTRUCTION

For self-testing

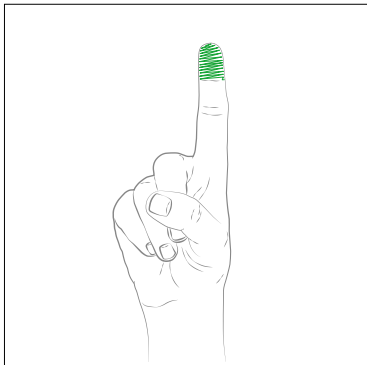
### STEP 1



**Please note: The lancing device can only be triggered once.**

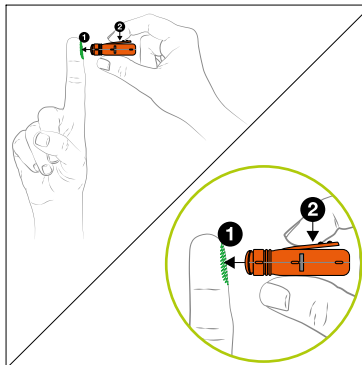
Twist the grey cap on the automatic lancet until cap separates easily from lancet body. Then twist it at least two more times before removing the cap, otherwise the proper function can not be ensured.

### STEP 2



Slowly massage your fingertip and clean it using the alcohol pad. Wait until the fingertip is dry, as residual alcohol can interfere with the test result.

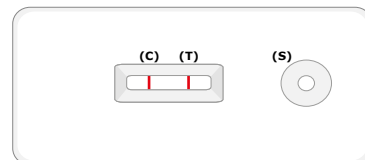
### STEP 3



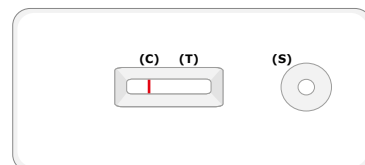
Press the automatic lancing device with the round opening firmly against the clean fingertip ① and activate it by pushing the button ②

### TEST RESULT

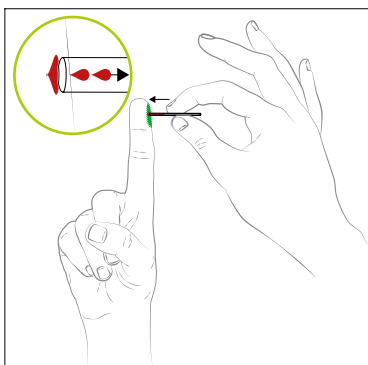
#### POSITIVE TEST RESULT



#### NEGATIVE TEST RESULT

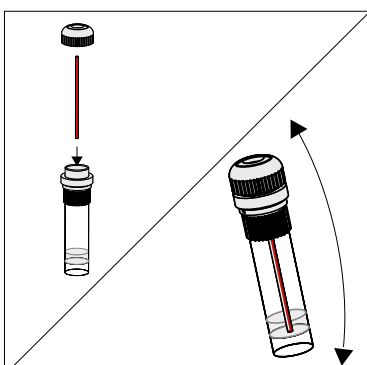


### STEP 4



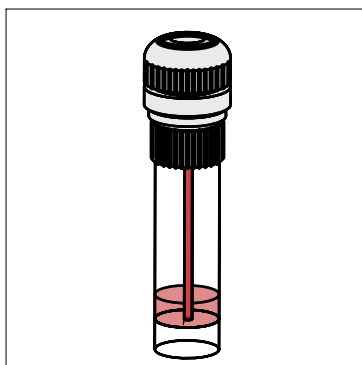
Open the plastic container and carefully remove the glass capillary tube. Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally against the blood drop on the finger until it has completely filled.

### STEP 5



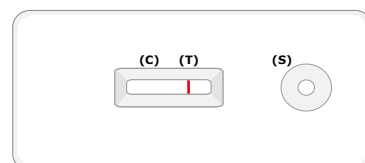
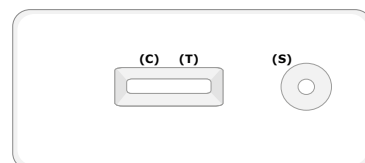
Insert the filled glass capillary into the solution bottle and screw the cap back on. Mix the content of the solution bottle by turning it gently upside down several times until the blood from the glass capillary tube is mixed with the solution.

### STEP 6

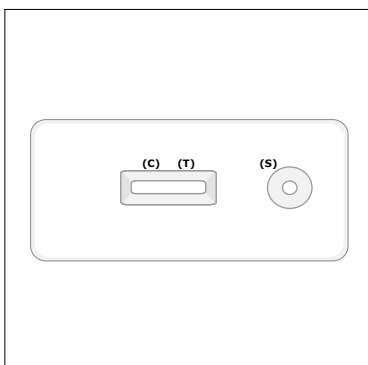


Before twisting off the cap, let the sample mixture settle back to the bottom of the solution bottle. Only then twist off the cap.

#### INVALID TEST RESULT

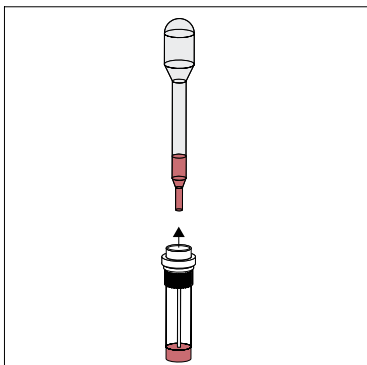


### STEP 7



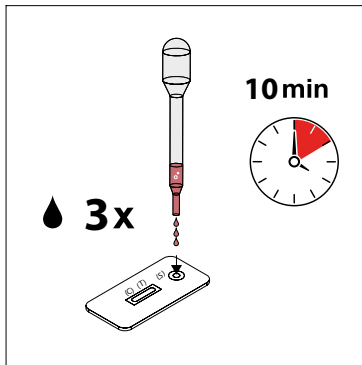
Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

### STEP 8



Use the pipette to remove a few drops of the diluted sample.

### STEP 9



Hold the pipette with the sample mixture straight over the test cassette and squeeze gently to add exactly 3 drops to the sample well (S). Please note that there should be no liquid applied to the result windows marked with the letters (T) and (C). Do not touch or move the test cassette after adding the drops to the sample well (S).

Read the result 10-15 minutes after adding the sample. Low values may be missed before the 10 minutes have elapsed, and false positive results may occur after more than 15 minutes.

[www.zuhausestest.de](http://www.zuhausestest.de)  
[www.helicheck.com](http://www.helicheck.com)



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