Veroval®
SELF-TEST

HARTMANN

Stomach prevention

Rapid test for the detection of the bacterium Helicobacter Pylori

10 min | Accuracy > 96 %

Medical self-tests for home use

A risk for the stomach: The bacterium Helicobacter Pylori

Painful inflammations of the stomach lining with nausea and pain are often caused by colonisation of the stomach with the bacterium Helicobacter Pylori. Chronic inflammations of the stomach lining (gastritis) or even a stomach ulcer might be additional sequelae. In addition, Helicobacter Pylori is associated with diseases such as stomach and lymph node cancer.

Knowing where you stand: Stomach prevention rapid test

The Stomach prevention rapid test enables you to find out quickly and simply whether you carry the Helicobacter Pylori bacterium. Should this be the case, you can discuss how to proceed with your doctor.

How reliable is the Veroval® test?

The Stomach prevention rapid test was developed for the purpose of making the accuracy and dependability of modern diagnostics also available for private use at home. It is based on the immunological detection of antibodies against the Helicobacter Pylori bacterium in the blood. **Accuracy, as evidenced by performance evaluation studies, is greater than 96 %.**

Is the test complicated to perform?

No: All you need are clean washed hands, a clock and a flat table surface. The exact test procedure is described overleaf. It is necessary to read the instruction leaflet thoroughly to understand how the result is determined and interpreted. All details should be understood before performing the test.

Performance data:

		Reference test		
Stomach prevention Rapid test		Positive	Negative	**Total**
	Positive	63	2	65
	Negative	4	86	90
	Total	67	88	**155**

Sensitivity: 94.03 % Specificity: 97.73 % Accuracy: 96.92 %

What should I pay attention to?

Warnings and important notes:

- The test is intended only for use outside the body.
- Do not consume any of the test components. Avoid skin and eye contact with the sample dilution buffer.
- Keep the test out of the reach of children.
- Do not expose the test to direct sunlight or frost. Do not freeze. Store in a dry place between 10 °C and 27 °C.
- The product may be used only until the imprinted expiry date.
- If the details of the instruction leaflet are not correctly followed, the test may produce false results.
- Do not use the test if the packaging is damaged. Do not use damaged test components.
- False-negative results* may occur in rare cases.
- All test components are intended only for use with this test. Do not re-use the test after use!
- The test should be performed immediately or within one hour after opening the foil bag.
- Poor eyesight, colour blindness or inadequate lighting can compromise the correct interpretation of the test.
- All test components can be discarded in the domestic waste.

Important information:
Positive test results may also occur for perfectly harmless reasons – negative results, however, do not always mean a complete all-clear. The final diagnosis should be made by a physician. To identify new risks promptly, regularly repeating the self-tests for stomach and intestinal prevention is recommended.

* **False negative** = a negative test result is wrongly displayed, even though the result is actually positive.

www.veroval.en

Materials

- 1 test cassette in foil bag
- 1 pipette
- 1 container with sample dilution buffer
- 2 automatic lancing devices (1 replacement) with sterile lancet for taking the blood sample

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

STERILE R CE 0120

- 1 glass capillary tube in protective container
- 1 alcohol swab

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim,
Germany

CE

- 1 plaster

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim,
Germany

CE

- 1 instruction leaflet

Explanation of symbols

Consult instruction leaflet	IVD In vitro diagnostic product (for use outside the body)	Expiry date (see imprint on packaging)
10°C – 27°C Store in a dry place at 10–27°C. Do not freeze.	Σ 1 Contents sufficient for 1 test	2 Do not re-use
Manufacturer	STERILE R Sterilised by irradiation	LOT Batch number (see imprint on packaging)
10 min Reaction time in the test cassette	Rapid test for self-testing	

NanoRepro AG
Untergasse 8
D-35037 Marburg

CE 0483

Distributed by:
EN – PAUL HARTMANN Ltd.
Heywood OL10 2TT
office@en.hartmann.info

Instruction leaflet in English
Last revised November 2015 (Rev.00)

Veroval®
SELF-TEST

HARTMANN

Stomach prevention
Rapid test for self-testing
This is how it's done:

1

- Lay out the test components on the table in front of you. At this stage, do not open the foil packaging.

(1) Container with sample dilution buffer
(2) Alcohol swab
(3) Automatic lancing device
(4) Glass capillary tube in protective container
(5) Test cassette in foil bag
(6) Pipette
(7) Plaster

Preparation

- Allow the test cassette and sample dilution buffer to reach room temperature before starting the test (15 °C to 27 °C). Open the container of the sample dilution buffer by removing the lid and place it upright on the table.

2

- Twist the grey cap of an automatic lancing device (3) until it detaches. Then twist fully another 2 times.
- Massage the tip of your index finger and clean with the alcohol swab (2). Allow your finger to dry.
- Press the lancing device with the round opening against the side of the clean fingertip (a) and activate the release mechanism (b).

3

- Open the protective container (4) and carefully remove the glass capillary tube.
- Squeeze a drop of blood from the fingertip.
- Hold the glass capillary tube horizontally into the drop of blood until it has filled completely.
- Use the enclosed plaster (7) if required.

4

- Place the filled glass capillary tube into the container with the sample dilution buffer (1).
- Close the container tightly with the lid. Now shake the container a few times until the blood from the glass capillary tube has mixed completely with the solution and the liquid has collected again at the bottom of the container. Now open the container lid.

5

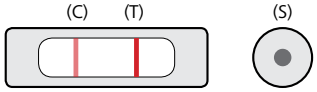
- Open the foil packaging shortly before use and lay the test cassette on a flat surface.

6

- Using the pipette (6), remove a few drops of the diluted sample.
- With the filled pipette (6), drop 3 drops from above into the round application field (S) of the test cassette (5). **Please ensure that no liquid is applied to the result window (T) or (C).** After applying the drops, do not touch or move the test cassette.
- **After adding the 3 drops, read off the result after exactly 10 minutes.**

To interpret the result, initially determine whether a line can be seen in the test window under (C). It is irrelevant how intense or faint the control line is.

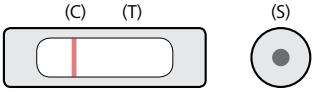
Positive result



The test result is **positive** if a light to dark red line appears in the control field (C) and a light or dark red line can be discerned in the test field (T).

The test result means that IgG antibodies associated with Helicobacter Pylori, are detectable in your blood sample. Detection of these antibodies indicates - with a high degree of probability - existing or recent infection with Helicobacter Pylori. You should contact your doctor to obtain a final diagnosis.

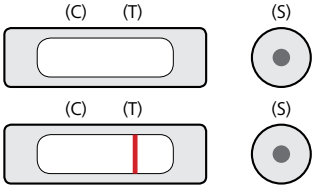
Negative result



The test result is **negative** if a light to dark red line appears in the control field (C) and no red line can be discerned in the test field (T).

The test result means that no IgG antibodies associated with Helicobacter Pylori could be detected in your blood sample. An infection with Helicobacter Pylori can virtually be ruled out. If gastrointestinal disorders or other symptoms persist, further diagnostic clarification by your doctor is necessary.

Invalid result



If you do **not** see a **control line (C) or** see **only a test line (T)**, the test did not proceed correctly and is invalid.

Check whether you have followed all points of the instruction leaflet exactly. Perform a new test with a new blood sample.