

Gluten intolerance

Rapid test for the detection of celiac disease

10 min



Accuracy
98 %



A sensitive issue for the stomach and intestines: the protein gluten

Frequently occurring unclear gastrointestinal disorders – such as bloating or also diarrhoea – may be caused by intolerance to gluten, a protein present in many foods. Gluten intolerance, also called celiac disease, may additionally manifest as notable weight loss, deficiency signs or also skin diseases.

Knowing where you stand: gluten intolerance rapid test

The Gluten intolerance rapid test from Veroval® enables you to find out quickly and reliably whether your disorders are caused by intolerance to gluten. If so, you can discuss with your doctor whether a gluten-free diet may be a sensible solution.

How reliable is the Veroval® test?

The Gluten intolerance 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 detection of transglutaminase antibodies (IgA antibodies), which are indicators of gluten intolerance. This test is suitable both for initial diagnosis and for follow-up testing of therapy. This is because the a-tTG-IgA antibodies regress within a few weeks during a gluten-free diet. After 6 months, the antibodies are no longer detectable.

Accuracy, as evidenced by performance evaluation studies, is 98 %.

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			Total
	Positive	Negative		
Gluten intolerance Rapid test	Positive	49	1	50
	Negative	1	29	30
	Total	50	30	80

Sensitivity: 98.00 % Specificity: 96.67 % Accuracy: 98.00 %

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 (e.g. with IgA deficiency).
- 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.

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

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



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



- 1 plaster



- 1 instruction leaflet

Explanation of symbols

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

NanoRepro AG
Untergasse 8
D-35037 Marburg



Distributed by:
GB – PAUL HARTMANN Ltd.
Heywood OL10 2TT

Gluten intolerance

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 sample dilution buffer by removing the lid and place it upright on the table.

2

- (a) Press the lancing device with the round opening against the side of the clean fingertip and activate the release mechanism (b).
- (b) Massage the tip of your index finger and clean with the alcohol swab (2). Allow your finger to dry.

- Twist the grey cap of an automatic lancing device (3) until it detaches. Then twist fully another 2 times.
- Press the lancing device with the round opening against the side of the clean fingertip (a) and activate the release mechanism (b).

3

- (4) Hold the glass capillary tube horizontally into the drop of blood until it has filled completely.

- 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 5 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 5 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 shows that IgA antibodies, which are associated with gluten intolerance, are detectable in your blood sample. Detection of these antibodies indicates - with a high degree of probability - the presence of gluten intolerance. 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 shows that no IgA antibodies, which indicate gluten intolerance, are detectable in the blood sample. The presence of gluten intolerance 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.