

GlutenCHECK®

Celiac disease. Quick check, timely identification!

Device for self-testing

INSTRUCTIONS FOR USE

GLUTENCHECK Rapid diagnostic test Celiac disease/Blood test

GlutenCHECK is a reliable and simple rapid diagnostic self test (immuno-chromatographic) for the detection of celiac disease associated IgA antibodies in a blood sample from the fingertip.

Read the instructions carefully before testing. Please perform the test in a well illuminated room.

WHAT IS CELIAC DISEASE?

Celiac disease is a lifelong, serious gastrointestinal disorder which can cause a wide spectrum of clinical symptoms such as diarrhoea, abdominal distension, malnutrition, weight loss or skin disorders. The illness is caused by a permanent intolerance to gluten, a complex mixture of proteins found in wheat, rye, barley and spelt. The symptoms of disease can only be avoided by following a gluten free diet.

TEST PRINCIPLE

GlutenCHECK is an immuno-chromatographic rapid diagnostic home test which detects the IgA antibodies in a blood sample taken from the fingertip. If the sample contains these antibodies the testing card will indicate a red coloured line in the testing and control field. An integrated control system ensures the correct use of the test.

The test requires only one drop of blood from the fingertip. The test performance takes only 5 minutes.

CONTENTS:

- 1 testing card and pipette
- 1 sterile automatic lancet
- 1 plastic vessel with glass capillary
- 1 alcohol-soaked swab
- 1 plaster
- 1 tube with 0.5ml sample dilution buffer
- 1 instruction for use

GlutenCHECK

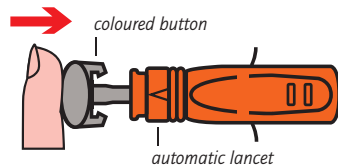
Preparations

- Before taking the blood sample prepare all necessary test components:
 - the automatic lancet
 - the alcohol-soaked swab
 - the glass capillary
- Remove the cap and open the tube containing the buffer.
- Then take the test card and the pipette out of the aluminium pouch.
- Place the test card horizontally on a dry surface.
- When the aluminium pouch has been opened you should carry out the test within 10 minutes.

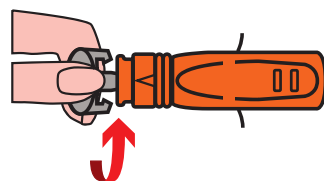
TEST PROCEDURE

1. Place the opened tube with the sample dilution buffer in front of you.

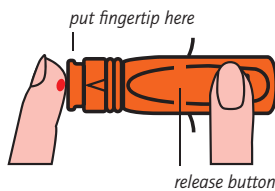
2. Press the coloured cap of the automatic lancet until it clicks into the casing.



3. After the audible click twist off the coloured cap.

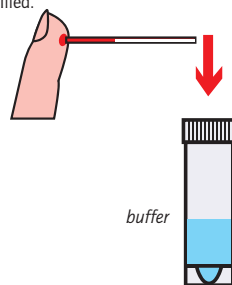


4. Gently massage the fingertip and clean it with the alcohol-soaked swab.

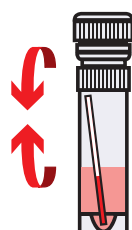


5. Press the round opening of the automatic lancet firmly against the cleaned fingertip and activate it with the button. The puncture is practically unnoticeable.

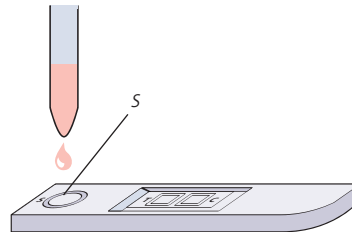
6. Press a drop of blood out of your fingertip. Then open the plastic vessel and remove the glass capillary carefully. Hold one end of the glass capillary horizontally in the drop of blood until it has filled.



7. Put the filled glass capillary in the tube containing buffer and close the tube firmly with the cap. Shake the tube several times until the blood from the capillary is mixed with the buffer.



8. Open the buffer tube and take a few drops of diluted sample with the pipette. Hold the pipette containing the diluted blood sample vertically over the round sample well (S) and drop 3 drops in it.



9. Now do not move or touch the test card for two minutes. The test result can be read after approx. 5 minutes. Do not read the test result after more than 10 minutes.

INTERPRETATION OF RESULTS

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



The test result is **negative** if a red control line appears in the control field (C) and no red line forms in the test field (T).



The test result is **invalid** if no red control line appears. It is likely that you did not follow the instructions correctly or that the test unit is damaged. Please repeat the test with a new test kit.

RESULTS

A **positive result** indicates that there are celiac disease associated IgA antibodies in the tested blood. There is a high probability (> 97%) of an existing celiac disease. You should consult your doctor to discuss further treatment.

A **negative result** indicates that there are no celiac disease associated IgA antibodies in the tested blood. An existing celiac disease can virtually be ruled out. If gastrointestinal complaints are present, further medical investigation is necessary.

STORAGE

Store the devices and accessories in room temperature (10-27°C). The shelf life of the tests is 18 months; storage conditions must be followed. The date of expiry is indicated on the aluminium pouch of the test device as well as on the outer carton box.

WARNINGS AND LIMITATIONS

- If the instructions are not followed in detail then the results of the test might be false.
- Do not start a gluten free diet without consulting your doctor.
- Do not reuse the test or test accessories.
- Do not use the test beyond the expiration date.
- Do not use the test if the aluminium pouch is damaged. Do not use broken accessories.
- Perform the test no longer than 10 minutes after opening the aluminium pouch.
- The sample buffer contains 0,09% sodium azide. Avoid contact with the skin. Do not swallow.
- The incidence (frequency in 100.000 persons) of a lack of IgA antibodies in patients with celiac disease is 2-3%. These cases cannot be diagnosed with GlutenCHECK.
- **GlutenCHECK does not substitute medical diagnosis. In case of celiac disease always consult your doctor.**

www.glutencheck.com

 Follow instruction	IVD for in-vitro diagnostics only (use outside body)	 See imprint on package
 Store (10-27°) dry, DO NOT FREEZE!	 Tests per package	 Do not reuse
 Instructions English Information: February 2011	 NanoRepro AG Untergasse 8 D-35037 Marburg	 See imprint on package

CE 0197
Instructions English
Information: February 2011

NanoRepro AG
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