

INSTRUCTIONS FOR USE

INTRODUCTION

Gluten intolerance (celiac disease), known as sprue in adults, is an autoimmune disorder of the small intestine, when the immune system attacks the body's own tissues. The common symptoms of gluten intolerance include bloating and diarrhea, caused by a reaction to a gluten protein found in many foods. The following symptoms could be also a sign of gluten intolerance, such as weight loss, malnutrition and skin disorders.

GlutenCHECK® is intended as an aid in the diagnosis of gluten intolerance. GlutenCHECK® as an immunochromatographic rapid test detects the presence of anti-tTG IgA antibodies in whole blood.

If the sample contains anti-tTG IgA antibodies, these will bind with the colloidal gold labelled anti-IgA antibodies and the tTG (derived from the lysis of red blood cells in the dilution buffer). tTG will then bind the complex to the stationary protein line (test line) forming a visible, red line. The test has also a control system with a control line.

GlutenCHECK® is suitable for both, an initial diagnosis of gluten intolerance as well as a therapy follow-up. a-tTG-IgA antibody level should fall when gluten is removed from the diet. After 6 months on gluten-free diet the antibodies will often become undetectable.

The diagnosis must be confirmed by a physician with further recommendation to maintain a gluten-free diet.

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 cassette (tTG-IgA, 5 U/mL) 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

- 1 alcohol pad
- 1 plaster
- 1 instruction pamphlet

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.

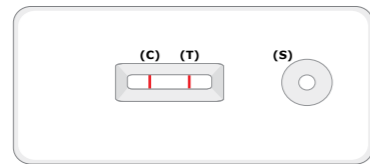
EVALUATION OF TEST RESULTS

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.

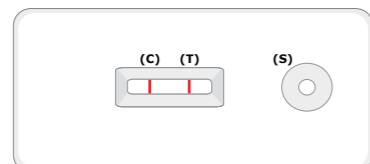
The test result indicates that blood sample contains gluten intolerance specific IgA antibodies, indicating with a high probability existing gluten intolerance. The diagnosis must be confirmed by a physician.



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.

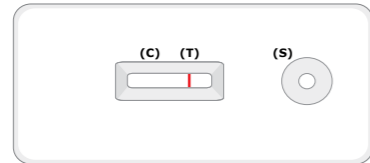
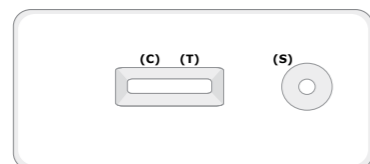
The test result indicates that gluten intolerance specific IgA antibodies are not present in the blood sample. No gluten intolerance has been detected. If there are any gastrointestinal symptoms, please, visit a physician for further medical investigation.



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

Gluten-CHECK	Reference Test		
	Positive	Negative	Total
Positive	49	1	50
Negative	1	29	30
Total	50	30	80

Sensitivity: 98,00%
Accuracy: 98,00%

Specificity: 96,67%
Trueness: 97,50%

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.
- False negative result may occur only in few medical cases, such as IgA deficiency.
- 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 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.

BIOLOGICAL REFERENCE RANGE AND LITERATURE

GlutenCHECK® detects tTG-IgA values greater than 5 U/mL with a positive test result. A. Di Sabatino et al. The function of tissue transglutaminase in celiac disease/Autoimmunity Reviews 11 (2012) 746753.

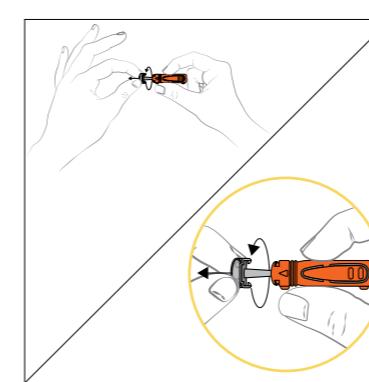
For further information regarding the biological reference range or literature, please contact the manufacturer.

For self-testing

STEP-BY-STEP INSTRUCTION

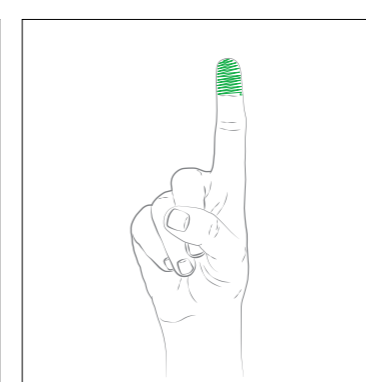
For self-testing

STEP 1



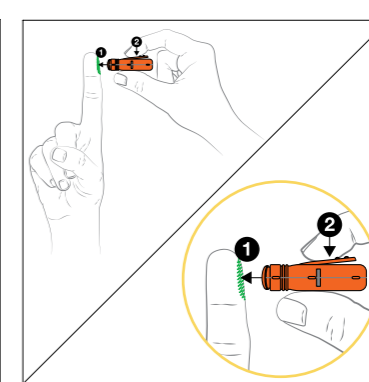
Twist the grey cap on the automatic lancet until cap separates easily from lancet body. Then twist it at least two more times before removing the cap, otherwise the proper function can not be ensured.

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.

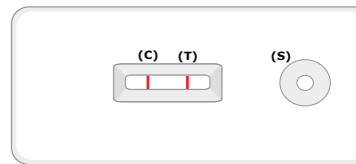
STEP 3



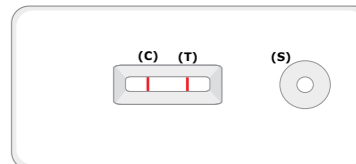
Press the automatic lancing device with the round opening firmly against the clean fingertip 1 and activate it by pushing the button 2.

TEST RESULT

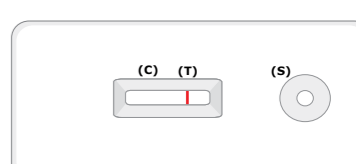
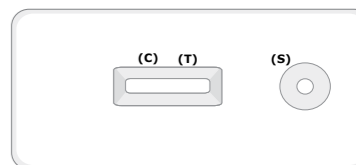
POSITIVE TEST RESULT



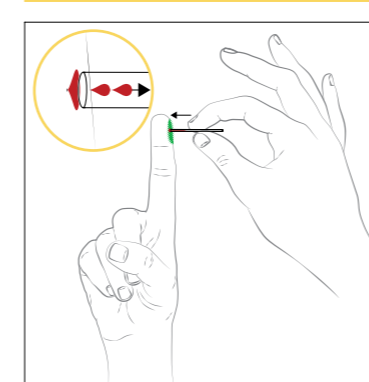
NEGATIVE TEST RESULT



INVALID TEST RESULT

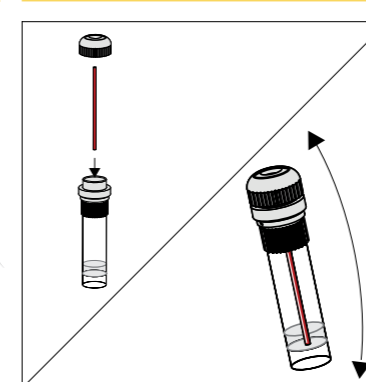


STEP 4



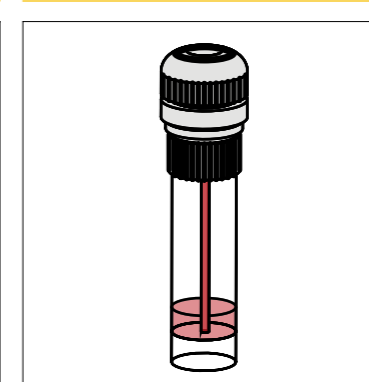
Open the plastic container and carefully remove the glass capillary tube. Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally against the blood drop on the finger until it has completely filled.

STEP 5



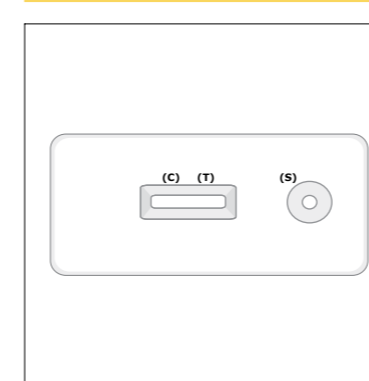
Insert the filled glass capillary into the solution bottle and screw the cap back. Mix the content of the solution bottle by turning it gently upside down several times until the blood from the glass capillary tube is mixed with the solution.

STEP 6



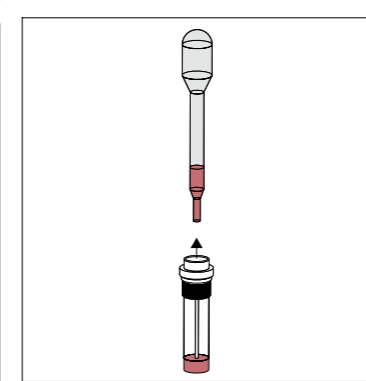
Before twisting off the cap, let the sample mixture settle back to the bottom of the solution bottle. Only then twist off the cap.

STEP 7



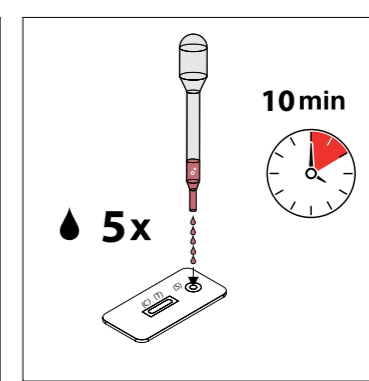
Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

STEP 8



Insert the pipette into the solution mixture and add a few drops of the sample mixture.

STEP 9



Hold the pipette with the sample mixture straight over the test cassette and squeeze gently to add exactly 5 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).

After adding the 5 drops to the sample well, read the result after 10 minutes. After more than 15 minutes false-positive results may occur.

Please give us your feedback on our product by simply filling in the form at the website.

www.zuhausestest.de | www.glutencheck.com

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)