Gluten intolerance (celiac disease), known as sprue in adults, is an autoimmune disorder of the small intestine, where 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 labeled gold particles to form a line. The test result indicates that gluten intolerance specific IgA antibodies are not present in the blood sample. No Control line (C) has been detected. If there are any gastrointestinal symptoms, please visit a physician for further medical investigations.

**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 plaster
- 1 pipette
- 1 alcohol pad
- 1 instruction pamphlet

**TEST PREPARATION**
- Take the cassette and solution bottle and stand at a room temperature (15°C to 27°C) before performing the test. Open the solution bottle with the sample dilution buffer by peeling off the foil and cut the cap and let it stand upright on a table.

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

**STEP-BY-STEP INSTRUCTION**

**STEP 1**
Twist the grey cap on the automatic lancet until it separates easily from the lancet body. Then twist it at least two more times before removing the cap, otherwise the proper function can not be ensured.

**STEP 2**
Insert the filled glass capillary into the solution bottle and screw the cap back. Mix the contents 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 3**
Ensure the automatic lancing device with the round opening firmly against the clean finger tip and activate it by pushing the button 5x.

**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 drops on the finger until it has completely filled.

**STEP 5**
Gently 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 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 bottle and add a few drops of the sample mixture.

**STEP 9**
Hold the pipette with the sample mixture right over the test cassette and immediately to add exactly 5 drops to the sample well (S). Please note, that there should be no liquid applied to the test window 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.

**POSITIVE TEST RESULT**
If there is no Control line (C) or only a faint red to dark red Control line (C) position, it does not matter how strong or weak a Control line (C) is. The test result indicates that gluten intolerance specific IgA antibodies are not present in the blood sample. Does not state 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 and 27°C.

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

**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.

**INFORMATION**
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 and 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 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.

For self-testing

Follow instructions
In vitro diagnostic medical device (for external use)
Manufacturer
Stabilization by irradiation
LOT
Best before (See imprint on package)
Content sufficient for 1 test
Do not know
State of Temp. –20°C DO NOT FREEZE
Instructed English Revision from 2017-11 (Rev. 02)

**www.zuhaustest.de** | **www.glutencheck.com**