

autotest GLUTEN®



USER INSTRUCTIONS



SYMBOL KEY:



Caution, running buffer contains sodium azide 0.09%; toxic if ingested, in contact with an acid liberates a highly toxic gas. Harmful to aquatic organisms, causing long term adverse effects. Contains gentamicin sulfate. Can cause an allergic reaction. Avoid all contact with eyes, skin or clothing. Collect spillage.

AAZ-IMB
41 rue de Bellevue
92100 Boulogne-Billancourt - France



AAZ_AG_14A (20191212) User Instructions for autotest GLUTEN®

FRANÇAIS
ENGLISH
DEUTSCH
ITALIANO
ESPAÑOL
NEDERLANDS

- autotest GLUTEN® is a home test for detecting coeliac disease from a sample of blood taken from the fingertip.
- autotest GLUTEN® is a single-use in vitro diagnostic device.
- autotest GLUTEN® is designed for use by individuals in a non-medical environment.
- Please read the instructions carefully and thoroughly before starting the test.
- Take the test in a well-lit place. You will need a watch or timer.

KIT CONTENTS



THE HOME TEST STEP BY STEP

Further information and a demonstration video are available on autotest-sante.com

STEP 1

1. Open the sachet **A** and take out the test cassette **B**. Place it on a clean, flat surface.



2. Unscrew the cap from the vial of diluent **C**, open the plastic tube **D** and put down the capillary tube **E** within reach.

STEP 2

1. Wash your hands with soap and hot water then dry them before going on to the next step.
2. Remove the sterile swab **F** from its sachet, sterilize the fingertip and wait for your finger to dry.



3. Take the lancet **G** and remove its clear cap. Apply its red side to your finger and press hard until you feel the needle going in.



4. Press the fingertip to form a large drop of blood for the sample.



STEP 3

1. Take the capillary tube **E** and place it horizontally in the drop of blood until it is completely full.



2. Put the filled capillary tube **E** in the vial of diluent **C** and close it with its cap.



3. Shake the vial of diluent **C** by inverting several times until the blood from the capillary tube **E** is completely mixed in with the diluent.



4. Remove the cap from the vial of diluent **C** again and extract the diluted sample using the pipette **H** by pressing its bulb.

5. Hold the pipette **H** vertically and remove 3 drops of the diluted sample in the sample well (S) of the test cassette **B**.



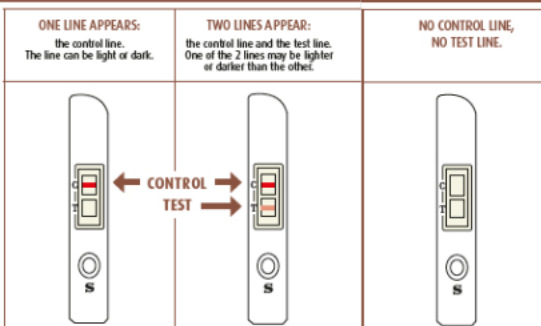
STEP 4

1. Make a note of the time and wait for 5 minutes before reading the result.
2. Put on the plaster **I**.



DO NOT READ BEYOND TO MIN

READING THE HOME TEST RESULTS



YOUR HOME TEST IS NEGATIVE

YOU PROBABLY DO NOT HAVE COELIAC DISEASE

The test shows that there are no IgA^a anti-transglutaminase antibodies in the examined blood. The possibility of coeliac disease can be practically eliminated. If the gastro-intestinal pain continues see your doctor.

YOUR HOME TEST IS POSITIVE

YOU PROBABLY HAVE COELIAC DISEASE

1. SEE A DOCTOR as soon as possible and tell him/her that you have just taken the autotest GLUTEN® and your result is positive.
2. The result of your home test must be confirmed by a confirmation laboratory test.
3. You must not start a gluten-free diet before your doctor has received the results of the confirmation tests. He/she will confirm the diagnosis and prescribe the gluten-free diet.

YOUR HOME TEST IS INCONCLUSIVE OR INVALID

SEE YOUR DOCTOR

- Two scenarios are possible:
- 1st scenario: you may have a deficiency of total IgA^a.
 - You cannot be detected by autotest GLUTEN®.
 - 2nd scenario: you may have made a handling error or the test may not have worked. Your test is therefore invalid.

IF YOUR HOME TEST DOES NOT MATCH ANY OF THE CASES SHOWN HERE, YOUR RESULT IS INVALID.

Use lancets may be considered by your local authorities as medical waste. To reduce the risk of injury with used devices, follow the local recommendations for their disposal. Ask your pharmacist. More information on autotest-sante.com

PRINCIPLE AND PERFORMANCES OF THE TEST

Coeliac disease is an auto-immune disease of the intestine triggered by the consumption of gluten. It manifests as various symptoms: diarrhoea, tiredness, abdominal pain, weight loss, anaemia... If in doubt about the reason for your symptoms, have yourself screened and have the diagnosis confirmed by your doctor before starting a gluten-free diet or changing your eating habits.

autotest GLUTEN® is a home test for detecting coeliac disease but the final diagnosis must be after a confirmation test, by a doctor.

In cases of coeliac disease, a specific antibody is found in the patient's blood: the IgA anti-transglutaminase antibody. This is the marker that is detected and turns the line positive.

False negatives (around 2% of coeliac disease sufferers) found with the usual laboratory tests and 1st-generation quick tests are due to a deficiency of total IgA. The second-generation autotest GLUTEN® was designed to correct this defect. This total IgA deficiency is indicated by the absence of the control line C. In this case, your doctor will prescribe a dose of IgG anti-transglutaminase in the laboratory.

The ESPGHAN (European Society for Paediatric Gastroenterology Hepatology and Nutrition) suggests that the dose of total IgA be given as first-line treatment. During a gluten-free diet, the level of coeliac disease auto-antibodies will decrease and become undetectable after the latest 6 months after the change of diet. Consequently you will have a negative test result if you follow a gluten-free diet.

This autotest GLUTEN® is a good tool for monitoring the observance of a gluten-free diet under doctor's instructions among patients with coeliac disease.

Test sensitivity and specificity study^{***}, compared with the laboratory test, the sensitivity is of 95.7% and the specificity of 97.1%. The concordance of reading of the results of the quick tests was of 100% between two investigators. The test shows a positive predictive value (PPV) of 100% in the 44 positive patients with the quick test who agreed to undergo an intestinal biopsy. These patients all exhibited the lesions of the duodenal mucosa typical of coeliac disease.

Reliability: the feasibility study of this home test by lay-people showed that over 96% of participants who used this home test obtained an interpretable result.

^{***} Study carried out on 150 patient samples compared with a laboratory test (BAMVO et al. Alimentary Pharmacology & Therapeutics).

PRECAUTIONS AND WARNINGS

- If the use instructions are not correctly followed, the test results may be false.
- If a gluten-free diet is already in progress, the test may give a false negative.
- A final diagnosis must be given only by a doctor, in conjunction with the clinical symptoms.
- The incidence of the total IgA deficiency is of approximately 2% among patients with the illness. Patients having a total IgA deficiency cannot be diagnosed by autotest GLUTEN®.
- Do not begin a gluten-free diet without consulting a doctor.
- Do not use the test if the expiry date has expired.
- Do not use the test if the foil pouch is damaged.
- Do not use damaged accessories.
- When the foil pouch is open, you must take the test within 60 minutes.
- The vial of diluent contains 0.09% sodium azide. Avoid contact with skin. Do not swallow!
- All the components of this test are designed for this test only. Do not reuse the test or accessories.
- Do not mix contents coming from different kits.
- Keep autotest GLUTEN® out of reach of children.

^aIgA: Immunoglobulin. ^bThe incidence of total IgA deficiency in the general population is approximately 0.5%. The deficiency is symptomatic in most cases.