

TEST GLUTEN

Deamidated Gliadin IgG

Exacto®

EXACTO® Test Gluten is an easy-to-use, reliable self-test that can be performed at home for the initial screening of celiac disease, also known as gluten intolerance.

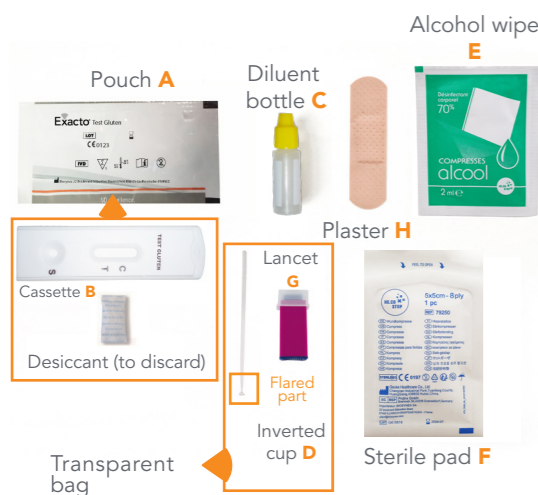
Celiac disease is a chronic disease of the small intestine accompanied by a multitude of symptoms of varying intensity, such as flatulence, diarrhea, abdominal pain, loss of appetite, weight loss, headache, chronic fatigue, eczema, sleep disorders, depression, etc.

The causative agent of celiac disease is a peptide, called gliadin, contained in the dietary gluten. The digestion of gliadin leads to the formation of deamidated gliadin peptides which, in people with celiac disease, trigger an abnormal immune reaction with the production of antibodies responsible for inflammation of the intestine.

EXACTO® Test Gluten is an immunochromatographic test for the detection of these antibodies specifically produced in case of celiac disease and directed against deamidated gliadin peptides.

Being on a gluten-free diet for several months prior to the test may lead to the disappearance of the celiac disease specific antibodies and may lead to a false negative result. The screening disease, and therefore the test, must be performed as part of a diet containing gluten to give a reliable result.

KIT CONTENT



ADVICE FOR SAMPLING

First, wash your hands with hot water and dry them properly. Warm water helps improve blood circulation at the fingertips.

You can let your hand hang loose along your body for about 1 minute so that more blood flows into it.

It is recommended to puncture the left hand for right-handed people, and the right hand for left-handed people.

Preferably prick the tip of the finger on the side: this is where the blood flow is the highest and the sensitivity is minimal. Avoid areas where the skin is thicker, so more difficult to prick.

It may happen that a drop of blood does not appear right away. In this case, you may wait a little and gently massage your finger, from the base to the pricked area. If the «S» test well is not completely filled with blood (step 13), you may form a new drop of blood and transfer it into the «S» test well using the inverted cup.

BLOOD COLLECTION

- 1 Please, read the leaflet entirely.** Have a watch or a timer (only equipment not provided at hand).
- 2** Wash your hands with soap and warm water, then dry them before processing to the next step.
- 3** Open the box and **remove all the items from their packaging.** Place them on a dry, clean surface. Identify each item of the kit (see kit content on the left, count 8 items from A to H).
- 4** Open the pouch **A** and remove the cassette **B**. Use the test within one hour.
- 5** Unscrew the cap of the diluent bottle **C** and place it vertically on the working area.
- 6** Take the alcohol wipe **E** out of its pouch and disinfect the tip of the finger chosen for sampling.
- 7** Remove the sterile pad **F** from its pouch and wipe off the traces of alcohol.
- 8** Remove the cap from the lancet **G**.
- 9** Apply the lancet **G** on the fingertip. Trigger it by pressing firmly on the other end.

- 10** Squeeze the tip of the finger to form a large drop of blood.
- 11** Place the flared part of the inverted cup **D** in contact with the drop of blood to fill the cup entirely.

TEST PROCEDURE

- 12** Immediately transfer the drop of blood into the **S** well of the cassette **B** (the drop of blood must be in direct contact with the bottom of the well).
- 13** Check that the bottom of round well **S** is completely red before proceeding to the next step. Otherwise, form a new drop of blood by pressing firmly the tip of the pricked finger.
- 14** Unscrew the cap of the diluent bottle **C**. Transfer **3 drops** into the **S** round well of the cassette **B**.
- 15** Start the timer or write down the time of deposit. **Wait 10 minutes to read the result.** Do not read beyond 20 minutes. During this time you can put on the plaster **H**.

INTERPRETATION

	NEGATIVE	POSITIVE	INVALID
PLACE YOUR TEST HERE			
	The result of the test is NEGATIVE if a colored band appears only in the control zone (C). No colored bands appear in the test zone (T). A negative result indicates the absence of anti-deamidated gliadin antibodies and thus avoids the risk of celiac disease. If symptoms persist as part of a gluten-containing diet, consult your doctor.	The result of the test is POSITIVE if a colored band is visible both in the control zone (C) and in the test zone (T). A positive result indicates the presence of anti-deamidated gliadin antibodies and suggests with a high probability the diagnosis of celiac disease. Please, consult your doctor for a definitive diagnosis and adequate treatment.	The result is INVALID if no colored band is visible in any zone, or if no colored band appears in the control zone (C). You may perform a new test.

PERFORMANCES

EXACTO® TEST GLUTEN has undergone assessments. A 96.7% correlation between EXACTO® TEST GLUTEN and an ELISA laboratory test was observed.

- A clinical study performed on 179 sera samples showed that EXACTO® TEST GLUTEN has a sensitivity of 93.8% and a specificity of 97.9%.
- A practicability study conducted with a laymen population showed that 100% of participants obtained a correct and interpretable result.
- A readability study confirmed that 99.1% of the different types of results were interpreted correctly.

QUESTIONS AND ANSWERS

What is the difference between "gluten intolerance" and Celiac disease?

Gluten intolerance is also known as Celiac disease. Celiac disease is a chronic autoimmune bowel disease triggered by the consumption of gluten or gluten-containing food.

Is a positive result with the EXACTO® Test Gluten self-test sufficient to diagnose celiac disease?

The EXACTO® Test Gluten self-test allows you to determine at home, quickly and safely whether you are likely to have celiac disease. If this is the case, consult your doctor for a definitive diagnosis and take the appropriate measures.

I have changed my lifestyle for a gluten-free diet. Can I still use the EXACTO® Test Gluten self-test?

A gluten-free diet for 1 to 3 months prior to testing may result in the disappearance of celiac disease specific antibodies and may thus interfere with test positivity. We therefore recommend using the EXACTO® Test Gluten self-test as part of a gluten-containing diet in order to obtain a reliable result.

The result of my EXACTO® Test Gluten self-test is negative. Am I gluten tolerant?

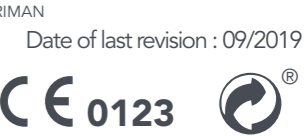
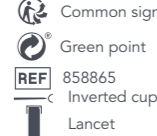
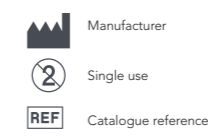
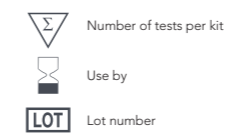
The EXACTO® Test Gluten self-test only detects the presence in your blood of anti-deamidated gliadin antibodies characteristic of celiac disease. Other types of gluten hypersensitivity exist with symptoms suggestive of functional digestive disorders and/or allergic manifestations in subjects not diagnosed with celiac disease. If your symptoms persist as part of a gluten-free diet despite a NEGATIVE result of the EXACTO® Test Gluten self-test, consult your doctor.

PRECAUTIONS FOR USE

- Do not freeze. Keep in a dry place between 2°C and 30°C.
- Remove the test cassette from the sealed pouch and use it within one hour.
- Run the test in a place where the temperature is between 15°C and 30°C.
- This test should be used only from a blood sample and should be performed immediately after blood sample collection at the fingertip.
- Single use.
- The bottom of the sample well must be completely red before adding the diluent.
- Keep the self-test and all components out of children's reach; ingesting the diluent may be dangerous and the lancet could potentially cause injury.
- Do not use the self-test beyond the expiry date printed on the aluminium pouch and on the carton box.
- A positive result must be confirmed by a histological analysis of the small intestine after biopsy. Consult your doctor to determine the suitability of a gluten-free diet.
- This test does not replace the doctor's diagnosis. Contact your doctor if you think you are suffering from celiac disease.
- Erroneous results may be obtained:
 - If the test is not used according to the instructions in the package leaflet,
 - If the aluminum pouch is damaged or if the test is not performed immediately after opening the aluminum pouch,
 - If the storage conditions are not respected or if the test is performed after the expiration date on the aluminum pouch.
- The used test cassette and all test components can be disposed of with household waste.
- All components included in this test are for this test only. Do not reuse this test and / or its components.

BIBLIOGRAPHY

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