

GlutenTox[®]Home

Quick test for the detection of gluten in food, beverages
and oral hygiene products

1. Intended purpose and Introduction

GlutenTox Home is a rapid and user-friendly test for the detection of gluten, which is harmful for celiac disease sufferers, in food, beverages and oral hygiene products.

Celiac disease is a disorder that damages the small intestine causing the atrophy of the intestinal villi, which interferes with the absorption of nutrients such as proteins, lipids, carbohydrates, mineral salts and vitamins. This disease is caused by an inappropriate response of the immune system to gluten (a mix of proteins found in cereals) from wheat, barley, rye, and to a lesser extent, from oat, leading to diarrhea, vitamin and mineral deficiencies, anemia and thin bones (osteoporosis). Celiac disease affects people of all ages.

Currently, the only treatment for celiac disease sufferers is a strict, lifelong gluten-free diet which presents great difficulties because gluten, in addition to being present in many foods, may also be found in food additives and preservatives.

According to the Codex Alimentarius Commission and the EC Regulation 41/2009 on the composition and labeling of foodstuffs suitable for people intolerant to gluten, food can be considered as “gluten-free” if its gluten content does not exceed 20 parts per million (ppm*).

* Milligrams of gluten per kilo of food (mg/kg).

2. Supplied materials

GlutenTox Home 2 units (KIT3009/KT-5472)	GlutenTox Home 5 units (KIT3010/KT-5000)
<ul style="list-style-type: none">• GlutenTox Home cassette and plastic pipette, in foil pouch (x2)• Disposable plastic spoons (x2)• Extraction bottle with yellow cap (x2)• Disposable plastic pipette (x2)• Dilution bottle with blue cap (x2)• Instructions leaflet	<ul style="list-style-type: none">• GlutenTox Home cassette and plastic pipette, in foil pouch (x5)• Disposable plastic spoons (x5)• Extraction bottle with yellow cap (x5)• Disposable plastic pipette (x5)• Dilution bottle with blue cap (x5)• Instructions leaflet

3. Useful but not supplied materials

- Mortar or any other utensil to grind the sample
- Non-powdered disposable gloves
- Alcohol (ethanol)
- Scale (precision 0.1 g)
- Watch (a stopwatch is preferable)

4. Storage conditions

The product must be stored at room temperature (15 - 25 °C/ 59 - 77 °F). Do not open the foil pouch containing the GlutenTox Home cassette until the time of use. After the analysis all GlutenTox Home components may be disposed in the regular trash.

5. Precautions

- The use of non-powdered disposable gloves is recommended, in order to avoid dust contamination of the test. If you do not have disposable gloves, wash your hands thoroughly before the test.
- Once the GlutenTox Home cassette has been removed from the pouch, it must be used as soon as possible under strict clean conditions.
- Do not use any material from the kit after the expiration date.
- Do not drink any solution (liquid) from the kit and **keep out of reach of children**.

6. Warning and limitations

Gluten extraction efficiency may be lower although still sufficient, when preparing for analysis the following types of samples:

- Foods containing low amounts of polyphenols or tannins, (e.g. samples with less than 70% of chocolate, black tea, coffee, wine, berries, etc.)
- Samples with antioxidants, such as vitamins A, E and C.
- Food heat-treated with temperatures above 180 °C (356 °F).

When testing the types of samples described above, working under conditions of maximum sensitivity is advised (10 drops of the extract to the [dilution bottle with blue cap](#), see section 7.5 below).

IMPORTANT NOTE!: In these cases it has been found that at least 25% of the total content of gluten present in the sample is extracted. Therefore, if a negative result is obtained when working under conditions of maximum sensitivity (with 10 drops), it can be assured that the food contains less than 20 ppm of gluten and, therefore, it can be considered as "gluten-free" and suitable for celiacs in accordance with current regulations.

IMPORTANT NOTE!: GlutenTox Home is not recommended* for food samples with a high content of polyphenols and tannins, i.e. foods in which the major component (> 70%) is chocolate, black tea, coffee, wine, berries, etc.; in these cases, the extraction process can be insufficient and therefore underestimate the amount of gluten in the sample.

* For more information contact your supplier.

7. Sample preparation and analysis

IMPORTANT NOTE!

- **Before using the kit, clean thoroughly with soap and water the utensils and working areas that may be in contact with the sample. Rinse well. After cleaning, it is highly recommended to wipe them with a clean cloth dampened with alcohol.**
- **If a food has several parts, be sure to take a representative sample of each one and prepare a final, homogeneous sample. If you do not do this, and the gluten was distributed unevenly in the food, a false negative could be obtained.**

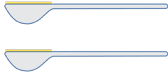
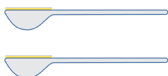


7.1. If the sample is liquid, shake it vigorously to homogenize it completely before sampling. If the sample is semi-liquid or doughy, stir it with the help of a toothpick or clean spoon to obtain a homogeneous mixture.

If the sample is solid, grind it as much as possible using a mortar and/or a domestic meat grinder/mincer, which must be perfectly clean. If the food sample is very hard (sweets, nougat, etc.) fragment it first with a knife or a small hammer to achieve an efficient grinding.

7.2. Use the provided spoon with leveled amounts of sample following the instructions in Table 1 or, if you have an appropriate scale⁽¹⁾, weigh 1 gram of sample. If the sample is liquid, use one leveled spoonful or take 1 milliliter of the liquid.

(1) The use of a scale increases the accuracy of the analysis process.

Table 1. Amount of sample depending on the type of food

Type of sample	Examples	Spoonful
Flours, fine powders	Corn flour, rice flour, milk powder, spices, rolled oats, etc.	
Fine crumbs	Bread, cookies, cakes, snacks, etc.	
Liquids and sauces	Milk, juice, condensed milk, yogurt, soup, gravy, sauce, cream, mouthwash, toothpaste, etc.	
Meat, fish and cold meat	Meat, fish, sausage, black pudding, pâté, canned meat and fish, etc.	

7.3. Add the content of the spoon, the gram or the milliliter to one **extraction bottle with yellow cap**.

7.4. Close the bottle, shake it vigorously for at least 2 minutes and let it settle for about 5 minutes so that the solids fall to the bottom of the tube. The settling time will depend on the type of sample.

7.5. Open one **dilution bottle with blue cap**. Using one disposable plastic pipette, take some liquid from the **extraction bottle with yellow cap** and add either **10 or 2 drops** to the **dilution bottle with blue cap** according to your required threshold/limit of detection (LOD) (Table 2). Mix softly for at least 15 seconds. Discard the plastic pipette.

Table 2.

n° drops	LOD
10	5 ppm
2	20 ppm

7.6. Open the pouch containing the GlutenTox Home cassette and the plastic pipette. Use this pipette to take some liquid from the **dilution bottle with blue cap** and add **10 drops** to the S zone of the cassette. Do not use the pipette that you used in step 7.5.

7.7. Wait 10 minutes to see the final result (if the sample has a high concentration of gluten, the result may appear in less than 1-2 minutes).

IMPORTANT NOTE!

- Wait 10 minutes to read the result. Do not wait longer, as the results may vary.

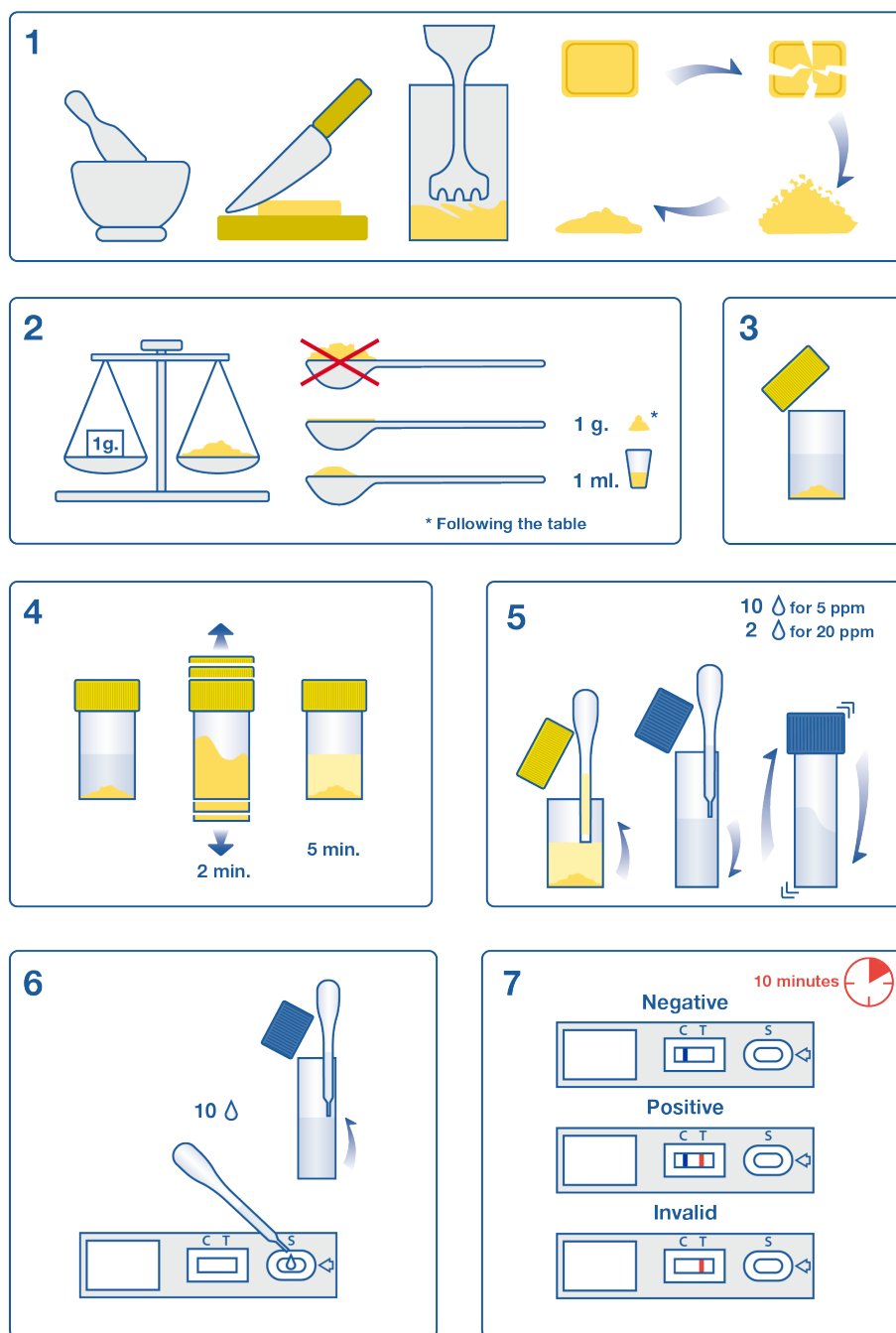


Figure 1. Preparation and analysis of samples.

8. Interpretation of results

Negative: A single BLUE line (control line) appears in the control zone (C) of the cassette. This line is also the internal control of the process. The presence of the blue line indicates that the volume of sample added to the cassette was sufficient and that the procedure has been correctly followed.

Positive: In addition to the control line (BLUE), a RED line (test line) appears in the test zone (T). The intensity of the red line in the test zone will vary depending on the gluten concentration present in the sample.

The threshold of detection depends on the number of drops (10 or 2 drops) added to the dilution bottle with blue cap in step 7.5. (see Table 3).

Table 3. Interpretation of results ⁽²⁾

		Gluten content in the sample	
		10 drops	2 drops
Test Result	Positive	> 5 ppm	> 20 ppm
	Negative	< 5 ppm	< 20 ppm

⁽²⁾ The results are qualitative for limit of detection.

Invalid: The control line (BLUE) does not appear, whether or not the result line appears (RED). The most common causes for the appearance of an invalid result are: an insufficient quantity of sample, following an incorrect procedure, or deterioration of the reagents. In the case of invalid results, it is necessary to repeat the experiment with a new test always following a correct procedure. If the problem persists, you must contact the supplier and stop using the test.

9. Analytical features

9.1. Sensitivity

The detection limit of the assay is 5 ppm of gluten, working at maximum sensitivity (10 drops). This detection limit is always reached in simple samples, such as raw materials, foods with limited degree of processing and non heat-processed foods. The high sensitivity of the test complies fully with the Codex Alimentarius guidelines and Regulation (EC) 41/2009, which sets a limit of 20 ppm to consider the food as "gluten-free".

9.2. Specificity

This test can specifically detect the presence of the toxic fraction of the prolamins of wheat (gliadin), rye (secalin), barley (hordein) and also of varieties of oat (avenin) that can be toxic and therefore harmful for celiac patients. However, no positive signal is observed when samples contain vegetal ingredients safe for celiac disease sufferers, like rice, corn, soy, buckwheat, sesame, millet, teff, quinoa and amaranth.



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