GlutenTox Home

Quick test for the detection of gluten in foods

Ed.2 - January 2010

Biomedal DIAGNOSTICS

1. Intended purpose

GLUTENTOX Home Kit is a rapid and user-friendly test for the detection of gluten in food and drinks which is harmful for celiac disease sufferers.

2. Introduction

Celiac disease is a disorder which damages the small intestine causing the atrophy of the intestinal villi and intervenes 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 [ref.1].

Nowadays, the only treatment for celiac disease sufferers is a lifelong gluten-free diet, which might not always be easy to follow because gluten, in addition of being present in many foods, may also be found in food additives and conservant.

According to the Codex Alimentarius Commission, food can be considered as "gluten-free" if the amount of gluten does not exceed 20 parts per million (ppm), and is considered as "very low in gluten content" if the amount of gluten does not exceed 100 ppm.

3. Storage conditions

The product must be stored at a temperature ranging from 2°C to 30°C in its sealed box for optimal use until expiry date printed on it. Do not open before use.

4. Precautions

- Only for foodstuff analysis, **except for food containing chocolate.**
- To avoid contaminations that interfere with the analysis, the use of non-powdered disposal gloves is recommended. If you do not dispose of disposal gloves, wash your hands thoroughly before the test.
- Once the GlutenTox Home stick has been removed from its metallic envelope, it must be used as soon as possible under strict clean conditions.
- Do not use any material from the kit after the expiry date.
- Do not drink any solution (liquid) from the kit.
- **Keep out of reach of children**.

5. Supplied materials

- GlutenTox Home Sticks (x5) and plastic pipette (x5) contained in metallic envelope.
- Disposal plastic spoons (x5).
- Extraction bottle with yellow cap (x5).
- Disposal plastic pipette (x5).
- Dilution bottle with blue cap (x5).
- Instructions leaflet.

6. Useful but not supplied materials

- Watch (a stopwatch is preferable).
- Scale.
- Disposal gloves.
- Mortar or any other utensil to grind the sample.
- Alcohol.

7. Preparation and sample analysis

IMPORTANT NOTE !

- Before and after using the kit clean the utensils and the areas in which the sample has entered in contact, with soap and water, and rinse well. After cleaning, it is highly recommended to wipe them with a clean cloth dampened with alcohol.

1. Grind the sample as much as possible using a mortar and/or a domestic meat grinder/mincer which must be perfectly clean. If the food sample is too hard (sweets, nougat, etc.) previously fragment it with a knife or a little hammer to achieve and efficient grinding.

2. Weit 1 gram of sample on a scale. If you do not dispose of a scale, use the provided spoon with leveled amounts the sample following the table. If the sample is liquid, take 1 milliliter of the liquid, or use leveled spoon .

Kind of food	Examples	Spoonful
Flours, Fine powders	Maize flour, rice flour, powdered milk, spices, etc.	
Fine crumbs	Bread, cookies, cakes, snacks, etc.	
Liquids	Milk, condensed milk, yogurt, soup, gravy, etc.	

3. Add the gram, the milliliter or the content of the spoon to the extraction bottle (EB) with yellow cap.

4. Close the bottle, shake vigorously for at least two minutes and let it settle for about 5 minutes so that the solid rests fall on the bottom of the tube. The settling time will depend on the type of sample.

5. Using the disposal plastic syringe, take some liquid from the extraction bottle (EB) with yellow cap and add 2 drops to the dilution bottle (DB) with blue cap. Mix softly for at least 15 seconds.

6. Open the **metallic envelope (GT)**, and remove the stick and the plastic pipette (do not re-use the pipette from point 5). With the pipette, add 5-6 drops from the dilution bottle (DB) with blue cap to the S zone on the stick. Wait for 10 minutes to see the final result (if there is a high concentration of gluten, the result may appear in less than 1-2 minutes).

GlutenTox home

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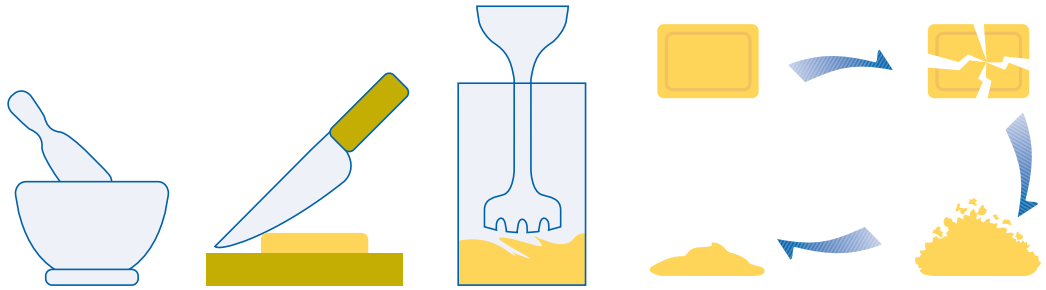

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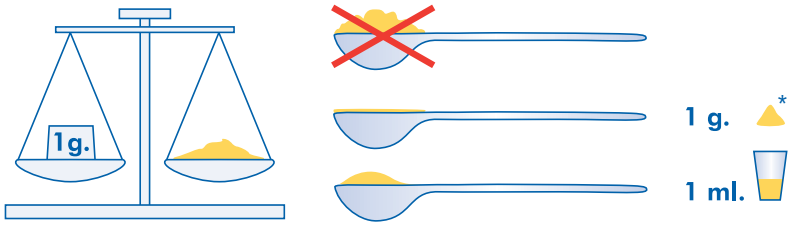

* Following the table

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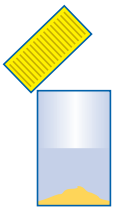

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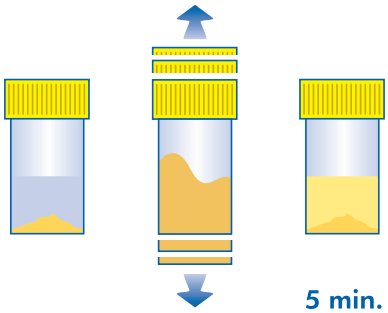

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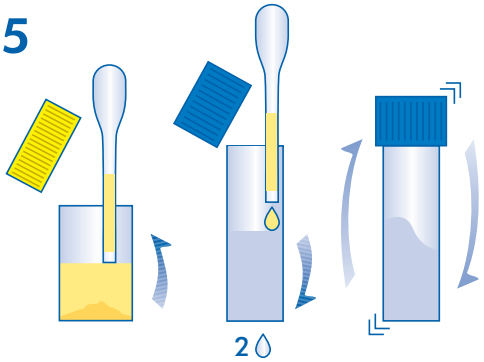

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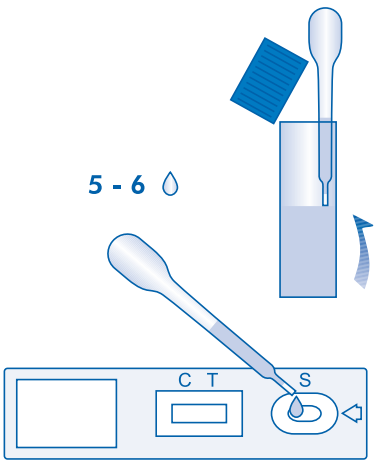

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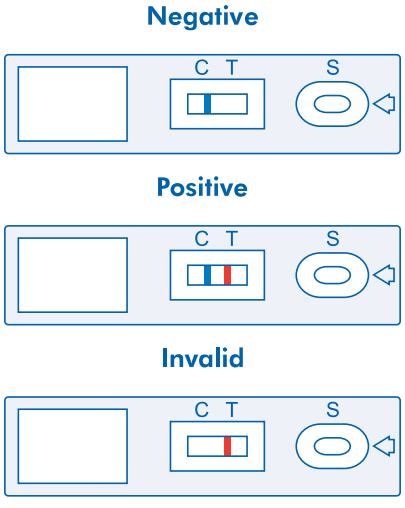

7. Analysis of the results (**GLUTENTOX Home Kit** follows the Codex Alimentarius norms):

Negative result: a single Blue line (control line) appears in the central part of the test (C). The sample contains less than 20 ppm of gluten and is suited for celiacs.

Positive result: in addition to the control line (Blue), a RED line also appears in the central part of the test (T). The sample contains more than 20 ppm of gluten and is not suited for celiacs.
NOTE: The intensity of the red line will depend on the quantity of gluten contained in the sample.

Invalid result: if the Blue control line does not appear, the test is considered as invalid, even if a RED line appears. An invalid result may be due to: an insufficient quantity of sample, a mistake done while following the steps of the manual, or the deterioration of the reagents. In case of an invalid result, it is necessary to repeat the test, and if the problem persists, you must contact your supplier.

8. Quality control

The internal control is included in the test. The blue line that appears on the stick is the inner/internal control of the test which checks that the sample volume is sufficient and that the followed procedure is adequate.

9. Features of GlutenTox Home Kit

The detection limit of the test is 20 ppm.

10. Specificity of the test

GLUTENTOX Home can detect the presence of the toxic fraction for celiac disease sufferers of the prolamins of wheat, rye and barley. However, when the samples contain rice and corn, no positive signal is observed, as these cereals are safe for celiac disease sufferers.
If a type of food is composed of several different structures, take a sample of each part to ensure that the final sample is homogeneous. If you don't do so and gluten was distributed unevenly in such type of food, the result could be negative even if it contains more than 20 ppm of gluten.

11. Reference

1. Shan L., et al.; "Structural basis for gluten intolerance in celiac sprue"; Science; 2002; 297: 2275-2279.

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