

GlutenTox[®] Pro Surface

Quick test for the detection of gluten on surfaces

GlutenTox[®] Pro Surface

Contents

- 1. Intended purpose 2
- 2. Introduction 2
- 3. Test basis..... 2
- 4. Supplied materials (for 50 tests)..... 3
- 5. Useful but not supplied materials..... 3
- 6. Storage conditions 3
- 7. Precautions 3
- 8. Surface analysis 3
 - 8.1. Preparation and sample analysis 3
 - 8.2. Interpretation of results 4
- 9. Quality control 4
- 10. Analytical features 4
 - 10.1. Sensitivity 4
 - 10.2. Specificity 4
 - 10.3. Internal validation 5
- 11. Intellectual property..... 5
- 12. References 5

1. Intended purpose

GlutenTox® Pro Surface is a rapid and user-friendly test for the detection of gluten on surfaces.

2. Introduction

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 [ref. 1 and 2], 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.

3. Test basis

GlutenTox Pro Surface is an immunochromatographic test (lateral flow test) that can be used to control the cleanliness of food production zones through surface analysis, a prerequisite to prevent the risk of cross-contamination in the final product.

The detection step is based on the reaction of the 33mer-like immunotoxic peptides of gluten in the sample with the colored conjugates (monoclonal anti-gliadin 33mer antibody / red colored microsphere) previously fixed on the stick [ref. 3 and 4]. This complex spreads by capillarity through the stick. If the result is positive, a RED line appears in the result zone of the stick. The absence of the RED line indicates a negative result. Whether or not gluten is present, the mixture of the conjugate moves through the stick up to the control region where, if the test was properly performed, a BLUE line (control line) will appear, due to accumulation of blue microspheres included also in the stick.

The test enables quick decisions and corrective actions in case there is any risk of contamination along the production chain.

4. Supplied materials (for 50 tests)

- GlutenTox Pro stick (x50) 2 tubes.
- Plastic pipette (x50).
- Blue cap bottle with dilution solution (x50).
- Instructions leaflet.

5. Useful but not supplied materials

- Non-powdered disposable gloves.
- Watch (a stopwatch is preferable).

6. Storage conditions

The product must be stored at a temperature ranging from 15 °C - 25 °C (59 °F - 77 °F) during the shelf life of the kit.

To obtain optimal test performance, the product must be stored in its original packaging, and used before expiration date printed on the tube of sticks.

WARNING: The tube with the sticks should not be opened until its time of use. All components of the kit are fully disposable in ordinary trash or recyclable where appropriate.

7. Precautions

- To avoid contaminations that interfere with the analysis, the use of non-powdered disposable gloves is recommended. If you do not have disposable gloves, wash your hands thoroughly before the test.
- Once the GlutenTox Pro stick has been removed from the tube, it must be used as soon as possible under strict clean conditions. Close the tube afterwards.
- Do not use any material from the kit after the expiration date.
- Do not drink any solution (liquid) from the kit (the extraction solution contains alcohol [ethanol]).
- **Keep out of reach of children.**

8. Surface analysis

8.1. Preparation and sample analysis

- 8.1.1. Rub the cotton wool side of the stick against a surface of at least 16 cm²/2.46 inch² or in a line of 40 cm/15.6 inch. The area selected for analysis must be representative of the total area of interest.
- 8.1.2. Open a dilution bottle with blue cap and place inverted cap on a clean surface. Use a new, disposable plastic pipette to place 10 drops from the dilution bottle into the blue cap. Put the cotton wool side of the stick in contact with the liquid present in the blue cap until all the liquid is absorbed. Let it stand in the blue cap.
- 8.1.3. **Wait 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).

IMPORTANT NOTE!

- **Wait 10 minutes to read the result. Do not leave the stick longer than indicated, as the results may vary.**

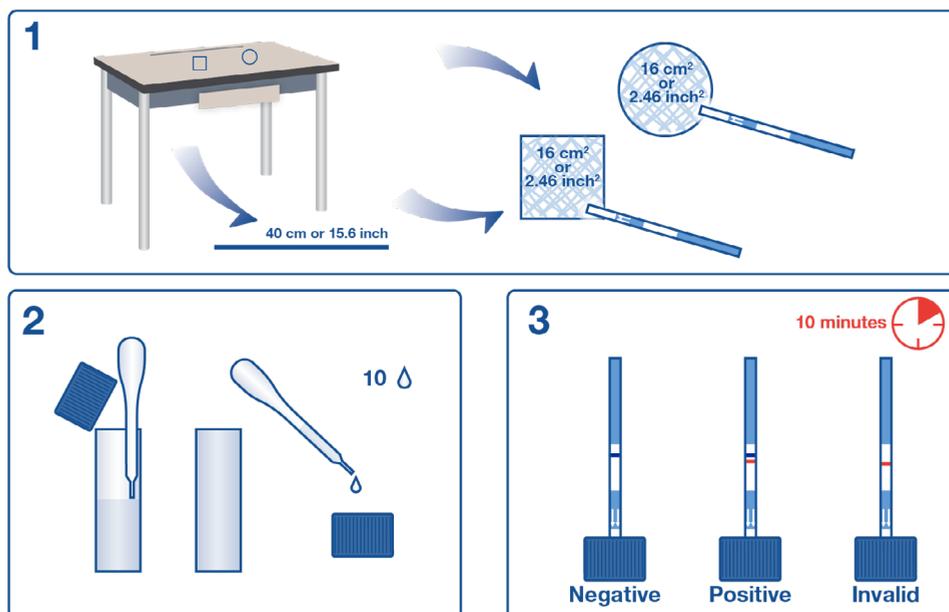


Figure 1. Procedure for surface analysis.

8.2. Interpretation of results

Negative: A single BLUE line (control line) appears in the central part of the stick (control zone).

Positive: In addition to the control line (BLUE), a RED line (result line) appears in the result zone.

The intensity of the red line in the results zone will vary depending on the gluten concentration present in the sample.

Invalid: The control line (BLUE) does not appear, whether or not the result line appears (RED).

9. Quality control

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

10. Analytical features

10.1. Sensitivity

The result obtained with the test indicates the presence or absence of gluten on the analyzed surface; it cannot be extrapolated into any value of gluten in ppm.

Positive results from a surface size of 16 cm²/2.46 inch² or a line of 40 cm/15.6 inches indicate a minimum detection of 10 ng/cm² of gluten from the surface [ref. 5].

10.2. Specificity

This test can specifically detect the presence of the toxic fraction (33mer) of the prolamins of wheat (gliadin), rye (secalin), barley (hordein) and as well varieties of oat [ref. 2] (avenin) that can be toxic and therefore harmful for celiac patients. Furthermore, the test will not cross-react with samples containing rice, corn, soy, buckwheat, sesame, millet, teff, quinoa and amaranth.

Note: To estimate gluten in a sample with this test, the prolamins content has been adjusted multiplying by factor = 2.

10.3. Internal validation

To ensure the test stability, different surfaces contaminated with gliadin have been tested; including stainless steel, plastic, rubber, sealed ceramic, food-grade painted wood. After analyzing the surfaces with GlutenTox Pro Surface in all types of matrices the results were satisfying and consistent with the validated method for the Codex Alimentarius, which demonstrates that the test can be used on a broad range of surfaces.

11. Intellectual property

The immunoreagents used in this kit are commercialized under the exclusive license for biological material from the Spanish National Research Council (CSIC).

12. References

1. SHAN L., *et al.*; "Structural basis for gluten intolerance in celiac sprue"; *Science*; 2002; 297: 2275-9.
2. COMINO I., *et al.*; "Diversity in oat potential immunogenicity: basis for the selection of oat varieties with no toxicity"; *Gut*; 2011; 60:915-922.
3. MORON B., *et al.*; "Sensitive detection of cereal fractions that are toxic to celiac disease patients by using monoclonal antibodies to a main immunogenic wheat peptide", *Am. J. Clin. Nutr*, 2008; 87:405-414.
4. MORON B., *et al.*; "Toward the Assessment of Food Toxicity for Celiac Patients: Characterization of Monoclonal Antibodies to a Main Immunogenic Gluten Peptide" *PLoS ONE* 2008; 3(5): e2294.
5. SIGLEZ M.A., *et al.*; "Método de detección de gluten en superficies"; *Alimentaria*; 2010; 411:67-70.

GlutenTox[®] Pro Surface

Notes



Americas:

Hygiena Headquarters

941 Avenida Acaso
Camarillo, CA 93012
1-805-388-8007

Hygiena Canada

11 - 3750A Laird Road
Mississauga, Ontario L5L 0A6
1-833-494-4362 (Toll-free)
or 1-416-686-7962

Hygiena Mexico, S.A. de C.V.

Calle 3 Anegas 409 Bodega 5, Col. Nueva Industrial
Vallejo, Delegación Gustavo A. Madero, C.P. 07700,
CDMX, México.
+52 (55) 5281-4108 y 5281-4146

International:

Hygiena International

8, Woodshots Meadow
Watford, Hertfordshire
WD18 8YU, UK
+44 (0)1923-818821

Hygiena (Shanghai) Trading Co., Ltd.

Rm.7K, No.518, Shangcheng Rd.
Pudong New District
Shanghai, China 200120
+86 21-5132-1081, +86 21-5132-1077,
+86 21-5132-1078

Hygiena Diagnóstica España S.L.

P. I. Parque Plata, Calle Cañada Real 31-35,
41900, Camas, Sevilla, Spain
+34 954-08-1276

www.hygiena.com

enquiries@hygiena.com