1. Product Description

GlutenTox® Home is an immunochromatographic test for the detection of gluten in food and beverages. GlutenTox® Home can also be used for detecting the presence of gluten in oral hygiene products.

The test consists of an extraction stage using a simple procedure which is common to all types of food. The detection step is based on the reaction of the immunotoxic fractions of gluten in the sample with the colored conjugates (monoclonal anti-gliadin 33mer antibody / red colored microsphere) previously fixed on the stick. 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 antibodies have been immobilized. If the test is properly realized a BLUE line (control line) will appear.

These rapid tests are especially useful in determining the sources of suspected gluten contamination. They can be used in the home or while traveling, and are also suitable for commercial kitchens to verify the safety of dishes intended for gluten-free customers.

2. Sensitivity/Specificity

- The detection limit is 5 ppm of gluten after.
- Specific to the toxic fraction of prolamins of wheat (gliadin), barley (hordein), rye (secalin) and oat (avenin).
- No cross-reactivity is observed with soy, rice and corn.

3. Kit components

**GlutenTox® Home 2 units (KT-5472)**
- GlutenTox® Home stick (x2) and plastic pipette (x2) contained in metallic envelope.
- Disposable plastic spoons (x2).
- Extraction bottle with yellow cap (x2).
- Disposable plastic pipette (x2).
- Dilution bottle with blue cap (x2).
- Instructions leaflet.

**GlutenTox® Home 5 units (KT-5000)**
- GlutenTox® Home stick (x5) and plastic pipette (x5) contained in metallic envelope.
- Disposable plastic spoons (x5).
- Extraction bottle with yellow cap (x5).
- Disposable plastic pipette (x5).
- Dilution bottle with blue cap (x5).
- Instructions leaflet.

4. Storage/Expiry

The product must be stored at a temperature ranging from 2°C to 30°C / 35.6°F to 86°F. To obtain optimal test performance, the product must be stored in its original packaging, and used before expiration date printed on the envelope. The envelope 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.

5. Precautions and safety

- 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® Home stick has been removed from the envelope, 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 (the extraction solution contains alcohol [ethanol]).
- Keep out of reach of children.
6. Applications
- Easy: does not require any lab equipment and can be used by non-specialists.
- Suited for food that is not labeled or homemade.
- Very useful to test food at home, in restaurants, in school canteens, hospital kitchens or while traveling.

7. Validation
To ensure the test's ability to analyze a wide range of samples of different types, different commercial samples have been tested. After analyzing the samples with GlutenTox® Home 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 samples.

<table>
<thead>
<tr>
<th>Group</th>
<th>Tested samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flour and semolina</td>
<td>Corn flour, precooked corn flour, corn semolina, rice flour, wheat flour, buckwheat flour</td>
</tr>
<tr>
<td>Milk products</td>
<td>Cow milk, milk with soluble fiber, milk with cereals, natural or flavored yogurt, cheese spread, shredded cheese blend</td>
</tr>
<tr>
<td>Baked and cereal products</td>
<td>Toast, bread stick, biscuits (rich tea), chocolate cookies, Madeleine, cake, cornflakes, pastas, corn pancakes, rice cakes, spelt cake, snacks</td>
</tr>
<tr>
<td>Meat products</td>
<td>Minced turkey, minced chicken, turkey sausage, chicken nuggets, pork sausages, chorizo</td>
</tr>
<tr>
<td>Fishery products</td>
<td>Cod and hake</td>
</tr>
<tr>
<td>Vegetables</td>
<td>Lettuce mix, fried vegetables</td>
</tr>
<tr>
<td>Broth, soups, creams and dry mixes</td>
<td>Vegetable broth, chicken rice soup, dehydrated vegetable soup, stock cubes, vegetable soup, peanut butter</td>
</tr>
<tr>
<td>Sauces, dressing, spices and condiments</td>
<td>Yogurt salad dressing, ketchup, soy sauce, salad dressing, garlic powder, paprika powder, cooking cream</td>
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<tr>
<td>Sugars</td>
<td>Glucose syrup, powdered sugar</td>
</tr>
<tr>
<td>Prepared meals and dishes</td>
<td>Meatballs in sauce with peas, Meat Ravioli in Egg Dough, bean stew</td>
</tr>
<tr>
<td>Fatty foods</td>
<td>Olive oil, sunflower oil, butter, margarine, cream</td>
</tr>
<tr>
<td>Acidic foods</td>
<td>Tomato sauce, wine vinegar, apple cider vinegar, lemon juice</td>
</tr>
<tr>
<td>Beverages</td>
<td>Water, milk, fruit juices, beer, soy drinks, rice drinks, oat drinks, soft drinks</td>
</tr>
<tr>
<td>Oral hygiene products</td>
<td>Toothpaste, mouthwash</td>
</tr>
</tbody>
</table>

8. References
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", 2008; 87:405-414.