1. **Product Description**

**GlutenTox® Pro** is a rapid and user-friendly immunochromatographic test for the detection of gluten in food and beverages with different composition and processing level, from raw materials to processed food.

**GlutenTox® Pro** can also be used for detecting the presence of gluten in oral hygiene products, such as toothpaste and mouthwash, which is useful since these products may be ingested. In addition, **GlutenTox® Pro** 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.

This rapid test are specially useful in routine monitoring of gluten to ensure that products comply with a program of Hazard Analysis and Critical Control Points (HACCP), and to ensure proper labeling. They also allow quick decisions and corrective actions in case there is any risk of contamination along the production chain.

**GlutenTox® Pro** is based on an anti-gliadin-33mer mouse monoclonal antibody (G12) that is specific to the toxic fraction of gluten (33-mer peptide) and reacts to prolamins of wheat (gliadin), barley (hordein), rye (secalin), and oat (avenin).

2. **Sensitivity/Specificity**

- Detection limit of the assay 5 ppm of gluten in samples (detection limit of the strip - 15 ng/mL of gliadin).
- Specific to prolamins of wheat (gliadin), barley (hordein), rye (secalin) and oat (avenin).
- Does not cross react with soy, rice or corn.

3. **Kit components**

- GlutenTox® Pro sticks (x25) in a tube.
- Plastic pipettes (x50).
- Disposable plastic spoons (x25).
- Extraction bottles with yellow cap (x25).
- Dilution bottles with blue cap (x25).
- Instructions leaflet.

4. **Storage/Stability**

To obtain optimal test performance, the product must be stored in its original packaging between 2°C and 30°C and used before expiration date. 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.

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® Pro stick has been removed taken out 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 expiry date.
- Do not drink any solution (liquid) from the kit (the extraction solution contains alcohol [ethanol]).
- Keep out of reach of children.

6. **Applications**

- For semi-quantification of gluten in food, beverages and other consumer products, including personal care and cosmetic products.
- For quality control of gluten free food.
- To trace gluten contamination in food and working surfaces.
- For safety regulation according to HACCP, IFS and BRC programs.
7. Validation

To ensure the test’s ability to analyze all types of food (of diverse nature) and other samples such as cosmetics and personal care products, different commercial samples have been tested. After analyzing the samples with GlutenTox® Pro in all types of matrices tested (see Table 1) the results were satisfactory and consistent with the gluten found with the official method, which demonstrates the applicability of test on a broad range of samples.

Table 1. Samples tested for validation of GlutenTox® Pro.

<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>
</tr>
<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>

7. 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.

4. SIGLEZ M.A., et al.; ”Método de detección de gluten en superficies”; Alimentaria; 2010; 411:67-70