Biomedical S.L. GlutenTox® Pro Test Kit

Granted PTM Status

Biomedical, S.L.
GlutenTox® Pro
Cat. Nos.: KT-5560 (25 analysis);
KT-5288 (5 analysis)
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Gluten is a mix of water-insoluble proteins [prolamins (gliadins in wheat, hordeins in barley, secalins in rye, etc.) and glutelins] found in the seeds of cereals that can cause adverse health effects to people intolerant to gluten (oats can be tolerated by most but not all people who are intolerant to gluten). People with celiac disease, which affects people of all ages, suffer from a permanent intolerance to gluten. 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.

The GlutenTox® Pro method is an immunochromatographic assay for the detection of gluten in food and beverages (with nonhydrolyzed gluten) with different composition and levels of processing, from raw materials to processed food (see Figure 1). In addition, the GlutenTox® Pro test kit 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.

Method performance was reviewed by the AOAC Research Institute and was found to meet manufacturer specifications. The following matrices have been validated according to AOAC Performance Tested MethodsSM (PTM) protocols: rice flour, bread/biscuit, rolled oats, pâté, and yogurt. Food-grade painted wood, plastic, rubber, sealed ceramic, and stainless steel have been validated per AOAC PTM protocol for environmental surface testing.

The test consists of an extraction stage using a simple procedure, which is common to all types of food (no extraction step must be performed for environmental surface testing). 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 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 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 anti-mouse monoclonal antibodies have been immobilized. When the test was properly realized a blue line (control line) appears.

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 result 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).

Validation Study Discussion

The GlutenTox® Pro method did not show neither cross-reactivity nor interference to any of the compounds included in the list of Validation Procedures for Quantitative Gluten ELISA Methods: AOAC Allergen Community Guidance and Best Practices and performed as expected in the selected food matrices (rice flour, bread, rolled oat, pâté, and yogurt) and test conditions (spike level and detection threshold combinations), with 5 ppm being the lowest concentration of gluten that can be detected with the kit.

In all matrices tested, the GlutenTox® Pro test kit demonstrated 100% specificity [probability of detection (POD) 0.00, confidence interval (CI) 0.00-0.11] at 0 ppm spiked level of gluten and 100% sensitivity (POD 1.00, CI 0.89-1.00) at each spiked level of gluten and threshold level combinations. No false-negative results were obtained in the food matrix study. The assay did not experience hook effect at any threshold level tested when the rice flour matrix was spiked at very high spiked levels of gluten (10,000 ppm).

The kit also performed as expected in the incurred bread sample, and the results obtained in the incurred matrix study were consistent with those obtained in the selected food matrix study with bread. In both studies, false-negative and/or overestimated results were not observed.

Results obtained when the GlutenTox® Pro method was tested with the selected environmental surfaces

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demonstrated a 100% specificity (POD 0.00, CI 0.00-0.11) at the unspiked level of gluten contamination and a 100% sensitivity (POD 1.00, CI 0.89-1.00) at the high level of gluten contamination (400 ng/16 cm²) in each of the environmental surfaces analyzed.

At the low level of gluten contamination (16 ng/16 cm²), the GlutenTox®Pro assay was able to detect as little as 16 ng gluten when analyzed with the environmental surface matrices.

The lot-to-lot data and the accelerated stability data (10, 20, 35, 50, and 90 days at 42°C) showed evidence that the kit is stable and can be consistently manufactured with reproducible quality.

Test kit variation data between three test kits of a single lot of GlutenTox®Pro demonstrated no statistical difference in gluten detection between the test kits.

No false-negative results were observed in the entire validation study.

Robustness data indicated that the GlutenTox®Pro assay remained unaffected by minor variations in procedural parameters with the exception of the amount of time that the test strip was left in the dilution sample solution before reading the result. Due to the test format, there must be sufficient time for the dilution sample solution to travel up the test strip, and this time cannot be shortened.

Conclusion

The GlutenTox®Pro test kit is a quick and easy-to-use screening method for the detection of gluten in raw or cooked foods and on environmental surfaces and is also a stable and cost effective kit recommended for consumers, commercial kitchens, and industry. The instructions for use include the possibility of choosing different detection threshold levels of gluten according to the end user requirements.

The method is specific and reliable and provides sensitive and accurate test results and is especially useful in routine monitoring to ensure that products comply with a program of Hazard Analysis and Critical Control Point (HACCP), and to ensure proper labeling. It also allows quick decisions and corrective actions in case there is any risk of contamination along the production chain.

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Mention of trade names or commercial products is for identification only and does not constitute preference over similar ones not mentioned. If you are interested in submitting an article regarding a test kit that has been granted Performance Tested MethodsSM status, contact Deborah McKenzie, senior director, standards development and the Research Institute, at dmckenzie@aoac.org.