

FOR IMMEDIATE RELEASE

## **Hygiena<sup>®</sup> receives AOAC certification for GlutenTox<sup>®</sup> ELISA Rapid G12 Kit (PTM #042301)**

*AOAC RI PTM certification awarded to Hygiena, confirming performance claims of its kit in spiked food matrices (gluten free soy flour, corn bread, seasoning mix, rolled oats and evaporated milk) and incurred food (baked bread) with gluten from wheat, barley or rye flour.*

**Camarillo, California (April 28<sup>th</sup>, 2023)** — Hygiena<sup>®</sup> is pleased to announce that its GlutenTox<sup>®</sup> ELISA Rapid G12 Kit, which is an improved test for the most immunotoxic peptide in gluten, was evaluated and approved by the AOAC *Performance Tested Methods*<sup>SM</sup> (PTM) Program. The evaluation consisted of calibration, selectivity, recovery, bias, LOD/LOQ, repeatability precision, intermediate precision, product consistency, stability, robustness and matrix studies for all claimed gluten sources (wheat, barley and rye).

The test, which provides more accurate results in less time than other ELISA tests for gluten, uses the G12 antibody to identify the 33-mer (part) peptide segment of the gliadin protein in food samples, which is part of the gluten protein complex. This “33-mer” peptide is the most immunotoxic part of the gluten protein and induces celiac disease in susceptible people.

Celiac disease is a serious autoimmune disease that occurs in genetically predisposed people where the ingestion of gluten leads to damage in the small intestine. It is estimated to affect 1 in 100 people worldwide.<sup>1</sup> The 33-mer peptide shows high resistance to complete digestion by human digestive enzymes. Focusing on this peptide fragment provides more objective information to help people with celiac disease and gluten intolerance to avoid foods that contain gluten.

The GlutenTox ELISA Rapid G12 is the first assay to be granted PTM certification using wheat, barley and rye flour and has several advantages by design. It is based on the enzyme-linked immunoassay (ELISA) test, a proven laboratory workhorse for more than 40 years, and provides fast, convenient and accurate measurement of gluten down to 1.2 ppm (0.6 ppm of gliadin). In addition, the kit is more stable during temperature changes and delivers positive results even in highly contaminated samples (a limitation of other gluten tests). Finally, GlutenTox ELISA Rapid G12 tests have shorter incubation times, allowing for an accurate-analytic measurement of gluten in 90 minutes.

“We are extremely proud that our products continue to be recognized by such globally acknowledged organizations as the AOAC INTERNATIONAL, whose validations have a reputation for the highest standards of excellence and thorough analysis. With additional benefits like faster time to results, less susceptibility to temperature and nontoxic reagents, we are confident our newly certified kit will mark a significant advance in the ability to detect gluten proteins that are so harmful to those sensitive to even low levels of gluten,” said Steven Nason, CEO at Hygiena.

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<sup>1</sup> [What is Celiac Disease? | Celiac Disease Foundation](#)



**PRESS RELEASE**

For more information, please visit: [GlutenTox® Pro - Allergen Detection - Hygiena](#)

**Hygiena – We create innovative diagnostics for a healthier world**

**About Hygiena**

At Hygiena, our mission is to create innovative diagnostics for a healthier world. We develop, produce and provide best-in-class One Health Diagnostics™ solutions from farm to fork to our global customer bases. As one of the few organizations in the world to uniquely focus on food safety throughout the value chain, we maintain the belief that the health of people is closely connected to the health of animals and our shared environment. Our molecular rapid tests and analysis tools for food and beverage safety, veterinary diagnostics and environmental monitoring help prevent illness, save lives and contribute to making the world a safer place. As the global leaders in rapid diagnostic tests, we provide solutions that are reliable, easy to use and accurate, backed by industry-leading customer service and support. With a sizeable global presence, Hygiena is headquartered in Camarillo, California with numerous offices and customer application centers in the Americas, Europe, Africa, Asia and Australia. We also partner with over 180 distributors in more than 100 countries worldwide. Learn more about us at [www.hygiena.com](http://www.hygiena.com).

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