

**FOR IMMEDIATE RELEASE**

**ResearchDx and Targeted Genomics Announce FDA 510(k) clearance for GlutenID Celiac Genetic Health Risk Test**

**Irvine, California – January 28, 2025** – ResearchDx and Targeted Genomics are excited to announce that the GlutenID Celiac Genetic Health Risk Test has received FDA 510(k) clearance (K241456). GlutenID is an over-the-counter (OTC) Genetic Health Risk Assessment System designed to assess an individual’s risk of developing celiac disease. The test identifies clinically relevant genetic variants using a saliva sample collected at home and sent to ResearchDx’s PacificDx Laboratory for analysis. It is intended for users 18 years of age and older.

“We are thrilled to have worked with Targeted Genomics to receive FDA 510(k) approval for this innovative diagnostic platform,” said Mathew Moore, Principal of ResearchDx. “This accomplishment is a significant milestone for our team and our client. The site-specific FDA clearance for this groundbreaking test represents a major step forward in how patient testing is conducted in the U.S. and we are excited to offer this test through our clinical laboratory, PacificDx” (A ResearchDx company).

“This outcome is the result of our team’s hard work to bring about this important FDA clearance,” said Shelly Gunn, Medical Director at Targeted Genomics. “The approval highlights our team's dedication and collective commitment to advancing healthcare through precision medicine. We are incredibly grateful for ResearchDx’s expertise and efforts in securing FDA clearance on our behalf and their continued support in offering testing services at their PacificDx facility. We are excited about the positive impact this test will have on individuals at risk for celiac disease.”

The FDA 510(k) clearance affirms the continued confidence in ResearchDx and Targeted Genomics’ ability to deliver innovative, high-quality solutions that address the evolving needs of the healthcare industry. Both companies remain dedicated to advancing the role of genomic diagnostics in improving patient care and outcomes.

**About ResearchDx:**

ResearchDx is a leading provider of outsourced diagnostic development services to advance precision medicine. ResearchDx specializes in comprehensive assay development, from concept and biomarker discovery to clinical validation, regulatory approval, and final kit manufacturing.

**About Targeted Genomics:**

Targeted Genomics is a family-owned company dedicated to improving the understanding and treatment of celiac disease through genetic wellness. The GlutenID® test was developed to identify genetic risk factors for celiac disease. Targeted Genomics is committed to advancing precision diagnostics and supporting personalized healthcare solutions.

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