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PerkinElmer Receives FDA Clearance for EUROIMMUN Anti-Tissue Transglutaminase ELISA

Serological testing plays critical role in helping diagnose patients with celiac disease

WHAT: [PerkinElmer, Inc.](#), a global leader committed to innovating for a healthier world, today announced that its EUROIMMUN [Anti-Tissue Transglutaminase \(tTG\) ELISA](#) has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). The test system is designed to help clinicians confirm or exclude a celiac disease diagnosis.

HOW IT WORKS: People with celiac disease, who eat foods containing gluten, will have elevated levels of certain antibodies in their blood because gluten triggers a reaction from their immune system. These antibodies are directed against gluten and attack tTG, the body's own gluten-processing enzyme, located in the small intestine—which is why they are considered the most important serological markers for celiac disease.

PerkinElmer's EUROIMMUN anti-tTG ELISA helps clinical laboratories screen patients more accurately by determining and quantifying immunoglobulin class A (IgA) and class G (IgG) anti-tTG antibodies.

WHY: Celiac disease affects more than 3 million Americans today, but because the disease often manifests primarily as mild gastrointestinal or atypical symptoms, up to 97% go undiagnosed.^[1]

“Greater diagnostic accuracy is needed to ensure patients receive proper treatment and prevent further health complications,” said Wolfgang Schlumberger, Ph.D., vice chairman, EUROIMMUN. “Our comprehensive portfolio for autoantibody detection in celiac disease, combined with a wide range of automated workflow solutions, provides the sensitivity and specificity necessary for clinical laboratories to reliably identify those

¹ University of Chicago School of Medicine Celiac Disease Center. **Celiac disease facts and figures.** 2018.

living with this chronic autoimmune disorder, and expedite the time to diagnosis.”

MORE: As part of its autoantibody diagnostics portfolio, PerkinElmer also offers the EUROIMMUN anti-endomysium IFA kit and EUROIMMUN anti-deaminated gliadin (GAF-3X) ELISA. Using the anti-tTG ELISA IgA and anti-GAF-3X ELISA IgG together provides increased diagnostic accuracy for celiac disease and allows for the identification of patients with selective IgA deficiency, who are otherwise missed by IgA-only assays.^[2,3,4]

EUROIMMUN, a PerkinElmer company, is widely recognized as a global leader in autoimmune testing and an emerging force in infectious disease and allergy testing. Its expertise and capabilities extend across immunology, cell biology, histology, biochemistry and molecular biology.

About PerkinElmer

PerkinElmer, Inc. is a global leader committed to innovating for a healthier world. Our dedicated team of about 12,500 employees worldwide is passionate about providing customers with an unmatched experience as they help solve critical issues especially impacting the diagnostics, discovery and analytical solutions markets. Our innovative detection, imaging, informatics and service capabilities, combined with deep market knowledge and expertise, help customers gain earlier and more accurate insights to improve lives and the world around us. The Company reported revenue of approximately \$2.8 billion in 2018, serves customers in more than 150 countries, and is a component of the S&P 500 Index. Additional information is available through 1-877-PKI-NYSE, or at www.perkinelmer.com

Media Contact:

Sara LaFauci
sara.lafauci@perkinelmer.com
+1-781-663-6946

² Wolf J, Hasenclever D, Petroff D, Richter T, Uhlig HH, Laass MW, Hauer A, Stern M, Bossuyt X, de Laffolie J, et al. **Antibodies in the diagnosis of coeliac disease: a biopsy-controlled, international, multicentre study of 376 children with coeliac disease and 695 controls.** PLoS One 9 (2014) e97853.

³ Wolf J, Petroff D, Richter T, Auth MKH, Uhlig HH, Laass MW, Lauenstein P, Krahl A, Handel N, de Laffolie J, et al. **Validation of Antibody-Based Strategies for Diagnosis of Pediatric Celiac Disease Without Biopsy.** Gastroenterology 153 (2017) 410-419 e417.

⁴ Villalta D, Tonutti E, Prause C, Koletzko S, Uhlig HH, Vermeersch P, Bossuyt X, Stern M, Laass MW, Ellis JH, et al. **IgG antibodies against deamidated gliadin peptides for diagnosis of celiac disease in patients with IgA deficiency.** Clinical Chemistry 56 (2010) 464 – 468.