

# Confidence in serology...diagnosing Celiac Disease without biopsy

A photograph of two women running on a grassy hill under a blue sky. The woman on the left is wearing a light-colored top and dark pants, while the woman on the right is wearing a blue long-sleeved shirt and light-colored pants. They are both smiling and appear to be in good health.

**ProCeDE study:  
EliA Celikey has best-in-class tissue  
transglutaminase IgA performance for  
Celiac Disease assessment<sup>1</sup>**

## The ProCeDE study reinforces the outstanding clinical relevance of tissue transglutaminase (tTG) IgA testing with EliA Celikey IgA

ProCeDE is a large, international prospective study which validates the \*ESPGHAN evidence-based approach to guide the diagnosis of celiac disease without the need for biopsy in patients with symptoms suggestive of celiac disease.<sup>1</sup>

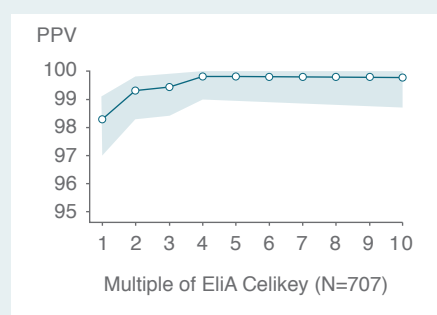
The test kit selection influence the accuracy of celiac disease antibody tests.<sup>2</sup>

The study compares tTG IgA diagnostic kits from 8 different manufacturers, across 33 sites over several years, with samples from more than 700 patients, 18 years old or younger.

Outcome:

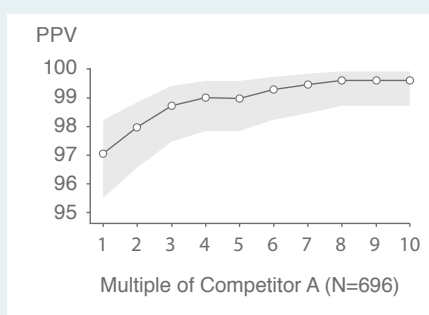
- The validity of the ESPGHAN approach was proven for all the tTG IgA tests included
- EliA Celikey IgA exhibited exceptional performance reaching a 99% PPV at only 2x its upper limit of normal (ULN)
- In symptomatic patients HLA analyses did not increase the diagnostic accuracy

### EliA Celikey IgA



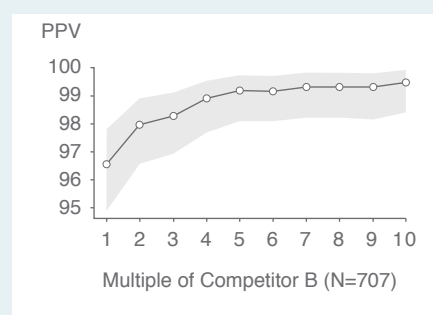
**Reaches PPV=99% at 2x ULN**

### Competitor A



**Reaches PPV=99% at 4-5x ULN**

### Competitor B



**Reaches PPV=99% at 5-6x ULN**

Results determined using recommended manufacturer cut-offs.  
Figure adapted from Werkstetter KJ, et al. 2017.<sup>1</sup>

### When using tTG values to diagnose celiac disease, consider using EliA Celikey IgA

At 2x ULN EliA Celikey IgA achieves a PPV of 99%, a diagnostic accuracy that was shown to be outstanding compared to other tTG IgA tests.<sup>1</sup>

### Autoimmune Expertise, Quality and Efficiency

EliA assays are fully-automated, accurate and reproducible tests with outstanding performance characteristics ensuring a confident diagnosis.

\*ESPGHAN: European Society of Pediatric Gastroenterology, Hepatology and Nutrition Serological tests

PPV: positive predictive value

ULN: upper limit of normal

References: 1. Werkstetter KJ, et al. *Gastroenterology* 2017; doi: 10.1053/j.gastro.2017.06.002 [epub ahead of print]. 2. Husby S, et al. *Journal Pediatric Gastroenterology and Nutrition* 2012; 54(1): 136–160.

Find out more at [thermofisher.com/EliA](http://thermofisher.com/EliA)

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