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One in 100 people worldwide have celiac disease[1]

Despite the above mentioned prevalence,[1] celiac disease remains challenging for healthcare professionals to be diagnosed accurately. Delivering reliable, high-specificity results, EliA™ Celikey and EliA™ Gliadin^{DP} tests aid in the clinical diagnosis of celiac disease[2–4] as part of a fully automated gastrointestinal test panel with simple workflow and walkaway efficiency.

That is the EliA distinction, powered by two decades of expertise in autoimmune diseases.

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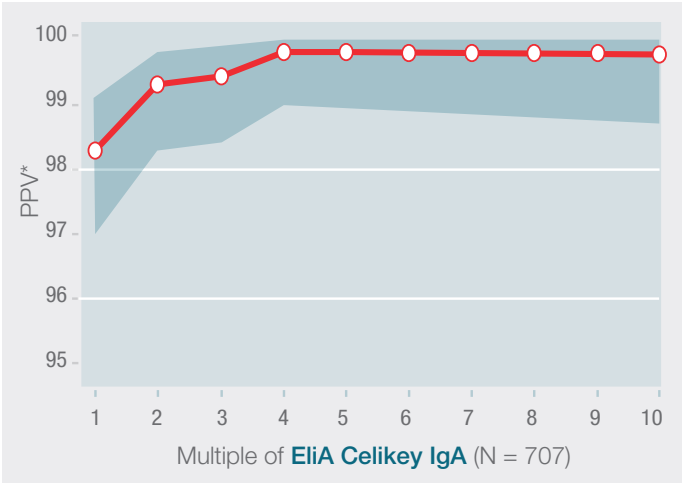
Identifying more celiac disease patients safely and accurately

Roughly 1% of the world's population has celiac disease (CD), but most cases – an estimated 90%[5] – go unidentified.[1] Under-diagnosed, the average time from symptom onset to correct diagnosis of CD is 11–13 years.[6,7] Under-managed, CD leads to patient anxiety and can result in long-term complications or even development of intercurrent autoimmune diseases.[8] Systematic, reliable testing to support correct and timely diagnosis can greatly improve patient quality of life.[9]

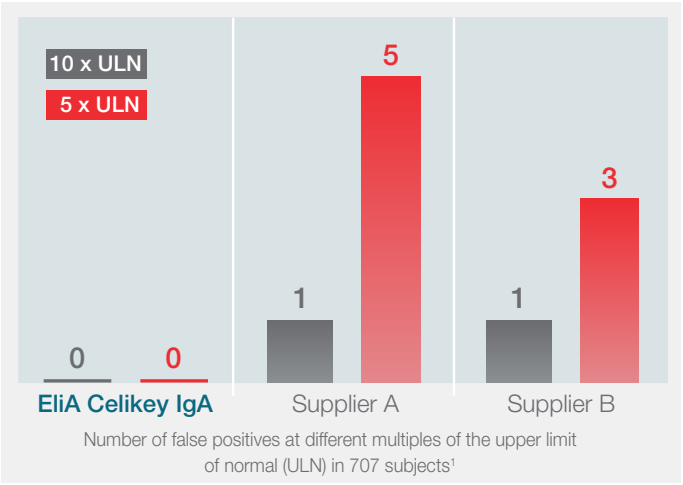
The EliA™ Celiac Portfolio (EliA Celikey tests and EliA Gliadin^{DP} tests) delivers high diagnostic certainty to support the clinical diagnosis of celiac disease (CD):

- EliA Celikey IgA test has a positive predictive value (PPV) of 100% in symptomatic patients where tests showed tissue transglutaminase (tTG) IgA levels ≥100 EliA U/mL, enabling accurate diagnosis of CD without intestinal biopsy.[10,11]
- The PPV of EliA Celikey IgA reaches 99% even with results as low as 2 x ULN, i.e., double the upper limit of normal. This diagnostic accuracy demonstrably surpasses that of other tests.[2]
- In the non-biopsy approach of the ESPGHAN guidelines, fully automated testing with EliA Celikey IgA minimizes the number of false positives,[2] boosting the diagnostic accuracy of this non-invasive approach.[3]
- The EliA Gliadin^{DP} IgG test supports with high reliability identifying CD patients[12] following the guidelines for diagnosing celiac disease.[13]

Both positive and negative test results provide valuable information. Negative results help guide decisions to refocus patient diagnosis and care.[14] Conversely, positive results help provide effective and timely treatment. As a result, reduced exposure to disease triggers can slow down or even stop disease progression while mitigating CD-related processes and intestinal damage,[15] thereby substantially improving quality of life.[16]



Positive predictive value (PPV) of the EliA Celikey IgA test at 1 to 10 multiples of the upper limit of normal (ULN). PPV reaches 99% already at 2x ULN.[2]



False positives detected by EliA Celikey IgA test at 5x ULN and 10x ULN compared to alternative diagnostic suppliers. No false positive results were obtained in 707 subjects.[2]

Laboratory testing to support celiac disease diagnosis without biopsies

A broad portfolio for the *in vitro* diagnosis of wheat-related conditions

The EliA Celiac Portfolio expands your testing menu with a clinically relevant and workflow-optimized testing algorithm to aid in the diagnosis of CD.[2,3] With lean workflows, the EliA Celiac Portfolio integrates easily into daily routines of medium and high-throughput clinical laboratories. Among them, the high-performance tissue transglutaminase EliA Celikey IgA test has a specificity of 98.5%, highlighting confidence in the clinical diagnosis of CD[12] and potentially helping reduce endoscopies more than any other automated assay.[2]

Lean workflow. Walkaway efficiency. Highly predictive and widely validated.

As a fully automated gastrointestinal test panel, the EliA and ImmunoCAP™ tests differentiate among gastrointestinal related conditions in a single, highly predictive diagnostic tool that has been widely validated.[2,17–19] The outcome? Reduced workload and turnaround time to aid correct diagnoses.

Test				Indication
EliA™ Celikey IgA	EliA™ Celikey IgG	EliA™ Gliadin^{DP} IgA	EliA™ Gliadin^{DP} IgG	Celiac disease
EliA™ Calprotectin 2	EliA™ ASCA IgA	EliA™ ASCA IgG		Inflammatory bowel disease
EliA™ Intrinsic Factor	EliA™ Parietal Cell			Pernicious anemia (autoimmune atrophic gastritis)
ImmunoCAP™ Specific IgE tests				Food allergies

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Phadia™ Laboratory Systems

Designed for diagnostic testing today and tomorrow

Phadia™ 200 instrument

Phadia™ 250 instrument

Phadia™ 2500+

Phadia 2500+ comprises Phadia™ 2500, Phadia™ 2500E and Phadia™ 2500EE

Phadia™ 5000+

Phadia 5000+ comprises Phadia™ 5000, Phadia™ 5000E and Phadia™ 5000E+E

Phadia Laboratory Systems are engineered to accommodate fully automated autoimmunity and allergy diagnostics on a single instrument and at any throughput. Every Phadia System includes expert service and support via remote troubleshooting and, combined with the reliability of EliA and ImmunoCAP tests, is our commitment to keeping your CD diagnostic routines running efficiently, with minimal downtime and exceptional time and cost savings.

Technical data

			Cut-off		
Product	**Article No.**	**Package size**	**negative**	**equivocal**	**positive**
EliA™ Celikey IgA	14-5517-01	4 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ Celikey IgG	14-5518-01	2 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ Gliadin^{DP} IgA	14-5538-01	4 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ Gliadin^{DP} IgG	14-5539-01	4 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ ASCA IgA	14-5635-01	4 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ ASCA IgG	14-5633-01	4 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ Intrinsic Factor	14-5668-01	2 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ Parietal Cell	14-5669-01	2 x 12	< 7 EliA U/mL	7–10 EliA U/mL	> 10 EliA U/mL
EliA™ Calprotectin 2	14-6748-01	4 x 12	≤ 50 mg/kg	–	> 50 mg/kg
ImmunoCAP™ Specific IgE tests		Please refer to thermofisher.com/immunocap			

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