

Navigate celiac disease with confidence

**Rely on Thermo Fisher Scientific's solutions to aid
the diagnosis of patients with celiac disease**



Pinpointing celiac disease can be challenging

Your laboratory can help shorten the time to a correct diagnosis

Unmanaged celiac disease can cause long-term negative health effects

Today, clinical laboratories are in the unique position to spearhead more timely and accurate diagnosis of celiac disease. This is important for an autoimmune disorder that affects 1 in 100 people worldwide¹, many of whom wait 10 to 13 years from onset of symptoms to a correct diagnosis.^{2,3}

Laboratories can easily add celiac serological testing into their autoimmune testing panel. The EliA™ Celiac Portfolio (EliA™ Celikey tests and EliA™ Gliadin^{DP} tests) complements your testing menu with a clinically relevant and workflow-optimized testing panel to aid in the diagnosis of celiac disease.

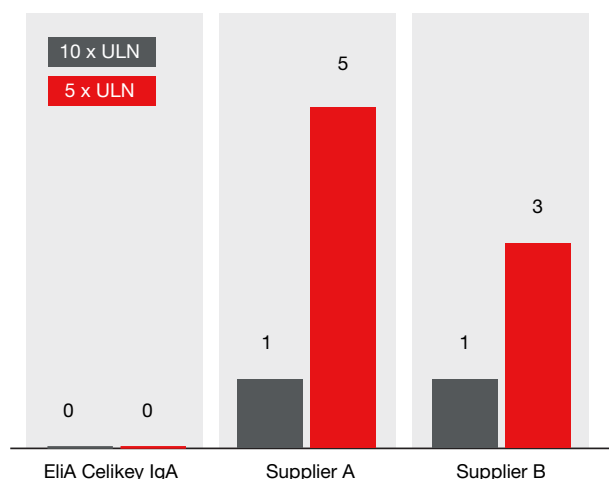
Benefits of the EliA™ Celiac Portfolio

- High specificity and sensitivity tests
- Controlled antigen quality
- Workflow-optimized testing panel
- Clinically accurate and reliable diagnostic coverage

EliA™ Celikey IgA test outperforms other manufacturers tests in specificity^{4,5}

The recommended first-line test for celiac diagnosis, according to international guidelines¹, is a tissue transglutaminase IgA (tTG-IgA) test, together with total IgA to check for IgA deficiency.^{1,5,6} EliA™ Celikey IgA is a fully automated and clinically relevant test that offers 99% specificity for tTG-IgA.^{4,5}

Higher specificity means fewer false positives^{1,7}

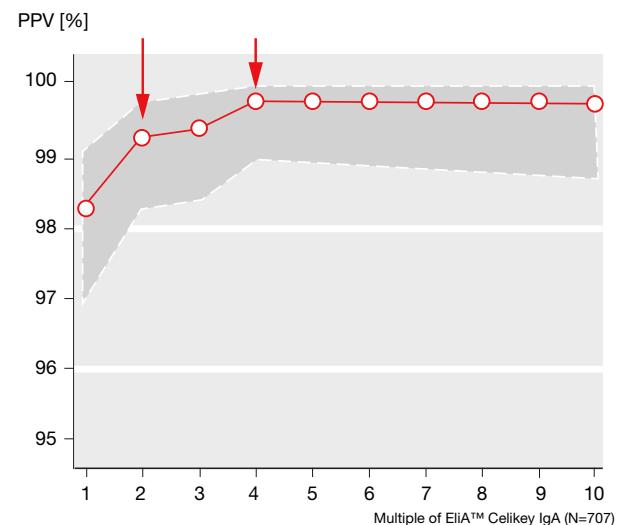


A study of 707 subjects in 21 countries comparing fully automated testing of EliA™ Celikey IgA to the brands of alternative diagnostic suppliers showed high diagnostic certainty and specificity.

- Zero false positive results detected at five times the upper limit of normal (5x ULN*) and at ten times the upper limit of normal (10x ULN).⁷
- In the non-biopsy approach of the ESPGHAN⁸ guidelines, the EliA™ Celikey IgA test results in fewer false positives, boosting the diagnostic accuracy of this non-invasive approach.^{7,9}

*Upper Limit of Normal

99% positive predictive value (PPV) at 2x ULN⁷



The positive predictive value (PPV) of the EliA™ Celikey IgA test shows a degree of accuracy that demonstrably surpasses that of other tests.⁷

- EliA™ Celikey IgA has high specificity, with a PPV of 99% at 2x ULN (20 EliA U/ml).⁷
- EliA™ Celikey IgA test has a positive predictive value (PPV) of 100% in symptomatic patients where tests showed tissue transglutaminase (tTG) IgA levels $\geq 10xULN$ (100 EliA U/ml), being highly supportive of a non-biopsy diagnostic approach to CeD.^{11,12}

Add EliA™ Gliadin^{DP} IgG test to aid in the identification of additional patients

The EliA™ Gliadin^{DP} IgG test supports with high reliability the identification of additional CeD patients^{10,12} and follows the 2020 ESPGHAN guidelines for the diagnosis of celiac disease¹. This test could be used as a second-line testing on patient samples that show IgA deficiency.⁵

The EliA™ Gliadin^{DP} IgG test supports with high reliability the identification of additional CeD patients.^{10,12}

Celiac Disease tests panel

Together, EliA™ Celikey IgA and EliA™ Gliadin^{DP} IgG tests form a highly reliable testing recommendation for all patient age groups, with high diagnostic accuracy.^{7,11} This strong combination provides high sensitivity with high specificity, aiding in increasing the number of patients who are accurately diagnosed for celiac disease,¹³ including testing in children <2 yrs.^{1,5,6}



Fast. Accurate. Automated. Put our EliA™ Celiac tests to work.

You might have noticed that assay quality can vary significantly among manufacturers – leading to fluctuations in sensitivity and specificity. Additionally, manual testing can be time-consuming.

To avoid quality issues and speed up testing, we developed a broad test panel called EliA™ Celiac Portfolio.

99%

**EliA™ Celikey IgA
has a 99% specificity
to tTG-IgA auto-
antibodies⁴**

To support optimal workflows, EliA™ Celiac Portfolio tests run on our Phadia™ Laboratory Systems. They are based on more than 20 years of experience in EliA™ Autoimmunity Disease testing.

It all starts with controlled antigen quality

All our products are produced under the high standards needed for CE marking and FDA clearance. We manufacture our own antigens at our Biotechnology Center of Excellence in Freiburg, Germany. Optimized process for research, development and manufacturing in autoimmunity including:

- **Recombinant antigen production**
 - **Purification of antigens from native sources**
 - **Highly automated manufacturing with full traceability of all steps for low lot-to-lot variation**
 - **Quality management**
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Phadia Laboratory Systems

Rely on Thermo Fisher Scientific Laboratory Systems to aid the diagnosis of patients with celiac disease

With a Phadia™ Laboratory instrument installed in your laboratory, you can offer an exceptionally high level of service to your customers. Not only do you gain access to two top-level celiac disease tests that offer highly accurate results on the first run, you also have up to 700 other reliable EliA™ or ImmunoCAP™ tests*. Phadia™ instruments are fully automated and designed to optimize workflow efficiency, whatever the size and test volume of your laboratory. Our family of instruments*

is adapted to fit your specific needs, allowing you to scale up seamlessly as your laboratory operations grow. Should you have questions, our team of experts is always on hand for service and remote trouble shooting – all to ensure that your celiac disease and other testing runs smoothly and efficiently.

* Availability of instruments and products may vary depending on market

Phadia™ Laboratory Systems: Made to fit



Phadia™ 200 instrument



Phadia™ 250 instrument



Phadia™ 2500+ series**



Phadia™ 5000+ series***

** Phadia 2500 + series comprises Phadia 2500, Phadia 2500E and Phadia 2500EE

*** Phadia 5000 + series comprises Phadia 5000, Phadia 5000E and Phadia 5000E+E

Technical and ordering information

Product	Article No.	Package size	Cut-off		
			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

References

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