ThermoFisher SCIENTIFIC

Laboratory technical bulletin

EliA™ Celiac Disease (CeD) tests

Test name	Common name	Test code	CPT code	Included in Insert lab name test menu
EliA™ Celikey IgA Well	Tissue Transglutaminase (tTG) IgA	Acy	86364	☐
EliA™ Celikey IgG Well	Tissue Transglutaminase (tTG) IgG	Gcy	86364	☐
EliA™ Gliadin^{DP}	Deamidated Gliadin IgA	Agp	86258	☐
EliA™ Gliadin^{DP}	Deamidated Gliadin IgG	Ggp	86258	☐

Method	Fluoroenzyme immunoassay (FEIA)
Change	As of Enter date, EliA Celiac Disease (CeD) assays will be processed in our lab using the Phadia ☐ 250 ☐ 2500 instrument and EliA assays.
Specimen (EliA™ Celikey)	Human serum or plasma (EDTA)
Specimen (EliA™ Gliadin^{DP})	Human serum or plasma (lithium heparin, or EDTA)
Availability	Enter TAT

Measuring ranges[1-4] Each assay has an upper measuring limit and values that exceed these limits will be reported as "greater than".		
	EliA™ Celikey IgA	1.0 - 128 EliA U/mL
	EliA™ Celikey IgG	1.7 – 227 EliA U/mL
	EliA™ Gliadin^{DP} IgA	1.3 - 142 EliA U/mL
	EliA™ Gliadin^{DP} IgG	1.4 – 302 EliA U/mL

Background

Celiac disease (CeD) is a life-long abnormal immune system response to gluten present in wheat, barley, and rye, resulting in chronic inflammation and damage to small intestine lining.[5,6] CeD is multisystemic disorder and is not an isolated intestinal disease.[5] However, CeD is often identified by small bowel injury and the presence of specific antibodies.[5] In many cases, there is a significant delay from first reported symptoms to a CeD diagnosis.[6] Untreated CeD negatively impacts quality of life, which is why shortening the diagnostic delay may improve patient outcomes and quality of life.[6]

Duodenal biopsy is often required to confirm the diagnosis of CeD, however, detection of CeD-specific antibodies such as tTG in the serum is useful at initial screening of patients with suspicion of CeD.[5] Despite biopsy being a common approach for determining CeD, it remains an invasive procedure.[7] Data shows that tTG titres of ≥10× the upper limit of normal (ULN) have a 98.1-100% positive predictive value in identifying intestinal changes diagnostic of CeD.[7]

Populations at risk

CeD is a common disorder, with a 1% prevalence in most populations.[5] Diagnosis has risen in recent decades as a result of both increased awareness and testing in addition to a general rise in autoimmunity.[5]

The American College of Gastroenterology Guidelines recommend the following individuals be tested for CeD:[5]

- Patients exhibiting symptoms or signs of malabsorption—like chronic diarrhea with weight loss, steatorrhea, abdominal pain, and bloating
- Patients presenting with symptoms, signs, or laboratory findings for which CeD is a potential treatable cause
- Patients with a first-degree relative diagnosed with CeD should be evaluated if they exhibit possible signs, symptoms, or laboratory evidence of the disorder
- Consider testing asymptomatic relatives of individuals with a confirmed diagnosis of CeD who are first-degree family members

Results interpretation[1-4]

Test	Unit	Negative	Equivocal	Positive	
EliA™ Celikey IgA	EliA U/mL	< 7	7–10	> 10	For equivocal results, it is recommended to retest the patient after 8 – 12 weeks.
EliA™ Celikey IgG	EliA U/mL	< 7	7–10	> 10	
EliA™ Gliadin^{DP} IgA	EliA U/mL	< 7	7–10	> 10	
EliA™ Gliadin^{DP} IgG	EliA U/mL	< 7	7–10	> 10	

Limitations

- The use of plasma preparations with heparin is not recommended because heparin interferes with measurement of tTG antibodies.[1,2]
- Like the majority of laboratory tests a clinical diagnosis should be based on all available evidence and not a single diagnostic method result.[1-4]
- Antibody prevalence in autoimmune patients varies widely depending on disease area.[1-4]

Who do I contact for interpretation or additional information?

Name

Company

Phone number

Email

References

1. EliA Celikey IgA Directions for Use. (2024). Phadia 250 Laboratory System. **2.** EliA Celikey IgG Directions for Use. (2024). Phadia 250 Laboratory System. **3.** EliA Gliadin^{DP} IgA Directions for Use. (2024). Phadia 250 Laboratory System. **4.** EliA Gliadin^{DP} IgG Directions for Use. (2024). Phadia 250 Laboratory System. **5.** Rubio-Tapia A, Hill ID, Semrad C, et al. American College of Gastroenterology Guidelines Update: Diagnosis and Management of Celiac Disease. Am J Gastroenterol. Jan 01 2023;118(1):59-76. doi:10.14309/ajg.0000000000002075 **6.** Norström F, Lindholm L, Sandström O, Nordyke K, Ivarsson A. Delay to celiac disease diagnosis and its implications for health-related quality of life. BMC Gastroenterol. Nov 07 2011;11:118. doi:10.1186/1471-230X-11-118 **7.** Penny HA, Raju SA, Lau MS, et al. Accuracy of a no-biopsy approach for the diagnosis of coeliac disease across different adult cohorts. Gut. May 2021;70(5):876-883. doi:10.1136/gutjnl-2020-320913

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