



CELIAC DISEASE SCREENING TEST

Rapid immunochromatographic manual self-test for the qualitative detection of anti-deamidated gliadin peptide IgG and anti-tissue transglutaminase IgA in human capillary blood sample for the screening of celiac disease



CELIAC DISEASE

Celiac Disease (CD), is a chronic inflammatory disorder of the small intestine, produced by the ingestion of dietary gluten products in genetically predisposed people. It is a multifactorial disease, including genetic and environmental factors. Environmental trigger is represented by gluten while the genetic predisposition has been identified in the major histocompatibility complex region which cause the presence of specific antibodies against gluten and its components. Celiac disease is not a rare disorder like previously thought, with a global prevalence around 1.5%. The reason of its under recognition is mainly referable to the fact that about half of affected people do not have the classic gastrointestinal symptoms, but they present non specific manifestations or have no symptoms at all.

GLIADIN AND CD ANTIBODIES

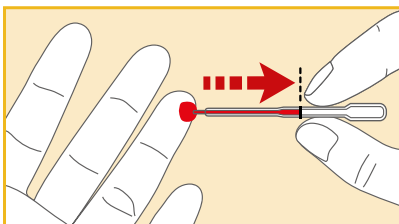
Gluten is a protein found in wheat, barley, rye, spelt and many other cereals, composed by glutenin and gliadin which is the part of gluten responsible of Celiac Disease. Recent studies have shown that celiac sufferers produce specific antibodies that are detectable in the blood. Among them, IgG anti-deamidated gliadin peptides (anti-DGP) and IgA anti-tissue transglutaminase (anti-tTG) antibodies show a high correlation with celiac disease, thus allowing high accuracy in screening for the disease.

WHO ARE THE INTENDED USERS

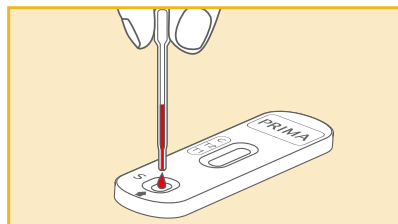
Symptomatic patients (e.g. diarrhoea, abdominal pain and bloating, weight loss, tiredness and/or headache), those with a family predisposition (risk of up to 20% for first-degree relatives), individuals with vitamin deficiencies (e.g. iron, ferritin, folic acid, vitamin D, vitamin B12 and calcium) and high risk groups (subjects with iron deficiency anaemia, Down syndrome, type 1 diabetes mellitus, osteoporosis).

HOW TO USE IT

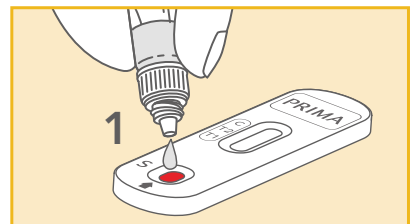
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 1 drop into the well and wait 10 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.



REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
CE2H8800KIT01E5	CELIAC DISEASE SCREENING TEST	1 TEST	24 MONTHS

WHY - BENEFITS

A self-test represents an important tool that is simple, rapid, and non-invasive in the screening process for potential celiac patients. It allows for the quick large-scale identification of individuals at risk, helping to prevent complications associated with the disease and to select those who require further diagnostic investigations.

TEST PRINCIPLE

CELIAC DISEASE SCREENING TEST is a manual immunochromatographic self-test device designed to detect the presence of IgG anti-DGP and IgA anti-tTG antibodies in capillary blood. When present, the target antibodies bind to gold nanoparticle-conjugated reagents, migrate via capillary action along the membrane, and produce visible colored lines at the specific test regions. In the absence of these antibodies, no test lines appear, indicating a negative result. A control line is always displayed to confirm correct test execution and reagent functionality.

TECH SPECS

	MEASURING RANGE	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
T1	min: 5 U/mL max: 302 U/mL	84.30%	90.10%	86.94%
T2	min: 12 U/mL max: 128 U/mL	98.31%	98.02%	98.17%

Performance data obtained by a clinical study on 266 real samples. Thermo Fisher Phadia 250 assay has been utilized as reference methods.

CLINICAL EVIDENCES

1. Lindfors, K., Ciacci, C., Kurppa, K. et al. Coeliac disease. Nat Rev Dis Primers 5, 3 (2019).
2. Al-Toma et al. European Society for the Study of Coeliac Disease (ESsCD) guideline for coeliac disease and other gluten-related disorders. United European Gastroenterol J. 2019 Jun;7(5):583-613.
3. King, et al. 2020. Incidence of Celiac Disease Is Increasing Over Time: A Systematic Review and Meta-Analysis. The American Journal of Gastroenterology 115 (4): 507-25.
4. Parrinello G., Da Re M., Grizzo F., Camelliti S., Cozzi M., Marinoni F., Villalta D. Diagnostic accuracy of a novel point-of-care test for simultaneous detection of anti-transglutaminase IgA and anti-deamidated gliadin IgG antibodies. J Clin Lab Anal. 2024.