



CELIAC TEST

Self-test to check for the presence of anti-deamidated gliadin (anti-DGP) antibodies, IgA and IgG, in the blood, for celiac disease screening



CELIAC DISEASE

Celiac Disease (CD), also known as "celiac sprue", is a chronic inflammatory disorder of the small intestine, produced by the ingestion of dietary gluten products in susceptible 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%. 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 nonspecific manifestations of nutritional deficiency or have no symptoms at all.

GLUTEN, GLIADIN AND DGP

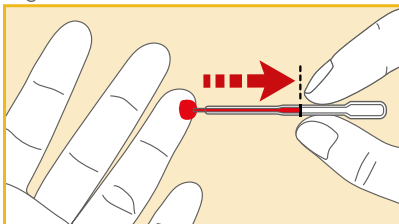
Gluten is a protein found in wheat, composed by glutenin and gliadin. It helps foods maintain their shape, acting as a glue that holds food together. Gliadin is a peptide water-soluble component of gluten and it can pass through the intestinal epithelium. Gliadin is the part of gluten responsible of Celiac Disease. DGP: Deamidated gliadin peptides are the result of the action of Transglutaminase Enzyme and its detection could increase sensitivities, specificities and accuracies of celiac disease screening.

WHO ARE THE INTENDED USERS

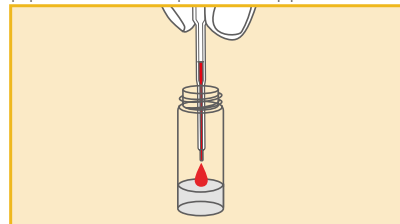
Patients with symptoms (abdominal bloating and pain, chronic diarrhea, vomiting, constipation, weight loss, fatigue, irritability), patients with a first degree family member with CD, and people with Type I diabetes.

HOW TO USE IT

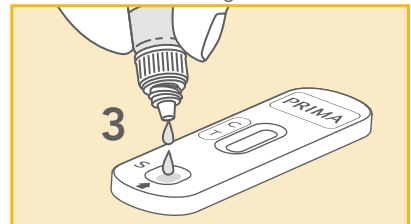
1) Take a blood sample after pricking the finger.



2) Put the blood collected with the pipette into the opened dropper vial.



3) Add 3 drops of liquid 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.

WHY - BENEFITS

Underdiagnosis is common and the quality-of-life impact of symptoms may be severe. Checking the presence of specific antibodies against DGP is a useful tool to detect Celiac disease.

TEST PRINCIPLE

CELIAC TEST is based on an immunochromatographic reaction. If the antibodies (IgA and IgG) are present into the sample, they will react with the deamidated gliadin. A positive result means that the concentration of antibodies is nearby to 20 AU/mL.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
20 AU/mL	81,25%	94,10%	90,00%

Performance data obtained by two clinical study with 200 participants enrolled. ImmunoCap Thermofisher DGP IgG/IgA (ELISA) assay and Zenit RA Menarini DGP IgG/IgA (Chemiluminescent IA) assay have been utilized as reference methods.

CLINICAL EVIDENCES

1. P.D. Mooney, S.H.Wong, A.J.Johnston, M.Kurien, A.Avgerinos and D.S.Sanders "Increased detection of celiac disease with measurement of Deamidated Gliadin Peptide Antibody before endoscopy" *Cli., Gastroenterology and Hepatology* 2015;13:1278-1284
2. N. R. Lewis & B. B. Scott "Meta-analysis: deamidated gliadin peptide antibody and tissue transglutaminase antibody compared as screening tests for coeliac disease" *Alimentary Pharmacology & Therapeutics*
3. A. Lammi, P. Arikoski, S. Simell, T. Kinnunen, V. Simell, S Paa-vaanen-Huhtala, A. Hinkkanen, R. Veijola, M. Knip, J. Toppari, O. Vaarala, O. Simell, and J. Ilonen "Antibodies to Deamidated Gliadin Peptide in Diagnosis of Celiac Disease in Children" *Gastroenterology - JPGN* 2015;60: 626-631



REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100077-1	CELIAC TEST	1 TEST	24 MONTHS