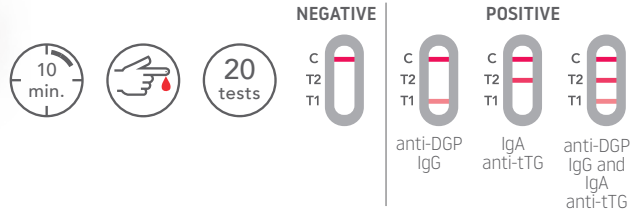




CELIAC RAPID TEST

Rapid test for the qualitative detection of IgG anti-gliadin deamidated peptide (DGP) and IgA anti-tissue transglutaminase (tTG) antibodies in whole blood, serum or plasma samples for screening of celiac disease



CELIAC DISEASE

Celiac disease is an autoimmune disorder that affects genetically predisposed individuals and is caused by intolerance to gluten (a protein complex typical of certain cereals, especially wheat and corn) that leads to a state of chronic inflammation of the small intestine. Worldwide incidence is estimated to be 1.5% of population, with high incidence in women and children. Recent studies shown that celiac subjects produce specific antibodies versus gliadin deamidated peptide (IgG anti-DGP) and tissueTransglutaminase (IgA anti-tTG).

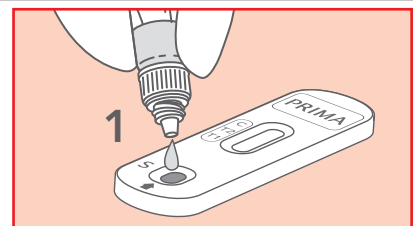
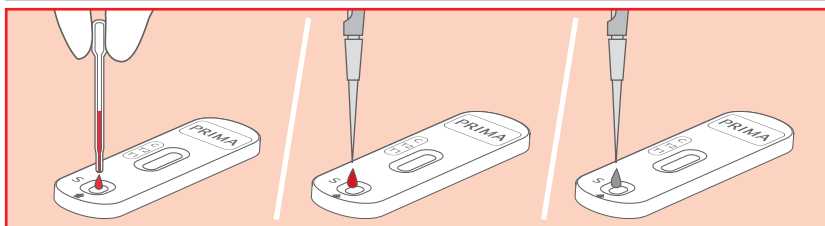
WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present the following symptoms: weight loss, persistent diarrhea, bloating and stomach pain, constipation and tiredness. Significant growth delay can also be observed in children due to malabsorption of necessary nutrients.

TEST PRINCIPLE

CELIAC RAPID TEST is a rapid immunochromatographic lateral flow assay for the detection of IgG anti-gliadin deamidated peptide (DGP) and IgA anti-tissue transglutaminase (tTG) antibodies in whole blood or serum/plasma, thanks to special gold conjugate antibodies embedded to a test strip with two different test lines.

HOW TO USE IT



CONTENT: 20 test cassettes; 20 pipettes; 2 vials with diluent; 1 instructions for use leaflet.

TECH SPECS

	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
T1 (IgG anti-DGP)	84,30%	90,10%	86,94%
T2 (IgA anti-tTG)	98,31%	98,02%	98,17%

Performance data obtained on a total of 266 participants comparing the test with a quantitative commercial laboratory test used as a reference method (Thermo Fisher Phadia 250 - Thermo Fisher Scientific Inc.).

CLINICAL EVIDENCES

- 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.
- Lindfors, et al. Celiac disease. *Nat Rev Dis Primers* 5, 3 (2019).
- Husby, Steffen, Sibylle Koletzko, Ilma Korponay-Szabó, Kalle Kurppa, Maria Luisa Mearin, Carmen Ribes-Koninckx, Raanan Shamir, et al. 2020. "European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Celiac Disease 2020". *Journal of Pediatric Gastroenterology and Nutrition* 70 (1): 141-56.
- Al-Toma, et al. European Society for the Study of Celiac Disease (ESSCD) guideline for Celiac disease and other gluten-related disorders. *United European Gastroenterol J.* 2019 Jun;7(5):583-613.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800077IP-20P	CELIAC RAPID TEST	20 TESTS	24 MONTHS