

Xeliac[®] Test

*Detection of IgA, IgG and IgM anti-tTG antibodies.
High sensitivity and specificity.*



Fast



Reliable
and precise



For adults
and children



Whole blood
drops / serum

Rapid test for coeliac disease
Result in less than 10 minutes
For professional & self-test use

Xeliac[®]Test

Rapid test for coeliac disease on whole blood

Why Eurospital

Eurospital is a family company with more than 30 years of experience in the identification of both symptomatic and asymptomatic coeliac disease patients, owner of the European Patent (EP 0912898) for the use of the tissue transglutaminase (tTG) as a marker for the *in vitro* determination of the coeliac disease.

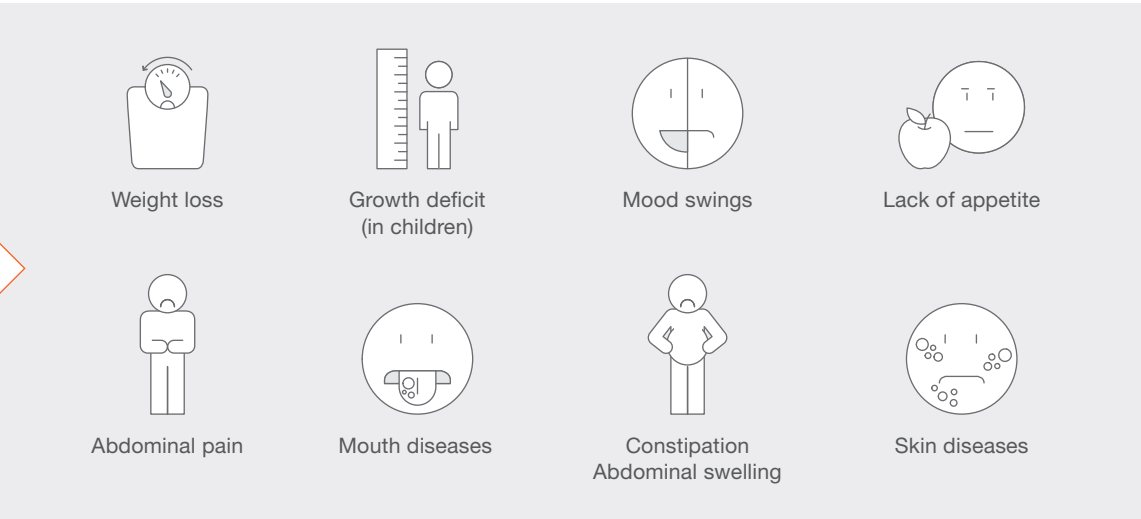
What is coeliac disease

Coeliac disease is a chronic inflammatory autoimmune disorder occurring in genetically predisposed people where the ingestion of gluten (a protein present in wheat, rye, barley and other cereals) leads to damage to the small intestine mucosa, due to an excessive immune response. Coeliac disease is characterized by the serological presence of specific antibodies (IgA, IgG and IgM) directed against both tTG (a human ubiquitous enzyme with a role in wound healing, apoptosis and cell differentiation) and gliadin, one of the protein components of gluten.

When people with coeliac disease eat gluten, their body mounts an immune response that leads to damage to the villi, protrusions of the small intestine mucosa responsible for nutrient absorption. When the villi get damaged, nutrients cannot be properly absorbed, thus causing various symptoms such as weight loss, diarrhoea and/or growth deficit (in children).

Coeliac disease can develop at any age in genetically predisposed people after gluten ingestion. Even though the pathology itself is not hereditary, the predisposition to develop coeliac disease is such, meaning that it runs in families. **People with first-degree relatives (parent, child, sibling) with coeliac disease have a 1 out of 10 risk to develop the same pathology.** Coeliac disease is estimated to affect worldwide 1% of the general population. Left untreated, coeliac disease can lead to additional serious health problems.

WHICH ARE THE MOST COMMON COELIAC DISEASE SYMPTOMS



- Weight loss
- Growth deficit (in children)
- Mood swings
- Lack of appetite
- Abdominal pain
- Mouth diseases
- Constipation
Abdominal swelling
- Skin diseases

What is Xeliac[®] Test

Xeliac[®] Test is a rapid test being the perfect **first approach** to identify coeliac patients, both adults and children, by detection of anti-tTG antibodies (IgA, IgG and IgM) in human whole blood or serum samples. Also the few individuals with a low IgA titre can be identified as such patients. The test must be performed when the individual is under a normal diet regimen, without restrictions and containing gluten. Since coeliac disease is a reversible pathology, a gluten free diet would lower down the presence of anti-tTG antibodies, thus having a possible coeliac patient resulting negative to the test. Individuals resulting positive to the test must consult a physician and be further assessed before being definitely identified as coeliac patients.

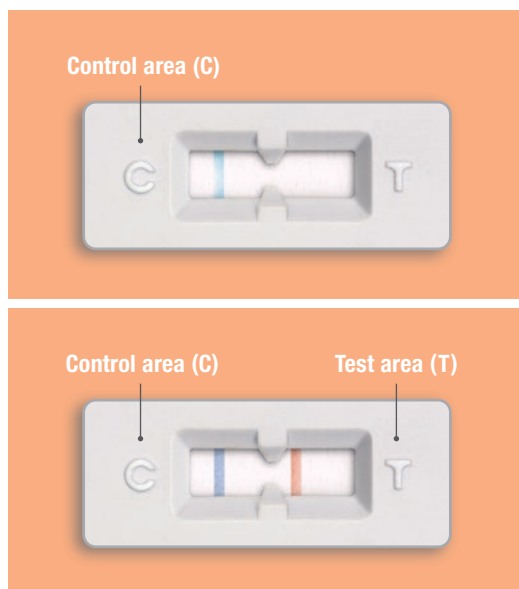
How to perform the self-test from drops of blood

1. Open the lancet
2. Puncture a fingertip
3. Fill the pipette with blood
4. Pour the blood into the test cassette
5. Add 2 drops of diluent
6. Wait from 3 to 5 minutes, then read the test

All the components needed to perform the test are provided

Protocol for serum samples is available in the IFUs.

How to read the test



When the test is negative:

- Only a light blu line appears in the control area (C).
- The individual is identified as negative to coeliac disease unless:
 - if under a gluten free diet regimen;
 - with low total antibody titre.

In both cases the test should be repeated after a while and under a diet regimen containing gluten, when symptoms of coeliac disease continue to be evident.

When the test is positive:

- A red line appears in the test area (T) together with a light blu line in the control area (C).
- The red line indicates a possible coeliac patient.
- The individual must consult a physician and undergo further laboratory testing to confirm/deny the presence of coeliac disease.

Sensitivity

96.5%

Specificity

97.3%

Why is Xeliac® Test a valuable product

- Rapid self-test for the identification of IgA, IgG and IgM antibodies against tTG
- Test result readable in less than 10 minutes from a drop of whole blood or serum samples
- Easy, reliable and precise, for both adults and children
- Ideal for individuals with IgA deficiency
- Product configuration available for both pharmacy (1 test per box) and laboratory (25 tests per kit)



More information and scientific references on:
www.eurospital.com

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