

Description

Eu-tTG *New* is a new chromogenic enzyme immunoassay, based on human recombinant antigen and 5-calibrator-standard curve, for the quantitative detection of IgA and IgG antibodies against tissue transglutaminase, which is the reference test for the in vitro diagnosis of coeliac disease.

Configuration

Eu-tTG IgA <i>New</i>	code 9105
Eu-tTG IgG <i>New</i>	code 9106

Each kit contains reagents for 96 assays.

Indications

Eu-tTG *New*: the Elisa “Anti-endomysial” test

It has been proven that tissue transglutaminase (tTG) is the endomysial autoantigen of coeliac disease.⁽¹⁾

Eu-tTG *New* is the standardised immunological determination of anti-tTG antibodies, recently indicated by the scientific community as the reference test for the diagnosis and follow-up of coeliac disease.

Eu-tTG *New*: not only gastroenterology

Eu-tTG *New* can play a fundamental role in both large and specific screening projects, especially for mono-symptomatic or atypical cases where symptoms can be attributed to coeliac disease such as: recurrent abortions, teeth enamel hypoplasia, alopecia, osteoporosis, type I diabetes mellitus, sterility, sideropenic anaemia resistant to iron therapy, epilepsy and others.

Features of the products

- Human recombinant antigen obtained from prokaryotic cells (*E.coli*) to avoid cross-reaction with nuclear eukaryotic antigens
- Calibration curve for a proper patient follow-up
- Ready-to-use reagents
- Unique sample dilution for both IgA and IgG (1:101)
- Total incubation time: 90 minutes at room temperature
- Products manufactured and commercialised by Eurospital, based on the invention of the German scientists Schuppan and Dieterich who provided Eurospital with exclusive world wide licence of use

Procedure outline

The test procedure is based on the following steps:

- Addition of calibrators, positive and negative controls and diluted sera
- 45 Minutes incubation at room temperature
- Washing step by means of diluted wash buffer
- Addition of conjugate
- 30 Minutes incubation at room temperature
- Washing step by means of diluted wash buffer
- Addition of substrate
- 15 Minutes incubation at room temperature
- Addition of stop solution
- Reading at 450 nm

Performance

A multicentre study involving 4 reference centres has been carried out to evaluate Eu-tTG IgA and IgG *New* diagnostic sensitivity and specificity. The study included coeliac patients (based on biopsy proven diagnosis, clinical symptoms and serologic assays) and healthy patients.

Results ⁽²⁾

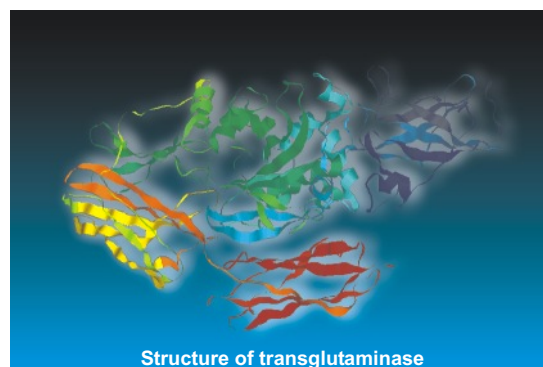
Eu-tTG IgA <i>New</i>		
	Coeliac patients	Healthy subjects
positive	204	4
negative	2	272
total	206	276

Eu-tTG IgG <i>New</i>		
	Coeliac patients	Healthy subjects
positive	105	15
negative	74	261
total	179	276

Conclusions

The study proved that Eu-tTG IgA and IgG *New* are reliable test for the in vitro diagnosis of coeliac disease in patients without total serum IgA deficiency.

	Eu-tTG IgA <i>New</i>	Eu-tTG IgG <i>New</i>
Diagnostic sensitivity	99,0%	58,7%
Diagnostic specificity	98,6%	94,6%



Gliadin, Transglutaminase and HLA: three pieces of the coeliac puzzle

Tissue transglutaminase is present in the bowel and can come into contact with the gliadins or the gliadin fragments introduced with food. Since gliadins are a transglutaminase substrate, they can be bound to other proteins, by forming covalent bonds. Transglutaminase itself could bind with gliadin, thereby transforming itself into a "non-self" protein capable of activating a response by the immune system.

Conversely, in the absence of an accepting lysine, gliadins can be deamidated into some specific glutamine residues of which they abound. Deamidation introduces negative charges into gliadin peptides, thereby allowing their binding with the Class II HLA DQ2 and DQ8 molecules present on the surface of APC cells. This bond leads to the activation of T CD4+ lymphocytes and subsequently to immune response. This immune response presents with anti-gliadin antibodies and anti-tissue transglutaminase auto-antibodies; the latter, at the present state of knowledge, are the most sensitive immunological marker for the diagnosis of coeliac disease. The genetic layout is important; by determining the DQ2 and DQ8 haplotypes an exclusion diagnosis can be presented for this disease. Non DQ2 and non DQ8 subjects do not appear to be predisposed to the disease.



Literature

- (1) Dieterich W. et al. "Identification of tissue Transglutaminase as the autoantigen of Celiac Disease" *Nat Med* 1997; 3:797-801.
- (2) Dati interni Eurospital.
- (3) Kiren V. et al. "New dimension of coeliac iceberg in childhood by using human tissue transglutaminase based Elisa test" *J pediatr Gastroenterol Nutr* 2001; 32:360.
- (4) Galeano Brandt K. et al. "Prevalence of CD related autoantibodies in north east of Brazil".
- (5) Berti I. et al. "Prevalence of coeliac disease among risk groups and the general population in USA" *Gastroenterology* 2000; 118:A816.