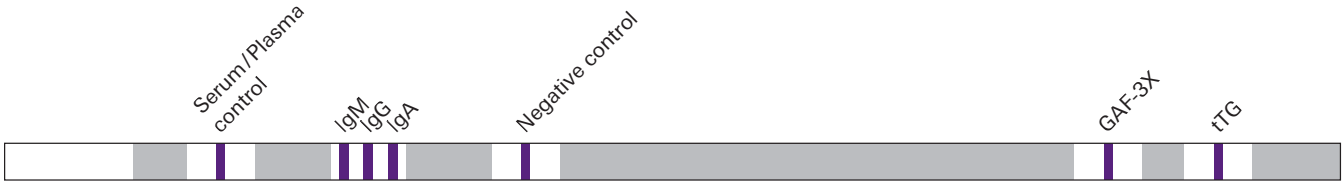
EUROLINE Coeliac Disease Profile (IgA, IgG)



- **Qualitative in vitro determination of human IgA and IgG antibodies against tissue transglutaminase (tTG) and gliadin-analogue fusion peptide (GAF-3X)**
- **Identification of a possible IgA deficiency using serum/plasma control bands**
- **Detection of a 10-fold increased antibody concentration above the upper threshold value of the normal range ("10 x upper limit of normal"; > 10 x ULN) in the evaluation by EUROBlotOne and EUROLineScan**

Technical data

Antigens	Recombinant tissue transglutaminase (tTG) and recombinant gliadin-analogue fusion peptide (GAF-3X)
Sample dilution	Serum or plasma, 1 : 101 in sample buffer
Test procedure	30 min / 30 min / 10 min (sample / conjugate / substrate incubation), room temperature, fully automatable
Test kit format	16 membrane strips, kit includes all necessary reagents
Automation	Compatible with the EUROBlotOne or EUROBlotMaster from EUROIMMUN; the evaluation is performed using the EUROLineScan software.
Order no.	**DL 1910-1601 A** **DL 1910-1601 G**

Clinical significance

Gluten-sensitive enteropathy (coeliac disease) is a systemic autoimmune disease with a pronounced genetic predisposition, which occurs in affected patients as a reaction to the consumption of gluten. Gluten is a protein mix which is found in different grains (e.g. wheat, barley, rye). The prevalence of coeliac disease in Europe is estimated to be approx. 1%. However, atypical or mild symptoms are suspected to lead to a large number of undiagnosed cases. The clinical symptoms comprise not only the inflammation of the mucous membrane of the small intestine, but also fatigue, borborygmus, stomach ache and diarrhoea, as well as weight loss, anaemia, fertility, growth disorders and osteoporosis. Genetic components as well as environmental factors play a role in the development of coeliac disease. The most important protein for the pathogenesis is gliadin. It is taken up with the food and can only be partially digested in the intestine. In coeliac disease patients, the remaining gliadin peptides can pass the epithelium of the small intestine and enter the underlying connective tissue. There, the protein fragments are deamidated by the enzyme tissue transglutaminase (tTG). The amino acid glutamine is transformed into glutamate. If there is a genetic predisposition (human leukocyte antigens (HLA)-DQ2 or DQ8), these modified peptides are increasingly presented to the immune system via antigen-presenting cells. As a consequence, pro-inflammatory cytokines are secreted and antibodies against both specific, deamidated gliadin epitopes and the body's enzyme tTG are produced.

Serological detection of disease-specific antibodies (IgA and IgG) is an essential element of coeliac disease diagnostics. IgA antibodies against tTG are considered the most specific and sensitive indicator. IgA and IgG antibodies directed against the relevant deamidated gliadin epitopes can be detected using test systems based on the gliadin-GAF-3X antigen. For a reliable diagnosis, the detection of antibodies against both tTG and GAF-3X is recommended. A 10-fold increase in the antibody concentration of the upper limit of the normal range (10x upper limit of normal, > 10 x ULN) is considered a threshold value for the diagnosis of coeliac disease without the need for an additional biopsy. When evaluating the EUROLINE Coeliac Disease Profile with the EUROLineScan software, exceeding titers are automatically displayed. Moreover, the IgA-specific serum/plasma control band on the EUROLINE Coeliac Disease Profile (IgA) can indicate IgA deficiency syndrome, which is frequent in coeliac disease patients.

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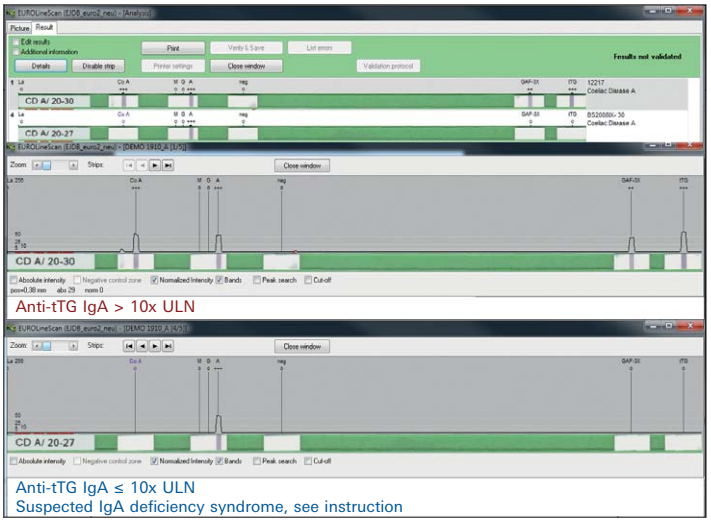
Test principle

The test kit contains test strips coated with parallel lines of highly purified antigens. In the first reaction step, diluted patient samples are incubated with the immunoblot strips. In the case of positive samples, specific IgA and IgG antibodies (also IgM) will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using enzyme-labelled antibodies of class IgA or IgG (enzyme conjugate), which promote a colour reaction upon addition of the substrate solution. Correct performance of all test steps is confirmed by staining of several control bands.

Automated processing

EUROBlotOne is a fully automatic device for the standardised processing of EUROIMMUN line assays (EUROLINE, EUROLINE-WB, Westernblot) – from sample recognition to the final test result. Samples are pipetted by the device and all incubation and washing steps are carried out automatically. Finally the data of the pictures taken by the integrated camera are automatically evaluated and digitally archived by the EUROLineScan software. Alternatively, the immunoblot strips can be incubated by the EUROBlotMaster and scanned using a flatbed scanner. Also in this case, the automatic evaluation is carried out by the EUROLineScan software. The bidirectional communication with a laboratory information management system for import of work lists and export of results is enabled by EUROLineScan or, optionally, the laboratory management software EUROLabOffice 4.0. A separate results sheet can be produced for each sample.



Study data

Several serum panels, which were precharacterised by a CE-notified ELISA reference test, were investigated for autoantibodies against GAF-3X and tTG. With reference to these ELISA test systems, sensitivities of 88.9% each were obtained for IgA (n = 45), and IgG (n = 46) for GAF-3X antibodies, at specificities of 97.0% and 100.0%, respectively. For anti-tTG, the sensitivities were 100.0% each for IgA (n = 44) and IgG (n = 44) at specificities of 96.9% and 100.0%, respectively.

EUROLINE Coeliac Disease Profile		Sensitivity [%]*	Specificity [%]*	[n]
GAF-3X	IgA	88,9	100,0	45
	IgG	88,9	97,0	46
tTG	IgA	100,0	100,0	44
	IgG	100,0	96,9	44

*: with respect to pre-characterised samples of an ELISA test system

In order to determine the reference range, a sample panel of healthy blood donors was investigated (n = 150). All samples were negative apart from one sample which was positive for IgA against GAF-3X (it also showed positive in an additional test using Anti-GAF-3X ELISA IgA).

Literature

1. Fasano A. **Celiac disease – how to handle a clinical chameleon**. N Engl J Med 348:25 (2003).
2. Husby S, et al. **European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Coeliac Disease 2020.** J Pediatr Gastroenterol Nutr 70(1):141-156 (2020).
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DL_1910_D_UK_A02, 10/2022