IMMUNOLOGY – FOOD INTOLERANCE AND INTESTINAL AUTOIMMUNITY
– **TRANSGLUTAMINASE** | **DEAMIDATED GLIADIN** | **GLIADIN** | **MILK** | **ASCA**

Transglutaminase | Deamidated gliadin
Gliadin | Milk | ASCA

Enzyme immunoassays for the diagnosis of coeliac disease, food intolerance and inflammatory bowel disease

ELISA kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum and plasma

CE IVD Diagnostic kits are intended for professional use in the laboratory.

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Introduction

Coeliac sprue (Coeliac disease) is a common term for a cosmopolitan disease that occurs in people of all ages. It is a hereditary autoimmune disease caused by gluten intolerance. The main symptoms include inflammatory changes in the small intestine mucosa, diarrhoea, anaemia, weight loss and general disorders in somatic and psychic development. If gluten is not completely and permanently removed from patient's food, their immune system gets exhausted, the disease affects other organs and further autoimmune diseases and complications may develop, most of them being life threatening.

Gluten intolerance (simple) should not be confused with coeliac disease. Gluten intolerance can proceed in parallel with cow's milk intolerance and intestinal mucosa changes, without activation of transglutaminase. In this case, there is no progress of coeliac disease.

Cow's milk intolerance is a disease affecting children and adults. It is caused by intolerance to cow's milk proteins (β-lactoglobulin, α-lactalbumin, casein). General symptoms include vomiting, diarrhoea and abdomen aches, and malabsorption syndrome, respectively.

ASCA (antibodies to Saccharomyces cerevisiae), which react against mannan antigen in the cell wall of the yeast, are very specific for Crohn's disease. Crohn's disease together with ulcerative colitis belongs to a group of nonspecific inflammatory bowel diseases. Crohn's disease is a chronic disease of the whole digestive tract, which can cause extraintestinal complications. Inflammation of the gastrointestinal tract leads to absorption problems developing diarrhea and malabsorption syndrome.

Clinical Application

Coeliac Sprue

The diagnostics of the disease is based on clinical manifestation, enterobiopsy and laboratory tests. Detection of highly specific IgA and IgG antibodies to Deamidated gliadin and Transglutaminase is very important and useful for proper diagnosis of coeliac disease and also for monitoring of the effects of gluten--free diet treatment.

Gluten intolerance

Detection of specific IgA and IgG antibodies to gluten (or rather, to its specific α-gliadin fraction), is a key finding, leading to a proper diagnosis of gliadin intolerance and also to monitoring of gluten-free diet treatment effects.

Cow's milk intolerance

Detection of specific IgA, IgG and IgM antibodies to cow's milk proteins is an essential finding in differential diagnostics of gastro-enteric diseases, in children especially.

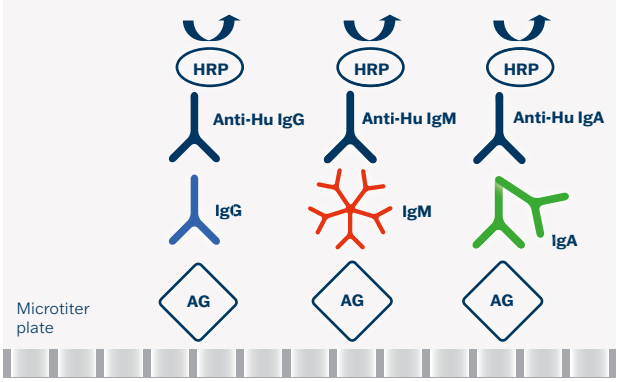
ASCA

Diagnosis of the disease is based on clinical manifestation, results of laboratory tests, endoscopic and imaging methods. Detection of highly specific IgA and IgG antibodies to Saccharomyces cerevisiae (ASCA) together with detection of anti-neutrophil cytoplasmic antibodies (ANCA) is valuable in a differential diagnosis of inflammatory bowel disease (IBD). ASCA are detected in 60-80% of Crohn's patients and in 5–15% of those with ulcerative colitis. ASCA can be increased also in patients with celiac disease etc.

ELISA

Test Principle

The assays are based on a sandwich type of ELISA method.



Summary Protocol

Step		Test steps
	1.	Dilution of samples – serum/plasma (1+100); for ASCA (1+50)
	2.	Pipette Controls and diluted samples 100 µl – Blank = 100 µl Sample diluent; for ASCA Blank = empty well
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 4 times
	5.	Add Conjugate 100 µl – Blank; for ASCA Blank = empty well
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 4 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 15 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

Transglutaminase
Human tissue recombinant tTG

Deamidated gliadin
Deamidated gliadin peptide DGPx1

Gliadin
Antigenic extract of gluten, with specific protein antigens, especially α-gliadin

Milk
Whole delipidated antigen, prepared from cow's milk, rich in proteins (casein, α-lactalbumin and β-lactoglobulin)

ASCA
Highly purified mannan from Saccharomyces cerevisiae

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF and calibrators included
- Semiquantitative evaluation of results (Index of Positivity) or quantitative evaluation of results (U/ml)
- Easy assay procedure

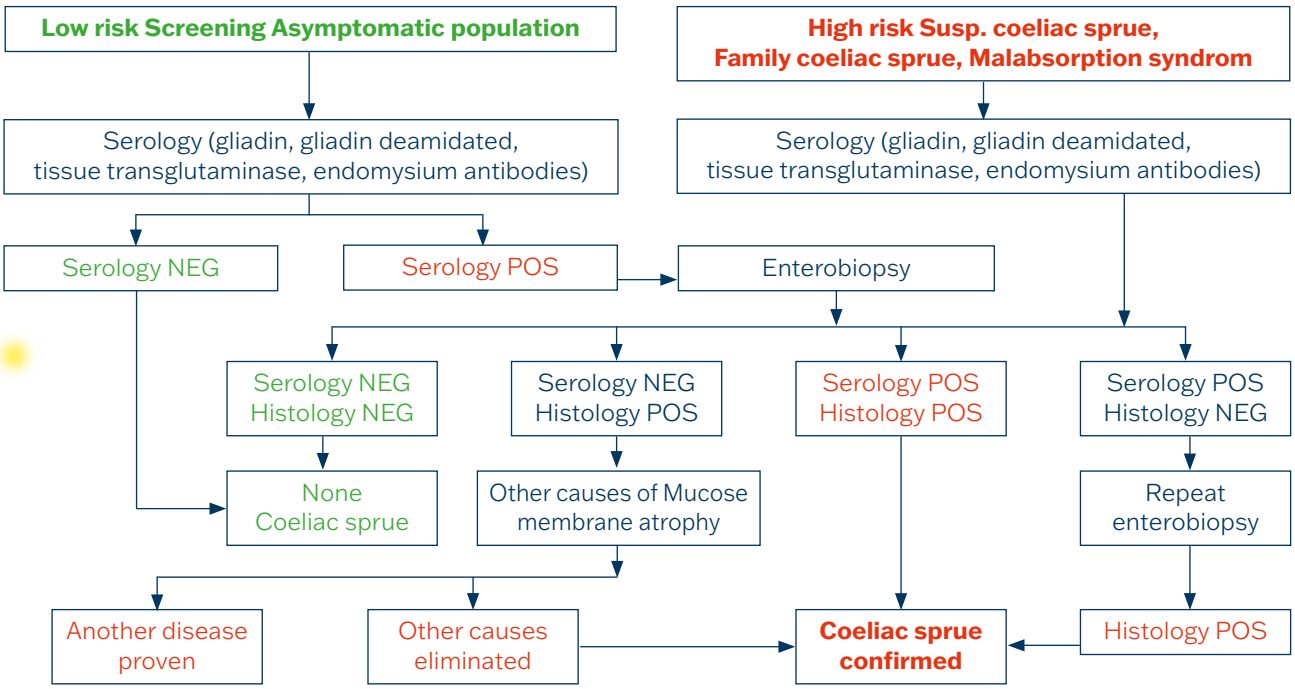
Advantages

- Identical assay procedure
- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Short total assay time
- Quantitative evaluation available
- Ready for automation
- Customer support

Coeliac Sprue

Interpretation of the results

Coeliac Sprue – Diagnostic Scheme



Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA Transglutaminase IgA	97.7%	97.7%
EIA Transglutaminase IgG	97.7%	97.7%
EIA Gliadin DA IgA	97.7%	97.7%
EIA Gliadin DA IgG	97.7%	97.7%

Clinical Data

Coeliac Sprue – Correlation of Methods

EIA Transglutaminase IgA and IFA EmA IgA antibodies correlation

Number of corresponding results: 96.2%		EIA Transglutaminase IgA	
		negative	positive
EmA IgA	–	23	0
	+	3	53

EIA Transglutaminase IgA and EIA Gliadin DA IgA antibodies correlation

Number of corresponding results: 93.75%		EIA Transglutaminase IgA	
		negative	positive
Gliadin DA IgA	–	25	4
	+	1	50

EIA Gliadin DA IgA and IFA EmA IgA antibodies correlation

Number of corresponding results: 98.85%		EIA Gliadin DA IgA	
		negative	positive
EmA IgA	–	42	1
	+	0	44

The borderline results were excluded from evaluation

Food Intolerance

Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA Milk IgA	95.2%	95.5%
EIA Milk IgG	95.0%	95.2%
EIA Milk IgM	95.2%	95.5%
EIA Gliadin IgA	95.5%	95.5%
EIA Gliadin IgG	95.5%	95.5%

Cross-reactivity

	EIA Milk IgA		EIA Milk IgG		Eia Milk IgM	
Category	n	Positive result	n	Positive result	n	Positive result
Borrelia spp	6	0	5	0	6	0
RF	16	0	12	0	16	0
ANA	17	0	14	0	17	1
ASCA	6	1	7	1	6	1
tTG	5	0	4	0	5	0
Helicobacter pylori	8	0	12	0	8	0
Yersinia spp.	6	0	9	0	6	0
TPO, TG	2	0	3	0	2	0
Total	**66**	**2**	**66**	**1**	**66**	**2**

Cross-reactivity

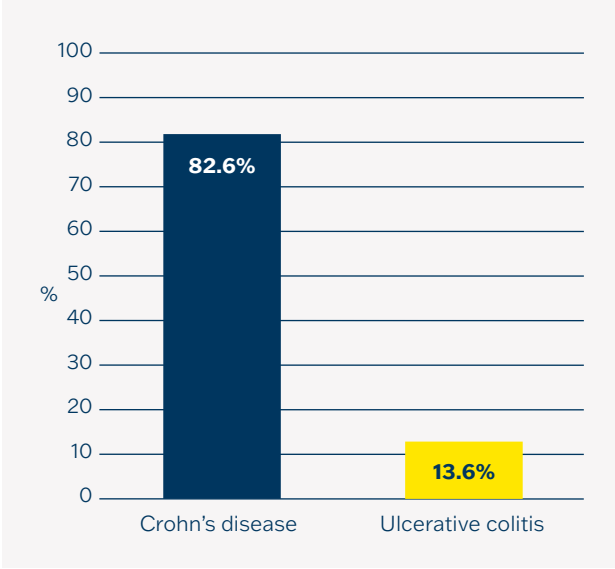
	EIA Gliadin IgA		EIA Gliadin IgG	
Category	n	Positive result	n	Positive result
Borrelia spp	9	0	9	0
RF	11	0	11	0
ANA	15	0	15	0
ASCA	8	0	8	1
Helicobacter pylori	9	0	9	0
Yersinia spp.	9	0	9	0
TPO, TG	5	0	5	0
Total	**66**	**1**	**66**	**1**

Inflammatory bowel disease (IBD)

Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA ASCA IgA	98.5%	98.1%
EIA ASCA IgG	98.6%	99.1%

EIA ASCA IgA and IgG



Comparison of the detection of anti-Saccharomyces cerevisiae antibodies in patients with confirmed Crohn's disease (n = 23) and ulcerative colitis (n = 22) using TestLine EIA kits

Ordering information

ELISA – COELIAC DISEASE

Cat. No.	Product	No. of Tests
GDA096	EIA Gliadin DA IgA	96
GDG096	EIA Gliadin DA IgG	96
tTA096	EIA Transglutaminase IgA	96
tTG096	EIA Transglutaminase IgG	96

ELISA – FOOD INTOLERANCE

Cat. No.	Product	No. of Tests
GIA096	EIA Gliadin IgA	96
GIG096	EIA Gliadin IgG	96
MiA096	EIA Milk IgA	96
MiG096	EIA Milk IgG	96
MiM096	EIA Milk IgM	96

ELISA – IBD

Cat. No.	Product	No. of Tests
ScA096	EIA ASCA IgA	96
ScG096	EIA ASCA IgG	96

*All ELISA kits are also available as SmartKits for Agility®

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Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

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