

## Serological parameters in diagnostics

Valid from January 28<sup>th</sup>, 2019

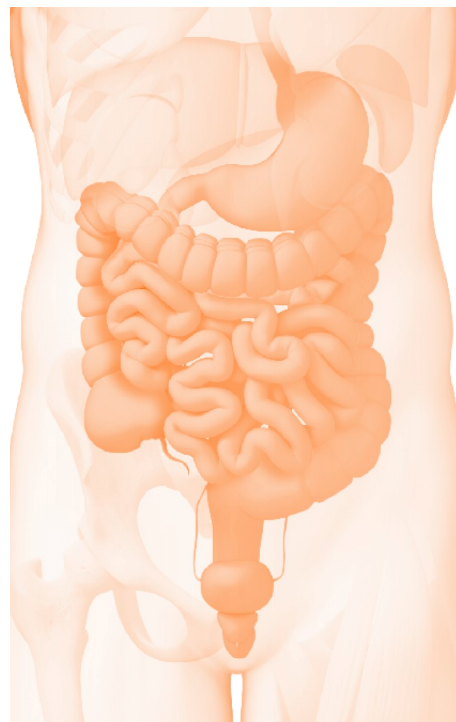


# Celiac disease - Overview

## Celiac disease

is a long-term, serious autoimmune disorder, where the ingestion of gluten (a protein found in wheat, rye and barley) leads to damage in the small intestine. It affects one out of every 100 individuals, that experience symptoms like chronic diarrhoea, abdominal distention, malabsorption, loss of appetite and (in children) a failure to thrive.

If diagnosed late, celiac disease can be also comorbid with other autoimmune disorders, like neuropathies or multiple sclerosis.



## Diagnosis

Current diagnostics of celiac disease comprises an invasive small intestine biopsy, demonstrating a "flat" mucosa prior to a gluten-free diet and the following reconstitution of the mucosa after the onset of the diet.

Determination of anti-deamidated gliadin (anti-DG) and anti-tissue transglutaminase (anti-tTG) IgG and IgA antibodies by ELISA, as well as the detection of anti-endomysium IgA by immunofluorescence have been considered so far the best serological methods for celiac disease diagnostics.

## Generic Assays

offers for the diagnosis of celiac disease a wide range of classical assays like ELISA, LINE and IFA, as well as a unique test based on the patented CytoBead® technology.

External evaluations (e.g. MHRA 2003) confirm the quality of our **Anti-tTG IgA ELISA**

Competitors	A	B	C	D	E	F	G	GA Generic Assays (formerly MEDIPAN brand)	H	I	J
Sensitivity %	54	58	64	75	54	58	85	81	58	69	65
Specificity %	100	100	100	99	100	100	97	99	100	100	99
Overall Agreement %	93	94	95	95	94	94	95	96	94	96	94

MHR Evaluation Report: Eleven anti-tissue transglutaminase IgA assays, UK NEQAS 2003



# Celiac disease - Innovative technology

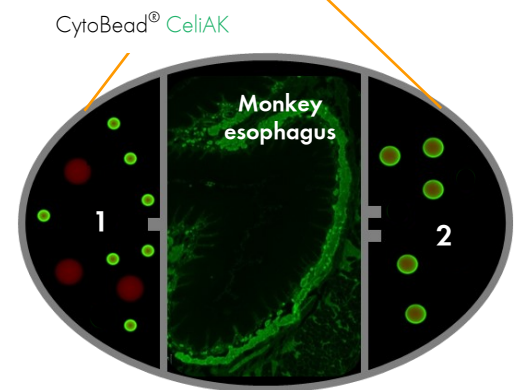
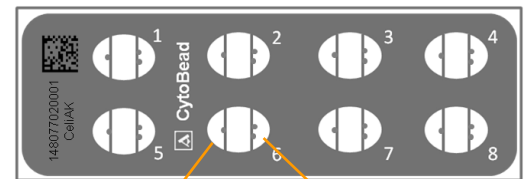
## Fast and easy diagnostics of celiac disease and simultaneous detection of IgA deficiency

CytoBead® technology represents the next generation of IFA arrays in diagnostics. It is a combination of immunofluorescence screening assay and antigen-coated beads for verification of the obtained result.

CytoBead® CeliAK contains a section from monkey esophagus for screening purposes and additionally a compartment (1) with beads coated with tTG (tissue transglutaminase) or DG (deamidated gliadin) antigens. Positive fluorescence of the beads confirms the IFA finding (see the table below).

A second compartment (2) contains anti-IgA antibody-coated beads to screen for potential IgA deficiency in case of the negative IFA result, limiting the number of false negative celiac disease diagnoses.

CytoBead® is a patented technology of GA Generic Assays.



Example of a sample:

- positive for anti-endomysium antibodies (middle compartment)
- positive for anti-tTG (small beads) but negative for anti-DG (large beads - compartment 1)
- and IgA competence (anti-IgA beads positive in compartment 2)

### Unique combination of esophageal tissue with antigen-coated beads

#### Advantages of CytoBead® CeliAK:

- Screening with **standardized monkey esophageal tissue**
- Confirmation of celiac-specific antigens
- Exclusion of IgA deficiency

## CytoBead® CeliAK

Pattern Tissue	Compartment	Bead (positive)	Coating	Clinical relevance
honeycomb pattern of smooth muscle layer in esophagus tissue	1		tTG	Celiac disease, dermatitis herpetiformis
	1		DG	
	2		anti-IgA	IgA deficiency

Also available as quantitative assay on AKLIDES®/akiron® systems



## References

Grossmann K, Röber N, Hiemann R, Rödiger S, Schierack P, Reinhold D, Laass M.-W., Conrad K, Roggenbuck, D.: **Simultaneous detection of celiac disease-specific IgA antibodies and total IgA.** *Auto Immun Highlights.* 2016 Dec, 7(1): 2

Husby S, Koletzko S et.al.: **European Society for Paediatric Gastroenterology, Hematology, and Nutrition Guidelines for the Diagnosis of Coeliac Disease.** *JPGN.* 2012 Jan, 53(1)

Conrad K et al.: **A new dot immunoassay for simultaneous detection of celiac specific antibodies and IgA-deficiency.** *Clin Chem Lab Med.* 2012 Feb; 50(2):337-43

# Celiac disease - available assays

Manual ELISA assays (ready for open automates)				
Order No	3710	3810	4033	4044
	GliaDea IgA	GliaDea IgG	Anti-hu tTG IgA	Anti-hu tTG IgG
Deamidated gliadin	+	+		
Tissue transglutaminase			+	+
Manual LINE assays (ready for open automates)				
Order No	4202	4208	4290	
	CeliAK IgG LINE	CeliAK IgA LINE	Gastro 5 LINE	
Deamidated gliadin	+	+	+	
Tissue transglutaminase	+	+	+	
IgA deficiency		+	+	
PCA			+	
Intrinsic factor			+	
Mannan			+	
Fully automated dot assays [for DotDiver2.0 system only]				
Order No	5014	5015	 <b>DotDiver2.0</b>	
	DotDiver CeliAK IgA	DotDiver CeliAK IgG		
Deamidated gliadin	+	+		
Tissue transglutaminase	+	+		
IgA deficiency	+			
Immunoflourescence (IFA) assays [also available for AKLIDES® / akiron® systems]				
Order No	86096	86048	8064	
	EmA IFA	EmA IFA	CytoBead® CeliAK	
Deamidated gliadin			+	
Tissue transglutaminase	+	+	+	
IgA deficiency			+	



**GA Generic Assays GmbH**  
 Ludwig-Erhard-Ring 3  
 15827 Dahlewitz/Berlin  
 Germany

Phone: +49 33708 9286 0  
 Fax: +49 33708 9286 50  
 info@genericassays.com  
 www.genericassays.com