

# Celiac Disease

Serological parameters for the diagnosis of  
gluten-sensitive enteropathies



## Product Highlights

- Comprehensive Portfolio for Celiac Disease-Specific Antibody Tests
- Second Generation IFA Technology (CytoBead®)
- Analyzers for Tests Automation

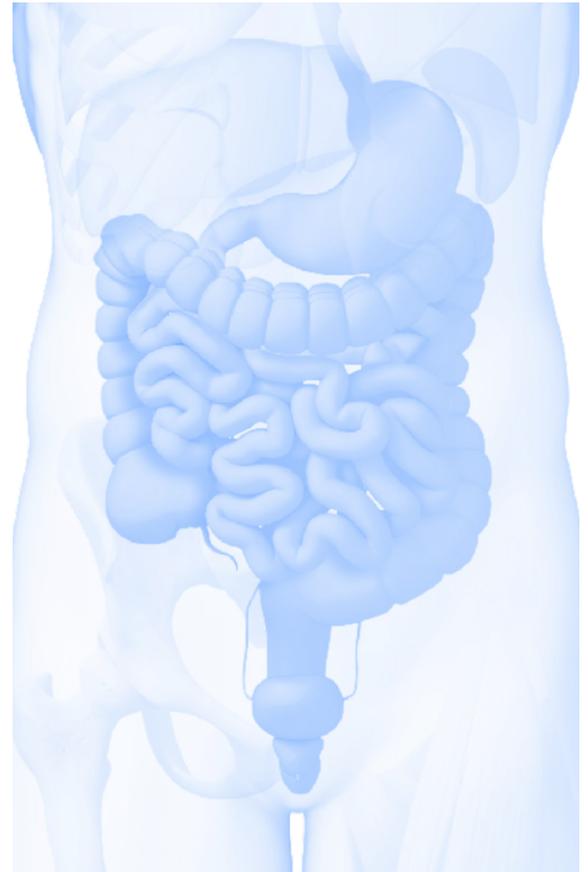
## Celiac Overview

### Celiac disease

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 diarrhea, 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.<sup>1</sup>

### 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 solid phase assays as e.g. ELISA or immunoblot<sup>2</sup>, as well as the detection of anti-endomysium IgA by immunofluorescence have been considered so far the best serological methods for celiac disease diagnostics.



### External evaluations confirm the quality of our anti-tissue transglutaminase IgA ELISA

Competitors	A	B	C	D	E	F	G	GA Generic Assays	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

# Celiac disease - Innovative technology

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

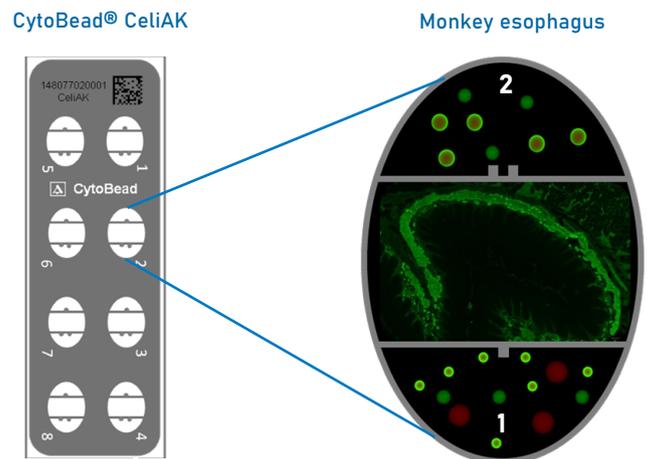
CytoBead® technology represents the second generation of IFA arrays in diagnostics. It is a combination of immunofluorescence screening assay and antigen coated beads for confirmation of the obtained result.<sup>3</sup>

CytoBead® CeliAK contains a section of 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 classical 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.

**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



### Example of a sample:

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

### CytoBead® CeliAK

Tissue Pattern	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® NEO systems

<sup>1</sup>Husby S et al.: European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Coeliac Disease. J Pediatr Gastroenterol Nutr. 2020, 70(1):141-156.

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

<sup>3</sup>Grossmann K et al.: Simultaneous detection of celiac disease-specific IgA antibodies and total IgA. Auto Immun Highlights. 2016, 7(1): 2.

## Automated



## Celiac disease - available assays

### akiron® NEO/AKLIDES® - Automated IFA Assays

[for akiron® NEO and AKLIDES® systems only]

	AKLIDES® EmA	AKLIDES® CytoBead® CeliAK
REF	4131 / 4132	4271
Deamidated gliadin		+
Tissue transglutaminase	+	+
IgA deficiency		+

### DotDiver2.0 - Automated Dot Assays

[for DotDiver2.0 system only]

	DotDiver CeliAK IgA	DotDiver CeliAK IgG
REF	5014	5015
Deamidated gliadin	+	+
Tissue transglutaminase	+	+
IgA deficiency	+	

## Manual

### Manual LINE Assays

	CeliAK IgA LINE	CeliAK IgG LINE
REF	4208	4202
Deamidated gliadin	+	+
Tissue transglutaminase	+	+
IgA deficiency	+	

### Manual IFA Assays

	EmA IFA	CytoBead® CeliAK
REF	86048 / 86096	8064
Deamidated gliadin		+
Tissue transglutaminase	+	+
IgA deficiency		+

## Contact

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### ELISA Assays

	REF	Deamidated gliadin	Tissue transglutaminase
GliaDea IgA	3710	+	
GliaDea IgG	3810	+	
Anti-hu-TransG	4033		+
Anti-hu tTG IgG	4044		+