

Celiac Disease

Tools to Aid in the Accurate Diagnosis of
Celiac Disease



**Inova
Diagnostics**

A Werfen Company

Celiac Disease

Experts in autoimmunity

Inova Diagnostics provides a comprehensive menu of products to aid in the diagnosis of celiac disease and to differentiate between different gastrointestinal manifestations.

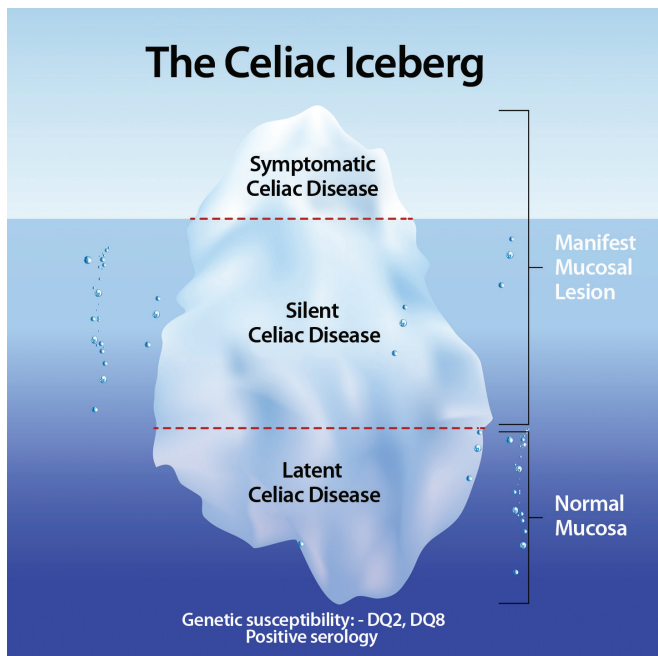
QUANTA Flash[®] is our brand of specially designed chemiluminescent reagents for use on the BIO-FLASH[®] fully automated random access analyzer. QUANTA Flash[®] reagents offer a broader analytical measurement range, higher sensitivity and precise quantitation, giving clinicians added clarity in the diagnosis of celiac disease (CD).⁷ The **QUANTA Lite**[®] ELISA tests are high quality reagents which are compatible with a variety of automation solutions offered through Inova Diagnostics. The **NOVA Lite**[®] IFA slide kits have been recognized for quality and consistency when it comes to immunofluorescent assays (IFA). The new addition of 2D barcoding and automated digital archiving systems increases efficiency and allows for positive patient identification.

As a global leader in autoimmunity testing, Inova Diagnostics offers a variety of unique assays to increase accuracy and confidence in the diagnosis of gastrointestinal illnesses including celiac disease. Innovation has been the driving force behind the development of novel assays to aid in the diagnosis of celiac disease such as deamidated gliadin peptide (DGP), and anti F-Actin.⁸

Sensitivity and specificity of routine celiac tests		
	Sensitivity n=46 [†]	Specificity n=48
QUANTA Lite [®] tTG IgA	97.8%	96.6%
QUANTA Lite [®] DGP IgG	83.3%*	98.9%
QUANTA Lite [®] DGP IgA	86.9%	79.8%
NOVA Lite [®] EMA	95.6%	100.0%

* Both IgA deficient samples were DGP IgG positive
Adapted from Volta et al. J Clin Gastro 2010

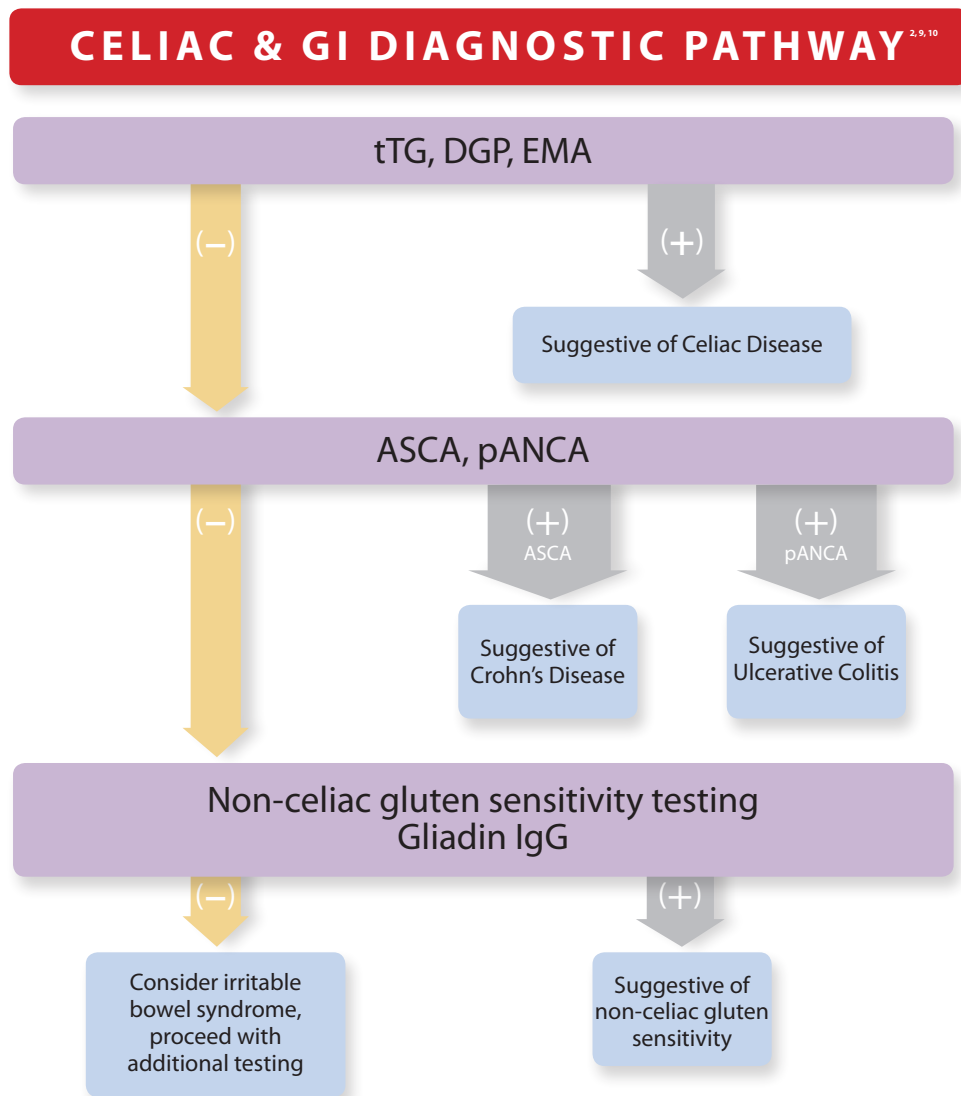
[†] Excluding 2 IgA deficient samples



The worldwide prevalence of celiac disease is estimated to be between 0.6-1.0%; Europe has the highest prevalence at 2.4% in some countries.² However, in Asian countries with an increased "western diet" including wheat based products, the global incidence has been steadily increasing.

Gastrointestinal Disease

The cause of chronic lower gastrointestinal upset can come from a number of sources, often making diagnosis difficult. The QUANTA Lite and NOVA Lite (in the case of ANCA) tests below provide reliable results to help clinicians assess the root cause.



Abbreviations

ANCA	Anti-neutrophil cytoplasmic antibodies
ASCA	Anti-Saccharomyces cerevisiae antibody
DGP	Anti-deamidated gliadin peptide
EMA	Anti-endomysial antibody
tTG	Anti-tissue transglutaminase antibody



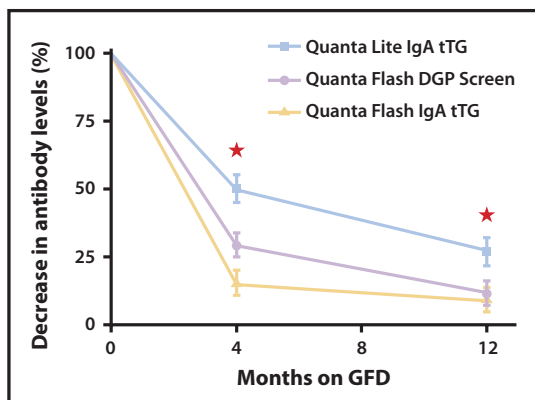
Testing strategies provided for informational purposes only. Testing and diagnosis should be determined by a licensed clinician.

Important celiac tests you should know about

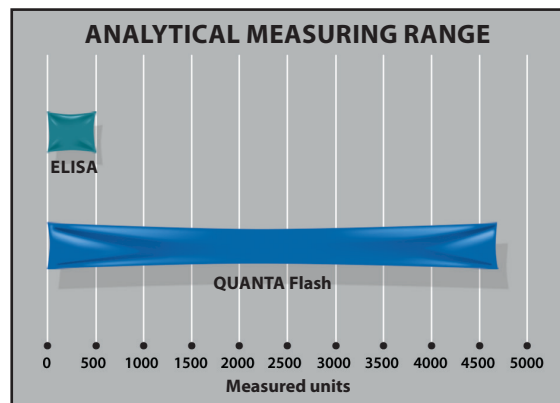
Get clear answers to solve your most difficult cases

QUANTA Flash celiac disease tests

The **QUANTA Flash tTG and DGP** assays are fully automated micro particle chemiluminescent immunoassays for the semi-quantitative detection of antibodies in human serum. **The advantage of the chemiluminescent technology is the broad analytical measuring range and high resolution or better discrimination than traditional methods.** The QUANTA Flash assays may also be useful for monitoring diet compliance showing a significant and rapid decline in antibody levels over traditional ELISA assays when a patient removes gluten from their diet.⁵



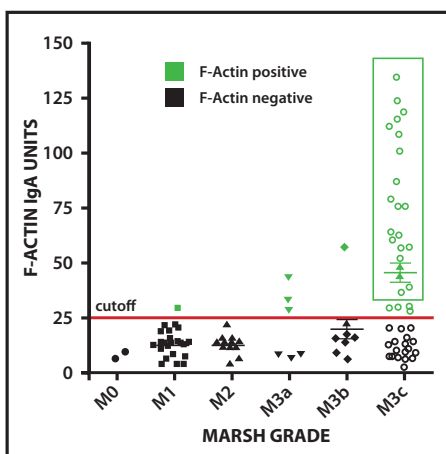
Data adapted from Aita et al.



Chemiluminescence immunoassay (CIA) technology can significantly increase the analytical measuring range

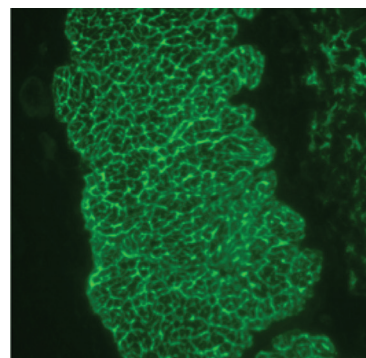
QUANTA Lite F-Actin

The **QUANTA Lite F-Actin Test** has been shown to detect F-Actin IgA antibodies in a high percentage of CD patients with significant intestinal villous atrophy.⁶ In patients with severe intestinal damage, 59.4% were positive for F-Actin IgA, with 89.2% of positive patients being Marsh levels 3a,b,c. **Measurement of F-actin IgA antibodies may aid in the serological assessment of patients with celiac disease in the absence of an intestinal biopsy.**



NOVA Lite Monkey Esophagus

The **NOVA Lite** products are well known for their high quality and consistency when it comes to IFA testing. The NOVA Lite slides can be processed on the automated solutions offered through Inova Diagnostics. **Barcoded slides in conjunction with QUANTA Link® deliver positive patient identification eliminating transcription related errors.**



NOVA Lite endomysial positive result (Primate Distal Esophagus)



Barcoded slides

Celiac Disease

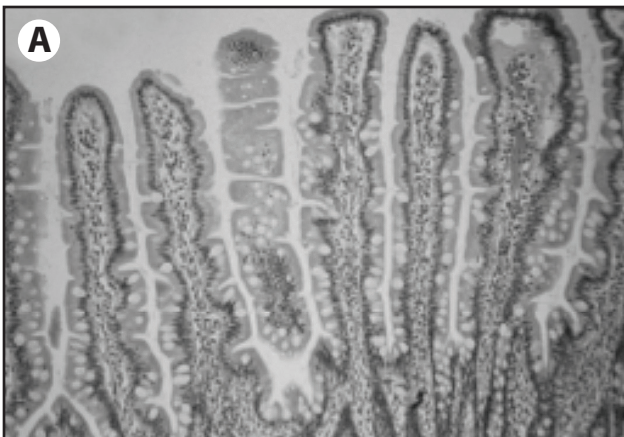
Serology assays can help guide accurate diagnosis

Celiac disease is an immune-mediated enteropathy precipitated by exposure to gluten-containing grains, resulting in inflammation to the small intestine.¹ The inflammation leads to damage and atrophy of the intestinal villi which are responsible for nutrient absorption. Some of the classic gastrointestinal clinical symptoms of celiac disease may include abdominal cramping and distention, chronic diarrhea or constipation, and steatorrhea with malabsorption. Celiac disease is also associated with a variety of non-gastrointestinal clinical manifestations including arthritis, iron deficiency, metabolic bone disease and neuropsychiatric symptoms. Symptoms for celiac disease are often nonspecific and can make the diagnosis challenging. The ratio of symptomatic to asymptomatic celiac disease is estimated to be 1:7.

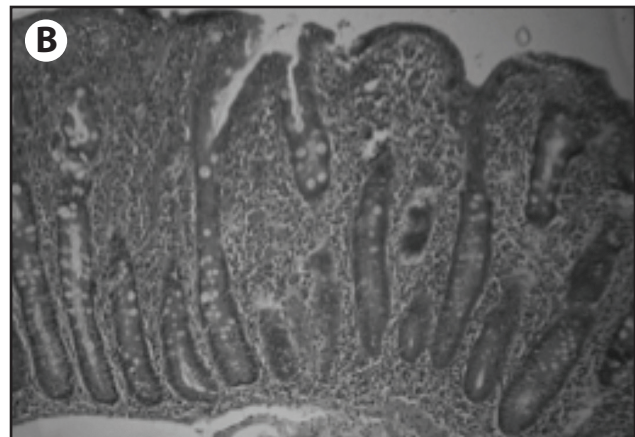
Recent advances in serology testing have resulted in improved patient management for the diagnosis and treatment of celiac disease. However, the average length of time for a symptomatic person to be accurately diagnosed is approximately four years.² Delays in diagnosis dramatically increase the risk of other co-morbidities such as other autoimmune disorders, neurological disorders, osteoporosis and even cancer.³ Once an accurate diagnosis is made, the treatment for celiac disease is an adherence to a lifelong elimination of gluten from the diet. After initiation of a gluten free diet (GFD) improvements begin within weeks and the small intestine will completely heal in 6-18 months.⁴

The current gold standard for the diagnosis of celiac disease remains to be biopsy for the assessment of villous atrophy based on the Marsh-Oberhuber classification system. However, laboratory tests are key tools to aid in the accurate and timely diagnosis of celiac disease helping to identify when biopsy is needed. In the case of pediatric patients, or others at risk of complications from endoscopy, recent guidelines state that in a subgroup of children with high serum tTG values (>10 times the upper limit of normal) and confirmation by a secondary test (endomysial (EMA) or HLA genetic testing), celiac disease diagnosis could be established without histological evaluation.⁷

In cases where a clinical diagnosis is ambiguous, serological markers play a key roll in determining if performing a gluten challenge is appropriate. Serological markers can detect changes in autoantibody levels in as little as 4 weeks from initiation of a gluten challenge. Autoantibody levels may continue to increase in reaction to the introduction of gluten for 2-3 months after return to a gluten free diet.¹⁰



A. Normal intestinal villi create 200 sq meters of absorption area



B. Total villous atrophy decreases absorption area to about 2 meters

Celiac Disease Tests

Product ordering information

Method	Name	Package	Part#
ELISA	QUANTA Lite h-tTG IgA (Native human red blood cell)	1 x 96 wells	708760
	QUANTA Lite h-tTG IgG (Native human red blood cell)	1 x 96 wells	708755
	QUANTA Lite R h-tTG IgA (Recombinant)	1 x 96 wells	704605
	QUANTA Lite R h-tTG IgG (Recombinant)	1 x 96 wells	704610
	QUANTA Lite Gliadin IgA II (DGP)	1 x 96 wells	704525
	QUANTA Lite Gliadin IgG II (DGP)	1 x 96 wells	704520
	QUANTA Lite Celiac DGP Screen	1 x 96 wells	704545
	QUANTA Lite h-tTG Screen	1 x 96 wells	704570
	QUANTA Lite h-tTG/DGP Screen	1 x 96 wells	704575
	QUANTA Lite F-Actin IgA	1 x 96 wells	704500
IFA	NOVA Lite Monkey Espohagus (IgG and IgA conjugates)	10 x 25 wells 25 x 10 wells	704145 704150
	NOVA Lite Monkey Espohagus (IgA conjugate only)	25 x 10 wells	704155
	Chemiluminescence	QUANTA Flash h-tTG IgA	50 Test Cartridge 100 Test Cartridge
	QUANTA Flash h-tTG IgG	50 Test Cartridge	701108
	QUANTA Flash DGP IgA	50 Test Cartridge	701168
	QUANTA Flash DGP IgG	50 Test Cartridge	701173
	QUANTA Flash DGP Screen	50 Test Cartridge	701113

For more information contact your Inova representative, call customer service at +1-858-586-9900, or visit our website at www.inovadx.com

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