

# EFFECTIVE JANUARY 3, 2018 NEW CELIAC DISEASE TESTING

Effective January 3, 2018, Wisconsin Diagnostic Laboratories (WDL) will be performing celiac disease serology using an in-house assay on the BioPlex 2200 (Bio-Rad) multiplex platform. Testing will be performed Monday through Friday, 3rd shift. Please see the American College of Gastroenterology (ACG) recommended algorithm and clinical performance of each serologic marker attached.

Panel/Individual Test Name	Mnemonic	Components	СРТ	Test Code
Celiac antibody panel*	CELIAC AB PN	tTG IgA, DGP IgA tTG IgG, DGP IgG	83516x4	1003606
Tissue Transglutaminase, IgA*	TRANSGLU A	tTG lgA	83516	3520665
Tissue Transglutaminase, IgG	TRANSGLU G	tTG lgG	83516	3520666
Deamidated Gliadin, IgA*	DEAMGLIAD A	DGP IgA	83516	3520656
Deamidated Gliadin, IgG	DEAMGLIAD G	DGP IgG	83516	3520659

<sup>\*</sup> Tests including an IgA marker also contain an internal control for total IgA to identify patients with low IgA or selective IgA deficiency (IgA < 7 mg/dL), removing the need to order a quantitative total IgA test. Only IgG serotypes will be reported for samples with IgA < 7 mg/dL.</p>

#### **Clinical implications:**

- Numeric results between current and new assays cannot be used interchangeably.
- Cut-off for the new assay is 15 U/mL for all serologic markers.
- Clinical performance between current and new assays is comparable, with the following sensitivities and specificities.

	<u>Current</u> - Inova Diagnostics		<u>New</u> - BioPlex 2200	
Marker	Sensitivity	Specificity	Sensitivity	Specificity
tTG lgA	97%	98%	100%	100%
DGP IgA	77%	79%	98%	99%
tTG lgG	34%	57%	100%	100%
DGP IgG	75%	75%	99%	99%

# The following panels will be inactivated:

Panel Name	Mnemonic	Components	
Gluten Sensitivity Evaluation	Gluten EV	tTG IgA, DGP IgA_tTG IgG, DGP IgG, total IgA, EMA IgA	
Gliadin Antibodies, IgA and IgG	GLIAD AB	DGP IgA, DGP IgG	

**NOTE:** EMA Endomysial Antibody, IgA (ENDO IGA) will continue to be available as a stand-alone test.

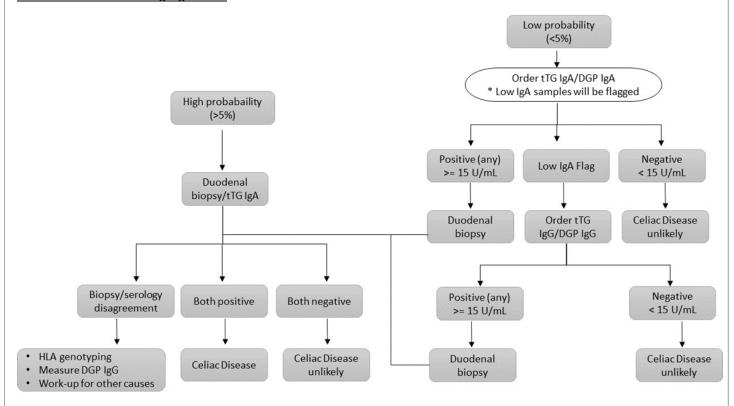
#### For questions and additional information, please contact:

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## ACG recommended testing algorithm1:



## Clinical performance of each serological marker<sup>2</sup>:

Serologic Tests	Sensitivity	Specificity
tTG IgA	98%	98%
EMA	95%	99%
DGP IgA	88%	95%
tTG IgG	70%	95%
DGP IgG	80%	98%

NOTE: tTG IgA and EMA have comparable sensitivity and specificity.

## **References:**

- 1. Rubio-Tapia A, Hill ID, Kelly CP, Calderwood AH, Murray JA. Diagnosis and Management of Celiac Disease. Am J Gastroentrol 2013; 108:656-676.
- 2. Leffler DA, Schuppan D. Update on Serologic Testing in Celiac Disease. Am J Gastroenterol. 2010; 105: 2520-2524.