Introduction of Celiac Disease Panel at UVMMC

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On July 26, 2017, the Immunology Laboratory will offer a Celiac Disease Screening Panel for the initial evaluation of patients exhibiting symptoms of celiac disease. The panel consists of a total serum IgA and an anti-TTG IgA and will include a brief interpretive comment. These changes are the culmination of a quality improvement study performed in our laboratory and reflect best practice and published guidelines for testing.[1] As a consequence both celiac disease cascades from Mayo Medical Laboratories will no longer be orderable in PRISM. Both the Celiac Disease Serology Cascade and the Celiac Disease Comprehensive Cascade may be ordered as a miscellaneous test from Mayo Medical Laboratories with Pathology review and approval...

Celiac Disease (CD) is a systemic immune-mediated disorder triggered by dietary gluten in genetically susceptible persons, affecting approximately 1% of the general population. CD is characterized by a specific serum autoantibody response and variable damage to the small-intestinal mucosa. Diagnosis of this disease can be elusive since patients can exhibit a broad range of clinical presentations.

Evaluation of patients for gluten-related disorders is a common presentation at primary care clinics. Greater numbers of patients are presenting to providers than in the past with questions and concerns about gluten sensitivity. The clinical presentation of patients with gluten-related disorders is variable and non-specific, with considerable overlap between entities. For this reason, laboratory testing is a critical component of the evaluation. Intestinal biopsy is the gold standard for diagnosis of celiac disease in the United States; however, laboratory testing is widely used as first line assessment for patients, and to select subsets of patients for referral to endoscopy.

Numerous serologic tests are commercially available. The most common tests include anti-endomysial antibodies (EMA), anti-transglutaminase antibodies (TTG), anti-deamidated gliadin peptide antibodies (DGP), and total serum IgA. Both IgA and IgG based methods are available. IgA-based methods in general provide highly sensitive detection for celiac disease, although the sensitivity and specificity of individual tests varies by method and among assays and may not be standardized between different labs. The positive predictive value of serologic methods is affected by the low prevalence of celiac disease in the general population. Genetic testing is available and includes HLA-DQ2/DQ8 typing methods such as polymerase chain reaction and sequencing.

Expert consensus guidelines for diagnosis of celiac disease have been published worldwide; however, few are evidence-based. The American College of Gastroenterology (ACG) published evidence-based consensus guidelines [1] in 2013 which state that the single best test for detection of celiac disease is the IgA anti-TTG in adults. Adding a total serum IgA test is recommended for patients in whom there is a possibility of IgA deficiency. IgG based testing may be used in special circumstances, and genetic testing should not be routinely used in the initial diagnosis of celiac disease.

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Importantly, all testing should occur when the patient is eating a gluten containing diet, and intestinal biopsy should be pursued even if serology is negative and clinical suspicion for disease remains high.

REFERENCES:

1. Rubio-Tapia A, Hill ID, Kelly CP, Calderwood AH, Murray JA. (2013). ACG Clinical Guidelines: Diagnosis and Management of Celiac Disease. Am J Gastroenterol; 108:656-676.

SPECIMEN INFORMATION

Celiac Disease Panel	
Test Code	CDP
Test Note	Testing includes Tissue Transglutaminase Antibody IgA, Serum IgA and an interpretation.
Sample Requirements	Collect 4 mL SST and submit 1.0 mL serum refrigerated, minimum volume is 0.6 mL. Serum is stable at 2-8 degrees C for up to 7 days, for longer storage freeze at minus 20 degrees C.
Interpretation	If TTAB positive (>10.0): "Celiac disease possible. Consider referral to gastroenterology specialist for consideration for biopsy." If IgA is age-specific normal and TTAB is equivocal (4.0-10.0): "Equivocal serology, celiac disease cannot be excluded. Referral to gastroenterology specialist recommended for additional evaluation." If IgA is age specific normal and TTAB is negative (<4.0): "Negative Serology. Celiac disease unlikely. Approximately 10% of patient with celiac disease are sero-negative. Patients who are already adhering to a gluten-free diet may be sero-negative. If celiac disease is highly clinically suspected, referral to gastroenterology for additional evaluation is recommended." If IgA is >7 mg/dl, but lower than age-specific normal and TTAB is negative or equivocal (<10.1): "Low total serum IgA; Recommend referral to gastroenterology specialist for additional evaluation." If IgA is below detection (<7 mg/dl) and TTAB is negative or equivocal (<10.1): "Total serum IgA deficiency; Recommend referral to gastroenterology specialist for additional evaluation." If TTAB negative or equivocal (<10.1) and age <1: "Celiac disease interpretation in children less than one year of age is difficult. Recommend referral to gastroenterology specialist for additional evaluation if clinically indicated."

FOR MORE INFORMATION

Contact Laboratory Customer Service or email the Lab Ambassadors for clinical questions.

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WEBSITE

UVMLabs.TestCatalog.org/

SPECIMEN INFORMATION CONTINUED

Tissue Transglutaminase Antibody IgA	
Test Code	TTAB
CPT	83516
Division:	Immunology
Method	Inova Quanta Lite R h-tTG IgA ELISA
Instrumentation	Dynex DSX
Test Schedule / Analytical Time / Test Priority	Monday, Wednesday Friday / Same day / Not available STAT
Reference Range	<4.0 U/mL

IgA					
Test Code	IGA				
CPT	82784				
Division:	Chemistry-2				
Method	Rate Nephelometry				
Instrumentation	Beckman Immage 800				
Test Schedule / Analytical Time / Test Priority	Monday – Friday, run starts at 10 am / Same day /Not available STAT				
Reference Range	**Age**	**Sex**	**Low**	**High**	**Units**
	0-29 days	All	1.4	3.6	mg/dL
	1 month	All	1.3	52	mg/dL
	2 months	All	2.8	47	mg/dL
	3 months	All	4.6	46	mg/dL
	4 months	All	4.4	72	mg/dL
	5 months	All	8	83	mg/dL
	6 months	All	8	67	mg/dL
	7-9 months	All	11	89	mg/dL
	10-11 months	All	16	83	mg/dL
	1 year	All	14	105	mg/dL
	2 years	All	14	122	mg/dL
	3 years	All	22	157	mg/dL
	4-5 years	All	25	153	mg/dL
	6-8 years	All	33	200	mg/dL
	9-17 years	All	45	237	mg/dL
	>18 Years	All	82	453	mg/dL