Endomysial Antibody NOT Recommended

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While a number of tests are available to aid in the diagnosis of celiac disease (CD), it is often difficult to know when these tests are appropriate and if they add additional information concerning the patient's disease state or would change treatment or disease management.

A review of current published literature suggests that IgA anti-endomysial antibody testing (EMA), an immunofluorescent assay, has limited clinical utility. Although EMA has a specificity and sensitivity of >95%, it has been suggested that EMA is less sensitive, especially among celiac children under two years of age, as well as in the elderly population. In addition, it has been reported that false negative EMA results may be associated with milder small-bowel mucosal lesions. Despite the high accuracy of EMA, it has the distinct disadvantages compared to other serologic tests in that it is expensive, subjective, and labor-intensive, requiring experienced personnel to perform. The technical disadvantages of the EMA resulting in significant inter-observer and inter-site variability have led to the EMA being largely replaced by newer enzyme-linked immunosorbent assays (ELISA), such as the anti-tissue transglutaminase (tTG) and/or anti-deamidated gliadin peptide (DGP). (3)

In 1997, research studies identified the ubiquitous enzyme tTG as the auto antigen, which reacts with EMA, leading to the development of ELISAs that detect antibodies against tTG. tTG assays demonstrated high sensitivity (>95%) and high specificity (>95%) with lower cost and greater reproducibility, due to the advent of automation, than immunofluorescent assays and for these reasons, has become the most common and preferred screening test for celiac disease diagnosis and monitoring.(3)

To confirm these findings our Immunology Laboratory at UVM Medical Center examined the results of patients for whom both IgA anti-tissue transglutaminase (IgA tTG) (SQ Test Code: TTAB) testing and IgA anti-endomysial antibody (SQ Test Code: END) testing were performed.

From January 1, 2015 to June 30, 2016, 369 TTAB and END were both performed on a total of 337 patients. Of these 337 patients, 330 were negative for both TTAB and END, 4 were positive for both TTAB and END, 3 were positive for TTAB and not END, and 0 were negative for TTAB and positive for END as illustrated in the table below.

	IgA Anti-Tissue Transglutaminase Antibody		
Anti-Endomysial Antibody		**NEG**	**POS**
	NEG	330	3
	POS	0	4

Reviewed by Clayton Wilburn, MD Director of Clinical Chemistry

December 7, 2018

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These results clearly indicate that there is little added value of the EMA test in addition to, or as a substitution for IgA tTG testing. Further, since the EMA is considered unreliable in monitoring response to treatment (1), there may be little indication for repeat testing in this scenario.

With the above data confirming published studies that EMA testing has little diagnostic value and with the consideration that EMA testing is not included in the algorithm for celiac disease (CD) suggested by the American College of Gastroenterology (ACG) (2), **EMA testing will no longer be orderable as a stand-alone test beginning 10/10/2016.** It will still be available, as a reflex test only, as part of the Celiac Disease Comprehensive Cascade (Test Code: CDCC) and the Celiac Disease Serology Cascade (Test Code: CDSC) sent to Mayo Medical Labs (MML). However, it is reflexed only when the IgA tTG is weak positive. NOTE: Please refer to the UVMMC Laboratory Services Directory for specific test information including sample requirements, cascade test components, and criteria for cascade reflex testing (http://uvmlabs.testcatalog.org/). In keeping with the algorithm used by MML, all weak positive TTAB will include a comment that suggests follow-up testing for anti-endomysial antibodies and/or anti-deamidated giadin peptide antibodies if clinically indicated. A serum sample will be available for at least seven days for add-on testing if needed. From September 1, 2015 to August 31, 2016, we reported 39 weak positive TTAB results out of 2,337 total TTABs ordered which is a weak positive rate of only 1.7%.

Test Name	Primary Code	SQ Code	PRISM Code
Gliadin Antibody Panel	DGP	DGP	LAB821
Tissue Transglutaminase AB IgA	TTAB	TTAB	LAB723

REFERENCES

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2. Rubio-Tapia A, Hill ID, Kelly CP, Calderwood AH, Murray JA, American College of Gastroenterology. ACG clinical guidelines: diagnosis and management of Celiac disease. *Am J Gastroenterol.* 2013; 108:656-676.
3. Kaswala, DH, Veeraraghavan, G, Kelly, CP, Leffler, DA. Celiac Disease: Diagnostic Standards and Dilemmas. *Diseases*. 2015; 3: 86-101.

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December 7, 2018