

NEW TEST ANNOUNCEMENT

MML JACKSONVILLE

NOTIFICATION DATE: November 13, 2012 **EFFECTIVE DATE:** December 11, 2012

TISSUE TRANSGLUTAMINASE (TTG) ANTIBODIES, IGA AND IGG PROFILE, SERUM #800356

USEFUL FOR:

- Evaluating patients suspected of having celiac disease; including patients with compatible clinical symptoms, patients with atypical symptoms, and individuals at increased risk (family history, previous diagnosis with associated disease, positivity for HLA DQ2 and/or DQ8).
- Monitoring adherence to gluten-free diet in patients with dermatitis herpetiformis and celiac disease.

Profile Information:

| Test ID | Reporting Name | Available Separately | Always Performed |
|---------|------------------------------------|----------------------|------------------|
| 800354 | Tissue Transglutaminase Ab, IgA, S | Yes | Yes |
| 800355 | Tissue Transglutaminase Ab, IgG, S | Yes | Yes |

METHODOLOGY: Enzyme-Linked Immunosorbent Assay (ELISA)

REFERENCE VALUES:

tTG Antibody, IgA <4.0 U/mL (negative) 4.0-10.0 U/mL (weak positive) >10.0 U/mL (positive)

tTG Antibody, IgG <6.0 U/mL (negative) 6.0-9.0 U/mL (weak positive) >9.0 U/mL (positive)

SPECIMEN REQUIREMENTS:

Container/Tube: Preferred: Red top

Acceptable: Serum gel tube

Specimen Volume: 0.5 mL of serum

SPECIMEN STABILITY INFORMATION:

| Specimen Type | Temperature | Time |
|------------------|--------------------------|---------|
| Serum | Refrigerated (preferred) | 7 days |
| | Frozen | 14 days |

CAUTIONS:

- This test should not be solely relied upon to establish a diagnosis of celiac disease. It should be used to identify patients who have an increased probability of having celiac disease in whom a small intestinal biopsy is recommended.
- Affected individuals who have been on a gluten-free diet prior to testing may have negative results.
- For individuals who test negative for tissue transglutaminase (tTG) IgA and positive for tTG IgG, IgA deficiency should be considered.
- If serology is negative or there is substantial clinical doubt remaining, then further investigation should be performed with endoscopy and bowel biopsy. This is especially important in patients with frank malabsorptive symptoms since many syndromes can mimic celiac disease. For the patient with frank malabsorptive symptoms, bowel biopsy should be performed regardless of serologic test results.

FEE: Please contact your Regional Manager for your account's fee information.

CPT CODE: 83516 X 2

DAY(S) SET UP: Monday through Saturday **ANALYTIC TIME:** 1 day

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or Greg Renkly, MML Laboratory Technologist Resource Coordinator Telephone: 800-533-1710