NEW TEST

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Celiac Disease Reflexive Cascade, Serum

3016817, CELIACRFLX

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube (SST).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP standard transport tube. (Min: 1.5 mL)
Transport Temperature:	Refrigerated
Unacceptable Conditions:	Contaminated, grossly hemolyzed, grossly icteric, or grossly lipemic.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 1 week; Frozen: 15 days
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)
Performed:	Sun-Sat
Reported:	2-6 days
Note:	The most sensitive and specific serologic test for celiac disease diagnosis is tissue transglutaminase (tTG) IgA isotype in individuals who produce sufficient total IgA. For individuals who are IgA deficient, testing for tTG and deamidated gliadin (DGP), IgG antibodies is recommended. The Celiac Disease Reflexive Cascade begins with the assessment of Immunoglobulin A (IgA) levels using internal control beads. The assay does not measure the actual IgA concentration but flags in the event of low or deficient IgA detected in the sample. In the presence of a low or deficient IgA flag, tTG IgG and DGP IgG antibody testing will be added. No flag indicates IgA competent state and tTG IgA results will be evaluated as an initial screening. If tTG IgA antibody result is negative, then no further testing will be performed. If tTG IgA antibody is weak or moderate positive with results greater than 5 FLU but less than 10 FLU, additional testing for endomysial (EMA) IgA and deamidated gliadin Peptide (DGP) Antibody, IgA antibodies will

	be added and reported. If tTG IgA antibody is positive with results greater than 10 FLU, then no further testing will be performed. If both tTG IgA (<1.02 FLU) and DGP IgA (<0.72 FLU) results are below the limit of detection, then tTG IgG and deamidated gliadin IgG antibody testing will be added even in the absence of IgA control flag due to a suspected low IgA state in the patient. While ordering for celiac disease diagnosis, all serology tests should be performed while the patient is on a gluten-containing diet. Upon initiation of gluten-free diet, antibody titers decline in the treatment responsive patients and the timeframe to normalize varies by case. If serology is negative and suspicion for celiac disease is strong, intestinal biopsy may still be warranted for establishing diagnosis. Dermatitis herpetiformis may exhibit uneven antibody patterns than in celiac disease. Preferred test for initial diagnosis is serum Immunobullous Disease Antibody Panel (ARUP test code 3001409) and should be used in conjunction with this celiac disease reflexive cascade (ARUP test code 3016817)
CPT Codes:	86364; if reflexed additional CPT codes may apply: 86364, 86231; 86258 x2
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Presence of the tissue transglutaminase (tTG) IgA antibody is associated with gluten-sensitive enteropathies such as celiac disease and dermatitis herpetiformis. Individuals with positive results should be confirmed with small intestinal biopsy to establish celiac disease diagnosis. tTG IgA antibody concentrations greater than 50 FLU exhibits higher correlation with results of duodenal biopsies consistent with celiac disease. For antibody concentrations greater than or equal to 5 FLU but less than 10 FLU, additional testing for endomysial (EMA) IgA concentrations may improve the positive predictive value for disease. A decrease in tTG IgA antibody concentration after initiation of a gluten-free diet may indicate a response to therapy.

Reference Interval:

Test Number	Components	Reference Interval
	Tissue Transglutaminase (tTG) Ab, IgA	0.00 - 4.99 FLU

HOTLINE NOTE: Refer to the Hotline Test Mix for interface build information.