TEST CHANGE

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: 30 days
Methodology:	Semi-Quantitative Particle-Based Multianalyte Technology (PMAT)
Performed:	Sun-Sat
Reported:	2-6 days
Note:	In individuals who produce sufficient IgA, the most sensitive and specific serologic test for celiac disease (CD) diagnosis is tissue transglutaminase (tTG) IgA. In individuals who are IgA deficient, tTG IgG and deamidated gliadin peptide (DGP) IgG antibody testing is recommended. This reflexive panel test begins by assessing the presence of immunoglobulin A (IgA) using internal control beads. This assay does not measure IgA but flags samples when ~~low or~~ deficient for IgA ~~is detected~~. In the presence of ~~low or~~ deficient IgA (flags), tTG IgG and DGP IgG antibody testing will be added. In samples with sufficient IgA (no flag), tTG IgA concentrations will be measured as an initial screen. If tTG IgA results are not elevated (>1.02-4.99 FLU),~~negative,~~ then no further testing will be performed. If tTG IgA results are a weak or moderate positive (~~greater than~~ 5-~~FLU but less than~~ 10 FLU), additional testing for endomysial antibody (EMA) IgA and deamidated gliadin peptide (DGP) antibody IgA will be added and reported. If tTG IgA results are a strong positive (>~~(greater than~~ 10 FLU), then no further testing

	will be performed. If both tTG IgA and DGP IgA are below the limit of detection (tTG less than 1.02 FLU and DGP less than 0.72 FLU), then serum total IgA will be measured quantitatively. If the measured IgA concentration is below the lower limit of the age group reference interval, then tTG IgG and DGP IgG antibody testing will be added and reported. ~~, even in the absence of an IgA control flag, due to a suspected low-IgA state in the patient.~~ Refer to the Additional Technical Information document for more details. All serologic tests used to diagnose CD should be performed while the patient is on a gluten-containing diet. Upon initiation of a gluten-free diet, antibody titers decline in treatment-responsive patients and the time frame to normalize titers varies by case. Close clinical correlation with continued testing may be indicated in patients who have a family history or increased risk for CD. If serology is negative and suspicion for CD remains strong, intestinal biopsy may still be warranted to establish a diagnosis. In patients with dermatitis herpetiformis (DH), uneven antibody patterns are possible. Concurrent immunobullous disease panel testing and CD reflexive panel testing are recommended to assess for DH.
CPT Codes:	86364; if reflexed, add ~~additional CPT codes may apply:~~ 86364~~,~~; 86231; 86258 x2; 82784
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: There is a reflexive pattern change associated with this test. One or more orderable or component has been added or removed to the reflexive pattern. Refer to the Hotline Test Mix for interface build information.