Overview

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 disorder, positivity for HLA DQ2 and/or DQ8)

Screening test for dermatitis herpetiformis, in conjunction with endomysial antibody test

Monitoring adherence to gluten-free diet in patients with dermatitis herpetiformis and celiac disease

Testing Algorithm

The following algorithms are available in Special Instructions:

-Celiac Disease Comprehensive Cascade

-Celiac Disease Diagnostic Testing Algorithm

-Celiac Disease Gluten-Free Cascade

-Celiac Disease Routine Treatment Monitoring Algorithm

-Celiac Disease Serology Cascade

Special Instructions

- Celiac Disease Diagnostic Testing Algorithm
- Celiac Disease Comprehensive Cascade
- Celiac Disease Gluten-Free Cascade
- Celiac Disease Routine Treatment Monitoring Algorithm
- Celiac Disease Serology Cascade

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

Cascade testing is recommended for celiac disease. Cascade testing ensures that testing proceeds in an algorithmic fashion. The following cascades are available; select the appropriate one for your specific patient situation.

-CDCOM / Celiac Disease Comprehensive Cascade: complete testing including HLA DQ

-CDSP / Celiac Disease Serology Cascade: complete testing excluding HLA DQ

-CDGF / Celiac Disease Gluten-Free Cascade: for patients already adhering to a gluten-free diet

To order individual tests, see Celiac Disease Diagnostic Testing Algorithm in Special Instructions.

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-General Request (T239)

-Gastroenterology and Hepatology Client Test Request (T728)

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	21 days	
	Frozen	21 days	

Clinical and Interpretive

Clinical Information

Celiac disease (gluten-sensitive enteropathy, celiac sprue) results from an immune-mediated inflammatory process following ingestion of wheat, rye, or barley proteins that occurs in genetically susceptible individuals. The inflammation in celiac disease occurs primarily in the mucosa of the small intestine, which leads to villous atrophy. Common clinical manifestations related to gastrointestinal inflammation include abdominal pain, malabsorption, diarrhea, and constipation. Clinical symptoms of celiac disease are not restricted to the gastrointestinal tract. Other common manifestations of celiac disease include failure to grow (delayed puberty and short stature), iron deficiency, recurrent fetal loss, osteoporosis, chronic fatigue, recurrent aphthous stomatitis (canker sores), dental enamel hypoplasia, and dermatitis herpetiformis. Patients with celiac disease may also present with neuropsychiatric manifestations including ataxia and peripheral neuropathy, and are at increased risk for development of non-Hodgkin

lymphoma. The disease is also associated with other clinical disorders including thyroiditis, type I diabetes mellitus, Down syndrome, and IgA deficiency.

Celiac disease tends to occur in families; individuals with family members who have celiac disease are at increased risk of developing the disease. Genetic susceptibility is related to specific HLA markers. More than 97% of individuals with celiac disease in the United States have DQ2 and/or DQ8 HLA markers, compared to approximately 40% of the general population.

A definitive diagnosis of celiac disease requires a jejunal biopsy demonstrating villous atrophy. Given the invasive nature and cost of the biopsy, serologic and genetic laboratory tests may be used to identify individuals with a high probability of having celiac disease. Subsequently, those individuals with positive laboratory results should be referred for small intestinal biopsy, thereby decreasing the number of unnecessary invasive procedures (see Celiac Disease Diagnostic Testing Algorithm in Special Instructions). In terms of serology, celiac disease is associated with a variety of autoantibodies, including endomysial, tissue transglutaminase (tTG), and deamidated gliadin antibodies. Although the IgA isotype of these antibodies usually predominates in celiac disease, individuals may also produce IgG isotypes, particularly if the individual is IgA deficient. The most sensitive and specific serologic tests are tTG and deamidated gliadin antibodies.

The treatment for celiac disease is maintenance of a gluten-free diet. In most patients who adhere to this diet, levels of associated autoantibodies decline and villous atrophy improves. This is typically accompanied by an improvement in clinical symptoms.

See Celiac Disease Diagnostic Testing Algorithm in Special Instructions for the recommended approach to a patient suspected of celiac disease.

An algorithm is available for monitoring the patient's response to treatment, see Celiac Disease Routine Treatment Monitoring Algorithm in Special Instructions.

Reference Values

<4.0 U/mL (negative)

4.0-10.0 U/mL (weak positive)

>10.0 U/mL (positive)

Reference values apply to all ages.

Interpretation

The finding of tissue transglutaminase (tTG)-IgA antibodies is specific for celiac disease and possibly for dermatitis herpetiformis. For individuals with moderately to strongly positive results, a diagnosis of celiac disease is likely and the patient should undergo biopsy to confirm the diagnosis.

If patients strictly adhere to a gluten-free diet, the unit value of IgA-anti-tTG should begin to decrease within 6 to 12 months of onset of dietary therapy.

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 and in whom a small intestinal biopsy is recommended.

Affected individuals who have been on a gluten-free diet prior to testing may have a negative result.

For individuals who test negative, IgA deficiency should be considered. If total IgA is normal and tissue transglutaminase (tTG)-IgA is negative, there is a low probability of the patient having celiac disease and a biopsy may not be necessary.

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.

The antibody pattern in dermatitis herpetiformis may be more variable than in celiac disease; therefore, both endomysial and tTG antibody determinations are recommended to maximize the sensitivity of the serologic tests.

Clinical Reference

1. Green PH, Cellier C: Celiac disease. N Engl J Med 2007;357:1731-1743

2. Harrison MS, Wehbi M, Obideen K: Celiac disease: More common than you think. Cleve Clinic J Med 2007;74:209-215

3. Rose C, Dieterich W, Brocker EB, et al: Circulating autoantibodies to tissue transglutaminase differentiate patients with dermatitis herpetiformis from those with linear IgA disease. J Am Acad Dermatol 1999;41:957-961

4. Dale JC, Homburger HA, Masoner DE, Murray JA: Update on celiac disease: New standards and new tests. Mayo Communique 2008;33.6:1-9

Performance

Method Description

Microwells are precoated with recombinant human tissue transglutaminase (tTG) antigen, the antigen has been expressed in Baculovirus cells and the expression construct used a cDNA coding for the long spliced isoform of human tTG.

Calibrators, controls, and diluted patient samples are added to the wells and autoantibodies recognizing the tTG antigen bind during the first incubation. After washing the wells to remove all unbound proteins, purified peroxidase-labeled rabbit antihuman IgA (alpha chain specific) conjugate is added. The conjugate binds to the captured human autoantibody and the excess unbound conjugate is removed by a further wash step.

Bound conjugate is visualized with 3,3'5,5' tetramethylbenzidine substrate, which gives a blue reaction product, the intensity of which is proportional to the concentration of the autoantibody in the sample. Phosphoric acid is added to each well to stop the reaction. This produces a yellow end point color, which is read at 450 nm. Testing is performed on the Agility instrument by Dynex.(Package insert: QUANTA Lite R h-tTG IgA. Inova Diagnostics, Inc. San Diego, CA, 92131. rev. 7, 1/2015.)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

83516

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
TTGA	Tissue Transglutaminase Ab, IgA, S	46128-5

Result ID	Test Result Name	Result LOINC Value
TTGA	Tissue Transglutaminase Ab, IgA, S	46128-5