

Celiac Profile

sample type: **SERUM**

Celiac disease is defined as a genetic, immune mediated enteropathy of the small bowel that results in malabsorption. The disease is characterized by a sensitivity to the proteins found in wheat, and to a lesser extent, barley and rye. It is now considered the most common food intolerance world wide, affecting as many as 1% of the population.

Who Should be Tested for Celiac Disease?

The clinical presentation of celiac disease has many faces and, as a consequence, the disease is often misdiagnosed. In fact, the average time from disease to diagnosis is 11 years. Those afflicted may have classic gastrointestinal (GI) symptoms or may only exhibit extra-intestinal manifestations. Even in the absence of overt GI complaints, avoidance of gluten is imperative owing to the risk of lymphoma and other malignancies associated with celiac disease. Clinicians should therefore consider routine screening for patients with the following clinical indications:

Typical Celiac Indications

Chronic diarrhea
Malabsorption
Abdominal distention
Unexplained weight loss

*Other high risk groups include:
first degree relatives, siblings
and those with Immunoglobulin
A (IgA) deficiency.*

Atypical Celiac Indications

Type 1 diabetes
Anemia
Osteoporosis
Chronic fatigue
Autoimmune disorders
Dermatitis herpetiformis
Behavioral changes
Irritable bowel syndrome
Infertility/Miscarriage
Neurological symptoms

Diagnosing Celiac Disease

Patients with celiac disease are 10-15 times more likely to have IgA deficiency than the general population. Testing for total IgA increases the diagnostic accuracy by ruling out false negative results in those who are IgA deficient.

IgA-tTG (Anti-Tissue Transglutaminase) and IgG-tTG enzymes are highly sensitive markers for identifying celiac disease. When IgA-tTG is positive, testing for IgA-Anti-endomysial Antibodies (IgA-EMA) is routinely performed. This further enhances the accuracy of the profile and helps identify those with silent and latent forms of the disease.

Clinicians also have the option of testing two additional analytes:

- IgA Anti-Gliadin Antibodies (IgA-AGA)
- IgG Anti-Gliadin antibodies (IgG-AGA)

These antibodies can be performed as part of the initial diagnostic evaluation, or on their own to monitor compliance to a gluten free diet or evaluation of systemic symptoms.

Treating Celiac Disease

Treatment requires life-long abstinence from gluten containing foods. With the need for such a restrictive diet, it is important to accurately determine who has the condition. The Celiac Profile from Genova Diagnostics incorporates the most advanced non-invasive markers along with traditional serological tests.

• Analytes:

Total IgA
IgA Anti-Tissue Transglutaminase
IgG Anti-Tissue Transglutaminase
IgA Anti-Endomysial Antibodies
- Optional Add-on Analytes-
IgA Anti-Gliadin Antibodies
IgG Anti-Gliadin Antibodies

• Specimen Requirements:

- 3 ml serum in SST, shipped refrigerated
- Specimen collected Monday to Thursday

• Before Patient Takes this Test:

See instructions inside test kit for details

Celiac Profile



63 Zillicoa Street
Asheville, NC 28801
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Patient: **SAMPLE PATIENT** Order Number:
Age: 17 Completed: July 28, 2006
Sex: F Received: July 19, 2006
MRN: Collected: July 19, 2006

Immunologic Markers

Analyte	Result	Reference Range
Anti-Tissue Transglutaminase IgA	14.12	<=3.99 U/mL
Anti-Tissue Transglutaminase IgG	2.23	<=5.99 U/mL
Total IgA	139.8 Sufficient	62.0-343.0 mg/dL
Anti-Endomysial IgA	Detected	Not Detected

Commentary

Commentary is provided to the practitioner for educational purposes, and should not be interpreted as diagnostic or treatment recommendations. Diagnosis and treatment decisions are the responsibility of the practitioner.

The performance characteristics of all assays have been verified by Genova Diagnostics, Inc. All assays are cleared by the U.S. Food and Drug Administration.

Positive IgA Tissue Transglutaminase (IgA-tTG)

IgA-tTG is a highly sensitive (~98%) marker for the assessment of celiac disease in IgA competent individuals. A positive result strongly suggests the possibility of celiac disease, especially with positive IgA-EMA. Biopsy confirmation and symptom reduction after a gluten free diet will definitively verify the presence of celiac disease.

Negative IgG Tissue Transglutaminase (IgG-tTG)

IgG-tTG is considered the most specific (100%) serological marker in the assessment of celiac disease. Negative IgG-tTG results, coupled with negative IgA-tTG results (in IgA competent individuals) rules out the presence of celiac disease.

IgA sufficient

Total IgA levels within the aged matched reference range suggest adequate production of this immunoglobulin.

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This test reveals important clinical information about:

- Immunoglobulin A (IgA) status - to rule out false negatives in IgA- immunodeficient individuals
- The presence of celiac disease - by utilizing the most accurate and comprehensive non-invasive markers that when combined, identify or rule out with confidence the diagnosis of celiac disease
- Compliance to a gluten free diet - by assessing IgA and IgG Anti-Gliadin levels, clinicians can monitor dietary changes and determine if hidden sources of gluten are still present

For test kits, clinical support, or more information contact:

Client Services
Genova Diagnostics
63 Zillicoa St.
Asheville, NC 28801-1074
800-522-4762 • Fax: 828-252-9303

More detailed publications with references are also available: www.GDX.net