



# CELIAC DISEASE TESTING SERVICES



# CELIAC DISEASE

## LabCorp features a full-service offering to support physicians in the evaluation of patients for celiac disease. LabCorp's leading services include

- Antibody profile testing
- HLA (DQA and DQB) genotyping with relative risk assessment
- Celiac disease pathology (small bowel biopsy)
- Expert consultation
- Extensive network of managed care health plans
- More than 1700 patient service centers nationwide

### Celiac Disease Antibody Testing

Celiac disease antibody tests can be used to screen patients with suspected disease or monitor adherence and response to a gluten-free diet.<sup>5,6</sup> Individuals with active celiac disease will have elevated levels of one or more specific CD antibodies. No single antibody offers 100% sensitivity and specificity, but detection rates can be improved by testing for multiple antibodies.<sup>1,3</sup> IgA class antibodies are commonly used for celiac disease testing; however, IgG antibodies may be used as an alternative for patients who are IgA deficient.<sup>1,3</sup>

Celiac Disease Antibodies	Sensitivity <sup>6,7</sup>	Specificity <sup>6,7</sup>
Tissue transglutaminase (IgA)	87% - 100%	91% - 100%
Deamidated gliadin peptide (DGP) (IgA and IgG)	~ 75%	~ 94%
Endomysial antibodies (EMA) IgA	90% - 100%	98% - 100%

Antibody tests are commonly used in combination<sup>3</sup> and are not indicated for patients on a gluten-free diet.

### Benefits of Celiac Disease Antibody Testing

- Cost effective and noninvasive method to evaluate patients suspected of celiac disease
- Helps identify individuals for whom endoscopic biopsy confirmation would be useful
- A positive antibody result is highly suggestive of celiac disease
- Antibody testing may fail to detect celiac disease due to
  - Gluten-free diet<sup>3</sup>
  - IgA deficiency<sup>3</sup>

Celiac disease (CD) is estimated to affect 1 out of every 100 people, yet fewer than 5% of patients with celiac are diagnosed as having the disease.<sup>1,2</sup> Early diagnosis and lifelong treatment with a gluten-free diet are critical to relieve symptoms and reduce risk of complications such as secondary autoimmune disorders.<sup>3</sup> Identifying those patients who have true celiac gluten sensitivity can be challenging, due to variable, nonspecific symptoms and varying age of onset.<sup>3,4</sup> Antibody testing, HLA genetic testing, and/or a small bowel biopsy can be used to support a diagnosis of celiac disease.<sup>3</sup>

### Celiac Disease Genetic Testing

HLA DQA/DQB genetic testing has emerged as an important tool in evaluating patients for celiac disease. The HLA-DQ2 allele has been found in 90% to 95% of celiac cases, and HLA-DQ8 has been identified in most remaining cases.<sup>1</sup> Thus, a negative HLA-DQA/DQ8 test result essentially excludes celiac disease as a diagnosis.<sup>3,8</sup> Although a positive result is not diagnostic, it is indicative of a higher probability for celiac disease.<sup>3</sup>

### Estimated Celiac Risk from Associated HLA Genotypes<sup>9,10</sup>

HLA DQ2/DQ8 Genotype	Risk
DQ2+DQ8	1:7 (14.3%)
DQ2+DQ2 or DQ2 Homozygous DQB1*02	1:10 (10%)
DQ8+DQ8	1:12 (8.4%)
DQ8+DQB1*02	1:24 (4.2%)
Homozygous DQB1*02	1:26 (3.8%)
DQ2 alone	1:35 (2.9%)
DQ8 alone	1:89 (1.1%)
General population risk (genotype unknown)	1:100 (1%) <sup>1,3</sup>
½ DQ2: DQB1*02	1:210 (0.5%)
½ DQ2: DQA1*05	1:1842 (0.05%)
No HLA-DQA/DQB susceptibility alleles	1:2518 (<0.04%)

NOTE: Actual risk for celiac disease may be greater than shown above when there are symptoms of celiac disease, positive results from celiac antibody tests, positive intestinal biopsy, or if there is a family history of celiac disease.

### Benefits of Celiac Disease Genetic Testing

- Can effectively rule out celiac disease
- Useful when diagnosis of celiac disease is unclear
  - Ambiguous antibody test results<sup>3</sup>
  - Equivocal intestinal biopsy results<sup>3</sup>
  - Discrepancy between antibody and biopsy findings<sup>5</sup>
- Can be performed when patient is on a gluten-free diet
- Can help assess celiac disease risk in first-degree relatives of affected patients<sup>3</sup>
- Only needs to be performed once in a lifetime because a person's genes do not change over time

### Celiac Consultation

LabCorp's celiac expertise extends beyond tests to include consultative services. LabCorp's scientific staff—including Dr Annette Taylor, a geneticist and recognized leader in the celiac field—can provide client consultations and are readily accessible to answer questions on test selection and results.

For more information about our HLA testing or for a celiac genetic consultation, call 800-533-1037.

## Celiac Disease Test Profiles [Components]

	Test No
<b>Celiac Disease Comprehensive Antibody Profile (tTG/DGP/EMA)</b> Tissue transglutaminase IgA & IgG; Deamidated gliadin IgA & IgG (DGP); Endomysial IgA; Total IgA	165126
<b>Celiac Disease Complete Antibody Profile I (tTG/DGP)</b> Tissue transglutaminase IgA & IgG; Deamidated gliadin IgA & IgG (DGP); Total IgA	341142
<b>Celiac Disease Antibody Profile II (tTG/EMA)</b> Tissue transglutaminase, IgA & IgG; Endomysial antibody IgA; Total IgA	165134
<b>Celiac Disease Antibody Profile (tTG/EMA) w/ Reflex</b> Tissue transglutaminase, IgA; Endomysial antibody IgA; Total IgA w/ reflex to Tissue transglutaminase, IgG if Total IgA is decreased.	165142
<b>Celiac Disease Antibody Screen (tTG/DGP) w/ Reflex</b> Tissue transglutaminase IgA; Deamidated gliadin IgA (DGP); Total IgA w/ reflex to Endomysial IgA if Tissue transglutaminase IgA is weak positive	165118
<b>Celiac Disease Pediatric Antibody Cascade (tTG) w/ Reflex</b> Tissue transglutaminase IgA; Total IgA; Tissue transglutaminase IgG. Testing starts with tTG IgA. If tTG IgA is positive, testing stops. If tTG IgA is negative or weakly positive, testing reflexes to total IgA. If total IgA is normal or high, testing stops. If total IgA is low, testing reflexes to tTG IgG.	164700
<b>Gluten Sensitivity Screen (tTG/DGP/AGA/wheat IgE) w/ Reflex</b> IgA and IgG antibodies to deamidated gliadin peptide and tissue transglutaminase (tTG/DGP screen), IgG antibodies to gliadin (AGA), wheat allergen-specific IgE (wheat IgE). Profile starts with tTG/DGP screen test. If positive, testing stops. If negative, testing reflexes to the AGA test. If positive, testing stops. If negative, it reflexes to the wheat IgE test.	164125
<b>Celiac Disease HLA DQ Association (DQA/DQB)</b>	167082
<b>Celiac Disease Pathology (small bowel biopsy)</b> -- Dianon Pathology is LabCorp's specialty testing laboratory for anatomic pathology. <a href="#">Please contact your local account representative for information on establishing services.</a>	

### References

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- Pietzak MM, Schofield TC, McGinnis MF, and Nakamura RM. Stratifying risk for celiac disease in a large at-risk United States population by using HLA alleles. *Clin Gastroenterol Hepatol* 2009; 7: 966-971.



LabCorp clients can choose from multiple antibody profiles including reflex options for IgG antibody tests for cost-effective testing.