

PROMETHEUS® Celiac PLUS

Cat. # 6355

Product Description

PROMETHEUS® Celiac PLUS includes both PROMETHEUS® Celiac Serology and PROMETHEUS® Celiac Genetics.

PROMETHEUS® Celiac Serology is a comprehensive serum antibody profile. By combining important serologic markers for diagnosing celiac disease and utilizing a 5-marker panel including deamidated gliadin peptide antibodies IgA and IgG, this test offers consistent results from a recognized leader in celiac testing.

PROMETHEUS Celiac Genetics analyzes a patient's genetic profile for genes specifically associated with celiac disease. Advanced high-resolution DNA probe analysis of HLA-DQ haplotypes allow for disease risk stratification^a depending upon which HLA genes are detected. Also, testing can predict with a 95% to 100% negative predictive value (NPV) that the patient will not develop celiac disease if HLA-DQ2 and HLA-DQ8 haplotypes are not present.

- An evaluation of antibodies and genetic markers associated with celiac disease to assist physicians with diagnosis and risk assessment.
- PROMETHEUS Celiac PLUS is only offered at Prometheus.
- **Specimen Requirements** - Whole blood, 5.0 mL: EDTA / Lavender Top Tube & Serum, 2.0 mL: SST or Red Top Tube.
- **Shipping and Handling** - Ambient or refrigerated.
- **Storage Conditions/Stability** - 7 days ambient; 14 days refrigerated.
- **Turn Around Time** - 3 business days from date of receipt.
- **Reference Range:**
 - Deamidated gliadin peptide antibody IgG ELISA: < 4.9 EU/ml
 - Deamidated gliadin peptide antibody IgA ELISA: < 6.1 EU/ml
 - Anti-human tTG IgA ELISA: <10.3 U/mL
 - Anti-endomysial IgA IFA: Negative
 - Total serum IgA: < 3 years: 8-220 mg/dL; 3-13 years: 41-395 mg/dL; >13 years: 44-441 mg/dL
 - HLA-DQ2/DQ8: Not Detected (Allele frequency varies by ethnic population)

Facilities Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in several states including New York and California.
- Prometheus is CLIA certified and CAP accredited. All laboratory tests have been validated in accordance with the guidelines established by these and other applicable agencies. Currently, Food and Drug Administration (FDA) approval is not required for Celiac PLUS testing performed by Prometheus.

CPT Codes (as applied by Prometheus)

- **83520(X3)**, ELISA; antibody specific (Deamidated gliadin peptide IgA, Deamidated gliadin peptide IgG, anti-tissue transglutaminase IgA)
- **88347**, Anti-endomysial (EMA) IgA antibody by IFA
- **82784**, Total serum IgA, by nephelometry
- **83891**, Isolation or extraction of highly purified nucleic acid
- **83900(X2)**, Amplification of patient nucleic acid, multiplex, first two nucleic acid sequences for DQA1 & DQB1
- **83896(X72)**, Nucleic acid probes, DQA1 and DQB1
- **83912**, Interpretation and report

Literature References

- Pietzak M, et al, Stratifying Risk for Celiac Disease in a Large At-Risk United States Population by Using HLA Alleles. *Clin Gastroenterol Hepatol*. 2009; 7:966 - 971.
- Green PHR, Jabri B. Coeliac disease. *Lancet*. 2003;362(9381):383-391.
- Fasano A, Berti I, et al, Prevalence of celiac disease in at-risk and not at-risk groups in the United States: a large multicenter study. *Arch Intern Med*. 2003; 163: 286-292.
- Koning F, Schuppan D, Cerf-Bensussan N, Sollid LM, Pathomechanisms in celiac disease. *Best Pract Res Clin Gastroenterol*. 2005; 19: 373-387.
- Mothes, T., Deamidated Gliadin Peptides as Targets for Celiac Disease-Specific Antibodies; *Advances in Clinical Chem*, 2007; Vol. 44, 35-63.

a. Patent pending