

## Test Description

PROMETHEUS<sup>®</sup> Celiac PLUS includes both PROMETHEUS<sup>®</sup> Celiac Serology and PROMETHEUS<sup>®</sup> Celiac Genetics.

PROMETHEUS<sup>®</sup> Celiac Serology is a comprehensive serum antibody profile. By combining the most important serologic markers for diagnosing celiac disease and utilizing a 5-marker panel including deamidated gliadin peptide, EMA-IgA and tTG-IgA, this test offers reliable and consistent results from a recognized leader in celiac testing. Knowledge of serologic markers may help detect celiac disease by providing serologic answers.

PROMETHEUS<sup>®</sup> 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 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** - 2.0 mL serum (SST or Red Top Tube) and 2.0 mL whole blood EDTA / Lavender Top Tube
- **Shipping Requirements**- Ambient or cold pack
- **Storage Stability** - 7 days ambient; 30 days refrigerated
- **Turn Around Time** - 3 business days from date of receipt

## Test Information

Catalog Number	Test Name	Assay	Reference Value	Result Identifier*
6360	Celiac PLUS	Deamidated Gliadin Peptide Antibody, IgG (DGP IgG)	< 20 CU	A00034
		Deamidated Gliadin Peptide Antibody, IgA (DGP IgA)	< 20 CU	A00035
		Anti-Human Tissue Transglutaminase IgA (tTG IgA)	< 20 CU	A00013
		Anti-Endomysial IgA IFA (EMA IgA)	Negative	A00003
		Total Serum IgA by Nephelometry (Total IgA)	<3 years: 8-220 mg/dL; 3-13 years: 41-395 mg/dL; >13 years: 44-441 mg/dL	A00012
		HLA-DQ2 / HLA-DQ8 Genotype	Not Detected (Allele frequency varies by ethnic population)	A00022

\*Result identifier provided for use in HL7 applications.

## Laboratory Description

- Prometheus is located in San Diego, CA. Tax ID# 33-0685754 NPI# 1073642641
- Licensed in several states including New York and California.
- This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. Prometheus Laboratories Inc. is a CAP-accredited CLIA laboratory.

## CPT<sup>®</sup> Codes (as applied by Prometheus)

- 82397 (x3) Chemiluminescent assay; Deamidated Gliadin Peptide Antibody, IgA specific, Deamidated Gliadin Peptide Antibody, IgG specific, Anti Human Tissue Transglutaminase (hu-tTG)
- 88346 (x1) Anti-endomysial (EMA) IgA antibody by IFA
- 82784 (x1) Total serum IgA, by Nephelometry
- 81382 (x2) HLA-DQA1, HLA-DQB1

## 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.

This test may be covered by one or more US pending or issued patents - see prometheuslabs.com for details.

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