

## Test Description

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 genetic markers HLA-DQ2/DQ8 associated with celiac disease to assist physicians with risk assessment
- PROMETHEUS<sup>®</sup> Celiac Genetics risk stratification is only offered at Prometheus
- FDA cleared LABType<sup>®</sup> SSO typing assay used
- **Specimen Requirements** – 5.0 mL whole blood in 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*
6260	Celiac Genetics	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 Codes (as applied by Prometheus)

- **81382(x2)**, HLA-DQA1, HLA-DQB1

## Literature References

- Green PHR, Jabri B. Coeliac disease. *Lancet*. 2003;362(9381):383-391.
- 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.
- 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.

Assays and methods within this test may be covered by one or more US pending patents. For details, please visit [www.prometheuslabs.com](http://www.prometheuslabs.com)