Test Description

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

PROMETHEUS® 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® 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

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

*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)

- 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

- 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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