

For the person in every patient

PROMETHEUS® Celiac Serology Cat. # 1155

Test Description

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 peptides, 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.

- An evaluation of antibodies associated with celiac disease to assist physicians with diagnosis and dietary compliance
- Specimen Requirements 2.0 ml Serum, SST or Red Top Tube
- . Shipping Requirements Ambient or cold pack
- Storage /Stability 7 days ambient, 30 days refrigerated
- Turn Around Time 2-3 business days from date of receipt

Test Information

Catalog Number	Test Name	Assay	Reference Value	Result Identifier
1155	Celiac Serology	Deamidated Gliadin Peptide Antibody, IgG (DGP igG)	<4.9 EU/mL	A00034
		Deamidated Gliadin Peptide Antibody, IgA (DGP IgA)	<6.1 EU/mL	A00035
Anti-Human Tissue Transglutaminase IgA ELISA (TTG Ig Anti-Endomysial IgA IFA (EMA IgA) Total Serum IgA by Nephelometry (Total IgA)		Anti-Human Tissue Transglutaminase IgA ELISA (TTG IgA)	<10.3 U/mL	A00013
		Anti-Endomysial IgA IFA (EMA IgA)	Negative	A00003
	<3 years: 8-220 mg/dL; 3-13 years: 41-395 mg/dL; >13 years: 44- 441 mg/dL	A00012		

^{*}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)

- 83520(X3), ELISA; antibody specific (Deamidated Gliadin Peptide IgA, Deamidated Gliadin Peptide IgG, Anti-Tissue Transglutaminase IgA)
- 88346(X1), Anti-Endomysial (EMA) IgA Antibody by IFA
- 82784(x1), Total Serum IgA, by Nephelometry

Literature References

- Fasano A, Berti I, Gerarduzzi T, et al. Prevalence of celiac disease in at-risk and not-at-risk groups in the United States. Arch Intern Med. 2003;163:286-292.
- Green PHR, Jabri B. Coeliac disease. Lancet. 2003;362(9381):383-391.
- Mothes, T., Deamidated Gliadin Peptides as Targets for Celiac Disease-Specific Antibodies; Advances in Clinical Chem, 2007; Vol. 44, 35-63.

 $Assays \ and \ methods \ within \ this \ test \ may \ be \ covered \ by \ one \ or \ more \ US \ pending \ or \ issued \ patents. \ For \ details, \ please \ visit \ \underline{www.prometheuslabs.com}$

CEL16003 1/16

Ordering Recommendation

Preferred reflex screening test for celiac disease. May aid in monitoring adherence to gluten-free status.

Cascade contains all tests, including IgA levels necessary for initial serologic evaluation of celiac disease.

Celiac Disease Reflexive Cascade

2008114





Celiac Disease

Malabsorption

Mnemonic	Methodology
CELIAC REF	Quantitative Nephelometry/Semi-Quantitative
	Enzyme-Linked Immunosorbent Assay//Semi-
	Quantitative Indirect Fluorescent Antibody
Performed	Reported
Sun-Sat	2-6 days
New York DOH Approval Status	
This test is New York DOH approved.	

Specimen Required

Submit With Order

Patient Preparation:

Collect: Serum separator tube

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 2 mL serum to an ARUP Standard

Transport Tube. (Min: 1 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Plasma. Contaminated, hemolyzed, grossly icteric or grossly lipemic specimens.

Remarks:

Stability: After separation from cells: Ambient: 8 hours; Refrigerated: 8 days; Frozen: 1 year (if frozen within 24 hours)

Reference Interval

Effective February 16, 2016

Test Number	Components	Reference Interval			
0050340	Immunoglobulin A	Effective February 16, 2016			
		0-30 days: 1-7 mg/dL			
0051689	Celiac Disease Dual Antigen Screen	19 Units or less: Negative - No significant level of detectable IgA or IgG antibodies against human tissue transglutaminase or gliadin peptide. 20 Units or greater: Positive - Presence of IgA and/or IgG antibodies against human tissue transglutaminase and/or gliadin peptide; suggests possibility of certain gluten sensitive enteropathies such as celiac disease and dermatitis herpetiformis.			
0051357	Deamidated Gliadin Peptide (DGP) Antibody, IgA	19 Units or less: Negative 20-30 Units: Weak Positive 31 Units or greater: Positive			
0051359	Deamidated Gliadin Peptide (DGP) Antibody, IgG	19 Units or less. Negative 20-30 Units: Weak Positive 31 Units or greater: Positive			
0097709	Tissue Transglutaminase (tTG) Antibody, IgA	3 U/mL or less: Negative 4-10 U/mL: Weak Positive 11 U/mL or greater: Positive			
0050736	Endomysial Antibody, IgA by IFA	Less than 1:10			
0056009	Tissue Transglutaminase Antibody, IgG	5 U/mL or less: Negative 6-9 U/mL: Weak Positive 10 U/mL or greater: Positive			

Interpretive Data

Refer to report.

Note

The Celiac Disease Reflexive Cascade begins with Immunoglobulin A. Depending on findings, one or more reflexive tests may be required in order to provide a clinical interpretation. Tests added may include Tissue Transglutaminase Antibody, IgA; Tissue Transglutaminase Antibody, IgG; Endomysial Antibody, IgA by IFA; Deamidated Gliadin Peptide (DGP) Antibody, IgA; Deamidated Gliadin Peptide (DGP) Antibody, IgA; Deamidated Gliadin Peptide (DGP) Antibody, IgG; and/or Celiac Disease Dual Antigen Screen. Refer to the Celiac Testing Algorithm found at http://www.arupconsult.com/Algorithms/CeliacDz.pdf. Additional charges apply.

CPT Code(s)

82784; if reflexed additional CPT codes may apply: 83516, 83516 x2 and/or 86256. add 83516; if reflexed to tTG IgA and Gliadin IgA, add 83516 x 2; if reflexed to tTG IgG and Gliadin IgG, add 83516 x2; if IgA is greater than or equal to the normal age range, add 83516; if reflexed, add 86256 and 83516.

Components

Component Test Code*	Component Chart Name	LOINC
0050340	Immunoglobulin A	2458-8

^{*} Component test codes cannot be used to order tests. The information provided here is not sufficient for interface builds; for a complete test mix, please view this test within the Laboratory Test Directory found at www.aruplab.com

Aliases