



Test Description

The PROMETHEUS[®] IBD sgi Diagnostic[™] test is the next generation IBD diagnostic test and the first and only test that combines serologic, genetic, and inflammation markers in a proprietary Smart Diagnostic Algorithm to provide added IBD diagnostic clarity. This test helps physicians differentiate IBD vs. non-IBD and CD vs. UC in one comprehensive blood test. Important features of the test include the following:

- A quantitative analysis of serologic, genetic and inflammation markers combined with the Prometheus Smart Diagnostic Algorithm (pattern-recognition technology) for IBD prediction and differentiation
- PROMETHEUS IBD sgi Diagnostic is only offered at Prometheus.
- **Specimen Requirements** – 2.0 mL Serum (Red Top or SST) and 2.0 mL Whole Blood EDTA / Lavender Top Tube
- **Shipping Requirements** - Ambient or cold pack
- **Storage /Stability** - 7 days ambient, 21 days refrigerated
- **Turn Around Time** – 3 to 4 business days from date of receipt.

Test Information: NOTE: Patient test results are based on the Smart Diagnostic Algorithm which interprets patterns among the assay values.

Catalog Number	Test Name	Assay	Reference Value	Result Identifier*
1800	IBD sgi Diagnostic	ASCA IgA ELISA	<8.5 EU/mL	A00036
		ASCA IgG ELISA	<17.8 EU/mL	A00037
		Anti-OmpC IgA ELISA	<10.9 EU/mL	A00040
		Anti-CBir1 IgG ELISA	<78.4 EU/mL	A00039
		Anti-A4-Fla2 IgG ELISA	<44.8 EU/mL	A00041
		Anti-FlaX IgG ELISA	<33.4 EU/mL	A00042
		IBD-specific pANCA AutoAntibody ELISA	<19.8 EU/mL	A00038
		IBD Specific pANCA IFA Perinuclear Pattern	Not Detected	A00023
		IBD Specific pANCA IFA DNase Sensitivity	Not Detected	A00030
		ATG16L1 SNP (rs2241880)	No Mutation Detected	A00047
		ECM1 SNP (rs3737240)	No Mutation Detected	A00049
		NKX2-3 SNP (rs10883365)	No Mutation Detected	A00048
		STAT3 SNP (rs744166)	Mutation Detected	A00050
		ICAM-1	<0.54 µg/mL	A00043
		VCAM-1	<0.68 µg/mL	A00044
		VEGF	<345 pg/mL	A00045
		CRP	<13.2 mg/L	A00046
		SAA	<10.9 mg/L	A00051

SNPs included have been shown to be associated with IBD, however the presence of these mutations do not indicate that the patient has IBD. Use of these SNPs in association with the serology and inflammation markers allows for improved differentiation between UC and CD.

*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(X8)**, ELISA; antibody specific for each serology bio-marker (see above)
- **82397(X3)**, ICAM, VCAM, SAA Chemiluminescent Assay
- **86140(X1)**, CRP
- **88347(X2)**, IBD Specific pANCA; Indirect Immunofluorescent assay, IgG specific & DNase sensitivity
- **81479(x4)**, ATG16L1 SNP rs2241880; ECM1 SNP rs3737240; NKX2-3 SNP rs10883365; STAT3 SNP rs744166

Literature References

- CuffariC, DubinskyM, Seidman E. The evolving role of serologic markers in the management of pediatric IBD. *Gastroenterol Hepatol.* 2009, 5(2):1-14
- Schoepfer AM, Schaffer T. Mueller S. et al. Phenotypic associations of Crohn’s disease with antibodies to flagellins A4-Fla2 and Fla-X, ASCA, pANCA, PAB, and NOD2 mutations in a swiss cohort. *Inflamm Bowel Dis.* 2009; 15(9):1358-1467
- Fleshner P, Ippoliti A, Dubinsky M. et al. Both preoperative perinuclear antineutrophil cytoplasmic antibody and anti-CBir1 expression in ulcerative colitis patients influence pouchitis development after ileal pouch-anal anastomosis. *Clin Gastroenterol Hepatol.* 2008;6(5):561-568
- Dubinsky MC, Kugathasan S, Mei L. et al. Increased immune reactivity predicts aggressive complicating Crohn’s disease in children. *Clin Gastroenterol Hepatol.* 2008; 6(10):1105-1111
- Tyler AD, Milgrom R, Xu W. et al. Antimicrobial antibodies are associated with a Crohn’s disease-like phenotype after ileal pouch-anal anastomosis. *Clin Gastroenterol Hepatol.* 2012; 10(5):507-512

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