



**Test Description**

The PROMETHEUS<sup>®</sup> IBD sgi Diagnostic<sup>®</sup> test is 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	Assay	Reference Value	Result Identifier*	LONIC Code**
1800	ASCA IgA ELISA	<9.2 EU/mL	A00036	47320-7
	ASCA IgG ELISA	<11.9 EU/mL	A00037	47321-5
	Anti-OmpC IgA ELISA	<11.3 EU/mL	A00040	66482-1
	Anti-CBir1 IgG ELISA	<35.4 EU/mL	A00039	50979-4
	Anti-A4-Fla2 IgG ELISA	<32.4 EU/mL	A00041	59060-4
	Anti-FlaX IgG ELISA	<36.0 EU/mL	A00042	59060-4
	IBD Specific pANCA IFA Perinuclear Pattern	Not Detected	A00023	72521-8
	IBD Specific pANCA IFA DNase Sensitivity	Not Detected	A00030	53029-5
	ATG16L1 SNP (rs2241880)	Variant Not Detected	A00047	51969-4
	ECM1 SNP (rs3737240)	Variant Not Detected	A00049	51969-4
	NKX2-3 SNP (rs10883365)	Variant Not Detected	A00048	51969-4
	STAT3 SNP (rs744166)	Variant Detected	A00050	51969-4
	ICAM-1	<0.52 µg/mL	A00043	17174-4
	VCAM-1	<0.75 µg/mL	A00044	75627-0
	VEGF	<393 pg/mL	A00045	34694-0
	CRP	<13.4 mg/L	A00046	1988-5
	SAA	<22.9 mg/L	A00051	1847-3

\*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 all 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(X6)**, ELISA; antibody specific for each serology bio-marker (see above)
- **82397(X4)**, ICAM, VCAM, SAA, VEGF Chemiluminescent Assay
- **86140(X1)**, CRP
- **88346(X1)**, pANCA; Indirect Immunofluorescent assay IgG specific
- **88350(X1)**, DNase sensitivity; Indirect Immunofluorescent assay IgG specific, DNase digested slide
- **81479(x4)**, ATG16L1 SNP rs2241880; ECM1 SNP rs3737240; NKX2-3 SNP rs10883365; STAT3 SNP rs744166

**Literature References**

1. Cuffari C, DubinskyM, Seidman E. The evolving role of serologic markers in the management of pediatric IBD. *Gastroenterol Hepatol.* 2009; 5(2):1-14
2. 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
3. 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
4. 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 or issued patents. For details, please visit [www.prometheuslabs.com](http://www.prometheuslabs.com). IBD16006 6/17

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