PROMETHEUS®
Therapeutics & Diagnostics

PROMETHEUS® IBD sgi Diagnostic®
Cat. #1800

Test Description

The PROMETHEUS® IBD sgi Diagnostic® 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	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
- **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

- Cuffari C, DubinskyM, Seidman E. The evolving role of serologic markers in the management of pediatric IBD. Gastrenterol 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

 IBD16006 01/16

ARUP LABORATORIES | LABORATORY TEST DIRECTORY

Inflammatory Bowel Disease Differentiation Panel

2013270

ARUP Consult®
Disease Topics

- Inflammatory Bowel Disease - IBD

Ordering Recommendation

May be a useful tool for distinguishing ulcerative colitis (UC) from Crohn disease (CD) in patients with suspected inflammatory bowel disease.

Mnemonic

IBD PAN

Methodology

Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Semi-Quantitative Indirect Fluorescent Antibody

Performed

Sat-Sun

Reported

1-4 days

New York DOH Approval Status

This test is New York DOH approved.

Submit With Order

Specimen Required

Patient Preparation: N/A

Collect: Serum Separator Tube (SST).

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.6 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.

Remarks: N/A

Stability: After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval

Test Number	Components	Reference Interval
	Saccharomyces cerevisiae Antibody, IgG	20.0 Units or less: Negative 20.1-24.9 Units: Equivocal 25.0 Units or greater: Positive
	Saccharomyces cerevisiae Antibody, IgA	20.0 Units or less: Negative 20.1-24.9 Units: Equivocal 25.0 Units or greater: Positive
0050811	Anti-Neutrophil Cytoplasmic Antibody, IgG	Less than 1:20: Not significant

Interpretive Data

Refer to report.

Note

This test may be a useful tool for distinguishing ulcerative colitis (UC) from Crohn disease (CD) in patients with suspected inflammatory bowel disease. If the ANCA screen detects antibodies at a 1:20 dilution or greater, then a titer to end point will be added. Additional charges apply. ANCA IFA is simultaneously tested on ethanol- and formalin-fixed slides to allow differentiation of C- and P-ANCA patterns.

CPT Code(s)

86671 x2; 86255; if reflexed, add 86256

Components

Component Test Code*	Component Chart Name	LOINC
0050562	S. cerevisiae Antibody, IgG	47321-5
0050563	S. cerevisiae Antibody, IgA	47320-7
0050811	Anti-Neutrophil Cytoplasmic Ab, IgG	29967-7
2013271	EER Inflammatory Bowel Disease Panel	
2013448	Inflammatory Bowel Disease Interp	

** 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

- ASCA
- atypical p-ANCA Ab
- atypical p-ANCA IgG
- Atypical perinuclear anticytoplasmic neutrophil Ab
- Atypical perinuclear anticytoplasmic neutrophil IgG
- IBD Differentiation Profile
- S. cerevisiae Ab
- Saccharomyces cerevisiae Antibody