



PROMETHEUS® IBD Serology 7 Cat # 1007

Product Description

PROMETHEUS® IBD Serology 7 is the most comprehensive inflammatory bowel disease (IBD) test available. Utilizing several proprietary and patented markers and incorporating sophisticated pattern recognition technology, results may help physicians diagnose IBD and differentiate between ulcerative colitis (UC) and Crohn's disease (CD).

- A quantitative analysis of bio-markers combined with Prometheus Smart Diagnostic Algorithm^a (pattern-recognition technology) for IBD prediction and differentiation.
- PROMETHEUS IBD Serology 7 is only offered at Prometheus.
- **Specimen Requirements** - Serum, 2.0 mL: SST or Red Top Tube.
- **Shipping and Handling** - Ambient or refrigerated.
- **Storage Conditions/Stability** - 7 days ambient; 14 days refrigerated.
- **Turn Around Time** – 3 to 4 business days from date of receipt.
- **Reference Range: NOTE: Patient test results are based on the Smart Diagnostic Algorithm which interprets patterns between the 7 assay values. Assay and reference values are provided for prognostic interpretation.**
 - ASCA IgA ELISA: <20.5 EU/mL
 - ASCA IgG ELISA: <22.2 EU/mL
 - anti-OmpC^a IgA ELISA: <28.8 EU/mL
 - anti- CBir1^a ELISA: <34.9 EU/mL
 - AutoAntibody ELISA: <18.7 EU/mL
 - IFA Perinuclear Pattern: Not Detected
 - DNase Sensitivity^b: Not Detected

Facilities Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in several states including New York and California.
- Prometheus is CLIA certified and CAP accredited. All laboratory tests have been validated in accordance with the guidelines established by these and other applicable agencies. Currently, Food and Drug Administration (FDA) approval is not required for IBD Serology 7 testing performed by Prometheus.

CPT Codes (as applied by Prometheus)

- **83520(X5)**, ELISA; antibody specific for each bio-marker. (See above.)
- **88347(X2)**, IBD Specific pANCA^P; Indirect Immunofluorescent assays, IgG specific & DNase sensitivity.

Literature References

- Targan SR, Landers CJ, Yang H, et al. Antibodies to CBir1 flagellin define a unique response that is associated independently with complicated Crohn's disease. *Gastroenterology*. 2005;128:2020-2028.
- Abreu MT, et al. Use of serologic tests in Crohn's disease. *Clin Perspect Gastroenterol*. 2001;155-164.
- Vasiliauskas EA, Kam LY, Karp LC, et al. Marker antibody expression stratifies Crohn's disease into immunologically homogenous subgroups with distinct clinical characteristics Vasiliauskas. *Gut*. 2000;47(4):487-496.
- Targan SR. The Utility of ANCA and ASCA in Inflammatory bowel disease. *Inflamm Bowel Dis*. 1999; 5(1):61-3.
- Ruemele FM, Targan SR, Levy G, et al. Diagnostic accuracy of serological assays in pediatric inflammatory bowel disease. *Gastroenterology*. 1998;115(4):822-829.