PROMETHEUS®
Therapeutics & Diagnostics
For the person in every patient

PROMETHEUS® Crohn's Prognostic
Cat. #2001

Test Description

PROMETHEUS® Crohn's Prognostic test is the first and only test that combines proprietary serologic and genetic (serogenetic) markers in a logistic regression model to provide individualized probabilities for developing disease complications after diagnosis in patients with Crohn's disease. This test may allow physicians to stratify their CD patients according to their risks of developing complications over time and personalize the disease treatment plan for the patients.

- PROMETHEUS Crohn's Prognostic is only offered at Prometheus
- **Specimen Requirements -** 2.0 mL serum and 2.0 mL whole blood: EDTA / Lavender Top Tube
- **Shipping Requirements -** Ambient or cold pack
- **Storage Stability -** 7 days ambient or refrigerated
- **Turn Around Time -** 4-7 business days from date of receipt

Test Information

Catalog Number	Test Name	Assay	Reference Value	Result Identifier*
2001	Crohn's Prognostic	ASCA IgA ELISA	<9.2 EU/mL	A00036
		ASCA IgG ELISA	<11.9 EU/mL	A00037
		Anti-OmpC IgA ELISA	<11.3 EU/mL	A00040
		Anti-CBir1 IgG ELISA	<35.4 EU/mL	A00039
		Anti-I2 ELISA	<368 EU/mL	A00033
		IBD Specific pANCA IFA Perinuclear Pattern	Not Detected	A00023
		IBD Specific pANCA IFA DNAse Sensitivity	Not Detected	A00030
		SNP 8 (R702W) [C2104T]	Variant Not Detected	A00014
		SNP 12 (G908R) [G2722C]	Variant Not Detected	A00015
		SNP 13 (1007fs) [3020insC]	Variant Not Detected	A00016

* 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(X5),** ELISA; antibody specific for each bio-marker. (*See above*.)
- **88346(X1),** pANCA; Indirect Immunofluorescent assay IgG specific
- **88350(X1),** DNAse sensitivity; Indirect Immunofluorescent assay IgG specific, DNAse digested slide
- **81401(X1)**, NOD2 (SNP 8, SNP 12, SNP 13) molecular pathology procedure

* The AMA-CPT® Editorial Panel, at its October 2012 meeting, added PROMETHEUS® NOD2/CARD15 to the list of assays to be reported using 81401.

Literature References

1. Abreu MT, Taylor KD, Lin YC, et al. Mutations in NOD2 are Associated with Fibrostenosing Disease in Patients with Crohn's Disease. *Gastroenterology*. 2002;123(3):679-688.
2. Lichtenstein GR. Emerging prognostic markers to determine Crohn's disease natural history and improve management strategies: A review of recent literature. *Gastroenterology Hepatol*. 2010;6(2):99-107
3. Ippoliti A, Devlin S, Mei L, et al. Combination of innate and adaptive immune alterations increased the likelihood of fibrostenosis in Crohn's disease. *Inflamm Bowel Dis*. 2009 Dec 21.
4. 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.
5. Abreu MT, et al. Use of serologic tests in Crohn's disease. *Clin Perspect Gastroenterol.* 2001;155-164.
6. Data on file, Prometheus Laboratories Inc., San Diego, CA.

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