



PROMETHEUS[®] Monitr[™] Crohn's Disease
Cat. # 7300

Test Description

The PROMETHEUS[®] Monitr[™] Crohn's Disease test is the first serum monitoring test that measures mucosal healing status in adult Crohn's disease patients. The test applies an algorithm to the concentrations of 13 biomarkers in order to produce a quantitative Mucosal Healing Index Score ranging from 0-100. The Mucosal Healing Index Score is intended to aid in the assessment of active disease in Crohn's disease patients in conjunction with clinical evaluation performed by a healthcare professional. Prometheus Monitr is not intended or validated to diagnose Crohn's disease.

- **PROMETHEUS Monitr Crohn's Disease is only offered by Prometheus**
- **Specimen Requirements** - 2.0 mL Serum, SST or Red Top Tube
- **Shipping Requirements** – Refrigerated preferred, ship with cold pack
- **Storage / Stability** - 24 hours ambient, 14 days refrigerated
- **Turn Around Time** - 3 business days from date of receipt

Test Information

Test Name & Catalog Number	CPT Code	Assay	CDEIS <3 Range*	Result Identifier**
Monitr Crohn's Disease 7300	83520	Ang 1	≤ 451 U/mL	A00103
	83520	Ang 2	≤ 266 U/mL	A00099
	83520	CEACAM 1	≤ 208 U/mL	A00097
	83520	VCAM 1	≤ 358 U/mL	A00101
	86141	hsCRP	≤ 5 mg/L	A00075
	83520	SAA 1	≤ 16 U/mL	A00105
	83520	IL 7	≤ 302 U/mL	A00095
	83520	TGFα	≤ 181 U/mL	A00100
	83520	EMMPRIN	≥ 240 U/mL	A00107
	83520	MMP 1	≤ 150 U/mL	A00108
	83520	MMP 2	≥ 383 U/mL	A00109
	83520	MMP 3	≤ 85 U/mL	A00110
	83520	MMP 9	≤ 211 U/mL	A00104

*Based on population of Crohn's disease patients with CDEIS < 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(x12) (see above for specific assay information)
- 86141, C-reactive protein; high sensitivity (hsCRP)

Literature References

- Data on file, Prometheus Laboratories Inc. DOF17-002, 07/2017.
- Kelly OB, Silverberg MS, Dulai PD, et al. Development and validation of a multi-marker serum test for the assessment of mucosal healing in Crohn's disease patients. *American College of Gastroenterology*; October 13-18, 2017; Orlando, FL.
- Vuitton L, Marteau P, Sandborn WJ, et al. IOIBD technical review on endoscopic indices for Crohn's disease clinical trials. *Gut*. 2016;65(9):1447-1455.
- Peyrin-Biroulet L, Sandborn W, Sands BE, et al. Selecting therapeutic targets in inflammatory bowel disease (STRIDE): determining therapeutic goals for treat-to-target. *Am J Gastroenterol*. 2015;110(9):1324-1338.
- Christensen B, Rubin DT. Understanding endoscopic disease activity in IBD: how to incorporate it into practice. *Curr Gastroenterol Rep*. 2016;18(1):5.

This test may be covered by one or more US pending or issued patents – see prometheuslabs.com for details

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