



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 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, 7 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 | ≤ 696 U/mL | A00103 |
| | 83520 | Ang 2 | ≤ 512 U/mL | A00099 |
| | 83520 | CEACAM 1 | ≤ 284 U/mL | A00097 |
| | 86141 | hsCRP | ≤ 11 mg/L | A00075 |
| | 83520 | EMMPRIN | ≥ 188 U/mL | A00107 |
| | 83520 | IL 7 | ≤ 498 U/mL | A00095 |
| | 83520 | MMP 1 | ≤ 282 U/mL | A00108 |
| | 83520 | MMP 2 | ≥ 226 U/mL | A00109 |
| | 83520 | MMP 3 | ≤ 177 U/mL | A00110 |
| | 83520 | MMP 9 | ≤ 404 U/mL | A00104 |
| | 83520 | SAA 1 | ≤ 45 U/mL | A00105 |
| | 83520 | TGFα | ≤ 335 U/mL | A00100 |
| | 83520 | VCAM 1 | ≤ 596 U/mL | A00101 |

*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.

Assays and methods within this test may be covered by one or more US pending patents. For details, please visit www.prometheuslabs.com

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