

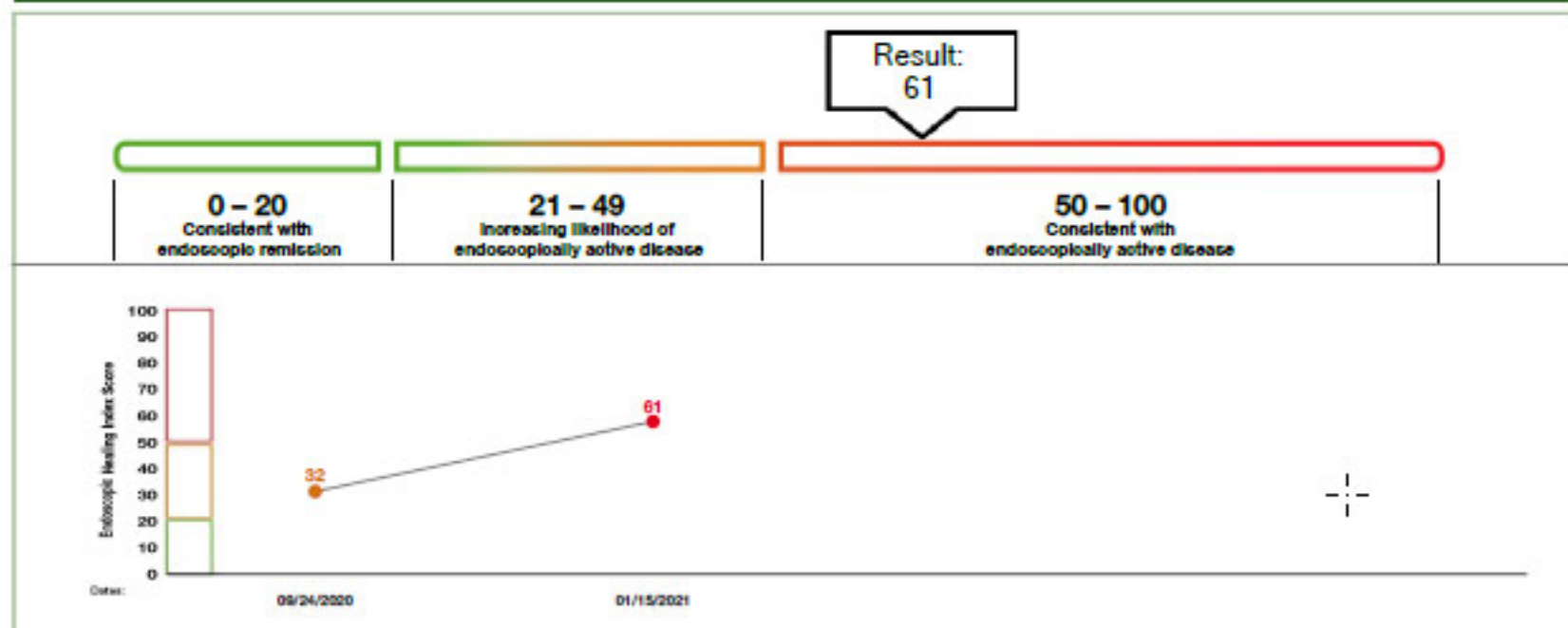
Patient Name: Doe, John

Ordered By: Example Physician

Birth Date:	Sex:	SSN:	Order ID:	Patient ID:	Report Recipient:	Contact Info:
01/01/1980	M		1122334	5555555	Example Physician GastroClinic New York, NY 10029	P: 2125555555 F: 2125555555

Ordered:	Collected:	Type:	Reported:	Sample ID:	Institution Sample ID:
01/19/2021	01/17/2021 4:08 PM	Serum	01/22/2021	SX123456789	J1111111

Endoscopic Healing Index (EHI) Score



	Inflammation		Cell adhesion		Angiogenesis		Immune recruitment	Growth factors	Matrix remodeling				
Biomarkers	hsCRP (mg/L)	SAA (mg/L)	CEACAM 1 (ng/mL)	VCAM 1 (ng/mL)	ANG 1 (ng/mL)	ANG 2 (ng/mL)	IL 7 (pg/mL)	TGFα (pg/mL)	EMMPRIN (ng/mL)	MMP 1 (ng/mL)	MMP 2 (ng/mL)	MMP 3 (ng/mL)	MMP 9 (ng/mL)
Value	9.3	2.5	36	827	217	1.2	9.6	17.5	3.3	8	271	30	930
Reference Range	< 3.0	< 2.0	< 60	< 1131	< 217	< 4.0	< 12.4	< 15.4	> 2.2	< 13	< 295	< 31	< 742

General Test Information:

- The PROMETHEUS Monitr Crohn's Disease test applies an algorithm to the protein concentrations of 13 biomarkers in order to produce a quantitative Endoscopic Healing Index (EHI) Score ranging from 0 to 100. The Monitr test was validated against endoscopy-paired serum samples from adult Crohn's disease patients (n=195). The EHI Score is intended to aid in the assessment of endoscopic disease activity in adult Crohn's disease patients in conjunction with clinical evaluation performed by a healthcare professional. The Monitr test is not intended to diagnose Crohn's disease.¹
- At a cut-off of 20, the sensitivity of Monitr was 83.2% (95% CI: 75.0-89.6) and specificity was 36.6% (95% CI: 26.2-48.0) for ruling out endoscopically active disease.¹
- For cut-offs ≥ 20 but < 50, specificity steadily increased as EHI scores approached 50 indicating a higher likelihood of active disease.¹
- At a cut-off of 50, the specificity of Monitr was 87.8% (95% CI: 78.7-94.0) and sensitivity was 30.1% (95% CI: 21.8-39.4) for ruling in endoscopically active disease.¹
- In a sub-cohort of 81 adult Crohn's disease patients, compared to inflammatory markers (hsCRP and fecal calprotectin), an EHI cutoff of 20 resulted in a sensitivity of 91.7% and a specificity of 42.4% and an EHI of 50 resulted in a specificity of 90.9% with a sensitivity of 35.4%.¹
- EHI cut-off of 20 showed higher sensitivity and specificity than a clinically relevant hsCRP score of 3 mg/L (hsCRP sensitivity of 62.5% with 63.6% specificity). EHI cut-off of 50 showed similar sensitivity and specificity to a clinically relevant fecal calprotectin score of 250 µg/g (fecal calprotectin sensitivity of 43.8% with 100% specificity).¹
- EHI demonstrated consistent performance across disease locations.¹
- Test results are a collective evaluation using nephelometry, chemiluminescence, and magnetic bead-based multiplex methods.
- * Endoscopically active disease defined as CDEIS ≥ 3, SES-CD ≥ 2 or SES-CD = 2 if only one intestinal segment had a score of 2 and scores of 0 in remaining segments.

References: 1. D'Haens G, Kelly O, Battat R, Silverberg MS, Laharie D, Louis E, Savarino E, Bodini G, Yarur A, Boland BS, Aff W, Li X-j, Hale M, Ho J, Kondragunta V, Huang B, Kuy C, Okada L, Hester KD, Bray KR, Mimms L, Jain A, Singh S, Collins A, Valasek MA, Sandborn WJ, Vermeire S, Dulai PS. Development and Validation of a Test to Monitor Endoscopic Activity in Patients With Crohn's Disease Based on Serum Levels of Proteins. *Gastroenterology*. 2020 Feb;158(3):515-526.e10

Reviewed By Curtis A. McGuyer, MD

Test results should be used in conjunction with other clinical and diagnostic findings. The healthcare provider is responsible for the use of this information in the management of their patient. The test was developed and its performance characteristics determined by Prometheus. It has not been cleared or approved by the U.S. FDA. The test is used for clinical purposes and should not be regarded as investigational or for research. Prometheus is CAP-accredited (5805501) and CLIA-certified (0500917432) as qualified to perform high complexity testing. The test may be covered by one or more U.S. pending or issued patents – refer to prometheuslabs.com.

Prometheus, Anser, FIBROSpect, IBD agi Diagnostic, LactoTYPE and Monitr are trademarks or registered marks of Prometheus. All other trademarks and service marks are the property of their respective owners.
©2021 Prometheus Laboratories Inc. All rights reserved.

Laboratory Director: Curtis A. McGuyer, MD

Prometheus
Laboratories

9410 Carroll Park Drive
San Diego, CA 92121
858-423-5227 • 858-824-0896 fax
www.prometheuslabs.com

7360v5(01/21)