PROMETHEUS®
Monitr™
Crohn's Disease

SAMPLE REPORT

Test Results

FINAL REPORT

Patient Name: Example Patient

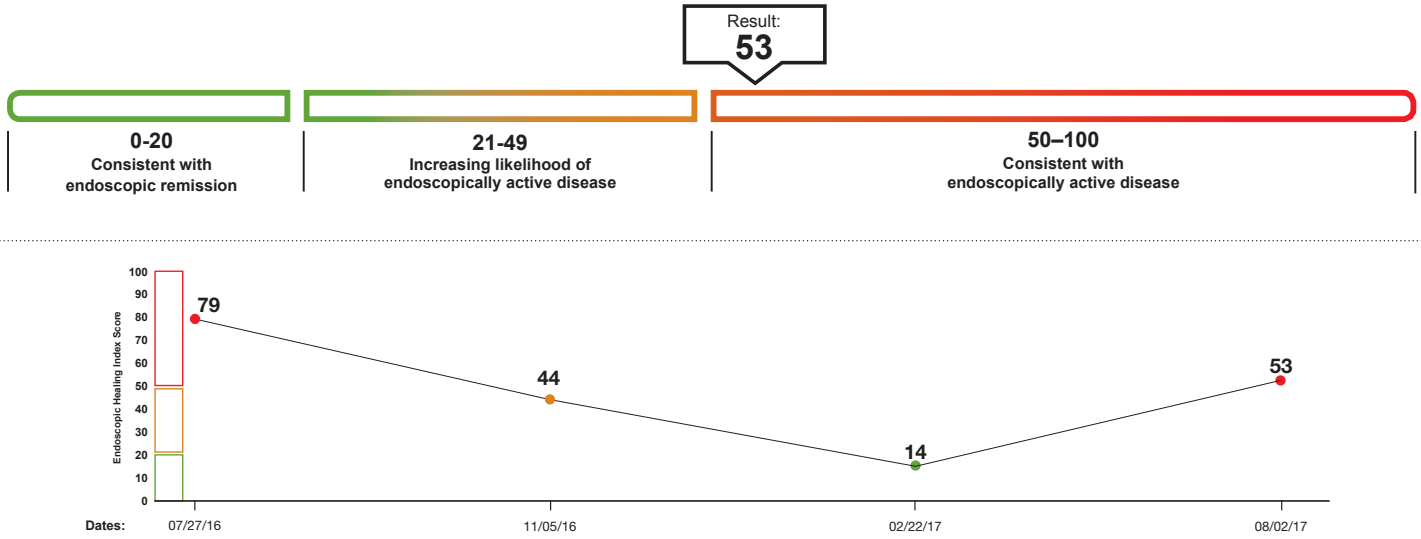
Ordered By: Example Physician M.D.

Birth Date:	Sex:	SSN:	Order ID:	Patient ID:
MM/DD/YYYY	**M**		**12345678910**	**12345678910**

Report Recipient:	Contact Info:
Example Physician Office 555 Example Street City, State 99999 US	P: 555-555-3456 F: 555-555-3456

Ordered:	Collected:	Type:	Reported:	Sample ID:	Institution Sample ID:
03/02/2020	**03/01/2020 8:50**	**Serum**	**03/04/2020**	**15224DA88**	**SV015445451**

Endoscopic Healing Index (EHI) Score



	Inflammation		Cell adhesion		Angiogenesis		Immune recruitment	Growth factors	Matrix remodeling				
Biomarkers	**hsCRP** mg/L	**SAA 1** mg/L	**CEACAM 1** ng/mL	**VCAM 1** ng/mL	**ANG 1** ng/mL	**ANG 2** ng/mL	**IL7** 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	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Reference Value	< 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 and magnetic bead-based multiplex methods.

** Endoscopically active disease defined as CDEIS ≥ 3, SES-CD>2 or SESCD=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, Afif 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

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