

SAMPLE LETTER OF MEDICAL NECESSITY
FOR PROMETHEUS® IBD Serology 7

(Please customize based on your patient's medical history, treatment experience, and/or claims adjudication. Please notify Prometheus' Billing Department at (888) 892-8391 if you are filing an appeal as we may be able to assist)

<DATE>

John Smith, Medical Director
Red Cross Red Shield
P.O. Box 12345
Los Angeles, CA 90060

Regarding Patient: Jane Doe
Date of Birth : February 25, 1969
ID Number: XXXX123456789
Date of service: July 4, 2007
Provider: Ulysses Grant, MD
Claim Number: 111111 (If available)

Dear Dr. Smith:

I am writing to request full coverage or at least in-network benefit coverage for the PROMETHEUS® IBD Serology 7 diagnostic panel for my patient, Jane Doe. I am Ms. Doe's gastroenterologist practicing at Sunnyvale Community Hospital in San Diego, CA. I consider this test a medically necessary step in the diagnosis and treatment of my patient. My patient has a history of *(diarrhea, GI bleeding, abdominal pain, and nonspecific enteritis)*.

(List information relevant to the patient's symptoms, treatment and test results if applicable. If a claim for this test has already been processed, address each reason for denial or unacceptable payment listed on the EOB. Include a copy of the patient's chart notes when applicable.)

PROMETHEUS IBD Serology 7 helps diagnose inflammatory bowel disease (IBD) and differentiate between ulcerative colitis (UC) and Crohn's disease (CD). Knowledge of serologic markers may help determine more severe disease phenotypes, help predict disease behavior, and potentially avoid a costly workup. Serologic markers can also help predict response to some therapeutics. **(AND)** There is no in-network laboratory near my patient willing to refer this test to Prometheus or able to provide comparable testing. **(OR)** I directed my patient to utilize an in-network laboratory, but her blood sample was referred to Prometheus without our knowledge. I've included information about the PROMETHEUS IBD Serology 7 diagnostic test.

Please approve full coverage for the PROMETHEUS IBD Serology 7 or at least apply in-network benefit coverage waiving all out of network deductibles for laboratory testing. If necessary, please review these services for any "wrap around benefits" provided under her plan.

Thank you for your prompt attention. I look forward to receiving a written response from you within two weeks. Please contact me at XXX-XXX-XXXX if you require any additional medical information concerning Ms. Doe.

Sincerely,

Ulysses Grant, MD
Sunnyvale Community Hospital
12345 Sunnyvale Road
San Diego, CA 92121
XXX-XXX-XXXX

Attachments:

1. PROMETHEUS IBD Serology 7 Diagnostic Product Detail Sheet
2. Patient Chart Notes
3. Lab Results
4. Other

For additional information about PROMETHEUS IBD Serology 7 or procedure code descriptions, contact Prometheus at 1-888-892-8391.



PROMETHEUS® IBD Serology 7 Cat # 1007

Product Description

PROMETHEUS® IBD Serology 7 is the most comprehensive inflammatory bowel disease (IBD) test available. Utilizing several proprietary and patented markers and incorporating sophisticated pattern recognition technology, results may help physicians diagnose IBD and differentiate between ulcerative colitis (UC) and Crohn's disease (CD). Knowledge of serologic markers may help determine more severe disease phenotypes, and help predict disease behavior.

- A quantitative analysis of bio-markers combined with the Smart Diagnostic Algorithm^b (pattern-recognition technology) for IBD prediction and differentiation
- PROMETHEUS IBD Serology 7 is only offered at Prometheus
- **Specimen Requirements** - Serum, 2.0 mL: SST or Red Top Tube
- **Shipping and Handling** - Ambient or refrigerated
- **Storage Conditions/Stability** - 7 days ambient; 14 days refrigerated
- **Turn Around Time** – 3 to 4 days
- **Reference Range: NOTE: Patient test results are based on the Smart Diagnostic Algorithm. Assay and reference values are provided for prognostic interpretation.**
 - ASCA IgA ELISA: <20.0 EU/mL
 - ASCA IgG ELISA: <40.0 EU/mL
 - Anti-OmpC^a IgA ELISA: <16.5 EU/mL
 - Anti-CBir1^a ELISA: <21.0 EU/mL
 - AutoAntibody ELISA: <12.1 EU/mL
 - IFA Perinuclear Pattern: Not Detected
 - DNase Sensitivity^a: Not Detected

Facilities Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in several states including New York and California.
- Prometheus is CLIA certified and CAP accredited. All laboratory tests have been validated in accordance with the guidelines established by these and other applicable agencies. Currently, Food and Drug Administration (FDA) approval is not required for IBD Serology 7 testing performed by Prometheus.

CPT Codes (as applied by Prometheus)

- **83520(X5)**, ELISA; antibody specific for each bio-marker. (*See above.*)
- **88347(X2)**, IBD specific pANCA, Indirect Immunofluorescent assays, IgG specific & DNase sensitivity.

Literature References

- 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.
- Abreu MT, et al. Use of serologic tests in Crohn's disease. *Clin Perspect Gastroenterol*. 2001;155-164.
- Fleshner PR, Vasiliauskas EA, Kam LY, et al. High level perinuclear antineutrophil cytoplasmic antibody (pANCA) in ulcerative colitis patients before colectomy predicts the development of chronic pouchitis after ileal pouch-anal anastomosis. *Gut*. 2001;49(5):671-677.
- Vasiliauskas EA, Kam LY, Karp LC, et al. Marker antibody expression stratifies Crohn's disease into immunologically homogenous subgroups with distinct clinical characteristics Vasiliauskas. *Gut*. 2000;47(4):487-496.
- Targan SR. The Utility of ANCA and ASCA in Inflammatory bowel disease. *Inflamm Bowel Dis*. 1999; 5(1):61-3.
- Ruemele FM, Targan SR, Levy G, et al. Diagnostic accuracy of serological assays in pediatric inflammatory bowel disease. *Gastroenterology*. 1998;115(4):822-829.

- a. patented
- b. patent pending