

SAMPLE LETTER OF MEDICAL NECESSITY
FOR PROMETHEUS® IBS Diagnostic

(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® IBS 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 *(lower abdominal pain, diarrhea, constipation, bloating, urgency, abdominal distention, and nausea)*.

(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 is the only laboratory offering the first blood-based biomarker test for Irritable Bowel Syndrome (IBS) including patented and proprietary markers and a Smart Diagnostic Algorithm^a that can aid in the diagnosis of IBS. **(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 IBS Diagnostic panel.

Please approve full coverage for the PROMETHEUS IBS Diagnostic 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 IBS Diagnostic Product Detail Sheet
2. Patient Chart Notes
3. Lab Results
4. Other

For additional information about PROMETHEUS IBS Diagnostic or procedure code descriptions, contact Prometheus Laboratories Inc. at 1-888-892-8391.



PROMETHEUS[®] IBS Diagnostic
Cat # 8000

Product Description

PROMETHEUS[®] IBS Diagnostic is the first blood-based biomarker test for Irritable Bowel Syndrome (IBS). Utilizing proprietary and patented markers and incorporating sophisticated pattern recognition technology PROMETHEUS IBS Diagnostic can aid clinicians in the diagnosis of IBS. PROMETHEUS IBS Diagnostic was validated using well-characterized IBS samples collected from recognized IBS experts and GI clinics. The samples were either Rome II or Rome III positive and the patients had a diagnosis of IBS for greater than one year. The test has a sensitivity of 50%, specificity of 88% with an overall accuracy of 70%.^a

General Test Information^a

Sensitivity = 50% Specificity = 88%

Total Cohort = 1721 Serum Samples.
Validation Cohort = 516 Serum Samples
(50% IBS, 36% Non-IBS Disease Controls, and 14% Normal Controls)

When ruling in IBS:

(~75% probability of disease as determined by the physician)

94% of positive test results are true positives
38% of negative test results are true negatives

When ruling out IBS:

(~25% probability of disease as determined by the physician)

85% of negative test results are true negatives
61% of positive test results are true positives

- A quantitative analysis of bio-markers combined with Prometheus Smart Diagnostic Algorithm^b (pattern-recognition technology) for IBS prediction
- PROMETHEUS IBS Diagnostic is only offered at Prometheus
- **Specimen Requirements** – Separated Serum, 2.0 mL: **SST only; centrifuge and refrigerate within 2 hours**
- **Shipping and Handling** – Refrigerated or Frozen
- **Storage Conditions/Stability** – 7 days refrigerated, 30 days frozen
- **Turn Around Time** – 7 days
- **Reference Value: NOTE: Patient test results are based on the Smart Diagnostic Algorithm which interprets patterns between the 10 assay values.**
 - BDNF (Brain-Derived Neurotrophic Factor) 7536.5 – 31324.4 pg/ml
 - NGAL (Neutrophil Gelatinase-Associated Lipocalin) 28.3 – 272.5 ng/ml
 - TWEAK (TNF-related Weak Inducer of Apoptosis) 351.6 – 1751.7 pg/ml
 - GRO-α (Growth-Regulated Oncogene Alpha) 26.4 – 499.3 pg/ml
 - IL-1β (Interleukin -1 Beta) 279.5 – 1358.6 fg/ml
 - TIMP-1 (Tissue Inhibitor of Metalloproteinase-1) 156.1 – 410.6 ng/ml
 - ASCA-IgA (Anti-Saccharomyces cerevisiae Antibody) < 20.0 EU/ml
 - CBir1 (Anti-CBir1 Antibody) < 21.0 EU/ml
 - ANCA (Anti-Human Neutrophil Cytoplasmic Antibody) < 12.1 EU/ml
 - tTG (Anti-Human Tissue Transglutaminase IgA) < 4.0 U/ml

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 IBS Diagnostic testing performed by Prometheus.

CPT Codes (as applied by Prometheus)

- **83520(X4)**, ELISA; antibody specific for bio-markers ASCA-IgA, CBir1, ANCA, and tTG.
- **82397(X6)**, CHEMILUMINESCENT Assay for biomarkers BDNF, NGAL, TWEAK, GRO-α, IL-1β, and TIMP-1.

References available upon request.

a. Data on file
b. Patent Pending