

**SAMPLE LETTER FOR PATIENT TO REQUEST COVERAGE**  
**FOR PROMETHEUS<sup>®</sup> IBS Diagnostic**

*(Please edit appropriately based upon your own information and medical history)*

<DATE>

Red Cross Red Shield  
P.O. Box 12345  
Los Angeles, CA 90060

Regarding PROMETHEUS<sup>®</sup> IBS Diagnostic:

Name: Jane Doe  
Date of Birth: February 25, 1969  
Insurance ID: XXXX123456789  
Policy Holder: Mr. John Doe

Dear Medical Director, Preauthorization Department:

I am writing to request coverage for the PROMETHEUS IBS Diagnostic panel that my gastroenterologist, Ulysses Grant at Sunnyvale Community Hospital in San Diego, CA has ordered. My doctor and I feel that this test is a medically necessary step and we would like to use the PROMETHEUS IBS Diagnostic to assist in making a clinical diagnosis of Irritable Bowel Syndrome (IBS).

***(Describe all information relevant to your symptoms and treatment.)***

Prometheus is the only laboratory offering the first blood-based biomarker test for IBS including patented and proprietary markers and a Smart Diagnostic Algorithm<sup>a</sup> that can aid in the diagnosis of IBS. ***(AND)*** There is no in-network laboratory near me willing to refer this test to Prometheus or able to provide comparable testing. I've included information about the PROMETHEUS IBS Diagnostic.

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 my plan.

Thank you for your prompt attention. I look forward to receiving a written response from you within two weeks.

Sincerely,

Jane Doe  
1234 Main Ave.  
Los Angeles, CA 90210  
XXX-XXX-XXXX

cc: Dr. Ulysses Grant

**Attachments:**

1. PROMETHEUS<sup>®</sup> IBS Diagnostic Product Detail Sheet

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%.<sup>a</sup>

**General Test Information<sup>a</sup>**

**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<sup>b</sup> (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