

SAMPLE PATIENT APPEAL LETTER
FOR PROMETHEUS® IBS Diagnostic

(Please edit appropriately based upon your own information and medical history. Please notify Prometheus' Billing Department at (888) 892-8391 when filing an appeal as we may be able to assist.)

Note to Patient: *If coverage was denied by your Medical Group rather than your Insurance Carrier, this letter should be addressed to the Medical Director at the Medical Group with a copy to your Insurance Carrier.*

<DATE>

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

Regarding PROMETHEUS® IBS Diagnostic testing for:

Name:	Jane Doe	Claim #:	11111
Date of Birth:	February 25, 1969	Date of service:	July 4, 2007
Insurance ID:	XXXX123456789	Original Claim:	\$259.50
Policy Holder:	Mr. John Doe	Date of EOB:	July 31, 2007

(This letter will need to address each specific reason for denial or unacceptable payment listed on the insurance EOB.)

Dear Medical Appeals Reviewer:

I am writing to appeal your decision about medical coverage for the PROMETHEUS IBS Diagnostic panel that my gastroenterologist, Dr. Ulysses Grant at Sunnyvale Hospital in San Diego, CA ordered. Dr. Grant and I felt that this test was a medically necessary step in the diagnosis and treatment of my symptoms. I would like to address these coverage issues hoping that you will reconsider your decision given the new information listed below.

(Describe all information relevant to your symptoms and treatment)

I am 39 years old, and because of my symptoms of (*lower abdominal pain, diarrhea, constipation, bloating, urgency, abdominal distention, and nausea*) my doctor ordered the PROMETHEUS IBS Diagnostic to aid in my clinical evaluation and for additional information to make a more informed decision into my illness.

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 me willing to refer this test or able to provide comparable testing. **(OR)** I utilized a network doctor and laboratory, but my blood sample was referred to Prometheus without my 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 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® 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%.^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