



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, 38% 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 business days from date of receipt.
- **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)	< 20.5 EU/mL
○ CBir1 (Anti-CBir1 Antibody)	< 34.9 EU/mL
○ ANCA (Anti-Human Neutrophil Cytoplasmic Antibody)	< 18.7 EU/mL
○ tTG (Anti-Human Tissue Transglutaminase IgA)	< 10.3 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.

Literature References

Lembo AJ, Neri B, Tolley J, et al. Use of serum biomarkers in a diagnostic test for irritable bowel syndrome. *Aliment Pharmacol Ther.* 2009;29:834-42.

Lois A, Wang D, Barken D, et al. Development of a diagnostic test for irritable bowel syndrome. *Am J Gastroenterol.* 2008;103:1198.

a. Data on file
b. Patent Pending