

Overview

Profile Information

| Test Id | Reporting Name | Available Separately | Always Performed |
|---------|-------------------------------------|----------------------|------------------|
| FIBD1 | PROMETHEUS IBD sgi Diagnostic, S | No | Yes |
| FIBD2 | PROMETHEUS IBD sgi Diagnostic, B | No | Yes |

Method Name

Enzyme Linked Immunosorbent Assay (ELISA), Chemiluminescent, Immunofluorescence Assay (IFA), multiplexed Polymerase Chain Reaction (PCR) allelic discrimination assays.

NY State Available

Yes

Specimen

Specimen Type

Serum
Whole Blood EDTA

Specimen Required

Requires both whole blood and serum

- Note:** Specimens must be shipped together
- Note:** Informed consent required from NYS clients

Blood:

Collect 2 mL lavender top EDTA whole blood. Ship refrigerate.

Serum:

Draw blood in a plain, red-top tube(s). (Serum gel tube is acceptable.) Spin down and send 2 mL of serum refrigerated.

Specimen Minimum Volume

Blood = 2 mL, Serum = 2 mL

Reject Due To

| | |
|---------------|--|
| Thawing** | Cold OK; Warm OK |
| other reasons | If both serum and EDTA whole blood are not received. |

| | |
|---------------|--|
| for rejection | |
|---------------|--|

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|------------------|--------------------------|---------|-------------------|
| Serum | Refrigerated (preferred) | 21 days | |
| | Ambient | 7 days | |
| Whole Blood EDTA | Refrigerated (preferred) | 21 days | |
| | Ambient | 7 days | |

Clinical & Interpretive

Clinical Information

Combines serologic, genetic, and inflammation markers to help differentiate Inflammatory Bowel Disease (IBD) vs non-IBD and ulcerative colitis (UC) vs Crohn's disease (CD).

The PROMETHEUS IBD sgi Diagnostic is the 4th-generation IBD diagnostic test and the first and only test to combine serologic, genetic, and inflammation markers in the proprietary Smart Diagnostic Algorithm for added diagnostic clarity. This test aids healthcare providers in differentiating IBD vs non-IBD and CD vs UC in one comprehensive blood test. This assay includes 9 serological markers ASCA IgA, ASCA IgG and proprietary markers anti-Fla-X, anti-A4-Fla2, anti-CBir1, anti-OMPC, and DNase-sensitive pANCA that helps identify patients with IBD and utilizes Smart Diagnostic Algorithm Technology to improve the predictive accuracy. Genetic susceptibility influences immune responses, and this assay includes evaluation of ATG16L1, STAT3, NKX2-3, and ECM1. Inflammatory markers include VEGF, ICAM-1, VCAM-1, CRP, SAA. While most other labs only offer assay values, PROMETHEUS IBD sgi Diagnostic provides added clarity in diagnosing IBD, UC, and CD.

Reference Values

Testing is complete. Final report has been sent to the referring laboratory.

Performance

Method Description

A proprietary algorithm is applied to the serologic, genetic, and inflammatory markers.

PDF Report

Referral

Day(s) Performed

Monday through Friday

Report Available

6 to 8 days

Performing Laboratory Location

Prometheus Laboratories, Inc.

Fees & Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

Test results should be used in conjunction with other clinical and diagnostic findings. The healthcare provider is responsible for the use of this information in the management of their patient. The test was developed, and it's performance characteristics determined by Prometheus. It has not been cleared or approved by the U.S. FDA. The test is used for clinical purposes and should not be regarded as investigational or for research. Prometheus is CAP-accredited (6805501) and CLIA-certified (05D0917432) as qualified to perform high complexity testing. The test may be covered by one or more U.S. pending or issued patents-refer to prometheuslabs.com

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CPT Code Information

82397 x 4
83520 x 6
86255 x 2
81479
86140

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|-------------------------------|--------------------|
| FIBDD | PROMETHEUS IBD sgi Diagnostic | Not Provided |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|----------------------------------|---------------------|
| Z2743 | PROMETHEUS IBD sgi Diagnostic, S | Unable to Verify |
| Z2744 | PROMETHEUS IBD sgi Diagnostic, B | Unable to Verify |