MAYO CLINIC LABORATORIES

Test Definition: FIBDD

PROMETHEUS IBD sgi Diagnostic

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	Ambient	7 days	
	Refrigerated (preferred)	21 days	
Whole Blood EDTA	Ambient	7 days	
	Refrigerated (preferred)	21 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

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