Lab Dept:	Serology
Test Name:	**IBD FIRST STEP ASSAY**

General Information

Lab Order Codes:	IBDF
Synonyms:	Anti-Human Neutrophil Indirect Immunofluorescent assay, IgG specific; Anti-Human Neutrophil Indirect Immunofluorescent assay, IgG specific; DNase digested slide; Modified Anti-Saccharomyces cerevisiae ELISA, IgA specific; Modified Anti-Saccharomyces cerevisiae ELISA, IgG specific; Modified Anti-Human Neutrophil ELISA, IgG specific; Modified Anti-OmpC ELISA, IgA specific; IBD – Inflammatory Bowel Disease
CPT Codes:	83520 x4 - Immunoassay, analyte, quantitative; not otherwise specified
	88347 x2 - Immunofluorescent study, each antibody; indirect method (if screen is positive)
Test Includes:	IBD First Step result. If the result is positive, then the result is reflexed to the confirmatory system. The result will state if markers are detected or not detected. The testing gives the positive predictive value of IBD probability. Also states probability of Ulcerative Colitis or Crohn's Disease. Specific test values include: ASCA IgA, ASCA IgG, Anti-OmpC IgA, Neutrophil Autoantibody, IFA Perinuclear Pattern, DNAse Sensitivity, Neutrophil-Specific Nuclear Antibody

Logistics

Test Indications:	Differentiation of Crohn's Disease and Ulcerative Colitis in patients with IBD.
Lab Testing Sections:	Serology - Sendouts
Referred to:	Prometheus Laboratories
Phone Numbers:	
Minneapolis:	612-813-6280
Saint Paul:	651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	5 - 7 days
Special Instructions:	This is a screening test. If positive, IBD First Step Confirmatory will be

Specimen

Specimen Type: Whole blood

Container: Red top tube, plain, no gel

Draw Volume: 6.0 mL (Minimum: 1.5 mL) blood

Processed Volume: 2.0 mL (Minimum: 0.5 mL) serum

Collection: Routine venipuncture

Special Processing: Lab Staff:

1. Complete all parts of the Prometheus test requisition form and keep appropriate copy for your files.

2. Use serum separator Vacutainer® tube and centrifuge the clotted sample before packaging to partition the serum away from the red cells **or** use a red top Vacutainer® tube and centrifuge the clotted sample and put serum into a plastic serum transport tube. Prometheus will supply SST tubes if requested. The specimen is stable at room temperature for up to 7 days.

3. Label each specimen with the patient's name, collection date and date of birth, or social security number.

4. Place the sample tubes in the slots in the styrene base. Screw caps on plastic serum tubes must be reinforced with adhesive tape or lab film.

5. Place the absorbent material (Drimop) over the tubes.

6. Place the styrene lid over the base and absorbent material. Seal the lid to the base with the red sealing tape provided.

7. Place the sealed styrene tray into the small plastic zip-lock bag. Then place zip-lock bag back into the serum specimen transportation kit

8. Fold and insert the Prometheus Copy of the test requisition form and billing information into the kit.

9. Close the kit, place into the Airborne Biological Specimen Bag and seal. Three Prometheus transportation kits will fit into one Airborne bag.11. Fill in your return address information on the pre-printed Airborne Airbill, and adhere the label to the specified location on the Airborne Bag.

10. Call Airborne Express at (800) 247-2676 for pick-up

Patient Preparation:	None	
Sample Rejection:	N/A	

Interpretive

Reference Range:

Assay	Reference Range
IBD First Step Result	Markers Not Detected
ASCA IgA ELISA	<20.0 EU/mL
ASCA IgG ELISA	<40.0 EU/mL
Anti-OmpC ELISA	<16.5 EU/mL
Neutrophil Autoantibody ELISA	<12.1 EU/mL
IFA Perinuclear Pattern	Not Detected
DNAse Sensitivity	Not Detected
Neutophil-Specific Nuclear Autoantibody	Not Detected

Critical Values: N/A

Limitations: Less than 10% of patients with Markers Not Detected profile have IBD.

Methodology: ELISA

Confirmatory testing: Indirect immunofluorescent assay

Contraindications: N/A

References: Prometheus GI Disease Management and package insert

Prometheus Laboratories Web Page www.prometheuslabs.com