GENERAL TEST REQUISITION

Prometheus Laboratories

ALL INFORMATION REQUESTED BELOW IS REQUIRED

The following information is required to efficiently and expediently process testing and/or submit insurance claim(s) on your patient's behalf.

For assistance, contact Prometheus client services at 888-423-5227.

Patient Information

Last Name: _____

First Name: _____ MI: _____

DOB (mm/dd/yyyy): ____/____/_____ SSN: _____-_____-_____ Sex: ☐ M ☐ F

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

Provider Signature

I certify that the ordered test(s) is/are reasonable and medically necessary for the diagnosis, care, and/or treatment of this patient's condition as documented in the medical record.

For genetic testing only: My signature indicates I have read and understand the genetic consent requirement for my patient on the back page and acknowledge I have obtained consent from my patient.

Provider Signature: _____

Provider Name: _____ **Date:** _____

Billing Information

BILL: ☐ Insurance ☐ Laboratory ☐ Patient/Self-Pay ☐ Provider Account

INSURANCE: Please complete ALL information below AND attach a copy (front and back) of primary & secondary insurance card(s).

Parent/Guardian Name (if applicable): _____
If patient is a minor (<18 at time of testing), parent/guardian is responsible for payment.

Insurance Carrier: _____ Policy #: _____

Group Name: _____ Group #: _____

Preauthorization/Reference # (if available): _____

Policyholder

If patient is NOT the policyholder, please complete the following

Name: _____

DOB (mm/dd/yyyy): _____/_____/_____ SSN: _____-_____-_____

Phone: _____ Relation to Patient: _____

Provider/Account Information

Account Name/Address:

Phone: Fax:

Provider/NPI:

Sample Collection Information

Date (mm/dd/yyyy): _____/_____/_____ Time: _____ ☐ AM ☐ PM

Patient ID: _____ Sender Sample ID: _____

MEDICARE ONLY - HOSPITAL STATUS WHEN SAMPLE WAS COLLECTED:

☐ Hospital inpatient ☐ Hospital outpatient ☐ Non-hospital patient

Laboratory/Other Name/Address:

Phone: Fax:

Results: ☐ Mail ☐ Fax ☐ No Results to Lab

ICD-10 Diagnosis Code

Primary ICD Code (REQUIRED)		Additional ICD Code(s) (OPTIONAL)					
1		2		3		4	

Select Test(s) To Be Performed

IBD Diagnosis & Disease Monitoring

☐ **IBD sgi Diagnostic®** (#1800†)
Combines serologic, genetic, and inflammatory markers to help differentiate IBD vs non-IBD and UC vs CD.

- ☐ ADD **RiskImmune®** (#3600†)
  (Conditional order following result of "Pattern Consistent with IBD")
- ☐ ADD **Monitr® Crohn's Disease** (#7300)
  (Conditional order following result of "Pattern Consistent with Crohn's disease")
- ☐ ADD **Crohn's Prognostic** (#2001†)
  (Conditional order following result of "Pattern Consistent with Crohn's disease")

☐ **Monitr® Crohn's Disease** (#7300)
Assesses endoscopic disease activity in CD patients ≥18 years old.

☐ **Crohn's Prognostic** (#2001†)
Serogenetic profile evaluating probability of disease progression in CD.

☐ **7C4 Diagnostic Test** (#8205)
Measures 7α-hydroxy-4-cholesten-3-one (7C4) to determine if bile acid malabsorption may be the underlying cause of a gastrointestinal symptoms.

Therapeutic Selection & Drug Monitoring

☐ **RiskImmune®** (#3600†)
Aids in predicting risk of antibody formation to IFX, ADA or biosimilars.

☐ **Anser® IFX** (#3150)
Simultaneously measures serum IFX and ATI. Select biologic (optional):
☐ **REMICADE®** (infliximab) ☐ **AVSOLA®** (IFX-axxq) ☐ **INFLECTRA®** (IFX-dyyb) ☐ **RENFLEXIS®** (IFX-abda)

☐ **Anser® ADA** (#3170)
Simultaneously measures serum ADA and ATA. Select biologic (optional):
☐ **HUMIRA®** (adalimumab)
☐ **Adalimumab Biosimilar:** _____

☐ **Anser® VDZ** (#3180)
Simultaneously measures serum VDZ and ATV.

☐ **Anser® UST** (#3190)
Simultaneously measures serum UST and ATU.

Last Administered Dose: (OPTIONAL)

Interval: ☐ 4 ☐ 6 ☐ 7 ☐ 8 ☐ 10 ☐ 14 ☐ Other: _____ ☐ days ☐ weeks

Infusion/Injection Date (mm/dd/yyyy): / / Dose: ☐ mg/kg ☐ mg

☐ **TPMT Genetics** (#3300†)
Aids in individualized thiopurine dosing based on patient TPMT genotype.

☐ **TPMT Enzyme** (#3320)
Phenotyping test that aids in individualized thiopurine dosing.

☐ **Thiopurine Metabolites** (#3200)
Aids in optimization of thiopurine dosing to achieve clinical response.

Current Therapeutic: (OPTIONAL)

☐ 6-MP _____ mg/day ☐ AZA _____ mg/day ☐ Other _____ mg/day

Celiac, Liver & Lactase Non-Persistence

☐ **Celiac PLUS** (#6360†)
Includes Celiac Genetics and Celiac Serology

- ☐ ONLY **Celiac Genetics** (#6260†)
- ☐ ONLY **Celiac Serology** (#1155)
  Includes the following:
  - ☐ Anti-Human Tissue Transglutaminase IgA (tTG IgA) (#1405)
  - ☐ Anti-Endomysial IgA (EMA IgA) (#1505)
  - ☐ Total serum IgA (#1605) ☐ DGP IgA (#1255) ☐ DGP IgG (#1355)

☐ **FIBRO*Spect*® HCV** (#4000)
Assessment of liver fibrosis severity for HCV patients.

☐ **FIBRO*Spect*® NASH** (#4100)
Assessment of liver fibrosis severity for NASH patients.

☐ **Lacto*TYPE*®** (#6100†)
Genetic test that aids in identification of primary lactase non-persistence.

Specimen collection requirements on back.

IBD: inflammatory bowel disease; UC: ulcerative colitis; CD: Crohn's disease; IFX: infliximab; ATI: antibodies-to-IFX; ADA: adalimumab; ATA: antibodies-to-ADA; VDZ: vedolizumab; ATV: antibodies-to-VDZ; UST: ustekinumab; ATU: antibodies-to-UST

SPECIMEN COLLECTION AND HANDLING PROCEDURE

Test Ordered (Turnaround Time)[a]	Transportation Kit Requirements	Specimen Type	Specimen Collection Tube	Specimen Volume	Storage Conditions	Specimen Stability
IBD sgi Diagnostic (4 days)	Ambient or cold pack acceptable	SERUM **AND** WHOLE BLOOD	Serum Separator Tube or Red-Top Tube **AND** EDTA/Lavender-Top Tube	2.0 mL serum **AND** 2.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 21 days
Monitr Crohn's Disease (5 days)	Refrigeration preferred, ship with cold pack	**SPUN** SERUM	**SPUN** Serum Separator Tube	2.0 mL	Room temperature or refrigerated Do not freeze	Room temp: 3 days Refrigerated: 14 days
Crohn's Prognostic (7 days)	Ambient or cold pack acceptable	SERUM **AND** WHOLE BLOOD	Serum Separator Tube or Red-Top Tube **AND** EDTA/Lavender-Top Tube	2.0 mL serum **AND** 2.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 7 days
7C4 Diagnostic Test (7 days)	Cold pack required	SERUM	Serum Separator Tube or Red-Top Tube	1.0 mL serum	Refrigerated Do not freeze	Room temp: 3 days Refrigerated: 7 days
RiskImmune (4 days)	Ambient or cold pack acceptable	WHOLE BLOOD	EDTA/ Lavender-Top Tube	2.0 mL	Room temperature or refrigerated Do not freeze	Room temp: 10 days Refrigerated: 30 days
Anser IFX, ADA, UST, VDZ (3 days)	Ambient or cold pack acceptable	SERUM	Serum Separator Tube or Red-Top Tube	2.0 mL (0.5 mL for Peds)	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 9 days
TPMT Genetics (4 days)	Ambient or cold pack acceptable	WHOLE BLOOD	EDTA/ Lavender-Top Tube	2.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 10 days Refrigerated: 30 days
TPMT Enzyme (3 days)	Refrigerated preferred, ship with cold pack	WHOLE BLOOD	EDTA/ Lavender-Top Tube	5.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 24 hours Refrigerated: 8 days
Thiopurine Metabolites (3 days)	Refrigerated preferred, ship with cold pack	WHOLE BLOOD	EDTA/ Lavender-Top Tube	5.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 24 hours Refrigerated: 8 days
Celiac PLUS (Genetics & Serology) (4 days)	Ambient or cold pack acceptable	SERUM **AND** WHOLE BLOOD	Serum Separator Tube or Red-Top Tube **AND** EDTA/Lavender-Top Tube	2.0 mL serum **AND** 2.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 30 days
Celiac Genetics (4 days)	Ambient or cold pack acceptable	WHOLE BLOOD	EDTA/ Lavender-Top Tube	2.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 30 days
Celiac Serology (4 days)	Ambient or cold pack acceptable	SERUM	Serum Separator Tube or Red-Top Tube	2.0 mL serum (0.5 mL for peds)	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 30 days
FIBRO*Spect* HCV, NASH (7 days)	Ambient or cold pack acceptable	SERUM	Serum Separator Tube or Red-Top Tube	2.0 mL serum (0.5 mL for peds)	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 30 days
Lacto*TYPE* (7 days)	Ambient or cold pack acceptable	WHOLE BLOOD	EDTA/ Lavender-Top Tube	2.0 mL whole blood	Room temperature or refrigerated Do not freeze	Room temp: 10 days Refrigerated: 30 days

[a]Business days from date of receipt.

Specimens should be labeled with 2 identifiers and date of collection. Examples of acceptable identifiers include, but are not limited to, patient name, date of birth, hospital number, requisition, accession, or unique random number. Unlabeled specimens will not be accepted for testing.

SHIPPING INSTRUCTIONS: Prometheus has an agreement with FedEx® for express overnight delivery within the United States and Canada. Please call FedEx at 1-800-GoFedEx (463-3339) to schedule a pickup. FedEx will pick up your specimens and ship them to Prometheus Laboratories Inc in San Diego at no expense to you. Prometheus will provide specimen transportation kits upon request. **NOTE:** Multiple specimens may be shipped in a single transportation kit. **For more information, call Client Services at 888-423-5227, or go to www.prometheuslabs.com.**

ACKNOWLEDGMENT OF INFORMED CONSENT FOR GENETIC TESTING

I warrant that this test was ordered and that I have obtained the appropriate prior written consent. This written consent was signed by the person who is the subject of the test (or if that person lacks capacity to consent, signed by the person authorized to consent for that person) and includes the following (unless certain that the following information is not required by the state in which I practice):

1. The purpose of this test is to determine if the patient may have a variant in the gene(s) being tested, which has been found to be associated with this condition.
2. This test will only test for this specific condition and will not detect ALL possible variants within this gene, nor will it detect variants in other genes.
3. Prior to my signature of the written consent, a qualified healthcare professional discussed with the patient the genetic test ordered and described the steps involved in the test, the constraints of the procedure, and its accuracy.
4. My patient was advised by a qualified healthcare professional of the risks and benefits of genetic testing, and advised of the significance of a positive and negative result.
5. The patient understands that a positive test result is an indication that the patient may be predisposed to, or have, the condition listed above.
6. The patient understands that the test may fail, that the results may be non-informative or not predictive for his/her case, and that the test may reveal information that is unrelated to their intended purpose.
7. No unauthorized test is performed on specimens.
8. NY-state specimens will be destroyed within 60 days after collection when no longer required for clinical purposes.
9. The informed consent does not authorize the use or release of any other identified medical information unrelated to this genetic test.
10. The patient understood that he/she could see professional genetic counseling prior to undergoing the testing procedure, and received written information identifying a genetic counselor or medical geneticist by his/her treating provider.

Prometheus tests are laboratory-developed tests that were developed and validated under Federal CLIA laboratory guidelines by Prometheus. Prometheus, Anser, Monitr, RiskImmune, IBDsgi Diagnostic, FIBRO*Spect* and Lacto*TYPE* are registered trademarks of Prometheus Laboratories Inc, San Diego, California. All other trademarks or service marks are the property of their respective owners.