

Patient Information

Last Name: _____

First Name: _____ MI: _____ Sex: ☐ M ☐ F

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

Parent/Guardian (if applicable): _____
(REQUIRED if patient is <18 years old at time of sample collection)

Address: _____ City: _____

State: _____ Zip: _____ Phone: _____

ICD-10 Diagnosis Code(s)

Primary ICD-10 Code (REQUIRED)	Additional ICD-10 Code(s) (OPTIONAL)			
1	2	3	4	

Billing Information

BILL: ☐ Insurance* ☐ Laboratory ☐ Patient/Self-Pay ☐ Provider Account
*Please provide details below AND attach a front/back copy of insurance card(s).

Insurance Carrier: _____ Policy #: _____

Provider/Account Information

Account Name/Address: _____

Phone: _____ Fax: _____

Ordering Provider Selection & Signature (REQUIRED)

**Clearly select the ordering provider from list below (circle or ✓).
If provider is not listed, please provide their FULL NAME AND NPI:**

Provider: _____ NPI: _____

I certify 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. If this patient is <18 years old at the time of testing, the parent/guardian has been informed that they will be responsible for any costs associated with testing.

***Informed consent for genetic testing:** I have read and understand the genetic consent requirement on page two and acknowledge I have obtained consent from my patient.

Signature: _____

Name: _____ Date: _____

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

All information requested is REQUIRED to process testing and/or submit insurance claims on your patient's behalf.

Select Test(s) To Be Performed

— Diagnosis & Risk Stratification —

- ☐ **IBD sgi Diagnostic^{®†}** (#1800)
Aids in diagnosis and differentiation of IBD from non-IBD and UC from CD.
- Conditional testing if IBD sgi result is indicative of IBD —
- ☐ ADD **Respondr[®] TNF[†]** (#4200) | Note: Patient must be ≥35 kg
Patient Weight in kg at Sample Collection (REQUIRED)*: _____ kg
- Conditional testing if IBD sgi result is indicative of CD —
- ☐ ADD **Monitr[®] Crohn's Disease** (#7300) | Note: Patient must be ≥12 years old
- ☐ ADD **Crohn's Prognostic[†]** (#2001)
- ☐ **Monitr[®] Crohn's Disease** (#7300)
Measure and track endoscopic disease activity in CD patients ≥12 years old.
- ☐ **Crohn's Prognostic** (#2001)
Evaluate probability of disease progression in CD patients.

— Therapeutic Selection —

- ☐ **Respondr[®] TNF[†]** (#4200) **New**
Indicates likelihood of anti-TNF response, prior to initiation of therapy, by assessing pre-therapy drug clearance and genetic predisposition to immunogenicity.
- Patient Weight at Sample Collection (REQUIRED)***
- | | | |
|--------------------------------------|----------|---|
| Weight (kg)
<i>kg = lbs ÷ 2.2</i> | _____ kg | Note: Patient must be ≥35 kg at time of sample collection. |
|--------------------------------------|----------|---|

— Precision-Guided Dosing —

- ☐ **PredictrPK[®] IFX Induction** (#3500)
Predicts IFX levels at 4-, 6- and 8-weeks post induction dose 3; calculates IFX clearance and measures serum IFX, ATI and albumin in IV IFX-treated IBD patients.
Sample collection: ≤3 days prior to IFX induction dose 3.

IFX Intravenous (IV) Induction Dosing (REQUIRED)*

	Infusion Date (mm/dd/yyyy)	Total Dose (mg) <i>e.g. 485 mg</i>	Weight (kg) <i>kg = lbs ÷ 2.2</i>
Dose 1		_____ mg	_____ kg
Dose 2		_____ mg	_____ kg
Dose 3*		_____ mg	_____ kg

*Scheduled infusion date, estimated total dose and anticipated patient weight.

- ☐ **PredictrPK[®] IFX Maintenance** (#3400)
Predicts IFX trough levels with current & alternative dosing; calculates IFX clearance and measures serum IFX, ATI and albumin in IV IFX-treated IBD patients.
Sample collection: ≤3 days prior to week 14 or, after ≥14 weeks of IV IFX therapy, anytime ≥20 days after any maintenance infusion, up to and including at trough.

Current Intravenous (IV) IFX Dosing (REQUIRED)*

Last Infusion (mm/dd/yyyy)	_____	Interval (weeks)	<input type="checkbox"/> 4 <input type="checkbox"/> 6 <input type="checkbox"/> 8 <input type="checkbox"/> Other:
Total Dose (mg) <i>e.g. 485 mg</i>	_____ mg	Weight (kg) <i>kg = lbs ÷ 2.2</i>	_____ kg

- ☐ **PredictrPK[®] ADA Maintenance** (#3700)
Predicts ADA levels with alternative dosing; calculates ADA clearance and measures serum ADA, ATA and albumin in SC ADA-treated IBD patients ≥12 years old.
Sample collection: Anytime within the injection interval after ≥8 weeks of ADA therapy.

Current Subcutaneous (SC) ADA Dosing (REQUIRED)*

Last Injection (mm/dd/yyyy)	Dose (mg)	Interval (days)
	<input type="checkbox"/> 40 <input type="checkbox"/> 80	<input type="checkbox"/> 7 <input type="checkbox"/> 14 <input type="checkbox"/> Other:

- ☐ **PredictrPK[®] VDZ Maintenance** (#3800) **New**
Predicts VDZ trough levels with current & alternative dosing; calculates VDZ clearance and measures serum VDZ, ATV and albumin in IV VDZ-treated IBD patients ≥18 years old.
Sample collection: ≤3 days prior to week 14 or, after ≥14 weeks of IV VDZ therapy, anytime ≥20 days after any maintenance infusion, up to and including at trough.

Current Intravenous (IV) VDZ Dosing (REQUIRED)*

Last Infusion (mm/dd/yyyy)	Dose (mg)	Interval (weeks)
	300	<input type="checkbox"/> 4 <input type="checkbox"/> 6 <input type="checkbox"/> 8 <input type="checkbox"/> Other:

- ☐ **PredictrPK[®] UST Maintenance** (#3900) **New**
Predicts UST trough levels with current & alternative dosing; calculates UST clearance and measures serum UST, ATU and albumin in SC UST-treated IBD patients ≥18 years old.
Sample collection: ≤3 days prior to week 16 or, after ≥16 weeks of UST therapy, anytime ≥20 days after any maintenance injection, up to and including at trough.

Current Subcutaneous (SC) UST Dosing (REQUIRED)*

Last Injection (mm/dd/yyyy)	Dose (mg)	Interval (weeks)
	90	<input type="checkbox"/> 4 <input type="checkbox"/> 6 <input type="checkbox"/> 8 <input type="checkbox"/> Other:

Miscellaneous Testing

- ☐ **Other Prometheus Testing[†]:** _____

*Acknowledgment of informed consent required if genetic testing is indicated above.

— Specimen collection requirements on page 2 —

*Acknowledgment of informed consent for genetic testing required.
*Failure to provide the required data may result in reporting delay/cancellation.

Specimen Collection and Handling Procedures

Test Ordered	Turnaround Time ^a	Transport Kit and Storage Conditions	Specimen Type and Volume	Specimen Collection Tube	Specimen Stability
7C4 Diagnostic	7 days	Cold pack REQUIRED Do not freeze	1.0 mL Serum	Serum Separator Tube or Red-Top Tube	Room temp: 3 days Refrigerated: 7 days
Anser[®] ADA, IFX, RZB, UST, VDZ	3 days	Ambient or cold pack Do not freeze	2.0 mL Serum (0.5 mL for Peds)	Serum Separator Tube or Red-Top Tube	Room temp: 14 days Refrigerated: 14 days
Celiac PLUS[†]	4 days	Ambient or cold pack Do not freeze	2.0 mL Serum AND 2.0 mL Whole Blood	Serum Separator Tube or Red-Top Tube AND EDTA/Lavender-Top Tube	Room temp: 7 days Refrigerated: 30 days
Celiac Genetics[†]	4 days	Ambient or cold pack Do not freeze	2.0 mL Whole Blood	EDTA/Lavender-Top Tube	Room temp: 7 days Refrigerated: 30 days
Celiac Serology	4 days	Ambient or cold pack Do not freeze	2.0 mL Serum (0.5 mL for peds)	Serum Separator Tube or Red-Top Tube	Room temp: 7 days Refrigerated: 30 days
Crohn's Prognostic[†]	7 days	Ambient or cold pack Do not freeze	2.0 mL Serum AND 2.0 mL Whole Blood	Serum Separator Tube or Red-Top Tube AND EDTA/Lavender-Top Tube	Room temp: 7 days Refrigerated: 7 days
IBD sgi Diagnostic[†]	4 days	Ambient or cold pack Do not freeze	2.0 mL Serum AND 2.0 mL Whole Blood	Serum Separator Tube or Red-Top Tube AND EDTA/Lavender-Top Tube	Room temp: 7 days Refrigerated: 21 days
Monitr Crohn's Disease	5-7 days	Cold pack preferred Do not freeze	2.0 mL SPUN Serum	SPUN Serum Separator Tube	Room temp: 3 days Refrigerated: 14 days
PredictrPK ADA, IFX	3 days	Ambient or cold pack Do not freeze	2.0 mL Serum (0.5 mL for Peds)	Serum Separator Tube or Red-Top Tube	Room temp: 14 days Refrigerated: 14 days
PredictrPK UST, VDZ	3 days	Ambient or cold pack Do not freeze	2.0 mL Serum	Serum Separator Tube or Red-Top Tube	Room temp: 14 days Refrigerated: 14 days
ResponDr TNF[†]	4 days	Ambient or cold pack Do not freeze	3.0 mL Whole Blood	EDTA/Lavender-Top Tube	Room temp: 10 days Refrigerated: 30 days
Thiopurine Metabolites	3 days	Cold pack preferred Do not freeze	5.0 mL Whole Blood	EDTA/Lavender-Top Tube	Room temp: 24 hours Refrigerated: 8 days
TPMT Enzyme	3 days	Cold pack preferred Do not freeze	5.0 mL Whole Blood	EDTA/Lavender-Top Tube	Room temp: 24 hours Refrigerated: 8 days
TPMT Genetics[†]	4 days	Ambient or cold pack Do not freeze	2.0 mL Whole Blood	EDTA/Lavender-Top Tube	Room temp: 10 days Refrigerated: 30 days

^aBusiness days from date of receipt.

[†]Acknowledgment of informed consent for genetic testing required.

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 prometheuslabs.com.**

Important Ordering Information

ResponDr[®] TNF PredictrPK[®]

ResponDr TNF and **PredictrPK** require specific patient and treatment inputs for processing and resulting. You may need to request this data from the infusion center.

Failure to provide the required data, at the time of ordering, may result in reporting delays and/or possible cancellation.

Weight in kg

- Patient's weight, in kilograms (kg), at the time of sample collection (**ResponDr TNF**) or at the designated infusion (**PredictrPK IFX**)
- Formula for reference: kg = lbs ÷ 2.2

Total Dose in mg

- Total amount of intravenously administered IFX, in mg (e.g. "485 mg")
Note: We CANNOT accept derived dosing such as "5 mg/kg"
- If not all IFX in a vial is given, estimate the total dose given to the nearest 5 mg

Dose 3 Data (PredictrPK IFX Induction)

As sample collection occurs prior to infusion/dose 3, please provide:

- Scheduled date of infusion 3
- Anticipated total IFX dose, in mg, to be administered
- Estimated patient weight, in kg, at infusion 3

Example orders are provided for illustrative purposes only.

☒ ResponDr[®] TNF[†] (#4200)

Patient Weight at Sample Collection (REQUIRED)*

Weight in kg (kg = lbs ÷ 2.2)	67.9 kg	Note: Patient must be ≥35 kg at time of sample collection.
----------------------------------	---------	---

☒ PredictrPK[®] IFX Maintenance (#3400)

Current Intravenous (IV) IFX Dosing (REQUIRED)*

Last Infusion (mm/dd/yyyy)	04/09/2025	Interval (weeks)	<input type="checkbox"/> 4 <input type="checkbox"/> 6 <input checked="" type="checkbox"/> 8
Total Dose (mg) e.g. 485 mg	400 mg	Weight (kg) kg = lbs ÷ 2.2	78.2 kg

☒ PredictrPK[®] IFX Induction (#3500)

IFX Intravenous (IV) Induction Dosing (REQUIRED)*

	Infusion Date (mm/dd/yyyy)	Total Dose (mg) e.g. 485 mg	Weight (kg) kg = lbs ÷ 2.2
Dose 1	07/18/2025	250 mg	42.7 kg
Dose 2	08/01/2025	250 mg	43.1 kg
Dose 3*	08/29/2025	350 mg	44.2 kg

REQUIRED 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.
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 analytically and clinically validated by Prometheus Laboratories Inc. under federal Clinical Laboratory Improvement Amendments (CLIA) guidelines, and are performed exclusively in our high complexity CLIA certified and College of American Pathologists accredited clinical laboratory. As laboratory developed tests, they have not been cleared or approved by the US FDA. The tests may be covered by one or more US pending or issued patents - see prometheuslabs.com/patents. Prometheus, Anser, IBD sgi Diagnostic, Monitr, PredictrPK and ResponDr are registered trademarks of Prometheus Laboratories Inc, San Diego, California. All other trademarks or service marks are the property of their respective owners. ©2025 Prometheus Laboratories Inc. All rights reserved.