DISEASE MONITORING REQUISITION

PredictrPK® Anser® Monitr® RiskImmune®

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 RiskImmune® 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

PredictrPK® Testing

Precision-guided dosing, with PredictrPK®, requires patient-specific inputs. For assistance providing the required information, please refer to page 2 of this requisition or contact Prometheus client services at 888-423-5227.

Failure to provide the required data, at the time of ordering, may result in reporting delay/possible cancellation. Please be as precise as possible.

☐ PredictrPK® IFX Induction (#3500)

In adult and pediatric IBD patients, estimates IFX levels at 4-, 6- and 8-weeks post induction dose 3; and measures serum IFX, ATI and albumin at time of sample collection.

Serum collection: ≤3 days prior to IFX induction dose 3.

Induction Dosing Information: (ALL SECTIONS REQUIRED)

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

*Dose 3: Provide scheduled infusion date, estimated total dose & estimated patient weight

☐ PredictrPK® IFX Maintenance (#3400)

In adult and pediatric IBD patients, estimates IFX trough levels with current & alternative dosing regimens; and measures serum IFX, ATI and albumin at time of sample collection.

Serum collection: After ≥14 weeks of continuous IFX therapy, serum can be collected ≤3 days prior to week 14 or ≥20 days after the last maintenance infusion, up to and including trough.

Last Administered IFX Infusion: (ALL SECTIONS REQUIRED)

Interval (q x weeks): ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ Other: _____

/ /	mg	kg
Date of Last Infusion (mm/dd/yyyy)	Total Dose in mg (e.g. 485 mg)	Weight in kg (kg = lbs ÷ 2.2)

☐ PredictrPK® ADA Maintenance (#3700) New

In adult Crohn's disease patients, measures ADA clearance, serum ADA, ATA and albumin at time of sample collection; and estimates ADA levels with alternative dosing regimens.

Serum collection: After 8 weeks of continuous, on-time, ADA therapy, serum can be collected anytime within the injection interval.

Current ADA Dosing: (ALL SECTIONS REQUIRED)

Interval (days): ☐ 7 ☐ 14 ☐ Other: _____		/ /
Dose (mg): ☐ 40 ☐ 80		Date of Last Injection (mm/dd/yyyy)

☐ 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

☐ RiskImmune® (#3600) Acknowledgment of informed consent required.

Aids in predicting risk of antibody formation to IFX, ADA or biosimilars.

☐ Monitr® Crohn's Disease (#7300)

Assesses endoscopic disease activity in CD patients ≥18 years old.

Specimen collection requirements on back.

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
PredictrPK IFX Induction, Maintenance (3 days)	Ambient or cold pack acceptable	SERUM	Serum Separator Tube or Red-Top Tube	2.0 mL (1.0 mL for Peds)	Room temperature or refrigerated Do not freeze	Room temp: 14 days Refrigerated: 14 days
PredictrPK ADA Maintenance (3 days)	Ambient or cold pack acceptable	SERUM	Serum Separator Tube or Red-Top Tube	2.0 mL	Room temperature or refrigerated Do not freeze	Room temp: 7 days Refrigerated: 9 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
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
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

[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.**

PredictrPK®

IMPORTANT ORDERING INFORMATION

PredictrPK IFX Induction (#3500), IFX Maintenance (#3400) and ADA Maintenance (#3700) are precision-dosing tests that require patient-specific inputs. All information requested, in their respective sections on page one, must be provided for specimen to be tested and results reported.

Failure to accurately provide the required data at the time of ordering may result in reporting delay or cancellation.

Pay careful consideration to the following sections for PredictrPK IFX Induction and PredictrPK IFX Maintenance:

For "Total Dose in mg" section(s), we CANNOT accept derived dosing such as "5 or 10 mg/kg"

- Total IFX dose administered at designated infusion in mg (e.g. "485 mg").
- If not all IFX in a vial is given, estimate the total dose to the nearest 5 mg. Note: You may need to request this information from the infusion center.

For the "Weight in kg" section(s):

- Patient's weight, in kilograms (kg), at time of infusion.
- Formula for reference: kg = lbs ÷ 2.2

PredictrPK® IFX Induction

	Date of Dose 1 (mm/dd/yyyy)	Total Dose in mg (e.g. 485 mg)	Weight in kg (kg = lbs ÷ 2.2)
Dose 1	04 / 09 / 2022	485 mg	91.6 kg

PredictrPK® IFX Maintenance

Date of Last Infusion (mm/dd/yyyy)	Total Dose in mg (e.g. 485 mg)	Weight in kg (kg = lbs ÷ 2.2)
04 / 09 / 2022	485 mg	91.6 kg

EXAMPLE

ACKNOWLEDGMENT OF INFORMED CONSENT FOR GENETIC TESTING (REQUIRED FOR RISKIMMUNE® 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.