PRECISION-GUIDED CARE REQUISITION

PredictrPK® Anser® Monitr® RiskImmune®

Prometheus Laboratories

All information requested below is REQUIRED to process testing and/or submit insurance claim(s) on your patient's behalf.
Prometheus Client Services | 888-423-5227 | 6:00am - 4:30pm Pacific Time

Patient Information

Last Name: _____

First Name: _____ MI: ____

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

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

Provider Signature

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.

RiskImmune® only: I have read and understand the genetic consent requirement on page two and acknowledge I have obtained consent from my patient.

Signature: _____

Provider Name: _____ Date: _____

Billing Information

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

*Complete all information below AND attach a front/back copy of insurance card(s).

Insurance Carrier: _____ Policy #: _____

Group Name: _____ Group #: _____

Preauthorization/Reference # (if available): _____

Parent/Guardian Name† (if applicable): _____
(†Responsible for payment if patient is less than 18 years old at time of testing.)

Policyholder

If patient is NOT the policyholder, please complete the following

Full Name: _____

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

Phone: _____ Relation to Patient: _____

Provider/Account Information

Account Name/Address:

Phone: Fax:

Provider/NPI (**please clearly select or provide if not listed below**):

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 two 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)

Adult & pediatric IBD: Predicts IFX levels at 4-, 6- & 8-weeks post induction dose 3; measures IFX clearance, 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: Scheduled infusion date, estimated total dose & estimated patient weight

☐ **PredictrPK® IFX Maintenance** (#3400)

Adult & pediatric IBD: Predicts IFX trough levels with current & alternative dosing; measures IFX clearance, serum IFX, ATI and albumin at time of sample collection.

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

Last Administered 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)

Adult Crohn's disease: Predicts ADA levels with alternative dosing; measures ADA clearance, serum ADA, ATA and albumin at time of sample collection.

Serum collection: Anytime within the injection interval after 8 weeks of ADA therapy.

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 & ATI.

☐ **Anser® ADA** (#3170)
Simultaneously measures serum ADA & ATA.

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

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

Select Biologic (OPTIONAL)

Anser IFX Testing
- ☐ **REMICADE®** (infliximab)
- ☐ **INFLECTRA®** (infliximab-dyyb)
- ☐ **AVSOLA®** (infliximab-axxq)
- ☐ **RENFLEXIS®** (infliximab-abda)
- ☐ **Other IFX:** _____

Anser ADA Testing
- ☐ **HUMIRA®** (adalimumab)
- ☐ **Other ADA:** _____

Last Administered Dose: (OPTIONAL)

Last Dose (mm/dd/yyyy):	Dose:	☐mg ☐mg/kg	Interval:	☐days ☐weeks

☐ **RiskImmune®** (#3600) Acknowledgment of informed consent required.
Aids in predicting risk of antibody formation to IFX, ADA and their biosimilars.

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

Specimen collection requirements on page 2.

IFX: infliximab; ATI: antibodies-to-IFX; ADA: adalimumab; ATA: antibodies-to-ADA; VDZ: vedolizumab; ATV: antibodies-to-VDZ; UST: ustekinumab; ATU: antibodies-to-UST

DX.1001v12 (04-2024)

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.

Total Dose in mg

- Total IFX dose administered at designated infusion in mg (e.g. "485 mg").
- We CANNOT accept derived dosing such as "5 or 10 mg/kg"
- If not all IFX in a vial is given, estimate the total dose administered to the nearest 5 mg.
  Note: You may need to request this information from the infusion center.

Weight in kg

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

PredictrPK IFX Induction

Induction Dosing Information: (ALL SECTIONS REQUIRED)			
Dose 1	03 / 10 / 2024	300 mg	55 kg
Dose 2	03 / 24 / 2024	400 mg	57 kg
Dose 3*	04 / 21 / 2024	600 mg	61 kg
	Infusion Date (mm/dd/yyyy)	Total Dose in mg (e.g. 485 mg)	Weight in kg (kg = lbs ÷ 2.2)

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

PredictrPK IFX Maintenance

Last Administered Infusion: (ALL SECTIONS REQUIRED)		
Interval (q x weeks): ☐4 ☐5 ☐6 ☐7 ☒8 ☐9 ☐10 ☐Other:_____		
06 / 25 / 2024	350 mg	68 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

Current ADA Dosing: (ALL SECTIONS REQUIRED)		
Interval (days): ☐7 ☒14 ☐Other:_____		05 / 02 / 2024
Dose (mg): ☒40 ☐80		Date of Last Injection (mm/dd/yyyy)

Example PredictrPK orders provided for illustrative purposes only.

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.

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, PredictrPK, Anser, Monitr and RiskImmune are registered trademarks of Prometheus Laboratories Inc, San Diego, California. All other trademarks or service marks are the property of their respective owners.