DISEASE MONITORING REQUISITION

PredictrPK® Anser® Monitr® RiskImmune®

Prometheus Laboratories

PATIENT INFORMATION

Last Name: _____

First Name: _____ MI: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

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

BILLING INFORMATION

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

SIGNATURE REQUIRED

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

For RiskImmune® testing only: If applicable, my signature below indicates that I have read and understand the genetic consent requirement for my patient on the back page and acknowledge that I have obtained the appropriate consent from my patient.

Provider Signature: _____ **Date:** _____

Provider Name: _____

INSURANCE: Please attach a copy (front and back) of primary & secondary insurance card(s) and complete all information below. **NOTE:** Parent or guardian information is required if patient is a minor. Parent or guardian is responsible for payment.

PREAUTH/REFERENCE #: _____

Name of Parent or Guardian: (If patient is under 18 years of age)

_____

Insurance Carrier: _____ Policy #: _____

Group Name: _____ Group #: _____

Policyholder

Name: _____ Relation to Patient: _____

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

Phone #: _____

PROVIDER/ACCOUNT INFORMATION

Account Name/Address:

Phone #: Fax #:

Provider/NPI #:

SAMPLE COLLECTION INFORMATION

Date Collected (mm/dd/yyyy): ____/____/____ Time Collected: _____ ☐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

Specimen collection requirements on back.

SELECT THE TEST(S) TO BE PERFORMED

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

☐ PredictrPK® IFX Induction (#3500)

Estimates infliximab (IFX) induction concentration at various timepoints for next dosing cycle to support early IFX optimization; and measures serum IFX, antibodies-to-IFX (ATI) and albumin at time of sample collection.

Eligibility: Ordering constitutes attestation that patient has received IFX induction dose 1 and 2 but has not yet received dose 3. Serum collection: ≤3 days prior to dose 3.

Induction Dosing Information: (ALL SECTIONS REQUIRED)

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

For the sections below:
- Total IFX dose at infusion in mg (e.g. 485 mg). We **CANNOT** accept "5 or 10 mg/kg".
- If not all IFX in a vial was given, estimate the total dose to the nearest 5 mg. Note: You may need to request this information from the infusion center.

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

Scheduled date for Induction Dose 3 must be ≤3 days from date of sample collection

Dose 3	Scheduled Date of Dose 3 (mm/dd/yyyy)	Est. Total Dose in mg (e.g. 485 mg)	Est. Weight in kg (kg = lbs ÷ 2.2)
		mg	kg

☐ PredictrPK® IFX Maintenance (#3400)

Estimates infliximab (IFX) maintenance concentration for the next dosing cycle with current dosing regimen and with alternative dose/interval combinations; and measures serum IFX, antibodies-to-IFX (ATI) and albumin at time of sample collection.

Eligibility: Ordering constitutes attestation that patient has received IFX continuously for ≥14 weeks. Serum collection: ≤3 days prior to week 14 dose or ≥20 days after last infusion.

Last Administered IFX Infusion: (ALL SECTIONS REQUIRED)

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

For the section below:
- Total IFX dose at infusion in mg (e.g. 485 mg). We **CANNOT** accept "5 or 10 mg/kg".
- If not all IFX in a vial was given, estimate the total dose to the nearest 5 mg. Note: You may need to request this information from the infusion center.

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

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

☐ Anser® IFX (#3150)

Measures infliximab (IFX) and antibodies-to-IFX (ATI) in serum. Validated for use with:

☐**REMICADE®** (infliximab) ☐**INFLECTRA®** (infliximab-dyyb) ☐**RENFLEXIS®** (infliximab-abda) ☐**AVSOLA®** (infliximab-axxq)

☐ Anser® ADA (#3170)

Measures adalimumab (ADA) and antibodies-to-ADA (ATA) in serum.

☐ Anser® VDZ (#3180)

Measures vedolizumab (VDZ) and antibodies-to-VDZ (ATV) in serum.

☐ Anser® UST (#3190)

Measures ustekinumab (UST) and antibodies-to-UST (ATU) in serum.

Last Administered Dose: (OPTIONAL)

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

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 infliximab, adalimumab or biosimilars.

☐ Monitr® Crohn's Disease (#7300)

13 biomarkers to assess endoscopic disease activity in adult Crohn's disease patients.

SPECIMEN COLLECTION AND HANDLING PROCEDURE

Test Ordered (Turnaround Time)[a]	Transportation Kit Requirements	Specimen Type Required	Tube for Specimen Collection	Recommended Specimen Volume	Storage Conditions	Stability of Specimen
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 refrigerate Do not freeze	Room temp: 14 days Refrigerated: 14 days
Anser • IFX (infliximab) • ADA (adalimumab) • VDZ (vedolizumab) • UST (ustekinumab) **(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 refrigerate 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 refrigerate 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 refrigerate 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.**

IMPORTANT INFORMATION FOR PREDICTRPK IFX

PredictrPK IFX Induction (#3500) and Maintenance (#3400) 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 the "Total Dose in mg" section(s):

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

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.