PredictrPK™ Anser® Monitr® RiskImmune™

Prometheus Laboratories

TEST REQUISITION

PATIENT INFORMATION

Last Name: _____

First Name: _____ MI: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

DOB: ____/____/_____ (MM/DD/YYYY) Sex: ☐ M ☐ F SSN: _____-_____-_____

BILLING INFORMATION

BILL: ☐ Provider account ☐ Insurance ☐ Laboratory ☐ Patient

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.

Provider Signature: _____ Date: _____

Print Name: _____

PRIMARY INSURANCE: As a courtesy, we will bill your insurance. Please attach a copy (front and back) of 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.**

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

_____

Insurance Carrier: _____ Policy #: _____

Group Name: _____ Group #: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone #: _____ Fax #: _____

Policyholder Name: _____

Policyholder ID # (SSN): _____

Policyholder DOB: ____/____/_____ (MM/DD/YYYY) Relation to Patient: _____

Policyholder Phone #: _____

SECONDARY INSURANCE: Attach a copy (front and back) of the secondary insurance card. Provide the insurance name, policy number and group name, billing address and phone, policyholder name, ID #, date of birth, relation to patient, and phone number.

PREAUTH/REFERENCE #: _____

ACKNOWLEDGMENT OF INFORMED CONSENT FOR GENETIC TESTING

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/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

ICD CODES(S):

Primary Code							
1		2		3		4	

SELECT THE TEST(S) TO BE PERFORMED

☐ PredictrPK™ IFX (#3400) — New

Estimates infliximab (IFX) level in serum at next maintenance trough given current dose/interval and alternative dose/intervals. Measures antibodies to IFX, IFX levels and albumin at the time of sample collection.

Dose Information: **All information required**

☐ Yes, this patient has received IFX continuously (no drug holiday) for at least 14 weeks and sample was collected ≥ 20 days post infusion.

Date of last infusion: ____/____/_____ (MM/DD/YYYY)

Dose (total mg): _____ (e.g. 500 mg)

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

☐ Other, please specify _____

Weight: _____ kg (e.g. 59.1 kg = 130 lbs ÷ 2.2 lbs/kg)

Anser®

☐ Anser IFX (#3150)

Measures infliximab (IFX) and antibodies-to-infliximab (ATI) levels in serum. Validated for use in patients treated with these medications:

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

☐ Anser ADA (#3170)

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

☐ Anser VDZ (#3180)

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

☐ Anser UST (#3190)

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

Dose Information: (Optional)

Infusion/Injection Date: ____/____/_____ (MM/DD/YYYY)

Dose: _____ mg or _____ mg/kg

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

☐ Other, please specify _____

☐ Monitr® Crohn's Disease (#7300)

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

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

Aids in predicting risk of antibody formation to infliximab, adalimumab or biosimilars.

Specimen collection requirements on back.

SPECIMEN COLLECTION AND HANDLING PROCEDURE

Test Ordered (Turnaround Time From Date of Receipt)[a]	Transportation Kit Requirements	Type of Specimen Required	Tube for Specimen Collection	Recommended Specimen Volume	Storage Conditions	Stability of Specimen
PredictrPK IFX (3 days)	Refrigeration preferred, ship with cold packs	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: 3 days Refrigerated: 3 days
Anser (ADA, IFX, 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 refrigerate Do not freeze	Room temp: 7 days Refrigerated: 9 days
Monitr (4 days)	Refrigeration preferred, ship with cold pack	SERUM	**SPUN** Serum Separator Tube	2.0 mL	Room temperature or refrigerate Do not freeze	Room temp: 3 days Refrigerated: 14 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

[a] Business Days

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, and requisition, accession, or unique random number. Unlabeled specimens will not be accepted for testing.

IMPORTANT INFORMATION FOR PREDICTRPK

PredictrPK is a precision-dosing test that requires patient-specific inputs for testing to occur. **All information requested in the PredictrPK box on the first page must be provided for specimen to be tested and results reported.** The patient must have received IFX therapy continuous for at least 14 weeks (specimen should be collected 20 days or more after last infusion) and the date of the last/most recent infusion is required. The dose should be the total mg provided at last infusion. The interval is the anticipated number of weeks between the last infusion and the next infusion upcoming. Weight should be provided in kg.

SHIPPING INSTRUCTIONS: Prometheus has an agreement with FedEx Express for priority overnight delivery service within the United States and Canada. Please call FedEx to schedule a pickup at 1-800-GoFedEx (463-3339). 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.**

ACKNOWLEDGEMENT OF INFORMED CONSENT

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.