

PLEASE PRINT

SAMPLE COLLECTION INFORMATION

DATE COLLECTED (required): _____

TIME COLLECTED: _____

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 #: _____

CONTACT: _____

RESULTS: Mail Fax No results to lab

PATIENT INFORMATION (REQUIRED)

LAST NAME: _____

FIRST NAME: _____ MI: _____

ADDRESS: _____ APT #: _____

CITY: _____ STATE: _____ ZIP: _____

HOME PHONE #: _____

OTHER PHONE #: _____

DOB: _____ SEX: M F SSN: _____

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: _____

BILLING INFORMATION (REQUIRED)

BILL: Provider account Insurance Laboratory Patient

MEDICARE - MEDICAL NECESSITY NOTICE: When ordering tests for which Medicare reimbursement will be sought, physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient, rather than for screening purposes.

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

ORDERING PROVIDER'S 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: _____ 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 #: _____

PROVIDER/ACCOUNT INFORMATION

ACCOUNT NAME/ADDRESS: _____

PHONE #: _____ FAX #: _____

PROVIDER/NPI #: _____

ICD CODE(S) (required):

| | | | |
|--------------|---|---|---|
| Primary Code | | | |
| 1 | 2 | 3 | 4 |

CLINICAL DIAGNOSIS: _____

ANSER REASON FOR ORDER (PLEASE SELECT ONE):

- Midinduction level Secondary loss of response Restart after drug holiday
 Postinduction level Infusion/allergic reaction Side effects
 Primary nonresponse Maintenance (asymptomatic)

MUST PROVIDE DOSAGE INFORMATION

Infusion/Injection Date: _____ / _____ / _____
Dose: _____ mg or _____ mg/kg
Frequency: Every _____ weeks

SELECT THE APPROPRIATE TEST TO BE PERFORMED

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.

Monitr Crohn's Disease—#7300

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

RiskImmune—#3600†

Aids in predicting risk of antibody formation to infliximab, adalimumab or biosimilars (By selecting an ADD option below, you are ordering a conditional add-on test following a RiskImmune result consistent with an increased risk of antibody formation to infliximab or adalimumab.)

- ADD TPMT Genetics - #3300†**
 ADD TPMT Enzyme - #3320

TPMT Genetics—#3300†

TPMT Enzyme—#3320

Thiopurine Metabolites—#3200†

Current therapeutic:
 6-MP _____ mg/day AZA _____ mg/day Other _____ mg/day

If billing differs from Anser for other test(s) ordered, please list test name(s) below and select which entity should be billed separately.

Test Name(s) _____

Bill to:

- Provider Account Patient Medicare Insurance Laboratory

† Acknowledgment of informed consent for NY state. Specimen collection requirements on back.

SPECIMEN COLLECTION AND HANDLING PROCEDURES

| 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 |
|--|--|------------------------------|---|--------------------------------|--|---|
| 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 <u>Do not freeze</u> | Room temp: 7 days Refrigerated: 9 days |
| Monitr Crohn's Disease (4 days) | Refrigeration preferred, ship with cold pack | SERUM | SPUN Serum Separator Tube | 2.0 mL Serum | Room temperature or refrigerate <u>Do not freeze</u> | Room temp: 3 days Refrigerated: 14 days |
| RiskImmune (4 days) | Ambient or cold pack acceptable | WHOLE BLOOD | EDTA/Lavender- Top Tube | 2.0 mL Whole Blood | Room temperature or refrigerate <u>Do not freeze</u> | Room temp: 10 days Refrigerated: 30 days |
| TPMT Genetics (4 days) | Ambient or cold pack acceptable | WHOLE BLOOD | EDTA/Lavender- Top Tube | 2.0 mL Whole Blood | Room temperature or refrigerate <u>Do not freeze</u> | Room temp: 10 days Refrigerated: 30 days |
| TPMT Enzyme (3 days) | Refrigerated preferred, ship with cold pack | WHOLE BLOOD | EDTA/Lavender- Top Tube | 5.0 mL Whole Blood | Room temperature or refrigerate <u>Do not freeze</u> | Room temp: 24 hours Refrigerated: 8 days |
| Thiopurine Metabolites (3 days) | Refrigerated preferred, ship with cold pack | WHOLE BLOOD | EDTA/Lavender- Top Tube | 5.0 mL Whole Blood | Room temperature or refrigerate <u>Do not freeze</u> | Room temp: 24 hours Refrigerated: 8 days |

^aBusiness 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.

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):

- 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.
- 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.
- 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.
- 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.
- The patient understands that a positive test result is an indication that the patient may be predisposed to, or have, the condition listed above.
- 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.
- No unauthorized test is performed on specimens.
- NY-state specimens will be destroyed within 60 days after collection when no longer required for clinical purposes.
- The informed consent does not authorize the use or release of any other identified medical information unrelated to this genetic test.
- 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.

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