CDPATH™
PERSONALIZED PROGNOSTIC TOOL

TEST REQUISITION

PLEASE PRINT *DENOTES REQUIRED FIELD

SAMPLE COLLECTION INFORMATION

DATE COLLECTED*:

TIME COLLECTED:

PATIENT ID:

SENDER SAMPLE ID:

PROVIDER/ACCOUNT INFORMATION

ACCOUNT NAME/ADDRESS*:

PHONE*: FAX*:

PROVIDER/NPI*:

SENDING LABORATORY INFORMATION

LABORATORY/OTHER NAME/ADDRESS*:

PHONE*: FAX*:

CONTACT:

RESULTS*: ☐ Mail ☐ Fax ☐ No results to lab

PATIENT INFORMATION

LAST NAME*:

FIRST NAME*: MI:

ADDRESS: APT #:

CITY: STATE: ZIP:

HOME PHONE:

OTHER PHONE:

DOB*: mm / dd / yyyy SEX* ☐ M ☐ F

NOTE: CDPATH test can only be run on adult Crohn's disease patients (≥ 18 years old).

PRESCRIBER ATTESTATION*

My signature below indicates:

ACKNOWLEDGMENT OF INFORMED CONSENT FOR GENETIC TESTING
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.

ACKNOWLEDGMENT OF CLINICAL EXPERIENCE TESTING
I am ordering this test under a limited clinical experience testing program and I will not seek payment for or accept reimbursement from any third-party payer for this test. I attest that the patient receiving this testing is not covered by any government program such as Medicare, Medicaid, Department of Veteran's Affairs, Coast Guard, Public Health Service, Department of Defense or any similar or affiliated program.

ACKNOWLEDGMENT OF PATIENT DATA & RISK PROFILE USE
I have informed the patient that his/her data and risk profile will be used to characterize use of CDPATH™ in the real world setting.

PROVIDER SIGNATURE: _____ **DATE:** _____

CDPATH TESTING ONLY. NO SUBSTITUTIONS.

CHECK BOX ON LEFT NEXT TO TEST BEING ORDERED.

☐ CDPATH — #2050

CLINICAL DIAGNOSIS

ICD-10 code*: **Date of Crohn's Diagnosis*:** mm / dd / yyyy

DISEASE HISTORY

Does patient have a history of disease related complications?* ☐ Yes ☐ No

DISEASE LOCATION(S)

Small Bowel*	☐ **Present**	☐ **Absent**
Left Colon*	☐ **Present**	☐ **Absent**
Perianal*	☐ **Present**	☐ **Absent**
Upper GI Tract	☐ Present	☐ Absent
Right Colon	☐ Present	☐ Absent
Transverse Colon	☐ Present	☐ Absent

CDPATH RISK ASSESSMENT TEST INCLUDES:

Serologic Biomarkers		**Genetic Biomarkers**
ASCA IgA	Anti-CBir1 IgG	NOD2 (1007FS)
ASCA IgG	pANCA IFA	

Terms and Conditions: CDPATH is only validated in and can only be run on adult Crohn's disease patients (≥ 18 years old), diagnosed within the past ten (10) years, who have not experienced a Crohn's disease complication such as blockages, strictures or fistulas. Any requisitions which fail to meet these requirements will be canceled upon receipt. Beneficiaries of any state or federal health insurance program (including, but not limited to, Medicare, Medicaid, Department of Veteran's Affairs, Coast Guard, Public Health Service or Department of Defense) are excluded from participating in this program. Void where prohibited by law. Takeda reserves the right to change or end CDPATH at any time without notice, and other terms and conditions may apply. This test cannot be substituted for or combined with any other test and is only offered for a one-time use. By using the CDPATH test requisition, you are specifically requesting that your patient's specimen be sent to Prometheus Laboratories Inc. for testing and asking that no alternative test be performed.

Attention Laboratory

- Takeda has made arrangements with the healthcare practitioner (HCP) listed above to provide the CDPATH test at no charge in order for the HCP to gain clinical experience with the test.
- Only CDPATH can be ordered using this form.
- Please do not collect or process any insurance claims for this test.
- NO CHARGES should be billed to the patient for this test. Prometheus will not bill for testing or services related to testing.
- Specimen transportation kits containing pre-paid air bills can be provided upon request.

Questions

Contact CDPATH Client Services at Prometheus Laboratories Inc.
Monday - Friday 6:00am - 4:30pm Pacific Standard Time Toll-free:
877-556-8766 • Fax: 877-816-4019
9410 Carroll Park Drive, San Diego, CA 92121
www.prometheuslabs.com

Specimen collection requirements on back.

Takeda
Program sponsored by
Takeda Pharmaceuticals U.S.A., Inc.

Prometheus Laboratories
Laboratory Developed Test by
Prometheus Laboratories Inc.

SPECIMEN COLLECTION AND HANDLING PROCEDURES

Test Ordered Turnaround Time From Sample Collection Date	Specimen Requirements	Recommended Specimen Volume	Specimen Storage/Stability	Transportation Kit Requirements
CDPATH **7 business days**	SERUM **AND** WHOLE BLOOD in Spun Serum Separator or Red-Top Tube **AND** EDTA/Lavender-Top Tube	2.0 mL serum AND 2.0 mL whole blood	Room temp: 7 days	Ambient pack

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 Laboratories Inc. has an agreement with UPS® for priority overnight delivery service within the United States and Canada. Please call UPS to schedule a pickup at 1-800-PICK-UPS (1-800-742-5877). UPS will pick up your specimens and ship them to Prometheus Laboratories Inc. in San Diego at no expense to you. Prometheus Laboratories Inc. will provide specimen transportation kits upon request.

For more information, call CDPATH Client Services at 877-556-8766

ACKNOWLEDGEMENT OF INFORMED CONSENT FOR GENETIC 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. If the results are positive, the patient understands that he/she may wish to consider further independent testing, consult his/her provider, or pursue genetic counseling.
7. 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.
8. No unauthorized test is performed on specimens.
9. Specimens will be destroyed within 60 days after collection when no longer required for clinical purposes.
10. The informed consent does not authorize the use or release of any other identified medical information unrelated to this genetic test.
11. 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.

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