# CDPATH™ TEST REQUISITION

www.CDPATH.com

PLEASE PRINT LEGIBLY

MISSING INFORMATION COULD RESULT IN TEST CANCELLATION

## 1 PROVIDER INFORMATION

Account Name _____

Address _____

_____

Phone _____ Fax _____

Provider Name _____

NPI# _____

Results Delivery Preference ☐ Fax ☐ Mail

## 2 PRESCRIBER ATTESTATIONS

My signature below indicates:

**ACKNOWLEDGMENT OF INFORMED CONSENT FOR GENETIC TESTING**
I have reviewed and obtained the proper genetic consent required from my patient for the state in which I practice (NY state requirements provided on back page of form).

**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 Veterans 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 _____

## 3 PATIENT INFORMATION

Last Name _____ First Name _____ DOB _____ Sex ☐ F ☐ M

Address Line 1 _____ Address Line 2 _____

Patient **MUST** be ≥18 years old with Crohn's disease

City _____ State _____ ZIP _____

Primary Phone _____ Secondary Phone _____

## 4 CDPATH™ TESTING ONLY. NO SUBSTITUTIONS.

**CHECK BOX BELOW TO ORDER CDPATH TEST**

☐ CDPATH – #2050

MUST COMPLETE ALL BOXES TO ORDER CDPATH TEST

### CLINICAL DIAGNOSIS

ICD-10 code (must be Crohn's disease code): _____

Date of Crohn's diagnosis: mm / dd / yyyy

If diagnosed >10 years ago, patient is **NOT** eligible → STOP

### DISEASE HISTORY

*Does patient have a history of serious complications?*

- bowel strictures
- internal penetrating disease
- non-perianal surgery, such as bowel resection or stricturoplasty

☐ YES → If YES, patient is **NOT** eligible → STOP

☐ NO

### DISEASE LOCATION(S)

Must check **PRESENT** or **ABSENT** for each based on **greatest extent** of disease since diagnosis

| | Present | Absent | | Present | Absent | | Present | Absent |
|---|---|---|---|---|---|---|---|---|
| Small bowel | ☐ | ☐ | Perianal | ☐ | ☐ | Right colon | ☐ | ☐ |
| Left colon | ☐ | ☐ | Upper GI tract | ☐ | ☐ | Transverse colon | ☐ | ☐ |

### CDPATH RISK-ASSESSMENT TEST INCLUDES:

(No selection required)

Serologic Biomarkers
- ASCA IgA
- ASCA IgG
- Anti-CBir1 IgG
- pANCA IFA

Genetic Biomarkers
- NOD2 (1007FS)

**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 Veterans 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.

## 5 SAMPLE COLLECTION INFORMATION

Date Collected _____

Time Collected _____

Patient ID _____

Sender Sample ID _____

## 6 SENDING LABORATORY INFORMATION

Laboratory/Other Name _____

Address _____

Phone _____ Fax _____

Contact _____

Results Delivery Preference ☐ Fax ☐ Mail ☐ No results to lab

## 7 ATTENTION LABORATORY

- Takeda has made arrangements with the healthcare provider (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.

Takeda

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

Prometheus Laboratories

Laboratory Developed Test by
Prometheus Laboratories Inc.

### QUESTIONS?

Contact CDPATH Client Services at Prometheus Laboratories Inc.
Monday - Friday, 6:00 AM - 4:30 PM Pacific Standard Time
Toll-free: 877-556-8766 • Fax: 877-816-4019
9410 Carroll Park Drive, San Diego, CA 92121
**Specimen collection requirements on back.**

# 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<br>7 business days | SERUM **AND** WHOLE BLOOD in Spun Serum Separator or Red-Top Tube **AND** EDTA/Lavender-Top Tube | 2.0 mL serum<br>AND<br>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 FedEx® Express for priority overnight delivery service within the United States. Please call FedEx to schedule a pickup at 1-800-GoFedEx (1-800-463-3339). FedEx will pick up your specimens and ship them to Prometheus 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.

**ACKNOWLEDGMENT OF INFORMED CONSENT FOR GENETIC TESTING**

Please confirm the genetic testing requirements in your state prior to signing the acknowledgment on the first page.

**If you are practicing in New York State**, the following information reflects the New York State's requirements for informed 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).

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.

## QUESTIONS?

**Contact CDPATH Client Services at 877-556-8766**

**Operating hours: Monday - Friday, 6:00 AM - 4:30 PM Pacific Standard Time**



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