CDPATH

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FREQUENTLY ASKED QUESTIONS

Takeda

FREQUENTLY ASKED QUESTIONS

Click to jump to the answer

About CDPATH & Program Partners

- What is CDPATH?
- How was the CDPATH model developed and validated?
- What are the model variables?
- Are there any limitations of the CDPATH model?
- Why is Takeda offering this at no cost to eligible patients?
- What is the relationship between Takeda, Prometheus Laboratories Inc., Quest Diagnostics and MiTest Health?

Considering CDPATH

- How should a health care provider (HCP) determine if CDPATH is the appropriate clinical decision tool to use with their patient living with Crohn's disease (CD)?
- How is CDPATH different from other prognostic tools currently available for Crohn's disease in the US (such as PROMETHEUS® Crohn's Prognostic)?
- How are CDPATH and the prognostic tool called PROSPECT connected?
- What does CDPATH offer an HCP that they can't get by ordering serologic and genetic tests separately?

Availability, Eligibility & Cost

- Where is CDPATH available?
- Who is eligible?
- Can CDPATH be run on a patient more than once?
- Was CDPATH tested in a diverse population?
- Can CDPATH be used with pediatric patients?
- Does medication affect CDPATH eligibility and/or results?
- Why is CDPATH only available to patients within 10 years of diagnosis?
- How much does CDPATH cost?
- Can CDPATH be used with a patient population on state or federal health insurance programs (like Medicare/Medicaid)?
- Can patients who are on a state or federal health insurance program (like Medicare/Medicaid) pay for CDPATH out-of-pocket?

Testing Process

- Why is date of diagnosis, disease location, disease history, and an ICD 10 code required for the test?
- What disease location should be selected on the CDPATH test requisition form if a patient has had different disease locations over time?
- Where can a patient get their blood drawn at no cost?
- How can one find a participating phlebotomy location?
- Can a patient be sent to a hospital lab or in-office phlebotomist without the patient being charged for phlebotomy services?
- How long are blood samples kept by the processing laboratory?

Understanding/Using CDPATH Results

- How do patients and HCPs obtain CDPATH results?
- How were the low-, medium-, and high-risk ranges determined?
- Why is the CDPATH profile over the course of 3 years?
- How accurate of a risk predictor is CDPATH?
- How does one use CDPATH results?
- Who owns the CDPATH results data?

Getting More Information/Support

- How do HCPs and patients get started with CDPATH?
- Where can one get CDPATH program operational support?

About CDPATH

Click here to return to full FAQ list.

What is CDPATH?

CDPATH is a validated* risk assessment tool that helps adult patients living with Crohn's disease (CD) understand their potential risk for developing serious complications† within three years.

A personalized risk profile, combined with a health care provider's (HCP) clinical assessment, can facilitate more collaborative discussions about disease management.

How was the CDPATH model developed and validated?

CDPATH has been approved as a Laboratory Developed Test (LDT)* – a designation resulting from a multi-step process:

INDEPENDENT CLINICAL STUDY

first
THE MODEL WAS DEFINED

Through a Calibration Cohort[1]

The model was defined using a well-characterized calibration cohort of 243 adult patients (18 years and older) with Crohn's disease diagnosed within the last 15 years to identify statistically significant variables that predicted the potential of serious Crohn's disease-related complications within three years.†‡

next
CLINICAL RELEVANCE WAS ESTABLISHED

Through a Validation Cohort[1]

A well-characterized adult cohort of 109 patients with Crohn's disease who were within 15 years of diagnosis without a previous serious complication confirmed the clinical relevancy of the model.†‡

MODEL VALIDATION

finally
THE MODEL WAS DEVELOPED AND VALIDATED

By Prometheus Laboratories as a Laboratory Developed Test[2]

*The CDPATH risk assessment tool was developed and validated by Prometheus Laboratories Inc., a certified Clinical Laboratory Improvement Amendments (CLIA) laboratory and partner of Takeda, as a Laboratory Developed Test (LDT).

Prometheus Laboratories used calibration (N=106) and validation (N=32) cohorts of adult CD patients within 10 years of diagnosis without previous serious complications† to establish analytical and clinical validity in their validation process.

Prometheus Laboratories Inc. has received approval for CDPATH from the New York State Department of Health (NYS DoH) as an LDT.

†Serious complications are defined as bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty).

‡Patients were excluded if they had a complication at the time of diagnosis.

What are the model variables?

CDPATH analyzes patient characteristics, serologic factors, and a genetic factor to assess individual potential risk.[2]

PATIENT CHARACTERISTICS†	Capturing time from diagnosis is required to ensure CDPATH eligibility and serve as a baseline hazard function.	Time from diagnosis	Time between time of diagnosis and specimen collection (in months).
	Assessing an accurate disease location is required because where the disease occurs may determine the likelihood for complication(s) to occur.[3]	Small bowel disease	Describes CD located in the small intestine.
		Colonic disease	Describes CD located in the large intestine (right colon, transverse colon, left colon). Left colonic disease is the disease location element part of CDPATH.
		Perianal disease	Describes CD located at or near the anus.
		Upper GI disease*	Describes CD located in the stomach and esophagus
SEROLOGIC FACTORS	Measures of antibodies in the blood that may predict disease course.[4]	ASCA IgA ELISA ASCA IgG ELISA	A measure of antibodies in the immune system most often seen in patients with CD. There are two types of ASCA antibodies, IgG and IgA.
		pANCA IFA	A measure of antibodies against certain types of white blood cells most often seen in patients with UC.
		Anti-CBir1 IgG	A measure of antibodies that are produced by the immune system most often seen in patients with CD.
GENETIC FACTORS	A genetic factor may identify the likelihood of developing serious CD-related complications (defined as bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty).[3,5]	*NOD*2 SNP13 (1007fs)	A genetic factor that can be found in patients with CD.

*Upper GI disease is collected on the CDPATH test requisition but is not part of the CDPATH algorithm.

†Additional information collected on the test requisition but are NOT a part of the CDPATH algorithm: Crohn's diagnosis code, history of serious complications (defined as defined as bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty). gender, date of birth. This information is collected to verify CDPATH eligibility and contextualize report results.

ASCA=anti-Saccharomyces cerevisiae antibody; CBir1=anti-flagellin; CD=Crohn's disease; ELISA=enzyme-linked immunosorbent assay; GI=gastrointestinal; *NOD*2=nucleotide-binding oligomerization domain-containing protein 2; pANCA=perinuclear anti-neutrophil cytoplasmic antibody; SNP=single nucleotide polymorphism.

About CDPATH

Click here to return to full FAQ list.

Are there any limitations of the CDPATH model?

Testing was conducted only with patients from North America; the results for patients from other regions have not been established.[1]

Patients were recruited from large referral centers and may not be representative of all patients with Crohn's disease (CD).[1]

The validity of the model after the first complication* or surgery has not been tested or established; therefore, CDPATH may only be used one time for each patient.[1]

The model was built and established in patients who have had CD for up to 15 years. It is not understood whether the model is applicable to patients with long-standing CD beyond 15 years from diagnosis.[1]

When the model was validated by Prometheus Laboratories as a Laboratory Developed Test (LDT)†, only patients who had been diagnosed within 10 years were included,[2] therefore CDPATH is only approved for patients diagnosed within 10 years.

Why is Takeda offering this at no cost to eligible patients?

Takeda is offering CDPATH at no cost to eligible patients* as a demonstrated commitment to improving patient outcomes.

CDPATH is not affiliated or linked to any Crohn's disease treatments or drugs and test results do not provide any such recommendations. Results are intended to be used in combination with an HCP's clinical assessments to facilitate discussions with their patients regarding their Crohn's disease management.

What is the relationship between Takeda, Prometheus Laboratories Inc., Quest Diagnostics and MiTest Health?

Takeda is the sponsor for the CDPATH program and has partnered with MiTest Health and Prometheus Laboratories Inc. to bring CDPATH to market, providing access to HCPs and eligible patients at no charge.

Prometheus Laboratories Inc. is responsible for the development and validation of the Laboratory Developed Test (LDT) filing[2] under Clinical Laboratory Improvement Amendments (CLIA) and is the processing laboratory for CDPATH.

MiTest Health is a scientific consultant for Takeda and a key partner in the commercialization of the CDPATH Personalized Prognostic Tool.

Quest Diagnostics Patient Service Centers are within the network of participating locations where patients can have their blood drawn for CDPATH at no cost.

*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. 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. No insurance claims should be collected or processed, and no charges should be billed to the patient for CDPATH and shipping. Takeda has made arrangements with the processing laboratory to directly cover these charges. 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.

Considering CDPATH

Click here to return to full FAQ list.

How should an HCP determine if CDPATH is the appropriate clinical decision tool to use with their patient living with Crohn's disease (CD)?

A healthcare professional (HCP) should use their clinical assessment and patient's preferences when evaluating the most appropriate prognostic test to use. CDPATH may be a good fit, provided the patient meets all eligibility criteria.

How is CDPATH different from other prognostic tools currently available for Crohn's disease in the US (such as PROMETHEUS® Crohn's Prognostic)?

CDPATH uses a unique algorithm that incorporates patient characteristics, serologic factors, and a genetic factor to assess a patient with Crohn's disease individualized risk profile for developing serious complications* within 3 years.[2]

Prometheus Crohn's Prognostic evaluates serologic and genetic factors in a blood test that quantifies a patient's individual probability of developing disease complications over time (10 years). It is not offered free of charge nor does the test factor in clinical measures.[6,7]

How are CDPATH and the prognostic tool called PROSPECT connected?

CDPATH and the prognostic tool PROSPECT are the same. The organization known as MiTest Health developed the personalized risk assessment model and called it PROSPECT. Takeda began licensing the model in 2018 and the name was changed in 2020 to CDPATH.

What does CDPATH offer an HCP that they can't get by ordering serologic and genetic tests separately?

An HCP can order serologic and genetic tests separately, but these will not provide the individualized risk profile presented in the CDPATH test report.

HCP Portrayal

Availability, Eligibility & Cost

Click here to return to full FAQ list.

Where is CDPATH available?

CDPATH is currently available nationwide for use by US-based health care providers.

Who is eligible?

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. 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.

Can CDPATH be run on a patient more than once?

CDPATH may only be used one time for each patient. CDPATH has not been tested in the same patient more than once, so its applicability with patients who have already received previous CDPATH results has not been established.

Was CDPATH tested in a diverse population?

The CDPATH model was tested in patient cohorts with varying characteristics, including but not limited to, age, disease duration, and disease location.[1]

Can CDPATH be used with pediatric patients?

At this time, the CDPATH risk assessment tool has only been developed and validated by Prometheus Laboratories Inc., a partner of Takeda, as a Laboratory Developed Test (LDT) in patients 18 years and older. Prometheus has received LDT approval from the New York State Department of Health (NYS DoH).[2]

The independent clinical study for CDPATH did validate the tool in pediatric patients, but as mentioned, CDPATH is currently only approved for use among adult patients living with Crohn's disease.

Does medication affect CDPATH eligibility and/or results?

No, medication does not affect CDPATH results. In the independent clinical study used to design the CDPATH model, exploratory analyses of the associations between medication exposure and the primary outcome were performed. Medication exposure was not identified as a significant variable impacting risk of potential future complication and was thus not included in the model nor is it an eligibility consideration. Based on Harrell's C-statistic, the current model and the factors assessed present a good predictor of risk. The clinical validity of the CDPATH was further established by Prometheus Laboratories.[1,2]

Why is CDPATH only available to patients within 10 years of diagnosis?

The model was built and validated in patients who have had Crohn's disease for up to 15 years. However, when the model was validated by Prometheus Laboratories as a Laboratory Developed Test (LDT), only patients who had been diagnosed within 10 years were included.[1,2]

Availability, Eligibility & Cost

Click here to return to full FAQ list.

How much does CDPATH cost?

Takeda is offering CDPATH at no cost to eligible patients* when participating locations are used for the required blood draw. Participating locations can be found on www.CDPATH.com.

Can CDPATH be used with a patient population on state or federal health insurance programs (like Medicare/Medicaid)?

Unfortunately, at this time, Takeda is unable to offer CDPATH to 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).

However, Takeda is offering CDPATH at no cost to beneficiaries of commercial health care plans or those who are self-pay patients.

Can patients who are on a state or federal health insurance program (like Medicare/Medicaid) pay for CDPATH out-of-pocket?

Not at this time. Since the program is offered at no cost, there is no pathway for a patient who is on a government health care plan (like Medicare/Medicaid) to pay out-of-pocket.

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Why is date of diagnosis, disease location, disease history, and an ICD 10 code required for the test?

This information is necessary to ensure eligibility for CDPATH and is used in the creation of CDPATH's individual risk profile report results.

What disease location should be selected on the CDPATH test requisition form if a patient has had different disease locations over time?

"PRESENT" should be selected on the CDPATH test requisition form for the disease location (or locations) which reflects the greatest extent of the patient's disease at any time **since diagnosis**.

For example, if the most recent colonoscopy shows no active disease, but a prior colonoscopy had disease in the ileum and left colon, "PRESENT" should be selected for ileum and left colon on the CDPATH test requisition form and "ABSENT" for all other disease locations that do not apply.

Where can a patient get their blood drawn at no cost?

Participating locations for required blood draw include Quest Diagnostics Patient Service Centers, Prometheus-contracted phlebotomy sites, and mobile phlebotomy services. The cost of the blood draw, CDPATH, and shipping will be covered at participating location.

The required blood sample CAN be drawn at a non-participating location (e.g., health care provider office) but then only the cost of sample shipping at test processing would be covered. (Phlebotomy charges would not be covered by Takeda.)

How can one find a participating phlebotomy location?

A location finder is available on www.CDPATH.com.

CDPATH client services can also help HCPs and patients find a suitable location.

1-877-556-8766 | Monday–Friday | 6:00 am–4:30 pm Pacific Standard Time (PST)

Can a patient be sent to a hospital lab or in-office phlebotomist without the patient being charged for phlebotomy services?

Contact CDPATH client services to see if there is an arrangement in place with the hospital lab network or in-office phlebotomist. If an arrangement does not exist, the CDPATH client representatives can help provide alternative options.

How long are blood samples kept by the processing laboratory?

Blood samples will be destroyed within 60 days after collection when no longer required for clinical purposes. Please see the back of the CDPATH test requisition form (available in CDPATH specimen collection kits or on www.CDPATH.com) for additional phlebotomy details.

Understanding/Using CDPATH Results

Click here to return to full FAQ list.

How do patients and health care providers (HCPs) obtain CDPATH results?

CDPATH results are provided via Prometheus Laboratories Inc. to HCPs approximately 7 business days from the date of blood sample collection. Results are either faxed or mailed (depending on preference selected on the CDPATH Test Requisition Form). HCPs and patients should arrange a follow-up appointment to review results together.

How were the low-, medium-, and high-risk ranges used in CDPATH determined?

The risk cutoffs were initially defined via qualitative focus groups where patients were asked to define what low, medium, and high risk of a complication meant to them, as well as to quantify the percentage risk for each category.

Sequential focus groups were held where the percent cutoffs for low (0% - 19.9%), medium (20% - 59.9%), and high (≥60%) were presented to patients, and where they agreed that these risks represented clinically meaningful decision points.

Gastroenterologists were consulted to confirm the validity of the risk definitions with universal agreement from participants.[2]

Why is the CDPATH profile over the course of 3 years?

Cox regression analysis in the independent clinical study cohorts and the model validation cohorts revealed significant association between individualized risk assessment scores and CD complications at 3 years.[1,2] The median time to complication in the CDPATH model was 3.3 years (range: 0.3 - 15.7).[1]

How accurate of a risk predictor is CDPATH?

The ability of CDPATH to predict the potential risk of Crohn's disease complications is represented through Harrell's Concordance statistic (C-Statistic). For context, a C-Statistic value of 0.5 is the same as random chance and a value 1 is a perfect prediction. CDPATH demonstrated a consistent range of 0.70 to 0.73[2] across the independent clinical study and model validation, suggesting good predictive accuracy.

How does one use CDPATH results?

CDPATH results are one piece of information - the results are prognostic but not a final conclusion nor a guarantee. As such, HCPs should not rely primarily on the risk predictions from CDPATH to make a clinical diagnosis or treatment decision regarding an individual patient.

CDPATH is not affiliated or linked to any Crohn's disease treatments or drugs. Results are intended to be used in combination with an HCPs clinical assessment to facilitate discussions with their patients regarding their Crohn's disease management.

Disease management considerations may include, but are not limited to, appointment cadence, diet modifications, exercise, supplements, medications, or other approaches.[8-10]

Who owns the CDPATH results data?

Data are owned by Prometheus Laboratories Inc. Any publication would be done jointly by Takeda and Prometheus Laboratories Inc., based on pooled de-identified data.

Testing Process & Program Partners

Click here to return to full FAQ list.

How do HCPs and patients get started with CDPATH?

CDPATH testing for eligible patients begins by requesting a test kit. Kits can be requested via www.CDPATH.com or by calling CDPATH Client Services (1-877-556-8766 | Monday-Friday, 6:00 am-4:30 pm PT).

Visit www.CDPATH.com and/or see the kit insert for step-by-step CDPATH sample collection instructions.

Where can one get CDPATH program operational support?

CDPATH client services is available to answer questions about the CDPATH program and support the testing process.

Client Services Contact Information

1-877-556-8766

Operating Hours
Monday–Friday
6:00 am–4:30 pm
Pacific Standard Time (PST)

Fax: 1-877-816-4019
contactclientservices@prometheuslabs.com

HCP Portrayal

Patient Portrayal

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