CDPATH™
PERSONALIZED PROGNOSTIC TOOL

FINAL TEST REPORT

Patient Name: **Adams Jr, Jeremy R** MRN/Patient ID: **12345678910**

DOB: **MM/DD/YYYY** | Sex: **M** | ICD Code: **A12.3456** | Diagnosis: **Crohn's disease** | Date of Diagnosis: **02/15/2010**

Ordered by: **Mark Davis, MD**

Order ID: **12345678910**

Test Report Date: **XX/XX/XXXX**

Example Physician Office
555 Example Street Suite 101
City, State 99999 US

Contact Info:
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CDPATH™ calculates the individualized predicted risk over the next 3 years of developing complications from Crohn's disease, such as fistulas and blockages, which often lead to surgery. The risk score is determined by disease location, serologic profile, and NOD2 genotype. The test consists of ELISA, immunofluorescence, and PCR allelic discrimination assays.

RESULTS AND INTERPRETATION

CDPATH results are meant to be used in conjunction with clinical assessments to support and facilitate consultative discussions. The graph below shows the patient's risk of developing a disease complication based on specific characteristics of their Crohn's disease.

DISEASE LOCATION

- ☐ Upper GI Tract
- ☐ Small Bowel
- ☐ Right Colon
- ☐ Transverse Colon
- ☒ Left Colon
- ☐ Perianal

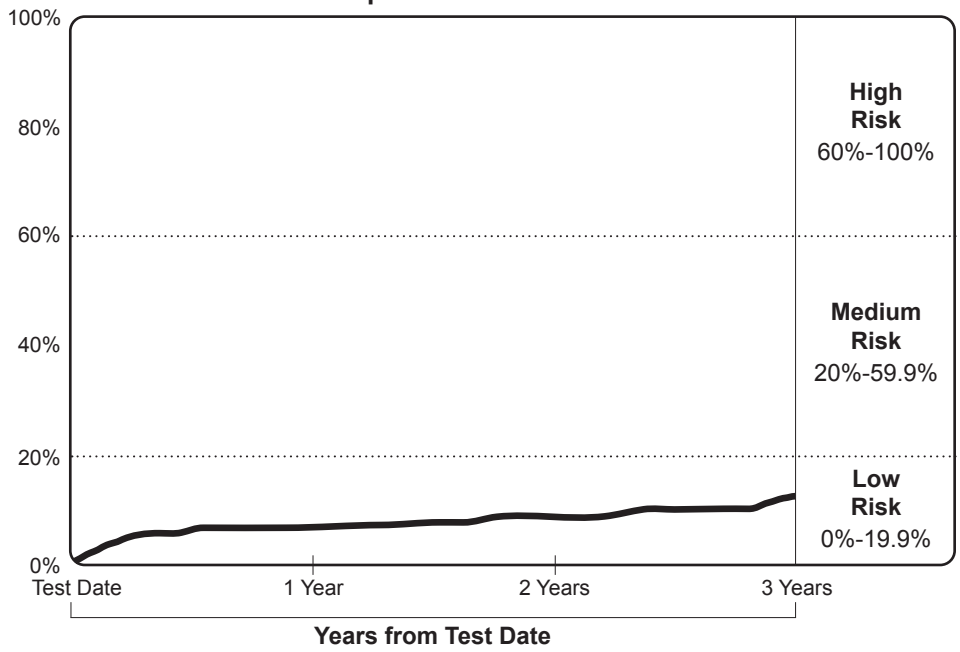
BLOOD TEST MARKERS*

ASCA IgA: 15.1 EU/mL
ASCA IgG: 13.2 EU/mL
anti-CBir1 IgG: 28.3 EU/mL
pANCA: Not Detected

GENETIC TEST*

NOD2 SNP13 (1007fs):
No Variant Detected

Predicted Risk of Complications from Crohn's Disease Over 3 Years



REPORT NOTES

Line 1
Line 2

CDPATH MODEL AND VALIDATION

The CDPATH model was designed using multivariate Cox proportional-hazards regression model analysis to identify statistically meaningful clinical, serologic, and genetic factors for predicting the likelihood of risk for CD complications[1]. The ability of the CDPATH model to predict disease-related complications in the validation group was done using a statistical tool called the Harrell's Concordance statistic (C-statistic). The C-statistic for the adult validation group was 0.71, where 0.5 = random chance and 1.0 = perfect prediction[2]. The CDPATH tool was validated in adult patients who had a Crohn's disease diagnosis within 10 years and had no previous complications.

***Test reference ranges:** ASCA IgA: <9.2 EU/mL; ASCA IgG: <11.9 EU/mL; anti-CBir1 IgG: <35.4 EU/mL; pANCA: Not Detected; NOD2 SNP13 (1007fs): No Variant Detected

Reference: 1. Siegel CA, Horton H, Siegel LS, et al. A validated web-based tool to display individualised Crohn's disease predicted outcomes based on clinical, serologic and genetic variables. *Aliment Pharmacol Ther*. 2016;43(2):267-271. **2.** Data on file. Prometheus Laboratories Inc.

Lab Director: Curtis A. McGuyer, MD
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Prometheus Laboratories

Laboratory Developed Test by Prometheus Laboratories Inc.

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CDPATH DISEASE LOCATION, AND SEROLOGIC AND GENETIC TEST INFORMATION

The CDPATH tool uses different clinical measures to assess individualized risk of developing a Crohn's disease complication for the future.[1]

Disease Location

- Upper gastrointestinal disease describes Crohn's disease located in the stomach and esophagus.
- Small bowel disease describes Crohn's disease located in the small intestine.
- Colonic disease describes Crohn's disease located in the large intestine (right colon, transverse colon, left colon).
- Perianal disease describes Crohn's disease located at or near the anus.

Serologic and Genetic Tests

- ASCA ELISA (anti-saccharomyces cerevisiae antibody) is a measure of proteins called antibodies that are produced by the immune system. There are 2 types of ASCA antibodies produced, IgG and IgA. ASCA is most often seen in patients with Crohn's disease, and is useful in distinguishing Crohn's disease from ulcerative colitis and predicting disease course.[2]
- pANCA (anti-neutrophil cytoplasmic antibody) is a measure of proteins called antibodies produced by your immune system that target certain types of white blood cells. pANCA is most often seen in patients with ulcerative colitis, and is useful in distinguishing ulcerative colitis from Crohn's disease and predicting disease course.[2]
- Anti-CBir1 IgG (anti-flagellin) is a measure of proteins called antibodies that are produced by the immune system. Anti-CBir1 IgG is most often seen in patients with Crohn's disease and may be a marker of Crohn's disease complications such as fistulas, perforations, and other serious problems.[2,3]
- NOD2 SNP13 (1007fs) is a genetic test that can identify the likelihood of developing Crohn's disease-related complications. NOD2 mutations are most often seen in patients with Crohn's disease.[4]

Genetic counseling is recommended to explain the implications of genetic test results.

Sample Type: **Serum**	Collected: **MM/DD/YYYY**	Received: **MM/DD/YYYY**
Reported: **MM/DD/YYYY**	Sender Sample ID: **15224502088**	Prometheus Sample ID: **SV01130031**
Sample Type: **Whole Blood**	Collected: **MM/DD/YYYY**	Received: **MM/DD/YYYY**
Reported: **MM/DD/YYYY**	Sender Sample ID: **15224502089**	Prometheus Sample ID: **SV01130032**

References: 1. Siegel CA, Horton H, Siegel LS, et al. A validated web-based tool to display individualised Crohn's disease predicted outcomes based on clinical, serologic and genetic variables. *Aliment Pharmacol Ther*. 2016;43(2):262-271. **2.** Mitsuyama K, Niwa M, Takedatsu H, et al. Antibody markers in the diagnosis of inflammatory bowel disease. *World J Gastroenterol*. 2016;22(3):1304-1310. **3.** Targan SR, Landers CJ, Yang H, et al. Antibodies to CBir1 flagellin define a unique response that is associated independently with complicated Crohn's disease. *Gastroenterology*. 2005;128(7):2020-2028. **4.** Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG clinical guideline: management of crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517.

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