



Proactive Health INTEGRATED PRS™ CORONARY ARTERY DISEASE

TEST CODE: PR42014

Overview

The MyOme Proactive Health Integrated Polygenic Risk Score™ (iPRS™) Coronary Artery Disease (CAD) test uses a Blended Genome-Exome (BGE) backbone built from whole exome sequencing and low coverage whole- genome sequencing to estimate risk of developing CAD.

Clinical Use

This test is a comprehensive risk assessment tool (not a diagnostic test) intended for individuals aged 40-79 years old who do not have a personal history of CAD. This tool provides a 10-year absolute risk of experiencing a CAD-related event and may assist with the development of a personalized treatment and management strategy in conjunction with standard clinical assessment.

Method

Genomic DNA is obtained from submitted samples and sequenced using Illumina technology. A PCR-free whole-genome library is constructed and a sub-aliquot is taken through PCR amplification and exome selection. The blended genome and exome libraries are sequenced to generate 2x150 bp paired-end reads resulting in low-coverage whole-genome and higher coverage exome data. Reads are aligned to human genome reference assembly GRCh38. Genotype likelihoods are estimated for bases covered by at least one sequencing read. Genotypes at additional sites are imputed based on a genotype reference panel. A PRS is calculated for each of 5 continental ancestries—African, Admixed American, East Asian, South Asian, and European—and standardized and weighted to produce a cross-ancestry PRS (caPRS). The caPRS is integrated with an individual's clinical risk based on the atherosclerotic cardiovascular disease (ASCVD) pooled cohort equations (PCE) model to estimate a 10-year risk of developing CAD.^{1,2}

Sample Types

- Blood (2 EDTA tubes)
- Saliva (2 tubes)
- Buccal (2 swabs)

Turnaround Times

- From sample received, most results are delivered in 5-6 weeks.*
- Follow-up testing or re-requisitions are typically completed in under 2 weeks, often within just a few days.

Included

- A cohesive report with the 10-year integrated risk of incident CAD and the 10-year clinical risk of incident ASCVD is provided. Integrated risk is reported as high, intermediate, borderline, or low based on guidelines published by the American College of Cardiology (ACC) and the American Heart Association (AHA).³ Actionable recommendations for reducing CAD risk are also included.

*Turnaround times are provided as estimates and begin once sample(s) are processed at MyOme. Turnaround times may be extended in cases outside of MyOme's control, including delays related to confirmation testing or other unforeseen circumstances.

1. MyOme Data on File 2. Medina-Inojosa J, Somers V, Garcia M, et al. Performance of the ACC/AHA Pooled Cohort Equations in Clinical Practice. *J Am Coll Cardiol*. 2023 Oct 10; 82(15):1499-1508. doi: 10.1016/j.jacc.2023.07.018. 3. Arnett D, Blumenthal R, Albert M, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019 Sep 10;74(10):1376-1414. doi: 10.1016/j.jacc.2019.03.009.

This test was developed, and its performance characteristics were determined, by MyOme, Inc., a clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and College of American Pathologist (CAP) accredited to perform high complexity clinical laboratory testing. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Test results should always be interpreted by a clinician in the context of clinical and familial data with the availability of genetic counseling when appropriate. MyOme is not responsible for the content or accuracy of third-party websites.