



# Proactive Health Plus

## INTEGRATED PRS™

### CORONARY ARTERY DISEASE

## TEST CODE: PR41016

### Overview

The MyOme Proactive Health Plus Integrated Polygenic Risk Score™ (iPRS™) Coronary Artery Disease (CAD) test uses a PCR-free whole-genome backbone to estimate risk of developing CAD based on clinical and genetic factors. High coverage (mean  $\geq 30x$ ) whole genome sequencing (WGS) allows MyOme to re-query a patient's genome as healthcare needs change and new information about the genome is discovered.

### 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 obtained from submitted samples is sequenced using Illumina technology. Reads are aligned to a human genome reference assembly. 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 equation (PCE) tool to estimate a 10-year risk of developing CAD.<sup>1,2</sup>

### Sample Types

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

### Turn Around Time

- From initial sample received, approximately 6 to 8 weeks
- For previously processed sample, approximately 24 to 48 hours

### 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).<sup>3</sup> Actionable recommendations for reducing CAD risk are also included.

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.

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.