



## TEST CODE: PR41027

### Overview

The MyOme Proactive Health Plus Integrated Polygenic Risk Score™ (iPRS™) Type 2 Diabetes (T2D) test uses a high coverage (mean  $\geq 30X$ ) PCR-free whole-genome backbone to estimate the risk of developing T2D based on clinical and genetic factors.

### Clinical Use

This test is a comprehensive risk assessment tool (not a diagnostic test) intended for individuals 35–70 years old without a personal history of diabetes or pre-diabetes. This tool provides a 10-year absolute risk of developing T2D. This tool may assist in 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 the human genome reference assembly GRCh38.p14. 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 non-genetic risk factors—age, sex, waist circumference, smoking status, blood pressure, family history of T2D, fasting glucose, HDL-C, and triglycerides—to estimate the 10-year risk of developing T2D.<sup>1</sup>

### 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 a few days.

### Included

- A cohesive report with the 10-year integrated risk of developing T2D and the average 10-year clinical risk for someone of the same age and sex in the general population.
- Integrated risk is reported as “not at increased risk” or “increased risk”, with “increased risk” defined as a 10-year risk of 15% or greater, matching the average risk associated with BMI  $\geq 25\text{kg/m}^2$  (overweight).<sup>2</sup>
- Actionable recommendations for reducing T2D risk, based on the American Diabetes Association Professional Practice Committee guidelines, are also included.<sup>3</sup>

\*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.

1.Ratman, D. et al. (2024, June). Utility of Polygenic Risk Scores for Prediction of Incident Type 2 Diabetes. Poster presented at: The European Human Genetics Conference; Berlin, Germany. 2. US Preventative Services Task Force. Screening for Prediabetes and Type 2 Diabetes. JAMA. 2021;326;(8):736–743. PMID: 34427594. 3. American Diabetes Association Professional Practice Committee. Prevention of Delay of Diabetes and Associated Comorbidities: Standards of Care in Diabetes- 2025. Diabetes Care. 2025;48(1 Supp 1):S50–S58. PMID: 39651971.

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.