Proactive Health Plus
INTEGRATED PRS™
BREAST CANCER

TEST CODE: PR41003

Overview

MyOme Proactive Health Plus Integrated Polygenic Risk Score™ (iPRS™) Breast Cancer test uses a PCR-free whole-genome backbone to estimate risk of developing breast cancer based on clinical and genetic factors. 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 women who have not previously been diagnosed with breast cancer and who do not have a clinically relevant variant in a breast cancer predisposition gene. This tool provides a 5-year and remaining lifetime risk of developing breast cancer 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 at ≥30x coverage. 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 risk alleles are standardized and weighted to produce a cross-ancestry PRS (caPRS). The caPRS is integrated with an individual's clinical risk based on the Tyrer-Cuzick (TC) model to estimate a 5-year and remaining lifetime risk of developing breast cancer.[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 5-year and remaining lifetime risk of developing breast cancer that includes actionable recommendations.

*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 unforseen circumstances.

1. Tshiaba P et al. Integration of a cross-ancestry polygenic model with clinical risk factors improves breast cancer stratification. JCO Precis Oncol. 2023. doi: 10.1200/PO.22.00447. **2**. Tyrer J et al. A breast cancer prediction model incorporating familial and personal risk factors. Stat Med. 2004. doi: 10.1002/sim.1668.

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.

