Jane Doe
Sex Assigned at Birth: Female
Date of Birth: 01/01/2001
Sample ID: SM004644
Sample Type: BLOOD
Collection Date: 05/23/2022
Received Date: 05/23/2022

Clinic: Cardiovascular Health Center
Physician: Maria Chen, M.D., Ph.D.
Phone: 510-555-0000
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Requisition ID:
RQ000059
Report Number:
RP12345
Report Date:
10/30/2025

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Your lifetime risk of developing breast cancer is elevated (greater than or equal to 20%) based on your integrated score.

CLINICAL CONTEXT: This test integrates known clinical risk factors and a polygenic risk score. It does NOT incorporate single gene findings in breast cancer predisposition genes.

RISK DETAILS

	LIFETIME RISK	5-YEAR RISK
Integrated Risk	29.4%	1.4%
Clinical Risk	16.6%	1.1%
General Population Risk	11.6%	0.4%

Integrated Risk: *The risk of developing breast cancer based on the combination of a polygenic risk score and the Tyrer-Cuzick clinical risk model.*
Clinical Risk: *The risk of developing breast cancer based on the Tyrer-Cuzick clinical risk model.*
General Population Risk: *The average risk of developing breast cancer for a biological female in the general population of the same age.*

NEXT STEPS

Next steps described in this section are based on lifetime risk as estimated by the integrated risk score.

- Individuals with an estimated lifetime breast cancer risk of 20% or higher should speak with their healthcare provider about published recommendations for increased breast cancer surveillance, as outlined below, as well as published recommendations for risk-reducing agents and comprehensive risk assessment [1,6].
- Annual mammograms starting at age 40 or 10 years younger than the earliest breast cancer diagnosis in the family (but no earlier than age 30)
- Annual breast MRI starting at age 40 or 10 years younger than the earliest breast cancer diagnosis in the family (but no earlier than age 25)
- These results should be interpreted in the context of the individual's personal medical history and family history. The patient's biological female relatives may wish to speak with their healthcare provider to undergo a personalized risk assessment.

MyOme, Inc.
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Report Information:
Jane Doe
DOB: 01/01/2001
Requisition ID: RQ000059

Lab Director:
Brynn Levy M.Sc.(Med)., Ph.D., FACMG
CLIA #05D2203070 CAP #8939502

REFERENCES

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2. Tshiaba et al. *Integration of a Cross-Ancestry Polygenic Model With Clinical Risk Factors Improves Breast Cancer Risk Stratification.* JCO Precis Oncol. 2023; 7(7):e2200447 PMID: 36809055
3. Tyrer et al. *A breast cancer prediction model incorporating familial and personal risk factors.* Stat Med. 2004; 23(23):1111-30 PMID: 15057881
4. Henricks et al. *Translating DPYD genotype into DPD phenotype: using the DPYD gene activity score.* Pharmacogenomics. 2015; 16(16):1277-86 PMID: 26501536
5. US Preventive Services Task Force et al. *Screening for Breast Cancer: US Preventive Services Task Force Recommendation Statement.* JAMA. 331(331):1918-1930 PMID: 38687503
6. Monticciolo et al. *Breast Cancer Screening for Women at Higher-Than-Average Risk: Updated Recommendations From the ACR.* J Am Coll Radiol. 20(20):902-914 PMID: 37150275

TEST METHODS

- Patient data is provided by the ordering physician. Specimen receipt, accessioning, data analysis and interpretation is performed by MyOme, Inc., 1505 Adams Drive, Suite B1, Menlo Park, CA 94025, CLIA#05D2203070. Blended Genome-Exome sequencing, excluding data analysis and interpretation, is performed by Broad Clinical Labs LLC, 27 Blue Sky Dr, Burlington, MA 01803, CLIA#22D2055652.
- Genomic DNA obtained from the submitted sample is used to construct genome and exome libraries and sequenced using Illumina technology. Reads are aligned to the NCBI GRCh38 reference assembly.
- 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 polygenic risk score (PRS) is calculated for each of 5 continental ancestries of which the patient is a part as the sum of the patient's risk alleles weighted by the allele-specific effect sizes. The raw scores are centered using four principal components and standardized with a population-specific standard deviation. Standardized PRSs weighted by fractional ancestry and ancestry-specific effect sizes are summed (caPRS) [1].
- The standardized PRS is integrated with the risk based on the Tyrer-Cuzick (TC) model to estimate a 5-year and remaining lifetime risk of developing breast cancer [3].
- **This tool cannot be used to detect rare pathogenic variants including those in hereditary cancer predisposition genes.**

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TEST LIMITATIONS

- The results of this test may not be valid if the patient has a pathogenic variant in a breast cancer predisposition gene. The integrated risk score estimate does not account for pathogenic variants in genes with limited or disputed breast cancer association (e.g. BRIP1), as the available data is currently insufficient to accurately quantify the breast cancer risk associated with these genes.
- The clinical risk based on the Tyrer-Cuzick risk model was calculated based on the patient data provided by the ordering physician. Incorrect or missing information will impact this calculation and the integrated risk score.
- A risk calculation will not be performed for biological males. A risk calculation will also not be performed for biological females who are under the age of 18, over the age of 84, known to carry a pathogenic variant in a breast cancer predisposition gene or have a personal history of breast cancer.
- A risk calculation will not be performed when there is missing information necessary to perform the calculation, including but not limited to age and first degree family history of breast cancer.
- The breast cancer integrated risk is a risk assessment tool NOT a diagnostic. These results should be interpreted in the context of the individual's personal medical history and family history.
- Performance of this tool may be reduced in certain populations.
- Like most tests, this test carries a risk of false negative or false positive results, which may be caused by, without limitation, sample contamination from biological or non-biological sources, specimen marking issues, rare genetic variants interfering with analysis, and other technical issues and limitations.

DISCLAIMERS

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).

REVIEWED BY

MyOme

MyOme Example Lab Director

10/30/2025

Date

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