**Jane Doe**
Biological Sex: Female
Date of Birth: 11/13/2018
Sample ID: SM12805
Sample Type: BLOOD
Collection Date: 11/13/2018
Received Date: 11/14/2018

**Clinic: The City Clinic**
**Physician: Jane Smith, M.D.**
Phone: 555-555-5555
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NPI: 0123456789

**Requisition ID:**
RQ12345
**Report Number:**
RP12345
**Report Date:**
11/01/2024

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## Your lifetime risk of developing breast cancer is average (less than 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** | 14.2% | 0.5% |
| **Clinical Risk** | 12.2% | 0.4% |
| **General Population Risk** | 11.7% | 0.1% |

**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 less than 20% can typically follow the general population recommendations from society guidelines, as outlined below. Please discuss the risk score as part of a comprehensive risk assessment with a healthcare provider, as some factors such as prior chest wall radiation, or mammographic breast density, may warrant additional breast cancer screening [1,4,5].
- Option to start annual mammograms at age 40 with recommendation to start by age 45.
- These results should be interpreted in the context of the individual's personal medical history or family history.

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## REFERENCES

1. Saslow et al. *American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography.* CA Cancer J Clin. 2007; 57(57):75-89. PMID: 17392385.
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. Oeffinger et al. *Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society.* JAMA. 2015; 314(314):1599-614. PMID: 26501536.
5. US et al. *Screening for Breast Cancer: US Preventive Services Task Force Recommendation Statement.* JAMA. 2024; 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. 2023; 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., 1455 Adams Dr., Ste 1150, Menlo Park, CA 94025, CLIA#05D2203070. Whole Genome 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 submitted samples was sequenced using Illumina technology. Reads were aligned to the NCBI GRCh37.p13 reference assembly.
- 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) [2].
- 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) to perform high complexity clinical laboratory testing. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).

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