ARTERA

Precision oncology, powered by AI

# ArteraAI Breast Cancer Test

## Who is this test for?

Patients with early-stage, invasive breast cancer need to make complex treatment decisions after surgical resection. While genomic-based risk stratification tools are widely used, these approaches are costly, consume valuable tissue, and can take weeks to deliver results. The ArteraAI Breast Cancer Test provides a faster and tissue-sparing alternative that enables broader accessibility across clinical settings.


The ArteraAI Breast Cancer Test is intended to assist clinicians with risk-based decision-making for patients with HR+/HER2- early-stage, N0 or N1, invasive breast cancer within recommended clinical treatment guidelines. The test provides personalized risk estimates, including 5- and 10-year risk estimates of distant metastasis (DM), and categorical risk groups (low vs high).

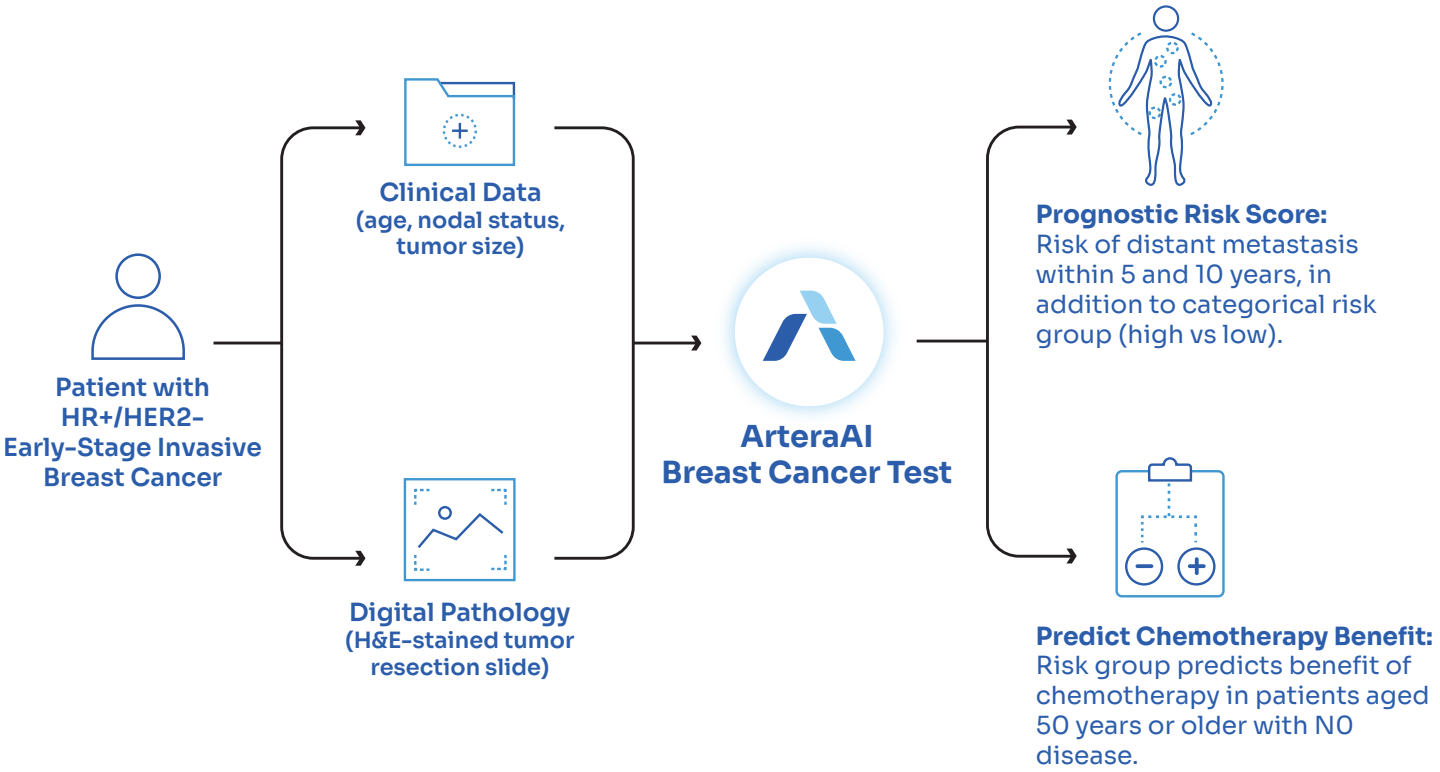
The test uses multimodal artificial intelligence (MMAI) to calculate a personalized risk score based on physician provided clinical variables and digitized histopathology images of the breast tumor resection specimen. The clinical variables include age, tumor size (in mm) and nodal status. The resection specimens must be treatment-naive and prepared from hematoxylin & eosin (H&E)-stained formalin-fixed paraffin-embedded tissue. Only a singe slide which contains the highest tumor grade with the highest tumor volume is required.

## MMAI Platform

The ArteraAI Breast Cancer Test uses a MMAI algorithm that was developed using data from over 12,000 patients enrolled in six Phase III clinical trials (WSG-ADAPT, WSG-Plan B, NSABP B-34, ABCSG-6, NSABP B-14, NSABP B-39).

The test produces a personalized risk score that has been validated to prognosticate clinical outcomes. This risk score is then used to produce both quantitative risk estimates (e.g. 5- and 10-year risk of distant metastasis assuming 5 years of adjuvant endocrine therapy) and stratify patients into categorical risk groups (low vs high) based on pre-specified risk score cut points.

In patients aged 50 years or older with N0 disease, this test can also help inform whether chemotherapy may provide benefit. Specifically, patients in the MMAI high risk group have been demonstrated to derive a substantial benefit from the addition of chemotherapy to endocrine therapy, whereas patients in the MMAI low risk group have been demonstrated to derive no benefit from the addition of chemotherapy.

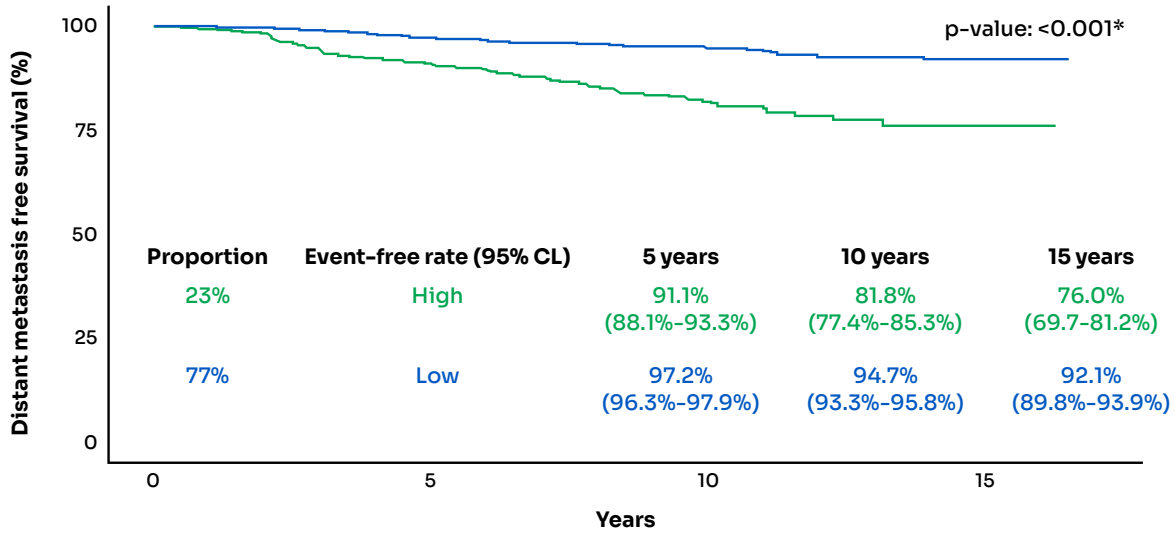


# Data Validation

Artera's MMAI model was externally validated in 2,109 patients from ABCSG-8, a trial of node-negative and node-positive patients with HR+/HER2- breast cancer who received endocrine therapy only. Although the cohort was overall lower-risk (22% Grade 1, 78% Grade 2 tumors), Artera's MMAI model classified 77% of patients as low-risk and 23% of patients as high-risk.

In univariable analyses, both the MMAI risk score and MMAI risk group were significantly associated with time to distant metastasis: MMAI score (HR [95% CI] = 2.22 [1.91-2.58], p<0.001) and MMAI risk group (HR [95% CI] = 3.53 [2.60-4.80], p<0.001). The estimated 10-year distant metastasis-free rates were 95% for low-risk and 82% for high-risk patients.

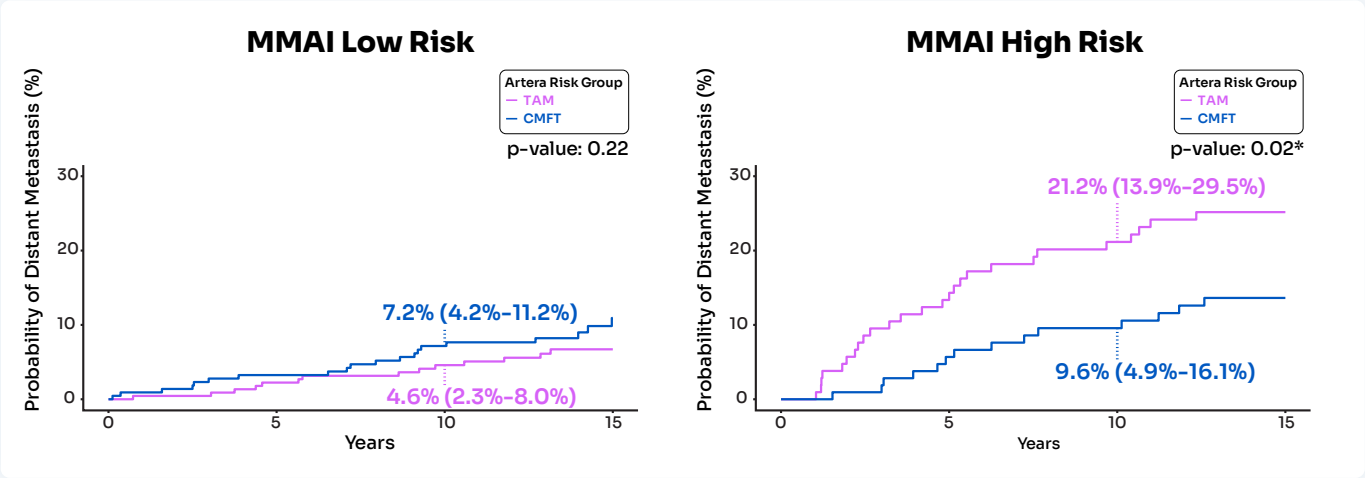
## Results of External Validation in ABCSG-8




| Proportion | Event-free rate (95% CL) | 5 years | 10 years | 15 years |
|---|---|---|---|---|
| 23% | High | 91.1% (88.1%-93.3%) | 81.8% (77.4%-85.3%) | 76.0% (69.7-81.2%) |
| 77% | Low | 97.2% (96.3%-97.9%) | 94.7% (93.3%-95.8%) | 92.1% (89.8%-93.9%) |

**MMAI effectively stratifies patients by risk, distinguishing those with more aggressive disease from those with less aggressive disease.**

## Results of Predictive Validation for Chemo Benefit in NSABP-20 Patients Aged ≥ 50




In addition, the MMAI model was validated in 1,763 patients from the NSABP B-20 trial, which randomized patients with N0, HR+ breast cancer to tamoxifen (TAM) with and without chemotherapy. In the TAM arm, the MMAI demonstrated strong prognostic performance. Both the MMAI score and MMAI risk groups were significantly associated with risk of distant metastasis: MMAI score (HR [95% CI] = 1.9 [1.6–2.4], p<0.001) and MMAI risk group (HR [95% CI] = 3.63 [2.42–5.40], p<0.001).

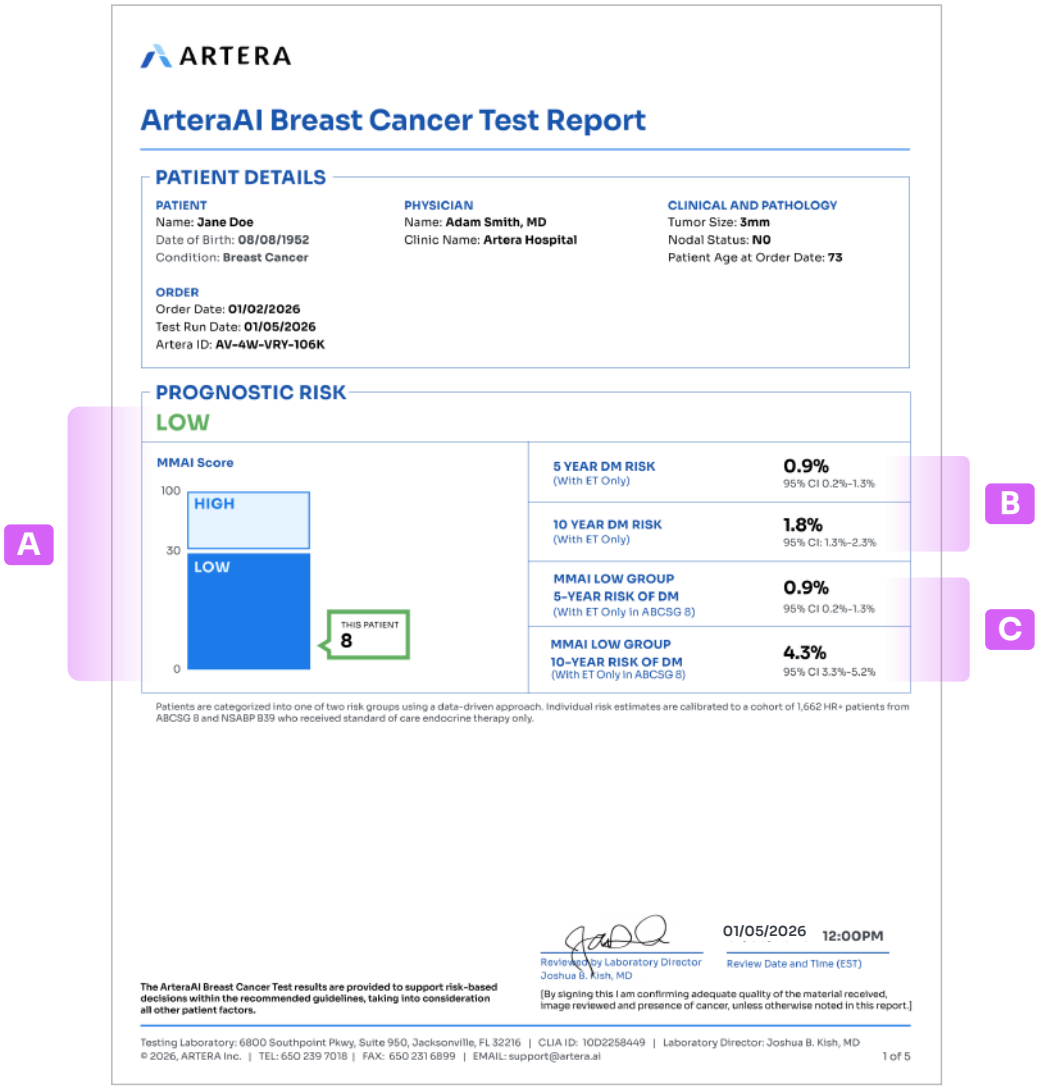
| Cohort | MMAI Risk group | Treatment Arms | 10-yr Absolute DM Diff | sHR (95%) | Interaction P-value |
|---|---|---|---|---|---|
| Age ≥ 50 | MMAI Low (68%) | CMFT vs TAM | -2.6% | 1.52 (0.77-3.02) | 0.01* |
| | MMAI High (32%) | | 11.6% | 0.47 (0.25-0.88) | |

In patients aged 50 years or older with node-negative disease, a significant interaction between the MMAI risk group and the use of chemotherapy (p = 0.01) supports that MMAI predicts which patients benefit from chemotherapy. Among patients aged 50 or older classified as MMAI high-risk (32%), the addition of chemotherapy was associated with a 52% relative 10-year distant metastasis risk reduction, whereas low-risk patients (68%) derived no benefit (10-year distant metastasis rate: 7% in CMFT vs. 5% in TAM).

**MMAI identifies 68% of patients aged 50 years or older with N0 disease who may not need chemotherapy, as a faster, lower cost, non-tissue consumptive alternative to genomic testing.**

# Sample Breast Cancer Test Report

**This is a sample ArteraAI Breast Cancer Test Report for a patient with HR+/HER2- early stage breast cancer who is 50 years old or older, and node negative.**



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ArteraAI Breast Cancer Test Report

PATIENT DETAILS

PATIENT
Name: Jane Doe
Date of Birth: 08/08/1952
Condition: Breast Cancer

PHYSICIAN
Name: Adam Smith, MD
Clinic Name: Artera Hospital

CLINICAL AND PATHOLOGY
Tumor Size: 3mm
Nodal Status: N0
Patient Age at Order Date: 73

ORDER
Order Date: 01/02/2026
Test Run Date: 01/05/2026
Artera ID: AV-4W-VRY-106K

PROGNOSTIC RISK

LOW

MMAI Score

100
HIGH
30
LOW
0
THIS PATIENT
8

| | |
|---|---|
| 5 YEAR DM RISK (With ET Only) | 0.9% 95% CI 0.2%-1.3% |
| 10 YEAR DM RISK (With ET Only) | 1.8% 95% CI: 1.3%-2.3% |
| MMAI LOW GROUP 5-YEAR RISK OF DM (With ET Only in ABCSG 8) | 0.9% 95% CI 0.2%-1.3% |
| MMAI LOW GROUP 10-YEAR RISK OF DM (With ET Only in ABCSG 8) | 4.3% 95% CI 3.3%-5.2% |

Patients are categorized into one of two risk groups using a data-driven approach. Individual risk estimates are calibrated to a cohort of 1,662 HR+ patients from ABCSG 8 and NSABP B39 who received standard of care endocrine therapy only.

01/05/2026 12:00PM

Reviewed by Laboratory Director Joshua B. Kish, MD

Review Date and Time (EST)

[By signing this I am confirming adequate quality of the material received, image reviewed and presence of cancer, unless otherwise noted in this report.]

The ArteraAI Breast Cancer Test results are provided to support risk-based decisions within the recommended guidelines, taking into consideration all other patient factors.

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**Prognostic Risk Group:** The MMAI Risk Group provides an assessment of the aggressiveness of the patient's breast cancer. In a validation dataset comprised of patients from NSABP B-14 and NSABP B-39, the MMAI categorized 68% and 32% of patients to MMAI low and high risk, respectively. For patients who are 50 years old or older and node-negative, the risk group is also predictive of chemotherapy benefit.

**MMAI Score:** The MMAI Score, which spans from 1 to 100, quantifies recurrence risk along a continuous spectrum. Scores are rounded to the nearest integer. A patient with an MMAI score of ≥ 30 is considered high risk.

B

**Individual Calibrated Risk:** The 5- and 10-year risk estimates indicate an individual patient's likelihood of developing distant metastasis, derived from a calibration cohort of NSABP B-39 and ABCSG-8 patients treated with standard of care endocrine therapy alone. These estimates can support more informed clinical decision-making.

C

**Group Average:** The group average risk of distant metastasis at 5- and 10-years are based on the rates observed for patients within the ABCSG-8 validation dataset.

# Getting the ArteraAI Breast Cancer Test

## Process

1.

The ArteraAI Breast Cancer Test is ordered by the treating physician.

2.

A single representative resection slide is sent to our lab for analysis. No additional medical procedures are required.

3.

The test results are sent to the physician.

4.

The treating physician and patient review the results together.

## How to Order

Physician orders the test by contacting **support@artera.ai**

## How to Order (UK Physicians)

For physicians in the UK, the ArteraAI Breast Cancer Assay is UKCA marked and available though Diagnexia. Please contact **info@diagnexia.com** to place an order.

## Cost of Test

We offer a Financial Assistance Program to help reduce the potential out-of-pocket costs associated with testing. The program has broad eligibility criteria, meaning that most patients with out-of-pocket costs will qualify for some level of financial assistance. Please contact **billing@artera.ai** to learn more.

**artera.ai**

**For billing inquries, please call: 1-650-239-7018**

## Testimonials

"Traditional approaches can result in patients, especially those who are post-menopausal with node-negative tumors, receiving chemotherapy with limited benefit while still facing significant toxicities. It's exciting to witness the emergence of new technologies that allow us to deliver the optimal breast cancer care."

*- Professor Nadia Harbeck, Director of the Breast Center at LMU University Hospital in Munich, Germany*

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The ArteraAI Breast Cancer Test is a Laboratory Developed Test that is now clinically available through a single CLIA-certified laboratory in Jacksonville, FL. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Please consult with your health care provider for personalized medical advice to determine if the ArteraAI Breast Cancer Test is appropriate for you.

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If you have any questions, please contact Artera® at: info@artera.ai



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