ARTERA

ArteraAI Breast Cancer Test Report

PATIENT DETAILS

PATIENT
Name: **Jane Doe**
Date of Birth: **08/08/1980**
Condition: **Breast Cancer**

ORDER
Order Date: **01/10/2026**
Test Run Date: **01/26/2026**
Artera ID: **AV-4W-VRY-106K**

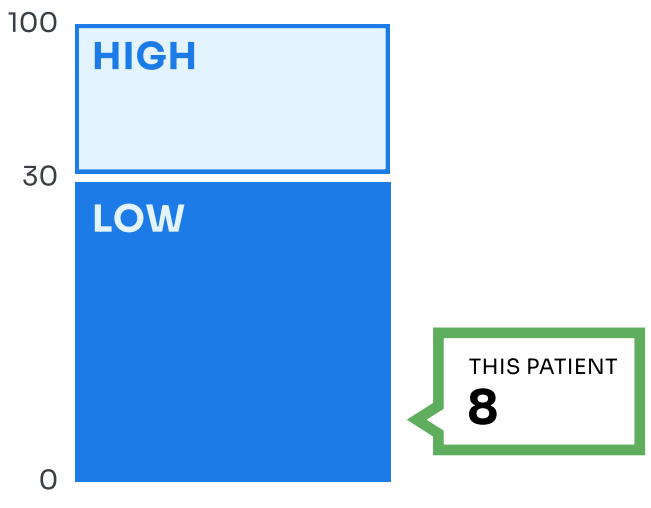
PHYSICIAN
Name: **Adam Smith, MD**
Clinic Name: **Artera Hospital**

CLINICAL AND PATHOLOGY
Tumor Size: **3mm**
Pathological Nodal Stage: **N1**
Age: **45**

PROGNOSTIC RISK

LOW

MMAI Score



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)	**0.9%** 95% CI 0.2%-1.3%
MMAI LOW GROUP 10-YEAR RISK OF DM (With ET Only)	**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.

Reviewed by Laboratory Director
Joshua B. Kish, MD

01/26/2026 12:00PM
Review Date and Time (EST)

The ArteraAI Breast Cancer Test results are provided to support risk-based decisions within the recommended guidelines.

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

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TEST DESCRIPTION

The ArteraAI Breast Cancer Test is a multimodal artificial intelligence (MMAI)-based test that leverages a unique algorithm that combines digital image and clinical data to estimate long-term clinical outcomes for patients with HR+/HER2- early stage, N0 or N1, invasive breast cancer. Hematoxylin and eosin (H&E)–stained slides from a breast cancer resection specimen are scanned at 20× magnification on a 3DHistech P1000 or Aperio GT450Dx scanner to create digital images. Image management and pathologist review is performed using the Lumea digital pathology system. Once a pathologist reviews these digital histopathology images and confirms a breast cancer diagnosis, the images and a limited set of clinical variables are assessed by the MMAI and test results are calculated through AI-based analysis.

INTENDED USE

The ArteraAI Breast Cancer Test is intended to assist clinicians with risk-based decisions for patients with HR+/HER2- early stage, N0 or N1, invasive breast cancer within recommended clinical treatment guidelines. The ArteraAI Breast Cancer Test is a laboratory developed test using artificial intelligence to assess physician-provided clinical variables and whole slide images of breast tumor resection specimens to provide risk estimates of distant metastasis for patients with breast cancer.

Resection specimens must be treatment-naive and prepared from hematoxylin & eosin (H&E)-stained formalin-fixed paraffin-embedded tissue. Sample requirement includes one H&E-stained slide containing the tumor that has the highest grade used by the pathologist in assessing the surgical resection specimen. The physician-provided clinical variables for MMAI score generation are age, tumor size (in mm) and nodal status. The ArteraAI Breast Cancer Test is intended for adults 18 years of age or older with HR+/HER2- early stage, N0 or N1, invasive breast cancer, without clinically or pathologically defined metastases.

MODEL INFORMATION

The AI algorithms used in the ArteraAI Breast Cancer Test were developed using multimodal deep learning trained on digital histopathology data and clinical data from multiple randomized controlled trials to estimate long-term clinically-relevant outcomes.

The MMAI model was trained on a dataset comprising digitized pre-treatment biopsy and surgical slides from >11,000 patients from five trials — WSG ADAPT, WSG PlanB, NSABP B14 Observation Arm, NSABP B34, and ABCSG 6 — incorporating image-based features such as AI-derived Ki67 scores, and AI-derived tumor grade alongside clinical variables including age, tumor size, nodal status to predict risk of DM. Cut points between risk groups were chosen to ensure sufficient sample sizes within risk categories, balancing statistical power for future validation and clinical interpretability. Based on clinically relevant differences in the time to DM between the low-risk and intermediate-/high-risk groups in additional analyses and validation of the test, the intermediate- and high-risk groups were combined; patients are classified into one of two risk groups: low-risk and high-risk (comprising intermediate- and high-risk patients).

To evaluate an individual patient's prognostic risk, a score (ranging from 0 to 100) and corresponding calibrated probability are provided for each of the following clinical endpoints: 5-year risk of DM and 10-year risk of DM. These clinical endpoints are calibrated to a cohort of 1,662 patients who received standard-of-care endocrine therapy (ET) alone in the ABCSG 8 and NSABP B39 trials.

The prognostic performance of the MMAI model was validated on three separate datasets:

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ArteraAI Breast Cancer Test Report

NSABP B14 and B39

MMAI scores were generated for 2,174 patients in B14, and 1,198 patients in B39 with HR+ Stage I-II EBC. The median follow-up time for B14 was 17.6 years, and 9.4 years for B39. The model demonstrated strong prognostic performance: in B14, the locked MMAI showed a 10-year time-dependent area under the receiver operating characteristic curve (tdAUC) of 0.71 (0.68-0.75) compared to the clinical comparator model (0.65 [0.62-0.69]); in B39, the 10-year tdAUC for MMAI was 0.72 (0.59-0.83) versus 0.69 (0.60-0.79) for the clinical comparator model. The MMAI score was significantly associated with risk of DM in both the B14 (hazard ratio (HR) [95% confidence interval (CI)] = 2.0 [1.8-2.3]) and B39 (HR [95%CI] = 2.3 [1.6-3.3]) cohorts. The score retained statistical significance after adjusting for age, tumor size, and pathological N stage in both the B14 (HR [95%CI] = 1.9 [1.7-2.2]) and B39 (HR [95%CI] = 2.1 [1.4-3.1]) cohorts.1

ABCSG 8

MMAI scores were generated for 2,109 patients. The median follow up time was 9.5 years. Despite the overall lower-risk profile of the population treated with ET only—comprising 22% Grade 1 and 78% Grade 2 tumors— the MMAI model classified 77% of patients as low-risk, 8.6% as intermediate-risk, and 14% as high-risk. The estimated 10-year distant metastasis-free rates were 95% (94%-96%) for low-risk, 90% (84%-94%) for intermediate-risk, and 79% (74%-84%) for high-risk patients. In univariate analysis, both the MMAI continuous score and MMAI risk groups were significantly associated with risk of DM: MMAI score (HR [95% CI] = 2.2 [1.9–2.6], p<0.001) and MMAI risk group (intermediate vs low risk HR [95% CI] = 2.2 [1.3-3.6], p = 0.002; high vs low risk HR [95% CI] = 4.5 [3.2–6.2], p<0.001).[2]

NSABP B20

A total of 1763 patients with median follow-up time of 14.2 years from B20 had MMAI scores generated for analyses. In the tamoxifen (TAM) arm, the MMAI demonstrated strong prognostic performance. Both the MMAI score and MMAI risk groups were significantly associated with risk of DM: 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).

The predictive ability of the MMAI model to determine whether or not a patient will benefit from the addition of chemotherapy to standard of care ET was demonstrated for patients who are node negative and 50 years of age or older.

In patients aged 50 or older, the utility of the MMAI model in predicting the value of chemotherapy (CT) in reducing the relative risk of DM was supported by a significant interaction between the MMAI risk group and the use of CT; CT vs no CT, interaction p = 0.01). Among patients >50 years classified as MMAI high-risk (32%), addition of CT was associated with a 52% relative 10-year DM risk reduction, whereas low-risk patients (68%) derived no benefit (10-year DM rate: 7% in CT vs. 5% in no CT). In patients under 50, MMAI was prognostic for risk of DM[3]

References

1. Geyer, Charles E. "Development of a Multi-Modal Artificial Intelligence (MMAI) Model for Predicting Distant Metastasis in HR+ Early-Stage Invasive Breast Cancer." Abstract presented at San Antonio Breast Cancer Symposium. December 12, 2025.
2. Filipits, Martin. "Independent Validation of a Pathology-Based Multimodal Artificial Intelligence Biomarker for Predicting Risk of Distant Metastasis in Postmenopausal, Estrogen Receptor-Positive, Early-Stage Breast Cancer Patients: Analysis of the ABCSG Trial 8." Abstract presented at San Antonio Breast Cancer Symposium. December 11, 2025.
3. Geyer, Charles E. "Evaluation of a Digital Pathology Based Multimodal Artificial Intelligence Model for Prognosis and Prediction of Chemotherapy Benefit in Node-Negative, Hormone Receptor-Positive Breast Cancer Patients: Analysis of the NSABP B-20 Trial." Paper presented at San Antonio Breast Cancer Symposium. December 10, 2025.