

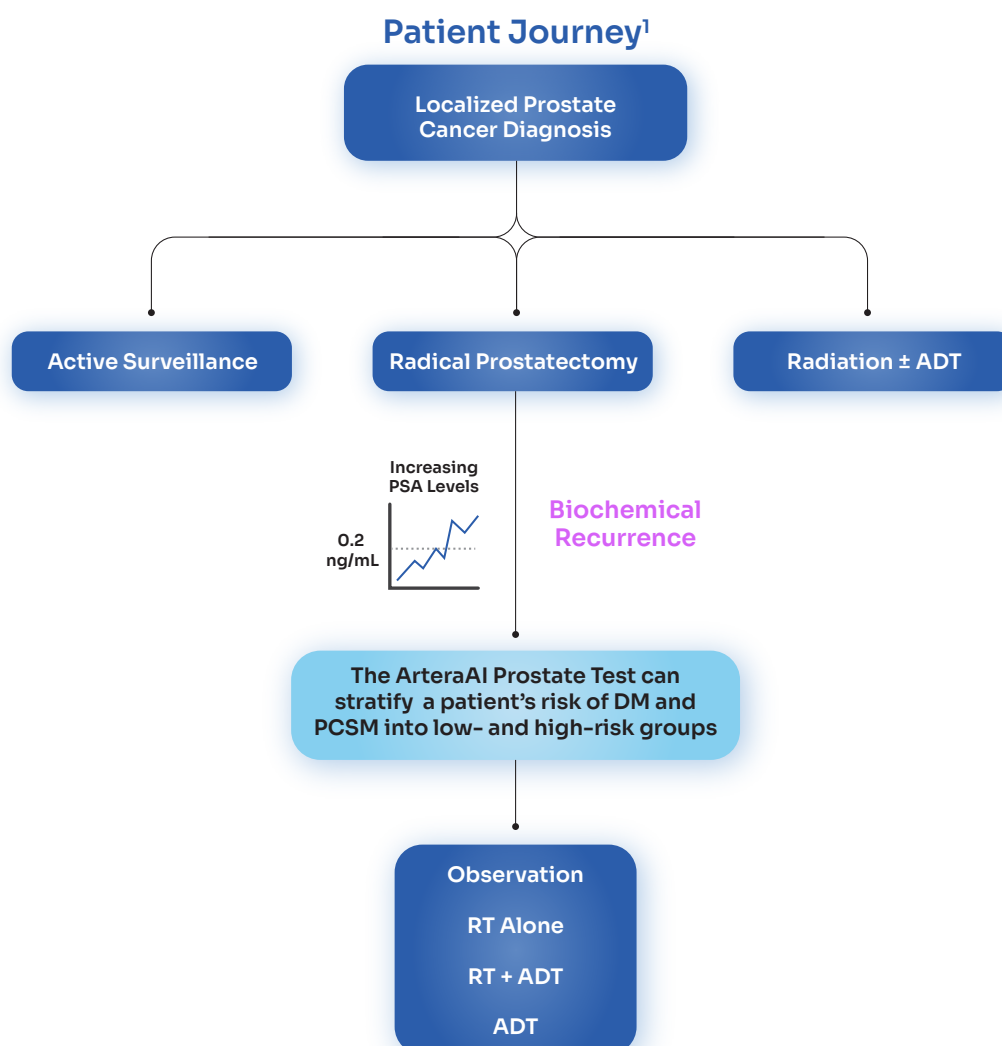
# ArteraAI Prostate Test

## *Post-RP Specimen*



## Who is this test for?

The ArteraAI Prostate Test is intended for use in patients with a biochemical recurrence following prostatectomy for localized prostate cancer and who have not yet received radiation or hormone therapy after prostatectomy. The test may not be appropriate for patients who received neoadjuvant therapy before prostatectomy. ArteraAI Prostate Test results are intended to inform risk-based clinical decisions as an adjunct to conventional clinical risk factors and other tools for determining the metastatic potential of the tumor and patient prognosis.<sup>1</sup>



## Why order this test?

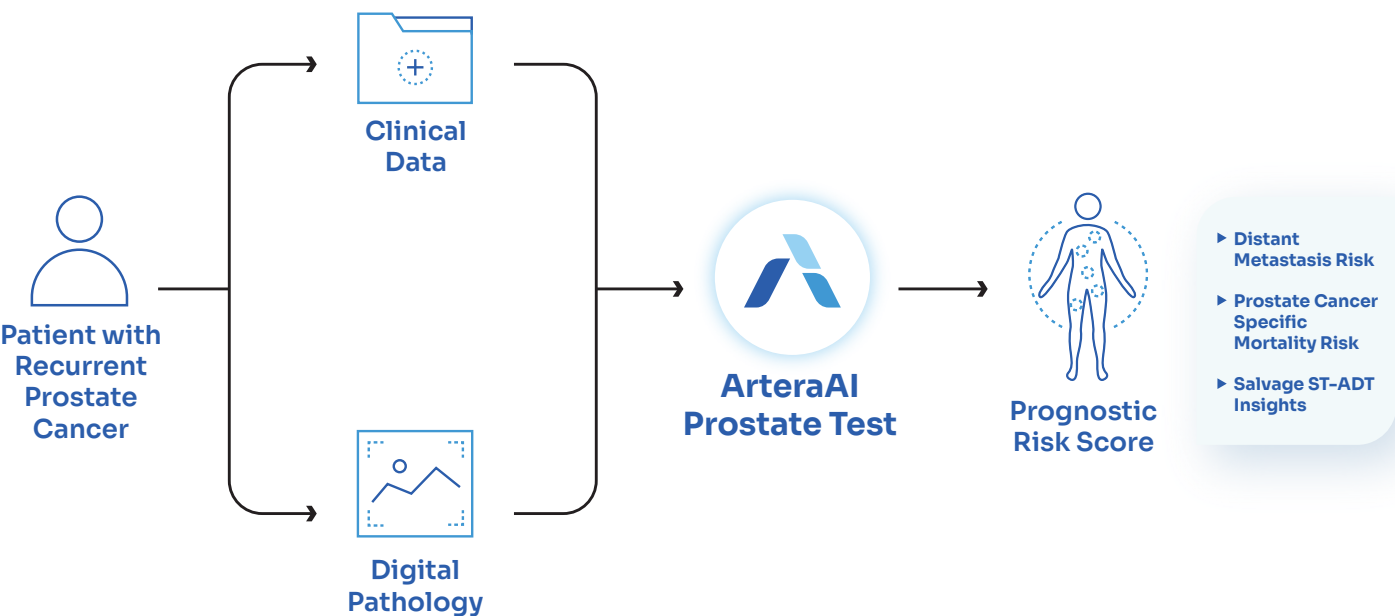
Patients with biochemical recurrence following radical prostatectomy face the decision to augment salvage radiation therapy with ADT to further decrease their risk of poor long-term outcomes. The ArteraAI Prostate Test can help provide insight into disease prognosis by estimating the risk for developing distant metastasis and prostate cancer specific mortality, based on individual patient characteristics. The test's prognostic risk assessment also provides insights into the potential benefit of adding ST-ADT to salvage radiation therapy. With the known side effects of ADT, such as sexual dysfunction, cognitive dysfunction, and metabolic syndrome, gaining a clear understanding of the risk-benefit of adding ST-ADT to salvage-RT could increase confidence in treatment decision-making.<sup>2</sup>

ArteraAI Multimodal Artificial Intelligence (MMAI)

The ArteraAI Prostate Test leverages a unique AI algorithm that was developed (n=1322) and validated (n=533) using data from two large, randomized, phase 3 clinical trials: NRG/RTOG 0534 and 9601. The test was developed and validated in patients without any nodal involvement (NO) at the time of biochemical recurrence. Two types of data—clinical data and prostatectomy tissue slide images—were used to develop the resulting model, the ArteraAI Prostate Test (Post-RP).<sup>1</sup>

The ArteraAI Prostate Test takes an individual patient's clinical data\* and histopathology images and produces a prognostic risk score for long-term clinical outcomes, such as risk of metastasis or death from prostate cancer.<sup>1</sup> The test can also help inform if adding ST-ADT to salvage radiation therapy may be of benefit.<sup>1</sup>

The ArteraAI Prostate Test utilizes existing prostatectomy slides with no additional preparation or procedures required.

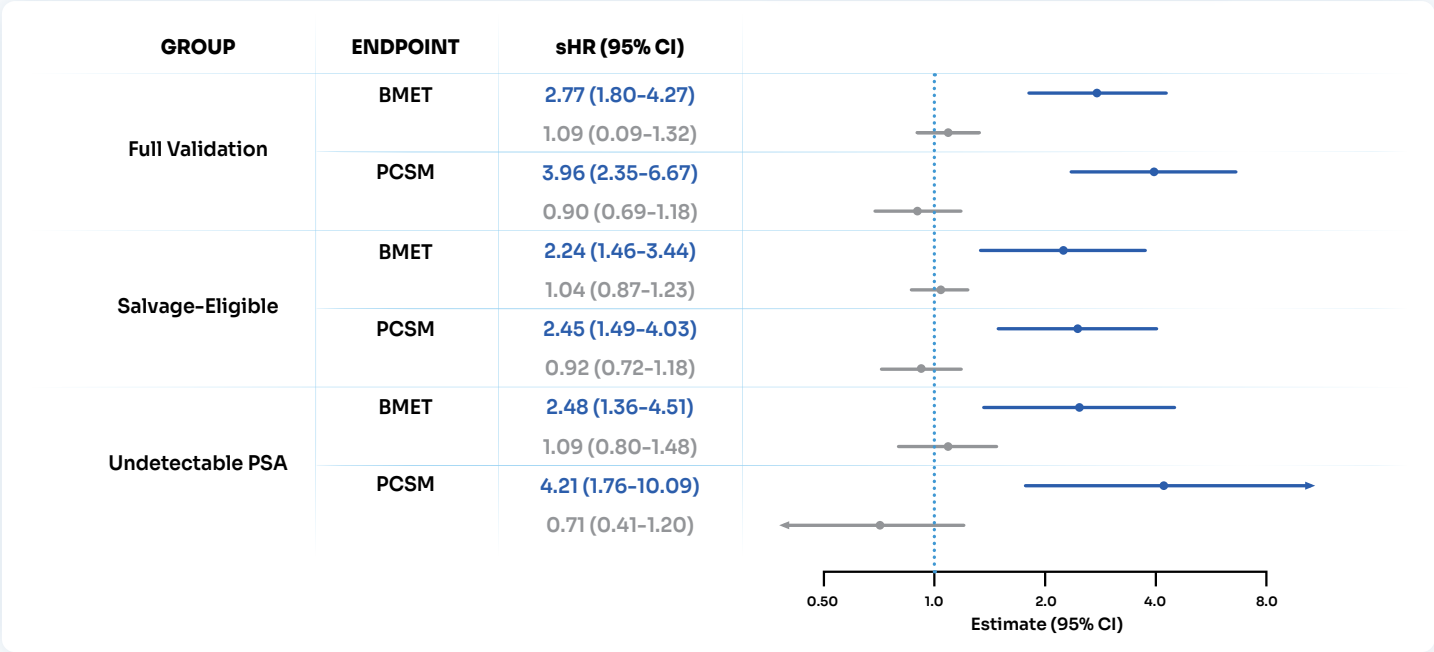


\*Clinical data required for the ArteraAI Prostate Test (Post-RP): age, pathologic T-stage, Gleason score, most recent post-RP PSA, and surgical margin status.

Post-RP MMAI Risk Score Predicts Adverse Outcomes  
Beyond Standard Clinical Variables<sup>3</sup>

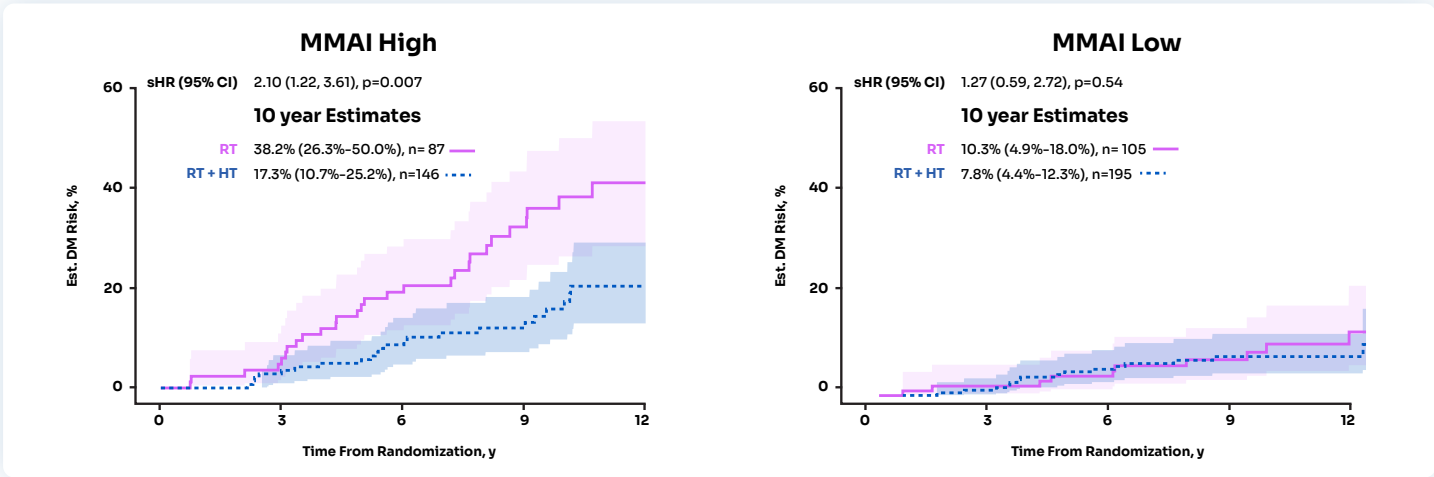
Validation in an independent institutional cohort of radical prostatectomy patients

CAPRA-S (continuous)    Artera RP MMAI raw score




BMET, bone metastasis; PCSM, prostate cancer specific mortality; RP, radical prostatectomy; sHR, subdistribution hazard ratio

MMAI Identified Patients Who Benefited From ADT  
Post Radical Prostatectomy<sup>1</sup>  
NRG/RTOG 9601 and 0534



The MMAI post-RP biomarker can identify patients who benefit the most from adding HT to salvage RT and may aid in personalization of treatment for these patients.

This is a sample Post-RP test report, run on a prostatectomy surgical specimen.



Name: John Doe  
Date of Birth: 08/08/1952

## ArteraAI Prostate Test Report (Post-RP)

### PATIENT DETAILS

**PATIENT**  
Name: John Doe  
Date of Birth: 08/08/1952  
Condition: Prostate Cancer

**ORDER**  
Order Date: 07/01/2023  
Test Run Date: 07/04/2023  
Artera ID: AM-4Y-VRD-005K  
Accession Number: ART-25-XXXX

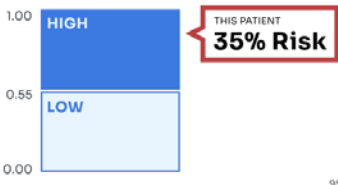
**CLINICAL AND PATHOLOGY**  
Specimen: Prostatectomy  
Pathological Tumor Stage: pT3a  
Surgical Margins: Positive  
Most Recent PSA (ng/mL): 0.54  
Gleason Score: 7 (4+3)  
Patient Age at Order Date: 72

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

### PROGNOSTIC RISK


**HIGH**  
ArteraAI Prognostic Raw Score=0.85

**10-YEAR RISK OF DISTANT METASTASIS**  
(With standard of care treatment)



95% CI: 25%-46%

**RISK COMPARED TO PATIENTS TREATED WITH SALVAGE THERAPY AFTER PROSTATECTOMY (NRG/RTOG 0534 and 9601)**



Patients from NRG/RTOG 0534 and 9601


This patient has a risk score that is **higher than 75%** of patients in the NRG/RTOG 0534 and 9601 trials who went on to receive salvage therapy

**5-YEAR RISK OF DISTANT METASTASIS**  
(With standard of care treatment)

8%  
95% CI: 5%-12%

**10-YEAR RISK OF PROSTATE CANCER SPECIFIC MORTALITY**  
(With standard of care treatment)

8%  
95% CI: 5%-12%

**ST-ADT INSIGHTS**  
**Likely to Benefit More from ST-ADT**  
On average, patients with this result had lower rates of distant metastasis when hormone therapy was added to salvage radiation therapy.

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

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Reviewed by Laboratory Director  
Joshua B. Kish, MD

12/04/2024 12:00PM  
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.]

1 of 4

- A Prognostic Risk:** The ArteraAI prognostic risk group explains how aggressive the patient's prostate cancer is. The 10-year risk of distant metastasis is reported as a continuous variable with a binary low- and high-risk categorization. These risk estimates are based on patients receiving standard of care treatment: salvage RT ± ADT.
- B Additional Prognostic Endpoints:** 5-year risk of distant metastasis and 10-year risk of prostate cancer-specific mortality are also reported to support optimized decision-making. These risk estimates are based on patients receiving standard of care treatment: salvage RT ± ADT.
- C Comparison to NRG/RTOG 0534 and 9601 Patient Cohorts:** This visualization shows how this patient's risk score compares to other patients who recurred after prostatectomy and were treated with salvage radiation therapy with or without ST-ADT. This comparison includes all treatment arms of NRG/RTOG 0534 and 9601.
- D ST-ADT Insights:** Based on the MMAI risk group stratification, MMAI High risk patients were likely to benefit more from the addition of ST-ADT to salvage RT whereas MMAI Low risk patients were likely to benefit less from the addition of ST-ADT.

## Billing Process Overview

1

### Test Order Placed



When the ArteraAI Prostate Test is ordered, insurance information is submitted to Artera as part of the ordering process.

2

### Benefit Investigation (BI)



Artera reviews insurance details to confirm coverage and estimate any out-of-pocket costs. If costs are expected to exceed \$285, Artera will attempt to contact the patient to discuss benefits, financial responsibility, and available payment options. Prompt responses help us provide clear cost information and avoid delays.

3

### Claims Submission



After the test is completed, Artera submits a claim directly to the insurance company. Any issues that arise during this process will be addressed to minimize disruptions.

4

### Patient Receives Explanation of Benefits (EOB)



An EOB will be sent by the insurance company. This document explains how the claim was processed. Please note: this is not a bill. It's simply a statement of what insurance covered and what financial responsibility there may be.

5

### Statement Generation



Once the insurance company processes the claim, Artera calculates any remaining patient financial responsibility. A detailed statement is then sent by mail, outlining the test cost, insurance payments, and any balance due.

6

### Payment and Collections



Artera offers flexible payment options, including payment plans and a Financial Assistance Program, to help reduce financial barriers and ensure patients can access the care they need.

# Getting the ArteraAI Prostate Test

## Process

1.



The ArteraAI Prostate Test is ordered by the treating physician.

2.



The original slide used to evaluate the surgical specimen is sent to our lab for analysis. No additional medical procedures are required.

3.



The test results are sent to the physician.

4.



Treating physician and patient review the results together.

## Ordering the Test

An ordering physician can get started by contacting [sales@artera.ai](mailto:sales@artera.ai) and someone from Artera will help you activate your account.

## Cost of Test

The out-of-pocket cost for the ArteraAI Prostate Test will be based on the patient's insurance plan. If the patient is covered by Medicare Plan B, they should have zero out-of-pocket costs for the ArteraAI Prostate Test.

If the patient is covered by private insurance, financial liability will be subject to the terms of the plan taking into consideration copays, coinsurance and deductibles. Artera offers a Financial Assistance Program to eligible patients to ensure out-of-pocket costs are no greater than \$285.

Please contact [billing@artera.ai](mailto:billing@artera.ai) for additional details about the cost of the test, insurance coverage, billing process, and payment options.



## Testimonials

"The ArteraAI Prostate Test is convenient and easily incorporated into our clinical workflows. I've been impressed with its clinical utility for patients with biochemical recurrence – which is why I get it for all those patients."

~ David Cahn, DO, MBS, FACOS  
MidLantic Urology

"The ArteraAI Prostate Test report is clear, straightforward, and easy to interpret. All clinical endpoints are valuable and directly applicable to treatment decisions and patient discussions."

~ Sean Collins, MD, PhD  
USF Health



### References

1. Data on File. Artera. 2024.
2. Nguyen PL, et al. *Eur Urol*. 2015;67(5):825-836.
3. Chien-Kuang CD, et al. 2025 ASCO Annual Meeting. Abstract 5106.

The ArteraAI Prostate 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 and determine if the ArteraAI Prostate Test is appropriate for you.

artera.ai



If you have any questions, please

contact Artera® at: [info@artera.ai](mailto:info@artera.ai) Artera®. All Rights Reserved. PML 119.B

