ARTERA

Precision oncology, powered by AI

ArteraAI Prostate Test

ArteraAI Prostate Test Overview

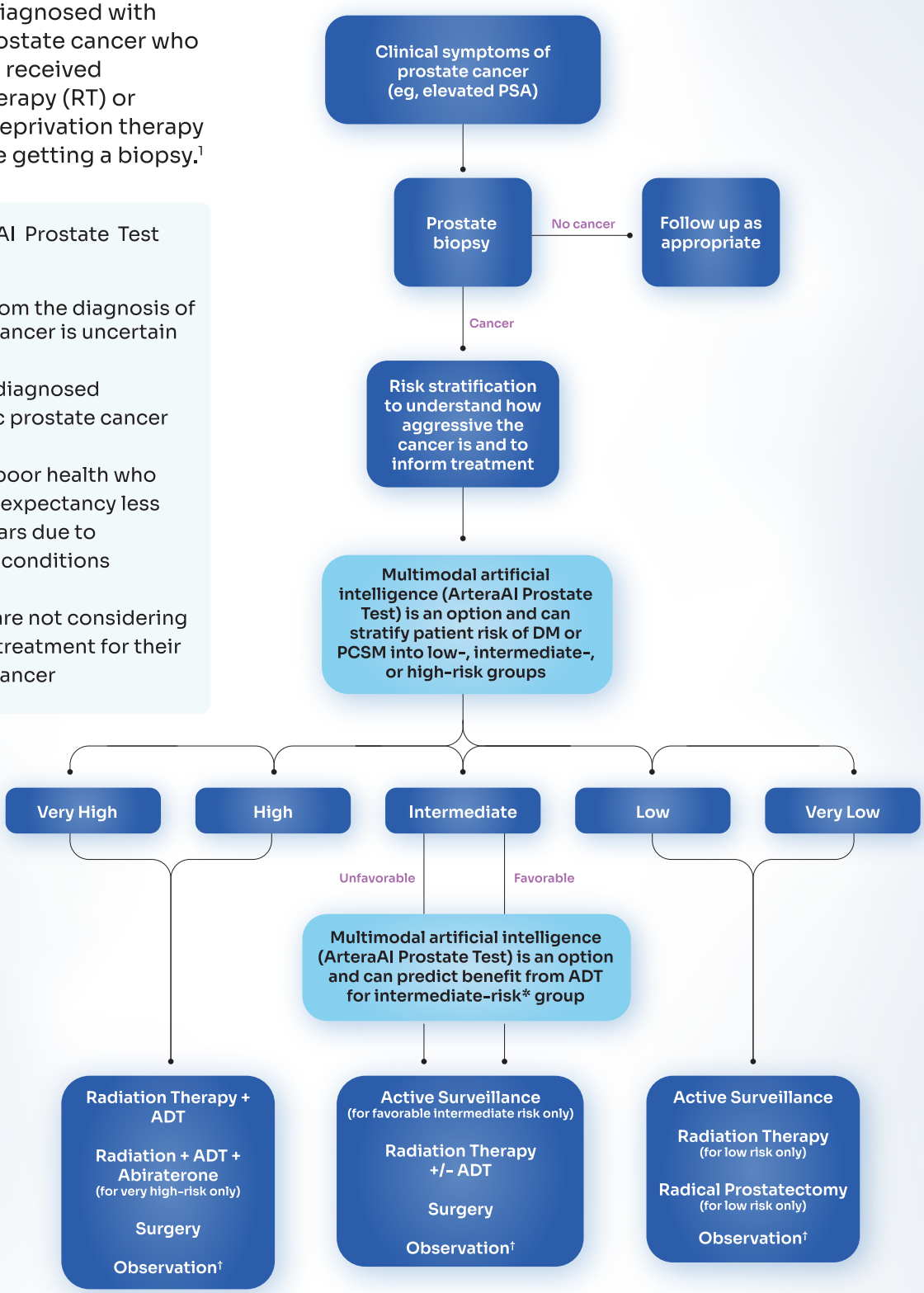
Who is this test for?

This test is for patients who have been diagnosed with localized prostate cancer who have not yet received radiation therapy (RT) or androgen-deprivation therapy (ADT) before getting a biopsy.[1]

The ArteraAI Prostate Test is not for:[1]

- Men in whom the diagnosis of prostate cancer is uncertain
- Men with diagnosed metastatic prostate cancer
- Men with poor health who have a life expectancy less than 10 years due to comorbid conditions
- Men who are not considering receiving treatment for their prostate cancer

Patient Journey[1,2]



*As categorized by NCCN risk grouping. †For patients with shorter life expectancy.
DM, distant metastasis; NCCN, National Comprehensive Cancer Network; PCSM, prostate cancer-specific mortality; PSA, prostate specific antigen.
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Why order this test?

Patients diagnosed with localized prostate cancer are faced with many treatment options that are guided by their prognostic risk grouping. This test can help provide insight into disease prognosis by estimating the risk for developing distant metastasis or prostate cancer specific mortality, based on individual patient characteristics. This information can be used to inform how aggressive treatment should be.

The ArteraAI Prostate Test is the first and only artificial intelligence (AI) test that can predict benefit from ADT. For patients with intermediate-risk* prostate cancer who are considering adding ADT to RT, this test can predict whether or not they will experience a significant reduction in the risk of distant metastasis by adding short-term ADT (ST-ADT) to RT. 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 RT could increase confidence in treatment decision-making.[3]

*As categorized by NCCN risk grouping.

The ArteraAI Prostate Test can help the patient and doctor determine the best cancer treatment plan.

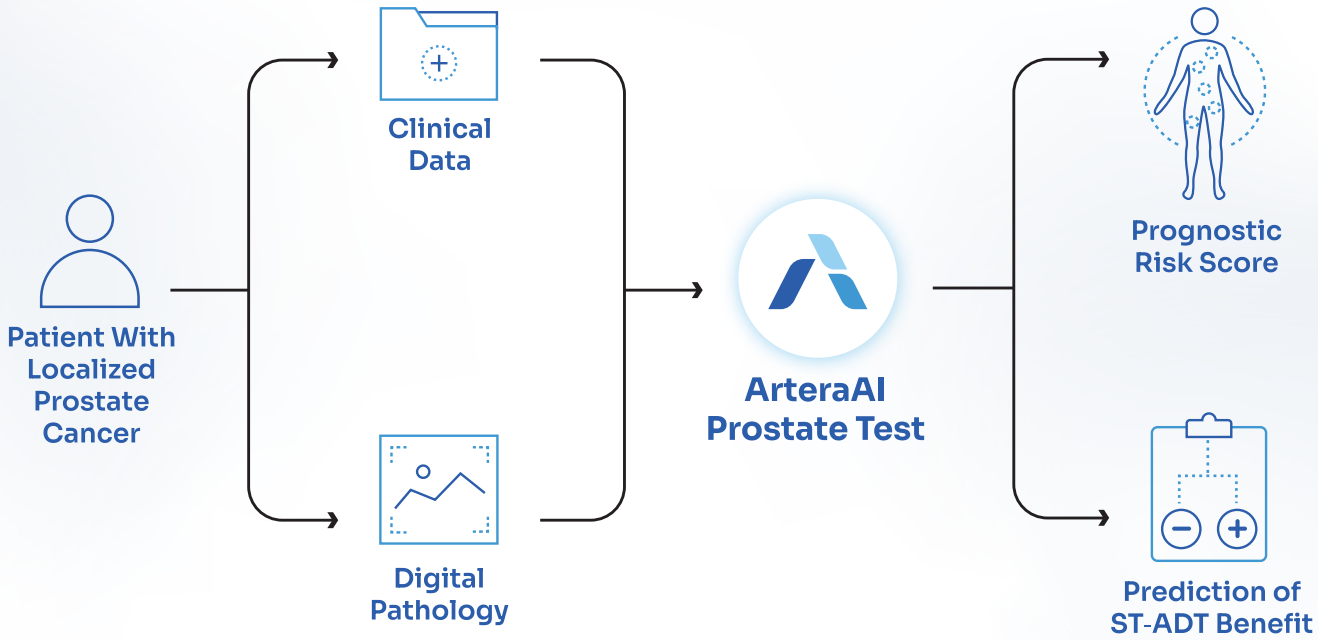
ArteraAI Multimodal Artificial Intelligence (MMAI)

The ArteraAI Prostate Test leverages a unique AI algorithm that was developed using data from multiple large, randomized, phase 3 clinical trials. Two types of data—clinical data and biopsy tissue slide image data—were used to develop the resulting model, the ArteraAI Prostate Test.[1,4]

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.[1,4] For intermediate-risk* patients, the test also produces a predictive result that informs whether or not the patient is predicted to benefit from adding ST-ADT to RT.[1,5]

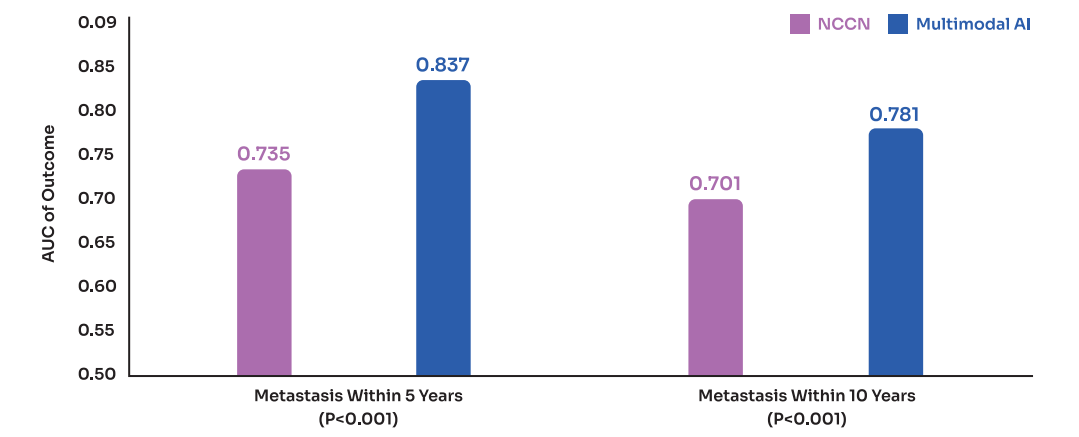
*As categorized by NCCN risk grouping.

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



MMAI Prognostic Biomarker Outperforms Standard Clinical Tools[4]

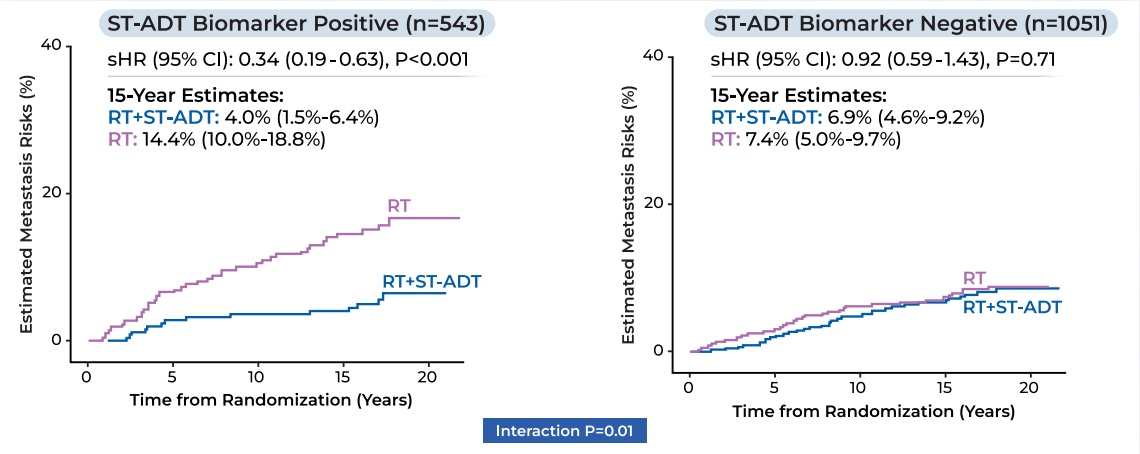
Performance of MMAI Model Compared With Standard National Comprehensive Cancer Network® (NCCN®) Risk Groups



The MMAI prognostic biomarker demonstrates superior performance (significantly higher AUC of outcome) compared with standard NCCN risk grouping for estimating the risk of distant metastasis within 5 or 10 years.[4]

MMAI Predictive Biomarker can Guide the Use of ST-ADT[5]

Probability of Developing Distant Metastasis Over Time with RT+ST-ADT vs RT Alone



Current standard of care for men with intermediate-risk localized prostate cancer includes treatment with ST-ADT in combination with RT, but a clinical study of the predictive biomarker used in the ArteraAI Prostate Test showed that only 34% of patients may actually need it.[5]

The predictive ST-ADT biomarker can identify which intermediate-risk* men may greatly benefit from those men who may receive little to no benefit from adding ST-ADT to RT.[5]

Multimodal artificial intelligence (ArteraAI Prostate Test) is the first and only AI test to be recommended as a prognostic and predictive tool in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer.[2]

*ST-ADT results are only reported for patients who have NCCN intermediate-risk disease.

AUC, area under the curve.

Interpreting Test Results

The ArteraAI Prostate Test is intended for use in patients with localized prostate cancer of any risk group. However, ST-ADT results are only reported for patients who have NCCN intermediate-risk disease.

ArteraAI Prognostic Risk

The ArteraAI prognostic risk group can explain how aggressive the prostate cancer is.

The ArteraAI prognostic risk scores can help determine the risk of distant metastasis within 5 or 10 years and prostate cancer-specific mortality within 10 years.

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ArteraAI Prostate Test Report

PROGNOSTIC RISK
INTERMEDIATE

10-YEAR RISK OF DISTANT METASTASIS
(With RT +/- systemic therapy)

HIGH
INTERMEDIATE
LOW
9% Risk

5-YEAR RISK OF DISTANT METASTASIS (With RT +/- systemic therapy) 3%

10-YEAR RISK OF PROSTATE CANCER SPECIFIC MORTALITY (With RT +/- systemic therapy) 10%

ST-ADT BIOMARKER
Positive
On average, patients with this result had **significant risk reduction** in distant metastasis with the addition of short-term androgen deprivation therapy.

CLINICAL INTERPRETATION
- This patient has a 9% risk of developing metastasis within 10 years based on analysis of data from clinical studies of patients who have had curative intent therapy
- In a clinical study of patients who have been treated with RT +/- ST-ADT, NCCN intermediate-risk patients in the ST-ADT biomarker (+) group
  - Had an average 2.9-fold (95% CI: 1.4–8.8) decrease in risk of distant metastasis within 15 years when treated with radiation therapy plus short-term androgen deprivation therapy compared with radiation therapy alone (Figure 1A)
  - Had an average metastasis risk reduction of 10% at 15 years

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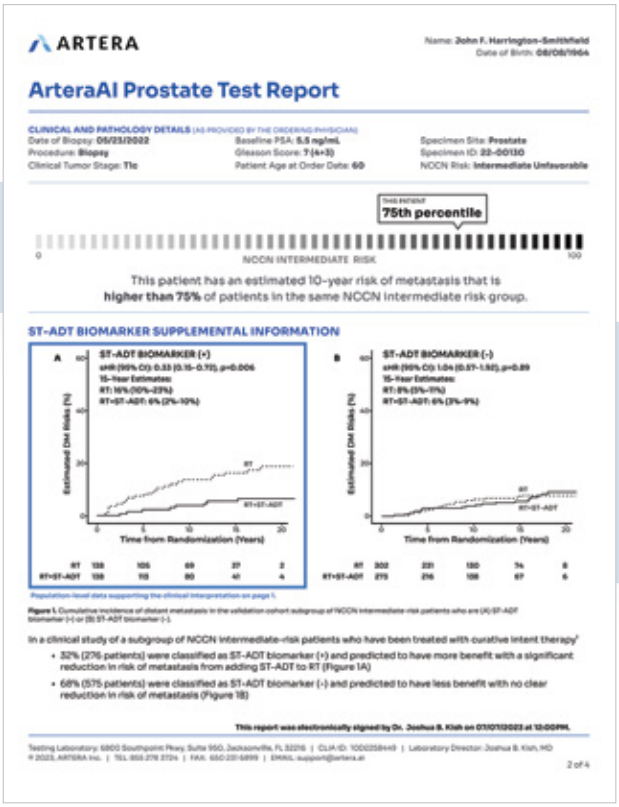
Predictive ST-ADT Biomarker

Men with intermediate-risk prostate cancer have many different treatment options, including hormone therapy.

Understanding the ST-ADT biomarker status can help to determine the likelihood of reducing the risk of distant metastasis at 15 years by adding ADT to RT.

Comparing the ArteraAI risk of distant metastasis within 10 years to other patients in the same NCCN risk group

There is variability among men with NCCN intermediate-risk disease. A visualization is provided to show how the patient's risk of metastasis, based on the ArteraAI risk score, compares to other men with NCCN intermediate-risk disease.



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ArteraAI Prostate Test Report

CLINICAL AND PATHOLOGY DETAILS

75th percentile

NCCN INTERMEDIATE RISK

This patient has an estimated 10-year risk of metastasis that is **higher than 75%** of patients in the same NCCN intermediate risk group.

ST-ADT BIOMARKER SUPPLEMENTAL INFORMATION

ST-ADT BIOMARKER (+)

ST-ADT BIOMARKER (-)

Time from Randomization (Years)

In a clinical study of a subgroup of NCCN intermediate-risk patients who have been treated with curative intent therapy
- 32% (276 patients) were classified as ST-ADT biomarker (+) and predicted to have more benefit with a significant reduction in risk of metastasis from adding ST-ADT to RT (Figure 1A)
- 68% (575 patients) were classified as ST-ADT biomarker (-) and predicted to have less benefit with no clear reduction in risk of metastasis (Figure 1B)

Meaning of ST-ADT Biomarker (+) or (-)

In a clinical study, intermediate-risk patients who were ST-ADT biomarker (+) had significantly reduced risk of metastasis at 15 years when adding ADT to RT; whereas patients who were ST-ADT biomarker (-) had little to no reduction in risk of metastasis with the addition of ADT.

Process

1.

The ArteraAI Prostate Test is ordered by the treating physician.

2.

The cancer tissue that was removed from the original biopsy 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

Treating physician can get started by contacting support@artera.ai and a member of our Customer Success Team will help you activate your account.

Cost of Test

The Centers for Medicare & Medicaid Services (CMS) have established a payment rate for the ArteraAI Prostate Test.

Patients who have questions or wish not to have the test performed should contact Artera's customer success team at 855-278-3724, and a team member will respond to your inquiry. If you are concerned about your ability to pay, Artera has a financial assistance program, which may limit out of pocket costs for qualifying patients.

References

1. Data on file. Artera, 2023.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Prostate Cancer V.3.2024. ©National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 12, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.
3. Nguyen PL, et al. *Eur Urol.* 2015;67(5):825-836.
4. Esteva A, et al. *NPJ Digit Med.* 2022;5. doi:10.1038/s41746-022-00613-w.
5. Spratt DE, et al. *NEJM Evidence.* Published 2023;2(8). doi:10.1056/EVIDoa2300023.

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

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