

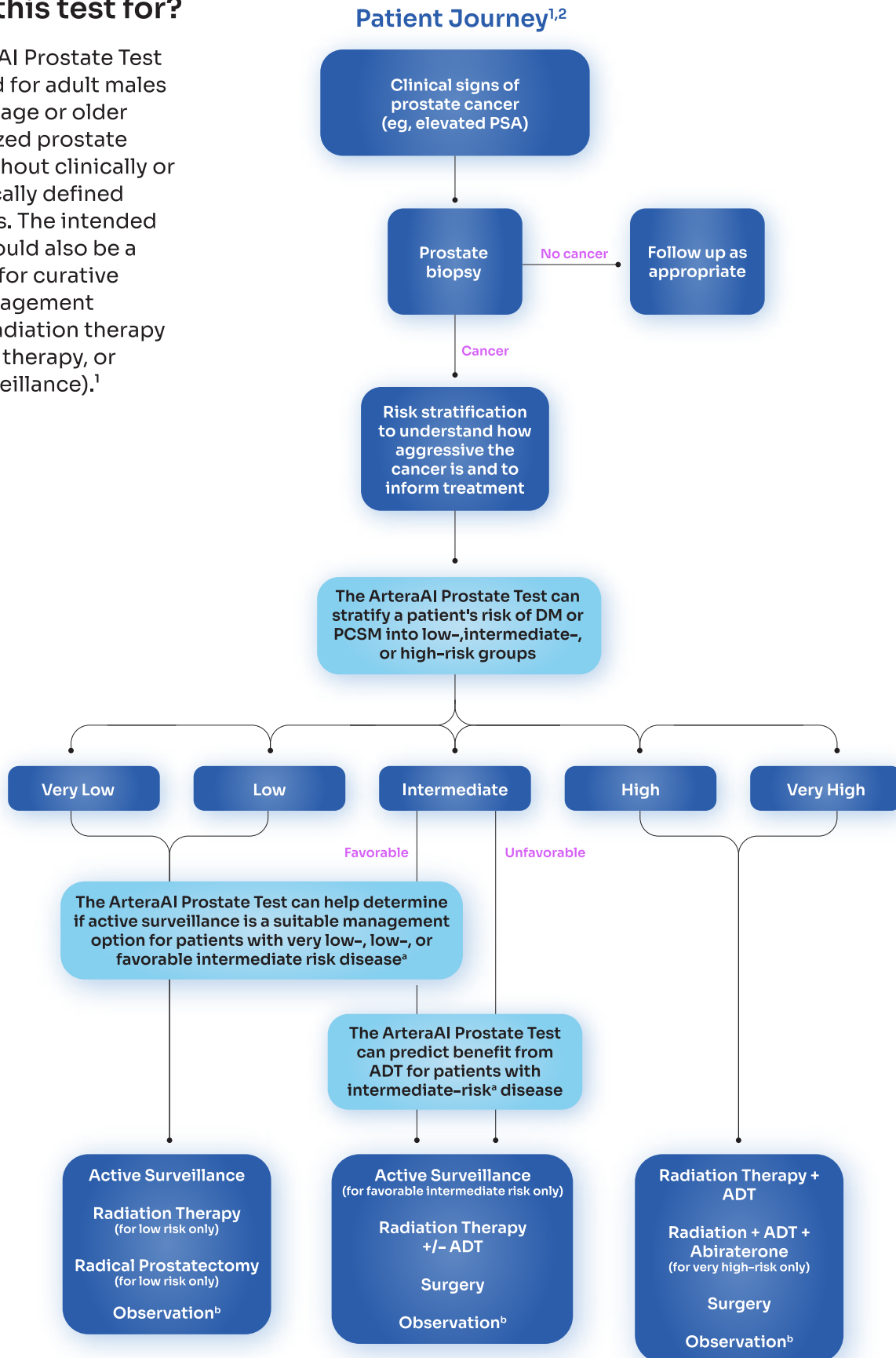
# ArteraAI Prostate Test



# ArteraAI Prostate Test Overview

## Who is this test for?

The ArteraAI Prostate Test is intended for adult males 18 years of age or older with localized prostate cancer, without clinically or pathologically defined metastases. The intended patient should also be a candidate for curative intent management (surgery, radiation therapy ± systemic therapy, or active surveillance).<sup>1</sup>



<sup>a</sup>As categorized by NCCN risk grouping. <sup>b</sup>For patients with shorter life expectancy.

DM, distant metastasis; NCCN, National Comprehensive Cancer Network; PCSM, prostate cancer-specific mortality; PSA, prostate specific antigen.

## Why order this test?

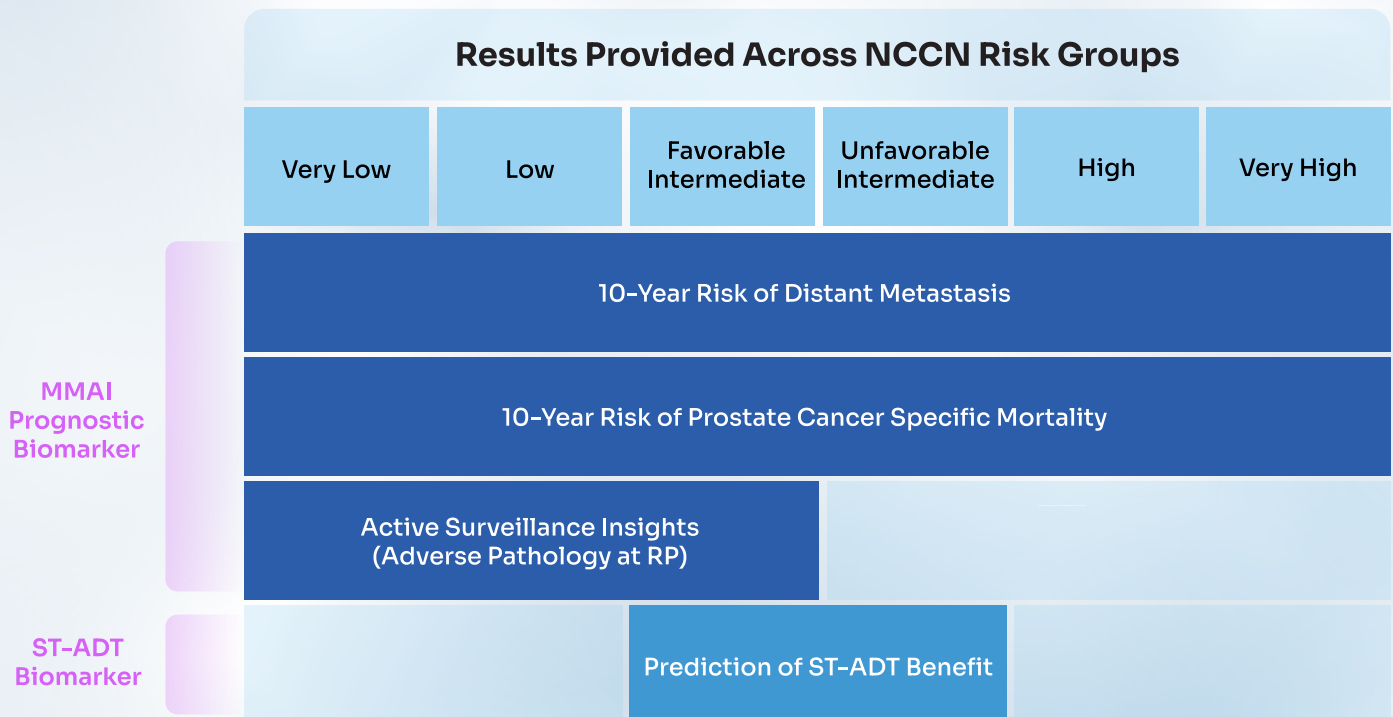
Patients diagnosed with localized prostate cancer are faced with many treatment options that are guided by their prognostic risk grouping. The ArteraAI Prostate Test can help provide insight into disease prognosis by estimating the risk for developing distant metastasis or prostate cancer specific mortality, based on individual patient characteristics. Additional insights are provided to guide decisions on active surveillance. This information can be used to inform treatment.

The ArteraAI Prostate Test can also predict benefit from ADT. For patients with intermediate-risk<sup>a</sup> 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.<sup>3</sup>

<sup>a</sup>As categorized by NCCN risk grouping.

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



# Science Behind the ArteraAI Prostate Test

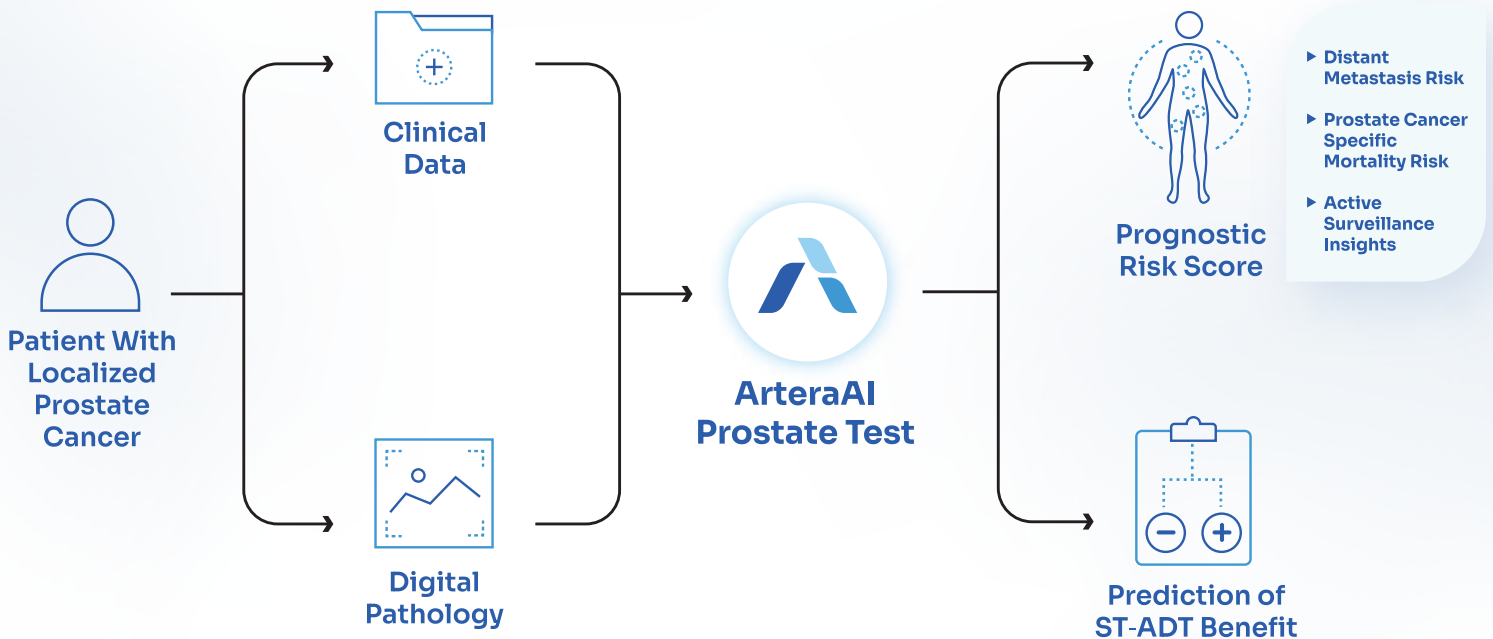
## ArteraAI Multimodal Artificial Intelligence (MMAI)

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.<sup>1,4</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>1,4</sup> For intermediate-risk<sup>a</sup> patients, the test also produces a predictive result that informs whether or not the patient is likely to benefit from adding ST-ADT to RT.<sup>1,5</sup>

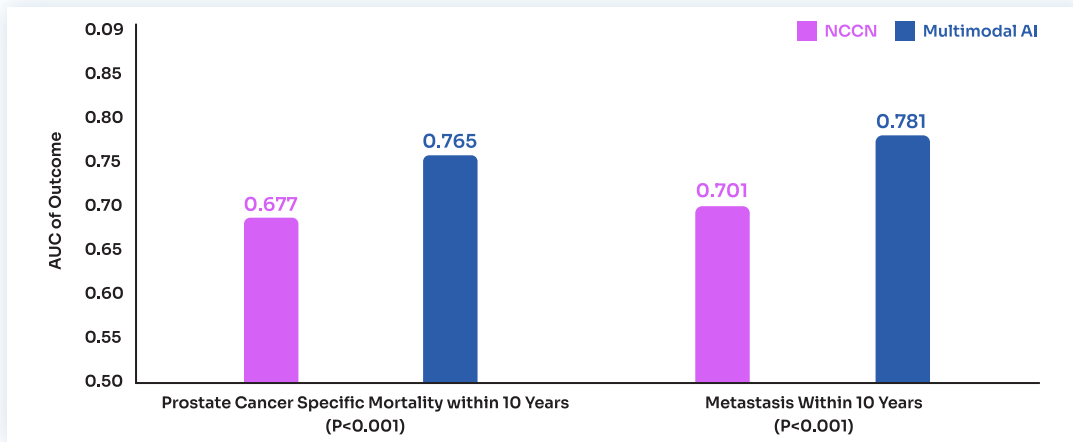
<sup>a</sup>As categorized by NCCN risk grouping.

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



# MMAI Prognostic Biomarker Outperforms Standard Clinical Tools<sup>4</sup>

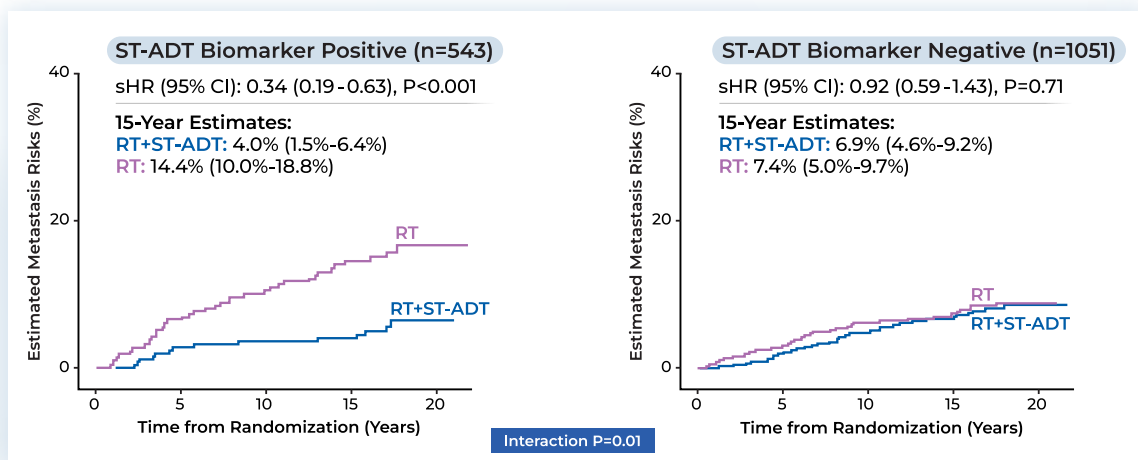
## Performance of MMAI Model Compared With Standard National Comprehensive Cancer Network® (NCCN®) Risk Groups



The MMAI prognostic biomarker demonstrates superior performance (significantly higher AUC of outcome) compared with standard NCCN risk grouping for estimating risk of distant metastasis or prostate cancer specific mortality within 10 years.<sup>4</sup>

## MMAI Predictive Biomarker can Guide the Use of ST-ADT<sup>5</sup>

### 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.<sup>5</sup>

The predictive ST-ADT biomarker can identify which intermediate-risk<sup>a</sup> men may greatly benefit from those men who may receive little to no benefit from adding ST-ADT to RT.<sup>5</sup>

**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.<sup>6</sup>**

<sup>a</sup>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. Active surveillance insights are only reported for those who have NCCN very low-, low-, and favorable intermediate-risk disease, and ST-ADT biomarker results are only reported for those who have NCCN intermediate-risk disease. This example is for a patient who has NCCN favorable intermediate-risk disease.

**ARTERA** Name: John Doe  
Date of Birth: 06/08/1964

### ArteraAI Prostate Test Report

**PATIENT DETAILS**

<b>PATIENT</b> Name: John Doe Date of Birth: 06/08/1964 Condition: Prostate Cancer	<b>PHYSICIAN</b> Name: Adam Smith, MD Clinic Name: Artera Hospital	<b>CLINICAL AND PATHOLOGY</b> Clinical Tumor Stage: T3c Pre-biopsy PSA: 3.8 ng/mL Gleason Score: 7 (3+4) Patient Age at Order Date: 71 NCCN Risk: Favorable Intermediate
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**ORDER**  
Order Date: 07/01/2023  
Test Run Date: 07/04/2023  
Artera ID: AM-4Y-VRD-005K

**PROGNOSTIC RISK**  
**LOW**  
ArteraAI Prognostic Risk Score=0.18

**10-YEAR RISK OF DISTANT METASTASIS**

HIGH	10%
INTERMEDIATE	3%
LOW	1.8% RISK

95% CI: 1.7%-2.3%

**ACTIVE SURVEILLANCE (AS) INSIGHTS**

This patient's relative risk of adverse pathology at radical prostatectomy (RP) is in the **50th percentile** of a cohort of patients managed with AS who had RP.

Consider AS | Consider AS or Definitive Therapy

ArteraAI Low Risk | ArteraAI High Risk

**10-YEAR RISK OF PROSTATE CANCER SPECIFIC MORTALITY** **0.8%**  
95% CI: 0.6%-1.0%

**ST-ADT BIOMARKER**  
**Negative**  
On average, patients with this result had **no clear risk reduction** in distant metastasis with the addition of short-term androgen deprivation therapy.

Reviewed by Laboratory Director: Joshua B. Kish, MD  
07/07/2023 12:00PM  
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 Prostate Test results are provided to support risk-based decisions within the recommended guidelines.

Testing Laboratory: 6900 Southpoint Pkwy, Suite 950, Jacksonville, FL 32276 | CUA ID: 1002258403 | Laboratory Director: Joshua B. Kish, MD  
© 2023, ARTERA Inc. | TEL: 650 239 7078 | FAX: 650 231 8999 | EMAIL: support@artera.ai

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- A ArteraAI Prognostic Risk:** The ArteraAI prognostic risk group can explain how aggressive the prostate cancer is. The ArteraAI prognostic risk score can help determine a patient's risk of distant metastasis and prostate cancer-specific mortality within 10 years.
- B Active Surveillance Insights:** Men with NCCN very low-, low-, and favorable intermediate-risk prostate cancer have various treatment options including active surveillance (AS). Comparing their risk of adverse pathology to that of other patients who were on AS and underwent radical prostatectomy can help determine if AS is a suitable management option.
- C Predictive ST-ADT Biomarker:** Men with NCCN intermediate-risk prostate cancer have many different treatment options, including hormone therapy. Understanding a patient's ST-ADT biomarker status can help determine the likelihood of reducing the risk of distant metastasis by adding ST-ADT to RT.

To view an interactive test report for a specific NCCN risk group, visit:  
[artera.ai/prostate-test-report](https://artera.ai/prostate-test-report)

# Getting the ArteraAI Prostate Test

## 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](mailto:support@artera.ai) and a member of our Customer Success Team will help you activate your account.

## Cost of Test

Artera® will work with your insurance company to seek reimbursement for this test. If you have Medicare Fee For Service, there is an established payment rate and you should have no out-of-pocket costs.

If your out-of-pocket costs are greater than \$285, please contact Artera to learn more about available financial assistance programs.

Patients who have questions or wish not to have the test performed should contact Artera and a team member will respond to your inquiry.

## Testimonials

"I think that this test is really transformative. We have never had any predictive biomarkers to use in clinical practice until now. We have been talking about this and wanting a tool like this for decades."

~ Daniel E. Spratt, MD  
University Hospitals Seidman Cancer Center

"I was looking for a treatment that could give me a better quality of life by minimizing the side effects...the ArteraAI Prostate Test revealed that I could avoid ADT and my treatment went well. I'm very glad I was able to avoid ADT."

~ Bruno, 59, Patient with Prostate Cancer



### References

1. Data on file. Artera, 2023.
2. PDQ Adult Treatment Editorial Board. Prostate Cancer Treatment (PDQ®). In PDQ Cancer Information Summaries [Internet] 2024. National Cancer Institute.
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.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2024. ©National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed June 4, 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.

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. 11/24

