ARTERA

Prostate Test Requisition Form

ORDER ID
(For Artera internal use only)

*Indicates a required field (these sections to be filled out by the ordering provider's office)

Patient Information

FIRST NAME*	LAST NAME*	DATE OF BIRTH*

ETHNICITY

☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Hispanic or Latino ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Other

Ordering Provider Information

FIRST NAME*	LAST NAME*	NPI*	CLINIC / HOSPITAL NAME*

PHONE NUMBER*	FAX*	EMAIL ADDRESS*

OFFICE CONTACT FIRST NAME	OFFICE CONTACT LAST NAME	OFFICE CONTACT EMAIL ADDRESS

Clinical Information

PRIMARY GLEASON SCORE	SECONDARY GLEASON SCORE
☐ 3 ☐ 4 ☐ 5	☐ 3 ☐ 4 ☐ 5

PSA LEVEL TAKEN PRIOR TO THIS BIOPSY (AND PRIOR TO ANY ONGOING TREATMENTS) (NG/ML)*

T-STAGE*

☐ T1a ☐ T1b ☐ T1c ☐ T2a ☐ T2b ☐ T2c ☐ T3a ☐ T3b ☐ T4

NCCN RISK CATEGORY*

☐ Very Low ☐ Low ☐ Favorable Intermediate ☐ Unfavorable Intermediate ☐ High ☐ Very High

Billing Information (include copy of insurance card(s))

PATIENT STATUS AT THE TIME OF BIOPSY*

☐ Hospital Inpatient - Date of Discharge [ ] ☐ Non-Hospital Outpatient
☐ Hospital Outpatient - Date of Discharge [ ]

Additional Information (the following must be attached)*

☐ Demographic / Face Sheet
☐ Copy of Insurance Card(s) (front and back)
☐ Pathology Report
☐ Copy of most recent office note

Test Selection

☐ ArteraAI Prostate (AP) Test

Ordering Provider Signature and Attestation

MEDICAL JUSTIFICATION* (PLEASE REFER TO THE BACK OF THIS PAGE FOR MEDICAL JUSTIFICATION DEFINITIONS)

Patient is being considered for the treatment below and is eligible for treatment intensification based upon cancer risk factors and other personalized considerations. Risk classification with the ArteraAI Prostate Test is indicated to help determine the optimal treatment plan: (select at least one)

☐ Active Surveillance ☐ Definitive Local Therapy ☐ Definitive Local Therapy + Systemic Therapy ☐ Other

Ordering Provider Signature and Attestation

I am the patient's treating physician, and my signature certifies that the clinical information entered on this form is accurate and that this test is medically necessary. I have determined that the patient meets all applicable eligibility criteria for the test; I will use the results to inform my treatment decisions and medical management for this patient. Specifically, the ArteraAI Prostate Test results, in conjunction with other clinical or relevant information, will be used to inform my judgment when determining whether this patient may be managed with active surveillance or definitive therapy, or when determining which form of definitive therapy is most appropriate, including but not limited to, the intensity or duration of treatment that is most appropriate (eg, radiation alone, radiation plus androgen-deprivation therapy, radical prostatectomy, etc). By signing this form, I attest that the patient's life expectancy is long enough to consider treatment for prostate cancer. I also confirm that the patient is able to tolerate definitive treatment for prostate cancer. I have obtained informed consent from the patient to bill for the ArteraAI Prostate Test, and I confirm that the primary diagnosis code is C61. I understand that the ArteraAI Prostate Test has not been reviewed by the FDA. I hereby authorize testing and confirm that I have obtained informed consent from the patient, to the extent required by law, to proceed with testing, for benefits to be paid to ancillary service providers like Artera, Inc. (and its affiliates), and for Artera, Inc. (and its affiliates) to release patient information for claims processing when necessary to obtain reimbursement for this service.

ORDERING PROVIDER SIGNATURE*	DATE*

▼ PATHOLOGY LAB ONLY ▼

Pathology Lab Information

LAB NAME				STREET ADDRESS	
CITY	**STATE**	**ZIP CODE**	**PHONE NUMBER**	**FAX**	**EMAIL ADDRESS**

SPECIMEN INFORMATION (this section to be filled out by the pathology laboratory)

Please send one (1) H&E slide or one (1) block containing one (1) biopsy core with the tumor that has the highest Gleason grade used by the pathologist in making his or her diagnosis for the patient. If the LUMEA BxChip is used, please send one (1) H&E slide containing up to six (6) biopsy cores that include the tumor that has the highest Gleason grade. The ArteraAI Prostate Test result is dependent on the highest Gleason grade as documented in the referring laboratory pathology report.

DATE OF BIOPSY*	SPECIMEN ID*	NUMBER OF SLIDES / BLOCKS*

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Medical Justification Definitions

Treatment Considered	Definition	These Patients Are Also Eligible for Treatment Intensification With (at Least):
Active Surveillance	Active surveillance or observation with PSA monitoring	RP, EBRT, brachytherapy, other treatment at discretion of physician
Definitive Local Therapy	Local treatment given with intent to cure the cancer (ie, EBRT, RP, brachytherapy, etc)	EBRT with a brachytherapy boost, or EBRT with the addition of ST-ADT
Definitive Local Therapy + Systemic Therapy	EBRT with the addition of ST-ADT or addition of LT-ADT (also known as standard ADT)	ST-ADT: EBRT with the addition of LT-ADT LT-ADT: EBRT with the addition of LT-ADT and a next-generation androgen-signaling inhibitor, or EBRT with the addition of LT-ADT and docetaxel chemotherapy
Other	Any treatment being considered that is not currently listed	

National Comprehensive Cancer Network® (NCCN®) Risk Category Classification

Risk Group	Clinical/Pathologic Features		
Very low	Has all of the following: ▪ cT1c ▪ Grade Group 1 ▪ PSA <10 ng/mL ▪ Fewer than 3 prostate biopsy fragments/cores positive, <50% cancer in each fragment/core ▪ PSA density <0.15 ng/mL/g		
Low	Has all of the following but does not qualify for very low risk: ▪ cT1-cT2a ▪ Grade Group 1 ▪ PSA <10 ng/mL		

Intermediate	Has all of the following:
	▪ No high-risk group features
	▪ No very-high-risk group features
	▪ Has one or more IRFs:
	  ▪ cT2b-cT2c
	  ▪ Grade Group 2 or 3
	  ▪ PSA 10-20 ng/mL
		Favorable Intermediate	Has all of the following:
			▪ 1 IRF
			▪ Grade Group 1 or 2
			▪ <50% biopsy cores positive (eg, <6 of 12 cores)

		Unfavorable Intermediate	Has one or more of the following: ▪ 2 or 3 IRFs ▪ Grade Group 3 ▪ <50% biopsy cores positive (eg, >6 of 12 cores)
High	Has no very-high-risk features and has exactly one high-risk feature: ▪ cT3a OR ▪ Grade Group 4 or Grade group 5 OR ▪ PSA >20 ng/mL		
Very High	Has at least one of the following: ▪ cT3c-cT4 ▪ Primary Gleason pattern 5 ▪ 2 or 3 high-risk features ▪ >4 cores with Grade Group 4 or 5		

Specimen Information and Order Acceptance Criteria

The ArteraAI Prostate Test result is dependent on the highest Gleason grade specimen as documented in the referring laboratory pathology report. Patient H&E slide(s) OR block(s) are accepted. Please see below for detailed acceptance criteria:

If shipping slides:

a. Please send one (1) H&E slide containing one (1) biopsy core with the tumor that has the highest Gleason grade used by the pathologist in making his or her diagnosis for the patient.

b. If the LUMEA BxChip is used, please send one (1) H&E slide containing up to six (6) biopsy cores that include the tumor that has the highest Gleason grade.

If shipping blocks:

c. Please send one (1) block containing one (1) biopsy core with the tumor that has the highest Gleason grade used by the pathologist in making his or her diagnosis for the patient.

Shipping Instructions

Detailed shipping instructions can be found on the “Pathology Laboratory Instructions” document included in the ArteraAI Prostate Test Kit.

Billing Information

If you or your patient have any additional questions about the out-of-pocket cost for the ArteraAI Prostate test, please contact Artera Billing at 1-650-239-7018.

ADT, androgen-deprivation therapy; EBRT, external beam radiation therapy; H&E, hematoxylin and eosin; IRF, intermediate risk factor; LT-ADT, long-term androgen-deprivation therapy; PSA, prostate-specific antigen; RP, radical prostatectomy; ST-ADT, short-term androgen-deprivation therapy.

© ARTERA Inc. 2024 | Phone: 1-650-239-7018 | Fax: 1-650-231-6899 | Email: support@artera.ai | Web: artera.ai | 6800 Southpoint Pkwy, Suite 950, Jacksonville, FL 32216 United States