

Pathology Laboratory Instructions

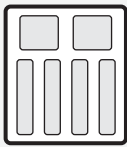
ArteraAI Prostate Test

The ArteraAI Prostate Test is an artificial intelligence–derived biomarker test that is designed to support risk-based clinical decisions for patients with localized prostate cancer.¹ The test is based upon the analysis of digital histopathology images (from H&E-stained slides) and specific clinical variables provided by the ordering clinician.¹ The subsequent test report summarizes a patient’s risk of distant metastasis and prostate cancer–specific mortality, as well as predicted magnitude of benefit with androgen-deprivation therapy for patients who are being considered for treatment with radiation therapy.^{1,2}

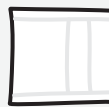
You are receiving this request for tissue specimen, because a clinician has ordered an ArteraAI Prostate Test for a patient whose tissue specimen resides at your laboratory. The test is conducted at Artera’s single-site, CLIA-certified laboratory located in Jacksonville, FL. This document provides instructions on how to send a specimen to Artera’s clinical laboratory.

Shipping Kit Contents

1x - foam insert



1x - gel pack



1x - plastic slide mailer (each mailer can hold up to 5 slides)



1x - 8”x 8” biohazard bag

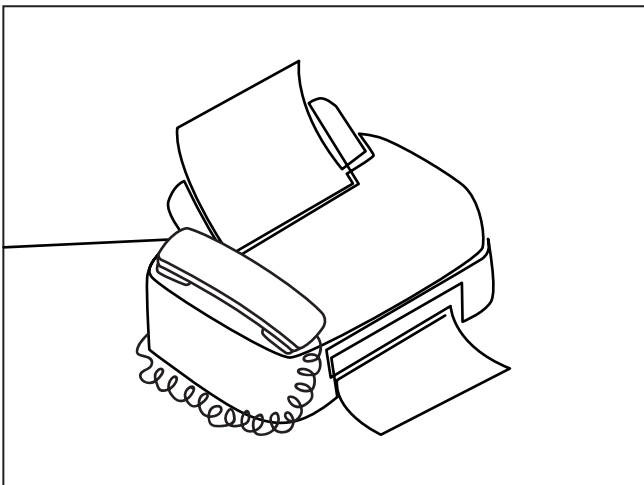


1x - FedEx clinical pack with a prepaid label to be used to ship tissue specimen to Artera’s lab



Order Fulfillment Instructions

- 1 A partially completed Test Requisition Form will be sent to your laboratory via fax.

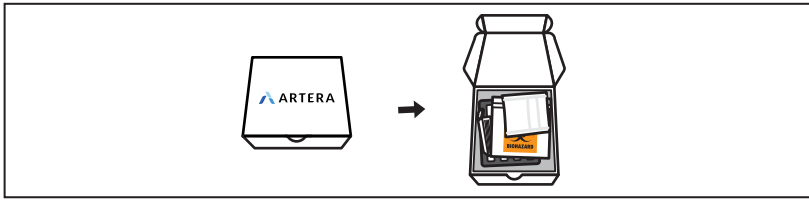


- 2 Within **24 hours**, review the Test Requisition Form and fill out all the required fields marked with an asterisk within the **“Pathology Lab Only”** section, which includes the following (see below):

- a DATE OF BIOPSY*
- b SPECIMEN ID*
- c NUMBER OF SLIDES/BLOCKS*

..... ▼ 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 BioChip 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*		
a	b		c		
© ARTERA Inc. 2024 Phone: 1-650-239-7010 Fax: 1-650-231-6899 Email: support@artera.ai Web: artera.ai 6800 Southport Pkwy, Suite 950, Jacksonville, FL 32216 United States					

3 Retrieve the ArteraAI Prostate Test Kit.

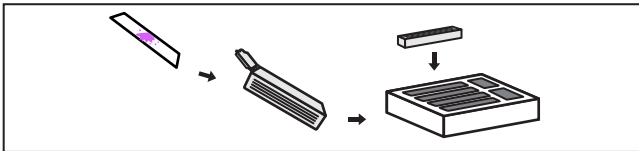


4 Prepare the patient's tissue specimen(s) for shipment. The ArteraAI Prostate Test result is dependent on the highest Gleason grade specimen as documented in the referring laboratory pathology report.

a Preferred method if shipping slides:

i 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. 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.

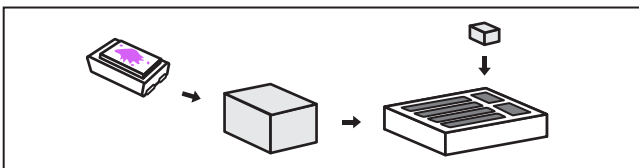
ii Insert **H&E slides** into the **plastic slide mailer** and place it into the **foam slots**.



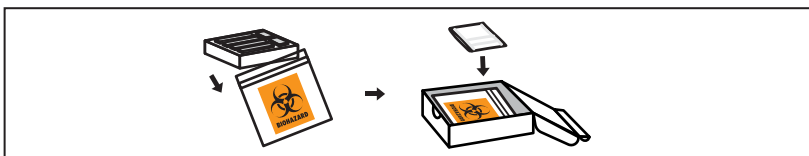
b If shipping block:

i 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.

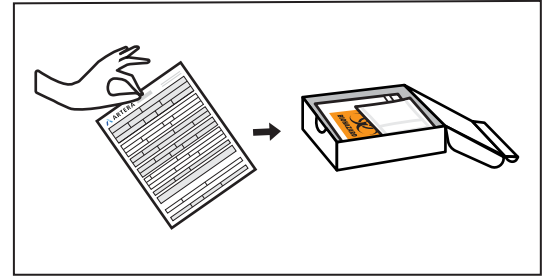
ii Place **block** into the **foam slot**.



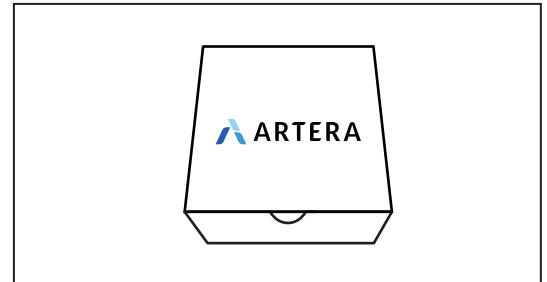
5 Place the foam insert (with slide mailer or block cassettes) into the biohazard bag, zip the bag closed, and place in kit box with an activated gel pack on top.



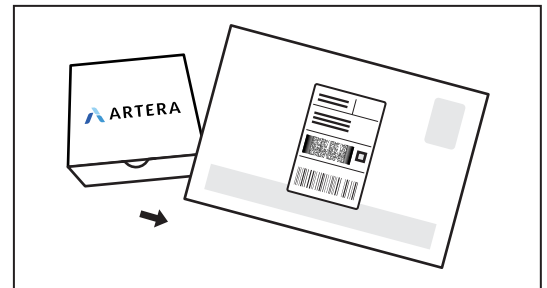
6 Place the fully completed Test Requisition Form into the kit box.



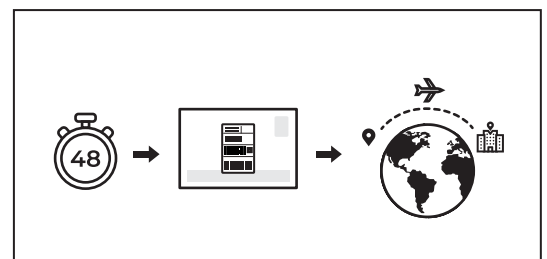
7 Once the test kit has all the required components, seal the box.



8 Place the kit box into the **prepaid** FedEx clinical pack.



9 Ship to the Artera CLIA lab within **48 hours** of receiving the Test Requisition Form.



Return of Specimens

Artera will promptly return the specimens to your laboratory after processing at our CLIA lab.

If you have any questions, please contact Artera support via email at **support@artera.ai** or by phone at 1-650-239-7018.

FFPE, formalin-fixed paraffin-embedded; H&E, hematoxylin and eosin.

1. Esteva A, et al. *NPJ Digit Med.* 2022;5(1):71. 2. Data on file. [ArteraAI Prostate Test Report]. Artera Inc. 2022.

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CLIA Lab: One Path Diagnostics, LLC, 6800 Southpoint Pkwy, Suite 950, Jacksonville, FL 32216, United States (**All patient specimens to be sent here**)