

<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Phase II trial of intravesical gemcitabine and MK-3475 (pembrolizumab) in the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer  Short Title- A031803	Version No: 2.1	Effective Date: 02/01/2024
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## CORRELATIVE SCIENCE PROCEDURE MANUAL

### 1. Purpose

This document describes the procedures required for the collection, shipping, and processing of biospecimens from patients enrolled or registered who have consented to participate in A031803. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by the Alliance Biorepository (i.e. Siteman Cancer Center Tissue Procurement Core at Washington University), prior to their use for protocol-specified and future, unspecified correlative science research studies. This document should be used by staff involved with any aspect of the A031803 biospecimen collection, processing, and submission, including staff at satellite institutions.

### 2. Scope

This document applies to all biospecimens collected specifically for A031803 only. Please refer to the trial protocol-specific language for additional details regarding eligibility, participant enrollment, data submission, and specific procurement procedures. **Please ensure that you are reading the most updated version of this document. This document may experience minor updates, revisions, and clarifications independent of a formal protocol amendment. The most recent version of this document may be found on the Alliance website and CTSU.**

### 3. Definitions

Term	Definition
ABWUSTL	Alliance Biorepository at Washington University in St. Louis
FFPE	Formalin Fixed, Paraffin Embedded
IHC	Immunohistochemistry
TURBT	Transurethral Resection of Bladder Tumor

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#### 4. Contact Information

<b>Protocol-related questions may be directed as follows:</b>	
<b>Questions</b>	<b>Contact (via email)</b>
Questions regarding patient eligibility, treatment, and dose modification:	Study Chair: Michael Woods, MD <a href="mailto:michael.woods@lumc.edu">michael.woods@lumc.edu</a>  Nursing Contact: Archana Ajmera, NP, AOCNP <a href="mailto:ajmera@ucsd.edu">ajmera@ucsd.edu</a>  Protocol Coordinator: Shiva Baghaie <a href="mailto:sbaghaie@bsd.uchicago.edu">sbaghaie@bsd.uchicago.edu</a>  (where applicable) Data Manager: Aaron Steele <a href="mailto:steele.aaron@mayo.edu">steele.aaron@mayo.edu</a>
Questions related to data submission, RAVE or patient follow-up:	Data Manager: Aaron Steele <a href="mailto:steele.aaron@mayo.edu">steele.aaron@mayo.edu</a>
Questions regarding the protocol document and model informed consent:	Protocol Coordinator: Shiva Baghaie <a href="mailto:sbaghaie@bsd.uchicago.edu">sbaghaie@bsd.uchicago.edu</a>
Questions related to IRB review:	Alliance Regulatory Inbox <a href="mailto:regulatory@allianceNCTN.org">regulatory@allianceNCTN.org</a>
Questions regarding CTEP-AERS reporting:	Alliance Pharmacovigilance Inbox <a href="mailto:pharmacovigilance@alliancenctn.org">pharmacovigilance@alliancenctn.org</a>
Questions regarding specimens/specimen submissions:	Alliance Biorepository at Washington University <a href="mailto:alliance@email.wustl.edu">alliance@email.wustl.edu</a>
Questions regarding drug supply:	NCI PMB: <a href="mailto:PMBAfterHours@mail.nih.gov">PMBAfterHours@mail.nih.gov</a>
Questions regarding drug administration:	Pharmacy Contact: Andrea Monckeberg <a href="mailto:mamonckeberg@lifespan.org">mamonckeberg@lifespan.org</a>

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**4.1** For information on using the BiOMS system, please refer to the ‘Help’ links on the BiOMS webpage to access the online user manual, FAQs, and training videos. To report technical problems, such as login issues or application errors, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org). For assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).

**4.2** For all other questions regarding biospecimen procurement and shipping procedures, please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu).

## 5. Site Preparation

**5.1** Please refer to A031803 protocol document for any specific requirements related to patient enrollment, registration, and regulatory compliance.

**5.2** Please ensure that you have appropriate log on credentials and can successfully access the BiOMS application. The BiOMS application is used for logging the collection and shipment of biospecimens to the Alliance Biorepository at Washington University. For training and assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).

## 6. Collection Schema

The following biospecimens are to be collected at each of the time points. Please refer to individual biospecimen collection and processing methods and specific shipping procedures below.

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Time Point	Kit (Y/N)	Biospecimen	Quantity	Collection / Processing Method	Shipping	Notes
<b>Mandatory for all patients registered to A031803</b>						
≤ 28 days after registration	N	H&E stained slides <b>OR</b> Scanned Slide Images	1	H&E stained slide for central pathology review (9.2)  Scanned Slide Images (9.5)	Ambient	1
<b>For patients registered to A031803-ST1</b>						
≤ 28 days after registration	N	Fixed tissue block	1	Fixed tissue block (9.3)	Ambient	2, 3
≤ 28 days after registration	N	Fixed tumor tissue slides	19	Unstained tissue slides + H&E stained slide for tissue QA (9.4)	Ambient	2, 3
Day 1 of Cycle 1	N	Whole blood (EDTA)	2 x 10 ml	Whole blood- EDTA tubes (10.1)	Ambient	2, 4, 7
Day 1 of Cycle 1	N	Urine	3 x 10 ml	Urine (11)	Cold Pack	2, 7
Day 1 of Cycle 2	N	Whole blood (EDTA)	2 x 10 ml	Whole blood- EDTA tubes (10.1)	Ambient	2, 4, 7
Day 1 of Cycle 2	N	Urine	3 x 10 ml	Urine (11)	Cold Pack	2, 7
Day 1 of Cycle 5	N	Whole blood (EDTA)	2 x 10 ml	Whole blood- EDTA tubes (10.1)	Ambient	2, 4, 7
Day 1 of Cycle 5	N	Urine	3 x 10 ml	Urine (11)	Cold Pack	2, 7

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At Progression	N	Fixed tissue block	1	Fixed tissue block (9.3)	Ambient	2, 5, 6
At Progression	N	Fixed tumor tissue slides	19	Unstained tissue slides + H&E stained slide for tissue QA (9.4)	Ambient	2, 5, 6
At Progression	N	Whole blood (EDTA)	2 x 10 ml	Whole blood- EDTA tubes (10.1)	Ambient	2, 4, 5
At Progression	N	Urine	3 x 10 ml	Urine (11)	Cold Pack	2, 5

**Notes:**

1. Submission of one (1) H&E stained slide from diagnostic paraffin tumor block containing bladder tissue from the diagnostic TURBT surgery specimen is **mandatory** for retrospective histopathology review. Alternatively, whole slide image scan files of the stained slides in .SVS file format may be uploaded digitally to the Biorepository, see section 9.5 for additional details.
2. Collection is optional for patients but requires all sites offer to patients to consent. Please see protocol-specific consent documents.
3. A paraffin tissue block containing bladder tissue from the diagnostic TURBT surgery specimen **OR** 18 unstained slides (16 x 10 um for DNA/RNA, 2 x 5 um for IHC) **AND** 1 H&E stained slide from such a block should be submitted for patients opting in for A031803-ST1, if available. If fewer than 18 unstained slides can be submitted, please prioritize the 2 x 5 um slides for IHC and submit as many unstained slides as possible for DNA / RNA (up to 16).
4. Whole blood (EDTA) 2 x 10 ml for PBMC isolation and cryopreservation at the biorepository.
5. Progression samples may be collected and submitted up to 3 months after progression.
6. One paraffin tissue block from progressive disease **OR** 18 unstained slides (16 x 10 um for DNA/RNA, 2 x 5 um for IHC) **AND** 1 H&E stained slide from such a block should be submitted for patients opting in for A031803-ST1, if available. If fewer than 18 unstained slides can be submitted, please prioritize the 2 x 5 um slides for IHC and submit as many unstained slides as possible for DNA / RNA (up to 16).
7. Specimen collected day 1 of cycles 1, 2, and 5 prior to starting treatment.

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## 7. Biospecimen Collection Kits

**7.1 There are no “kits” provided for submission of blood, tissue, or urine specimens for this study. Sites are responsible for acquiring materials for collection and shipping of these specimens to the Biorepository.**

**7.2 Please see Section 12 – Biospecimen Shipping for specific instructions on shipping to ABWUSTL.**

## 8. Biospecimen Labeling and Tracking

**8.1** All research biospecimens (vacutainer tubes, urine tubes, tissue bags) MUST be labeled with the Alliance patient ID number, patient initials (Last, First, Middle), the date and time (if applicable) of collection and specimen type.

**8.2** Surgical pathology tissue blocks should not be labeled in any manner. The institutional surgical pathology number (e.g. “S16-1234”) and the individual block identifier (e.g. “A3”) should be readable on the block. If tissue sections are being submitted instead of the block, each tissue section slide should be labeled with the Alliance study number (A031803), Alliance patient ID number, institutional surgical pathology number, the block identifier, section thickness (in um) and the serial section number. Provide **a de-identified copy of the surgical pathology report**, labeled with the Alliance patient ID number, corresponding to the blocks or slides submitted to ABWUSTL. Please ensure the institutional surgical pathology number and block ID are maintained on the surgical pathology report. See section 9 for additional details.

**8.3** Label all containers and vials with an indelible, solvent-resistant marker when they are at ambient temperature.

**8.4** Do not affix any labels to vials, slides or tubes. Label the collection containers directly with the marking pen.

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**8.5** All biospecimens that are collected and sent to the Alliance Biorepository must be **logged and tracked in BioMS**. The BioMS system is a web-based application that tracks the collection and shipping of biospecimens. Once individual biospecimens are logged and ‘shipped’ in the BioMS system, a packing manifest will be created by the system. This manifest must be printed out and must accompany all biospecimen shipments. To become familiar with the BioMS system and for further information about training, access, and use, please contact the BioMS Help desk at: 1-855-55-BIOMS or [bioms@alliancencn.org](mailto:bioms@alliancencn.org).

**8.6** In the event that BioMS cannot be accessed, please complete a BioMS Specimen Log and Shipping Manifest form which can be found here- <http://tinyurl.com/alliance-biomscontingency>.

## 9. Tissue Collection

### 9.1 Overview.

**9.1.1** Please refer to protocol-specific instructions for procedures related to actual tissue procurement from individual participants. The method for research tissue procurement (needle core biopsy, sampling of surgically resected tumor) is dependent upon the disease site and the individual patient.

**9.1.2** When procuring tissue biospecimens by any method, when possible, avoid tissue that is grossly necrotic, hemorrhagic, fatty, or fibrous. If in doubt, briefly (1 min or less) place the tissue segment in a sterile specimen cup containing physiologic (normal) saline to rinse the tissue. Necrotic, hemorrhagic, and fatty tissue will generally dissolve or float on the surface while tumor and parenchymal tissue will remain intact and sink to the bottom of the cup.

**9.1.3** During warm weather months, paraffin blocks and slides should be shipped in an insulated container that contains a refrigerant pack, to avoid heat > 25 degrees C (77degrees F) that may melt paraffin and damage the tissue specimens.

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## 9.2 Diagnostic H&E-Stained Slide for Central Pathology Review

**9.2.1** Retrospective central pathology review requires submission of one (1) H&E stained slide obtained from block containing bladder tissue from diagnostic TURBT surgery specimen.

## 9.3 Diagnostic and Progressive Pathology Fixed Tissue Blocks for ST1

**9.3.1** For patients who consent to A031803-ST1, one representative diagnostic block containing bladder tissue from prior TURBT surgery and one representative diagnostic block from progressive disease should be submitted.

**9.3.2** Any clinical surgical pathology block that is submitted for research studies will not be exhausted or rendered unsuitable for future diagnostic use. Any clinical surgical pathology block that is submitted will be returned within ten working days of written request, when needed for clinical management or clinical trial enrollment for a specific patient. Otherwise, all blocks will be returned to the submitting institution when the trial and correlative science study end points have been met.

**9.3.3** In the event that an institution will not release tissue blocks, the institution may instead submit one (1) H&E stained slide and eighteen (18) unstained slides from the requested block at each time point (at  $\leq 28$  days after registration and at progression). Please refer to section 9.4 for more details.



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#### 9.4 Unstained Tissue Slides from Diagnostic Fixed Tissue Block for ST1

**9.4.1** In cases where an institution is unwilling or unable to submit tissue blocks, a set of eighteen (18) unstained slides cut from a single block and containing adequate tumor cellularity may be sent as an alternative. **An H&E stained slide should accompany the unstained slides. The H&E stained slide should be cut from the same block from which the unstained slides were cut.** If fewer than the number of unstained slides requested from a block can be submitted, please prioritize slides for IHC and submit as many as possible for DNA / RNA (up to 18 unstained slides total at each time point). Please follow the procedures below for submitting unstained slides. If your pathology department is unwilling or unable to follow these tissue-sectioning instructions, please consider submission of tissue blocks, which can be cut at the biorepository and returned to your institution at a later date.

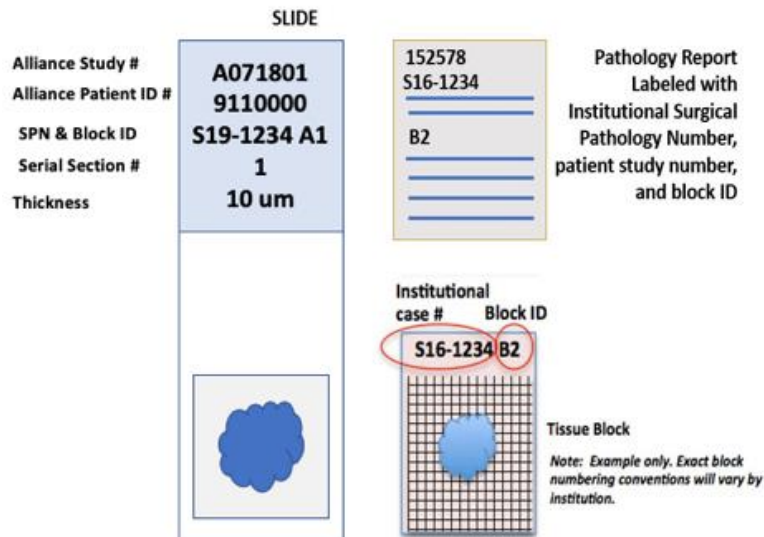
# of slides	Section thickness	Slide type	Purpose
1	5 micron	Charged	H&E stained slide
2	5 micron	Charged	IHC
16	10 micron	Non-Charged	DNA, RNA

**9.4.2** Serial tissue sections should be cut fresh from the appropriate formalin fixed, paraffin embedded tissue block.

**9.4.3** Cut sections at 5 micron or 10 micron thickness onto glass slides (charged or non-charged) as indicated above.

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- 9.4.4** Ensure that each slide is labeled with the Alliance study number (A031803), Alliance patient ID number, the institutional surgical pathology number and block ID, section thickness (in um), and the slide serial section number (1, 2, 3, etc.).
- 9.4.5** Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink.
- 9.4.6** No adhesives or other additives should be used in the water bath.
- 9.4.7** Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide.
- 9.4.8** When placing the sections onto the slides, ensure that the tissue is placed on the bottom third of the slide. Ensure that each serial section from the block is placed in the same orientation on each slide.
- 9.4.9** See figure below for proper mounting and labeling.



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**9.4.10** Air dry slides for 12-24 hours prior to shipping. Do not oven dry slides.

**9.4.11** Use slide mailers or a slide box to ship slides. Slides should not be touching each other. Ensure that slides from only one patient are placed in one slide mailer.

**9.4.12** Include a copy of the **de-identified pathology report with all slide submissions.**

## 9.5 Scanned Slide Images

**9.5.1** In cases where institutions are unwilling or unable to submit the requested fixed tissue block or fixed tissue slides, scanned slide images of an H&E-stained slide and/or any other stained slides produced for histopathologic diagnosis required by the protocol may be submitted.

**9.5.2** Scanned slide images will be uploaded via the Digital Pathology Image Portal (DPIP) in BioMS. Please see Appendix 1 for instructions on how to upload scanned slide images.

**9.5.3** Unless otherwise specified in the protocol correlative science manual (CSM), scanned slide images must be created using an Aperio / Leica scanner at 40X magnification in an .SVS file format.

**9.5.4** Scanned slide images should not contain PHI (patient name, date of birth, institutional surgical pathology number). The slide scanner should be configured to crop or exclude any image of the slide label. Alternatively, post-processing of the slide image file should remove the slide label image from the SVS file. **Images submitted with PHI or with the labels intact will not be accepted.**

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- 9.5.5** A digital de-identified pathology report (i.e. PDF file) must be included with all scanned slide image submissions, uploaded to BioMS. The surgical pathology number / accession number should be retained in order to correlate the report to the digital image specimen. The pathology report **must** also retain reference to individual block identifiers and must include the Alliance patient ID number and study ID so that each slide image can be correlated with the corresponding pathology report narrative. Please see Appendix 1 for instructions on how to upload the de-identified pathology report to BioMS.
- 9.5.6** The file name of the de-identified pathology report should correspond to the *Study ID, Alliance patient ID number, and last two digits of the institutional surgical pathology number* corresponding to the file name(s) assigned by DPIIP.
- 9.5.7** Once the images have been uploaded, site staff should send an electronic copy of the manifest to [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu).
- 9.5.8** Questions regarding appropriate image labeling, file naming conventions, and how to submit scanned slide images should be addressed to the Alliance Biorepository Protocol Management team ([alliance@email.wustl.edu](mailto:alliance@email.wustl.edu)). Questions related to BioMS should be addressed to the BioMS help desk ([bioms@alliancenctn.org](mailto:bioms@alliancenctn.org))

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## 10. Blood Collection Methods

### 10.1 Whole blood (EDTA- no processing)

**10.1.1** Collect whole blood by standard venous phlebotomy technique into each of the EDTA tubes. Invert tubes 10 times.

**10.1.2** Store EDTA tubes with whole blood at 4 degrees Celsius (i.e. refrigerated) until shipping. Do not freeze the tubes. **Please collect blood on Monday through Thursday only. The tubes must be received at the Biorepository within 24 hours of collection.** Ensure that the EDTA tubes are shipped at ambient temperature to avoid freezing.

**10.1.3** During warm weather months (i.e. June—August), a refrigerated pack (not frozen) should be included in the shipment to maintain ambient temperature. When shipping during other months of the year, a room temperature pack should be included in the shipment.

## 11. Urine Collection

**11.1** Instruct patients to collect approximately 50 ml of urine into a clean specimen cup.

**11.2** Within 60 minutes of collection, distribute 30 ml of urine into 3 x 10 ml KEDTA vacutainer tubes. Remaining urine may be discarded following standard institutional procedures.

**11.3** Urine in EDTA preservative may be held for up to 72 hours at 4 degrees Celsius (i.e. refrigerated) prior to shipping. **Urine tubes should be shipped on a cold pack to maintain temperature between 2—15 degrees Celsius.**

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## 12. Biospecimen Shipping

### 12.1 Overview

- 12.1.1** Blood tubes should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.
- 12.1.2** All blood should be shipped on the same day that it is collected (Monday – Thursday). Blood must be received by ABWUSTL within 24 hours of collection. If collected blood cannot be shipped on the same day that it is collected (e.g. Friday – Saturday or Holiday collections), please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu) for further instructions, at least 24 hours prior to anticipated collection.
- 12.1.3** Urine tubes should be packaged in an insulated container along with a cold pack to maintain temperature of 2—15 degrees Celsius while shipping. Urine may be held for up to 72 hours following collection.
- 12.1.4** Blocks and slides should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.
- 12.1.5** Place the original, completed copy of the BioMS packing manifest in the shipment. If sending tissue, include a copy of the de-identified surgical pathology report. Do not send specimens without a completed BioMS Packing Manifest or substitute “BioMS Downtime Form.” Biospecimens cannot be accepted without this completed form.
- 12.1.6** Do not ship on Friday, Saturday, Sunday or the day before a nationally recognized holiday.

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## 12.2 Shipping to ABWUSTL

**12.2.1 Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor.**

**Ship to:**

**Alliance Biorepository**

**c/o Siteman Cancer Center Tissue Procurement Core**

**Washington Univ. School of Medicine**

**425 S. Euclid Ave.**

**Room 5120**

**St. Louis, MO**

**63110-1005**

**Phone: 314-454-7615**

## 13. ABWUSTL Biospecimen Receipt and Quality Assurance Measures

**13.1** Upon receipt, all biospecimens will be accessioned into the TPC informatics system, OpenSpecimen.

**13.2** All biospecimens will be logged, associated, and tracked by the unique patient biopsy control number.

**13.3** Each individual biospecimen will receive and be physically labeled with a unique biospecimen identifier, associated with the biopsy control number in the TPC informatics system.

**13.4** Upon receipt, all physical biospecimens received will be reconciled with what is recorded on the BioMS packing manifest. Any discrepancies noted will be communicated to the Program Manager who will contact the submitting site for reconciliation.

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**13.5** Upon receipt, any biospecimen received that is not in appropriate physical condition (broken vials, frozen samples that are thawed, ambient samples that are frozen) will be reported to the Program Manager, who will contact the submitting site for reconciliation.

**13.6** Frozen aliquoted biofluids will be stored under liquid nitrogen vapor.

**13.7** All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol PI.

#### 14. Document History

Version	Description and Justification of Change	Author	Effective Date
2.1	Added contact table. Added digital image alternative to mandatory H/E slide submission. Added warm weather instructions for shipping.	KAL	02/01/2024
2.0	Updated collection instructions for urine. Updated Biorepository email addresses. Fixed minor typos and grammatical errors.	PAA	12/08/2020
1.0	New	PAA	12/17/2019

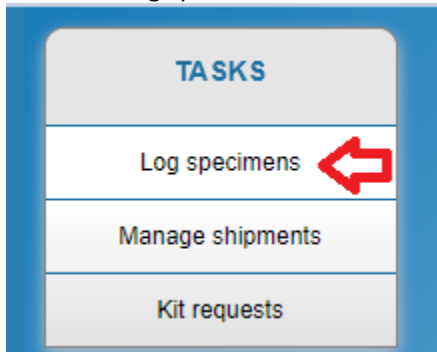


<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Phase II trial of intravesical gemcitabine and MK-3475 (pembrolizumab) in the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer  Short Title- A031803	Version No: 2.1	Effective Date: 02/01/2024
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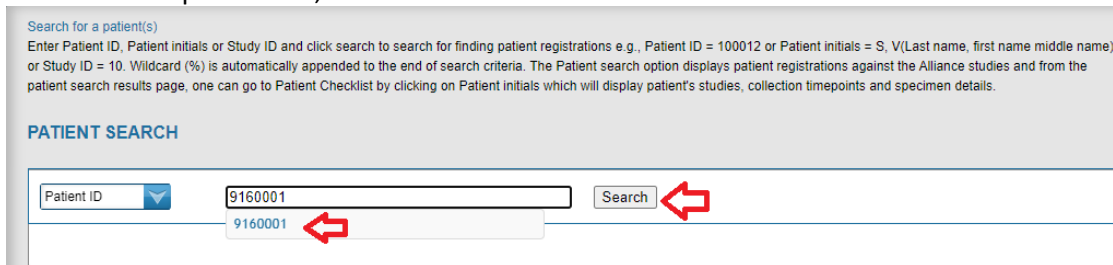
Appendix 1 - Digital Pathology Image Portal Instructions

Please note that while the Study ID and specimen requirement title might be different than your study, the concept is still the same.

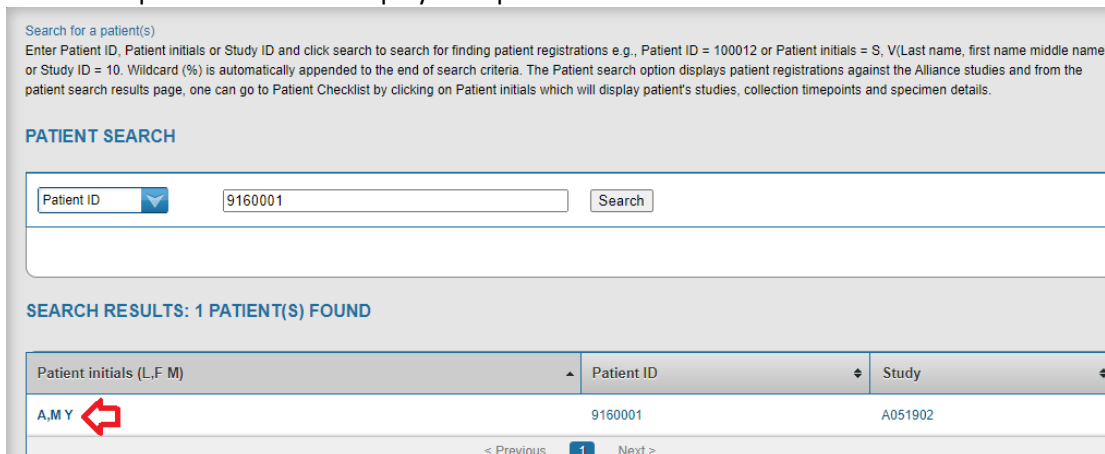
1. Login BioMS <https://bioms.wustl.edu/bioms/login>
2. Select "Log specimens" from the Task menu.



3. Enter the patient ID (obtained when registering the patient in OPEN), in the search field, select the matching ID from the drop-down list, click "Search."



4. Click the patient initials to display the Specimen Checklist view.



5. Click on the Alliance Digital Pathology Image (DPI) Portal Icon. Do not enter the slide count or collection date as only specimens in a "Pending" status can have images uploaded.

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count	<input type="text"/>	14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	<input type="text"/>	14 Pending	
<input type="checkbox"/>	A051902	Scanned Slide Images	1.0 count	<input type="text"/>	14 Pending	

6. A new browser tab will open displaying the DPI Portal. This tab must remain open during the entire loading process. Closing the new browser will terminate the loading process.

7. Please note the instructions at the top of the page. All files must be in .SVS format and cannot exceed 5GB  
 8. Enter the last 2 digits of the Surgical Pathology Number. (Example if the SPN is 24-12345, then enter 45)

9. Enter the block ID (Example: if the slide was cut from block A2 then scanned, enter A2)

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. You can continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the naming convention in the window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Please select	<input type="button" value="Choose File"/> No file chosen

10. Select the "Stain Type" from the drop-down list.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. You can continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the naming convention in the window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Please select	<input type="button" value="Choose File"/> No file chosen

11. Click Choose File, then select the file from your computer directory.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. You can continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the naming convention in the window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Hematoxylin and Eosin (H&E)	<input type="button" value="Choose File"/> No file chosen

12. BioMS will then rename the file to the DPI format (StudyID\_PatientID\_Last2Digitsof SPN\_BlockID\_Stain Type\_.svs

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
<input type="text" value="45"/>	<input type="text" value="A2"/>	Hematoxylin and Eosin (H&E) ▼	<input type="button" value="Choose File"/> patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	

13. If there are additional files to load for the patient, click Add and repeat steps 8-11

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Hematoxylin and Eosin (H&E) ▼	<input type="button" value="Choose File"/> patient_1_HE.svs
<input type="text"/>	<input type="text"/>	Please select ▼	<input type="button" value="Choose File"/> No file chosen

14. Once all files are selected, click "Upload File."

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*). Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *
<input type="text" value="45"/>	<input type="text" value="A2"/>	Hematoxylin and Eosin (H&E) ▼	<input type="button" value="Choose File"/> patient_1_HE.svs
<input type="text" value="45"/>	<input type="text" value="A2"/>	Ki67 (K67) ▼	<input type="button" value="Choose File"/> patient_1_Ki67.svs

15. BioMS will display a progress bar for each file. DO NOT close the DPI window as it will terminate the load process. Users can navigate to other windows during the load process.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
45	A2	Hematoxylin and Eosin (H&E)	<input type="button" value="Choose File"/> patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	<div style="width: 24%;"><div style="width: 24%;"></div></div> 24%
45	A2	Ki67 (K67)	<input type="button" value="Choose File"/> patient_1_Ki67.svs	A051902_9160001_45_A2_K67.svs	<div style="width: 35%;"><div style="width: 35%;"></div></div> 35%

**Warning:** Please ensure that this window remains open after initiating a file transfer request. Once the file transfer is complete, you will receive a completion message on this page. At that time, you can exit and close this page. While the file transfer is in progress, feel free to continue working in BioMS or other tasks. However, please **DO NOT CLOSE THIS PAGE** until the transfer is finished. Uploading

16. BioMS will display a successful message in the Alliance DPI portal and send an email to the user once all images are transferred.

**Alliance Digital Pathology Image (DPI) Portal**

**Instructions:** The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. Complete all mandatory fields (marked by \*) and click on 'Choose File' to select a file. To add more files, click on the 'Add' button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the transfer time depends on your internet upload speed. File transfer will be processed asynchronously, allowing you to continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The file you upload will be renamed as per the Alliance DPI Standard Operating Procedures. If you happen to close this window before the transfer is complete, you will need to upload the files again.

Study ID: A051902      Patient ID: 9160001      Collection Arm: Consented to Biobanking      Collection Event: Registration

Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
45	A2	Hematoxylin and Eosin (H&E)	<input type="button" value="Choose File"/> patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	<div style="width: 100%;"><div style="width: 100%;"></div></div> Completed
45	A2	Ki67 (K67)	<input type="button" value="Choose File"/> patient_1_Ki67.svs	A051902_9160001_45_A2_K67.svs	<div style="width: 100%;"><div style="width: 100%;"></div></div> Completed

**File Upload Completed Successfully!**  
Please click on the BioMS Patient Checklist link below to mark the Digital Specimen as collected and proceed to ship it to the respective repository. If you are not currently logged into BioMS, please log in on a different tab and then click on the BioMS Patient Checklist link below to complete the Digital Specimen collection and shipment process. Thank you.  
[BioMS Patient Checklist](#)

17. The Alliance DPI portal window may now be closed.

18. Navigate back to the patient's check list view to now log the images as "collected."

19. Enter the number of images loaded in the "Quantity" field.

20. Enter the date of the procedure (biopsy, surgery) in the "Collection Date."

Registration      On Therapy

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count	<input type="text" value="14"/>	Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count	<input type="text" value="14"/>	Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	<input type="text" value="14"/>	Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count	<input type="text" value="14"/>	Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	<input type="text" value="14"/>	Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	<input type="text" value="2"/> count	<input type="text" value="10/19/2022 00:00"/>	Pending	

21. Click the "Clip board" icon to load a digital copy of the corresponding surgical pathology report.

Registration		On Therapy				
Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count		14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count		14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm		14 Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	2 count	10/19/2022 00:00	14 Pending	

**SPECIMEN COMMENTS**

**⚠ If you are submitting tissue from a pathology block, slides, curls, etc. PLEASE remember to include a printed, de-identified copy of the corresponding pathology report in your shipment.**

**SPECIMEN ATTACHMENTS**

Title	Attachment	Action
<input type="text" value="Path Report Patient 1"/>	<input type="button" value="Choose File"/> A051902	
<input type="button" value="Add more"/>		

22. Click Save

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count		14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count		14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm		14 Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	2.0 count	10/19/2022 00:00	14 Collected	

Save Go to shipments

23. Click "Go To Shipments" to now create the digital shipment

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<b>Consented to Biobanking : Registration</b>						
<input type="checkbox"/>	A051902	FFPE Block- Tumor	1.0 count		14 Not Collected	
<input type="checkbox"/>	A051902	Unstained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	5 Unstained Slides (10um)- Tumor	5.0 count		14 Pending	
<input type="checkbox"/>	A051902	Stained Slides (4-5um)	0.0 count		14 Pending	
<input type="checkbox"/>	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm		14 Pending	
<input checked="" type="checkbox"/>	A051902	Scanned Slide Images	2.0 count	10/19/2022 00:00	14 Collected	

Save Go to shipments

24. From the Manage Shipment page, check the box for the specimen requirement, leave the shipment default to "Auto" and click the green arrow pointing to the right.



**SPECIMENS AND SHIPMENTS**

Filter By Ship To:

**SPECIMENS FOR 9160001 (A,M Y) AND STUDY A051902**

All

<input type="checkbox"/>	Specimen ID & Title	Patient ID & Initials	Study & TimePoint
<input checked="" type="checkbox"/>	135090740 - Scanned Slide Images	9160001 (A,M,Y)	A051902 - Registration

Auto  
Manual

→

→

←

25. BioMS will move the specimen requirement into an appropriate shipment. The shipment ID containing the specimen requirement will be displayed at the top of the screen.

Specimen(s) added to shipment(s) [135141040]

Logged into BioMS as BRINKA Logout ? Help

Review Pending Specimens and Shipments

Review the list of specimens and shipments pending to be shipped. To view the contents of a particular shipment, click on downward arrow icon below the box icon for the shipment. Select the shipment by clicking on the round button above the box icon for the shipment, then click on the appropriate button on the top/bottom of the shipments section to perform a particular action for the selected shipment.

**SPECIMENS AND SHIPMENTS**

Filter By Ship To:

**SPECIMENS FOR 9160001 (A,M Y) AND STUDY A051902**

All

<input type="checkbox"/>	Specimen ID & Title	Patient ID & Initials	Study & TimePoint
<input type="checkbox"/>			

Auto  
Manual

→

←

**SHIPMENTS**

Create Send Delete Print Edit

<input type="radio"/>		Shipment ID: 135141040
		Ship to: Alliance Biorepository Washington University St. Louis
		Ship method: Unspecified
		Status: Not Shipped

▼(1)

26. Click the radio button for the shipment, then click Send.

**SHIPMENTS**

Create Send Delete Print Edit

→


<input checked="" type="radio"/>		Shipment ID: 135141040
		Ship to: Alliance Biorepository Washington University St. Louis
		Ship method: Unspecified
		Status: Not Shipped

▼(1)


27. On the manifest page, enter your phone number, email address.
28. Select "Digital Upload" as the carrier.
29. Enter "N/A" for the tracking number.
30. Enter the date the images were transferred / uploaded as the shipment date.
31. Click Send Shipment.

Send shipment
← Back


**BioMS ShipmentID**



135141040

<b>Shipment ID</b>	135141040	<b>Status</b>	Not Shipped	<b>Carrier *</b>	Digital Upload
<b>Sender site *</b>	Washington University School of Medicine	<b>Receiver site</b>	Alliance Biorepository Washington University St. Louis	<b>Tracking number</b>	N/A
<b>From *</b>	660 South Euclid Avenue Saint Louis, Missouri 63110	<b>To</b>	425 S. Euclid Ave. RM 5120 St. Louis, Missouri 63101	<b>Shipping date *</b>	01/18/2024 
<b>Sender contact *</b>	Amy Brink	<b>Receiving site email</b>	tbank@wudosis.wustl.edu	<b>Received date</b>	
<b>Phone *</b>	999-999-9999	<b>Receiving site phone</b>	(314) 454-7615	<b>Notes</b>	
<b>Sender email *</b>	abrink@wustl.edu				

**CONTENTS**

BioMS Specimen ID	Specimen	Qty	Collection Date	Patient ID	Study ID	Epoch, Arm, CPE
 135090740	Scanned Slide Images	2.0 count	10/19/2022 00:00	9160001 (A,M Y)	A051902	Registration, Consented to Biobanking, Registration

32. Email a copy for the BioMS manifest to [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu)

For additional information and screen shots please visit

<https://washu.atlassian.net/wiki/spaces/BP/pages/468844574/Alliance+Digital+Pathology+Image+Portal+DPI>