	CORRELATIVE SCIENCE PROCEDURE MANUAL Biospecimen Collection for Phase II study of cabozantinib in combination with nivolumab	Version No: 3.2	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 all patients enrolled or registered on A031702. 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 A031702 biospecimen collection, processing, and submission, including staff at satellite institutions.

#### 2. Scope

This document applies to all biospecimens collected specifically for A031702 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

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#### 4. Contact Information

Protocol-related questions may be directed as follows:				
Questions	Contact (via email)			
Questions regarding patient eligibility, treatment, and dose modification:	Study Chair: Andrea Apolo, MD <u>andrea.apolo@nih.gov</u> Nursing Contact: Archana Ajmera, AP, AOCNP <u>aajmera@health.ucsd.edu</u> Protocol Coordinator: Aishwarya Vijendran <u>aishwaryav@bsd.uchicago.edu</u> (where applicable) Data Manager: Kelsey Peterson <u>Peterson.kelsey1@mayo.edu</u>			
Questions related to data submission, RAVE or patient follow-up:	Data Manager: Kelsey Peterson Peterson.kelsey1@mayo.edu			
Questions regarding the protocol document and model informed consent:	Protocol Coordinator: Aishwarya Vijendran aishwaryav@bsd.uchicago.edu			
Questions related to IRB review	Alliance Regulatory Inbox regulatory@allianceNCTN.org			
Questions regarding CTEP-AERS reporting:	Alliance Pharmacovigilance Inbox pharmacovigilance@alliancenctn.org			
Questions regarding specimens/specimen submissions:	ABWUSTL: alliance@email.wustl.edu			
Questions regarding drug supply	PMB: <u>PMBAfterhours@mail.nih.gov</u>			
Questions regarding drug administration	Pharmacy Contact: MAJ Jerline Hsin, Pharm D, BCOP, BCPS jerline.hsin.mil@mail.mil			

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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. 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.
- **4.2** For all other questions regarding biospecimen procurement and shipping procedures, please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or <u>alliance@wustl.edu</u>.

#### 5. Site Preparation

- **5.1** Please refer to A031702 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 both requesting biospecimen collection kits and 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.
- **5.3** Prior to collection of whole blood specimens, a biospecimen collection kit must be at the collection site. Please see section 7 for requesting biospecimen collection kits. Please allow at least 10 working days to receive the collection kit.
- **5.4** Please confirm that your institutional pathology department is willing to submit two (2) H&E stained slides from diagnostic tumor tissue for retrospective central pathology review. Institutions whose pathology department is unwilling to comply with slide submission should not enroll patients to this study.

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#### 6. Collection Schema

The following biospecimens are to be collected at each of the time points. Please refer to individual collection kit instructions, 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
		Mandatory for	r all patients register	red to A031702		
Baseline ( <u>&lt;</u> 14 days after registration)	N	H&E stained slides OR	2	H&E stained slides (9.2)	Ambient	1
<b>c</b> ,		Scanned slide images		Scanned slide images (9.5)	N/A	
		A03:	1702-ST1 and Biobar	ıking		
Baseline ( <u>&lt;</u> 14 days after registration)	N	Fixed tissue block	1	Fixed tissue block (9.3)	Ambient	2, 3
Baseline ( <u>&lt;</u> 14 days after registration)	N	Unstained slides	20-25	Fixed tissue slides (9.4)	Ambient	2, 3
Baseline ( <u>&lt;</u> 14 days after registration)	Y	Whole blood (Streck BCT tube)	2 x 8 ml	Plasma for cfDNA (10.1)	Ambient	2, 6
Baseline ( <u>&lt;</u> 14 days after registration)	Y	Whole blood for plasma	4 x 1 ml aliquots	Frozen plasma (10.2)	Dry Ice	2, 4, 6
Baseline ( <u>&lt;</u> 14 days after registration)	Y	Whole blood for "buffy coat"	1 aliquot	"Buffy Coat" (10.3)	Dry Ice	2, 4, 6
Baseline ( <u>&lt;</u> 14 days after registration)	Y	Whole blood (EDTA tube)	2 x 10 ml	Whole blood- EDTA tube (10.4)	Ambient	2, 5, 6
Baseline ( <u>&lt;</u> 14 days after registration)	Y	Whole blood for RNA (PaxGene)	1 x 2.5 ml	Whole blood- PaxGene tube (10.5)	Ambient	2, 6
	•				•	•
Cycle 2 Day 1	Y	Whole blood (Streck BCT tube)	2 x 8 ml	Plasma for cfDNA (10.1)	Ambient	2
Cycle 2 Day 1	Y	Whole blood for plasma	4 x 1 ml aliquots	Frozen plasma (10.2)	Dry Ice	2, 4
Cycle 2 Day 1	Y	Whole blood for "buffy coat"	1 aliquot	"Buffy Coat" (10.3)	Dry Ice	2, 4
Cycle 2 Day 1	Y	Whole blood (EDTA tube)	2 x 10 ml	Whole blood- EDTA tube (10.4)	Ambient	2, 5
Cycle 2 Day 1	Y	Whole blood for RNA (PaxGene)	1 x 2.5 ml	Whole blood- PaxGene tube (10.5)	Ambient	2
Cycle 3 Day 1	Y	Whole blood (Streck BCT tube)	2 x 8 ml	Plasma for cfDNA (10.1)	Ambient	2
Cycle 3 Day 1	Y	Whole blood for plasma	4 x 1 ml aliquots	Frozen plasma (10.2)	Dry Ice	2, 4
Cycle 3 Day 1	Y	Whole blood for "buffy coat"	1 aliquot	"Buffy Coat" (10.3)	Dry Ice	2, 4
Cycle 3 Day 1	Y	Whole blood (EDTA tube)	2 x 10 ml	Whole blood- EDTA tube (10.4)	Ambient	2, 5
Cycle 3 Day 1	Y	Whole blood for RNA (PaxGene)	1 x 2.5 ml	Whole blood- PaxGene tube (10.5)	Ambient	2

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#### Notes:

- For renal, testis, penile and prostate malignancies, submission of two (2) H&E stained slides from diagnostic tumor tissue for retrospective central pathology review is mandatory for patients registered to A031702. For histologic variants of urothelial carcinoma, all H&E slides from the surgical pathology specimen should be sent. See section 9.2 for additional details. Alternatively, scanned slide image files of the stained slides in .SVS file format may be uploaded digitally to the Biorepository. See section 9.5 for details.
- 2. Collection is optional for patients but requires all sites offer to patients to consent. Please see protocol-specific consent documents.
- A paraffin tissue block with adequate tumor <u>OR</u> 20-25 unstained slides from such block should be submitted for patients opting in for A031702-ST1. If fewer than 20 unstained slides can be submitted, please submit as many as possible.
- 4. Plasma and "buffy coat" (white blood cells) are obtained from the same, single tube of whole blood.
- 5. Whole blood sample in EDTA tubes will be collected for PBMC isolation and cryopreservation at the Biorepository.
- 6. Blood should be collected before patient receives first dose of study drug, recommend on the same day of registration.

#### 7. Biospecimen Collection Kits

#### 7.1 Blood Specimens

- **7.1.1** To facilitate the proper collection and shipping of whole blood specimens, biospecimen collection kits and materials will be provided. The cost of the kit and shipping the kit to the site will be paid for. The institution is expected to pay for shipping the kit with the biospecimens back to the Alliance Biorepository at Washington University in St. Louis via priority overnight shipping.
  - 7.1.1.1 NOTE: Kits will be sent via FedEx at no additional cost to the participating institutions. Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account for express service. The study will not cover the cost for rush delivery of kits.

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- 7.1.2 Kits should be requested at least 10 working days in advance of the anticipated collection date. As many as 3 kits can be requested at one time. Since the collection materials (vacutainer tubes) have expiration dates, do not request kits more than 90 days prior to their anticipated use. All kits must be requested by using the BioMS system.
- **7.1.3** Distributed kits will have a minimum shelf life of 90 days; unless precluded by the stability of a particular component.
- **7.1.4** Kit contents and specific instructions for use of the kit are provided in the kit box. Please return any used collection materials with the kit.
- **7.1.5** Once a kit is received, do not discard the outer cardboard overwrap. The kit, containing biospecimens, is to be shipped back in the same box.
- **7.1.6** Please return all components of the kit, regardless of whether they have been used or not. Kits and kit components are recycled when possible, minimizing the kit cost.
- **7.1.7** Well in advance of collecting biospecimens, inspect the biospecimen collection kit to ensure that all components are present and not expired, particularly if the kit has been onsite for longer than 30 days.
- **7.1.8** Note that individual kit components that are expired, damaged, or missing cannot be replaced. The remedy is to order a complete, new kit (Please note in your request that you are replacing an expired or damaged kit).
- **7.1.9** Please return all kits that have expired or missing components. Return the ENTIRE kit using the cheapest possible shipping method at your expense. DO NOT DISCARD kits that have missing or expired components. Recycling kits keeps the cost of kit materials to a minimum. Please note that all out-going and in coming kits are tracked, and sites that have requested many more kits than they have returned will be charged for non-returned kits.

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- 7.1.10 If a biospecimen collection component (e.g. vacutainer collection tube) is missing, damaged, or expired, the institution may substitute a like-kind collection tube from their own supply. However, note that some kit components are highly specialized (e.g. Streck BCT) and probably are not available at the institution.
- 7.1.11 Note that protocol requirements are based on blood volumes, not tube sizes. If the protocol requires the collection of 8 ml of whole blood, generally a 10 ml tube is provided in the kit for convenience. If desirable or necessary to collect 8 ml in 3 x 3 ml tubes (for example), that is permissible.

#### 7.2 Tissue Specimens

- **7.2.1** There is no independent "kit" for submission of paraffin blocks or slides.
- **7.2.2** Blocks and slides should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.
- 7.2.3 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 (77 degrees F) that may melt paraffin and damage the tissue specimens.
- 7.2.4 Please see Section 11 Biospecimen Shipping for specific instructions on shipping.

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#### 8. Biospecimen Labeling and Tracking

- **8.1** All research biospecimens (vacutainer tubes and 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 ("buffy coat," "plasma").
- 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 patient ID number, institutional surgical pathology number, the block identifier, 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. 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.
- **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 <u>bioms@alliancenctn.org</u>.
- 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- <u>http://tinyurl.com/alliance-biomscontingency</u>.

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#### 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.

#### 9.2 H&E Stained Slides for Mandatory Retrospective Central Pathology Review

- **9.2.1** For renal, testis, penile and prostate malignancies, two (2) representative H&E stained slides from diagnostic tumor tissue are required to be sent for all patients enrolled to A031702. For histologic variants of urothelial carcinoma, all H&E slides from the surgical pathology specimen with tumor will be reviewed to ensure that a substantial portion of the tumor shows this variant histology.
- **9.2.2** Ensure that each slide is labeled with the Alliance patient ID number, surgical pathology number, and institutional block ID.
- **9.2.3** Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink.
- **9.2.4** 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.
- 9.2.5 Include a copy of the **de-identified pathology report** with slides.

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#### 9.3 Fixed Tissue Block for A031702-ST1 / Biobanking

**9.3.1** For patients who consented to sub-study A031702-ST1 and/or biobanking for future research, a representative diagnostic block with adequate tumor should be submitted, if applicable.

#### 9.3.2 Include a copy of a de-identified pathology report with block submission.

9.3.3 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 (77 degrees F) that may melt paraffin and damage the tissue specimens.

#### 9.4 Unstained Slides from Diagnostic Fixed Tissue Blocks

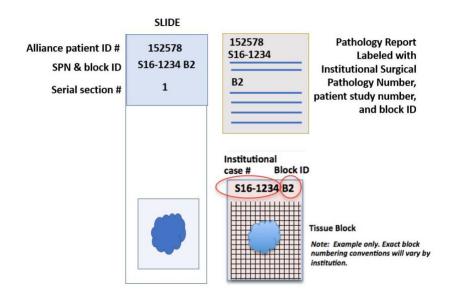
**9.4.1** In cases where an institution is unwilling or unable to submit a tissue block for substudy A031702-ST1 and/or biobanking for future research, a set of 20-25 unstained slides with adequate tumor may be sent as an alternative. If fewer than 20 unstained slides can be submitted, please submit as many as possible. 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 a tissue block, which can be cut at the biorepository and returned to your institution at a later date.

# of slides	Section thickness	Slide type	Purpose
20-25	10 micron	Positively 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 10 micron thickness as indicated onto positively charged slides.
- **9.4.4** Ensure that each slide is labeled with the Alliance patient ID number, the institutional surgical pathology number, block ID, and the slide serial section number (1, 2, 3, etc.).

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- **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.



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

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**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 a de-identified pathology report with all slide submissions.

9.4.13 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 (77 degrees F) that may melt paraffin and damage the tissue specimens.

#### 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 <u>must</u> 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 DPIP.
- **9.5.7** Once the images have been uploaded, site staff should send an electronic copy of the manifest to <u>alliance@email.wustl.edu.</u>
- **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). Questions related to BioMS should be addressed to the BioMS help desk (bioms@alliancenctn.org)

#### **10. Blood Collection Methods**

#### 10.1 Plasma Nucleic Acid (Streck) Tube Processing

**10.1.1** Collect 8 ml of blood into each of the Streck BCT tubes using standard venous phlebotomy. Invert tubes 10 times.

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10.1.2 Store Streck tubes with whole blood at room temperature. Do not freeze or refrigerate the tubes. The tubes may be stored for up to 72 hours at ambient temperature before shipment. Ensure that the Streck tubes are shipped at ambient temperature to avoid freezing. 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.

#### **10.2** Plasma Processing

- **10.2.1** Collect 10 ml of whole blood by standard venous phlebotomy technique into the purple top (EDTA) tube. Invert tube 10 times.
- **10.2.2** Within 2 hours of collection, spin the vacutainer tube at room temperature in a clinical centrifuge at 2500 xG for 15 minutes.
- **10.2.3** Carefully remove the plasma layer (~4 ml), without touching the white, buffy coat layer, and transfer to a new 15 ml conical centrifuge tube. Keep the vacutainer tube containing the white, buffy coat layer for white blood cell isolation (section 10.3).
- **10.2.4** Spin the centrifuge tube containing plasma at room temperature in a clinical centrifuge at 2500 xG for 15 minutes.
- **10.2.5** Label 4 cryovials as instructed in **section 8**. Make certain each vial is labeled completely and identically.
- **10.2.6** Carefully remove 4 ml of plasma (without touching the pellet) and divide into 4, 1 ml labeled cryovials.
- **10.2.7** Freeze plasma containing cryovials on dry ice or a -70 to -90 degree Celsius ultralow freezer. Store at -70 to -90 degrees C until ready for shipment on dry ice.

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#### 10.3 "Buffy Coat" (White Blood Cell) Processing

- **10.3.1** Follow procedures in **section 10.2** for collecting and processing plasma from EDTA tube.
- **10.3.2** Label 1 cryovial as instructed in section 8.
- **10.3.3** After removing the plasma, carefully remove the white, "buffy coat" white blood cell layer, avoiding the red blood cell mass as much as possible.
- 10.3.4 Transfer the buffy coat layer (approximately 0.2 0.5 ml) from EDTA tube into the labeled cryovial. Immediately freeze the cryovial of buffy coat on dry ice or in liquid nitrogen vapor. Do NOT freeze buffy coat cells by placing a warm tube in a -70 to -90 degree Celsius ultralow freezer. Once completely frozen, the cryovial containing the buffy coat cells may be stored at -70 to -90 degrees Celsius until ready for shipment on dry ice.

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

- **10.4.1** Collect 10 ml of whole blood by standard venous phlebotomy technique into each of the EDTA tubes. Invert tubes 10 times.
- 10.4.2 Store EDTA tubes with whole blood at 4 degrees Celsius (i.e. refrigerated) until shipping. Do not freeze the tubes. 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. 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.

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#### 10.5 PaxGene Blood RNA Tube Collection

- **10.5.1** Ensure that the PAXgene Blood RNA Tube is at 18–25°C prior to use and properly labeled with specimen identification.
- 10.5.2 If the PAXgene Blood RNA Tube is the only tube to be drawn, blood should be drawn into a "Discard Tube" prior to drawing blood into the PAXgene Blood RNA Tube so the interior volume of the blood collection set used during phlebotomy can be primed. Otherwise, the PAXgene Blood RNA Tube should be the last tube drawn in the phlebotomy procedure.
- 10.5.3 Using a blood collection set and a tube holder, collect blood into the PAXgene Blood RNA Tube using your institution's recommended procedure for standard venipuncture technique. The following techniques shall be used to prevent possible backflow:
  - a. Place donor's arm in a downward position.
  - b. Hold tube in a vertical position, below the donor's arm during blood collection.
  - c. Release tourniquet as soon as blood starts to flow into tube.
  - d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
- 10.5.4 Allow at least 10 seconds for a complete blood draw to take place. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder. The PAXgene Blood RNA Tube with its vacuum is designed to draw 2.5 ml of blood into the tube.
- **10.5.5** Immediately after blood collection, gently invert the PAXgene Blood RNA Tube 8– 10 times.

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**10.5.6** Store the PAXgene Blood RNA Tube upright at room temperature (18–25°C) for a minimum of 2 hours and a maximum of 72 hours before shipping. **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. Biospecimen Shipping**

#### 11.1 Overview

- **11.1.1** Please see the Directions for Use (DFU) document that is included in each kit for specific directions on how to package and ship biospecimens.
- 11.1.2 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, labeled with the Alliance patient ID number. Do not send specimens without a completed BioMS Packing Manifest or substitute "BioMS Downtime Form." Biospecimens cannot be accepted without this completed form.
- 11.1.3 All biospecimens should be shipped within the timeframes indicated above in sections 9 and 10. If collected biospecimens cannot be shipped within the specified timeframe (e.g. Friday Saturday or Holiday collections), please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or <u>alliance@email.wustl.edu</u> for further instructions, at least 24 hours prior to anticipated collection.
- 11.1.4 Do not ship on Friday, Saturday, Sunday or the day before a nationally recognized holiday.

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11.1.5 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

#### 12. ABWUSTL Biospecimen Receipt and Quality Assurance Measures

- **12.1** Upon receipt, all biospecimens will be accessioned into the TPC informatics system, OpenSpecimen.
- **12.2** All biospecimens will be logged, associated, and tracked by the unique patient biopsy control number.
- **12.3** 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.
- **12.4** 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.
- **12.5** 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.
- **12.6** Frozen aliquoted biofluids will be stored under liquid nitrogen vapor.

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

#### **13. Document History**

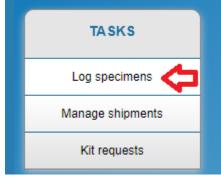
Version	Description and Justification of Change	Author	Effective Date
3.2	Added digital image alternative to mandatory H/E stained slides.	KL	02/01/2024
3.1	Added contact table, added warm weather shipping instructions, clarified expedited kit ordering	KL	06/27/2023
3.0	Updated Biorepository contact email Updated processing requirements Updated shipping requirements	AAW	07/01/2022
2.0	Updated Biorepository PM email Updated BioMS help desk email Clarified collection time point requirement Clarified requirement for slide labeling Removed signature page	ΡΑΑ	09/12/2019
1.0	New	PAA	03/20/2019

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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."

	9160001		Search 🗲		
Click the natien	t initials to display	the Specime	en Checklist vi	₽W.	
earch for a patient(s)	. ,				
	r Study ID and click search to search automatically appended to the end of				
	can go to Patient Checklist by clickin				
ATIENT SEARCH					
Patient ID	9160001		Search		
Patient ID	9160001		Search		

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.

Registra	Registration On Therapy						
Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions	
- • •	Consented to B	iobanking : Registration				1	
	A051902	FFPE Block- Tumor	1.0 count	14	Not Collected	🖹 🚯 📣	
	A051902	Unstained Slides (4-5um)	0.0 count	14	Pending	🗐 🐧 🚯	
	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	14	Pending	🗐! 🕔 🤹	
	A051902	Stained Slides (4-5um)	0.0 count	<u>14</u>	Pending	🗐 🚯 🦚	
	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	14	Pending	🗐 🚯 🚯	
	A051902	Scanned Stide Images	1.0 count	14	Pending		
					Save	Go to shipments	

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.

BioMS							
				nce Digital Pathology Image (DPI) Portal			
button. Finally, click 'Upload File' to	initiate transfer. Uplo	ading may take time du	e to the large size o	o 15 files at once. Complete all mandatory fields (marked of file(s), and the transfer time depends on your internet u	pload speed. File transfer will be processed as	synchronously, allowing	you to
continue using BioMS or perform w window before the transfer is comp			window open and o	cannot close it. The file you upload will be renamed as pe	r the Alliance DPI Standard Operating Proced	dures. If you happen to cl	ose this
		1	Collection Event:				
Study ID: Patient ID	: Collec	tion Arm:	Collection Event:				
Study ID:         Patient ID           A051902         9160001		tion Arm: nted to Biobanking	Registration				
				Select file to upload *	Upload File name	Upload progress	
A051902 9160001	Conse	nted to Biobanking			Upload File name	Upload progress	
A051902 9160001	Conse	nted to Biobanking Stain Type *	Registration	Select file to upload *	Upload File name	Upload progress	

- 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)

button. Finally, clic continue using Bio	ck 'Upload File' to i oMS or perform wo	nitiate transfer. Uplo ork on this PC. Howe	ading may take time	You can submit up to due to the large size on his window open and of	<b>b Ce Digital Pathology Image (DPI) Portal</b> o 15 files at once. Complete all mandatory fields (marked of file(s), and the transfer time depends on your internet up cannot close it. The file you upload will be renamed as per
Study ID: A051902	Patient ID: 9160001		tion Arm: nted to Biobanking	Collection Event: Registration	
Last 2 digits of Pathology#*	Surgical	Block ID: *	Stain Type *		Select file to upload *
45 🗲	I		Please select	~	Choose File No file chosen
Add Upload File	Cance	el	<u>.</u>		- 

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

_							
	button. Finally, click 'L continue using BioMS	Ipload File' to in or perform wor	itiate transfer. Uplo k on this PC. Howe	bading may take time o	. You can submit u due to the large si is window open a	liance Digital Pathology Image (DPI) Portal up to 15 files at once. Complete all mandatory fields (marke ze of file(s), and the transfer time depends on your internet nd cannot close it. The file you upload will be renamed as p	uplo
	<b>Study ID:</b> A051902	Patient ID: 9160001		etion Arm: Inted to Biobanking	Collection Even Registration	ent:	
	Last 2 digits of Sur Pathology# *	gical	Block ID: *	Stain Type *		Select file to upload *	
1	45		A2 🔷	Please select	~	Choose File No file chosen	
10	Add Upload File	Cance		un lint			
10.	Select the "Stain	Type" from	i the drop-dov	vn list.			
	button. Finally, click continue using BioM	'Upload File' to IS or perform w	initiate transfer. Up ork on this PC. How lete, you will need to Colle	loading may take time	B. You can submit due to the large s this window open	Iliance Digital Pathology Image (DPI) Portal up to 15 files at once. Complete all mandatory fields (marke size of file(s), and the transfer time depends on your internet and cannot close it. The file you upload will be renamed as p rent:	uple
	Last 2 digits of S Pathology#*	urgical	Block ID: *	Stain Type *		Select file to upload *	
	45		A2	Please select	~	Choose File No file chosen	
	Add Upload File		ces to protect health inform		struction. The	BioMS system encrypts data during electronic transmission to ensure confidentiality a llection, transmission, display, and maintenance of PHI.	nd em

#### 11. Click Choose File, the 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 t 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 up 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 window before the transfer is complete, you will need to upload the files again.

Study ID: A051902	Patient ID: 9160001		tion Arm: nted to Biobanking	Collection Event: Registration	
Last 2 digits of Su Pathology# *	ırgical	Block ID: *	Stain Type *		Select file to upload *
45		A2	(Hematoxylin and Eosin	(нго 📫	Choose File No file chosen
Add					
Upload File	Canc	el			

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

	button. Finally, click 'Upload File' to	initiate transfer. Uplo ork on this PC. Howe	ading may take time ver, you must keep	B. You can submit up to a due to the large size of this window open and of	of file(s), and the transfer time	I mandatory fields (marked b depends on your internet up	y *) and click on 'Choose File' to select a load speed. File transfer will be processe the Alliance DPI Standard Operating Pro	a file. To add more files, click on the 'Add' ad asynchronously, allowing you to cedures. If you happen to close this
	Study ID:         Patient ID:           A051902         9160001		tion Arm: nted 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 Eo	sin (HI 🗸	Choose File patient_1_HE svs		A051902_9160001_45_A2_HE.svs	
13	Add Upload File Cand		o load for	the natient	t click Add and	reneat stens 8	2-11	
13.			.0 1040 101	the patient			)-11	
	button. Finally, click 'L continue using BioMS window before the tra Study ID: A051902	Ipload File' to or perform w nsfer is compl Patient ID: 9160001	initiate trans ork on this P lete, you will	fer. Uploading i C. However, yo	may take time due t bu must keep this w I the files again. rm: C	i can submit up to o the large size of	file(s), and the transfer tim	mage (DPI) Portal e all mandatory fields (marke ne depends on your internet upload will be renamed as p
	Last 2 digits of Sur Pathology# *	gical Bloo	ck ID: *	Stain Type *		Select file to up	load *	
	45	A2		Hematoxylin and	d Eosin (HI ✔	Choose File patie	ent_1_HE.svs	
ţ,	\$──			Please select	~	Choose File No f	ile chosen	
	Add Upload File	Canc	el					
14.	Once all files are	selected, c	lick "Uplo	ad File."				
		,						
							Alliance Di	inital Path

# Instructions: The file format must be .svs, and each one cannot exceed 5GB. You can submit up to 15 files at once. C

button. Finally, click 'Upload File' to initiate transfer. Uploading may take time due to the large size of file(s), and the tra continue using BioMS or perform work on this PC. However, you must keep this window open and cannot close it. The window before the transfer is complete, you will need to upload the files again.

9160001	Collection Arm: Consented to Biobanking	Collection Event: Registration
ical Block ID: *	Stain Type *	Select file to upload *
A2	Hematoxylin and Eosin (HI 🗸	Choose File patient_1_HE.svs
A2	Ki67 (K67)	Choose File patient_1_Ki67.svs
		Cal     Block ID: *     Stain Type *       A2     Hematoxylin and Eosin (HI

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.

	button. Finally, click 'Upload F continue using BioMS or perfo	ile' to initiate trans form work on this F	sfer. Uploading may take time due t	Alliance Digital Pathology Image (DPI) Portal can submit up to 15 files at once. Complete all mandatory fields (marked b the large size of file(s), and the transfer time depends on your internet up ndow open and cannot close it. The file you upload will be renamed as per	oad speed. File transfer will be processed as	ynchronously, allowing you to
	Study ID:         Patien           A051902         91600			ollection Event: agistration		
	Last 2 digits of Surgical Pathology# *	Block ID: *	Stain Type *	Select file to upload *	Upload File name	Upload progress
l	45	A2	Hematoxylin and Eosin (HI 🗸	Choose File patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	24%
l	45	A2	Ki67 (K67)	Choose File patient_1_Ki67.svs	A051902_9160001_45_A2_K67.svs	36%
	Add					
l	Upload File	Cancel				
				t. Once the file transfer is complete, you will receive a completion message or other tasks. However, please DO NOT CLOSE THIS PAGE until the tra		lose this 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.

audy ID: Patie 051902 9160	ent ID: 001	Collection Arm: Consented to Biobanking	Collection Event: Registration		
ast 2 digits of Surgical athology# *	Block ID:*	Stain Type *	Select file to upload *	Upload File name	Upload progress
5	A2	Hematoxylin and Eosin (HI 🗸	Choose File patient_1_HE.svs	A051902_9160001_45_A2_HE.svs	Completed
	A2	Ki67 (K67)	Choose File patient_1_Ki67.svs	A051902_9160001_45_A2_K67.svs	Completed
	atient Checklist lin ink below to com	nk below to mark the Digital Spec	imen as collected and proceed to ship it to the respective tion and shipment process. Thank you.	repository. If you are not currently logged into BioMS, please log i	n on a different tab and then click

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."

Registrat	tion On Therap	yy .				
Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
— <b>•</b> 0	Consented to B	iobanking : Registration			[	
	A051902	FFPE Block- Tumor	1.0 count	14	Not Collected	i 🚯 🖧
	A051902	Unstained Slides (4-5um)	0.0 count	14	Pending	<u>i</u> ! 🐧 🞄
	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	14	Pending	🗐 🐧 🚯
	A051902	Stained Slides (4-5um)	0.0 count	14	Pending	🗐 🐧 📣
	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	<b>14</b>	Pending	🗐 🚯 📣
	A051902	Scanned Slide Images	2 count	10/19/2022 00:00 <b>14</b>	Pending	1 🕄 🕄 4

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

Registra	Registration         On Therapy								
Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions			
- •	Consented to B	iobanking : Registration			[				
	A051902	FFPE Block- Tumor	1.0 count	14	Not Collected	🖹 🕄 📣			
	A051902	Unstained Slides (4-5um)	0.0 count	14	Pending	🗐 🚯 🚯			
	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	14	Pending	🗐! 🚯 🦚			
	A051902	Stained Slides (4-5um)	0.0 count	14	Pending	🗐! 🚯 🦚			
	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	14	Pending	🗐! 🚯 📣			
	A051902	Scanned Slide Images	2 count	10/19/2022 00:00	Pending				

If you are submit remember to incl report in your shi	ting tissue from a pathology block, slides, curls, lude a printed, de-identified copy of the corresp inment	etc. PLEASE conding pathology
report in your sin	ipment.	
SPECIMEN ATTACH	MENTS	
SPECIMEN ATTACH	MENTS	
SPECIMEN ATTACHA	MENTS Attachment	Action
		Action
Title	Attachment	Action
Title	Attachment	Action
Title Path Report Patient 1	Attachment	Action
Title Path Report Patient 1 Add more	Attachment Choose File A051902	Action
Title Path Report Patient 1 Add more	Attachment	Action

Registra	Registration On Therapy								
Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions			
— ∎ ¢	— ■ Consented to Biobanking : Registration								
	A051902	FFPE Block- Tumor	1.0 count	14	Not Collected	i 🚯 🦚			
	A051902	Unstained Slides (4-5um)	0.0 count	14	Pending	🗐 🐧 🤱			
	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	14	Pending	🗐! 🐧 🦓			
	A051902	Stained Slides (4-5um)	0.0 count	14	Pending	🗐 🐧 🦓			
	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	14	Pending	🗐 🐧 🎄			
	A051902	Scanned Slide Images	2.0 count	10/19/2022 00:00	Collected	1 🗐 🕄 📣			
				⇒	Save	Go to shipments			

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

Registra	Registration On Therapy								
Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions			
- <b>•</b> •	Consented to B	iobanking : Registration			(				
	A051902	FFPE Block- Tumor	1.0 count	14	Not Collected	Ē 🕲 (	æ		
	A051902	Unstained Slides (4-5um)	0.0 count	<b>14</b>	Pending	🗐! 🐧 (	æ		
	A051902	5 Unstained Slides (10um)- Tumor	5.0 count	14	Pending	🗐 🕄 (	£		
	A051902	Stained Slides (4-5um)	0.0 count	<b>14</b>	Pending	🗐! 🕲 d	æ		
	A051902	2 Fixed Tissue Cores (4mm)- Tumor	2.0 gm	<b>14</b>	Pending	🗐! 🐧 (	£		
	A051902	Scanned Slide Images	2.0 count	10/19/2022 00:00	Collected	1	A		
					Save	😭 Go to ship	oments		

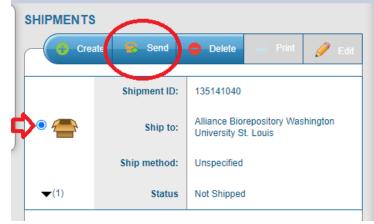
24. From the Manage Shipment page, check the box for the specimen requirement, leave the shipment default to "Auto" and click the green arrow pointing to the right.

Filter	By Ship To:	Please se	elect	1	¥
					•
PECIMENS	S FOR 9160	001 (A,M \	() AND STUD	Y A051902	• Au Ma
All	5 FOR 91600	001 (A,M Y	() AND STUE	OY A051902	•
	Specime Title		() AND STUE Patient ID & Initials	Study & TimePoint	•

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.

imen(s) added to shipment(s) [1351-	1040]			Log	ged into BioMS as E	BRINKA Logout	2
Review Pending Specimens an Review the list of specimens ar the shipment by clicking on the action for the selected shipmen	id shipments pending to be ship round button above the box icc						
SPECIMENS AND SHI							
Filter By Ship To:	Please select	V					
SPECIMENS FOR 916	0001 (A,M Y) AND STU	JDY A051902	Auto	SHIPMENTS			
All			O Manual	Create	e 😽 Send	😑 Delete 📙 Print	<i>)</i>
	en ID & Patient ID &	& Study &			Shipment ID:	135141040	
	en ID & Patient ID & Initials	& Study & TimePoint	👎	0	Ship to:	Alliance Biorepository Wash University St. Louis	ington
litie			1			University St. Louis	-
Intie			j	-	Ship method:	Unspecified	-

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



- 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.

	ShipmentID							Send shipment 🗭 Bac
Shipment ID	135141040		Status	Not Shipped	I		Digital Upload	i 👻
Sender site *	Washington University School	of Medic <mark>ine</mark> (Re	eceiver site	Alliance Bioreposito University St. Louis	ry Washington	Tracking		
From *	660 South Euclid Avenue Saint Louis, Missouri (		То	425 S.Euclid Ave. R St. Louis, Missouri (		Shipping date	01/18/2024	14
Sender contact *	Amy Brink	¥	Receiving site email	tbank@wudosis.wu	sti.edu	Received date		
Phone * Sender email *	999-999-9999 abrink@wustl.edu		Receiving site phone	(314) 454-7615		Notes		
CONTENTS	5							
BioMS S	pecimen ID	Specimen	Qty	Collection Date	Patient ID	Stud	y ID	Epoch, Arm, CPE
	135090740	Scanned Slide Ima	ages 2.0 count	10/19/2022 : 00:00	9160001 (A,M Y	) A0519	02	Registration, Consented to Biobanking, Registration

32. Email a copy for the BioMS manifest to alliance@email.wustl.edu

For additional information and screen shots please visit <a href="https://washu.atlassian.net/wiki/spaces/BP/pages/468844574/Alliance+Digital+Pathology+Image+Portal+DPI">https://washu.atlassian.net/wiki/spaces/BP/pages/468844574/Alliance+Digital+Pathology+Image+Portal+DPI</a>