BIOMARKER ELIGIBILITY TESTING AND CORRELATIVE SCIENCE PROCEDURE MANUAL

1. Purpose

This document describes the procedures required for the collection, shipping, and processing of biospecimens that are being submitted for 1) biomarker testing for eligibility determination and 2) correlative science testing for patients already enrolled or registered on A071701. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by the Alliance Biorepository at Mayo Clinic (ABMAYO) or at Massachusetts General Hospital (MGH) 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 A071701 biospecimen collection, processing, and submission, including staff at satellite institutions.

2. Scope

This document applies to all biospecimens collected specifically for the A071701 clinical trial study. Please refer to the trial protocol-specific language for additional details regarding eligibility, participant enrollment, and data submission. **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
ABMAYO	Alliance Biorepository at Mayo Clinic
MGH	Massachusetts General Hospital
FFPE	Formalin fixed, paraffin embedded
PK	Pharmacokinetic

4. Contact Information

4.1 For questions and problems related to protocol administration, eligibility, patient registration, and data submission, relevant contact information is listed on protocol pages 1 and 2.

4.2 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**.

4.3 For all other questions regarding biospecimen procurement and shipping procedures, please contact:

ABMAYO

- Paraffin-embedded tissue samples:
  Amanda Sand
  Phone: 1-507-284-3559
  Email: sand.amanda@mayo.edu
  Alliance inbox: NCCTGPATHOLOGY@mayo.edu
- Blood samples:
  Katie Halverson
  Phone: 1-507-293-7147
  Email: halverson.katie@mayo.edu

MGH

- Specimen receipt or status of biomarker testing:
  Nancy Higgins
  Phone: 1-617-643-8651
  Email: MGHTRLClinicalTrials@partners.org

5. Site Preparation

5.1 Please refer to A071701 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 Mayo Clinic and to MGH. 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 Identify a reliable source of dry ice for freezing and shipping biospecimens and a -70 to -90 degree Celsius freezer ("ultralow") in which frozen biospecimens may be stored prior to shipment.

5.4 Prior to collection of CSF and 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.

5.5 Please confirm that your institutional pathology department is willing to submit **at least** fifteen (15) 4-6 micron unstained slides and one (1) H&E stained slide at the required time point designated in this document and in the trial protocol. An institution whose pathology department is unwilling to comply with slide submission should not enroll patients to this study.

6. Collection Schema

The following biospecimens are to be collected at each of the time points listed in the table below. Please refer to individual collection kit instructions, biospecimen collection and processing methods, and specific shipping procedures that are detailed in this manual.

Time Point	Kit (Y/N)	Biospecimen	Quantity	Collection / Processing Method	Shipping	Recipient	Notes
Mandatory for all patients pre-registered to A071701							
≤ 120 days after pre-registration	N	**Metastatic Brain Tumor tissue slides** (from pre-existing diagnostic FFPE block)	15-25	Unstained tissue slides + H&E stained slide for SNAPSHOT NGS testing (9.2)	Ambient	MGH (12.2)	1
≤ 120 days after pre-registration	N	**Extracranial Tumor tissue slides** (from pre-existing diagnostic FFPE block)	15-25	Unstained tissue slides + H&E stained slide for SNAPSHOT NGS testing (9.2)	Ambient	MGH (12.2)	1
Mandatory for all patients consented to the MRTX849 arm of A071701							
Cycle 1 Day 1 Predose **AND** Cycle 1 Day 1 Peak	Y	Whole Blood for plasma for MRTX PK analysis	2 x 1 ml aliquots predose **AND** 2 x 1 ml aliquots peak	Frozen Plasma (10.3)	Dry Ice	ABMAYO-BAP Freezer (12.4)	5
Cycle 1 Day 15 Predose **AND** Cycle 1 Day 15 Peak	Y	Whole Blood for plasma for MRTX PK analysis	2 x 1 ml aliquots predose **AND** 2 x 1 ml aliquots peak	Frozen Plasma (10.3)	Dry Ice	ABMAYO-BAP Freezer (12.4)	5
Cycle 3 Day 1 Predose **ONLY**	Y	Whole Blood for plasma for MRTX PK analysis	2 x 1 ml aliquots predose **ONLY**	Frozen Plasma (10.3)	Dry Ice	ABMAYO-BAP Freezer (12.4)	
Cycle 5 Day 1 Predose **ONLY**	Y	Whole Blood for plasma for MRTX PK analysis	2 x 1 ml aliquots predose **ONLY**	Frozen Plasma (10.3)	Dry Ice	ABMAYO-BAP Freezer (12.4)	
Cycle 7 Day 1 Predose **ONLY**	Y	Whole Blood for plasma for MRTX PK analysis	2 x 1 ml aliquots predose **ONLY**	Frozen Plasma (10.3)	Dry Ice	ABMAYO-BAP Freezer (12.4)	

Optional for patients consented to the MRTX849 arm of A071701							
Cycle 1 Day 15 Peak	Y	CSF in Diamond Midi Centrifuge Tubes for MRTX PK	1 x 3 ml	CSF (11.1)	Dry Ice	ABMAYO- BAP Freezer (12.4)	5, 6
A071701 Biobanking							
≤ 90 days after registration	N	Fixed tissue block	1	Fixed tissue blocks (9.3)	Ambient	ABMAYO-FFPE Tissue (12.3)	2, 3
≤ 90 days after registration	N	Unstained tumor tissue slides	15	Unstained tissue slides (9.4)	Ambient	ABMAYO-FFPE Tissue (12.3)	2, 3
≤ 90 days after registration	Y	Whole blood (EDTA tube)	1 x 10 ml	Whole blood (10.1)	Refrigerated	ABMAYO-BAP Freezer (12.4)	2
≤ 90 days after registration	Y	Whole blood (Streck BCT tube)	2 x 10 ml	Plasma for cfDNA (10.2)	Ambient	ABMAYO-BAP Freezer (12.4)	2
Every 2 cycles during treatment	Y	Whole blood (Streck BCT tube)	2 x 10 ml	Plasma for cfDNA (10.2)	Ambient	ABMAYO-BAP Freezer (12.4)	2, 4
Progression	N	Fixed tissue block	1	Fixed tissue block (9.3)	Ambient	ABMAYO-FFPE Tissue (12.3)	2, 3
Progression	N	Unstained tumor tissue slides	15	Unstained tissue slides (9.4)	Ambient	ABMAYO-FFPE Tissue (12.3)	2, 3
Progression	Y	Whole blood (Streck BCT tube)	2 x 10 ml	Plasma for cfDNA (10.2)	Ambient	ABMAYO-BAP Freezer (12.4)	2

Notes:

1. Submission of diagnostic tumor tissue is mandatory for biomarker eligibility testing. This includes the H&E slide and tumor tissue recuts obtained from BOTH 1) a representative **metastatic brain tumor** diagnostic block AND 2) an **extracranial tumor** diagnostic block. The H&E slide should be from the same block from which the unstained slides were cut. Ideally the tissue sample should contain at least 1 cm^2 of representative and viable tumor tissue. If the tumor tissue area is <1 cm^2, then ideally 20-25 sections should be submitted to reduce the potential of ineligibility due to failed testing. For more details, see **section 9.2.** If the patient does not have evidence of extracranial metastatic disease, then the site may send only metastatic brain tumor sample and eligibility will be based on metastatic brain tumor sample. **Effective with protocol update #1: For patients who consent to biobanking on the screening model consent form, leftover tissue will be sent to the biobank for future research, regardless of whether or not an actionable mutation was identified on the screening tissue sample. This will not be applicable for patients consented prior to the release of update #1.**
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 from any primary, recurrent or metastatic tumor **OR** 15 unstained slides @ 10 micron thickness from such block should be submitted for patients opting in for A071701 biobanking. If fewer than 15 unstained slides can be submitted, please submit as many as possible (up to 15 slides).
4. Each cycle will consist of 28 days. Treatment will continue until disease progression or unacceptable adverse event.
5. Blood and CSF for the peak dose should be collected 4-6 hours after dose of MRTX849.
6. CSF should be collected only from patients who have received 7 consecutive days of MRTX849 (i.e. steady state). Lumbar puncture / CSF collection should occur within one hour of the peak (post-dose) timepoint whole blood collection for pharmacokinetics of C1D15.

7. Biospecimen Collection Kits

7.1 Blood and CSF Specimens

7.1.1 To facilitate the proper collection and shipping of whole blood and CSF 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 ABMAYO via priority overnight shipping. **NOTE: Kits will be sent via FedEx Ground 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 number or alternate billing number for express service. The study will not cover the cost for rush delivery of kits.**

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 Kit contents and specific instructions for use of the kit are provided in the kit box.

7.1.4 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.

7.1.5 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. **Please note, there are NO acceptable alternatives for CSF collection. A biospecimen collection kit MUST be used.**

7.1.6 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 12 – Biospecimen Shipping** for specific instructions on shipping to MGH and to ABMAYO.

8. Biospecimen Labeling and Tracking

8.1 All research biospecimens, with exception of surgical pathology blocks and tissue slides, MUST be labeled with the Alliance study number, Alliance patient ID number, patient initials (Last, First, Middle), the date and time (if applicable) of collection and specimen type (i.e. "plasma," "CSF," etc). Specimen labels must match BioMS records.

8.2 For Biomarker Eligibility Testing, surgical pathology tissue recuts should be labeled according to institutional standards, including the surgical pathology number (e.g. "S16-1234") and the individual block identifier (e.g. "A3"). Provide **a de-identified copy of the surgical pathology report**, labeled with the patient study number, corresponding to the blocks or slides submitted. Usually, this is generated by obscuring all PHI (names and dates) with white-out or a black magic marker, labeling each page of the report with the Alliance patient ID, and photocopying the report. However, please make sure to **maintain the pathology accession numbers** so the submitted slides can be matched directly to the pathology report. **A copy of the de-identified pathology report is required for each and every tissue submission.**

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 MGH or to ABMAYO must be **logged and tracked in BioMS** under A071701. Do not send samples to the Biorepository in which the patient has not been registered onto the study. 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@alliancenctn.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-bioms-contingency**.

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 Biomarker Eligibility Testing: Diagnostic Tumor Tissue Recuts and H&E-Stained Slides

9.2.1 Biomarker eligibility determination requires biomarker testing to be performed on recuts of pre-existing tumor tissue obtained from both a(an):

1) Metastatic brain tumor lesion
    a. Recuts from a single diagnostic FFPE block containing representative tumor tissue obtained from the site's pathology department.
    b. Ideally should contain at least 1 cm^2 of representative and viable tumor tissue.

c. A block where a diagnostic H&E slide is temporarily available for review by a A071701 study pathologist.

2) Extracranial tumor lesion
   a. Recuts from a single diagnostic FFPE block containing representative tumor tissue obtained from the site's pathology department.
   b. Can be from the primary disease site or any other extracranial tumor lesion from that patient.
   c. Ideally should contain at least 1 cm^2 of representative and viable tumor tissue.
   d. A block where a diagnostic H&E slide is temporarily available for review by a A071701 study pathologist.
   e. If the extracranial tumor lesion fails genetic testing or there is insufficient tissue for genetic testing, eligibility can be based on brain metastasis tissue alone.

9.2.2 A total of 15-25 unstained tissue sections from each of the two tumor samples are required to be submitted for each patient registered to A071701.

1) If the tumor tissue is <1 cm^2 in diameter, ideally 20-25 sections should be provided to improve the likelihood of adequate material for eligibility testing.
2) The site's pathology department may determine that fewer sections can be provided for testing under this protocol in order to avoid depleting either of the patient's tumor tissue blocks. While any amount of tissue recuts will be accepted, submitting fewer sections increases the chances of failure on biomarker eligibility testing.

9.2.3 Unstained sections of diagnostic tumor tissue for the metastatic brain lesion AND the extracranial tumor lesion should be prepared as follows:

1) Sections should be cut at 5 microns each.
2) Mount sections onto positively-charged glass microscope slides, with a single tissue per slide mounted in a similar orientation.
3) Air dry the slides only – Do Not Bake.

Unsectioned tumor blocks will not be accepted for submission.

# of slides	Section thickness	Slide type	Sample Types	Purpose
15-25	5 microns	Positively Charged	Metastatic Brain Lesion Extracranial Lesion	Biomaker Eligibility Testing (SNAPSHOT NGS)

9.3 Corollary Testing: Diagnostic Pathology Fixed Tissue Blocks

9.3.1 For patients who consented to **A071701 biobanking** for future research, a representative diagnostic block from any primary, recurrent, or metastatic tumor should be submitted, if applicable.

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 Include a copy of a de-identified pathology report, labeled only with the patient study number with all block submissions.

9.4 Corollary Testing: Unstained Tissue Slides

9.4.1 For patients who consented to A071701 biobanking for future research where an institution is unwilling or unable to submit the requested tissue block, a set of fifteen (15) unstained tumor tissue slides can be submitted as an alternative. If fewer than 15 unstained slides can be submitted, please submit as many as possible (up to 15 slides). Please follow the procedures below for submitting unstained tissue 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
15	10 microns	Non-Charged	Next Gen Sequencing

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 non-charged slides.

9.4.4 Ensure that each slide is labeled with the Alliance study number (A071701), Alliance patient ID number, surgical pathology number (SPN) and institutional block ID, slide serial section number (1, 2, 3, etc.), and thickness (10 microns). Please make sure to **maintain the pathology accession numbers** so the submitted slides can be matched directly to the pathology report.

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.

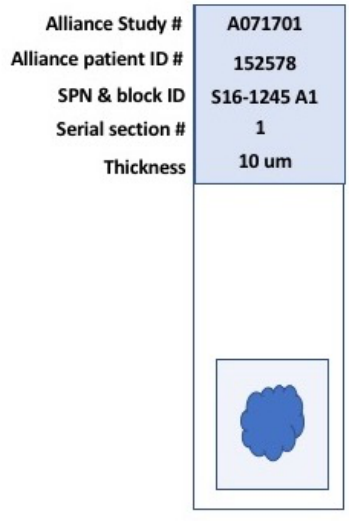
9.4.7 Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide.

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.

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.



10. Blood Collection Methods

10.1 Whole blood (EDTA Tube- no processing)

10.1.1 Collect 10 ml of blood into the EDTA tube using standard venous phlebotomy. Invert tube 10 times.

10.1.2 Store EDTA tube with whole blood at 4 degrees Celsius (i.e. refrigerated) until shipping. Do not freeze the tube. The tube may be stored for up to 72 hours at refrigerated temperature before shipment. If blood must be collected on Friday, it can be shipped on Friday for Saturday delivery. Ensure that the EDTA tube is shipped with a refrigerant pack to ensure proper temperature and to avoid freezing.

10.2 Plasma Nucleic Acid (Streck) Tube Processing

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

10.2.2 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. If blood must be collected on Friday, it can be shipped on Friday for Saturday delivery. Ensure that the Streck tubes are shipped at ambient temperature to avoid freezing.

10.3 Frozen Plasma Processing for PK Analysis

10.3.1 Collect 4 mL whole blood by standard venous phlebotomy technique into the purple top K2EDTA tube. Mix collection tube thoroughly by slowly inverting the collection tube approximately 8-10 times.

10.3.2 Place the collection tube in an ice/water bath immediately after collection and until centrifugation.

10.3.3 Within 60 minutes of collection, spin the vacutainer tube at 4 degrees Celsius in a refrigerated, clinical centrifuge at 1300 x G for 15 minutes. If a refrigerated centrifuge is not available, it is acceptable to spin at room temperature as long as sample is kept on ice immediately before and after spinning.

10.3.4 Label two (2) cryovials as instructed in **section 8.** Make certain each vial is labeled completely and identically.

10.3.5 Carefully remove the plasma layer (~2 ml), without touching the white, buffy coat layer, and divide equally into labeled cryovials (~1 ml per cryovial).

10.3.6 Within 90 minutes of collection, store the plasma PK aliquot samples in a - 70 to -90 degree Celsius ultralow freezer. Store at -70 to -90 degrees C until ready for shipment on dry ice. If an ultralow freezer is not available, it is acceptable to freeze at -20 degrees C, but specimens should be shipped as soon as possible following collection. **Specimens should be submitted to the Biorepository within 24 hours of collection. Batch shipment is not allowed.**

11. CSF Collection Methods

11.1 CSF (Diamond Midi Centrifuge Tube- No processing)

11.1.1 CSF should be collected directly from the lumbar puncture needle into the 5 ml sterile graduated polypropylene collection tubes provided in the CSF collection kit**.** Do **NOT** transfer CSF that has been collected in a different vessel into the provided collection tubes.

11.1.2 Lumbar puncture should be conducted following standard institutional procedures. Efforts should be taken to limit any CSF admixture with blood.

11.1.3 Collect at least 2 ml of CSF into tube but **DO NOT** exceed 3 ml. Unfilled volume in the tube is required to allow for a treatment solution to be added at the central analytical laboratory.

11.1.4 Immediately freeze CSF specimen at -70 to -90 degrees Celsius in an ultralow freezer. Specimen should remain frozen until ready for shipment on dry ice. **Specimens should be submitted to the Biorepository within 24 hours of collection. Batch shipment is not allowed.**

12. Biospecimen Shipping

12.1 Overview

12.1.1 Please see the instruction document that is included in each kit for specific directions on how to package and ship biospecimens.

12.1.2 Place the original, completed copy of the BioMS packing manifest in the shipment. If sending tissue, include a de-identified copy of the 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.

12.1.3 All biospecimens collected on the study should be shipped on the same day that they are collected. Biospecimens must be received by the recipient lab within 24 hours of collection. If biospecimens cannot be shipped on the same day they are collected, please contact appropriate personnel listed in **section 4.3** for further instructions, at least 24 hours prior to anticipated collection.

12.2 Shipping Diagnostic Tumor Specimens to The MGH For Biomarker Eligibility Testing

12.2.1 Enclose the slide mailers containing the unstained tumor tissue slides and the corresponding H&E stained slide within a padded envelope or small Styrofoam cooler.

12.2.2 Include the following items together in the shipment container (Testing will not be initiated until all specimens, corresponding H&E slides, and completed paperwork are received):

- The BioMS shipping manifest.
- A copy of the pathology report for the 1) the brain metastatic sample and 2) the extracranial tumor lesion that is being sent for biomarker testing.
  <u>Note</u>: It is essential that the institutional surgical number is clearly visible on the pathology report (not de-identified) so to determine which submitted sample is the brain lesion versus the extracranial lesion.
- An Alliance A071701 Biomarker Results Form with the top portion fully completed.
- 15-25 mounted sections of brain metastatic tumor tissue, clearly-labeled with surgical pathology number, placed in crush proof containers.
- The corresponding diagnostic H&E slide for the brain metastatic tumor tissue.
- 15-25 mounted sections of extracranial tumor tissue, clearly-labeled with surgical pathology number, placed in crush proof containers.
- The corresponding diagnostic H&E slide for the extracranial tumor tissue.

12.2.3 Ship for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies. **Ship specimens to the MGH on Monday through Thursday only. Do not ship on Fridays, Saturdays, or on the day before a national holiday.**

Using the preferred vendor, ship to:

John Iafrate, PhD, MD
c/o Nancy Higgins
Massachusetts General Hospital Cancer Center
55 Fruit Street, GRJ-1015
Boston, MA 021146
Phone: 617-643-8651

12.3 Shipping to ABMAYO- FFPE Tissue

12.3.1 Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor. **Ship specimens to ABMAYO on Monday through Friday only. Do not ship on Saturdays or on the day before a national holiday.**

Ship to:

Alliance Biorepository at Mayo Clinic- FFPE Tissue
Attn: PC Office (Study A071701)
RO-FF-03-24-CC/NW Clinic
200 First Street Southwest
Rochester, MN 55905
Phone: 507-266-0724

12.4 Shipping to ABMAYO- BAP Freezer

12.4.1 Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor. **Ship specimens to ABMAYO on Monday through Friday only. Do not ship on Saturdays or on the day before a national holiday.**

Ship to:

Alliance Biorepository at Mayo Clinic- BAP Freezer
ST-SL-16
150 Third Street SW
Rochester, MN 55902
Phone: 507-538-0602

13. ABMAYO Biospecimen Receipt and Quality Assurance Measures

13.1 All biospecimens sent to ABMAYO will be accessioned into the informatics system BioMS, at ABMAYO Research Laboratory Information Management System (RLIMS) which interfaces with BioMS.

13.2 All biospecimens received at the ABMAYO will be logged, associated, and tracked by the patient study ID number.

13.3 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 submitting site for reconciliation.

13.4 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.

13.5 All biospecimens submitted to ABMAYO will remain in storage until exhausted. In the event the patient withdraws consent, the specimens will be disposed/returned according to Alliance Policy and Procedure Chapter 11.

14. Document History

Version	Description and Justification of Change	Author	Effective Date
5.1	Updated effective date to match date of Mirati arm posting	PAA	02/15/2023
5.0	Added PK collection	PAA	06/27/2022
4.0	Removed PK collection Fixed minor grammatical errors and typos	PAA	04/07/2022
3.1	Updated Mayo BAP email address	PAA	08/12/2021
3.0	Added PK collection Fixed minor grammatical errors and typos	PAA, AC	04/27/2021
2.0	Removed signature page Updated Mayo contact information	PAA	08/18/2020
1.2	Corrected slide requirement Updated BioMS email address Updated shipping requirement for EDTA	RN, HT, PAA	05/30/2019
1.1	Clarification of eligibility	PKB, YW, PAA	01/28/2019
1.0	New	PAA	10/16/2018