

CORRELATIVE SCIENCE PROCEDURE MANUAL

AFT-57: RANDOMIZED PHASE II TRIAL OF NEOADJUVANT AND ADJUVANT ATEZOLIZUMAB WITH OR WITHOUT TIRAGOLUMAB IN CONJUNCTION WITH CHEMORADIOTHERAPY FOR UNRESECTABLE STAGE III NSCLC

VERSION: 1.1

VERSION DATE: 05/30/2023



AFT-57 Correlative Science Procedure Manual Signature Page

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1. PURPOSE

This document describes the procedures required for the collection, shipping, and processing of biospecimens from all patients enrolled or registered on AFT-57. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by the AFT Biorepository (AFB) (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 AFT-57 study biospecimen collection, processing, and submission, including staff at additional site locations.

2. SCOPE

This document applies to all biospecimens collected specifically for the AFT-57 study only. Please refer to the study 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 can be found on the AFT BioMS web site which is accessible via the AFT portal: (https://alliancefoundationtrials.org)

3. CONTACT INFORMATION

- 3.1. Please send any questions and problems related to protocol administration, eligibility, patient registration, and data submission, to the AFT Project Manager at: AFT57@alliancefoundationtrials.org or 1-781-956-9518.
- **3.2.** For questions about using the AFT BioMS web application for ordering kits, or registering and shipping biospecimens, please contact: 1-855-642-4667 or <u>aftbiomshelp@email.wustl.edu</u>
- **3.3.** For any other questions about biospecimen procurement and shipping procedures, please contact the AFB Program Manager at: 1-314-747-4402 or <u>afbhelp@email.wustl.edu</u>

4. SITE PREPARATION

- **4.1.** Please refer to the AFT-57 protocol for any specific requirements related to patient enrollment, registration, and regulatory compliance.
- **4.2.** The AFT BioMS application is used for both requesting biospecimen collection kits and for logging the collection and shipment of biospecimens to the AFT Biorepository. For training and assistance in using the AFT BioMS application, please see the AFT BioMS web site which is accessible via the AFT portal: <u>https://alliancefoundationtrials.org</u> or contact the AFT BioMS Helpdesk at: <u>aftbiomshelp@email.wustl.edu</u> or 1-855-642-4667.
- 4.3. Prior to collection of biospecimens, a biospecimen collection kit must be at the collection site.Please see section 6 for requesting biospecimen collection kits. Please allow at least 10 working days to receive the collection kit.



4.4. Please confirm that your institutional pathology department will release a tumor tissue paraffin block or unstained slides at each required time point designated in this document and in the study protocol. An institution whose pathology department is unwilling to comply with tumor tissue submission should not enroll patients to this study.

5. COLLECTION SCHEMA

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

Time Point	Kit Name	Biospecimen	Quantity	Collection / Processing Method	Recipient Lab / Shipping	Notes
	FO	R PATIENTS I	REGISTER	ED TO ARMS A	<u>& B</u>	
Baseline / Screening	No Kit	Fixed tumor tissue block- archival or fresh biopsy (current DX) <u>OR</u> Unstained tumor tissue slides	1 block <u>OR</u> 20 unstained slides (5 um)	Fixed tissue blocks (8.2) OR Fixed tissue slides (8.3)	AFB (10.2)	1
Baseline / Screening	No Kit	Fixed tumor tissue block (primary DX) <u>OR</u> Unstained tumor tissue slides	1 block <u>OR</u> 20 unstained slides (5 um)	Fixed tissue blocks (8.2) <u>OR</u> Fixed tissue slides (8.3)	AFB (10.2)	2
Baseline / Screening	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	
Baseline / Screening	Baseline- AFB	Whole blood (Heparin tube)	2 x 10 ml	Whole blood for PBMC (9.2)	AFB (10.2)	
				•		
Day 1- Concurrent	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	
Day 1- Concurrent	Day 1- AFB	Whole blood (Heparin tube)	2 x 10 ml	Whole blood for PBMC (9.2)	AFB (10.2)	
3 mo. after radiation	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	



End of treatment or Progression	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	
Progression or Recurrence	No Kit	Fixed tumor tissue block (fresh biopsy) <u>OR</u> Unstained tumor tissue slides	1 block <u>OR</u> 20 unstained slides (5 um)	Fixed tissue blocks (8.2) OR Fixed tissue slides (8.3)	AFB (10.2)	3
6 mo. Post Rx for patients without progression	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	4

Time Point	Kit Name	Biospecimen	Quantity	Collection / Processing Method	Recipient Lab / Shipping	Notes
	FOI	R PATIENTS R	REGISTER	ED TO ARM C ON	<u>ILY</u>	
Baseline / Screening	No Kit	Fixed tumor tissue block- archival or fresh biopsy (current DX) <u>OR</u> Unstained tumor tissue slides	1 block <u>OR</u> 20 unstained slides (5 um)	Fixed tissue blocks (8.2) OR Fixed tissue slides (8.3)	AFB (10.2)	1
Baseline / Screening	No Kit	Fixed tumor tissue block (primary DX) <u>OR</u> Unstained tumor tissue slides	1 block <u>OR</u> 20 unstained slides (5 um)	Fixed tissue blocks (8.2) OR Fixed tissue slides (8.3)	AFB (10.2)	2
Baseline / Screening	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	
Baseline / Screening	Baseline- AFB	Whole blood (Heparin tube)	2 x 10 ml	Whole blood for PBMC (9.2)	AFB (10.2)	
Day 1- Concurrent	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	



Day 1- Concurrent	Day 1- AFB	Whole blood (Heparin tube)	2 x 10 ml	Whole blood for PBMC (9.2)	AFB (10.2)	
Start of Week 4	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	
Start of Week 4	Week 4- AFB	Whole blood (Heparin tube)	2 x 10 ml	Whole blood for PBMC (9.2)	AFB (10.2)	
3 mo. after radiation	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	
3 mo. after radiation	3 mo- AFB	Whole blood (Heparin tube)	2 x 10 ml	Whole blood for PBMC (9.2)	AFB (10.2)	
End of treatment or Progression	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	
Progression or Recurrence	No Kit	Fixed tumor tissue block (fresh biopsy) <u>OR</u> Unstained tumor tissue slides	1 block <u>OR</u> 20 unstained slides (5 um)	Fixed tissue blocks (8.2) OR Fixed tissue slides (8.3)	AFB (10.2)	3
6 mo. Post Rx for patients without progression	Haystack	Whole blood (Streck BCT tube)	3 x 10 ml	Whole blood for cfDNA (9.1)	Haystack (10.3)	4

NOTES:

- 1. Submit a representative, archival tumor tissue block or unstained slides to AFB for correlative studies. If archival tissue is unavailable or determined to be inadequate, tumor tissue must be obtained from a biopsy performed at baseline/screening. Biopsy should be submitted as FFPE tissue block or unstained slides. **BLOCK SUBMISSION IS STRONGLY PREFERRED.**
- If current disease is a recurrent or progressive lesion, also submit a representative tumor tissue block or unstained slides from the primary tumor to AFB, if it is available. BLOCK SUBMISSION IS STRONGLY PREFERRED.
- 3. For patients who develop progression or recurrence, a biopsy to histologically confirm recurrence is recommended if feasible and clinically indicated. Ideally, this would occur prior to start of new cancer-directed therapy.
- 4. For patients who do not show signs of progression 6 months after the end of study treatment.



6. **BIOSPECIMEN COLLECTION KITS**

6.1. Blood Specimens

- **6.1.1.** To facilitate the proper collection and shipping of all biospecimens, biospecimen collection kits and materials will be provided. The cost of the kit and shipping the kit to the site will be paid for. A pre-paid FedEx waybill is provided for shipping the kit with the biospecimens back to Haystack and to the AFB at Washington University in St. Louis via priority overnight shipping.
- **6.1.2.** Kits should be requested at least 10 working days in advance of the anticipated collection date. As many as 2 kits can be requested at one time for specimens collected and shipped to AFB. As many as 10 kits can be requested at one time for specimens collected and shipped to Haystack. Since many of 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 using the AFT BioMS system.**
- 6.1.3. Kits are shipped to sites using standard FedEx shipping. If kits are needed urgently, please provide a Fedex account number which can be billed for priority shipping.
- **6.1.4.** Kit contents and specific instructions for use of the kit are provided in the kit box and are available for download on the AFT BioMS webpage which is accessible via the AFT portal: <u>https://alliancefoundationtrials.org</u>. **Please return any used collection materials with the kit**.
- **6.1.5.** 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.
- **6.1.6.** 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.
- **6.1.7.** 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.
- **6.1.8.** 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).
- **6.1.9.** Please return all kits that have expired or missing components. Return the ENTIRE kit using the pre-paid FedEx waybill provided. 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.
- **6.1.10.** 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 while some kit components are generic (Heparin tubes) others are highly specialized (Streck BCT tubes) and probably are not available at the institution.



- **6.1.11.** 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.
- **6.1.12.** Please see **Section 10 Biospecimen Shipping** for specific instructions on packaging biospecimens into the shipping kits for shipment to the AFT biorepository or to Haystack.

6.2. Tissue Specimens

- **6.2.1.** There is no independent "kit" for submission of paraffin blocks or slides.
- **6.2.2.** Blocks and slides should be packaged to avoid breakage using a padded envelope or preferably, a small Styrofoam container.
- 6.2.3. 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.
- **6.2.4.** Because paraffin tissue blocks or slides may be requisitioned and received from the surgical pathology department at a different time than the day of procurement for other biospecimens, paraffin blocks or slides may be sent independently of other biospecimens.
- **6.2.5.** Blocks may be shipped for standard overnight delivery according to institutional policies and using the preferred vendor.

7. BIOSPECIMEN LABELING AND TRACKING

- **7.1.** All research biospecimens (vacutainer tubes, tissue bags) MUST be labeled with the participant study number and patient initials (Last, First, Middle). Blood tubes should additionally be labeled with the date and time of collection. Streck BCT tubes in the Haystack kit are pre-labeled with spaces to write subject ID and date of collection.
- **7.2.** 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. Provide a **de-identified** copy of the surgical pathology report. Please ensure the institutional surgical pathology number (SPN) and block ID that match the SPN on the physical label on the tissue are maintained on the surgical pathology report. See **section 8** for additional details.
- **7.3.** Label all containers and vials with an indelible, solvent-resistant marker when they are at ambient temperature. Do not try to label frozen vials.
- **7.4.** Do not affix any labels to vials or tubes. Label the collection containers directly with a marking pen.
- **7.5.** All biospecimens that are collected and sent to the AFT Biorepository (AFB) or to Haystack **must be logged and tracked in AFT BioMS**. The AFT BioMS system is a web-based application that tracks the collection and shipping of biospecimens. Once individual biospecimens are logged and 'shipped' in the AFT 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 AFT BioMS system and for further information about training, access, and use,



please contact the AFT BioMS Help desk at: 1-855-642-4667 or <u>aftbiomshelp@email.wustl.edu</u>. Note that the AFT BioMS system is similar to but independent of the NCI BioMS application, which is used to manage biospecimens collected on NCI NCTN Alliance trials.

7.6. In the event that AFT BioMS cannot be accessed, please complete an AFT BioMS specimen manifest form, which can found here-

https://cbmiapps.wustl.edu/confluence/display/AB/Forms

7.7. The AFT-57 Test Requisition Form (TRF) must be submitted along with Streck tubes to Haystack. The TRF can be located in **Appendix 1** of this manual. The barcode provided in the Haystack biospecimen collection kit should be affixed to the top right corner of the TRF. The completed form should be scanned and emailed to <u>support@haystackoncology.com</u> at time of shipment. A hard copy of the TRF must also be included within the shipment.

8. TISSUE COLLECTION METHODS

8.1. Overview

- **8.1.1.** Please refer to protocol-specific instructions for procedures related to actual tissue procurement from individual participants.
- **8.1.2.** In order to be eligible for the study, all subjects must submit tumor tissue to AFB for central PD-L1 analysis and additional correlative studies such as tumor DNA/RNA-sequencing (see **study protocol section 6.1**).
- **8.1.3.** Tumor tissue should be of good quality based on total and viable tumor content. CT guided biopsy is preferred unless it is deemed unsafe per investigator, in which case EBUS (endobronchial ultrasound) is acceptable. Samples collected via **resection** (i.e., mediastinoscopy), **core needle biopsy** (5 cores are preferred but will accept a minimum of 3 with the understanding that there is a higher risk of failure, recommended minimum of 18-gauge needle, embedded in a single paraffin block), or **excisional, incisional, punch, or forceps biopsy** are acceptable. Fine-needle aspiration (defined as samples that do not preserve tissue architecture and yield cell suspension and/or smears), alcohol-fixed specimens, ascites fluid, bone metastases, brushing, cell pellets from pleural effusion, and lavage samples are not acceptable.

8.2. Diagnostic Pathology Fixed Tissue Blocks

8.2.1. This protocol requires submission of ONE representative, diagnostic pathology, formalin fixed paraffin embedded (FFPE) tumor tissue block from current disease. Additionally, if available, ONE representative, diagnostic pathology, formalin fixed, paraffin embedded tumor tissue block from the original tumor resection should also be sent, in cases which present as recurrent or progressive lesions. For patients who after enrollment and start of protocol therapy (or after completion of protocol therapy) develop progression or recurrence, then a biopsy to histologically confirm recurrence is recommended if feasible and clinically indicated. Ideally, this biopsy occurs prior to the start of a new cancer-



directed therapy. In those cases, a leftover tumor tissue block should be submitted for future correlative analyses.

- **8.2.2.** 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 correlative science study end points have been met.
- **8.2.3.** Include a copy of a de-identified pathology report. Please ensure the institutional surgical pathology number (SPN) and block ID that match the SPN on the physical label on the tissue are maintained on the surgical pathology report.
- **8.2.4.** In the event that an institution will not release a tumor tissue block, the institution may instead submit tissue sections, mounted and unstained to glass slides.
- 8.2.5.

8.3. Unstained Slides from Diagnostic Fixed Tissue Blocks

8.3.1. In cases where institutions are unable or unwilling to submit the requested tissue block, a set of 20 unstained tissue slides may be sent as an alternative. 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
20	5 micron	Positively Charged	Correlative Studies

- **8.3.2.** Serial, tissue sections should be cut fresh from the appropriate FFPE tissue block.
- **8.3.3.** Cut sections at 5 micron thickness as indicated onto positively charged slides.
- **8.3.4.** Ensure that each slide is labeled with the patient study number, the institutional surgical pathology number, institutional block ID, section thickness, and the slide serial section number (1, 2, 3, etc.).
- **8.3.5.** Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink.
- **8.3.6.** No adhesives or other additives should be used in the water bath.
- **8.3.7.** Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide.
- **8.3.8.** 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.
- **8.3.9.** See figure below for proper mounting and labeling





- 8.3.10. Air dry slides for 12-24 hours prior to shipping. Do not oven dry slides.
- **8.3.11.** Slides should not be touching each other. Ensure that slides from only one patient are placed in one slide mailer.
- **8.3.12.** Include a copy of a de-identified pathology report. Please ensure the institutional surgical pathology number (SPN) and block ID that match the SPN on the physical label on the tissue are maintained on the surgical pathology report.

9. BLOOD COLLECTION METHODS

9.1. Whole blood - Streck tubes (no processing) for cfDNA

- 9.1.1. Using a 21 gauge straight needle, collect 10 ml of blood into each of the three Streck BCT tubes using standard venous phlebotomy. Allow 60-90 seconds for each tube to fill. Gently invert tubes 10 times immediately after draw to ensure adequate mixing and preservation.
- 9.1.2. Keep Streck tubes with whole blood at room temperature. Do not freeze or refrigerate the tubes. It is preferred that the tubes be shipped within 24 hours of collection. However, samples collected on Fridays or on days before a holiday should be kept at room temperature and shipped on the next business day. Ensure that the Streck tubes are shipped at ambient temperature to avoid freezing.

9.2. Whole blood- Heparin tubes (no processing) for PBMC

9.2.1. Collect 10 ml of blood into each of the heparin tubes using standard venous phlebotomy. Invert tubes 10 times.



9.2.2. Store heparin tubes with whole blood at ambient temperature until shipping. Do not freeze or refrigerate the tubes. The tubes must be received within 24 hours of collection (e.g. Friday—Saturday collections or Holiday collections are not allowed). Ensure that the heparin 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. BIOSPECIMEN SHIPPING

10.1. Overview

- 10.1.1. Please see the Directions for Use (DFU) document that is included in each kit, for specific directions on how to package and ship biospecimens. The DFU document is also available for download on the AFT BioMS webpage which is accessible via the AFT portal: (<u>https://alliancefoundationtrials.org</u>).
- **10.1.2.** Place the original, completed copy of the AFT BioMS Packing Manifest in the kit. If sending tissue, include a copy of the de-identified surgical pathology report, labeled with the patient study number. Do not send specimens without a completed AFT BioMS Packing Manifest or substitute "AFT BioMS Downtime Form". Biospecimens cannot be accepted without this completed form.
- 10.1.3. The AFT-57 Test Requisition Form (TRF) must be submitted along with Streck tubes to Haystack. The TRF can be located in Appendix 1 of this manual. The barcode provided in the Haystack biospecimen collection kit should be affixed to the top right corner of the TRF. The completed form should be scanned and emailed to support@haystackoncology.com at time of shipment. A hard copy of the TRF must also be included within the shipment.
- 10.1.4. All biospecimens should be shipped within timeframes indicated in sections 8 and 9. If collected biospecimens cannot be shipped within the specified timeframes (e.g. Friday Saturday or Holiday collections), please contact the AFB Program Manager at 1-314-747-4402 for further instructions, at least 24 hours prior to anticipated collection.
- 10.1.5. Do not ship on Friday, Saturday, Sunday or day before a nationally recognized holiday.

10.2. Shipping to AFB

10.2.1. Enclose specimens within the ambient shipper. Ship container for PRIORITY OVERNIGHT DELIVERY using the pre-paid FedEx waybill provided.Ship to:



AFT 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

10.3. Shipping to Haystack

10.3.1. Place filled Streck tubes in the tube sleeve. Insert sleeved Streck tubes into biohazard bag. Wrap gel pack around biohazard bag and place within the provided box along with the BioMS manifest and completed TRF. Place the box inside the provided FedEx return envelope. Ship for PRIORITY OVERNIGHT DELIVERY using the pre-paid FedEx waybill provided.

Ship to:

Haystack Oncology, Inc. 301 West 29th Street, Suite 2004U Baltimore, MD 21211 USA +1 (410) 297-1000

11. AFB BIOSPECIMEN RECEIPT AND QUALITY ASSURANCE MEASURES

- **11.1.** Upon receipt at AFB, all biospecimens will be accessioned into the TPC informatics system, OpenSpecimen.
- **11.2.** All biospecimens will be logged, associated, and tracked by the unique patient biopsy control number.
- **11.3.** 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.
- 11.4. Upon receipt, all physical biospecimens received will be reconciled with what is recorded on the AFT BioMS packing manifest. Any discrepancies noted will be communicated to the AFB Program Manager who will contact the submitting site for reconciliation.
- 11.5. 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 AFB Program Manager, who will contact the submitting site for reconciliation.
- **11.6.** Aliquoted biofluids will be stored under liquid nitrogen vapor.
- **11.7.** All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol principal investigator.



12. DOCUMENT HISTORY

VERSION	DESCRIPTION AND JUSTIFICATION OF CHANGE	AUTHOR	EFFECTIVE DATE
1.1	Removed references to kits being provided for tissue specimens	KL	05/30/2023
1.0	New	KL, PAA	05/05/2023



INSERT APPENDIX 1- HAYSTACK TRF

Haystack MRD[™] Test Clinical Study Test requisition form



Study Information

Haystack Trial Code:	AFT-57
Collection Site:	
Form completed by: _	
Contact email:	

Patient and Sample Information

ubject ID:
iological sex: 🗌 Male 🗋 Female
ate of birth:
tudy arm: 🗌 A 🗌 B 🗋 C
imepoint: 🗌 Baseline / Screening
Day 1 – Concurrent
Start of week 4 (Arm C patients only)
3 mo. after radiation
End of treatment or progression
6 mo. post-rx (for patients without progression)
ate of blood collection:
ample ID (Subject ID-MMDDYYYY):*Sample ID = "Subject ID: - Date of blood collection

Instructions

- Ship blood to Haystack Oncology *within 24 hours of collection.* Samples collected on Friday should be kept at room temperature and shipped the following Monday.
- Include this completed form in the shipment with the sample.
- Email a copy of this completed form to *support@haystackoncology.com*