

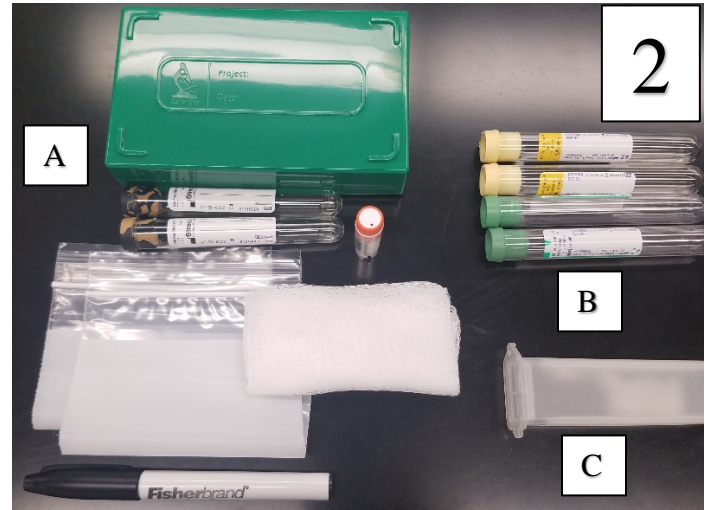
**Collection Protocol Title:** Biospecimen Collection for Phase II Trial of Induction Immunotherapy with Atezolizumab for Patients with Unresectable Stage IIIA and IIIB NSCLC Eligible for Chemoradiotherapy with Curative Intent.

**Collection Protocol Short Title:** AFT-16

**Collection Protocol PI:** AFT Administrator

**Collection Time Points:** (1) Screen (2) Day 1-Concurrent (3) C1D1-Consolidation (4) 3M Post Treatment (5) 6M Post Treatment (6) End Of Study

**Biospecimen Collection Kit Contents:**



Set #	Component	QTY	Time Points
1	STP 309SYS kit (Outer box w/pre-printed Biological Substance, Category B and UN 3373 Markings and Insulated Chest).	2	(1)(2)(3)(4)(5)(6)
	Return/Forwarding FedEx Air Bill (not pictured)	3	(1)(2)(3)(4)(5)(6)
	100 mL Absorbent Strip	2	(1)(2)(3)(4)(5)(6)
	Saf-T-Rap® Sticky Side Bubble Wrap - 6 x 12 Inches	4	(1)(2)(3)(4)(5)(6)
	Disposable Secondary Pressure Vessel (Medium) (Outer envelope – 7 1/2 x 9 1/2” OD, Leak proof polybag – 8 1/2 x 10 1/2” ID)	2	(1)(2)(3)(4)(5)(6)
	Saf-T-Temp controlled room temperature (CRT) PCM packs - 500G (not pictured)	2	(1)(2)(3)(4)(5)(6)
2	Fisherbrand™ Fine Tip Marking Pens, black	1	(1)(2)(3)(4)(5)(6)
	Fisherbrand™ Polypropylene Slide Mailers, holds 5 slides, 3x1" in size, model 2	1	(1)
	Minigrip™ Reclosable White Specimen Bags, 4X6	2	(1)
	Gauze Sponge Medi-Pak™ Performance Plus Cotton Gauze 12-Ply 2 X 2 Sterile	4	(1)
	Slide box, holds 25 slides, plastic green	1	(1)
	Corning™ Internally Threaded Cryogenic Vials, polypropylene 2ml	1	(1)
	Whole Blood Tube, Streck Cell-Free DNA BCT® (Black/Brown Marble Top, 8mL)	2	(1)(2)(3)(4)(5)(6)
	Whole Blood Tube, Lithium Heparin (Green Top, 10mL)	2	(1)(2)(3)(4)(5)(6)
Whole Blood Tube, ACD Solution A (Yellow Top, 8.5ml)	2	(1)(2)(3)(4)(5)(6)	

See backside for Collection Site Instructions

\*\*\* CONTROLLED DOCUMENT \*\*\*

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### Collection Site Packaging Instructions

Follow packaging instructions. Properly packed, these kit will ensure ambient specimens remain at appropriate temperatures for up to 24hr. Do *NOT* freeze or refrigerate the Saf-T-Temp controlled room temperature (CRT) PCM pack that is included in the shipping kit.

### Specimen Processing

- 1) Refer to the Correlative Science Procedure Manual (CSPM) for instructions regarding specimen collection.
- 2) All research biospecimens (blood collection tubes, cryovial, specimen bags, slide holders) **MUST** be labeled with the Participant study number and Participant initials (Last, First, Middle) using the permanent marker provided with the kit. Blood tubes must also be labeled with date and time of collection.

### Specimen Packaging

- 1) **Shipping to AFB- Refer to picture 2A**
  - a. Transfer unstained slides into the 25-slot slide box provided. If an H&E slide is submitted, transfer slide into 25-slot slide box. Place the piece of gauze on top of the slides, secure the lid of the slide box with tape and wrap the slide box with bubble wrap. Place inside shipping container.
  - b. Wrap each FFPE block with gauze and place inside separate 4x6 re-closable bags. Place inside shipping container.
  - c. Cut tissue sections (10-8 micron tissue sections) and transfer to cryovial provided. Place inside shipping container.
  - d. Collect whole blood in Streck Cell-Free DNA BCT® tubes according to CSPM instructions. Wrap blood tubes with bubble-wrap and transfer into the leak-proof inner polybag (biohazard) of the disposable secondary pressure vessel along with the 100mL absorbent strip. Seal the polybag by removing the red tape, place inside the white Tyvek envelope and seal. Place inside shipping container.
- 2) **Shipping to OSU-Refer to picture 2B**
  - a. Collect whole blood in ACD and Heparin blood tubes according to CSPM instructions. Wrap blood tubes with bubble-wrap and transfer into the leak-proof inner polybag (biohazard) of the disposable secondary pressure vessel along with the 100mL absorbent strip. Seal the polybag by removing the red tape, place inside the white Tyvek envelope and seal. Place inside shipping container.
- 3) **Shipping to HistoGeneX NV-Refer to picture 2C**
  - a. Cut 4 unstained slides for PD-L1 immunohistochemistry, place inside the Polypropylene Slide Mailer, seal lid with tape and wrap with bubble-wrap. Place inside shipping container provided by site.

### Preparing the Shipping Containers

- 1) Register specimen collection information in the AFT BioMS tracking database, which **is accessible via the AFT portal (<https://alliancefoundationtrials.org>)**. Place a copy of the AFT BioMS packing slip inside of each shipping container.
- 2) If applicable, include a de-identified copy of the institutional surgical pathology report for the slides and blocks enclosed.
- 3) Close the outer corrugated box for specimens shipped to the AFB or OSU and secure with packaging tape.
  - a. A shipping container is not provided for specimens shipped to HistoGeneX NV. Sites are requested to use standard FedEx box/envelope mailers or other ambient shipping containers approved for used at their respective site.
- 4) A completed FedEx Air Bill is included for each kit. Do not interchange FedEx air-bills between kits.
  - a. Refer to the CSPM for AFB, OSU and HistoGeneX NV shipping addresses.
- 5) Do not ship on Friday, Saturday, Sunday or day before a nationally recognized holiday.

### Requesting Additional Biospecimen Collection Kits

- 1) All Biospecimen Collection Kits provided by the AFT Biorepository must be requested through the AFT Biospecimen Management System (AFT BioMS); **do not call, email or fax the biorepository**. Please contact the AFT BioMS Helpdesk (aftbiomshelp@bmi.wustl.edu or 855-642-4667) for questions regarding kit requests through the AFT BioMS application.
- 2) Kit requests will be processed and distributed within 10 working days of request receipt.
  - a. The number of kits distributed per request may be limited based upon accrual rate of the trial or due to kit availability. Requesting sites will be notified in advance if the number of kits received will differ from what was requested.
  - b. Distributed kits will have a minimum shelf life of 90 days, unless precluded by the stability of a particular component.
  - c. In the event a kit has expired components, the **entire kit** must be returned to the AFT Biorepository.