

Collection Protocol Title: Comparison Of Operative To Monitoring And Endocrine Therapy (Comet) Trial For Low Risk DCIS: A Phase Iii Prospective Randomized Trial

Collection Protocol Short Title: AFT-25

Collection Protocol PI: AFT Administrator

Collection Time Points: (1) Screen (2) Progression

Biospecimen Collection Kit Contents: Single Shipper



| Set # | Component | QTY | Time Points |
|-------|---|-----|-------------|
| 1 | Single shipper (Outer box w/ pre-printed Biological Substance, Category B, UN 3373 Markings, Insulated Chest) | 1 | (1) (2) |
| | FedEx Air bill for return shipment (<i>Not Pictured</i>) | 1 | (1) (2) |
| | Disposable Secondary Pressure Vessel (Medium) (Outer envelope, Inner leak proof polybag) | 1 | (1) (2) |
| | Saf-T-Rap® Sticky Side Bubble Wrap - 6 x 12 Inches | 2 | (1) (2) |
| | 100 mL Absorbent Strip | 1 | (1) (2) |
| | Saf-T-Temp controlled room temperature (CRT) PCM packs - 500G (<i>Not Pictured</i>) | 1 | (1) (2) |
| 2 | Marking pen (Black) | 1 | (1) (2) |
| | Streck Cell-Free DNA BCT® Tube (Black/Brown Marble top, 10mL) | 2 | (1) (2) |
| | Vacutainer® K2 EDTA Tube (Lavender top, 10ml) | 1 | (1) (2) |
| | Slide box, holds 25 slides, plastic green | 1 | (1) (2) |
| | Gauze, sterile cotton (2" x 2") | 2 | (1) (2) |
| | Minigrip Bag (4" x 6") | 1 | (1)(2) |

See backside for Collection Site Instructions

*** CONTROLLED DOCUMENT ***

This document is maintained electronically in the Tissue Procurement Core shared Quality Controlled Documents folder. It is the responsibility of the user to verify that any hard copy is the latest version by checking the shared folder.

Collection Site Packaging Instructions

Follow packaging instructions. Properly packed, this 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 for instructions regarding specimen collection and processing.
- 2) All research biospecimens (Vacutainer tubes, Streck tubes, slide holders and specimen bags) **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) Cut paraffin block sections to unstained slides and transfer into the 25-slot slide box provided. Place the piece of gauze on top of the slides before securing the lid of the slide holder with tape and wrap the 25-slot slide box with bubble wrap provided. Place inside shipping container.
- 2) Collect FFPE block according to instructions in the Correlative Science Manual; wrap block in gauze and place inside 4" x 6" re-closeable bag.
- 3) Wrap K₂ EDTA Vacutainer® tube and Streck Cell-Free DNA BCT® tubes with bubble-wrap and place inside the leak-proof inner poly bag (biohazard) of the disposable secondary pressure vessel along with the 100mL absorbent strip. Seal the poly bag by removing the red tape, place inside the white Tyvek® envelope and seal the Tyvek® envelope. Place inside shipping container.

Preparing the Shipping Container

- 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 the shipping container.
- 2) If applicable, include a de-identified copy of the institutional surgical pathology report pertaining to the FFPE block and/or slides enclosed.
- 3) Close the outer corrugated box and secure with packaging tape.
- 4) A completed FedEx Air Bill is included with the biospecimen collection kit in order to return the kit to the biorepository. Do not interchange FedEx air-bills between kits.
 - a. Ship to: AFT Biorepository at Washington University, c/o Siteman Cancer Center Tissue Procurement Core, 425 S. Euclid Ave., Rm 5120, St. Louis MO, 63110-1005; Phone (314-454-7615).
 - b. 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.