

## AFT-38

### Biospecimen Collection Kit Directions For Use

**Collection Protocol Title:** A Randomized, Open Label, Phase III Trial to Evaluate the Efficacy and Safety of PAIbociclib + Anti-HER2 Therapy + Endocrine Therapy vs. Anti-HER2 Therapy + Endocrine Therapy after INduction Treatment for Hormone Receptor Positive (HR+)/HER2-Positive Metastatic BreAst Cancer.

**Collection Protocol Short Title:** AFT-38

**Collection Protocol PI:** AFT Administrator

**Collection Time Points:**

Screening	Cycle 1 Day 1	End of Treatment
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#### Biospecimen Collection Kit Components:

##### 1. Components for Shipping Ambient Specimens:

QTY	Description
1	Cardboard box with Biological Substance, Category B, UN3373 markings
1	Styrofoam container
1	Outer Secondary Pressure Vessel (Tyvek)
1	Leak proof Biohazard bag with adhesive strip (for ambient specimens)
1	100 mL absorbant strip
2	Saf-T-Rap® Sticky Side Bubble Wrap
1	Saf-T-Temp controlled room temperature (CRT) PCM pack - 500G (DO NOT FREEZE OR REFRIGERATE)
1	Completed FedEx Return air-bill (Do not interchange FedEx air-bills between kits)

##### 2. Components for Specimen Collection:

Description	Time Point/QTY		
	Screening	Cycle 1 Day 1	End of Treatment
Black marking pen	1	1	1
RNAlater® Stabilization Solution	1		1
Streck Cell-Free DNA BCT® Tube (Black/Brown Marble top, 10mL)		2	2
Vacutainer® K2 EDTA Tube (Lavender top, 10mL)		1	
4"x6" Minigrip bag	1		
4"x4" gauze	2		
25 slide box holder	1		

*See Reverse Side for Specimen Processing and Packaging Instructions*

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### Biospecimen Collection Kit Directions For Use

#### Specimen Processing

1. Refer to the Correlative Science Procedure Manual (CSPM) for instructions regarding specimen collection and processing.
2. All research biospecimens (Vacutainer tubes, Streck tubes, RNAlater vial, 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-Ambient Shipping

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, secure the lid of the slide box with tape and wrap the slide box with bubble wrap. If a FFPE block is collected, wrap the FFPE block with gauze and place in the 4x6 Minigrip bag. Place inside shipping container
2. Wrap Vacutainer® EDTA and Streck Cell-Free DNA BCT® tubes with bubble-wrap. Transfer blood tubes and RNAlater specimen vials into the leak-proof inner biohazard bag along with the 100mL absorbent strip. Seal the biohazard bag by removing the red tape, place inside the white Tyvek® envelope and seal the Tyvek® envelope. Place inside shipping container.

#### Packaging Instructions

1. Follow packaging instructions to ensure kit's ambient specimens remain at appropriate temperatures for up to 24hr.
2. Register specimen collection information in the AFT BioMS tracking database (<https://alliancefoundationtrials.org>). Place a copy of the AFT BioMS packing slip inside of the shipping container.
3. If applicable, include a de-identified copy of the institutional surgical pathology report pertaining to the slides or FFPE block enclosed.
4. Close the outer corrugated box and secure with packaging tape.
5. 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).
6. **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**. Refer to the CSPM for instructions on how to order additional kits.
2. In the event a kit has expired components, the entire kit must be returned to the AFT Biorepository.

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### Biospecimen Collection Kit Directions For Use

**Collection Protocol Title:** A Randomized, Open Label, Phase III Trial to Evaluate the Efficacy and Safety of Palbociclib + Anti-HER2 Therapy + Endocrine Therapy vs. Anti-HER2 Therapy + Endocrine Therapy after Induction Treatment for Hormone Receptor Positive (HR+)/HER2-Positive Metastatic BreAst Cancer.

**Collection Protocol Short Title:** AFT-38

**Collection Protocol PI:** AFT Administrator

**Collection Time Points:**

Cycle 1 Day 22	Unplanned Palbociclib PK Assessment	Unplanned Trastuzumab/Pertuzumab PK Assessment
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### Biospecimen Collection Kit Components:

#### 1. Components for Shipping Frozen Specimens:

QTY	Description
1	Cardboard box with Biological Substance, Category B, UN3373 markings
1	Styrofoam container
1	Dry Ice label
1	6"x9" Biohazard bag (for frozen specimens)
1	Completed FedEx Return airbill (Do not interchange FedEx air-bills between kits)

#### 2. Components for Specimen Collection:

Description	Time point/QTY		
	Cycle 1 Day 22	Unplanned Palbociclib PK Assessment	Unplanned Trastuzumab/Pertuzumab PK Assessment
Black marking pen	1	1	1
Vacutainer® K2 EDTA Tube (Lavender top, 10mL)	1	1	
Vacutainer® No Additive Tube (Red top, 10 mL)			1
Transfer pipette	1	1	1
Corning® Cryovials with cap inserts (2.0mL)	1	1	2

*See Reverse Side for Specimen Processing and Packaging Instructions*

## Biospecimen Collection Kit Directions For Use

### Specimen Processing

1. Refer to the Correlative Science Procedure Manual (CSPM) for instructions regarding specimen collection and processing.
2. All research biospecimens (cryovials) **MUST** be labeled with the Participant study number and Participant initials (Last, First, Middle) using the permanent marker provided with the kit. Cryovials **MUST** also be labeled with **Serum** or **Plasma**.

### Specimen Packaging-Frozen Shipping

1. Place frozen serum/plasma aliquots inside the 6"x9" biohazard bag. Place the bag inside the shipping container and fill container immediately with dry ice.

### Packaging Instructions

1. Follow packaging instructions to ensure kit's frozen specimens remain at appropriate temperatures for up to 24hr and IATA Packaging instructions are followed for biological specimens shipped on dry ice.
2. Register specimen collection information in the AFT BioMS tracking database (<https://alliancefoundationtrials.org>). Place a copy of the AFT BioMS packing slip inside of the shipping container.
3. Close the outer corrugated box and secure with packaging tape.
4. If shipping frozen specimens, complete the Dry Ice label. Include name and address for shipper/recipient on the upper left and right side of the Dry Ice label. Dry ice weight = 3 Kg. Apply to one side of the shipping container. See Figure 1.
5. 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).
6. **Do not ship on Friday, Saturday, Sunday or day before a nationally recognized holiday.**



Figure 1

### 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**. Refer to the CSPM for instructions on how to order additional kits.
2. In the event a kit has expired components, the entire kit must be returned to the AFT Biorepository.

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 Palbociclib + Anti-HER2 Therapy + Endocrine Therapy vs. Anti-HER2 Therapy  
 + Endocrine Therapy after INduction Treatment for Hormone Receptor Positive  
 (HR+)/HER2-Positive Metastatic BreAst Cancer.

**Collection Protocol Short Title:** AFT-38

**Collection Protocol PI:** AFT Administrator

**Collection Time Points:** Cycle 4 Day 1

### Biospecimen Collection Kit Contents:

#### 1. Components for Shipping Specimens:

QTY	Description
1	Corrugated cardboard box (holds two Styrofoam containers)
1	Small Styrofoam container for ambient specimens
2	Gel packs (DO NOT FREEZE OR REFRIGERATE)
1	Absorbant sleeve for blood tubes
1	Pressure Biohazard bag with adhesive strip (for ambient specimens)
1	Large Styrofoam container for frozen specimens
1	Dry ice label
1	Completed FedEx Return airbill (Do not interchange FedEx air-bills between kits)

#### 2. Components for Specimen Collection:

Description	Time Point / QTY
	Cycle 4 Day 1
Black marking pen	1
6"x9" Biohazard bag (for frozen specimens)	1
Streck Cell-Free DNA BCT (Black/brown Marble Top, 10 mL)	2
Vacutainer® K2 EDTA Tube (Lavender top, 10 mL)	1
Vacutainer® No Additive Tube (Red top, 10mL)	1
Transfer pipette	1
Corning® Cryovials cap inserts (2.0mL)	2

*See Reverse Side for Specimen Processing and Packaging Instructions*

## Biospecimen Collection Kit Directions For Use

### Specimen Processing

1. Refer to the Correlative Science Procedure Manual (CSPM) for instructions regarding specimen collection and processing.
2. All research biospecimens (Vacutainer tubes, Streck tubes and cryovials) **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 and cryovials **MUST** be labeled with **Serum**.

### Specimen Packaging

1. Transfer serum aliquots into the 6"x9" Biohazard bag and place into the frozen specimen compartment of the shipper, immediately cover with at least 2 inches (3 Kg or ~6 lbs) of dry ice, and replace the lid.
2. Insert EDTA Vacutainer® and Streck Cell-Free DNA BCT® tubes into the slots in the absorbant sleeve and place the sleeve into the Pressure Biohazard bag. Seal the bag, place the bag between the two gel packs and place into the ambient container. Place ambient container on top of frozen container and cover with the lid. See Figure 1.

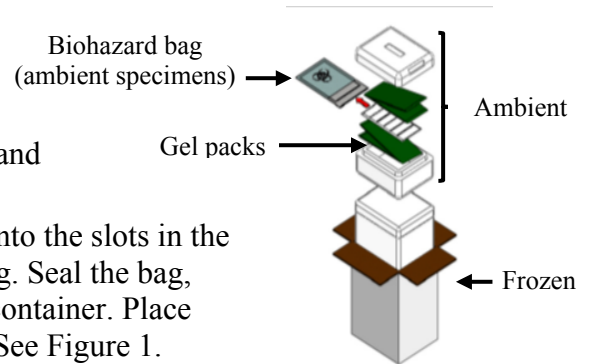


Figure 1

### Packaging Instructions

1. Follow packaging instructions to ensure kit's frozen and ambient specimens remain at appropriate temperatures for up to 24hr and IATA Packaging instructions are followed for biological specimens shipped on dry ice.
2. Register specimen collection information in the AFT BioMS tracking database (<https://alliancefoundationtrials.org>). Place a copy of the AFT BioMS packing slip inside the ambient shipping container.
3. Close carton and secure lid with packaging tape.
4. Complete the Dry Ice label. Include name and address for shipper/recipient on the upper left and right side of the Dry Ice label. Dry ice weight = 3 Kg. Apply to one side of the shipping container.
5. 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).
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2. In the event a kit has expired components, the entire kit must be returned to the AFT Biorepository.