

AFT-05

Biospecimen Collection Kit Directions For Use

Collection Protocol Title: PALLAS PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer (PALLAS)

Collection Protocol Short Title: AFT-05

Collection Protocol PI: AFT Administrator

Collection Time Points:

Cycle 1 Day 1	Cycle 6 Day 1	End of Treatment	5 Years	Recurrence
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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 specimen
1	Dry ice label
1	Completed FedEx Return airbill (Do not interchange FedEx airbills between kits)

2. Components for Specimen Collection:

Description	Time Points / QTY				
	Cycle 1 Day 1	Cycle 6 Day 1	End of Treatment	5 Years	Recurrence
Black marking pen	1	1	1	1	1
6"x9" Biohazard bag (for frozen specimens)	1	1	1	1	1
4"x6" Minigrip bag					1
2"x3" Minigrip bag	1				1
Streck Cell-Free DNA BCT® Tube (Black/Brown)	2	2	2	2	2
Vacutainer® K2 EDTA Tube (Lavendar top, 10mL)	2	1	1	1	1
Vacutainer® No Additive Tube (Red top, 10mL)	1				
Tissue cassette	1				1
Transfer pipette	2	1	1	1	1
Corning® Cryovials with cap inserts (2.0mL)	6	3	3	3	3
4"x4" gauze					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 **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 labeled with **Serum** or **Plasma**.

Specimen Packaging

1. Transfer frozen tissue cassette into the 2"x3" minigrip bag and put into the 6"x9" Biohazard bag, along with the serum and/or plasma.
2. Place the biohazard bag 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.
3. Wrap the FFPE block with gauze, place in the 4"x 6" minigrip bag.
4. 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. Place the bag and FFPE block between the two gel packs and place into the ambient container.
5. Place ambient container on top of frozen container and cover with the lid. See Figure 1.

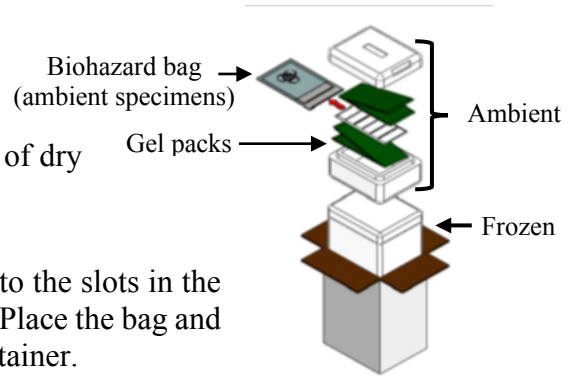


Figure 1

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 of the shipping container. If applicable, include a de-identified copy of the institutional surgical pathology report pertaining to the FFPE block enclosed.
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).
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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Collection Protocol Short Title: AFT-05

Collection Protocol PI: AFT Administrator

Collection Time Points:

Screening

Biospecimen Collection Kit Contents:

1. Components for Shipping Specimens: All Time Points

QTY	Description
2	FedEx Clinical Pak envelope
1	Completed FedEx air-bill (Do not interchange air-bills between kits)

2. Components for Specimen Collection:

	Time Point / QTY
Description	Screening
Styrofoam box with cardboard overwrap for FFPE block	1
Small refrigerant pack	1
4"x6" Minigrip bag	1
4"x4" gauze	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 **MUST** be labeled with the Participant study number and Participant initials (Last, First, Middle). Label 4x6 minigrip bag with Participant Study number

Specimen Packaging

1. Wrap the FFPE block with gauze, transfer into Minigrip bag, place in Styrofoam box with the refrigerant pack and place inside cardboard overwrap.

Packaging Instructions

1. Follow packaging instructions to ensure kit's ambient specimen 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. Include a de-identified copy of the institutional surgical pathology report pertaining to the FFPE block enclosed.
4. Place block box inside FedEx Clinical Pak envelope shipping envelope and seal.
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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