

Blood Collection and Shipping for Isolation of Viable Circulating Tumor Cells		
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## 1.0 PURPOSE/SCOPE

This Standing Operating Procedure (SOP) describes the procedures for collecting, preparing, and shipping human blood specimens from Clinical Centers for use in patient-derived model (PDM) generation such as patient-derived xenografts (PDX) and primary tissue in vitro cell models. This SOP was developed by NCI-F/FNLCR in collaboration with the Developmental Therapeutics Clinic, National Cancer Institute and NCI-designated Cancer Centers participating on an NCI multicenter Tissue Procurement Protocol. This SOP is used/performed by the Clinical Centers collected patient blood samples and the Biological Testing Branch (BTB) at NCI-Frederick, Frederick National Laboratory for Cancer Research.

## 2.0 SAFETY

All fresh human tissue, including whole blood and its purified components, are handled under Biosafety Level 2 (BSL2) conditions. All work is conducted in a biological safety cabinet (BSC) using personal protective equipment and avoiding the use of sharps where possible. All materials potentially exposed to the human material is treated with a 10% bleach solution for a minimum of 10 minutes, double bagging for autoclaving or incineration. Consult with your facility safety professionals regarding the safe handling of BSL2 studies.

## 3.0 MATERIALS & EQUIPMENT

### 3.1 Blood Collection

- 3.1.1 BD Vacutainer Glass Blood Collection Tubes; do not use after expiration date. Two Sodium Heparin , 6-mL draw capacity, Green BD Hemogard™ closure (Becton Dickinson, Cat#: 367878)

### 3.2 Overnight Shipping

- 3.2.1 2 Falcon conicals with absorbent material enclosed
- 3.2.2 Two (2) Specimen tube labels
- 3.2.3 ZipLock bag - to protect Shipping Manifest upon return
- 3.2.4 Two (2) Controlled room temperature (CRT) gel packs
- 3.2.5 Styrofoam box
- 3.2.6 Shipping cardboard box

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## 4.0 OPERATING PROCEDURES

### Important:

- Processing limitations:
  - A minimum volume of 6-mL blood draw per Na Heparin tube is needed for processing. Fill one tube with 6-mL of blood rather than two tubes with 3-mL each if there is a clinical reason to limit the amount of blood being drawn.
- Blood specimens **MUST** be prepared and shipped at 22°C ± 3°C (RT).
- All samples **MUST** be shipped on day of collection and received within 24-h of collection at the processing laboratory for implantation into mice or ex vivo culture.
- Tumor and blood specimens are shipped in **SEPARATE** containers under **DIFFERENT** shipping conditions.

### 4.1 Day of Blood Collection, Just Prior to Specimen Receipt

4.1.1 Prepare specimen tube labels with specimen ID.

4.1.2 Remove the two Sodium Heparin tubes from the Shipping Kit and apply the labels. If the tubes are kept in the patient suite, bring the labels to the suite so they can be applied to the tubes immediately following blood collection.

4.1.3 If shipping material, ensure that overnight shipping has been arranged.

### 4.2 Whole Blood Collection into Sodium Heparin Tubes

4.2.1 Clinical Specimen Support Lab Personnel should arrive at the collection site early enough to allow sufficient time to set up supplies, collect relevant clinical information, and ensure rapid transport of specimens to the laboratory for preparation for shipping.

4.2.2 Collect whole blood aseptically by venipuncture or from a venous port into the two Sodium Heparin tubes. Due to the potential for unanticipated technical variables, blood should not be obtained from an arterial source.

4.2.3 Fill each tube with a **minimum of 6-mL volume** until the blood flow stops to ensure the correct ratio of sample to anticoagulant.

4.2.4 **Gently invert** the tube 8-10 times to mix; tube inversion prevents clotting. **Do not shake** the tube; vigorous mixing can cause hemolysis.

4.2.5 **Do not** refrigerate or freeze specimens; keep tubes at room temperature.

**Important:** Do not place tube(s) on ice. If the clinical staff placed the tubes on ice, make a notation on the Specimen Log ([Appendix 1](#)) and place the tube at room temperature before proceeding.

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## 5.0 PACKAGING OF BLOOD SPECIMENS FOR OVERNIGHT SHIPMENT

### Important:

- Ideally, blood collection, processing and implantation/ex vivo culture would occur at the same building/facility.
- For overnight shipping: All whole blood tubes **MUST** be shipped on the day of collection and received within 24-h of collection at the processing laboratory for isolation of viable circulating tumor cells (CTCs).

**5.1 Complete a Shipping Manifest** ([Appendix 1](#)) for each specimen collected on the day of shipment.

### 5.2 Packaging Instructions

**5.2.1** Open the Blood Shipping kit which has been stored at room temperature and remove all contents.

**5.2.2** Place a room temperature gel pack in the bottom of a Styrofoam shipping container.



**5.2.3** Wrap absorbent paper around the two (2) specimen-filled Sodium Heparin tubes and place each into the provided 50-mL Falcon centrifuge tube.



**5.2.4** Place the 50-mL tubes into the Styrofoam box on top of the first gel pack, and then put a second room temperature gel pack on top of the tubes.



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- 5.2.5 Place the completed Shipping Manifest** with the Chain of Custody section signed on line #1 ([Appendix 1](#)) **in a sealed zip lock bag** and then place on top of the gel pack. Close the Styrofoam box and then seal the cardboard shipping box.



### 5.3 Shipping Instructions

- 5.3.1** Once the cardboard box is sealed, attach a return shipping label to the outside of the box; **do not obscure the UN3373 label.**
- 5.3.2 Important:** Patient samples that are being shipped are “live” specimens. Do not leave specimen boxes on shipping docks for prolonged lengths of time as a severe temperature drop or rise could compromise the viability of the patient specimens.

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## APPENDIX 1: SHIPPING MANIFEST AND CHAIN OF CUSTODY

Specimen ID
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### 1. Shipping Manifest

Include a copy of the manifest and signed, chain of custody section with every patient-derived model collection.

To be completed by the Clinical Center					
Blood Tube Type	Collection Date	Collection Time with time zone	Patient Gender	Histological Diagnosis (e.g., Colon ca, Breast ca, etc.)	CTEP SDC Code*
2 Tubes Blood  <input type="checkbox"/> Sodium Heparin (#1) <input type="checkbox"/> Sodium Heparin (#2)		<input type="checkbox"/> EDT <input type="checkbox"/> CDT <input type="checkbox"/> MDT <input type="checkbox"/> PDT	<input type="checkbox"/> Male <input type="checkbox"/> Female		

\*CTEP SDC Codes: [http://ctep.cancer.gov/protocolDevelopment/docs/SDCv10\\_M10.xls](http://ctep.cancer.gov/protocolDevelopment/docs/SDCv10_M10.xls)

### 2. Chain of Custody Signatures

Prior to shipping the Clinical Center Specimen Handling personnel should verify contents of and sign and date on line 1 below to verify contents of container.

Task	Responsible Party	Signature	Date
1. Shipment of blood tubes (22°C ± 3°C controlled temperature gel packs)	Clinical Center		/ /
2. Receipt of specimen: log receipt, verify specimen(s), and verify shipping conditions. If deidentification is required, remove provided ID label and replace with anonymized research ID.	Research Site: Receiving/ Honest Brokers		/ /
3. Receipt of specimen for research use.	Research Site: Laboratory		/ /

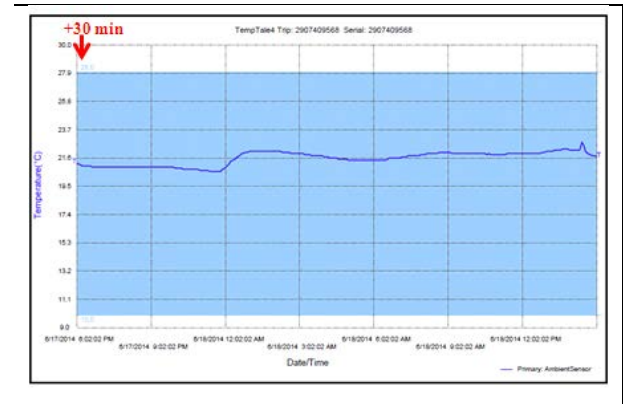
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## APPENDIX 2: OVERNIGHT SHIPPING TEMPERATURE MONITORING

Target Shipping temperature to obtain viable tumor tissue: 10°C-28°C

### Shipment with ambient, controlled room temperature packs (summer shipment)

- California to Maryland; June 17-18, 2014
  - 6/17/2014 CA regional temp max, 29°C
  - 6/18/2014 MD regional temperature max, 33°C
- 21 h 5 m monitoring period, 253 data points
- Min: +20.6°C
- Max +22.8°C



Blood Shipping Kit temperatures have been stable in our hands. Interior box temperature fluctuates no more than 4°C (n = 6).