

		GTEx Work Instruction for Yellow Kit Receipt and Shipping	
OP-0001-W1	VER. 1.2.0	Effective Date: 04/19/2012	Page 1 of 6

1. PURPOSE

This work instruction provides the specific steps necessary to pack and ship to the CBR-issued caHUB/GTEx Blood & Skin Biopsies Collection (the Yellow Kit).

The procedure section is divided into four subsections: the kit receipt at the Biospecimen Source Site (BSS); the alert of pending collection; packing instructions; and shipping instructions.

2. ENVIRONMENTAL HEALTH & SAFETY

- 2.1. Persons packaging and/or signing transport documents must be trained and/or certified to ship the appropriate hazard class according to International Air Transport Association (IATA)/International Civil Aviation Organization (ICAO) regulations.
- 2.2. Persons handling the PAXgene® blood collection tubes should be aware of the hazards associated with the chemicals and how to handle an accidental spill or exposure by reviewing the Material Safety Data Sheets. Chemical-appropriate gloves (latex or nitrile rubber) are required for persons directly handling the PAXgene® blood collection tubes.

3. PROCEDURE

Note: This same yellow kit is used for both Surgical and Post-Mortem Collections

Kit Receipt at the BSS

- 3.1. Contents (Refer to supplies shown in Figure 1)
 - 3.1.1. Labeled and insulated UN3373 fiberboard shipping box with external label “caHUB Collection Yellow kit” and an External Kit ID.
 - 3.1.2. **GTEx Discrepancy Checklist for Yellow Kit (OP-0001-W1-F1)** with gallon sized ziplock bag for paperwork.
 - 3.1.3. Three strips of 2-inch wide clear tape - to seal the outer cardboard box
 - 3.1.4. Two strips of narrow 12 inch long, clear tape to seal shipping canister
 - 3.1.5. 4 – 10mL ACD vacutainer blood collection tubes (labeled with sequence numbers 0001,0002, 0003, and 0004)
 - 3.1.6. 2 – 2.5ml PAXgene® RNA vacutainer blood collection tubes (labeled with sequence numbers 0005 and 0006)
-

		GTEx Work Instruction for Yellow Kit Receipt and Shipping	
OP-0001-W1	VER. 1.2.0	Effective Date: 04/19/2012	Page 2 of 6

NOT INCLUDED: 1 skin biopsy transport conical tube (labeled with sequence number 0008) *will not be included in this kit as the 50 ml media and conical tubes will be provided in the transport media kit* *Note: Biopsy transport media will be shipped separately on a monthly basis and receipt *should be confirmed per **GTEx Kit Discrepancy Checklist for Transport Media (OP-0001-F3)***.

Media expiration: The media expiration date is on the container label. The label includes identification of the product (MEM/BCS+), lot number, date of manufacturer, and date of expiration. The 30-day expiration is calculated from the date of manufacture.

Media disposal: The media needs to be disposed of at the BSS per local policy for media containing **bovine calf serum, MEM with glutamine, HEPES buffer, and gentamicin/amphotericin**. An email confirmation should be sent to the CBR confirming disposal of expired media.

- 3.1.7. 1 absorbent pad
- 3.1.8. 95 kPa shipping canister with internal biohazard bag, foam insert in lid, foam insert to hold tubes, and sealable plastic bag to house canister
- 3.1.9. 4 insulated bricks to increase thermal mass around the shipping canister
- 3.1.10. Styrofoam™ box insulation includes 4 sides, a bottom and a lid
- 3.1.11. “Peel off label when samples are shipped” on Fiberboard box



Figure 1: Supplies provided in the yellow kit.

		GTE_x Work Instruction for Yellow Kit Receipt and Shipping	
OP-0001-W1	VER. 1.2.0	Effective Date: 04/19/2012	Page 3 of 6

Alert of Pending Collection

- 3.2. Timeline of alert to CBR
 - 3.2.1. Upon shipment of specimen.
- 3.3. Send an e-mail notifying appropriate individuals at CBR and the LDACC of the shipment.
 - 3.3.1. **PLEASE INCLUDE THE GTEX CASE ID (GTEX-00000X) IN THE SUBJECT LINE OF ALL EMAIL.**
 - 3.3.2. Indicate notice of pending shipment.
 - 3.3.3. Indicate date specimen is anticipated to be shipped.
 - 3.3.4. Indicate date specimen is anticipated to arrive at the LDACC or CBR.
 - 3.3.5. Indicate tracking number/company using to ship specimen.
 - 3.3.6. Use the following instructions for the email template for correspondence to CBR and the LDACC:
 - 3.3.6.1. In addition to the GTE_x ID number, note Source of Collection, and kit type in the subject line for e.g.: **Name of BSS, GTEX-00000X, Yellow kit.**
 - 3.3.6.2. *Use the following template in the body of the email (Please note: Do not state Date of Collection or Procurement in the body of the email or subject line).*

Hello LDACC ,

Please consider this email notification that a GTE_x donor collection is underway.

- *The LaserShip[®] shipment to the LDACC will be shipped to you on <INSERT DATE> and is expected to arrive by <INSERT DATE>. The tracking number of the shipment to the LDACC is: <INSERT TRACKING NUMBER/COMPANY NAME>.*

Thank you,

The <INSERT SITE NAME> site

		GTEx Work Instruction for Yellow Kit Receipt and Shipping	
OP-0001-W1	VER. 1.2.0	Effective Date: 04/19/2012	Page 4 of 6

3.4. Method of alert to Shipping Vendor

Provide the Shipping Vendor with correct delivery address and recipient contact information, including specific instructions for deliveries outside of normal business hours, if applicable.

Packing Instructions

3.5. Packers and shippers of the yellow kit must be certified to ship IATA class 6.2 materials.

3.6. Upon receipt, verify contents of kit using the enclosed **GTEx Discrepancy Checklist for Yellow Kit (OP-0001-W1-F1)**.

3.7. If the kit is incomplete or discrepancies are noted:

3.7.1. Complete **GTEx Discrepancy Checklist for the Yellow Kit (OP-0001-W1-F1)**

3.7.2. Report defective kit to kit supplier (CBR).

3.7.3. CBR will follow-up with an action for resolution.

3.8. **On day kit is used**, follow these steps:

3.8.1. Arrange for shipment pick-up with Shipping Vendor so that samples are picked up as soon as possible after the tissue collection is finished. **THIS SHIPMENT MUST LEAVE THE BSS AS SOON AS POSSIBLE AFTER THE COMPLETION OF THE COLLECTION.**

3.8.2. When a yellow kit is to be used, retrieve the label sheet in the routine overpack kit.

3.8.3. Remove one label at a time from the labels found on the label sheet in the routine overpack kit and apply it to the appropriate vacutainer.

3.8.4. Collect blood in accordance with the tissue collection SOPs with adherence to the order of the draw.

Note: Any unused blood collection tubes should be returned in the yellow kit (and noted appropriately as "unused" or "empty" in the traveling manifest documentation.

3.8.5. The time that the last vacutainer receives blood is recorded on the CRFs. At the end of tissue collection, all data on the CRFs are entered into CDR.

3.8.6. Once the skin specimens are collected, they are placed into the conical tube containing approximately 50 mLs of transport media. Be sure to fill conical to top with extra media if needed to prevent skin samples sticking to conical cap. Replace cap, verify threading of cap and tube are aligned, and tighten just until resistance is met. Wrap the tube in parafilm. **Do NOT over tighten cap or the tube may leak in transit.**

3.8.7. The 50 mL conical tube is also labeled with a specimen ID that is supplied from the labels found on the label sheet in the routine overpack kit.

3.8.8. Open the shipping canister and remove top foam piece. Place blood vacutainers and biopsy-containing 50 mL conical tube into the spaces provided in the foam core inside the shipping canister. Replace top foam piece, seal shipping canister using the

- two thin clear strips of tape in an “X” arrangement, seal biohazard bag and replace shipping canister lid. Place the canister in the large sealable plastic bag.
- 3.8.9. Place the absorbent pad on the bottom of the Styrofoam™ box.
 - 3.8.10. Place two ROOM TEMPERATURE freezer bricks on top of the absorbent pad. **Do not refrigerate the insulated bricks.** These insulated bricks are there to increase the thermal mass in an attempt to maintain temperature (18 °C to 24 °C) while en route to the LDACC.
 - 3.8.11. Place the sealed plastic bag with the canister on top of the two room temperature freezer bricks.
 - 3.8.12. Place two more ROOM TEMPERATURE freezer bricks on top of the canister. **Do not refrigerate the insulated bricks.** These insulated bricks are there to increase the thermal mass in an attempt to maintain temperature (18 °C to 24 °C) while en route to the LDACC.
 - 3.8.13. Place the square Styrofoam™ lid over the shipping canister.
 - 3.8.14. Fold the plastic liner over the inner Styrofoam™ square.
 - 3.8.15. Place the **GTE_x Tissue Data Collection Form (from Bio4D)** (or other traveling manifest) *in the gallon-sized ziplock bag and on top of the Styrofoam™ lid.*
 - 3.8.16. Close the outer cardboard box and tape it closed.
 - 3.8.17. Remove the yellow-colored, “Peel off label before Samples are Shipped” label on the outside of the shipping package so that the UN3373 label that is underneath is visible.
 - 3.8.18. Verify all steps are complete. Ship to the LDACC so it arrives within 24 hours of blood collection.

Shipping Instructions

- 3.9. Ship the completed yellow kit to the correct recipient address. Delivery address may be different for shipments outside of normal business hours.

4. REFERENCES

- 4.1. GTE_x Kit Discrepancy Checklist for Transport Media, OP-0001-F3

5. ATTACHMENTS

- 5.1. GTE_x Discrepancy Checklist for Yellow Kit, OP-0001-W1-F1



caHUB The Cancer
Human Biobank

**GTEEx Work Instruction for Yellow Kit
Receipt and Shipping**

OP-0001-W1

VER. 1.2.0

Effective Date: 04/19/2012

Page 6 of 6
