		GTE_x Work Instruction for Blood and Skin Biopsy Receipt and Shipping (Yellow Kit)	
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1.0 PURPOSE

- 1.1 This work instruction provides the specific steps necessary to pack and ship the Comprehensive Biospecimen Resource (CBR)-issued GTE_x Blood & Skin Biopsies Collection Kit (the Yellow kit).
- 1.2 The procedure section is divided into subsections: the kit receipt at the biospecimen source site (BSS); packing instructions; shipping instructions; and the alert of shipment.

2.0 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) and proper Personal Protective Equipment (PPE) are required for persons directly handling the PAXgene[®] blood collection tubes.

3.0 PROCEDURE

Kit Receipt at the BSS

- 3.1 Upon receipt, verify the contents of kit by receiving in the Biorepository Information Management System (BRIMS).
- 3.2 If the kit is incomplete, discrepancies are noted, or the kit is damaged:
 - 3.2.1 Partially receive kit in BRIMS and email and/or call the CBR.
The CBR will follow-up with an action for resolution
- 3.3 Contents (Refer to supplies shown in Figure 1)
 - 3.3.1 Labeled and insulated UN3373 fiberboard shipping box with external label "GTE_x Collection Yellow kit" and an External Kit ID label
 - 3.3.2 1-gallon Ziploc bag for paperwork
 - 3.3.3 Three strips of 2-inch wide clear tape to seal the outer cardboard box
 - 3.3.4 Two strips of narrow 12-inch long, clear tape to seal shipping canister
 - 3.3.5 4 x 10mL ACD vacutainer blood collection tubes (labeled with sequence numbers 0001, 0002, 0003, and 0004)
2 x 2.5ml PAXgene[®] RNA vacutainer blood collection tubes (labeled with sequence numbers 0005 and 0006)
 - 3.3.6 1 absorbent pad

- 3.3.7 95 kPa shipping canister with internal biohazard bag, Styrofoam™ insert in lid, Styrofoam™ insert to hold tubes, and sealable plastic bag to house canister
- 3.3.8 4 insulated bricks to increase thermal mass around the shipping canister
- 3.3.9 Styrofoam™ box insulation includes 4 sides, a bottom and a lid
- 3.3.10 “Peel off label when samples are shipped” label on Fiberboard box



NOT INCLUDED: 1 skin biopsy transport conical tube (labeled with sequence number 0008) *will not be included in this kit, as the 50mL 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 in BRIMS.

Media expiration: The media expiration date is on the container label. The label includes identification of the product (MEM/BCS+), lot number, date of manufacture, and date of expiration. The media has a 28-day expiration.

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 Study Management Group CBR manager confirming disposal of expired media.



Figure 1: Supplies provided in the Yellow kit.

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Alert of Shipment

- 3.4 Timeline of alert to CBR
 - 3.4.1 Alert should be made upon shipment of specimen
- 3.5 Method of alert to the Laboratory, Data Analysis, and Coordinating Center (LDACC) and CBR: **EMAIL or automated alert**
 - 3.5.1 If by manual email, please follow guidelines: **PLEASE INCLUDE THE GTEX CASE ID (GTEX-XXXXXX) IN THE SUBJECT LINE OF ALL EMAILS.**
 - 3.5.2 Indicate notice of pending shipment
 - 3.5.3 Indicate date the shipment is anticipated to be sent
 - 3.5.4 Indicate date the shipment is anticipated to arrive at the LDACC
 - 3.5.5 Indicate tracking number/company used to ship specimens
 - 3.5.6 Email recipients at the LDACC and CBR
 - 3.5.7 Use the following instructions for the email template for correspondence to the LDACC:
 - 3.5.7.1 In addition to the GTEx ID number, note the Source of Collection, and kit type in the subject line for e.g.: **Name of BSS, GTEX-XXXXX, Yellow kit.**
 - 3.5.7.2 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 GTEx donor collection is underway. The MNX 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*

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3.6 Shipping Guidance for courier

3.6.1 Please provide courier with the following directions:

3.6.1.1 **Weekday Delivery (During normal business hours)**

3.6.1.1.1 Upon delivery, the **courier** will need to meet the LDACC staff at a designated location

Note: In case of emergency and/or the “on call” cell phone cannot be reached, the **courier** and/or the collection site should call the designated individuals at the LDACC

3.6.1.1.2 Direct delivery of the package a designated location

3.6.1.2 **Weekend Delivery/Evening Delivery (Outside of normal business hours)**. For shipments that will arrive during these times, please provide the **courier** with the following directions:

3.6.1.2.1 The courier will need to alert the LDACC “on call” staff directly via the “on call” cell phone as soon as the courier receives the package at the airport. They should confirm pickup and immediate delivery of the package.

3.6.1.2.2 The courier will need to deliver the package to the designated location at the LDACC

Packing Instructions

3.7 ***On day kit is used***, follow these steps:

Arrange for shipment pick-up so that samples are picked up as soon as possible after the tissue collection is finished by calling the courier. The following information should be used to arrange for a specimen pick-up:

Courier

Phone:

Account Number:



Online entry:

User ID:

Password:

Material Type: Human blood and tissue, non-infectious

IATA Classification: UN3373, Biological Substance Category B

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Delivery Deadline: Next scheduled flight out with the fastest delivery route. Please DO NOT give them a time frame for delivery as this will complicate the flight time schedules they review.

Destination: The LDACC (Normal weekday hours)
 The LDACC (off hours, weekends)

Courier note(s):
 Include additional contact information at the LDACC

THIS SHIPMENT MUST LEAVE THE BSS AS SOON AS POSSIBLE AFTER THE COMPLETION OF THE COLLECTION.

- 3.7.1 When a Yellow kit is to be used, retrieve the blood tube labels in the Routine Overpack kit (This is the kit correct? Might want to define it above as the routine overpack kit)
- 3.7.2 Using one label at a time, apply the labels to the appropriate vacutainer tubes
- 3.7.3 Collect blood in accordance with the tissue collection SOPs (PR-0004-W1-GTEx Work Instruction For Collection of Normal Tissues from Postmortem/Organ Procurement Cases) 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” on the yellow kit manifest)
- 3.7.4 Fill out and retain a copy of the **Chain of Custody** in BRIMS
- 3.7.5 Retrieve the skin biopsy transport conical tube with 50mL media from the transport media kit
- 3.7.6 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.
- 3.7.7 Apply the appropriate label indicating specimen ID to the 50 mL tube as is supplied within the Routine Overpack kit
- 3.7.8 Open the shipping canister and remove top Styrofoam™ piece. Place blood vacutainers and biopsy-containing 50mL conical tube into the spaces provided in the Styrofoam™ core inside the shipping canister. Replace top Styrofoam™ piece, seal inner biohazard bag, replace shipping canister lid, and seal shipping canister using the two thin clear strips of tape in an “X” arrangement. Place the canister in the large sealable plastic bag and close bag.
- 3.7.9 Place the absorbent pad on the bottom of the Styrofoam™ box
- 3.7.10 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 an ambient temperature (18°C to 24°C) while en route to the LDACC.

- 3.7.11 Place the sealed plastic bag with the canister on top of the two room temperature freezer bricks
- 3.7.12 Place two more ROOM TEMPERATURE freezer bricks on top of the canister. Do not refrigerate the insulated bricks. Again, these insulated bricks are there to increase the thermal mass in an attempt to maintain an ambient temperature (18°C to 24°C) while en route to the LDACC.
- 3.7.13 Fill out and print the **Manifest** from BRIMS and place a copy within the large Ziploc bag for paperwork and into the Yellow Kit. Please keep a copy for your records.
- 3.7.14 Fill out and print the **Chain of Custody (CoC)** from BRIMS and place a copy within the large Ziploc bag for paperwork and into the Yellow Kit. Please keep a copy for your records.
- 3.7.15 Place the square Styrofoam™ lid over the shipping canister.
- 3.7.16 Fold the plastic liner over the inner Styrofoam™ square.
- 3.7.17 Close the outer cardboard box and tape it closed.
- 3.7.18 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.
- 3.7.19 Verify all steps are complete. Ship to the LDACC institute so it arrives within 24 hours of blood collection.

Shipping Instructions

3.8 Ship the packaged yellow kit to the following address:

<u>Delivery estimated within normal business hours</u>	<u>Delivery estimated during off hours (evening, after 6 pm, or weekend)</u>
LDACC	LDACC
Contact:	Contact:
Courier note:	Courier note: