		GTEx Work Instruction for PAXgene Tissue Fixative/Stabilizer Collection Receipt and Shipping (Aqua Kit)	
OP-0001-W3	VER. 03.08	Effective Date: mm/dd/yyyy	Page 1 of 6

1.0 PURPOSE

- 1.1 This work instruction provides the specific steps necessary to pack and ship the CBR-issued GTEx PAXgene® Tissue Fixative/Stabilizer Kit (the Aqua 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® tissue containers 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-resistant gloves (latex or nitrile rubber) are required for persons directly handling the PAXgene® tissue containers.
- 2.3 Appropriate personal protective equipment should be worn at all times to include but not limited to:
 - 2.3.1 Gown or lab coat;
 - 2.3.2 Hair bonnet, mask, and shoe covers, per institutional requirements;
 - 2.3.3 Latex or nitrile rubber gloves.

3.0 PROCEDURE

Kit Receipt at the BSS

- 3.1 Upon receipt and before kit is used, verify contents using the list below; do NOT use kit if incomplete. If incomplete, receive the partial kit in BRIMS, and email or call the CBR and they will follow up with an action for resolution.
- 3.2 **Contents:** There are three fiberboard outer shipping boxes per kit set. (Figure 1 and the list below represent **one** fiberboard box of the collection set.) Due to IATA regulations, the quantity of acetic acid and methanol that is in each PAXgene® tissue fixative/stabilizer container requires that no more than 22 PAXgene® containers be shipped in a single Aqua kit box. As a result, 3 Aqua kit boxes are provided to transport 66 total PAXgene® tissue fixative/stabilizer containers. Inside each box, the PAXgene® containers and foam inserts will be sealed inside a leak-proof specimen bag with absorbent pads.
 - 3.2.1 1 fiberboard outer shipping box
 - 3.2.2 Twenty-two (22) PAXgene® tissue fixative/stabilizer containers (There are 66 containers total in the 3 boxes.)
 - 3.2.3 4 plastic canisters per box with screw-cap
Three canisters contain 6 PAXgene® tissue fixative/stabilizer containers. The fourth canister will only have 4 PAXgene® tissue fixative/stabilizer containers.

Please return all canisters from the aqua kits, even if empty.

The entire GTEx ID is applied to each PAXgene® tissue fixative/stabilizer container. The PAXgene® containers are labeled to record the times placed in solution #1 and #2, with the initials of the individual who placed the tissue cassette into each solution. The following are the sequence numbers on the labels assigned to PAXgene® tissue fixative/stabilizer containers; the sequence numbers range can accommodate the collection of all requested specimens:

0125-0126; 0225-0226; 0325-0326; 0425-0426; 0525-0526; 0625-0626; 0725-0726;
0825-0826; 0925-0926; 1025-1026; 1125-1126; 1225-1226; 1325-1326; 1425-1426;
1525-1526; 1625-1626; 1725-1726; 1825-1826; 1925-1926; 2025-2026; 2125-2126;
2225-2226; 2325-2326; 2425-2426; 2525-2526; 2625-2626; 2725-2726; 2825-2826;
2925-2926; 3025-3026; 3125-3126; 3225-3226; 3325-3326

NOTE: In the event of a compromised PAXgene® container (such as due to a spill), the BSS is directed to utilize a container leftover from a previous Aqua kit. The lot numbers of the PAXgene® containers are retained by the CBR and can be verified for expiration date if needed. As of the PAXgene® September 01, 2012 shipment from Qiagen, a shelf-life date is now printed on the container.

- 3.2.4 3 strips of adhesive tape (24" long)
- 3.2.5 8 narrow strips of tape (12" long)
- 3.2.6 1 Black label (5" X 7")
- 3.2.7 8 circular foam inserts with cut-outs for PAXgene® containers (2 per canister)
- 3.2.8 A total of 4 leak-proof biohazard bags to hold foam inserts (1 per canister)
- 3.2.9 2 freezer bricks (3-lbs each)
- 3.2.10 1 cardboard insert
- 3.2.11 1 cardboard divider
- 3.2.12 2 absorbent pads
- 3.2.13 1 set of Styrofoam insulation, including 1 bottom, 4 walls, and 1 lid
- 3.2.14 1-gallon plastic bag for paperwork

NOTE: Air Waybills will not be provided for this kit. Instead, each BSS must contact shipping company to schedule a pickup.

Figure 1: Contents of Aqua kit

All canisters, including empty ones, should be packed in the aqua kit.



Alert of Shipment


3.3 Timeline of alert to CBR

- 3.3.1 An alert should be sent upon shipment of specimens; call in or enter online all pertinent information for the shipper account (See “Shipper Instructions” for procedure).

NOTE: If a reference number is needed, please use the Kit reference number. This should be the GTEX case # and Kit #. (Example: GTEX Case ID:XXXXXX/Kit-XXXX).

- 3.4 Method of alert to CBR: **EMAIL**, or an automated alert may be used. *It is up to the BSS to determine how to consolidate alerts. As long as each receiving entity is notified, the specific structure of the alert can be flexible.*

- 3.4.1 **PLEASE INCLUDE THE GTEX CASE ID (GTEX-XXXXXX) IN THE SUBJECT LINE OF ALL EMAILS.**
- 3.4.2 Indicate notice of shipment.
- 3.4.3 Indicate the date shipment is anticipated to be sent.
- 3.4.4 Indicate the date the shipment is anticipated to arrive at the CBR.
- 3.4.5 Indicate the tracking number/company used to ship package.
- 3.4.6 Email notification of shipment is to be provided to the CBR.

		GTE_x Work Instruction for PAXgene Tissue Fixative/Stabilizer Collection Receipt and Shipping (Aqua Kit)	
OP-0001-W3	VER. 03.08	Effective Date: mm/dd/yyyy	Page 4 of 6

- 3.4.7 Use the following instructions for the email template for correspondence to CBR.
- 3.4.7.1 In addition to the GTE_x ID number, note Source of Collection in the subject line for e.g.: Name of BSS, **GTE_x-00000X, Aqua kit**.
- 3.4.7.2 *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 CBR,

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

The biospecimen shipment to CBR will be shipped to you on <INSERT DATE> and is expected to arrive by <INSERT DATE>. The tracking number of the shipment to the CBR is: <INSERT TRACKING NUMBER/COMPANY NAME>.

*Thank you,
The <INSERT SITE NAME> site*

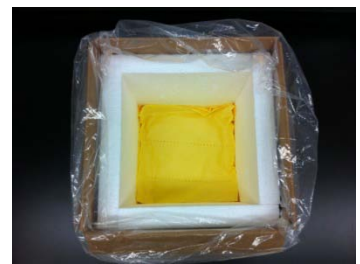
Packing Instructions

- 3.5 On day kit is used, complete the following steps:
- 3.5.1 Collect and fix/stabilize tissue in accordance with **GTE_x Tissue Processing Procedure, PR-0004** and the PAXgene[®] Tissue Container Product Circular.
- 3.5.2 After tissue samples are transferred from fixative (solution #1) to stabilizer (solution #2), arrange for shipment pick-up. Transfer of the tissue cassettes to stabilizer should occur between 6-24 hours of fixation. Make sure time in slot 1 and time in slot 2 are recorded and initialed.
- 3.5.3 Fill out all biospecimens and kit information in **BRIMS**.
- 3.5.4 Up to 6 PAXgene[®] tissue fixative/stabilizer containers are placed into the foam inserts in each plastic canister, the biohazard bag is sealed, and then the canister lid is securely fastened. Using the 1-inch wide strips, seal the canisters using the tape in an "X" arrangement. Again, note that one of the 4 canisters will always have no more than 4 PAXgene[®] containers. Return the canisters, even if empty.
- Note: When returning Aqua kits as Category B (UN3373), all unused PAXgene[®] containers must be removed.** For this reason, BSSs should retain any unused PAXgene[®] containers and not ship back. (The CBR will communicate with the BSSs on their stock levels and ship an extra empty Aqua box(es) which can be used with the excess PAXgene[®] containers.)
- Any mislabeled containers (containers in which the label does not match the embossed numbers) should NOT BE USED. Please mark with an "X", set aside, and**

dispose of according to local regulations. Contact the CBR regarding any mislabeled containers.

- 3.5.5 **Ensure that correct labels have been applied to any replacement containers used.**
- 3.5.6 There will be a total of up to 4 plastic canisters containing up to 22 total PAXgene® tissue containers (this number may be variable, dependent on the number of biospecimens collected).
- 3.5.7 In each shipping box, two absorbent pads are placed inside on the bottom of the box (Figure 3).

Figure 3: Two absorbent pads are added on the bottom of the box.




- 3.5.8 Place one 3-lbs frozen freezer brick at the bottom of the shipping box.
- 3.5.9 Four canisters containing the specimen containers are placed into a shipping box (Figure 4). **NOTE: All canisters are to be returned, even if empty.**

Figure 4: Packing 4 canisters containing specimen containers and freezer bricks.



- 3.5.10 The shipping box uses an internal cardboard divider to separate and stabilize the canisters. A cardboard insert is also supplied and should be placed over the canisters to further stabilize them during shipment.
- 3.5.11 Place one 3-lbs frozen freezer brick on top of the cardboard insert.
- 3.5.12 Fill out all pertinent sections of the **Chain of Custody** in **BRIMS**, print and place with each Aqua kit within the provided ziploc bag.
- 3.5.13 Please fill out the **Manifest** from **BRIMS** and place in the box within the ziploc bag. (Please be sure to keep copies of the above two documents, for your own records.)
- 3.5.14 Close each shipping box with tape.
- 3.5.15 Cover the Excepted Quantity sticker with the Black 5" x 7" label on the outside of the box and make sure the Category B (UN3373) sticker is displayed on the kit.
- 3.5.16 Verify all steps are complete.
- 3.5.17 Ship to the CBR as soon as possible after completion of tissue transition into stabilizer.

Shipping Instructions

		GTEx Work Instruction for PAXgene Tissue Fixative/Stabilizer Collection Receipt and Shipping (Aqua Kit)	
OP-0001-W3	VER. 03.08	Effective Date: mm/dd/yyyy	Page 6 of 6

3.6 Ship the completed Aqua kit to the CBR.

3.7 The following information should be used to arrange for a specimen pick-up:

Courier name:

Phone:

Account Number:

Online entry:

User ID:

Password:

Material Type: Human organ tissue, non-infectious

IATA Classification: UN3373, Biological Substance Category B

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 CBR

Contact Information:

Name:

Phone:

E-mail:

Deliver as soon as possible. Do not hold for regular business hours.