		GTEx Work Instruction for Aqua Kit Receipt and Shipping	
OP-0001-W3	VER. 1.2.0	Effective Date: 04/19/2012	Page 1 of 8

1. PURPOSE

This work instruction provides the specific steps necessary to pack and ship the CBR issued caHUB/GTEx PAXgene® Tissue Fixative/Stabilizer (the aqua kit).

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

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 blood collection tubes or 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. PROCEDURE

Kit Receipt at the BSS – Postmortem

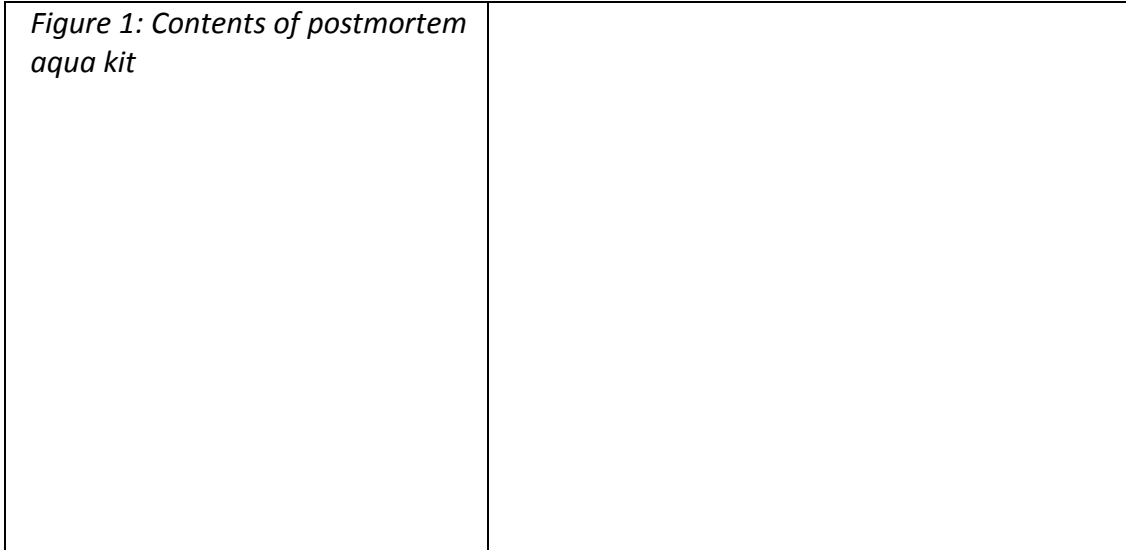
- 3.1. **Contents.** There are three fiberboard outer shipping boxes per kit set. (Figure 1 and the list below represent **one** fiberboard box of the collection set.)
 - 3.1.1. 1 fiberboard outer shipping box
 - 3.1.2. *A total of 22 PAXgene® tissue fixative/stabilizer containers (There are 66 containers total in the 3 boxes)*
 - 3.1.3. 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® containers. Due to IATA regulations, the quantity of acetic acid and methanol that is in each PAXgene® tissue fixative/stabilizer requires that no more than 22 PAXgene® containers be shipped in a single aqua kit. As a result, there needs to be 3 aqua kits 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.

The entire GTEx ID is applied to each PAXgene® tissue fixative/stabilizer along with a label that records the time 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 label assigned to PAXgene® tissue fixative/stabilizer container; the sequence number range can accommodate the collection:

0125-0126; 0225-0226; 0325-0326; 0425-0426; 0525-0526; 0625-26; 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 comprised 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.

- 3.1.4. 3-24 in long strips of adhesive tape
- 3.1.5. 8-12 in long narrow strips of tape
- 3.1.6. 1- 5" X 7" Black label
- 3.1.7. 8 circular foam inserts with cut-outs for PAXgene® containers (2 per canister)
- 3.1.8. A total of 4 leak-proof biohazard bags to hold foam inserts (1 per canister)
- 3.1.9. 2– 3 lb freezer bricks
- 3.1.10. 1 cardboard inserts
- 3.1.11. 1 cardboard dividers
- 3.1.12. 2 box absorbent pads
- 3.1.13. 1 set of Styrofoam insulation, including 1 bottom, 4 walls, and 1 lid
- 3.1.14. GTEx Discrepancy Checklist for Aqua Kit – Postmortem and a gallon plastic bag for paperwork





Kit Receipt at the BSS - Surgical

3.2. **Contents.** There is one fiberboard outer shipping box per kit set. (Figure 2 below represents one fiberboard box of the collection set.)

3.2.1. 1 fiberboard outer shipping box

3.2.2. A total of 10 PAXgene® tissue fixative/stabilizer containers

3.2.3. 2 plastic canisters with screw-cap and o-ring – Each canister must contain no more than 6 PAXgene® tissue fixative/stabilizer containers. Inside each canister, the PAXgene® containers and foam inserts will be sealed inside a leak-proof specimen bag with an absorbent pad.

The entire GTEx ID is applied to each PAXgene® tissue fixative/stabilizer along with a label that records the time 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 label assigned to PAXgene® tissue fixative/stabilizer container; the sequence number range can accommodate the collection:

0125-0126; 0225-0226; 0325-0326; 0425-0426; 0525-0526; 0625-0626

3.2.4. 3 wide strips of adhesive tape

3.2.5. 1- 5" X 7" Black label

3.2.6. 4 circular foam inserts with cut-outs for PAXgene® containers (2 per canister)

3.2.7. A total of 2 leak-proof biohazard bags (1 per canister)

3.2.8. 1 cardboard insert

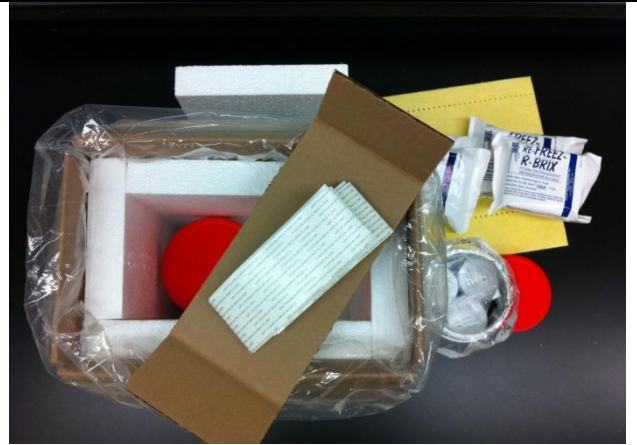
3.2.9. 4– 1 lb freezer bricks

3.2.10. 2 absorbent pads

3.2.11. Styrofoam insulation with 4 sides, 1 lid, and 1 bottom

3.2.12. GTEx Discrepancy Checklist for Aqua Kit – Surgical and a gallon plastic bag for paperwork

Figure 2: Contents of surgical aqua kit



Alert of Collection – Postmortem and Surgical

3.3. Timeline of alert to CBR

3.3.1. Upon shipment of specimen.

3.4. Send an e-mail notifying CBR of the shipment.

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-00000X) IN THE SUBJECT LINE OF ALL EMAILS.**

3.4.2. Indicate notice of shipment.

3.4.3. Indicate date specimen is anticipated to be shipped.

3.4.4. Indicate date specimen is anticipated to arrive at CBR.

3.4.5. Indicate tracking number/company used to ship specimen.

		GTEx Work Instruction for Aqua Kit Receipt and Shipping	
OP-0001-W3	VER. 1.2.0	Effective Date: 04/19/2012	Page 5 of 8

- 3.4.6. Use the following instructions for the email template for correspondence to CBR.
- 3.4.7.1 In addition to the GTEx ID number, note Source of Collection in the subject line for e.g.: Name of BSS, **GTEX-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 GTEx donor collection is being shipped.

- *The 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 – Postmortem

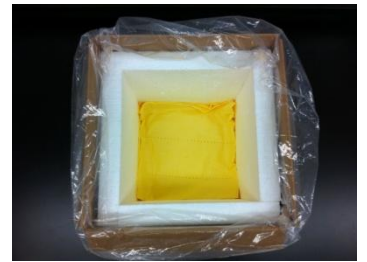
- 3.5. Packers and shippers of the aqua kit must be trained to handle IATA dangerous goods classes 3, 6.1, and 8. The regulations can change each year. **It is important that the BSS trained shipper review state and operator variations annually.**
- 3.6. Upon receipt and before kit is used, verify contents using the list above (do NOT use kit if incomplete using the **GTEx Discrepancy Checklist for Aqua Kit – Postmortem (OP-0001-W3-F2)**). If incomplete, report defective kit to kit supplier.
- 3.7. The CBR will follow up with an action for resolution.
- 3.8. On day kit is used, complete the following steps:
- 3.8.1. After tissue samples are transferred from fixative (solution #1) to stabilizer (solution #2), arrange for shipment pick-up with Shipping Vendor.
 - 3.8.2. Complete all needed information on the appropriate CRFs.
 - 3.8.3. Collect and fix/stabilize tissue in accordance with **GTEx Tissue Procurement SOP (PR-0004)** and PAXgene® Tissue Container Product Circular.
 - 3.8.4. 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 only 4 PAXgene® containers.
- Note: When returning aqua kits as Category B (UN3373), all unused PAXgene® containers must be removed.** Sites 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(s) 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 contact the CBR for further instruction.

Note: In the event of a comprised 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.

- 3.8.5. There will be a total of 4 plastic canisters containing either 4 or 6 PAXgene® tissue containers each.
- 3.8.6. 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.




- 3.8.7. Place one 3-lb frozen freezer brick at the bottom of the shipping box.
- 3.8.8. Four canisters containing the specimen containers are placed into a shipping box (Figure 4)

Figures 4: Packing 4 canisters containing specimen canisters with freezer bricks.



- 3.8.9. 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 stabilize them during shipment.
- 3.8.10. Place one 3-lb frozen freezer brick on top of the cardboard insert.
- 3.8.11. Include GTEx Tissue Data Collection Form with each aqua kit.
- 3.8.12. Include GTEx Chain of Custody Form (OP-0002-F1) with each aqua kit.
- 3.8.13. Each shipping box is closed with tape.
- 3.8.14. 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.
- 3.8.15. Verify all steps are complete.
- 3.8.16. Ship to CBR as soon as possible after completion of tissue transition into stabilizer.


		GTEx Work Instruction for Aqua Kit Receipt and Shipping	
OP-0001-W3	VER. 1.2.0	Effective Date: 04/19/2012	Page 7 of 8

Packing Instructions - Surgical

- 3.9. Packers and shippers of the aqua kit must be trained to handle IATA Dangerous Goods classes 3, 6.1, and 8. The regulations can change each year. **It is important that the BSS trained shipper review state and operator variations annually.**
- 3.10. Upon receipt and before kit is used, verify the contents. Do NOT use the kit if it is incomplete when verified against the **GTEx Discrepancy Checklist for Aqua Kit – Surgical (OP-0001-W3-F1)**. If incomplete, report defective kit to kit supplier (CBR).
- 3.11. The CBR will follow up with an action for resolution.
- 3.12. On the day the kit is used, complete the following steps:
 - 3.12.1. Arrange for shipment pick-up with Shipping Vendor so that samples are picked on the following day. **THIS SHIPMENT NEEDS TO BE SHIPPED AS SOON AS POSSIBLE AFTER ALL SAMPLES ARE TRANSFERED FROM SOLUTION #1 TO #2.**
 - 3.12.2. Complete all needed information on the appropriate CRFs.
 - 3.12.3. Collect and fix/stabilize tissue in accordance with **GTEx Tissue Procurement SOP (PR-0004)** and PAXgene® Tissue Container Product Circular.
 - 3.12.4. Up to 6 PAXgene® tissue fixative/stabilizer containers are placed into the foam inserts in each plastic canister.
 - 3.12.5. The large sealable bag in the inner cavity of each plastic container should be sealed to provide leak-proof protection. The biohazard bag is sealed and folded down.
 - 3.12.6. Securely fasten the canister lid. Using the 1 inch wide strips, seal the canisters using the tape in an “X” arrangement.

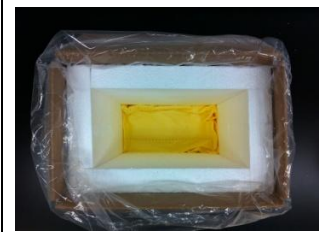
Note: When returning aqua kits as Cat B (UN3373), all unused PAXgene® containers must be removed. Sites should retain any unused PAXgene® containers and not ship back. (The CBR will communicate with the BSSs on their stock levels and ship an extra empty aqua box(s), which can be used with the excess 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 contact the CBR for further instruction.

Note: In the event of a comprised 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.
 - 3.12.7. There will be a total of 2 plastic canisters containing up to 6 PAXgene® tissue containers each.

		GTEx Work Instruction for Aqua Kit Receipt and Shipping	
OP-0001-W3	VER. 1.2.0	Effective Date: 04/19/2012	Page 8 of 8

3.12.8. Two absorbent pads is placed inside on the bottom of the box (Figure 5).

Figure 5: Two absorbent pads are placed on the bottom of the box.



3.12.9. Two canisters containing the specimen containers are placed into a shipping box with 4– 1 lb frozen freezer bricks (Figures 6).

Figure 6: Packing 2 canisters containing specimen canisters with freezer bricks.



3.12.10. Two frozen freezer bricks are place side-by-side at the bottom of the shipping box.

3.12.11. The cardboard insert is also supplied and should be place over the canisters to stabilize them during shipment.

3.12.12. Two frozen freezer bricks are place side-by-side on top of the cardboard insert.

3.12.13. Include GTEx Tissue Data Collection Form).

3.12.14. Include GTEx Chain of Custody Form (OP-0002-F1).

3.12.15. The Styrofoam™ lid is placed on top.

3.12.16. Each shipping box is closed with tape.

3.12.17. 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.

3.12.18. Verify all steps are complete and Ship to CBR as soon as possible after completion of tissue stabilization.

Shipping Instructions – Postmortem and Surgical

3.13. Ship the completed aqua kit to the correct recipient (CBR) address.

4. REFERENCES

- 4.1.1. GTEx Tissue Procurement SOP, PR-0004
- 4.1.2. GTEx Chain of Custody Procedure, OP-0002
- 4.1.3. PAXgene® Tissue Container Product Circular

5. ATTACHMENTS

- 5.1.1. GTEx Discrepancy Checklist for Aqua Kit – Surgical, OP-0001-W3-F1
- 5.1.2. GTEx Discrepancy Checklist for Aqua Kit – Postmortem, OP-0001-W3-F2