



1.0 PURPOSE

This procedure describes the process that biospecimen source sites (BSS's) follow to receive collection kits from the Van Andel Research Institute (CBR) and the process the BSS's use to package biospecimens and ship them to the CBR, the University of Miami Brain Bank (Brain Bank), or the Laboratory Data Analysis Coordinating Center (LDACC) at The Broad Institute.

2.0 SCOPE

This procedure applies to all of the organizations involved in the migration of biospecimens, specifically: the CBR, Brain Bank, and the participating Biospecimen Source Sites (BSS's).

3.0 RESPONSIBILITY

- 3.1 **Biospecimen Source Site (BSS):** They will collect and ship biospecimens to the appropriate processing/analysis facility.
- 3.2 **Comprehensive Biospecimen Repository (CBR):** The Van Andel Research Institute. They will manage the preparation and distribution of the shipping kits and receipt of the Aqua Kit specimen collection.
- 3.3 **Science Applications International Corporation - Frederick, Inc. (SAIC-F):** They will train the BSS's on the type of biospecimens to be collected and their transportation requirements, e.g., shipping temperature and International Air and Transportation Association (IATA) regulation.
- 3.4 **University of Miami Brain Bank (BB):** They will receive all brain and hair specimens from the BSSs.
- 3.5 **Laboratory Data Analysis and Coordinating Center (LDACC):** They will receive the blood and skin samples from the BSSs.

4.0 DEFINITIONS

- 4.1 **BB** – [University of Miami] Brain Bank. Receives all brain and hair specimens. Located in Miami, FL.
- 4.2 **Bio4D** – Computer system used by BSS's to enter collection and shipping information at the CBR.
- 4.3 **BSS** – Biospecimen source site. An institution contracted to perform tissue and data procurement.
- 4.4 **CBR** – Comprehensive Biospecimen Resource located at the Van Andel Research Institute in Grand Rapids, MI.
- 4.5 **CDR** – Comprehensive Data Repository.



- 4.6 **CRF** – Case report form. Paper form used to collect project related data.
- 4.7 **GTEEx** – Genotype-Tissue Expression project.
- 4.8 **IATA** – International Air Transport Association. The oversight authority for the airline industry.
- 4.9 **LDACC** – The Laboratory Data Analysis and Coordinating Center (LDACC) located at The Broad Institute in Boston, MA.
- 4.10 **PDF** – portable document format.
- 4.11 **SAIC – F** SAIC-Frederick, Inc.
- 4.12 **SOP** – standard operating procedure.
- 4.13 **TCDF** – tissue collection data form.

5.0 ENVIRONMENTAL HEALTH & SAFETY

- 5.1 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.
 - 5.1.1 Training may be conducted through the BSS or offered through SAIC-F.
 - 5.1.2 Verification of training materials, testing and certification must be provided to the SAIC-F team to certify all staff involved with shipping procedures.
- 5.2 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. Latex or nitrile rubber gloves are required for persons directly handling the PAXgene tissue containers.
- 5.3 Appropriate personal protective equipment should be worn at all times to include but not limited to:
 - Gown or lab coat;
 - Hair bonnet, mask, and shoe covers, per institutional requirements;
 - Latex or nitrile rubber gloves.

6.0 MATERIALS/EQUIPMENT

- 6.1 caHUB/GTEEx Blood & Skin Biopsies Collection (the yellow kit).
- 6.2 caHUB/GTEEx Whole Brain, Brain Stem and Hair Collection (the green kit).
- 6.3 caHUB/GTEEx PAXgene Tissue Fixative/Stabilizer (the aqua kit).



7.0 PROCEDURE

- 7.1 The procedural flow for kit receipt, verification, and shipping is outlined in **GTEEx Specimen Collection Supplies and Shipping Kit Process Flow (OP-0001-P1)**.

Kit Supplies to the BSS's

- 7.2 VARI will provide the following color-coded kits to each BSS: caHUB/GTEEx Blood & Skin Biopsies Collection shipped to the LDACC (yellow kit); caHUB/GTEEx Whole Brain, Brain Stem and Hair Collection shipped to the BB (green kit); and caHUB/GTEEx PAXgene Tissue Fixative/Stabilizer Collection to the CBR (aqua kit).
- 7.3 The BSS verifies the contents of routine kit shipments against the appropriate checklist, either the **GTEEx Kit Discrepancy Checklist for Routine Overpack for Postmortem Collections (OP-0001-F2)** or the **GTEEx Kit Discrepancy Checklist for Routine Overpack for Surgical Collections (OP-0001-F4)**.

Collection Event & Packing

- 7.4 Once a donor has been identified, retrieve the appropriate kit from the storage location.
- 7.5 If a brain is collected (not applicable for surgical collections), an automatic alert to the BB by EMAIL will be generated by QuickSTAT as listed in the instructions in the Alert of Pending Collection subsection of the **Work Instruction for Green Kit Receipt and Shipping (OP-0001-W2)**. A phone call must also be placed by the procurement team to alert the Brain Bank hotline of a shipment; which in turn alerts the on-call staff.
- 7.6 Collect the specimen(s) using the **GTEEx Tissue Procurement SOP (PR-0004)**.
- 7.7 Following the **GTEEx Bio4D BSS User Guide (PBS-01.062)**, print the **GTEEx Tissue Data Collection Form (from Bio4D)** (or other local traveling manifest) that will be included in the shipped aqua kits. For the yellow and green kits use the pre-printed TCDFs that are provided in the Routine Overpacks.
- 7.8 Prepare the collected specimen(s) for shipment using the appropriate color coded work instruction: use the **GTEEx Work Instruction for Yellow Kit Receipt and Shipping (OP-0001-W1)** for the yellow kit; the **GTEEx Work Instruction for Green Kit Receipt and Shipping (OP-0001-W2)** for the green kit; or the **GTEEx Work Instruction for Aqua Kit Receipt and Shipping (OP-0001-W3)** for the aqua kit.



Kit Shipping

- 7.9 Manually alert the LDACC Institute and VARI of the collection shipment using the appropriate color coded work instruction: for the aqua kit use the Alert of Pending Collection subsection in the **GTEX Work Instruction for Aqua Kit Receipt and Shipping (OP-0001-W1)**; and for the yellow kit use the Alert of Pending Collection subsection in the **GTEX Work Instruction for Yellow Kit Receipt and Shipping (OP-0001-W3)**.

8.0 REFERENCES

- 8.1 GTEEx Tissue Procurement SOP, PR-0004
- 8.2 GTEEx Bio4D BSS User Guide, PBS-01.062
- 8.3 Work Instruction for caHUB Data Entry at BSS, IT-0001-W1
- 8.4 Work Instruction for Shipping Receipt at Processing Facility, IT-0001-W2

9.0 ATTACHMENTS

- 9.1 GTEEx Kit Discrepancy Checklist for Routine Overpack for Postmortem Collections, OP-0001-F2
- 9.2 GTEEx Kit Discrepancy Checklist for Transport Media, OP-0001-F3
- 9.3 GTEEx Kit Discrepancy Checklist for Routine Overpack - Surgical Collections, OP-0001-F4
- 9.4 GTEEx Work Instruction for Yellow Kit Receipt and Shipping, OP-0001-W1
- 9.5 GTEEx Discrepancy Checklist for Yellow Kit, OP-0001-W1-F1
- 9.6 GTEEx Work Instruction for Green Kit Receipt and Shipping, OP-0001-W2
- 9.7 GTEEx Discrepancy Checklist for Green Kit, OP-0001-W2-F1
- 9.8 GTEEx Work Instruction for Aqua Kit Receipt and Shipping, OP-0001-W3
- 9.9 GTEEx Discrepancy Checklist for Aqua Kit - Surgical, OP-0001-W3-F1
- 9.10 GTEEx Discrepancy Checklist for Aqua Kit - Postmortem, OP-0001-W3-F2
- 9.11 GTEEx Specimen Collection Supplies and Shipping Kit Process Flow, OP-0001-P1
- 9.12 QuickSTAT Guide: How to use Quick Online Rx



APPROVALS

NAME / TITLE	DCO#
Angela Zimmerman, SAIC-F, Director of Operations	DCO-2012-04-16-12-1
Steve Buia, SAIC-F, Deputy Director	
Jim Vaught, caHUB Deputy Director	

INITIATION/REVISION HISTORY

REV #	DESCRIPTION OF CHANGE	AUTHOR	EFFECTIVE DATE
A	Original Release	Angela Zimmerman	5/27/2011
1.1.0	Reorganized into separate work instructions and updated with new packing & shipping instructions	Steve Buia	10/07/2011
1.1.1	Standardized the message alerts, minor language changes	Kim Valentino	01/11/2012
1.2.0	Minor textual changes, additional attachments	Kim Valentino	04/19/2012

DCO-2012-04-16-12-1



GTEx Kit Discrepancy Checklist for Routine Overpack for Postmortem Collections

OP-0001-F2

VER. 1.2.0

Effective Date: 04/19/2012

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Kit ID number on outside of box: _____

Condition of kit received

- Acceptable
- Damaged, usable
- Damaged, NOT usable, contact pbs.lab@vai.org or 616-234-5122

For damaged items, please insert comment at end of form clarifying problem(s)

Pre-labeled tissue cassettes for Aqua Kit

- Ziplock bag with 2 boxes of pre-labeled tissue cassettes for aqua kit (x1)
- Organ cassettes 33 (x2)

Collection supplies	Extra supplies not linked to specific collection
<input type="checkbox"/> GTEx Manifest: green kit with labels (x1) <input type="checkbox"/> GTEx Manifest: yellow kit with labels (x1) <input type="checkbox"/> GTEx Manifest: aqua kit – Postmortem (x1) <input type="checkbox"/> Sheet/roll of GTEx labels for PAXgene® container lids (x1) <input type="checkbox"/> Sheet of organ ID labels (x1) <input type="checkbox"/> Syringe/vacutainer adaptors (x2) <input type="checkbox"/> Pack of 50 disposable cutting boards (x1)	<input type="checkbox"/> Fiberboard box labeled with “caHUB Collection Routine Overpack – Postmortem” and an External kit ID label (x1) <input type="checkbox"/> GTEx Kit Discrepancy Checklist for Routine Overpack for Postmortem (x1) <input type="checkbox"/> PAXgene® tissue container product circular (x1)

Disposing of overpack supplies

All routine overpack supplies are new for each case. All leftover supplies from this kit should be disposed of at the BSS.

Comments:

Form completed by BSS staff (insert name)	Date and time form completed Date: _____ Time: _____
Form sent to SAIC-F by BSS staff (insert name) Only if discrepancy noted	Date and time form sent Date: _____ Time: _____



GTEEx Kit Discrepancy Checklist for Transport Media

OP-0001-F3

VER. 1.2.0

Effective Date: 04/19/2012

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Contents Checklist

Condition of shipment received

- Acceptable
- Damaged, usable
- Not usable, contact VARI at pbs.lab@vai.org or 616-234-5122

Note: For damaged items, please insert comment at end of form clarifying problem(s)

Kit ID

There is no kit ID linked to the provided media.

Timeline

The CBR will aim to provide monthly replacement shipments with a 2-3 day window for receipt prior to expiration of media already on site.

Media Expiration

Media expires 30 days from date of manufacture.

Package

- Fiberboard box
- 8 oz freezer brick, frozen (x2)
- Transport media, 50 ml conical tube
- Styrofoam insulation, 4 sides, a top, a bottom
- *Indicate number of tubes received: _____

Labeling Instructions

The yellow conical tube contains a label with sequence ID 0008. At the time of collection, the full GTEX ID label (found in the Routine Overpacks) can be applied to this tube and it can be added to the Yellow kit for shipment to the LDACC.

Storage Instructions

Each site should keep the vial refrigerated at 2 to 8 degrees Celsius until use.

Comments:

Form completed by BSS staff (insert name)	Date and time form completed
	Date: _____ Time: _____
Form sent to SAIC-F by BSS staff (insert name) <i>Only if discrepancy noted</i>	Date and time form sent
	Date: _____ Time: _____

		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)

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 **GTE_x 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.

		GTEEx 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. Method of Alert to the LDACC and CBR: **EMAIL**
- 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. Email recipients include:
1. bsp_lab@broadinstitute.org
 2. egelfand@broadinstitute.org
 3. pbs.lab@vai.org
 4. Gtex@mail.nih.gov
- 3.3.7. Use the following instructions for the email template for correspondence to CBR and the LDACC:
- 3.3.7.1. In addition to the GTEEx ID number, note Source of Collection, and kit type in the subject line for e.g.: **Name of BSS, GTEX-00000X, Yellow kit.**
- 3.3.7.2. *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 GTEEx 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

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Weekend Delivery/Evening Delivery

- 3.3.8. Outside of normal business hours. The LDACC and its receiving docks are closed on weekends, holidays, and after 6pm on business days. For shipments that will arrive during these times, please provide **LaserShip®** with the following directions:
- 3.3.8.1. **LaserShip®** will need to alert the LDACC “on call” staff directly via the “on call” cell phone (**617-963-4922**) as soon as LaserShip® receives the package at the airport. They should confirm pickup and immediate delivery of the package.
- 3.3.8.2. **LaserShip®** will need to deliver the package to the front desk at 320 Charles Street, Cambridge, MA 02141 (LDACC)

Weekday Delivery Receipt

- 3.3.9. During normal business hours
- 3.3.9.1. Follow the Weekday instructions starting at 3.3.1
- Upon delivery, **LaserShip®** will need to meet the LDACC staff at the rear entrance of 301 Binney Street (the rear entrance is on Rogers Street), at the corners of Rogers and Fulkerson Streets.

Note: In case of emergency and/or the “on call” cell phone cannot be reached, **LaserShip®** and/or the Collection site should call Scott Mahan at (508) 404-6204, or Kristin Ardlie at (617) 271-4160

- 3.4. **Method of alert to LaserShip®**
- 3.4.1. During normal business hours, Monday through Friday, 8am to 6pm, please provide LaserShip® with the following directions:
- 3.4.1.1. Direct delivery of the package to the loading dock at 301 Binney Street, Cambridge, MA 02142 (LDACC). Upon arrival at the loading dock, they will press #007 (Receiving) or #009 (BSP lab).

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. Convert to PDF and email to pbs.lab@vai.org and/or call 616-234-5122.
- 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 LaserShip® so that samples are picked up as soon as possible after the tissue collection is finished. Call 1-877-807-1010. **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 **GTEx 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 institute so it arrives within 24 hours of blood collection.

Shipping Instructions

3.9. Ship the completed yellow kit to the following address:

<u>Delivery estimated within normal business hours</u>	<u>Delivery estimated evening (after 6 pm) or weekend</u>
BSP Labs 301 Binney Street Lab 5076 Cambridge, MA, 02142	BSP Labs 320 Charles Street Lab 5076 Cambridge, MA, 02141
Contact: Scott Mahan at (508) 404-6204, or Kristin Ardlie at (617) 271-4160	Contact: Kristin Ardlie at (617) 714-7001
LaserShip note: Meet the LDACC staff at the <u>rear entrance of 301 Binney Street</u> (the rear entrance is on Rogers Street), at the corners of Rogers and Fulkerson Streets. Upon arrival at the loading dock, they will press #007 (Receiving) or #009 (BSP lab).	LaserShip note: Deliver the package to the front desk <u>320 Charles Street</u> , Cambridge, MA 02141 (LDACC)

4. REFERENCES

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

5. ATTACHMENTS

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



OP-0001-W1-F1

VER. 1.2.0

Effective Date: 04/19/2012

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Condition of kit received

- Acceptable
- Damaged, usable
- Damaged, NOT usable: contact pbs.lab@vai.org or 616-234-5122

For damaged items, please insert comment at end of form clarifying problem(s)

Kit ID number on outside of box (GTEx-XXXX): _____

- Fiberboard box with External label "caHUB Collection Yellow Kit" and External kit ID label (x1)**
- Strips of 2-inch wide, clear tape (x3) 12-inch strips of narrow, clear tape (x2)
- 1 lb freezer brick (x4) (Keep at room temperature. DO NOT FREEZE OR REFRIGERATE).
- Absorbent pad (x1)
- External "Peel off label when samples are shipped" label (x1)
- Styrofoam box insulation including 4 sides, bottom, and lid

- Shipping Canister with screw-cap lid and o-ring and Biohazard label (x1)**
- Circular foam canister lid insert (x1) Biohazard bag to hold foam insert (x1)
- Circular foam insert with cut-outs for tubes (x1) Gallon-sized ziplock bag to house canister(x1)
- 10mL ACD vacutainer tube with sequence 0001,0002,0003,0004 labels (x4)
- 2.5mL PAXgene® RNA vacutainer with sequence 0005 and 0006 labels (x2)

Forms

- GTEx Discrepancy Checklist for Yellow Kit form (x1) Gallon-sized ziplock bag for paperwork (x1)

Note: No Air Waybill is provided as part of the kit. Shipment must be arranged through LaserShip®.

Yellow Kit Blood Tubes	
Sequence 0001 (ACD) Lot #:	Expiration Date:
Sequence 0002 (ACD) Lot #:	Expiration Date:
Sequence 0003 (ACD) Lot #:	Expiration Date:
Sequence 0004 (ACD) Lot #:	Expiration Date:
Sequence 0005 (PAX) Lot #:	Expiration Date:
Sequence 0006 (PAX) Lot #:	Expiration Date:

Comments:

Form completed by BSS staff (insert name)	Date and time form completed
	Date: _____ Time: _____
Form sent to SAIC-F by BSS staff (insert name) Only if discrepancy noted	Date and time form sent
	Date: _____ Time: _____

		GTE_x Work Instruction for Green Kit Receipt and Shipping	
OP-0001-W2	VER. 1.1.1	Effective Date: 04/19/2012	Page 1 of 7

1. PURPOSE

This work instruction provides the specific steps necessary to pack and ship the VARI issued caHUB/GTE_x Whole Brain, Brain Stem and Hair Collection (the green 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.

3. PROCEDURE

Kit Receipt at the BSS

- 3.1. Contents correspond to supplies shown in Figure 1.
 - 3.1.1. 1 insulated UN3373 fiberboard box with outer green kit label and external ID label
 - 3.1.2. 1 plastic bucket with O-ring and hinge-pin lid (labeled with sequence number 0011 and Biohazard)
 - 3.1.3. 3 absorbent sheets
 - 3.1.4. 1 – 4 lb freezer brick, which goes inside the plastic bucket
 - 3.1.5. 4 – 3 lb freezer bricks that are inside a bubble sleeve or a ziplock bag
 - 3.1.6. 1 circular moldable foam insert with brain stem cut-out so the brain will sit on flat base in bucket (not shown in Figure 1).
 - 3.1.7. 1 rectangular foam strip that surrounds the brain
 - 3.1.8. 2 circular foam inserts
 - 3.1.9. 2 cardboard inserts
 - 3.1.10. 5 large sealable plastic bags for ice to pack the head
 - 3.1.11. 2 leak proof biohazard bags to house the brain
 - 3.1.12. Styrofoam™ insulation including 4 sides, a bottom and a lid (not shown in Figure 1)
 - 3.1.13. **GTE_x Discrepancy Checklist for Green Kit (OP-0001-W2-F1)** with bag for paperwork (not shown in Figure 1).
 - 3.1.14. Three 24-in tape strips to seal the fiberboard box (not shown in Figure 1).
 - 3.1.15. Unlabeled small manila envelope
 - 3.1.16. Small glassine envelope with sequence 0014.



Figure 1: Supplies provided in the green kit.

Alert of Completed Collection

- 3.2. Timeline of alert to the Brain Bank
 - 3.2.1. Immediately upon completion of procurement.
- 3.3. Method of alert to the Brain Bank: Phone and **QuickSTAT alert**
 - 3.3.1. Immediately contact the Brain Bank 24-hour hotline: 1-800-862-7246 (1-800-UM BRAIN)
 - 3.3.2. Use the following instructions for the email template for correspondence to Brain Bank:
 - 3.3.2.1 Enter all pertinent information/choose correct information in drop down menus into the Quick STAT module. (See" How to use Quick Online Rx" for procedure). **NOTE: Once a BSS goes online to setup a shipment, the system will prompt the user to enter a Kit reference number. This should be the GTEX case # and Kit #. (Example: GTEX Case ID:0000XXX/Kit-OXXX).**
 - 3.3.2.2 Print the shipping form twice (4 copies). Courier will sign, date and time one copy and return to BSS. The other 3 copies go with the courier with the shipment.
 - 3.3.2.3 When the pickup card is received in the Quick STAT system, an alert will be sent to the following:
 - Margaret Basile — mbasile@med.miami.edu
 - Yvonne Marcus — ymarcus@med.miami.edu
 - Lyne Bien-Aime — LBienAime@med.miami.edu
 - Deborah C. Mash — dmash@med.miami.edu
 - GTEX Email — Gtex@mail.nih.gov
 - The CBR—pbs.lab@vai.org

		GTEx Work Instruction for Green Kit Receipt and Shipping	
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3.4. Change in Delivery Status Alert Instructions

- 3.4.1. If a collection alert was forwarded to the Miami Brain Bank and it is later determined, for any reason, the shipment will be delayed, cancelled, or there is a mistake in information on the printed forms, call QuickSTAT IMMEDIATELY!
- 3.4.2. QuickSTAT will update any recipients with any delays, re-routes, etc.
- 3.4.3. An alert email will be issued to the following recipients:
 - Margaret Basile — mbasile@med.miami.edu
 - Yvonne Marcus — ymarcus@med.miami.edu
 - Lyne Bien-Aime — LBienAime@med.miami.edu
 - Deborah C. Mash — dmash@med.miami.edu
 - GTEx Email — Gtex@mail.nih.gov
 - The CBR—pbs.lab@vai.org

Packing Instructions

- 3.5. Packers and shippers of the green kit must be certified to ship IATA class 6.2 material.
- 3.6. Upon kit receipt, verify contents of kit using the list above (3.1).
- 3.7. If the kit is incomplete or broken
 - 3.7.1. Complete **GTEx Discrepancy Checklist for Green Kit (OP-0001-W2-F1)**.
 - 3.7.2. Convert to PDF and email to pbs.lab@vai.org and/or call 616-234-5122.
 - 3.7.3. CBR will follow-up with an action for resolution.

Note: There is a wait charge if the driver has to wait more than fifteen minutes for the specimen to be ready to receive. If the pick-up time needs to change after the initial request, call to have it modified.

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

<u>QuickSTAT Courier</u>	1-800-856-7828
<u>Account Number:</u>	12220
<u>Internal Reference:</u>	GTEX – 11-40195D-1
<u>Material Type:</u>	Human Brain tissue, non-infectious
<u>IATA Classification:</u>	UN3373, Biological Substance Category B
<u>Delivery Deadline:</u>	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.)
<u>Destination:</u>	University of Miami, Miller School of Medicine Department of Neurology, Brain Endowment Bank 1951 NW 7th Avenue Suite 240 Miami FL 33136 1-800-862-7246 (24-hr on call)

Special Instructions:

(1) Print the QuickSTAT form 2 times (4 copies). Courier should sign, date and time one copy for BSS records, and take the other three with the package.

(2) Deliver as soon as possible. Do not hold for regular business hours. Recipient can receive 24 hours a day, 7 days a week.

If Waybill is not provided: a) Write or place label indicating "Deliver as soon as possible" on outer box, b) contact courier representative to correct error for next pick-up.

3.8. On the day the kit is used, complete the following steps:

3.8.1. Arrange for shipment pick-up with QuickSTAT so the sample is picked up as soon as the brain, brain stem, and hair have been recovered. **THIS SHIPMENT MUST LEAVE THE BSS AS SOON AS POSSIBLE AFTER THE COLLECTION IS COMPLETED.**

3.8.2. Using the labels found on the label sheet in the overpack kit; transfer the full GTE_x specimen labels to the plastic bucket and manila envelope.

3.8.3. Whole Brain and Brain Stem Packing: Follow Figures 2 to 14 for packaging instructions.

3.8.4. Hair Packing: The hair sample placed inside the glassine envelope is then placed inside a manila envelope. Follow instructions for hair packing (Figure 12).

Figure 2: View at the bottom of the inside shipping package. There is a cardboard insert and a round foam disk for the plastic bucket to sit on to reduce vibration during shipping.



Figure 3: Place four -20 °C frozen 3-lb freezer bricks individually wrapped in bubble plastic along the outside walls of the shipping container.



Figure 4: Place one -20 °C frozen 4-lb freezer brick in plastic bucket.



Figure 5: Place foam with stem cut-out over 4-lb freezer brick.

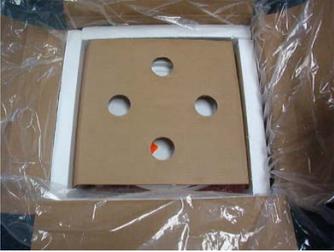


Figure 6: Place whole brain and brain stem into a leak-proof biohazard bag. Remove as much of the air as possible to prevent brain from moving during shipment.

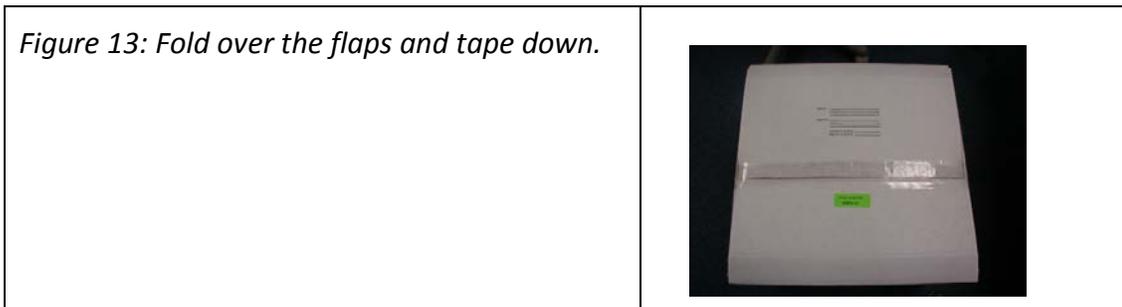


Figure 7: Place bagged whole brain and brain stem into a second leak-proof biohazard bag. Again, remove as much of the air as possible.



<p><i>Figure 8: With brain stem down, carefully slide brain into foam insert so the stem is in the foam cutout.</i></p>	
<p><i>Figure 9: Encircle the whole brain with the rectangular foam strip.</i></p>	
<p><i>Figure 10: Place a foam insert over the whole brain. Close the bucket. Take care not to catch the large side icepacks in the threads of the lid while closing.</i></p>	
<p><i>Figure 11: Add the cardboard insert so that it is inverted over the plastic bucket.</i></p>	
<p><i>Figure 12: Place the outer Styrofoam™ lid on top. Insert the following 3 items:</i></p> <ol style="list-style-type: none"> 1. Completed Chain of Custody Form (OP-0002-F1) 2. Completed GTEx Tissue Data Collection Form (PBS-01.062) found in the Bio4D Manual. 3. Manila envelope with the hair sample is placed on top 	

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3.8.5. Email a copy of the **Chain of Custody Form (OP-0002-F1)** to GTEEx@mail.nih.gov.

Shipping Instructions

3.9. Waiting for Shipment

3.9.1. If the courier pick-up is anticipated to be more than one hour from the time the kit is packed, please hold in a cold room at a temperature of 4°C until the courier arrives.

3.10. Verify the pick-up of the green kit by the courier.

3.11. Brain Bank Confirmation of Receipt

3.11.1. The BSS should expect an email confirmation of receipt from the Brain Bank.

4. REFERENCES

- 4.1. Chain of Custody Form, (OP-0002-F1).
- 4.2. GTEEx Tissue Procurement, SOP (PR-0004)
- 4.3. GTEEx Bio4D BSS User Guide, (PBS-01.062)

5. ATTACHMENTS

- 5.1. GTEEx Discrepancy Checklist for Green Kit, (OP-0001-W2-F1)
- 5.2. QuickSTAT Guide: How to use Quick Online Rx



GTEx Discrepancy Checklist for Green Kit

OP-0001-W2-F1

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Condition of kit received

- Acceptable Damaged, usable
- Damaged, NOT usable: contact pbs.lab@vai.org or 616-234-5122

For damaged items, please insert comment at end of form clarifying problem(s)

Kit ID number on outside of box (GTEx-XXXX): _____

- Fiberboard box with External label "caHUB Collection Green Kit" and External kit ID label (x1)**
- External "Peel off label when samples shipped" label covering up the "UN3373" and "Biological substance, Category B" labels (x1)
- Plastic bucket with Lid with hinge-pin closure labeled with with sequence 0011 label (x1)**

Other Shipping Supplies

- 4-lb freezer brick (x1) 3-lb freezer bricks in ziplock bags or bubble wrap (x4)
- Circular foam insert (x2) Cardboard inserts (x2)
- Moldable, rectangular foam strip (x1) 3mil thick ziplock bags for wet ice (x5)
- Circular foam insert with brain stem cut out (x1) Styrofoam™ lid, 4 sides, and bottom (x1)
- Biohazard bags to house brain(x2) 24-in long tape strips (x3)
- Absorbent pads (x3)

Forms

- GTEx Discrepancy Checklist for Green Kit form (x1) Gallon-sized ziplock bag for paperwork (x1)

Manila envelope

- Manila envelope Glassine envelope with Sequence 0014 label (x1)

Note: No Air Waybill is provided as part of the kit. Shipment must be arranged through QuickSTAT.

Comments:

Form completed by BSS staff (insert name)	Date and time form completed
	<i>Date:</i> _____ <i>Time:</i> _____
Form sent to SAIC-F by BSS staff (insert name) Only if discrepancy noted	Date and time form sent
	<i>Date:</i> _____ <i>Time:</i> _____

		GTEx Work Instruction for Aqua Kit Receipt and Shipping	
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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.

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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

NOTE: Air Waybills will not be provided for this kit. Instead, each BSS must contact LaserShip® to schedule a pick-up at 1-877-807-1010.

Figure 1: Contents of postmortem aqua kit



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

NOTE: Air Waybills will not be provided for this kit. Instead, each BSS must contact LaserShip to schedule a pick-up at 1-877-807-1010.

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. Method of alert to CBR: **EMAIL**
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.
 - 3.4.6. Email recipients include:
 - 1. pbs.lab@vai.org
 - 2. Gtex@mail.nih.gov

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- 3.4.7. 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 LaserShip® 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

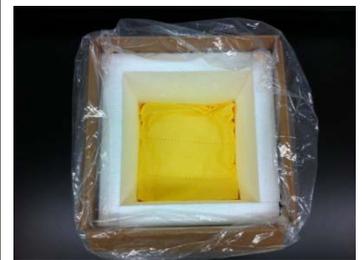
- 3.5. Packers and shippers of the aqua kit must be trained to handle IATA dangerous goods classes 3, 6.1, and 8. The regulations can change each year. **It is important that the BSS trained shipper review state and operator variations annually.**
- 3.6. Upon receipt and before kit is used, verify contents 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, scan the checklist to a PDF and email it to pbs.lab@vai.org or call 616-234-5122.
- 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 LaserShip®.
- 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.

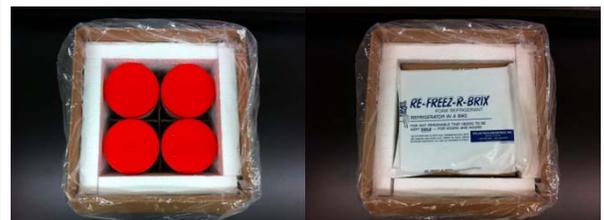
- 3.8.5. There will be a total of 4 plastic canisters containing either 4 or 6 PAXgene® tissue containers each.
- 3.8.6. In each shipping box, two absorbent pads are placed inside on the bottom of the box (Figure 3).

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.

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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, scan the checklist to a PDF and email it to pbs.lab@vai.org or call 616-234-5122 .
- 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 LaserShip® so that samples are picked on the following day. **THIS SHIPMENT NEEDS TO BE SHIPPED AS SOON AS POSSIBLE AFTER ALL SAMPLES ARE TRANSFERRED 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.

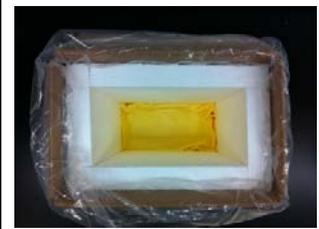
Note: When returning aqua kits as Cat B (UN3373), all unused PAXgene® containers must be removed. Sites should retain any unused PAXgene containers and not ship back. (The CBR will communicate with the BSSs on their stock levels and ship an extra empty aqua box(s), which can be used with the excess PAXgene®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

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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 (from Bio4D).

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 following address:

Van Andel Research Institute
333 Bostwick Ave, NE
Grand Rapids, MI 49503

Contact Information:

Dan Rohrer
616 234-5122
616 234-5300 (24 hours)
PBS.LAB@VAI.ORG

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4. REFERENCES

- 4.1.1. GTEEx Tissue Procurement SOP, PR-0004
- 4.1.2. GTEEx Chain of Custody Procedure, OP-0002
- 4.1.3. GTEEx Bio4D BSS User Guide, PBS-01.062
- 4.1.4. PAXgene® Tissue Container Product Circular

5. ATTACHMENTS

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



GTEx Discrepancy Checklist for Aqua Kit – Surgical

OP-0001-W3-F1

VER. 1.2.0

Effective Date: 04/19/2012

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Instruction: Use one form for each aqua kit received

Condition of kit received

- Acceptable Damaged, usable
 Damaged, NOT usable: contact pbs.lab@vai.org or 616-234-5122

For damaged items, please insert comment at end of form clarifying problem(s)

Kit ID number on outside of the box (GTEX-XXXX): _____

Fiberboard box with External label “caHUB Collection Aqua Kit – Surgical” and External kit ID label (x1)

<input type="checkbox"/> Shipping Canisters (x2) <input type="checkbox"/> External “Peel off label when samples shipped” label (x1) <input type="checkbox"/> Black 5" X 7" sticker to cover "Excepted Quantity" sticker upon return (x1)	<input type="checkbox"/> PAXgene tissue containers (x10) (<i>two per organ</i>) <input type="checkbox"/> Shipping canister with screw-cap lid and o-ring (x2) <input type="checkbox"/> Circular foam inserts with cut-outs for PAXgene containers (x4, 2 per canister) <input type="checkbox"/> Biohazard bag to hold foam insert (x2, 1 per canister)
--	---

Other Shipping Supplies

- Absorbent pad (x2) 18-in strip of wide, clear tape for outer box (x3)
 Strips of narrow, clear tape (x4) Cardboard insert (x1)
 1-lb freezer bricks (x4)
 Styrofoam™ insulation including lid, 4 walls, and bottom (x1)

Forms

- GTEx Discrepancy Checklist for Aqua Kit – Surgical form (x1) Gallon-sized ziplock bag for paperwork (x1)

Note: No Air Waybill is provided as part of the kit. Shipment must be arranged through LaserShip®.

Comments:

Form completed by BSS staff (insert name)	Date and time form completed
	<i>Date:</i> _____ <i>Time:</i> _____
Form sent to SAIC-F by BSS staff (insert name) Only if discrepancy noted	Date and time form sent
	<i>Date:</i> _____ <i>Time:</i> _____



GTEx Discrepancy Checklist for Aqua Kit – Postmortem

OP-0001-W3-F2

VER. 1.2.0

Effective Date: 04/19/2012

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Instruction: Use one form for each aqua box received

Condition of kit received

- Acceptable
- Damaged, usable
- Damaged, NOT usable: contact pbs.lab@vai.org or 616-234-5122

For damaged items, please insert comment at end of form clarifying problem(s)

Kit ID number on outside of box (GTEX-XXXX): _____

- Fiberboard box** labeled with External label “caHUB Collection Aqua Kit – Postmortem” and External kit ID label (x1)
- External “Peel off label when samples are shipped” label covering (x1)
- Black 5” X 7” cover-up label for covering “Excepted Quantity” sticker upon return (x1)

Other Shipping Supplies

<input type="checkbox"/> PAXgene tissue containers (x22 per box) (<i>two per organ</i>) <input type="checkbox"/> Shipping canister with screw-cap lid and o-ring (x4) <input type="checkbox"/> Circular foam inserts with cut-outs for PAXgene containers (x8, 2 per cylinder) <input type="checkbox"/> Biohazard bag to hold foam insert (x4, 1 per cylinder) <input type="checkbox"/> styrofoam insulation of 4 walls, bottom, and lid	<input type="checkbox"/> Absorbent pads (x2) <input type="checkbox"/> 24-in strip of wide, clear tape for outer box (x3) <input type="checkbox"/> 12-in strip of narrow, clear tape for inner canisters (x8) <input type="checkbox"/> 3-lb freezer bricks (x2) <input type="checkbox"/> Cardboard insert (x1) <input type="checkbox"/> Cardboard divider (x1) <input type="checkbox"/> Styrofoam® lid (x1)
--	--

Forms

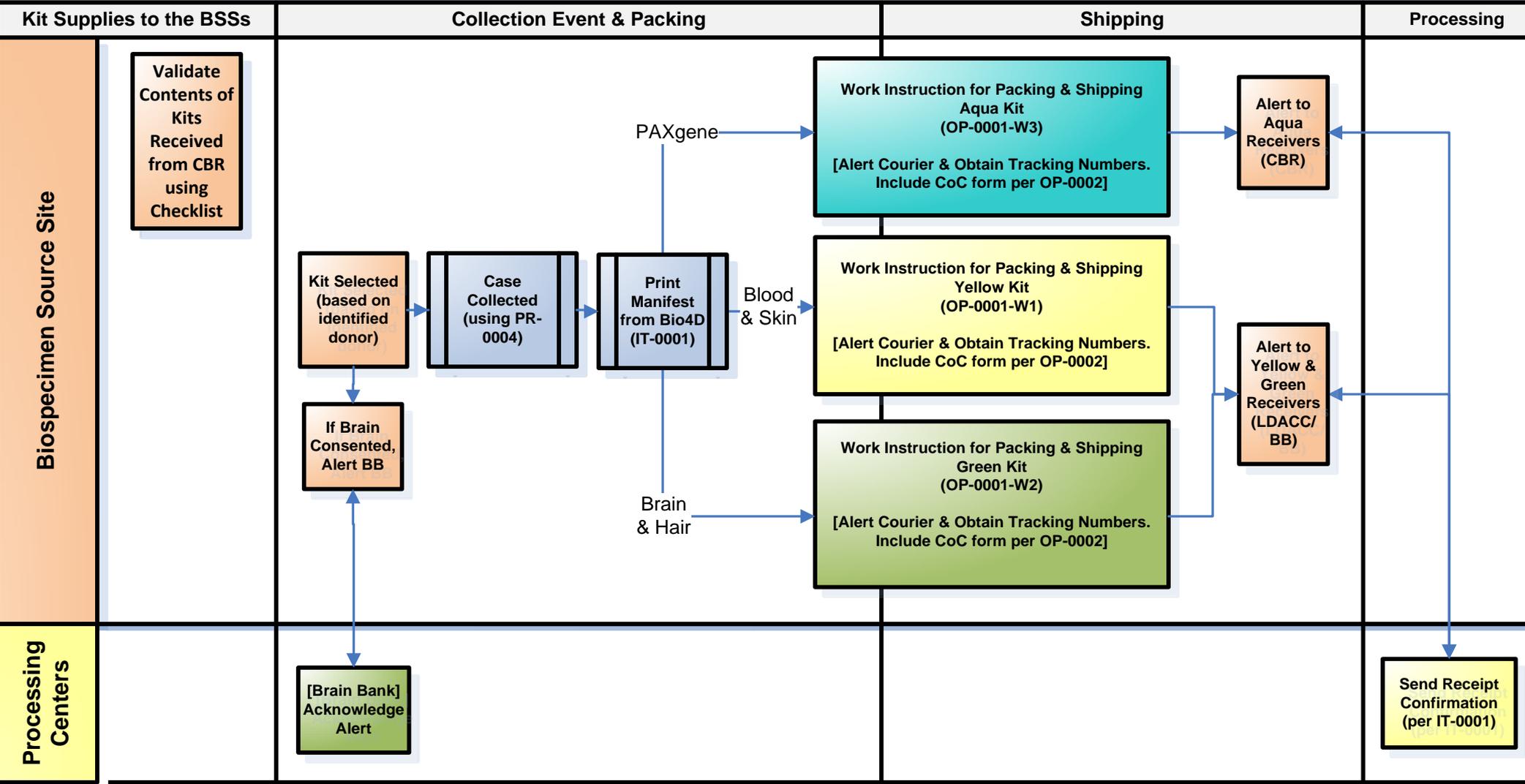
- GTEx Discrepancy Checklist for Aqua Kit – Postmortem form (x1)
- Gallon-sized ziplock bag for paperwork (x1)

Note: No Air Waybill is provided as part of the kit. Shipment must be arranged through LaserShip®.

Comments:

Form completed by BSS staff (insert name)	Date and time form completed
	Date: _____ Time: _____
Form sent to SAIC-F by BSS staff (insert name) <i>Only if discrepancy noted</i>	Date and time form sent
	Date: _____ Time: _____

Kit Receipt Supply Shipping Procedure Process Flow



PLACING CLINICAL TRIAL ORDERS

At the QuickOnline Main Menu, click on Place Clinical Trial Order to access a list of all of the existing Clinical Trials you can place an order for. If the Clinical Trial you need does not appear here, contact your administrator immediately. **The entire order can be placed in 4 very quick steps.**

1

Place Clinical Trial Order

Account No WEBDEMO

[Study](#) [Subject](#) [Specimen](#) [Order Information](#) [Confirm/Edit](#) [Order Submitted](#)

Protocol No	Title	Is Active	First Shipment Date	End Shipment Date
M HPV001	HPV Study	Y	May-07-2004	Dec-01-2006

Choose a Specimen:

[FROZEN SERUM](#)
[TEST MATERIAL](#)

Choose a Clinical Trial by **clicking on the specimen** you want to ship.

Enter the

- Number of Packages
- Unit Quantity for the Diagnostic Specimen
- Ready Date and Time
- Dry Ice Weight
- Total Shipment Weight

and click on **Create Order**.

Note: Sample description(s) will be pre-loaded into the system.

There are now only 2 quick steps to perform.

2

Place Clinical Trial Order

Account No WEBDEMO

[Study](#) [Subject](#) [Specimen](#) [Order Information](#) [Confirm/Edit](#) [Order Submitted](#)

Protocol No: M HPV001

Diagnostic Specimen Collection / Shipment

FROZEN SERUM

Number of Packages	Type of Packaging/Mat	Short Description	Full Description/ Comments	Unit Qty	Unit of measure	Unit Value
<input type="checkbox"/>	Box	PLASMA	TUBES CONTAINING A TOTAL VOLUME OF ____ ML OF HUMAN PLASMA SAMPLES. NOT KNOWN TO BE INFECTIOUS. FOR RESEARCH USE ONLY. HUMAN MATERIAL CONTAINING NO ANIMAL MATERIAL AND NOT OF TISSUE CULTURE ORIGIN. SAMPLES ARE PACKED ON DRY ICE AND MUST REMAIN FROZEN. NO COMMERCIAL VALUE. REASON FOR EXPORT: CLINICAL TRIAL SAMPLES SHIPPED TO BE USED FOR LABORATORY ANALYSIS IN CONNECTION WITH A PHARMACEUTICAL RESEARCH STUDY.	<input type="checkbox"/>	5.00ml	1.00

Ship to (Destination LAB)

QUALITY PROCESSING LAB / ROANOKE

Ready Date

| May | 02 | 2006 | 10 :47
dd hh mm

Shipment Information

Dry Ice Weight * 2.3 kg

Total Shipment Weight * lb

[Create Order](#) [Cancel](#)

3

Place Clinical Trial Order - Preview

Account No WEBDEMO

[Study](#) [Subject](#) [Specimen](#) [Order Information](#) [Confirm/Edit](#) [Order Submitted](#)

This page is used for reviewing your order before you submit it. You must still click on the "Submit Order" button in order for QuickOnline to receive it. Should you decide that you need to make changes to the order before submitting it, please click on the "Edit Order" button. Once you have submitted the order you must call your local Customer Service Office to change information on the order.

Account Information			
Name	ABC COMPANY	Account No	WEBDEMO
Caller	JOHN JONES	Phone	+49-731-150643
Shipment Information			
Status	Not Available	Service Type	BO-NON HAZARDOUS
Job No		Invoice No	
BOL No		Insurance Value	0.00 USD
Reference No	M HPV001	Customs Value	0.00 USD
Pieces	1 piece(s)	Commodity	CLINICAL SPECIMEN
Weight	23 lb(s)		
Cost Center			
Pickup		Delivery	
Ready Date:	May-05-2006 22:20	Deadline Date:	
JOHN JONES +49-731-150643 UNIVERSITY OF USLM DEPARTMENT TRANSFUSION MEDICINE 8 FLOOR ONCOLOGY DEPARTMENT HELMHOLTZSTRASSE 10 D-89081 GERMANY	DAVE HOGAN 800-488-4800 2254 QUALITY PROCESSING LAB 4 ROADWAY RD ROANOKE, VA 24005 UNITED STATES		
Packaging Information			
Is Dangerous	NO	Commodity Temperature	Dry Ice (-80c)
UN Number		Packaging Group	
Dimensional Packages Information			
Title	Actual Weight	Length	Width
Box	23 lb	45 in	76 in
		66 in	1360
			1
Diagnostic Specimen(s)			
Material	Quantity	Units of Measure	Subject ID
STUFF	12	SAL	
MUFFINS	1	56L.B	

[Submit Order](#) [Cancel Order](#)

[Edit Order](#)

The Document Center

4

Document Center - Job Details

[Recent Documents](#) [Job Search](#)

Online Document Center

[View a printable A4/B5/DCL](#)

[Print Labels](#)

[View a printable Commercial Invoice](#)

[Review Commercial Invoice](#)

[Place New Order](#)

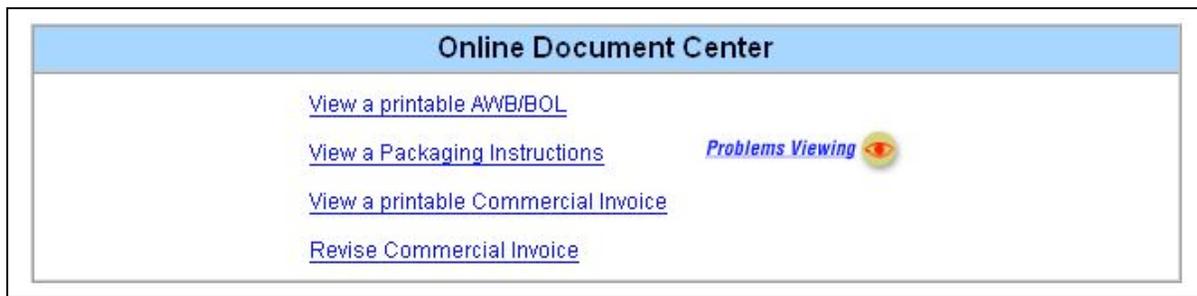
Account Information			
Name	ABC COMPANY	Account No	WEBDEMO
Caller	JOHN JONES	Phone	+49-731-150643
Shipment Information			
Status	New Shipment	Last Edit	May-05-2006
Job No	140051875W	Service Type	BO-NON HAZARDOUS
BOL No	140051979W	Invoice No	
Reference No	M HPV001	Insurance Value	0.00 USD
Pieces	1 piece(s)	Customs Value	0.00 USD
Weight	23 lb(s)	Commodity	CLINICAL SPECIMEN
Cost Center			
Pickup		Delivery	
Ready Date:	May-05-2006 22:20	Deadline Date:	
JOHN JONES +49-731-150643 UNIVERSITY OF USLM DEPARTMENT TRANSFUSION MEDICINE 8 FLOOR ONCOLOGY DEPARTMENT HELMHOLTZSTRASSE 10 D-89081 GERMANY	DAVE HOGAN 800-488-4800 2254 QUALITY PROCESSING LAB 4 ROADWAY RD ROANOKE, VA 24005 UNITED STATES		
Dimensional Packages Information			
Title	Actual Weight	Length	Width
BOX	23 lb	45 in	76 in
		66 in	1360
			1
Diagnostic Specimen(s)			
Material	Quantity	Units of Measure	Subject ID
STUFF	12	SAL	
MUFFINS	1	56L.B	
Status History			
Time	Event		
May-05-2006 22:20	New Shipment		

Review the Order – if it's okay, click on **Submit Order** button. (Click on Edit Order to go back).

The Order has been submitted. You can now proceed to the **Document Center** (at this screen).



Once you have submitted your order, you will see a section of the screen entitled Document Center, where you can print vital documents for your shipment. For example, you can use the link that says **View a Printable AWB/BOL** to print a Bill of Lading. Directly below that, you will see links to other documents you can print (such as Packaging Instructions):



For International shipments, if you need to print a Commercial Invoice (International Orders ONLY). QuickOnline automatically generates the Commercial Invoice for you. If you need to revise/edit the Commercial Invoice, simply click on the **Revise Commercial Invoice** link. The system will generate the Invoice for you.

Date of Export		Export Reference	
Apr	14	2004	EW4528202
dd		yyyy	
Tax Id No (EIN) or Shipper's VAT No		Consignee's Vat No	
<input type="text"/>		<input type="text"/>	
Shipper:		Consignee:	
UNIVERSITY OF ULM DEPARTMENT TRANSFUSION MEDICINE HELMHOLZSTRASSE 10 D-89081 GERMANY		QUALITY PROCESSING LAB 4 ROADWAY RD ROANOKE VA 24005 UNITED STATES	
KLAUS SCHWARZ +49-731-150642		DAVE HOGAN 800-488-4400 EXT 2258	
Country of Export	<input type="text"/>	Buyer (if other than Consignee)	
GERMANY	<input type="text"/>	Company Name <input type="text"/>	
Country of Manufacture	<input type="text"/>	Address1 <input type="text"/>	
GERMANY	<input type="text"/>	Address2 <input type="text"/>	
Country of Destination	<input type="text"/>	Address3 <input type="text"/>	
UNITED STATES	<input type="text"/>	City <input type="text"/>	
		State / Province <input type="text"/>	
		Country <input type="text"/>	
		Zip / Postal Code <input type="text"/>	

When **Revising the Commercial Invoice**, you will need to:

- Change the necessary fields.
- Click the **Preview Invoice** button.
- If you are satisfied with the result, click on the **Save Invoice** button.