1.0 STANDARD OPERATING PROCEDURE (SOP): SPECIMEN SHIPPING INSTRUCTIONS

1.1 Shipping Overview

Specimens which have been entered into the VSIMS database as part of the Lung Team Project 2 (LTP2), will be shipped to the Frederick National Laboratory for Cancer Research (FNLCR) in Frederick, MD (aka NCI-Frederick) for inventory, blinding, array, and shipment to testing laboratories. Post-analysis specimen remnants will return to the FNLCR for long-term storage at the NCI at Frederick Central Repository (repository).

1.2 To Initiate a Shipment:

1. Contact the FNLCR via email at: NCI-FrederickCSPBPTLStaff@mail.nih.gov to schedule a shipment. Sites should only ship **Monday through Wednesday**. However, the FNLCR is closed on Federal holidays and may also have abbreviated ship windows for the months of November and December for the Holidays. **Also, be aware of email notifications from the DMCC regarding FNLCR closures during holidays and inclement weather.**
2. Estimate the shipment weight (including container, dry ice and specimens to be shipped) and contact Jack Cunningham (jackcunn@bu.edu) to arrange to receive a pre-paid FedEx airbill to be used for shipment. Specimens will be shipped to the following address (when received, please verify that your airbill has the correct information):

    Norma Diaz
    BioProcessing Laboratory
    4600 Wedgewood Blvd Suite K
    Frederick, MD 21703
    (301) 732-8252
    NCI-FrederickCSPBPTLStaff@mail.nih.gov

1.3 Packaging Supplies for Shipment

Supplied by Boston:

- A Thermosafe multipurpose insulated shipment boxes. NCI-Frederick will return the shipment box to the site for reuse, if needed.
- UN3373 Biological Substance, Category B Labels
- UN1845 Class 9 Dry Ice labels

Each site should purchase:

- Absorbent pads
- Biohazardous leakproof bags
- Secondary container for the specimen such as a freezer box with internal grid dividers.
- Rubber bands
- Dry-ice
- Materials for shipping PAXgene tubes (see section 1.5)

1.4 Packing Requirements for UN3373 Biological Substance, Category B:

All shipments must conform with regulations for transport via air travel. Shippers should be certified to ship UN3373 Biological Substance, Category B and UN1845 Class 9 Dry ice by IATA, and should follow Packing Instruction 650 (PI 650). IATA Dangerous Goods Regulations are updated annually; make sure you are following the current year regulations. An example of the PI 650 can be found here:
https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-pi650.pdf

Labeling:

- To and From address labels
- 24-hour emergency contact (Must be answered by a person with knowledge of the dangerous good(s) being shipped) as a separate label or as part of the From label.
- UN3373 Biological Substance, Category B Hazard label

- UN1845 Class 9 Dry Ice label
- Two "This way up" Arrow labels on opposite sides of the box
  Note: With the exception of the arrows on two opposing sides, all other labels should be located on the same side as each other and may not overlap in any way.

Packaging:

- Leak-proof primary receptacle(s) must not contain more than 1L, such as cryovials.
- Leak-proof secondary packaging such as leakproof biohazard bag; and
- Either the primary or secondary packaging must be able to withstand 95kPa of internal pressure (Examples are cryovials with o-rings, snapcap microfuge tubes with cap locks, or blood tubes in canisters with an o-ring)
- Individual primary containers should be separated from each other (Examples are cryovials in a freezer storage box that has a grid divider, or blood tubes in padded sleeves inside a canister).
- A rigid outer packaging (the fiberboard box with the labels) that conforms to PI 650

Assembling:
Frozen liquid samples:

1. Check that all primary containers are closed all the way. Specimens can expand during the freezing process, which can make caps/lids loose.
2. Place primary containers into the dividers that will separate them (freezer box, padded tube slots, foam holders, etc.). If this container has a lid, secure it. For example, all freezer boxes should be held closed with a rubber band.
3. Place primary container with divider into the secondary container and add the required absorbent. For example, a freezer box with cryovials into a leakproof biohazard bag with absorbent sheets.
4. Repeat until all boxes are packaged.
5. Add sufficient dry ice to the packaging.
6. Include the printed manifest between the Styrofoam shipper and the outer fiberboard box.
7. Tape the packaging closed.
8. Verify all markings, labels, and FedEx label are attached.
9. Ship via FedEx.

Non-liquid samples:

1. Follow the same steps as for liquid samples, however, no absorbent sheets are needed.
2. The item being shipped should be in packaging that is sufficient to prevent poking through packaging. For example, brushes should not be shipped directly in a biohazard bag. Contact FNLCR for specific guidance on packaging selection, if needed. See Appendix 1 for examples of suitable packaging solutions.

1.5 Packaging PAXgene tubes for shipment:

These frozen tubes are very prone to cracking, so it's very important that they be packaged individually and padded/protected from the movements of transport. These tubes crack if not thawed step-wise, such as putting them on the counter without dry ice while packing. ALL Tubes should remain on dry ice, during the entire packaging process. Essentially, the packaging must meet PI 650 requirements for separation of the tubes, absorbent material, sufficient padding, leakproof layers, and able to withstand 95kPa.

***There are three options for shipping PAXgene:**

(1) Use 5-in boxes with 36-grid dividers so the tubes ship upright. Tubes in grid, grid in box, box in biohazard bag with absorbent sheet, in a Tyvek outer envelope.
(2) Use sleeves and biobags to ship the tubes laying down.
    a. (a) Tube in separator sleeves, in biohaz bag with absorbent sheet, wrapped in bubble wrap, in a freezer box, in a Tyvek outer envelope, or
    b. (b) tube in an absorbent sleeve, wrapped in bubble wrap, in a freezer box, in a biohazard bag, in a Tyvek envelope
(3) Use a tube mailer so the tubes ship laying down. Tubes in the mailer with absorbent sheet, in a biohazard bag, in the mailer box, in a Tyvek outer envelope.

Here are some example products for the above.
https://www.fishersci.com/shop/products/therapak-aqui-pak-absorbent-sleeves-1/22130043?ef_id=EAIaIQobChMI4b_NpZLw8wIVkqjICh3hJgbMEAQYAiABEgLB1vD_BwE:G:s&ppc_id=PLA_goog_2086145680_81843405274_22130043__386247001354_14906501898810458775&ev_chn=shop&s_kwcid=AL!4428!3!386247001354!!!g!827721591040!22130043&gclid=EAIaIQobChMI4b_NpZLw8wIVkqjICh3hJgbMEAQYAiABEgLB1vD_BwE

https://www.fishersci.com/shop/products/therapak-teartech-tube-shuttles-2/p-2682962

https://www.coleparmer.com/i/thermosafe-339-shipper-5-tube-mailer-13-x-103-mm-tubes-150-cs/0372701?PubID=UX&persist=true&ip=no&gclid=EAIaIQobChMIgpGziJPw8wIVy56zCh1lCwk-EAQYBCABEgKOo_D_BwE

https://us.shop.lifescience.inmarkinc.com/products/stp-710

1.6 "Shipping" Specimens in VSIMS:

1. Create the shipment in VSIMS (see section 5.6 of the Manual of Operations), and note the FedEx tracking number from the airbill created in Section 1.2, step 2 (above).
2. VSIMS will generate a Shipping List and send a confirmation email to FNLCR.
3. Print 2 copies of the Shipping List from VSIMS, put one in the box and keep the other with onsite study records.
4. Seal the box, affix the FedEx Shipping Label/Airbill, the UN3373 label, the Dry Ice label and place the box for pick up.

Please note the following important information:

- Biological Substance, Category B (UN3373) shipments may not be dropped off in a FedEx Express Drop Box
- FedEx Office Print & Ship Centers and FedEx World Service Center locations (other than those that do accept regular dangerous goods shipments) do not accept shipments classified as Biological Substance, Category B (UN 3373)
- Biological Substance, Category B (UN3373) shipments may be picked up by FedEx Express couriers or dropped off at specific locations. If you don't have a regular scheduled pickup, schedule a FedEx Express® pickup or call 1.800.GoFedEx (1.800.463.3339) to be directed to a FedEx location that accepts these shipments.

1.7 Specimens Received at FHLCR:

The FNLCR will confirm the package arrived via VSIMS. After a vial-level inventory and review, the FNLCR will confirm final receipt via VSIMS, or will enter an issue in VSIMS to resolve discrepancies.

Appendix: Examples of Appropriate Packaging


SAFI-PAK

Frozen, non-liquid packaging

Frozen liquid packaging

Frozen liquid specimen with secondary container (bag) that can withstand inner pressure of 95kPa