Standard Operating Procedure

Packing and Shipping of Ambient, Refrigerated, Frozen and Combined Biological Samples

I. POLICY: The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) ensure the safety and well-being of employees, students, and laboratory personnel in the transportation of any biological specimens by air, sea or land.

II. PURPOSE: The objective of this Standard Operating Procedure (SOP) is to provide guidance on the transport of specimens; it is intended to ensure that they are packaged and handled in a suitable manner to safeguard the health, safety and welfare of employees handling the pathological specimens and also to ensure that the specimens are packaged in suitable receptacles and maintained under suitable environmental conditions for transport (air, sea and land) to referral or other laboratories. This procedure also ensures that the integrity of the specimens is preserved for accurate analysis by the receiving laboratory.

III. Area(s) of Responsibility: This SOP applies to the Principal Investigator (PI), laboratory personnel and authorized students that collaborate in the laboratory facility.

IV. DEFINITIONS
1. Absorbent pack: A material included within a package to soak up liquids resulting from leakage or liquefaction of contents.
2. Ambient: this phrase means that the specimen must be at room temperature during the entire collection procedure.
3. UN3373 Biological Substance Category B: are specimens being transported for investigational purposes. Training requirements for persons responsible for packing and shipping biological substance, Category B, UN3373 has been redefined in the International Civil Aviation Organization (ICAO) Technical Instruction as well as the International Air Transport Association (IATA) dangerous goods regulations. Example may include human or animal excreta, secretions, blood tissue, and bodily fluids.
4. Cardboard box: a large box that is used to transport multiple packages.
5. Courier: is a person who delivers messages, packages, and mail.
6. Combined samples: this phrase means that the specimens that are in the box are in ambient and frozen state.
7. Dry Ice: Solid carbon dioxide that sublimes at −78.5°C (−110°F) and is used primarily as a coolant.
8. **Frozen**: this term indicates the specimen was properly maintained in frozen state, preferable below -20°C. Frozen specimens require dry ice to maintain a frozen state during shipment. Avoid a frost-free refrigerator during storage of specimens.

9. **Gel Pack**: is a portable plastic sac filled with water, or refrigerant gel or liquid. For use the contents are frozen in a freezer.

10. **IATA**: the International Air Transport Association works with its airline members and the air transport industry as a whole to promote safe, reliable, secure and economical air travel for the benefit of the world’s consumers. IATA’s 260 member airlines comprise 83% of all air traffic. IATA is present in some 60 countries over the world.

11. **Referring laboratory**: a laboratory that sends biological substance or environmental sample to a referral laboratory for further investigations.

12. **Refrigeration during collection**: this phrase means the specimen must be 2-8 °C during the entire collection procedure.

13. **Requisition form**: a formal written request on a pre-printed form that asks for information of the patient identification, information of the person collecting the sample(s) and also asks information to calculate specimen stability.

14. **Specimen Collection Bag**: these bags are designed for the safe transportation of specimens and documentation. Each bag is printed with the biohazard symbol and offers checkmark boxes to indicate special handling instructions.

15. **Shipper**: individual or agency that has the license to transport specimen

16. **Styrofoam container**: a type of polystyrene, a light white plastic container used especially for putting delicate objects inside the containers to protect them from damage, or for putting around something to prevent it from losing heat.

17. **White kit box**: it is a box with the visit specific collection supplies for the collection of the samples; expiration dates are printed on the outside of the kit box. The expiration date of each kit corresponds to the shortest expiration date of the tube(s) within the kit.

18. **UN1845**: is a label that indicates that dry ice is use as a refrigerant; must be on the same surface of the package as the hazard label or Class 9 label. When a company ships dry ice the shipment must be prepared by an employee trained in the Dangerous Goods regulations.
V. PACKAGING PROCEDURES FOR AMBIENT SAMPLES
Biological Substance, Category B

1. Call your courier to schedule your pick-up and notify the routine address.
2. Insert the tube(s) into the specimen collection bag containing an absorbent pack. Place bag on flat surface to minimize wrinkles, especially at adhesive sealing area. Remove tape liner to expose adhesive. Fold along bag opening so star is inside of box shape. Press from center to edge to seal.
3. Fold the white copy of the completed requisition form and place it into the pocket on the riverside side of the specimen collection bag. The bar code must be visible.
4. Take a gel pack and fill it to the indicator line with cool tap water. Seal the bag.
5. Lightly press the absorbent pack to expel its contents. Massage the bag until water has been absorbed and a gel material has formed. Expel the air from the gel pack and reseal.
6. Place the specimen collection bag on top of the gel pack. Wrap the gel pack around the specimen collection bag, sandwiching the specimens in the middle. Do not insert the specimen containers directly into the gel pack.
7. Place the gel pack in to the white kit box.
8. Insert the kit into the zip bag.
9. Place the zip bag into the shipping cartoon. Fill empty spaces with cushioning material (i.e. paper).
10. Seal the shipping cartoon securely. Affix the label with your address on the box. (See Appendix I)
11. Complete and affix the airway bill to the designated spot on the box. (See Appendix I)

VI. PACKAGING PROCEDURES FOR FROZEN SAMPLES
Biological Substance, Category B

1. Call your courier to schedule your pick-up and notify the routine address.
2. Insert the tube(s) into the specimen collection bag containing an absorbent pack. Place bag on flat surface to minimize wrinkles, especially at adhesive sealing area. Remove tape liner to expose adhesive. Fold along bag opening so star is inside of box shape. Press from center to edge to seal.
3. Fold the white copy of the completed requisition form and place it into the pocket on the riverside side of the specimen collection bag. The bar code or any other pertinent information must be visible.

4. Fill half of the styrofoam container with dry ice and insert the specimen collection bag(s). Then fill the container using at least 2.0 kg dry ice.

5. Replace the styrofoam lid. It is recommended that you ship no more than two specimen collection bags per 2.0 kilograms of dry ice.

6. Seal the shipping carton securely. Affix the label with your address on the box. (See Appendix II)

7. Complete and affix the shipping document to the designated spot on the box. (See Appendix II)

**VII. PACKAGING PROCEDURES FOR COMBINED AMBIENT - FROZEN SAMPLES**

*Biological Substance, Category B*

1. Call your courier to schedule your pick-up and notify the routine address.

2. Place the tube(s) into the specimen collection bag containing an absorbent pack. Place bag on flat surface to minimize wrinkles, especially at adhesive sealing area. Remove tape liner to expose adhesive. Fold along bag opening so star is inside of box shape. Press from center to edge to seal.

3. Fill half of the styrofoam container with dry ice and insert the specimen collection bag(s). Then fill the container using at least 2.0 kg dry ice.

4. Replace the styrofoam lid. Do not ship more than two specimen collection bags of frozen samples per shipment.

5. Place the cardboard space on top of the styrofoam.

6. For the ambient tubes, repeat step 1. Then fold the white copy of the completed requisition form and place it into the pocket on the reverse side of the specimen collection bag. The bar code or any other pertinent information must be visible.

7. Take a gel pack and fill it to the indicator line with cool tap water. Seal the bag.

8. Lightly press the absorbent pack to expel its contents. Massage the bag until water has been absorbed and a gel material has formed. Expel the air from the gel pack and reseal.

9. Place the specimen collection bag on top of the gel pack. Wrap the gel pack around the specimen collection bag, sandwiching the specimens in the middle. Do not insert the specimen containers directly into the gel pack. Ensure that ambient samples are placed in the fold of the gel pack.
10. Place the specimen collection bag on top of the gel pack, then wrapped in the gel pack into the kit box.
11. Insert the kit into the zip bag.
12. Place the zip bag into the cardboard box. Fill empty spaces with cushioning material (i.e. paper).
13. Seal the shipping carton securely. Affix the label with your address on the box. Place the specimen collection bag on top of the gel pack. Verify the amount of dry ice in kilograms on the UN1845 label. (See Appendix III)
14. Complete and affix the airway bill to the designated spot on the box. (See Appendix III)

VIII. PACKAGING PROCEDURES FOR REFRIGERATED SAMPLES
Biological Substance, Category B

1. Call your courier to schedule your pick-up and notify the routine address.
2. Place refrigerant pack in freezer overnight before packing
3. Place the tube(s) into the specimen collection bag containing an absorbent pack. Place bag on flat surface to minimize wrinkles, especially at adhesive sealing area. Remove tape liner to expose adhesive. Fold along bag opening so star is inside of box shape. Press from center to edge to seal.
4. Place one frozen refrigerant pack onto the styrofoam container.
5. Place a layer of paper towels on top of the refrigerant pack. Place the specimen collection bag containing refrigerated specimens into the styrofoam. Place a second layer of paper towels on top of the specimen collection bag followed by a second refrigerant pack. Fill the excess space with filler paper.
6. Replace the Styrofoam lid.
7. Seal the shipping carton securely. Affix the label with your address on the box. (See Appendix IV)
8. Complete and affix the airway bill to the designated spot on the box. (See Appendix IV)

IX. SHIPPING DOCUMENTS
Biological Substance, Category B

1. Call your courier to schedule your pick-up and notify the routine address.
2. Complete the required contact information fields.
3. You must enter the appropriate air bill number; total number of packages; signature of shipper, printed name and date. (See Appendix V)

X. References:

Covance Central Laboratory Services Manual; Revised January 31, 2014.
7. Insert the kit into the zip bag.  

8. Place the zip bag into the shipping carton. Fill empty spaces with cushioning material (i.e. paper).

Note: If the kit box is too large to place in the ambient shipping carton, wrap a rubberband around the Gel Pak. Place the Gel Pak containing the specimen collection bag inside the large zip bag. Place the zip bag into the shipping carton. Fill empty spaces with cushioning material (i.e. paper).

9. Seal the shipping carton securely. Affix the label with your address on the box as indicated on the picture above. 

Note: Your shipment may be delayed if the label is not affixed to the box.

10. **US domestic shipments:** Complete and affix the airway bill to the designated spot on the box.  
**Rest of world:** Insert the shipping documentation into the transparent pouch ensuring that the airway bill remains visible. Affix the pouch to the cardboard box on the “Place airway bill here” section.
5. Seal the shipping carton securely. Affix the label with your address on the box as indicated on the picture above.
   **Note:** Your shipment may be delayed if the label is not affixed to the box.

6. **US domestic shipments:** Complete and affix the shipping document to the designated spot on the box.
   **Rest of world:** Insert the shipping documentation into the transparent pouch ensuring that the airway bill remains visible. Affix the pouch to the cardboard box on the “Shipping documents” section.
9. Place the specimen collection bag wrapped in the Gel Pak into the white kit box.

10. Insert the kit into the zip bag.

11. Place the zip bag into the cardboard box. Fill empty spaces with cushioning material (i.e. paper).

**Note:**
If the kit box is too large to place in the shipping carton, wrap a rubber band around the Gel Pak. Place the Gel Pak containing the specimen collection bag inside the large zip bag. Place the zip bag into the shipping carton. Fill empty spaces with cushioning material (i.e. paper).

12. Seal the shipping carton securely. Affix the label with your address on the box as indicated on the picture above.

**Note:** Your shipment may be delayed if the label is not affixed to the box. Verify the amount of dry ice in kilograms on the UN1845 label.

13. **US domestic shipments:** Complete and affix the airway bill to the designated spot on the box.

**Rest of world:** Insert the shipping documentation into the transparent pouch ensuring that the airway bill remains visible. Affix the pouch to the cardboard box on the “Shipping documents” section.
5. Seal the shipping carton securely. Affix the label with your address on the box as indicated on the picture above. 
**Note:** Your shipment may be delayed if the label is not affixed to the box.

6. US domestic shipments: Complete and affix the airway bill to the designated spot on the box. 
**Rest of world:** Insert the shipping documentation into the transparent pouch ensuring that the airway bill remains visible. Affix the pouch to the cardboard box on the “Shipping documents” section.