		<b>Biospecimen Pre-Analytical Variables (BPV) Work Instruction for the Red (LN2) Kit Receipt and Shipping</b>	
OP-0014-W2	VER. 03.00	Effective Date: TBD	Page 1 of 5

## 1.0 PURPOSE

This work instruction provides the specific steps necessary to pack and ship the frozen blood derivatives and frozen tissue blocks in the BBRB/BPV LN2 Vapor Phase Kit (the Red Kit).

The procedure section is divided into four subsections: the kit receipt at the biospecimen source site (BSS), packing instructions, shipping instructions, and alert of shipment.


## 2.0 ENVIRONMENTAL HEALTH AND 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 regulations.
- 2.2. Persons packaging must be trained in the use, handling, and shipping of liquid nitrogen and vapor-phase shippers. Packers and shippers of the Red Kit must be certified to ship IATA class 6.2 material.
- 2.3. Use LN2 safe freezer gloves when working with LN2.

## 3.0 PROCEDURE

### Kit Receipt at the BSS

- 3.1. Contents correspond to supplies shown in Figure 1.
  - 3.1.1 BPV Discrepancy Checklist for Red Kit (OP-0014-W2-F1) with Ziploc bag (not shown in Figure 1).
  - 3.1.2 One zip tie and one FedEx tag (not shown in Figure 1).
  - 3.1.3 One ShipsLog magnetic key fob for starting the data logger (not shown in Figure 1).
  - 3.1.4 NOTE: Key fob not present with all CryoShippers.
  - 3.1.5 Liquid Nitrogen MVE vapor-phase CryoShipper with outer plastic shipping carton and data logger lid.
  - 3.1.6 Upon receipt and before kit is used, verify the contents. Do NOT use the kit if it is incomplete when verified against the **BPV Discrepancy Checklist for Red Kit (OP-0014-W2-F1)**.
  - 3.1.7 If the kit is incomplete or broken:
    - 3.1.7.1 Complete BPV Discrepancy Checklist for Red Kit (OP-0014-W2-F1).
    - 3.1.7.2 Convert to PDF and email to the appropriate email address or call the provided phone number.
    - 3.1.7.3 Comprehensive Biospecimen Resource (CBR) will follow up with an action for resolution.

		<b>Biospecimen Pre-Analytical Variables (BPV) Work Instruction for the Red (LN2) Kit Receipt and Shipping</b>	
OP-0014-W2	VER. 03.00	Effective Date: TBD	Page 2 of 5




*Figure 1: Red Kit (LN2 dry vapor shipper)*

### **Packing Instructions**

- 3.2. Please request a LN2 vapor-phase dry shipper at least 48 hours in advance of your shipment. Remember, the shipper will need to be charged prior to use at the BSS! Each BSS will not have its own shipper.
  - 3.2.1 Please email the appropriate personnel to request a Red Kit shipper. CC the BSS technical project manager (TPM), CBR TPM, and CBR coordinator on the email.
- 3.3. One day in advance of the shipment, complete the following steps:
 

NOTE: The BSSs will be directed to ship eight cases of frozen tissue and eight cases of frozen cryovials containing blood derivatives at a time to reduce shipping costs. Cases should be held at -135°C to -196°C until eight cases are ready to ship (fewer cases may be shipped under the direction of the BSS TPM). The vapor-phase shippers will hold three 2-inch freezer boxes holding no more than 21 cryosettes per box (7 per case) and one 2-inch freezer box of 80 cryovials (10 per case).

  - 3.3.1 Remove the MVE dry shipper from storage, and fill with LN2 to allow the shipper to charge.
  - 3.3.2 Open the outer plastic shipping container that the dewar is in and remove the round cork lid.
  - 3.3.3 Fill the unit to the bottom of the neck tube (the top of the inner steel lining).

		<b>Biospecimen Pre-Analytical Variables (BPV) Work Instruction for the Red (LN2) Kit Receipt and Shipping</b>	
OP-0014-W2	VER. 03.00	Effective Date: TBD	Page 3 of 5

3.3.3.1 Follow site-specific established safety practices and procedures for transferring LN2.

3.3.3.2 Transfer LN2 using LN2 hose with phase separator or pouring container using a funnel.

3.3.4 Replace cork lid and allow unit to stand for 24 hours (cooling down/charging unit) or 2 hours, depending on model being used.

**NOTE: 2 hour units will be labeled on the inner LN2 vessel as “QWick.” If the unit does not say “QWick,” it must be charged for 24 hours.**

3.3.5 For the 24 hour units, to achieve 100% absorbed capacity you may need to refill (top off at least once).

3.4. On the day of shipment, complete the following steps:

3.4.1 Pour off excess LN2 from the cryoshipper just prior to shipment. No liquid should be visible on the bottom of the inner dewar. Dispose of LN2 according to site-specific guidelines. It may be poured back into a dewar and left to safely evaporate.

3.4.2 Place the three 2-inch boxes containing the eight cases of BPV frozen tissue and cryovials to be shipped in the bottom of the dewar while wearing LN2 safety gloves.

3.4.3 Place the cork lid on the dewar. Be sure to follow the **LN2 Dry Shipper Data Logger Usage (PBS-01.090)** procedure for activating the logger prior to shipment.

3.4.4 Place a copy of the manifest and the **Chain of Custody Form (OP-0011-F1)** inside the outer plastic shipping container and beside the dewar. **Note: Keep a copy of each form for your records.**

3.4.5 Place the included pre-printed FedEx label on the FedEx tag and attach them to the outside of the vapor shipper using the included zip tie.

3.4.5.1 Close the outer shipping carton with the two latches. Feed the zip tie through the hole of the handle on one latch and into the spring attached to the carton. Once the zip tie is fed through the handle and carton, bend the FedEx tag in two so the two holes line up. Feed the zip tie through the holes in the tag and close the zip tie.

3.4.5.2 Place the pre-printed FedEx label on the FedEx tag where the tag says “Place Label Here.”

3.5. Remove the yellow “Peel Off Label When Samples Are Shipped” label, exposing the UN3373 label.

### Shipping Instructions

- 3.6. Contact the CBR to coordinate the shipment prior to sending the Red Kit.
- 3.7. Verify all packing steps are complete, and ship to the CBR via FedEx overnight using the included pre-printed FedEx return label.
- 3.8. Deliver to or call FedEx for shipment of the vapor shipper.

### Alert of Shipment

- 3.9. Timeline of alert to CBR
  - 3.9.1 Upon shipment of specimens; please coordinate with BSS TPM and CBR TPM.
- 3.10. Method of alert to CBR: **EMAIL**
  - 3.10.1 Please include all BPV case IDs (#) in the subject line of all email.
  - 3.10.2 Indicate notice of pending shipment.
  - 3.10.3 Indicate date of anticipated shipment.
  - 3.10.4 Indicate date of anticipated arrival at the CBR.
  - 3.10.5 Indicate tracking number used to ship specimens.
  - 3.10.6 Email recipients should include the appropriate personnel.
- 3.11. Use the following instructions for the email template for correspondence to the CBR:
  - 3.11.1 Subject line: name of BSS, all BPV case IDs (# X Donors), Red Kit
  - 3.11.2 Body of email:

*Hello CBR,  
Please consider this email notification that (#) cases of frozen tissue and (#) cases of frozen cryovials containing blood derivatives are being packed and shipped.*

    - *The FedEx shipment will be sent 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>.*

*Thank You,  
<Insert Site Name>*
- 3.12. Email a copy of the **Chain of Custody Form (OP-0011-F1)** to the appropriate personnel.

#### **4.0 ACRONYMS**

- 4.1. **BPV** Biospecimen Pre-Analytical Variables
- 4.2. **BSS** Biospecimen Source Site
- 4.3. **CBR** Comprehensive Biospecimen Resource
- 4.4. **IATA** International Air Transport Association
- 4.5. **TPM** Technical Project Manager

#### **5.0 REFERENCES**

- 5.1. Biospecimen Pre-Analytical Variables (BPV) Program Blood Sample Collection and Processing, PR-0005
- 5.2. Biospecimen Pre-Analytical Variables (BPV) Program Surgical Tissue Collection and Fixation, PR-0006
- 5.3. LN2 Dry Shipper Data Logger Usage, PBS-01.090
- 5.4. Chain of Custody Procedure, OP-0011

#### **6.0 ATTACHMENTS**

- 6.1. BPV Discrepancy Checklist for Red Kit, OP-0014-W2-F1
- 6.2. Chain of Custody Form, OP-0011-F1