

CHAPTER 5
SHIPPING PROCEDURES

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5.1 SHIPPING CBUS FROM COLLECTION CENTERS TO CORD BLOOD BANKS

Principle

Collected umbilical cord blood has been found to maintain cell viability when temporarily stored at 15° to 25°C. To ensure proper temperature maintenance during shipment, standard platelet shippers are used. In addition, shipments are tracked using a post-collection storage and shipment log. **This procedure should be followed in conjunction with SOP 3.4, Post-Collection Storage of CBU Prior to Transport to CBB Processing Laboratory.**

Specimen

Umbilical Cord Blood Units collected after placental delivery into a collection bag(s) containing CPD anticoagulant and packed in a numbered platelet shipper (see SOP 3.4).

Equipment

Packed Numbered Platelet Shipper

Supplies

Shipping Log
Adhesive Tape
Shipping Labels
Shipping Envelope

Procedure

1. Check the platelet shipper number against the number recorded on the Shipping Log.
2. Check the outside of the shipper for damage. If damage has occurred, transfer all packed items to a new shipper as described in SOP 3.4. Return the damaged shipper to the CBB Processing Laboratory.
3. Check the following labels are securely attached to the outside of the platelet shipper:
STUDY-SPECIFIC LABEL (See SOP 3.4, Post Collection Storage of CBUs Prior to Transport to CBB Processing Laboratory)
“CORD BLOOD BANK ADDRESS/IF SHIPMENT IS DELAYED ... NOTIFY”
“PERISHABLE”
“WARNING! DO NOT ICE”
Replace missing and/or loose labels.

4. Visually inspect stored CBUs to ensure that all zipper-locked bags are securely sealed. Seal bags if necessary.
5. Check unit bar codes against the bar codes on the Shipping Log and record the total number of units in the shipper. Resolve any discrepancies. Record unresolved discrepancies on the log.
6. Check for evidence of blood spills. Record evidence of blood spills in the appropriate 'Comment' line on the Shipping Log. Do not discard or transfer any unit to a new shipper if a blood spill occurs. All collected units will be discarded by the Cord Blood Bank.
7. Repack the shipper (see SOP 3.4). If substantial space exists, and/or extended storage is anticipated, add additional conditioned TSPs.
8. Complete the Shipping Log by recording the number of units packed, the date and time packing was completed, and the packer's study ID number. Sign the log and place in the shipper.
9. Place the foam plug in the box and push until it is on top of the TSPs. Close the shipper lid and tape the lid securely to the base.
10. Transport the filled shipper to the CBB Processing Laboratory. If a courier service is used for this purpose, verify that the shipper will be transported and handled carefully.

Quality Control

1. The above steps are the responsibility of a trained staff member.
2. One staff member will prepare and verify each shipment.
3. Documentation of this responsibility is indicated by the name/initials of the staff member on the Shipping Log.

5.2 SHIPPING CRYOPRESERVED CBUS TO TRANSPLANT CENTERS

Principle

Shipping of cryopreserved umbilical cord blood units requires that the unit remains in a frozen state for at least 72 hours. “Dry” shipper containers allow shipment of cryopreserved units at liquid nitrogen temperatures without the risk of liquid nitrogen spillage in transit. A fully charged “dry” shipper is capable of holding a temperature of $< -120^{\circ}\text{C}$ for a period of 8 days. This SOP outlines the steps performed to prepare, pack, and ship cryopreserved units using a “dry” shipper.

Specimen

Labelled frozen umbilical cord blood unit, contained in a metal canister and stored in a liquid nitrogen storage freezer in the liquid phase of liquid nitrogen.

Equipment

Validated “Dry” Shipper e.g. MVE Cryo-Mini
Polystyrene Outer Container

Reagent

Liquid nitrogen

Supplies

Thermal Exposure Indicator e.g. Cryoguard M-120
Federal Express Airway bill forms
Sealable Plastic Bag
Investigators Brochure MCC
COBLT Bar Codes (minimum of 8) CBU File
Labels - “Biological Product”, “Dry Shipper Containing Liquid Nitrogen”, “Do Not X-Ray”,
and “Do Not Invert or Tip”
Gloves for cryogenic work
Heavy Duty Scale

Procedure

1. Confirm that a validated “dry” shipper is available. See Procedure Notes for initial and ongoing validation requirements.
2. ● Confirm that a complete Investigators Brochure from the MCC and information from the Transplant Center have been received (SOP 4.5, Release from Long Term Storage). A complete Investigators Brochure has the following items: Transplant Center Feedback Sheet, Packing Information, Receipt Procedures, Procedure for Thawing Cryopreserved Cord Blood (CBU) for Transplant, Procedure for Infusing Thawed CBU,

and Product Information.

- Make arrangements with Federal Express and the receiving transplant center for pick up and delivery as detailed in the Release from Long Term Storage SOP 4.5. File air bill.
 - Complete the CBB Shipper Number, Federal Express Tracking Number, and CBB contact information on the Packing Information in the Investigators Brochure and fax a copy of this sheet to the receiver at the Transplant Center prior to shipment.
3. Prepare the “dry” shipper 24 hours before shipment by filling at least halfway with liquid nitrogen. Replace the cover and allow to stand to allow the liquid nitrogen to soak into the sponge material.
 4. Pour off any remaining free liquid nitrogen, weigh the shipper, and record the weight on the Transplant Center Feedback Sheet in the Investigators Brochure.
 5. Place the released cryopreserved CBU and thermal exposure indicator in a plastic bag and seal the bag to prevent leakage. Place the unit in the “dry” shipping container and close the shipper.
 6. Place the complete Investigators Brochure and COBLT Bar Code Labels in the top portion of the shipper. Close and lock the “dry” shipper top.
 7. Label the shipping container as “Biological Product”, “Dry Shipper Containing Liquid Nitrogen”, “Do Not X-Ray”, and “Do Not Invert or Tip”.
 8. Attach the following information:
 - Name and address of the receiving institution.
 - Name of receiving laboratory including the name, room number, and telephone number of the staff member responsible for receiving the shipment.
 - Description of contents.
 - Name and address, and telephone number of shipping institution, and name of the responsible person at the institution, as well as emergency notification instructions such as pager number for the responsible person.
 9. Turn shipment over to Federal Express courier.

Quality Control

1. Validated “dry” shippers will be used to ship cryopreserved CBUs to transplant centers.
2. The shipping container will be charged to its full capacity. When fully charged, the shipper should maintain a temperature at $< -120^{\circ}\text{C}$ for 8 days, according to manufacturer’s instructions.

Shipment will be by overnight courier.

3. Transplant Center staff will be notified of the expected arrival time, courier service and tracking numbers for the unit.
4. The unit's bar code number will be verified by two members of the Cord Blood Bank staff.
5. Transplant Center staff will notify Cord Blood Bank staff of arrival of the shipper.

Reference

Areman E, Deeg HJ, Sacher RA. Bone Marrow and Stem Cell Processing: A Manual of Current Techniques. F.A. Davis company, Philadelphia, 1992.

Procedure Notes

Validating "Dry" Shippers - Summary of Validation Requirements

- Initial Validation. Record daily temperature and weight of the charged "dry" shipper. Record for a total of 8 days from the time of charging.
- Quality Control. Upon return from transport, the "dry" shipper must be recharged and tested for temperature and weight for a period of 8 days from the time of the recharge. The results must be recorded.
- All "dry" shippers must be tested for temperature semi-annually (summer and winter).

Initial Validation

Upon receipt from the supplier or manufacturer, perform the following steps:

1. Remove the cover of the shipper.
2. Fill out the warranty activation card and return to the manufacturer.
3. Fill out the Vendor/Validation Sheet.
4. Obtain a liquid nitrogen supply tank. Attach an LN2 supply hose with phase separator to the LN2 tank.

NOTE: Use insulated gloves and face shield while filling the shipper with liquid nitrogen. Follow established safety practices and procedures for transferring liquid nitrogen.

5. Fill the vapor shipper to approximately 3/4 full.
6. Replace the cover and let stand for 24 hours, allowing the liquid nitrogen to be absorbed by the

shipper.

7. At the end of the 24-hour period, refill the shipper according to the steps above and let stand for an additional 24 hours.
8. After the second 24-hour period, pour off any remaining liquid nitrogen and weigh the shipper. Record the weight. Remove the shipper cover and insert a type J/K thermocouple probe into the center of the shipper in a manner such that the other end of the thermocouple remains outside of the shipper. Replace the cover and let stand for 1 hour.
9. At the end of 1 hour, attach a type J/K thermometer to the exposed end of the thermocouple. Turn the thermometer on and wait until the digital temperature display stops fluctuating. Record the temperature on the Initial Validation Sheet.

Acceptable temperature range: colder than -120°C .

10. Repeat steps 8 and 9 for 8 days. Calculate the evaporation rate by subtracting the weight of the shipper on the second day from the weight of the shipper on the first day. Record the rate.

NOTE: If it is not possible to check the temperature and weight on all 8 days (due to lab closure, weekends, etc.), it is important to check the temperature and weight on the eighth day. This will determine if the shipper has held an acceptable temperature through the maximum amount of time recommended by the manufacturer.

11. Record any uncommon occurrences such as excess frosting or sweating along the outside of the shipper or excess evaporation.
12. If the temperature and weight tests pass validation, the shipper is cleared for use.
13. If the shipper fails the validation tests in any manner, the manufacturer or service dealer must be contacted for further instructions. In this case, the shipper must not be used for transportation until it passes the validation requirements.

Validation After Use

1. Upon return of the “dry” shipper from the transplant center, inspect the following:
 - Check the outer polystyrene container for damage (cracks, indentations or holes, etc.).
 - Remove the “dry” shipper from the outer container and check for damage (cracks, dents, leakage, etc.).
2. Follow steps 1 through 12 above and record results.
3. The shipper must pass the validation requirements for continued service.

4. If the shipper does not pass the validation requirements, it must be taken out of service and referred to the manufacturer or service specialist.

Semi-Annual Validation

1. The temperature holding capabilities of the “dry” shipper must be checked once during the winter and once during the summer. Checks performed as part of the initial validation or validation after return from the transplant center may be used for the semi-annual validation.
2. Follow steps 1 through 12 above for the temperature requirements only.
3. The “dry” shipper must pass the temperature requirements for continued service.
4. If the “dry” shipper does not pass the temperature requirements, it must be taken out of service and referred to the manufacturer or service specialist.

References

Manufacturers’ Instruction Pamphlet

Code of Federal Regulations, 606.60, Title 21, 1996.