

CHAPTER 3
COLLECTION PROCEDURES

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3.1 COLLECTION KIT

Principle

The cord blood collection kit will be carefully assembled by the Cord Blood Bank (CBB) supervisor or his/her designate according to the following procedure. Kits will be distributed to the cord blood collector(s) prior to collection so that collection and processing of the umbilical cord blood unit, blood samples and paperwork may proceed as efficiently and with as little risk of error as possible. The contents and assembly of collection kits may be customized to suit individual collection center needs. Customized kits must be fully documented in the CBB's internal SOPs.

Materials

Large zipper-locked bag, 8½" x 11"
Set of COBLT study bar code labels
CPD cord blood collection bag
Volunteer Cord Blood Donor Identification Form
CBU Collection and Receipt Form
Medical History Form (optional)
Donor and Delivery Information Form
Maternal Sample Form
Zipper-locked bag, 8" x 10", with 2 pieces of gauze
Small manila envelope
Tubes for mother's samples (optional)
2 large manila envelopes (1 for bar code labels, one for mother/donor paperwork)

Procedure

1. Inspect the CPD cord blood collection bag to be sure it is intact. Place the bag in foil pouch (optional) and record the appropriate expiration date.
2. Place a study bar code label on all pages of each study form and on both large manila envelopes. Place all forms in one of the large manila envelopes and place the envelope in the zipper-locked bag.
3. Place a maternal study bar code label on the small manila envelope. Remove the rest of the maternal bar code labels from the study bar code label sheet and place them inside the small manila envelope.
4. Place the remaining study bar code labels in the second large manila envelope. Place the

envelope in the zipper-locked bag.

5. Place the collection bag, zipper-locked bag with gauze, and small manila envelope in the large zipper-locked bag.

NOTE: As each item is placed in the bag, inspect the bar code label to be sure it matches the bar code number on the label sheet.

6. Close the zipper-locked bag. The kit is now ready for distribution to the cord blood collectors at the collection sites.

Quality Control

1. One kit is to be assembled at a time, to eliminate the risk of mixing of label sets.
2. Numbers on the kit components are verified against those remaining on the label sheet.
3. Bar code label numbers for each collection kit will be recorded on the Label Release Log.

3.2 LABEL CONTROL

Principle

Bar coded labels provide an easy and accurate method for tracking and identifying CBUs and samples. The Cord Blood Transplantation Study uses labels bar coded with the standardized ISBT-128 system for CBUs, sample processing and data collection. Study labels are printed in sets with each set having a unique bar code number. Labels within the set are identically coded and are sized to fit on laboratory tubes, blood bags, and data forms. The COBLT Study bar code label set is illustrated in Figure 3.2.1.

Label sets are distributed to each Cord Blood Bank (CBB). The CBB supervisor or his/her designate distributes labels in collection kits. Labels are tracked using the Shipping Log and the Label Release Log.

Materials

COBLT Study Bar Code Label Set
Label Release Log

Procedures

Tracking Labels at the Cord Blood Bank

1. Ensure that all bar codes in the set are legible and that each set contains a complete set of labels (Figure 3.2.1). Remove from distribution incomplete sets or sets with illegible bar codes.
2. To release a set of labels, scan the bar code and complete the label release information on the Label Release Log in the COBLT Internet Data Entry System. Give the set of labels to the COBLT staff member responsible for assembling the collection kit.
3. At regular intervals defined by institutional procedures, use the label report utility in the study data system to print a list of released but unreturned labels. Labels not returned within 4 weeks of the release date should be located.

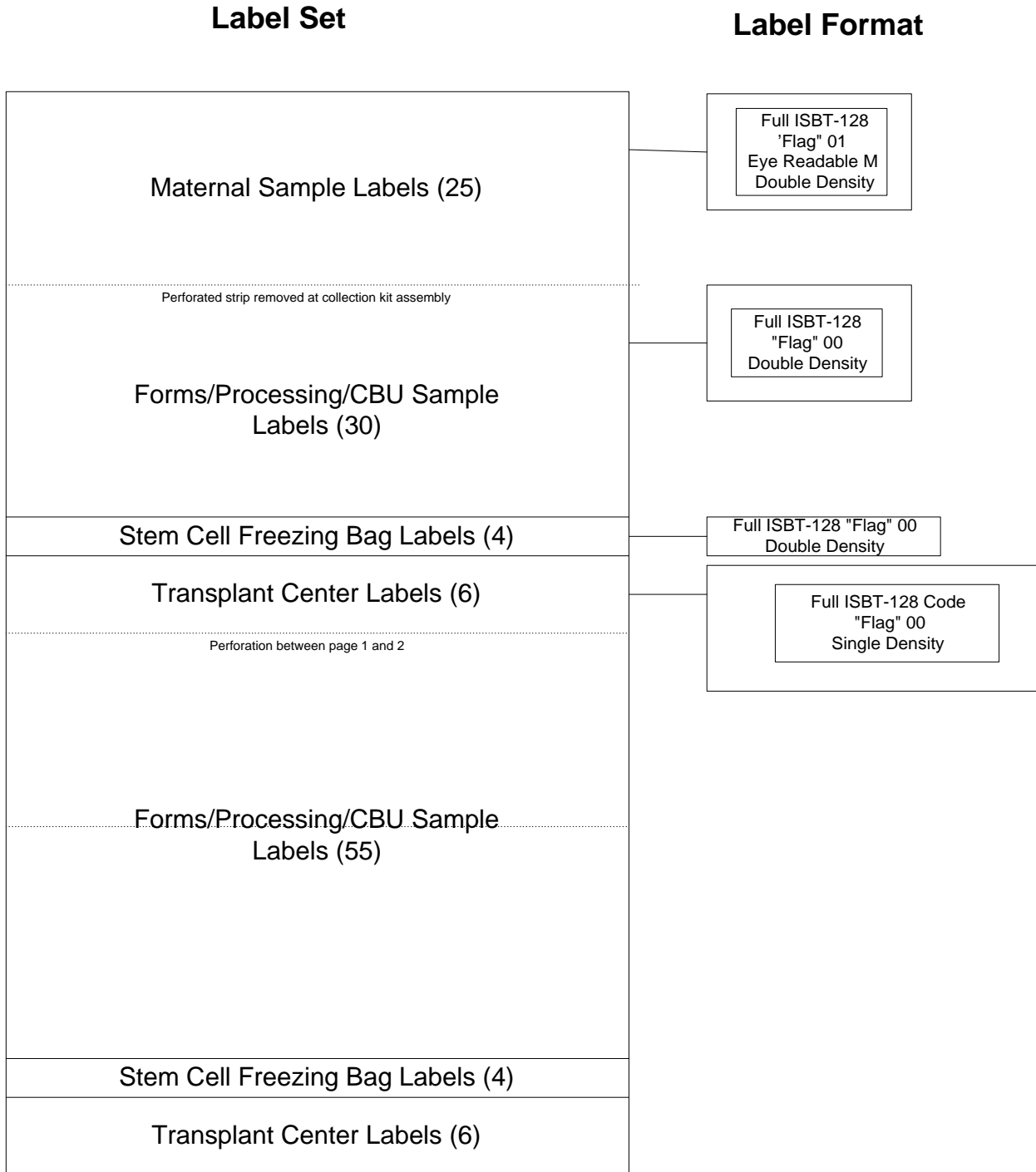
Tracking Labels at the Collection Center

All opened collection kits are to be returned to the CBB. If a kit is opened but not used and returned to the CBB using the Shipping Log, record the reason in the specify section of this log.

Quality Control

1. Labels will only be issued by the CBB supervisor or his/her designate.
2. All labels issued will be accounted for on appropriate logs and forms.

Figure 3.2.1
COBLT Study Bar Code Label Set



3.3 COLLECTION OF PLACENTAL BLOOD

Principle

Placental or umbilical cord blood contains hematopoietic stem and progenitor cells that can substitute for bone marrow in human bone marrow transplants. Placental or umbilical cord blood can be cryopreserved in the laboratory for later use.

Specimen

Placenta in collection container

Equipment

Collection Stand

Orbital Rotator (optional) e.g. Nutator, Clay Adams

Metal and Plastic Hemostats

Scale/Balance

Hand Sealer with Clips e.g. Fenwal Baxter
or Heat Sealer e.g. Sebra

Reagents

70% Isopropyl Alcohol

Supplies

CPD Placental/Umbilical Cord Blood Stem Cell Collection Set Pall Medical Corporation (Figure 3.3.1)

Collection Kit

Chux Pad Hospital Storeroom

Alcohol Wipes Hospital Storeroom

Iodophor-PVP Scrub and Wipes Hospital Storeroom

Nonsterile Gloves Hospital Storeroom

Sterile Gauze Pads Hospital Storeroom

Disposable Mask with Plastic Eye Shield (optional) Hospital Storeroom

Disposable Booties and Gowns Hospital Storeroom
(as required by collection facility)

Procedure

1. Before the delivery, ensure equipment and supplies are organized and complete.
2. Glove, then wait until the placenta is placed in the container and handed out from the delivery

room.

3. Verify that the label on the container holding the placenta matches the label on the collection bag. Have Labor and Delivery personnel sign the verification box on the reverse of the VDIF.
4. After double gloving, place the placenta fetal side down into the Chux pad which has been attached to the collection stand. Punch a hole in the middle of the Chux, then pull the cord through. Inspect the collection bag to be sure that it appears intact and close the blue clamps located on the tubing. Place the collection bag (Bag #1) of the CPD Placental/Umbilical Cord Blood Stem Cell Collection Set (Figure 3.3.1) on the scale including the tubing and attached needles to obtain the pre-collection weight. Record this weight on the CBU collection form.
5. Optional: Place a metal hemostat on the cord near the cord clamp and below the planned puncture site. This will serve as a means to hold the cord taut during the collection.
6. Rinse the blood off of the surface of the cord by squirting the cord with Isopropyl alcohol from a bottle.
7. Sterilize the cord according to institutional SOP. Do not touch the cord puncture site after it has been cleaned.
8. Remove the needle cap from one of the two donor needles attached to the collection bag (Bag #1, Figure 3.3.1). Hold the cord tight with the metal hemostat. Puncture the cord with the needle bevel turned away from you. (Optional: Use a small plastic hemostat to hold the needle in place by attaching the hemostat below the blue plastic grip site of the needle and the metal hemostat.) Open the blue clamp located on the tubing attached to the needle used to puncture the vein. Blood should flow through the tubing into the collection bag by gravity. Rotate the collection bag periodically to allow complete mixing of the CPD anticoagulant with the cord blood.
9. If necessary, rotate the placenta several times to get a better collection particularly when the cord is long; sometimes the placenta has to be raised out of the stand, but held over the Chux.
10. If blood flow ceases, but it appears that additional blood remains in the placenta, close the tubing attached to the first needle with the blue sliding clamp. Make a second puncture by selecting a site proximal to the placental surface. Clean the new site(s) using institutional SOP and proceed as in Step 8.
11. When the collection is completed (the cord will appear empty and mostly white-ish when all the blood has been removed), close off the tubing with the blue sliding clamp to prevent air from entering the bag. Vent the tubing by turning the white vent clamp clockwise. Strip any blood remaining in the tubing down into the collection bag. Heat seal the tubing at the site where the needles and tubing are joined. Cut off the needle(s), and place in a sharps container.
12. Weigh the collection bag and attached tubing containing the cord blood. Subtract the pre-

collection weight of the bag obtained in step #4 from the post collection weight to calculate the weight (Volume 1ml=1gm) of cord blood collected. Add 7.5 gms to adjust for the weight of the needles removed in step #11. Record the calculated weight/volume on the CBU Collection and Receipt Form in the collection kit.

Volume of CBU = (Post Collection weight +7.5 gm) - precollection weight

NOTE: The exact weight (in this example, 7.5 gm) to be added must be determined and validated at each bank.

13. Strip the tubing off the blood bag and sterility seal tubing directly underneath the Y-connection (the site where the tubing splits to the two collection needles). Cut away any excess tubing.
14. Compare the bar coded label on the bag with the Volunteer Cord Blood Donor Identification Form and the CBU Collection and Receipt Form. Complete all the collection information on the collection form.
15. Place the blood bag in the Collection Kit zipper-locked bag containing the gauze strips. Place this bag in the larger Collection Kit zipper-locked bag together with forms and bar code labels to be returned to the CBB.
16. Store the collection as indicated in SOP Section 3.4, Post Collection Storage of CBU Prior to Transport to CBB Processing Laboratory, or take directly to the processing laboratory.

Quality Control

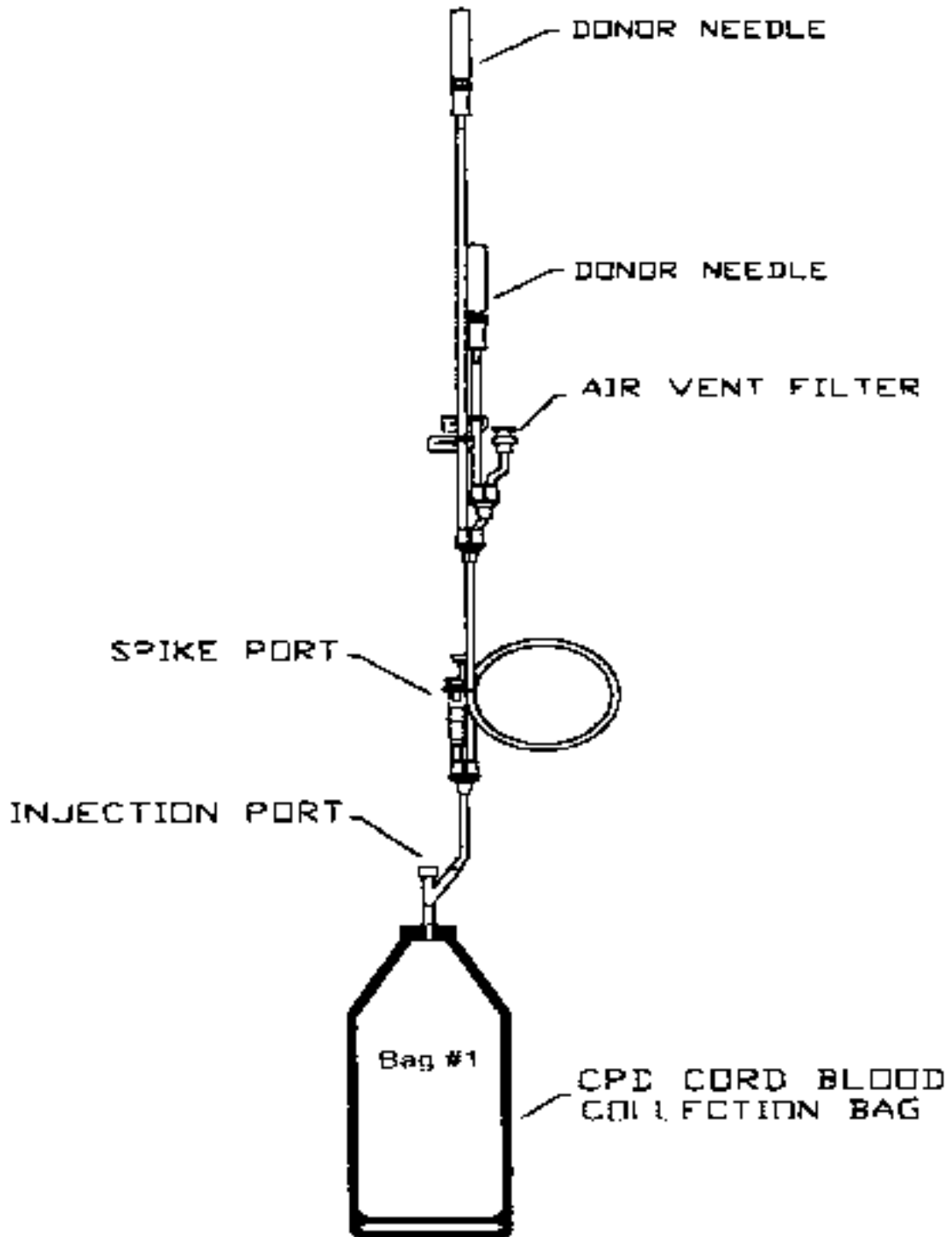
1. To ensure that contamination does not occur, collection kits will be pre-assembled and shipped to the collection centers.
2. All personnel will be trained prior to placental blood collections.

References

New York's Mount Sinai Hospital and The New York Blood Center

Dr. Pablo Rubinstein

Figure 3.3.1
CPD Placental/Umbilical Cord Blood Stem Cell Collection Unit (Set #1)



3.4 POST COLLECTION STORAGE OF CBUS PRIOR TO TRANSPORT TO CBB PROCESSING LABORATORY

Principle

Collected umbilical cord blood has been found to maintain cell viability when temporarily stored at temperatures of 15° to 25° C. Insulated platelet shippers with temperature stabilizing gel packs successfully maintain units within this temperature range for several hours. All platelet shippers used to transport COBLT CBUs to the CBB will be monitored to verify that internal temperatures remain within acceptable ranges.

Specimen

Cord Blood Units collected after placental delivery into a collection bag containing CPD anticoagulant.

Equipment

Numbered Platelet Shipper	EnduroTherm® E-38
2-4 3-lb Non-toxic Temperature Stabilizing Packs	e.g. Polar Pack, Arctic Ice
Thermometer	

Supplies

Large Plastic Bag	
Plastic-backed Absorbent Pad	e.g. Underpads, Kimberly-Clark
Shipping Log	
Shipping Labels	
COBLT Study Bar Code Labels	

Procedures

Preparing the Platelet Shipper

1. a. For new shippers, attach a study-specific label to the platelet shipper. The label should include the name of the study, the shipper number, and the dates a min/max thermometer was used. The unique shipper number should be recorded using a permanent ink marker.
- b. For used shippers, check the outside of the platelet shipper for damage. Return damaged shippers to the CBB Processing Laboratory.
2. Check that the platelet shipper number is legible. Check that the following labels are securely attached and legible:
STUDY-SPECIFIC LABEL (See Step 1a)

“CORD BLOOD BANK ADDRESS/IF SHIPMENT IS DELAYED ... NOTIFY”
“PERISHABLE”
“WARNING! DO NOT ICE”

Replace illegible, missing or loose identifiers.

3. Record the shipper number on the Shipping Log. Indicate on the study-specific label whether or not a min/max thermometer is used.
4. Place temperature stabilizing packs (TSP) (conditioned to 15-25° C) in the shipping container, laid flat and squeezed side by side. Add absorbent sheet, plastic side down. Place the plastic bag, the remaining conditioned TSPs, the Shipping Log, and the min/max thermometer (if applicable, see Quality Control instructions) in the shipper.
5. Replace the lid and store the shipper in a secure location at ambient room temperature of 15° - 25° C.

Storing Umbilical CBUs Following Collection

1. Remove the Shipping Log, top two TSPs, and min/max thermometer (if applicable) from the shipper. Place a bar code label from the collection kit on the Shipping log.
2. Visually inspect zipper-locked bags containing CBUs to ensure that they are sealed. Seal if necessary. Compare each CBU bar code label with the bar code label on the log. Complete “packing information” on the log. Resolve any discrepancies. Record unresolved discrepancies on the log.
3. Place the zipper-locked bag containing the CBU in the large plastic bag in the shipper. Place two TSPs on top of the plastic bag, laid flat and squeezed side by side.
4. Return the thermometer (if applicable, see Quality Control instructions) and Shipping Log to the shipper and replace the lid.

Quality Control

1. Platelet shippers will be placed in secured areas with limited access.
2. Preparation and packing of the shipper will be performed by trained staff.
3. All platelet shippers must have their internal temperatures monitored. New platelet shippers must have a min/max thermometer included for the first ten shipments. The temperature must be monitored monthly thereafter. Monitoring information will be recorded on the study label and the Shipping Log.
4. When shipping in extreme temperatures (< -10° C or > 37° C), a min/max thermometer must be placed in the platelet shipper.

5. Platelet shippers may not be used for long-term storage. Each shipper has been validated to remain within acceptable temperature ranges for a specified time period. CBUs may not be stored in the shippers for longer than this time period.

References

George VM, Pringle TC, Kline L, Friedman LI. Development and evaluation of a shipping system for platelet components. **Transfusion** 1996, 36, 335-338.