

HEALTHCARE PROVIDER

Instructions

KEEP THESE INSTRUCTIONS IN THE KIT

IMPORTANT: Prior to collection, insure donor eligibility requirements have been met as per FDA 21CFR 1271.75 subpart C donor eligibility, refer to Healthcare Provider Information form.

Keep collection kit at room temperature in a secure environment with parents at all times. When handling biological specimens, use gloves and other personal protective measures. Such protective clothing shall not be worn outside the work area. Maintain aseptic techniques and adequate room for collection processes and dispose of any medical waste in biohazard containers.

Umbilical Cord Blood
& Cord Tissue

Collection Kit

CryoCell
INTERNATIONAL

(800) 786-7235 • Cryo-Cell.com

1. PRIOR TO DELIVERY

□ COLLECTION KIT

Verify expiration date on the exterior of the kit. **DO NOT** use kit if it has reached its expiration date.

□ BIRTH MOTHER'S BLOOD COLLECTION



Draw birth mother's blood at the time the IV is started or prior to administration of 2000 mL IV fluids or any blood products. If the sample is not collected prior to delivery, it can be collected after delivery; however, the maternal blood collection will only be acceptable if the birth mother has not received either: ① blood products within 48 hours or ② more than 2 liters of IV fluid within 1 hour of the blood draw. In case of adoption or surrogacy, draw from the birth carrier.

If birth mother's blood was drawn greater than 40 hours prior to the cord blood collection, redraw mother's blood using same size and color tubes, and discard previous birth mother's blood tubes. Birth mother's blood must be received within 72 hours of collection.

Failure to follow these instructions could result in invalid infectious disease testing, which may cause the specimen to be ineligible for therapeutic use.

- Confirm patient's identity.
- Perform venipuncture to collect five tubes of birth mother's blood in this order: red-top tube, purple-top tubes and pink-top tube. In the case of multiple births, only one set of 5 tubes is required.
- All tubes must be at least 3/4 full for accurate results.
- Invert full tubes 4-5 times to mix anticoagulant.
- Record collection date and time of collection on already pre-identified labeled tubes. If pre-printed identification labels are not applied, please label with kit ID, name, date and time of collection on blank white labels. **Unidentified birth mother's blood tubes will not be processed.**
- Place each blood tube into the white absorbent sleeve. Place white absorbent sleeve into the small specimen bag and seal bag and then return to kit. (see Fig. 1).

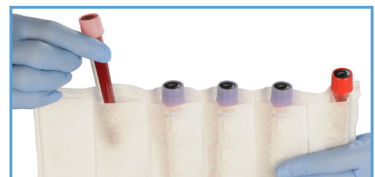


Fig. 1

2. AT DELIVERY

○ CORD BLOOD COLLECTION

Donor eligibility requirements must be met as per FDA 21CFR 1271.75 subpart C donor eligibility. Please refer to the Healthcare Provider Information form for physical exam guidance.



Do not initiate or continue the collection of the cord blood if medical complications are present that affect the safety of the birth mother or baby. If gestational age is less than 34 weeks, the healthcare collector should evaluate the safety of the baby before continuing with collection.

FOR MULTIPLE BIRTHS:

All babies shall be delivered before any cord blood collection begins.

- **Individual collections are required for each baby with separate collection bags.**
 - **Appropriately label each bag with name of child or Baby A, Baby B, etc. It is critical to clearly identify the baby source of each cord collection bag. Affix completed label to bag(s).**
- Cord blood collection bag is sterile and can be placed in sterile field.
 - Confirm the baby's identity prior to collection.
 - Collect cord blood while placenta remains in utero.
 - Prior to delivery of placenta, cleanse 4-8" (10-20cm) of the umbilical cord with the ChloraPrep applicator. Squeeze tabs together to activate cleaning device. Cleanse cord for 30 seconds (see Fig. 2) and allow air drying for approximately 1 minute while double clamping cord below cleansed site and cut cord between clamps.

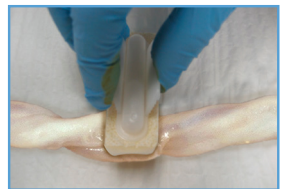


Fig. 2

Note: If the placenta is delivered prior to collection, immediately elevate the placenta to perform collection. Massage the placenta and umbilical cord with collection bag lowered.

□ CORD BLOOD COLLECTION CONTINUED

- Close white clamp on tubing (see Fig. 3).
- Remove the needle cap and insert the needle into the umbilical vein of the cleansed area.
- Open the white clamp and let umbilical cord blood flow into tubing and collection bag by lowering collection bag. **Collect as much cord blood as possible.** The collection bag can hold up to 210mL of cord blood.
- To facilitate a larger cord blood collection, massage fundus of the uterus to help initiate contraction. With one hand, hold the umbilical cord above needle insertion site, then squeeze cord in a pumping manner 1-3 times while holding needle in umbilical vein with other hand. Be careful not to contaminate insertion site. This will push blood forward and then backwards, opening the umbilical vein for a better blood flow.
- Agitate the collection bag frequently to ensure adequate mixing of the blood and anticoagulant.
- If the vein collapses, work your way up the cord using additional insertion sites and pump the umbilical cord. **All insertions shall be made within the aseptically prepared area.**
- When collection is completed, milk the blood remaining in the tubing down into the collection bag.
- Close the white clamp before removing the needle from the vein.
- Withdraw the needle from the cord and slide the needle guard over the exposed needle until the needle is completely retracted into the needle guard and secured (see Fig. 4).

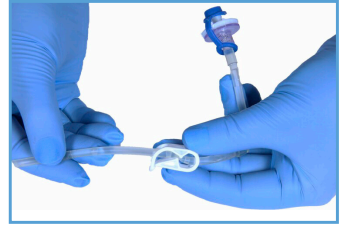


Fig. 3



Fig. 4

- Open blue cap on tubing to facilitate drainage into the bag (see Fig. 5). Once the tubing completely drains, close blue cap.
- Tie at least two (2) knots in the center of the long tubing to prevent blood from leaking out (see Fig. 6). **Do not suture tubing; do not cut tubing at ports.**



Fig. 5

- Cut off the protected needle **within one inch from needle** and discard in sharps container. Allow the white clamp to remain closed in place to further prevent leakage.

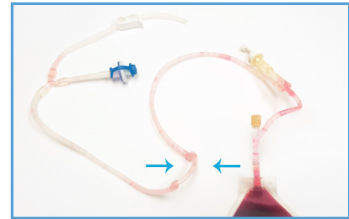


Fig. 6

- **Complete and apply pre-printed client identification label on cord blood collection bag.** A sufficient area of the bag should remain uncovered to permit inspection of the contents by the laboratory.
- If the pre-printed identification label is not available, locate the spare blank cord blood label contained inside the collection kit, complete to its entirety and apply to cord blood collection bag.
- Wrap the absorbent towel around cord blood bag. Place cord blood bag into the large specimen bag and seal and then return to kit.

CORD TISSUE COLLECTION



Verify with patient that cord tissue is to be collected.

Remove collection cup from the kit. The cord tissue collection cup cannot be placed in a sterile field.

- After collection of the cord blood, excise approximately 4-8" (10-20 cm) section of the whole umbilical cord. Cleanse cord thoroughly with antiseptic towelette (see Fig. 7).
- Transfer excised portion of the cord tissue to the collection cup provided in the kit (see Fig. 8). Coil if necessary and seal the container lid firmly.

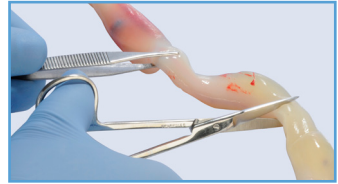


Fig. 7

- Record name, date and time of collection on the pre-printed client identification label on the cord tissue collection cup. If pre-printed identification label is not applied, please label with kit ID, name, date and time of collection on the spare blank cord tissue label contained inside the collection kit and apply to tissue cup.
- Wrap cord tissue cup in the thin cloth and place in the second large specimen bag provided in collection kit and seal to prevent leakage during shipment.



Fig. 8

3. AFTER COLLECTION

HEALTHCARE PROVIDER FORM

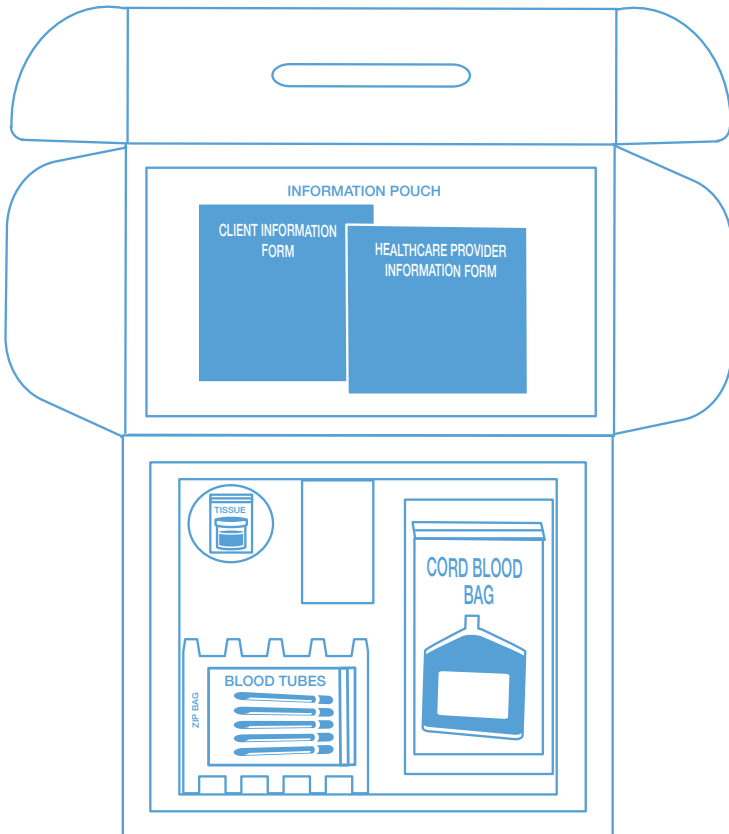
- Complete and sign the Healthcare Provider Information form.
- Insert completed Healthcare Provider Information form in the collection kit.

PACKAGING INSTRUCTIONS

- Place small specimen bag containing properly labeled birth mother's blood in the original cutout space. Place in horizontal position, **do not place blood tubes in each individual cut-out slot.**

- If cord tissue was collected, place specimen bag containing properly labeled cord tissue collection cup in the circular cut-out space, above the birth mother's blood.
- Place specimen bag containing properly labeled cord blood collection bag in the rectangular cutout space.
- Return completed kit to patient and advise them to call for medical courier pick-up.
- Any questions regarding the collection or packaging process, please call **(800)-786-7235, option 1.**

Packaging Diagram





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CUSTOMER SERVICE LINE - Option 1