SUMMARY CRYOCORD Plus COLLECTION PROCEDURE

Collection and Transportation Kit Content

1 **1 Single blood collection bag** with double collection tubing provided with clamp, needle, needle protector cap and needle guard on each side. Each unit contains 28,6ml of CPD anticoagulant solution for collection of 170ml of blood

2 **1 sterile blister containing:** 3 sterile gauze swabs 7.5 cm x 7.5 cm, 1 pair of scissors, 1 pair of tweezers and 1 surgical field

3 **2 Cleansing wipes**

4 **1 sterile tube for cord collection:** contains 25ml transport medium

5 **1 Absorbing cloth**

6 **1 95kPa Safety bag** with hermetic quick lock

7 **2 Instant cold packs** for temperature control during transport

8 **1 Neopor box** for transport (not shown)

Step 1 – General pre-collection preparation

***WARNING**: During the umbilical cord blood collection procedure, good laboratory and clinical practice are required; aseptic technique is mandatory!*

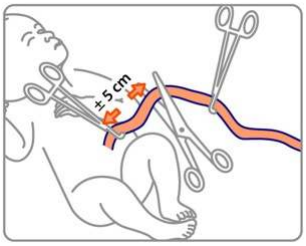
1. Check expiry date of the Collection Kit.

   Remove the sterile components from the collection kit inner box and inspect all of them for absence of visual defects.

   Read provided instructions and proceed as described further in this leaflet.

2. Immediately after birth, before the placenta is delivered or detached - *in utero* - the umbilical cord is clamped as close to the baby's abdomen as possible.

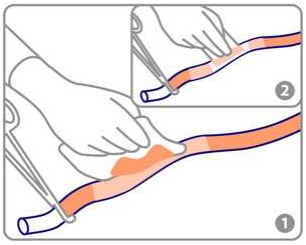
   A second clamp is placed on the umbilical cord, and the umbilical cord is cut between the two clamps, some 5 cm after the first clamp.



3. The baby is removed for further care, and umbilical cord blood collection procedure is started right away, but only after the necessary preparations as described in point 4 below are performed.

4. Using the sterile gauze, the debris and excess fluid are first removed from the umbilical cord puncture site, as close as possible to the cut end (see section n°1 in picture at the right).

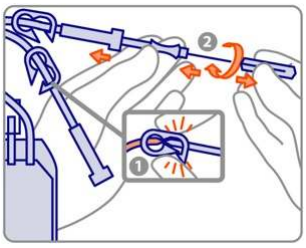
   The umbilical cord puncture site (i.e. the area where the needle will be injected and which was previously cleaned with the sterile gauze swab) is disinfected with the cleansing wipes (see section n°2 in picture) supplied with the collection kit.



Step 2 – Collection of the umbilical cord blood

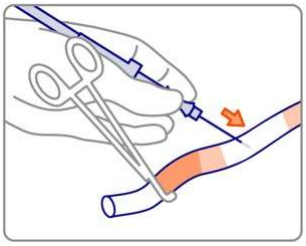
1. Remove the sterile blood bag unit from its primary plastic package and inspect it for absence of visual defects. The blood collection bag has double collection tubing with a clamp, a needle, a needle protector cap (transparent) and a needle guard (blue).
2. Select one or both tubing ends for use and **close the clamps on the non-used end** (see n°1 of picture at the right).

   Proceed with the other end and slide the blue needle guard off it upwards to completely free the needle and its transparent protector cap. To remove the needle protector cap, hold the needle base with one hand between thumb and index finger and twist the protector cap with the other hand to remove it by sliding it down the axis of the needle (see n°2 of picture at the right).



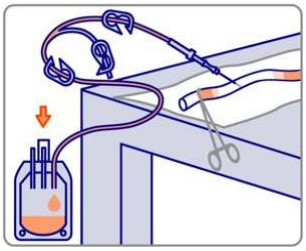
3. Now, perform the puncture after inspecting the bag, tubings, and needle for absence of visual defects.

   The blood should start flowing freely through the tube into the blood bag.



4. Place the collection bag such to assure that the bag's level is as low as possible below the level of the puncture site to allow the blood to flow freely into the collection bag by gravity.

   ! Note: Regular agitation of the blood bag during the course of the collection is required in order to allow proper mixing of the blood with the anticoagulant solution!



5. The blood bag must be filled to its full capacity if possible, however keep the quantity of blood within the limits indicated on the blood bag label.

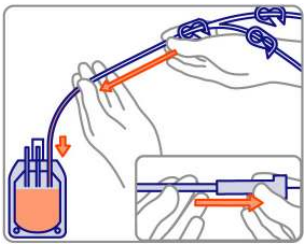
   If blood flow decreases or eventually stops, the whole procedure must be repeated using the second collection tubing and needle. (See Step 1.4 to Step 2.4 of this summary document). In this case, slide the blue needle guard downwards to fix it over the used needle and close the clamp on this tubing end.

   Then clean and disinfect a new puncture site carefully using the sterile gauze swabs and a new cleansing wipe repeating previous steps, however, this time inserting the needle closer to the placenta in order to maximize the blood volume collected in a sterile way.

6. After the blood collection bag is filled and collection procedure stopped, the remaining blood is squeezed from the tube into the blood bag.

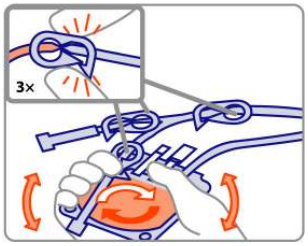
   Then close the clamp at the blood bag side as close as possible to the Y-connector. Also close the clamp at the needle side of the tubing.

   Withdraw the needle. Then hold the tubing above the blue needle guard with one hand and slide the needle guard completely down with the other hand until it covers completely the used needle.

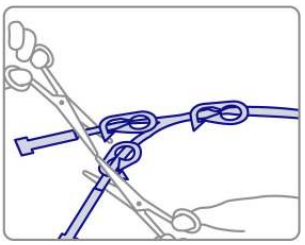


7. At the end of the collection the blood bag should be agitated once more to ensure proper final mixing of the blood with the anticoagulant.

   Make sure that all 3 clamps are closed.

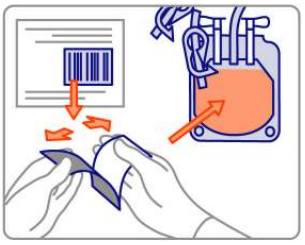


8. Then cut the collection tube(s) line with needle without removing the clamp on that line and discard in a safe manner according to applicable internal biological waste procedures.



9. Label the blood bag by affixing a completed Client ID Label with it's unique Client barcode sticker (supplied with the collection kit documentation).

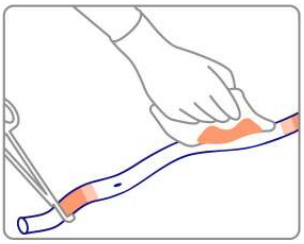
   ***WARNING**: The collected cord blood must be kept at room temperature; it should not be placed in a refrigerator or freezer.*



Step 3 – Collection of the umbilical cord segment

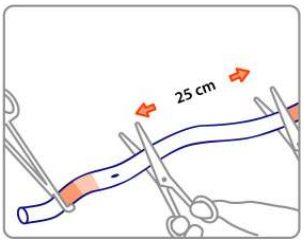
***WARNING**: During the umbilical cord segment collection procedure, good laboratory and clinical practice are required; aseptic technique is mandatory!*

1. Following the collection of the umbilical cord blood, a segment of the umbilical cord itself of about 25cm³ in volume (~ 25cm in length), is to be collected.
2. Select a part of the umbilical cord itself with a regular white structure and with a minimum number of nodes, from an area **not punctured** for the collection of the cord blood and closest to the placenta.
3. The debris and excess fluid (if any) is first removed from the selected umbilical cord area, using the sterile gauze(s).



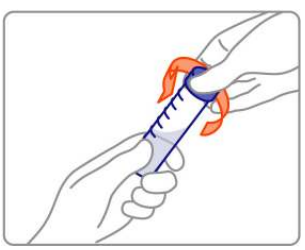
4. The selected and cleaned umbilical cord area (see points 2 and 3 above) is disinfected with the cleansing wipes that are supplied with the Collection Kit.
5. Cut the cleaned and disinfected segment of about 25cm or more of the umbilical cord using sterile scissors.

   ! Note: Take care to only select and collect a segment of the umbilical cord and that no other placental part(s) are introduced.



6. Open the 50 ml umbilical cord tissue collection tube prefilled with transport medium and delivered with the collection kit tube.

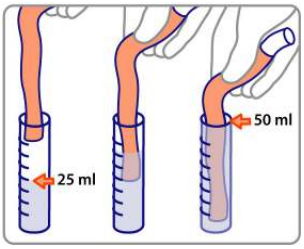
   ! Note: If by accident the transport tube does not contain any liquid anymore, it is essential to add 25ml of sterile physiological salt solution (0.9% NaCl) to the cord tissue to replace the spilled transportation liquid.

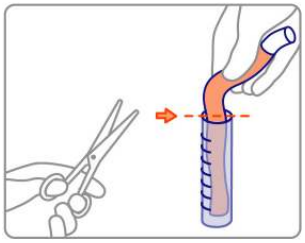


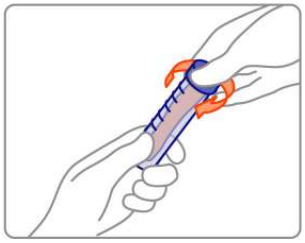
7. Transfer the cut umbilical cord tissue segment of about 25cm³ in an aseptic manner to the 50 ml.

Submerge the 25cm³ cord segment into the transportation tube in such manner that the liquid reaches the top of the tube.

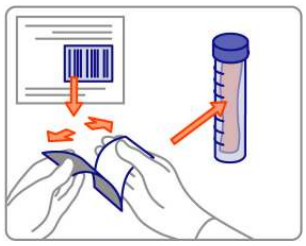
8. The remaining part of the cord segment above the tube must be cut away and discarded.
9. Close the collection tube containing the transport medium and the umbilical cord tissue segment tightly to prevent leakage during transportation.







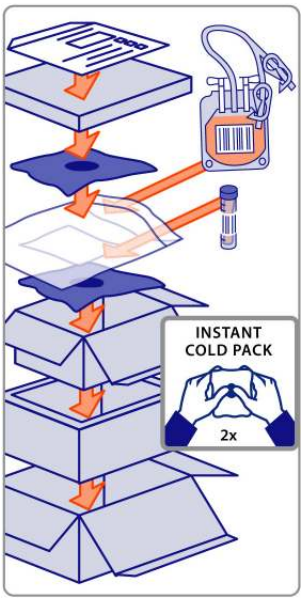
10. Label the collection tube by affixing a completed Client ID Label with it's unique Client barcode sticker (supplied with the collection kit documentation).

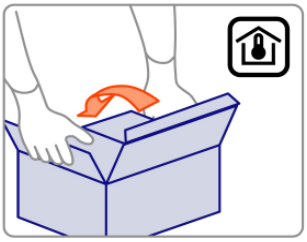


Step 4 – Packaging of collected samples in transport box

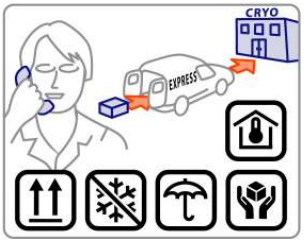
1. Insert the following <u>correctly labelled</u> samples in the provided 95kPa safety bag:
   - Blood bag with collected umbilical cord blood,
   - Tube with the umbilical cord,

   The 95kPa safety bag is then sealed.
2. Activate the instant cold packs (2x) as described in the provided instructions for use. Ensure that the cold packs start to cool before proceeding.
3. Then, place them in the inner cardboard transport box in the following order:
   - Small cold pack at the bottom
   - 95kPa safety bag with samples
   - Large cold pack above the 95kPa safety bag.
4. Then close the inner cardboard box.
5. Put the closed inner cardboard box in the Neopor box.
6. Close the Neopor box and put it in the outer cardboard box.
7. Finally place the document envelope , containing completed Forms 3,6,7 and 8 on top of the Neopor box
8. Close the outer cardboard box and place it into the plastic courier flyer bag, which is provided with the cord blood collection kit.





Step 5 – Contacting Cryo-Save to arrange courier services



1. Check that the sender's name (your doctor) and address details are complete on the provided **airwaybill, pro-forma invoice** (Form No. 5) and **specimen health certificate** (Form No. 4). Do not fill in any other parts of the airwaybill. Place this airawybill, the pro-forma invoice and the specimen health certificate in the clear window pouch on the **outside** of the courier bag.
2. **Contact CRYO-SAVE** customer services **to arrange specimen collection** by calling one of the following telephone numbers:

JOHANNESBURG	**011 803 4409**
CAPE TOWN	**021 671 2508**
DURBAN	**031 201 4420**

   Please give collection address including hospital name, floor and room number together with telephone number and name of person handling the specimen.
3. Please ensure that the collected sample is **STORED AT ROOM TEMPERATURE UNTIL COLLECTION.**

DO NOT REFRIDGERATE OR FREEZE

4. Although the courier may **not** be able to collect the shipment at night, please contact Cryo-Save on the above telephone numbers early the following day for us to arrange an early pick-up for that day.

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