

SUMMARY CRYOCORD 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 **3 sterile gauze swabs:** 7.5 cm x 7.5 cm
- 3 **2 Cleansing wipes**
- 4 **1 Absorbing cloth**
- 5 **1 95kPa Safety bag** with hermetic quick lock
- 6 **2 Instant cold packs** for temperature control during transport
- 7 **1 Neopor box** for transport (not shown)

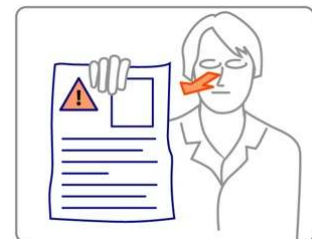
Step 1 – General pre-collection preparation

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.

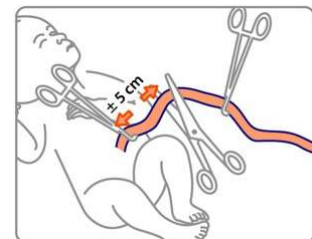
Remove the sterile components from the collection kit inner box and inspect all of them for absence of visual defects.

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



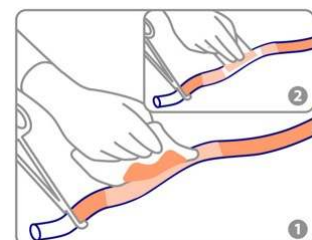
2. Immediately after birth, before the placenta is delivered or detached - *in utero* - the umbilical cord is clamped as close to the baby's abdomen as possible.

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.

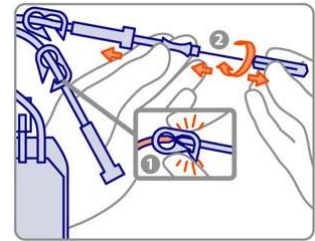


Step 2 – Collection of the umbilical cord blood

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).

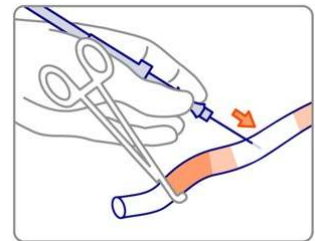
2. Select one or both tubing ends for use and **close the clamps on the non-used end** (see n°1 of picture at the right).

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).



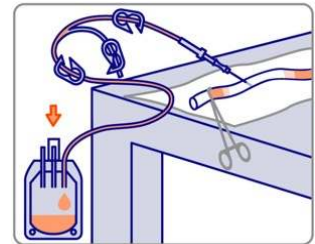
3. Now, perform the puncture after inspecting the bag, tubing, and needle for absence of visual defects.

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.

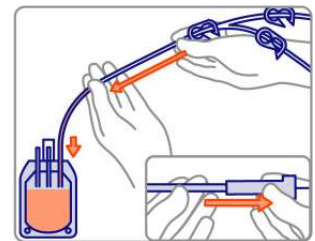
If blood flow decreases or eventually stops, the whole procedure must be repeated using the second collection tubing and needle. (See Step 1.4 to Step 2.4 of this summary document). In this case, slide the blue needle guard downwards to fix it over the used needle and close the clamp on this tubing end.

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.

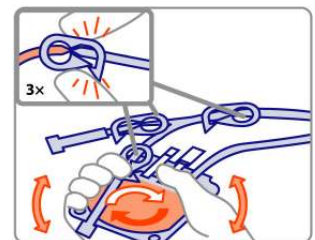
Then close the clamp at the blood bag side as close as possible to the Y-connector. Also close the clamp at the needle side of the tubing.

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.

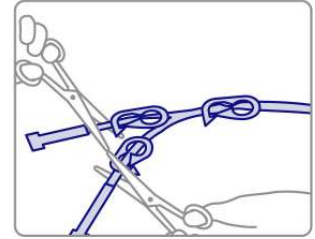


7. At the end of the collection the blood bag should be agitated once more to ensure proper final mixing of the blood with the anticoagulant.

Make sure that all 3 clamps are closed.

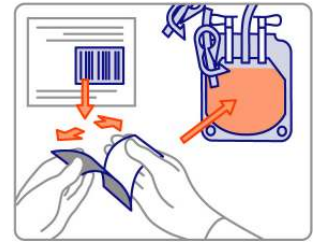


- Then cut the collection tube(s) line with needle without removing the clamp on that line and discard in a safe manner according to applicable internal biological waste procedures.



- Label the blood bag by affixing a completed Client ID Label with its 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.*



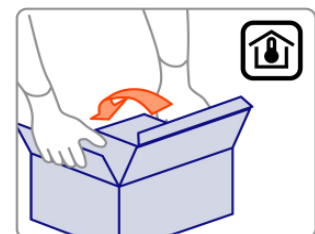
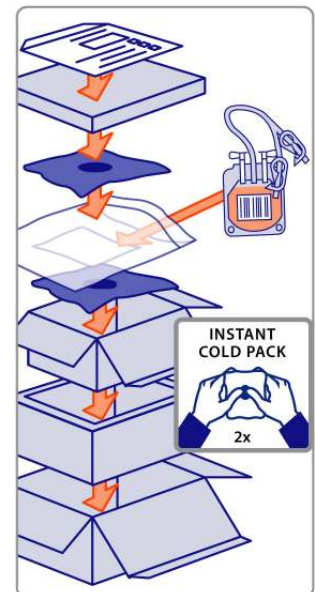
Step 3 – Packaging of collected samples in transport box

- Insert the correctly labelled blood bag with collected umbilical cord blood in the provided 95kPa safety bag.

The 95kPa safety bag is then sealed.

- Activate the instant cold packs (2x) as described in the provided instructions for use. Ensure that the cold packs start to cool before proceeding.
- 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.

- Then close the inner cardboard box.
- Put the closed inner cardboard box in the Neopor box.
- Close the Neopor box and put it in the outer cardboard box.
- Finally place the document envelope containing completed Forms 3,6,7 and 8 on top of the Neopor box
- Close the outer cardboard box keep it at room temperature.



Step 4 – Contacting 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 airwaybill, 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:

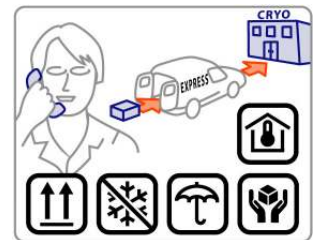
JOHANNESBURG	011 803 4409
CAPE TOWN	021 671 2508
DURBAN	031 201 4420

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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