Cord Blood and Cord Tissue Collection Guide (with Maternal Blood)

Contents of the Collection and Transportation Kit

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	S-Monovette 7.5ml Z-Gel for serum separation
9	1 Safety needle for S-Monovette 21Gx1½ “
10	2 Soft - Zellin swabs
11	1 Neopor box for transport

Kit Documents

Following documents/items are also provided with the kit in a separate envelope to facilitate procurement process:

- **Cord Blood and Cord Tissue Collection Guide**. This guide is provided for the information of the concerned Healthcare professional/Consultant Obstetrician/Phlebotomist.
- **Client ID Stickers**. Three stickers provided in a separate envelope for labelling the cord blood bag, cord tissue tube and maternal blood monovette.
- **Procurement Form.** The procurement form is to be completed and signed by the Healthcare Professional/Consultant Obstetrician/Phlebotomist who performs the collection. Parents are responsible for sending the completed Procurement Form back to Cells Limited in a self-addressed/stamped envelope provided.
- **Client Identification Form**. The completed form should be sent to the Lab with the cord blood, cord tissue and maternal blood samples pack.
- **Sending Procedure**. This document explains the shipment procedure for sending the pack by DHL courier. A DHL courier bag (Clear Flyer) along with a DHL Air shipment waybill is also provided for the purpose.

Step 1: General Pre-Collection Preparations

***WARNING**: During the umbilical cord blood collection procedure good laboratory and clinical practices are required; aseptical technique is mandatory.*

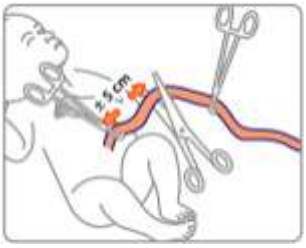
1. Check expiry date of the Collection Kit.

   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.

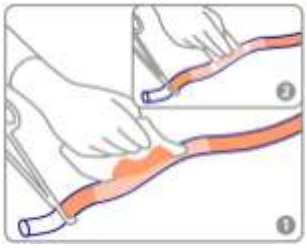
2. As soon as considered safe after birth, before the placenta is delivered or detached - the umbilical cord is clamped as close to the baby's abdomen as safe to do so.

   A second clamp is also placed on the umbilical cord, and the umbilical cord is cut between the two clamps, some 5 cm from the first clamp and the baby is removed for further care.



3. This follows the preparations for ex-utero collection of umbilical cord blood and cord tissue on the allocated site at the hospital.

4. Prepare the work surface for ex-utero collection of cord blood and cord tissue:



Place the placenta on the sterile surgical field cloth and allow the umbilical cord to hang down over the side (gravity plays an important part in collecting cord blood).

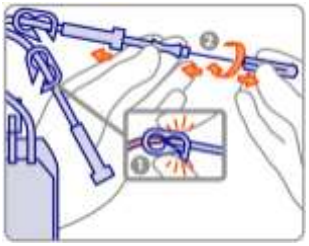
Clean the umbilical cord with the sterile gauze.

Disinfect the areas of the umbilical cord where the needle will be inserted (a sterile environment is a must).

Step 2 – Collection of the Umbilical Cord Blood

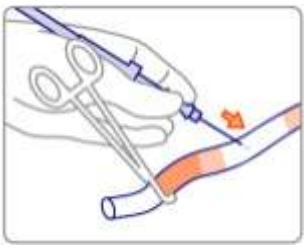
1. Remove the sterile blood bag unit from its primary plastic package and inspect it for absence of visual defects. The blood collection bag has double collection tubing with a clamp, a needle, a needle protector cap (transparent) and a needle guard (blue).

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



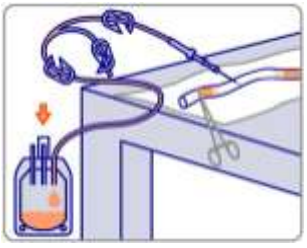
Proceed with the other end and slide the blue needle guard of it upwards to completely free the needle and its transparent protector cap. To remove the needle protector cap, hold the needle base with one hand between thumb and index finger and twist the protector cap with the other hand to remove it by sliding it down the axis of the needle (see the second picture on 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 ensure 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). In this case, slide the blue needle guard downwards to fix it over the used needle and close the clamp on this tubing end.

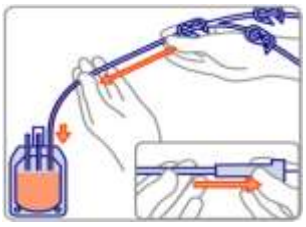
Then clean and disinfect a new puncture site carefully using the sterile gauze swabs and a new cleansing wipe repeating previous steps, however, this time inserting the needle closer to the placenta in order to maximize the

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.

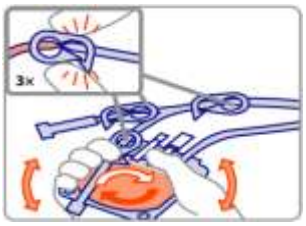
   Then close the clamp at the blood bag side as close as possible after the Y-connector. Also close the clamp at the needle side of the tubing.

   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 completely covers the used needle.

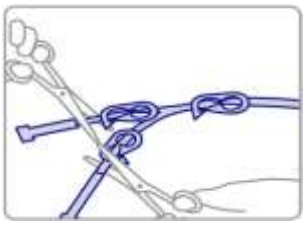


7. At the end of the collection the blood bag should be agitated once more to ensure proper final mixing of the blood with the anticoagulant.

   Make sure that all 3 clamps are properly closed.

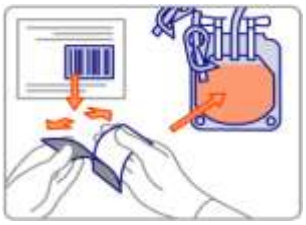


8. Then cut the collection tube(s) line with needle without removing the clamp on that line and discard the needle in a safe manner according to applicable internal biological waste procedures.



9. Label the blood bag with the collected umbilical cord blood by affixing Client ID Sticker provided with the Collection Kit.

   ***WARNING**: The collected cord blood must be kept at room temperature (between 1◦C and 30◦C); it should never be placed in a refrigerator, freezer or any other cold storage.*



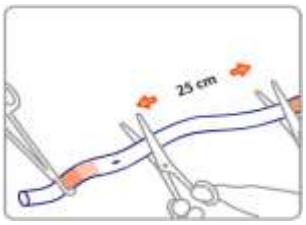
Step 3 – Collection of the Umbilical Cord Tissue

***WARNING**: During the umbilical cord tissue collection procedure good laboratory and clinical practices are required; aseptical technique is mandatory!*

1. Following the collection of the umbilical cord blood, a fragment 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 part (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 fragment of about 25cm or more of the umbilical cord using sterile scissors.

   Note: Only select and collect a fragment of the umbilical cord ensuring that no other placental part(s) are introduced.

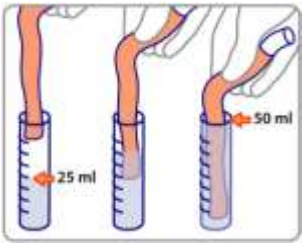


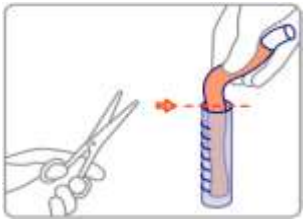
6. Open the 50 ml umbilical cord tissue collection tube prefilled with transport medium and delivered with the collection kit tube.

   Note: If by accident the transport tube does not contain any liquid, 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 fragment of about 25cm³ in an aseptic manner into the cord tissue tube provided in the kit.

   Measure the 25cm³ cord fragment by submerging it into the transportation tube in such manner that the liquid reaches the top of the tube.
8. The remaining part of the cord fragment above the tube must be cut away and discarded.
9. Close the collection tube containing the transport medium and the umbilical cord tissue fragment tightly to prevent leakage during transportation.
10. Label the cord tissue tube with the collected umbilical cord blood by affixing Client ID Sticker provided with the Collection Kit.





Step 4 – Collection of Mother's Blood

1. As far as possible and safe to do so, mother's blood sample should be collected just before or after the birth of the baby. In case the sample can not be collected for medical considerations, the law allows a seven-day window for collection of this sample.
2. The blood collection device needed for the mother's blood is supplied with the Collection Kit and full blood is collected from the mother following standard blood collection procedures.

   The remaining part of the blood collection device and the capped needle is removed in a safe manner, e.g. disposing the needle in a suitable needle waste container.

   Label the Monovette containing the mother's blood sample with the Client ID stickers provided with the kit.

IMPORTANT: **Following the collection procedure, makes sure that the umbilical cord blood bag, umbilical cord tissue tube and the monovette containing maternal blood are properly labelled by affixing the Client ID Stickers provided with the Collection Kit.**

Step 5 – Packaging of Collected Samples in Transportation Box

1. Insert the following correctly labelled samples in the provided 95kPa safety bag:
   - Blood bag with collected umbilical cord blood
   - Tube with the umbilical cord tissue
   - Monovette with maternal blood

   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 completed Identification Form on top of the Neopor box before closing the outer cardboard box.

2. Close the outer cardboard box containing the isolation box and put it at **room temperature** (between 1◦c and 30◦C).

   Note: Never put the collection kit in a refrigerator, freezer or any other cold storage.

Step 6 – Contacting courier services

1. After packaging of the collected samples, contact the courier service by using the information provided in the Sending Procedure supplied along with the Collection Kit.
2. The courier service will collect the packaged samples at the agreed time and deliver the package directly to the Cryo-Save Labs in Niel (Belgium).

   Note: Meanwhile, the packaged human material is stored as described in the instructions provided with the Collection Kit.