



STEM CELL LABORATORY (STCL)



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STCL-PROC-044

CBU PROCESSING VIA MANUAL METHOD

1 PURPOSE

- 1.1 Umbilical cord blood (UCB) units, collected from a single donor, can be processed to reduce volume via red blood cell (RBC) and plasma reduction using manual processing methods and a refrigerated centrifuge prior to cryopreservation. Hydroxyethyl starch (HES), a sedimentation agent, is used to assist with the isolation of the nucleated cell component fraction. These units are prepared for cryopreservation and storage for potential use in allogeneic bone marrow transplantation or autologous infusion. Samples from the buffy coat are used to determine total nucleated cell count, viability and stem and progenitor cell enumeration. Samples of RBC and plasma are taken for sterility and samples are saved for human leukocyte antigen (HLA) testing, if indicated, and future genetic or infectious disease testing.
- 1.2 Manual processing of UCBs is considered for the following reasons:
 - 1.2.1 When the cord blood (ONLY) volume is < 30 mL.
 - 1.2.2 When the automated equipment is down and no backup is available.
 - 1.2.3 If/when the medical director gives orders to process the unit manually.

2 INTRODUCTION

- 2.1 Umbilical cord blood is a useful source of hematopoietic stem cells for hematopoietic reconstitution in both the unrelated and related donor setting.
- 2.2 Umbilical cord blood collections are volume reduced to concentrate stem and progenitor cells in a small volume collection bag for cryopreservation and long-term storage under liquid nitrogen.
- 2.3 Specimen Requirements
 - 2.3.1 Umbilical cord blood units collected into Citrate Phosphate Dextrose (CPD) anticoagulant via the Carolinas Cord Blood Bank (CCBB) or collected remotely and shipped to the Stem Cell Laboratory (STCL).

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Stem Cell Laboratory Medical Director, Stem Cell Laboratory Manager, and representatives of the Stem Cell Laboratory staff are responsible for ensuring the requirements of this procedure are successfully met.
- 3.2 Technologists shall only handle one unit in the hood at any given time.
- 3.3 Processing of the cord blood (from collection to initiation of freezing) must be completed within 72 hours of collection.
- 3.4 Lot numbers must be recorded for all supplies, reagents and designated equipment used for processing on *STCL-FORM-050 Processing Lot Numbers - CBU*

Processing. Quality control checks, cleaning and serial numbers on all equipment used must be documented prior to use for processing.

- 3.5 Equipment shall be cleaned between uses on UCB units with an appropriate cleaning solution. This includes the surface of the biological safety cabinet (BSC), manual tubing strippers, scissors, pipettes, hemostats and sealers.

4 DEFINITION/ACRONYMS

4.1	BC	Buffy Coat (leuko-rich product)
4.2	BSC	Biological Safety Cabinet
4.3	C	Celsius
4.4	cm	centimeter
4.5	CBU	Cord Blood Unit
4.6	CCBB	Carolinas Cord Blood Bank
4.7	CDC	Centers for Disease Control
4.8	CPD	Citrate Phosphate Dextrose
4.9	DMSO	Dimethyl Sulfoxide
4.10	G	Gauge
4.11	g	gram
4.12	HES	Hespan
4.13	HLA	human leukocyte antigen
4.14	HPCA	Hematopoietic Progenitor Cell Assay
4.15	ISBT	International Society of Blood Transfusion
4.16	kg	kilogram
4.17	mL	milliliter
4.18	µL	microliter
4.19	RBC	Red Blood Cell
4.20	RPM	revolutions per minute
4.21	STCL	Stem Cell Laboratory
4.22	UCB	Umbilical Cord Blood
4.23	WBC	White Blood Cell

5 MATERIALS

5.1 SUPPLIES:

- 5.1.1 UCB collection bag
- 5.1.2 Transfer Freezing Bag Set, Medsep product code 791-02

NOTE: This set consists of two transfer bags (the processing bag, or bag #2, and the plasma bag, or bag #3) and a cryo bag.

- 5.1.3 Terumo sterile welding wafers
- 5.1.4 19 G luer lock needles
- 5.1.5 16 G luer lock needles
- 5.1.6 Isopropyl Alcohol wipes, Steri-Perox® Wipe, or equivalent
- 5.1.7 60 mL syringe
- 5.1.8 30 mL syringe
- 5.1.9 20 mL syringe
- 5.1.10 10 mL syringe
- 5.1.11 3 mL syringe
- 5.1.12 5 mL sterile snap cap tubes
- 5.1.13 5 mL phenotype sample tubes
- 5.1.14 ISBT barcode labels
- 5.1.15 Thermogenesis Demand 128 Cryo label
- 5.1.16 Cryovials
- 5.1.17 Nalgene nunc vials
- 5.1.18 Tube racks
- 5.1.19 BacT/Alert Aerobic Culture Bottle
- 5.1.20 BacT/Alert Anaerobic Culture Bottle
- 5.1.21 Microscope slides
- 5.1.22 Microscope slide holder
- 5.1.23 Freezer boxes with 10x10 grid inserts
- 5.1.24 Pipette Tips
- 5.1.25 Transfer Pipettes
- 5.1.26 Sharpie Marker
- 5.1.27 Pencil
- 5.1.28 Freezer boxes with 10 x 10 grid inserts
- 5.1.29 FTA cards
- 5.1.30 FTA bags – small zip lock bag
- 5.1.31 FTA card drying rack

5.2 REAGENTS:

- 5.2.1 Hespan (6% Hetastarch)
- 5.2.2 Trypan Blue Stain

5.2.3 Anti-A, Anti-B and Anti-D Reagents

5.2.4 Sysmex Cell Pack Reagent

6 EQUIPMENT

6.1 Biological Safety Cabinet

6.2 Barcode scanner

6.3 Label replicator with ISBT compatible scanner

6.4 Sterile Tubing Welder

6.5 Refrigerated Centrifuge

6.6 Centrifuge cups and inserts

6.7 Manual plasma extractor

6.8 Balance/Scale

6.9 Hemostats

6.10 Serofuge Centrifuge

6.11 Platform Rocker

6.12 Automated Hematology Analyzer

6.13 Ultra Low Freezer (~ -80°C)

6.14 Mini-Vortex

6.15 Sterile tubing sealer, adapted for both PVC and EVA tubing

6.16 Manual Tubing Stripper

6.17 2-20 µL Pipette

6.18 50-200 µL Pipette

6.19 Scissors

7 SAFETY

7.1 Wear all appropriate personal protective equipment when handling any/all potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coats, etc.

7.2 **NOTE:** A technologist will only handle/process one cellular product in the biological safety cabinet at any given time.

8 PROCEDURE

8.1 PRODUCT ENDPOINTS

8.1.1 Autologous Cord Blood Units (CBU) should contain >100 x 10⁶ cells and should be processed within 72 hours from collection.

8.1.2 Directed donor allogeneic CBUs should contain >10 x 10⁶ cells/kg of intended recipient body weight, if recipient weight is known, and should

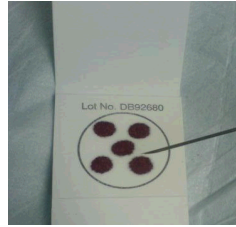
be processed within 72 hours from collection (*See appropriate age-specific growth charts published by the Centers for Disease Control (CDC)*).

- 8.1.3 If the CBU does not meet the above criteria, but is deemed necessary for storage by the medical director, a non-conforming product must be completed before the unit is administered to the recipient following *STCL-QA-007 Non-conforming Products – Receipt, Processing, Distribution, and Disposition*.

8.2 PROCEDURE

- 8.2.1 Place CBU on platform rocker. Turn rocker on and let unit rock gently for at least 5 minutes to allow for adequate mixing.
- 8.2.2 Locate the sheet of adhesive ISBT barcode labels included in the working folder. Verify that all barcodes match with the barcode label on the CBU.
- 8.2.3 Label *STCL-COLL-007 FRM2 Auto/Directed CBU Receipt Form* using an ISBT barcode, handwritten the mother's name on the form and complete the form.
- 8.2.4 Label a sterile snap cap tube using an ISBT 128 barcode and with a Sharpie marker handwritten "PRE" on the tube.
- 8.2.5 Label *STCL-PROC-042 FRM2 CBU Processing Worksheet* using an ISBT barcode and handwritten the mother's name on the form.
- 8.2.6 Obtain the weight/volume of the CBU using one of the following methods;
 - 8.2.6.1 Weigh the collection bag and subtract 65.0 g.
 - 8.2.6.2 Working in a BSC, disinfect the septum of the collection bag injection port and draw up the collected CBU using syringes and needles, measure volume and return blood to the collection bag.
- 8.2.7 Record the sample volume/weight of the bag on the *STCL-PROC-042 FRM2 CBU Processing Worksheet*.
- 8.2.8 Label two FTA cards with small ISBT 128 barcode labels. **NEVER handle the FTA cards with bare hands.**
- 8.2.9 Obtain 1.7 mL of cord blood from the syringe port of the collection bag using aseptic technique. These steps must be completed in a BSC.
 - 8.2.9.1 After disinfecting the septum of the injection port, use a 3 mL syringe and a needle to mix the blood in the tubing between the injection site and the bag.
 - 8.2.9.2 After mixing 2-3 times into the 3 mL syringe, remove 1.7 mL of UCB from the collection bag and complete the following steps for inoculating the FTA cards and preparing pre-count tube.

- 8.2.10 With needle bevel pointed downwards hold the needle at a 45 degree angle and carefully drop five small drops of blood onto the card within the printed circle.



- 8.2.10.1 Avoid puddling of the liquid sample as it will overload the chemicals on the card.
- 8.2.10.2 Do not rub or smear the blood onto the cards.
- 8.2.10.3 Make sure that you do not touch the surface of the card with the needle tip.
- 8.2.11 Dispense ~0.5mL of UCB in labeled sterile snap cap tube.
- 8.2.12 Split the remaining ~1.0 mL of UCB between aerobic and anaerobic culture bottles.
- 8.2.12.1 Label each bottle with an ISBT barcode and handwrite the mother's name, DD UCB "PRE", the date of inoculation and the inoculator's initials.
- 8.2.12.2 Remove the cap from the anaerobic bottle and disinfect the tops of both the anaerobic and aerobic culture bottles.
- 8.2.12.3 Inject ~0.5 mL UCB into each bottle.
- 8.2.13 Place FTA cards into the polyurethane drying rack to allow to air dry.
- 8.2.13.1 Blood on FTA cards must be completely dry (approximately 2 hours) before bagging separately*.
- 8.2.13.2 Place the bagged cards in the manila envelope in the corresponding working packet*.

NOTE: (*) Indicates that these steps do not have to be completed at this point in the process.

- 8.2.14 Using *STCL-EQUIP-002 Sysmex XS-1000i Hematology Analyzer for the Stem Cell Laboratory*, run automated complete blood count using sample in pre-count tube.
- 8.2.15 Once count is complete the results will print automatically. Verify the barcode on the printout to the barcode on your labeled tube.
- 8.2.16 Circle the Platelet (PLT) Count and verify that the count is $\geq 100,000$. If the count is $< 100,000$, an estimated platelet count must be ordered. A manual differential must be ordered on all CBUs.
- 8.2.17 Verify ISBT barcode labels, transcribe the WBC to the *STCL-PROC-042 FRM2 CBU Processing Worksheet* and calculate total volume and

total nucleated cell count of the UCB.

- 8.2.17.1 Autologous CBUs should contain >100 x 10⁶ cells.
- 8.2.17.2 Allogeneic CBUs should contain > 10 x 10⁶ cells/kg of intended recipient body weight if the recipient's weight is known. (See *STCL-PROC-044 JAI* for appropriate age-specific growth charts published by the Centers for Disease Control (CDC)).
- 8.2.17.3 If the CBU does not meet the above criteria, notify the medical director of results. The medical director will determine if CBU should be processed and stored. A non conforming product (per *STCL-QA-007*) will be required if the unit does not meet these specifications but the medical director still plans to process and store the unit for future infusion.
- 8.2.18 Hespan is added to help sediment the RBCs and concentrate the unit. Calculate the volume of HES to be added to the CBU using the following formula:
$$\text{Total Volume (Blood + CPD) mL} / 5 = (\text{Total HES}) \text{ mL}$$
- 8.2.19 Record the calculated volume on *STCL-PROC-042 FRM2 CBU Processing Worksheet*.
- 8.2.20 In the BSC, attach a needle to the appropriate syringe size to accommodate calculated HES volume.
- 8.2.21 Disinfect the septum of the injection port of the Hespan bag, insert the needle and withdraw the calculated amount of Hespan.
- 8.2.22 Disinfect the injection port of the UCB collection bag and inject the HES into the bag at a rate of approximately 2 mL/second. Manually agitate the CBU with one hand, while injecting the HES with the other hand, to rock the bag back and forth during infusion to gently mix the contents.
- 8.2.23 Note time of Hespan addition on the collection bag or *STCL-PROC-042 FRM2 CBU Processing Worksheet*.
NOTE: After HES addition, the CBU/HES mixture must incubate in a vertical state for a minimum of 20 minutes but no more than 120 minutes prior to manual RBC and plasma reduction. Record the hanging and start times as appropriate.
- 8.2.24 Sterile weld the CBU to the Transfer/Freezing Bag Set kit following the steps outlined in *CCBB-LAB-022 JAI Use of Terumo Sterile Tubing Welder*.
- 8.2.25 Label cryobag with Demand 128 ISBT Label.
 - 8.2.25.1 First, scan the barcode on the collection bag into the Zebra printer, the label will automatically print.

- 8.2.25.2 Handwrite, with a Sharpie marker, the following information on the large label: Auto/Directed UCB, mother's name and the date of processing/cryopreservation.
- 8.2.25.3 The large label adheres to 80% fraction of the cryobag and the small barcode label to the 20% fraction. Retain remaining ISBT label for cassette labeling during cryopreservation per *STCL-PROC-045 Cryopreservation and Storage of CBU*.
- 8.2.26 Centrifugation of the unit for RBC reduction
 - 8.2.26.1 Place the CBU collection bag (bag #1) into the collection bag insert and the stem cell processing set into a centrifuge cup. Extra bags should be folded gently and tucked between insert and cup.
 - 8.2.26.2 Add or adjust thin inserts to maintain the collection bag in an upright position free of folds or creases and placing the meniscus of the blood at or very close to the top of the insert.
 - 8.2.26.3 Balance the centrifuge cups with 10 g of each other.
 - 8.2.26.4 Centrifuge at 700 RPM for ten minutes with the **brake off** (program #1).
 - 8.2.26.5 After completion of the spin, carefully remove the entire centrifuge cup and place it near the manual plasma extractor.
- 8.2.27 Arrange the collection bag on the manual plasma extractor with label facing away so cells can be seen clearly. Place the processing set onto the scale.
- 8.2.28 Place the tubing from the collection bag (bag #1) to the processing bag (bag #2) into the tubing stabilizer. Allow the unit to settle by gravity for a few minutes if necessary (5 to 10 minutes). Record the time the hang started and completed and the total minutes that the unit was allowed to hang on *STCL-PROC-042 FRM2 CBU Processing Worksheet*.
- 8.2.29 Tare the scale.
- 8.2.30 Open the necessary clamps
- 8.2.31 Slowly close the front part of the extractor.
- 8.2.32 Using a hemostat to control and stop the flow, slowly express the supernatant into the processing bag (bag #2) in a manner to avoid turbulence.
- 8.2.33 As the red cells start to enter the processing bag (bag #2), monitor the scale to let 20 mL of RBC into the processing bag. Clamp the tubing closed.

NOTE: If mixing occurs, resulting in apparent retention of WBC in bag #1 or excessive transfer of RBCs to bag #2, return all material to bag #1

and reinitiate the procedure from step 8.2.26.

- 8.2.34 Close all clamps and heat seal the tubing with 3 seals. Cut the seal in the middle to remove the collection bag from the processing set.
NOTE: Leave enough tubing on each side to repeat sterile docking should the recovery warrant a second spin.
- 8.2.35 Preparation for centrifugation for plasma reduction
- 8.2.35.1 Place processing bag into appropriate centrifuge insert and cup. Plasma bag should be folded gently and tucked between the insert and the centrifuge cup.
- 8.2.35.2 Add inserts to insure bag stands upright without folds or creases if necessary.
NOTE: Taping the processing bag so the lower edge does not contact the bottom of the insert is also acceptable.
- 8.2.35.3 Balance the buckets within 10 g of each other.
- 8.2.35.4 Centrifuge at 1200 RPMs for 20 minutes with the **brake ON** (program #2).
- 8.2.36 Carefully remove the stem cell processing kit from the centrifuge cup and place the processing bag on to the plasma extractor with the label facing out. Place the plasma bag onto the scale. Express plasma into the plasma bag until approximately 21.5 mL of cells/plasma remain in the processing bag.
- 8.2.37 If mixing occurs, resulting in excessive retention of plasma in the processing bag or if there is excessive transfer of WBC to the plasma bag, return all material to the processing bag and repeat procedure beginning at step 8.2.35.
- 8.2.38 Temporarily close off the plasma bag. Do not permanently seal off this bag at this time as it will be ceded for a second spin should there be poor end recoveries.
- 8.2.39 With large ISBT barcode labels, label remaining forms to include
- 8.2.39.1 STCL-PROC-042 FRM1 CBU Processing Form
- 8.2.39.2 STCL-SOP-052 FRM1 Progenitor Cell Assay Form
- 8.2.39.3 STCL-PROC-035 FRM1 Manual Differential Cord Blood Units
- 8.2.39.4 FLOW-GEN-012 FRM5 Stem Cell Laboratory Flow Cytometry Worksheet
- 8.2.39.5 FLOW-FORM-012 Graft Characterization
- 8.2.39.6 STCL-FORM-050 Processing Lot Numbers - CBU Processing
- 8.2.39.7 STCL-PROC-045 FRM1 CBU Cryopreservation
- 8.2.39.8 CCBB-LAB-005 FRM1 CBU Disposition (*if applicable*)

- 8.2.40 With small ISBT barcodes label the following:
 - 8.2.40.1 1-Sterile snap cap tube (post processing sample)
 - 8.2.40.2 5-Phenotype tubes (1-post count tube, 4 tubes for ABO/Rh typing)
 - 8.2.40.3 17 nunc vials (6 for cord blood RBCs and 11 for cord blood plasma)
 - 8.2.40.4 2- cryovials (DMSO nuncs)
 - 8.2.40.5 1- Aerobic culture bottle and 1- Anaerobic culture bottle
 - 8.2.40.6 2-barcodes adhered to tray for BacT-Alert Log sheet and - 80° C Freezer Log sheet (*STCL-FORM-038*).
 - 8.2.40.7 10-14 ISBT barcode sheet for use by HPCA and flow
 - 8.2.40.8 4 ISBT barcode sheet for microscopic slides
- 8.2.41 Remove the pink striped maternal sample labels from the envelope in the packet and label seven nunc vials with the pink striped maternal sample labels. Place “S” on one of the vials for serum nunc.
- 8.2.42 Place any extra barcode labels in the manila envelope in the working packet.
- 8.2.43 Post CBU processing, and working in a BSC, mix the cells of the buffy coat bag (processing bag) well.
- 8.2.44 Disinfect the syringe port of the buffy coat bag.
- 8.2.45 Using a 3 mL syringe and a needle, remove 0.5 mL and place into a second sterile labeled snap cap tube. Confirm the labels by observation.
- 8.2.46 For post processing cell count sample, use a pipette to extract 160 µL of cell pack reagent and 40 µL (1:5 dilution) of buffy coat sample from the sterile snap cap tube and dispense into the labeled phenotype tube and mix the dilution well.
- 8.2.47 Using *STCL-EQUIP-002 Sysmex XS1000i Hematology Analyzer for the Stem Cell Laboratory*, run automated complete blood count. Results will print automatically. Verify the barcode on the printout to the barcode on the labeled tube. Record on Sysmex printout the dilution performed and show calculations.
- 8.2.48 Record and calculate the TNCC and percent recovery using *STCL-PROC-042 FRM2 CBU Processing Worksheet*.

NOTE: If the TNC recovery is < 60%, contact medical director to see if the CBU requires reprocessing. If TNC recovery is ≥ 60%, seal off and remove the plasma bag. Place the processing set into a refrigerator for a minimum of 15 minutes and a maximum of 2 hours and follow *STCL-PROC-045 Cryopreservation and Storage of CBU*.
- 8.2.49 If the TNC recovery is >60%, perform a viability count using *STCL-SOP-022 Viability Counts via Trypan Blue Dye Exclusion* or alternate

- method (if applicable).
- 8.2.50 Calculate and complete applicable sections of forms *FLOW-GEN-012 FRM5 Stem Cell Laboratory Flow Cytometry Worksheet* and *STCL-SOP-052 FRM1 Progenitor Cell Assay Form*.
 - 8.2.51 Label four microscopic slides with ISBT barcode labels. Using a pencil, label two of the slides with “PRE” (collection bag, pre-processing sample) and two with “POST” (buffy coat, post processing sample).
 - 8.2.52 Using a BSC and a pipette, remove 8µL of sample from the pre-count tube that was taken from the original collection bag. Split the 8µL between the two slides labeled “PRE” by placing a small drop on each slide. Then use clean slide to smear blood across slide.
 - 8.2.53 Repeat step 8.2.52 with the buffy coat, post processing sample and “POST” slides.
 - 8.2.54 Allow slides to air dry and then place into a slide holder.
 - 8.2.55 Stem Cell Laboratory analysis of post processing sample:
 - 8.2.55.1 Take buffy coat post processing sample tube, flow and progenitor forms, and 10-12 ISBT barcode labels to HPCA for plating and flow analysis.
 - 8.2.55.2 Take slides and *STCL-PROC-035 Manual Differential (Slide Method) – CBUs for CCB Program* to HPCA for staining. Stain one “PRE” and one “POST” slide with the Wright-Giemsa stain using the automated stainer. Leave the other slide unstained.
 - 8.2.55.3 Once slides are stained and read and testing is complete, the slides and all associated paperwork will be returned for filing with the CBU packet. Manual differential results will need to be recorded on the *STCL-PROC-042 FRM2 CBU Processing Worksheet*.
 - 8.2.56 ABO/Rh typing of the CBU
 - 8.2.56.1 Follow Procedure *STCL-SOP-049 ABO-Rh Typing* and record results on *STCL-SOP-049 FRM1 Blood Bank Worksheet* and on *STCL-PROC-042 FRM2 CBU Processing Worksheet*.
 - 8.2.57 RBC Distribution
 - 8.2.57.1 Using a BSC and aseptic technique, attach a needle to a syringe.
 - 8.2.57.2 Disinfect the syringe port on the residual RBC containing bag and insert needle. Extract ~18 mL of RBCs.
 - 8.2.57.3 Remove cap from anaerobic culture bottle, disinfect the tops of both the anaerobic and aerobic culture bottle. Inject ~2.5 mL of RBCs into each bottle.

- 8.2.57.4 With remaining RBC volume, fill six nunc vials with 1.5 mL each of RBCs. Confirm ISBT barcode labels by observation.
- 8.2.58 Plasma Distribution
 - 8.2.58.1 Using a BSC and aseptic technique, attach a needle to a 30 mL syringe.
 - 8.2.58.2 Disinfect the syringe port on the plasma bag and insert the needle. Extract 30 mL of plasma.
 - 8.2.58.3 If applicable, disinfect the tops of both the aerobic and anaerobic culture bottles. Inject ~7.5 mL of plasma into each bottle.
 - 8.2.58.4 With remaining plasma, fill 8 nunc vials with 1.5 mL each. Confirm ISBT barcode labels by observation.
- 8.2.59 Sterility Testing
 - 8.2.59.1 Enter CBU information and load sterility culture bottles per, *STCL-EQUIP-011 Sterility Cultures Using the BacT/Alert Microbiology System*.
 - 8.2.59.2 Place CBU ISBT barcode label and bottle ID labels onto *STCL-EQUIP-011 FRM1 BacT-Alert Log Sheet*.
 - 8.2.59.3 Bottles will be incubated for a minimum of 7 days. Any positive bottles are flagged by the analyzer. Positive and negative bottles will be unloaded and results printed for each unit. Results will be filed in the working packet.
 - 8.2.59.4 Any positive bottles will be forwarded to clinical microbiology for organism identification and sensitivity testing. Final microbiology results will be filed in the working packet along with all other test results.
- 8.2.60 Storage and Allocation of RBC and Plasma Nunc Vials
 - 8.2.60.1 All nunc vials will be stored in cardboard freezer boxes and assigned a location on the -80°C Freezer Log sheets *STCL STCL-FORM-038*. These specific freezer locations will be recorded on the *STCL-PROC-042 FRM1 CBU Processing Form* for ease in locating, should they be needed in the future.
 - 8.2.60.2 Twenty slots are assigned for each CBU; six slots for RBC nunc vials, seven slots for plasma nunc vials and seven slots for maternal nunc vials (see *STCL-COLL-007 JA10 Auto/Directed Maternal Blood Sample Processing*). Place the RBC and plasma nuncs in the assigned location for storage. Place any empty maternal sample nuncs in a sample tray and hold until maternal samples are received

and processed. Maternal nuncs will be placed into assigned location following processing.

- 8.2.60.3 The remaining plasma nunc vial will be placed in the freezer box labeled “CMV” located in the UltraLow Freezer in the CCBB Lab.

8.2.61 Follow *STCL-PROC-045 Cryopreservation and Storage of CBU*.

9 RELATED DOCUMENTS/FORMS

- 9.1 CCBB-LAB-005 FRM1 CBU Disposition
- 9.2 CCBB-LAB-022 JA1 Use of Terumo Sterile Tubing Welder
- 9.3 FLOW-FORM-012 Graft Characterization
- 9.4 FLOW-GEN-012 FRM5 Stem Cell Laboratory Flow Cytometry Worksheet
- 9.5 STCL-COLL-007 FRM2 Auto/Directed CBU Receipt Form
- 9.6 STCL-COLL-007 JA10 Auto/Directed Maternal Blood Sample Processing
- 9.7 STCL-EQUIP-002 Sysmex XS-1000i Hematology Analyzer for the Stem Cell Laboratory
- 9.8 STCL-EQUIP-011 Sterility Cultures Using the BacT/Alert Microbiology System
- 9.9 STCL-EQUIP-011 FRM1 BacT-Alert Log Sheet
- 9.10 STCL-FORM-038 -80C Freezer Log
- 9.11 STCL-FORM-050 Processing Lot Numbers - CBU Processing
- 9.12 STCL-PROC-035 Manual Differential (Slide Method) – CBUs for CCBB Program
- 9.13 STCL-PROC-035 FRM1 Manual Differential Cord Blood Units
- 9.14 STCL-PROC-042 FRM1 CBU Processing Form
- 9.15 STCL-PROC-042 FRM2 CBU Processing Worksheet
- 9.16 STCL-PROC-044 JA1 Growth Charts for Girls and Boys
- 9.17 STCL-PROC-045 Cryopreservation and Storage of CBU
- 9.18 STCL-PROC-045 FRM1 CBU Cryopreservation
- 9.19 STCL-QA-007 Non-conforming Products – Receipt, Processing, Distribution, and Disposition.
- 9.20 STCL-SOP-022 Viability Counts via Trypan Blue Dye Exclusion
- 9.21 STCL-SOP-049 ABO-Rh Typing
- 9.22 STCL-SOP-049 FRM1 Blood Bank Worksheet
- 9.23 STCL-SOP-052 FRM1 Progenitor Cell Assay Form

10 REFERENCES

- 10.1 American Association of Blood Banks (AABB). Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.
- 10.2 Foundation for the Accreditation of Cellular Therapy (NetCord-FACT) International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release Current edition.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	Barbara Waters-Pick	Updated references to forms and procedures throughout the document. Updated Section 5.1.6 to include Steri-Perox® Wipe Added section 7.2 to include <u>NOTE</u>: A technologist will only handle/process one cellular product in the biological safety cabinet at any given time. Included reference to Non-Conforming Product (NCP) instead of variance or unplanned deviations when UCBs do not meet specifications (Sections 8.1.3 and 8.2.17.3)

Signature Manifest

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STCL-PROC-044 CBU Processing via Manual Method

Author

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Richard Bryant (RB232)		28 Apr 2020, 08:40:31 AM	Approved

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