STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-PROC-036

DOCUMENT TITLE:

Thawing and Washing Umbilical Cord Blood Units Using an Automated Sepax System

DOCUMENT NOTES:

FACT # 6D.120
Document required for the BLA.

Document Information

Revision: 02	**Vault:** STCL-Processing-rel
Status: Release	**Document Type:** Processing

Date Information

Creation Date: 02 May 2014	**Release Date:** 06 May 2014
Effective Date: 06 May 2014	**Expiration Date:**

Control Information

Author: WATE02	**Owner:** WATE02
Previous Number: STCL-PROC-036 Rev 01	**Change Number:** STCL-CCR-197

STCL-PROC-036
THAWING AND WASHING UMBILICAL CORD BLOOD UNITS USING AN AUTOMATED SEPAX® SYSTEM

1 PURPOSE

1.1 To maximize viable cell recovery, cryopreserved cord blood units are rapidly thawed in a 37° C water bath until slushy. The use of the automated Sepax® 2 RM Cell Processor and sterile kit with the CORD WASH program is designed to remove cryoprotectant and hemolyzed plasma to generate cord blood units (CBU) for transplant. The automated wash program also includes two rinse steps of the cryobag with diluted cells to recover as many viable and functional cells as possible.

2 INTRODUCTION

2.1 Umbilical cord blood units that are cryopreserved with dimethyl sulfoxide (DMSO) have diminishing viability upon thawing, resulting in the potential for significant loss of cells available for transplantation. DMSO creates a hypertonic intracellular environment which can lead to sudden fluid shifts that compromise cell viability. In addition, DMSO causes adverse side effects in vivo after infusion, including blood pressure instability, fever, chills, and nausea. Lysis of red blood cells during thawing also leads to accumulation of free hemoglobin that can be nephrotoxic when infused intravenously. The automated wash procedure on the Sepax® 2 RM Cell Processor with the CORD WASH program and sterile kit is designed to dilute and remove DMSO and excess free hemoglobin from the thawed unit prior to infusion.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure describes in detail the preparation of a Dextran/Albumin buffer, the thawing of the cryopreserved cord blood, and the preparation and use of the automated wash procedure with the Sepax® 2 RM Cell Processor, CORD WASH program and sterile kit. This procedure covers all required steps for the application of this automated wash method with the Sepax® 2 RM Cell Processor up to the removal of the processed cells from the output bag and waste bag.

3.2 This automated wash procedure has been validated with cord blood cryobag units with a volume of 10 mls to 100 mls (cord blood unit plus DMSO) frozen in MedSep bags, Origen bags, etc. Any significant modifications to the procedure, instrument, kit, including cryobag and/or software program, should be documented and/or validated as equivalent for appropriate use.

4 DEFINITIONS/ACRONYMS

4.1 C	Celsius
4.2 CBU	Cord Blood Unit
4.3 DMSO	dimethyl sulfoxide

4.4 UCB	umbilical cord blood
4.5 ml	milliliters
4.6 w/v	weight/volume
4.7 SA	aerobic culture bottles
4.8 SN	anaerobic culture bottles
4.9 mm	millimeter

5 MATERIALS: Reagents and Supplies

5.1 CS600.1 kit, Biosafe (Figures 5 and 6)

5.2 Phase 5™ CryoPak° (2-8° C, TCP Reliable) gel blanket

5.3 Thermogenesis canister opener

5.4 Sterile and non-sterile zip-lock bags

5.5 Hemostats

5.6 Scissors

5.7 Dextran (10% Dextran 40 [LMD] in 0.9% NaCl), USP

5.8 Human Serum Albumin (HSA) 25% (w/v) USP

5.9 300 ml transfer pack

5.10 16 G needles

5.11 19 G needles

5.12 3 ml syringe

5.13 10 ml syringe

5.14 20 ml syringe

5.15 30 ml syringe

5.16 60 ml syringe

5.17 20 µl-200 µl pipet tips

5.18 Alcohol Prep Pads

5.19 ChloraPrep® SEPP® applicators

5.20 Sampling Site Coupler

5.21 Cell Pack buffer

5.22 Iodine swab sticks

5.23 Disposable Gloves

5.24 Cold protective insulated cryogloves

5.25 Alcohol

5.26 Validated Transport container

5.27 5 ml (12 X 75 mm) sterile polyproplyene culture tubes with snap caps

5.28 5 ml (12 X 75 mm) non-sterile, polystyrene culture tubes

5.29 Cryogenic vials

5.30 Sterile gauze squares

6 EQUIPMENT

6.1 Biosafe Sepax® 2 RM Cell Processor (Figure 1)

6.2 Biological Safety Cabinet (BSC) class II, laminar flow hood

6.3 Sterile Tubing Welder (docker)

6.4 Tubing Heat sealer

6.5 Electronic Balance

6.6 Waterbath 37°C

6.7 Refrigerator 2-8°C

6.8 Automated hematology analyzer

6.9 Brightfield microscope

6.10 20-200 µl pipettor

Figure 1

7 SAFETY

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

8 PROCEDURE

8.1 General Procedure notes:

8.1.1 Use aseptic technique in the BSC for all indicated processing steps, including all spiking of bags.

8.1.2 Allow only sterile materials to come in contact with the cellular product.

8.1.3 Record the manufacturer, lot number and expiration date of all reagents and disposables, Processing Lot Numbers.

8.1.4 Assemble all materials before thawing the cryopreserved product.

8.1.5 Handle the thawed cell suspension very gently. The cell membranes are fragile and the cells are easily lysed just after thawing.

8.1.6 The infusion time should be set up in advance with the nurse and the start time for this thawing procedure should be adjusted accordingly.

8.1.7 Verify the waterbath has sufficient water and the temperature is 37o C.

8.1.8 Prepare and label (ISBT128 barcode labels) paperwork

8.2 Preparation of Dextran-Albumin thawing solution:

8.2.1 Using aseptic technique spike a 300 ml transfer pack into a bag of Dextran.

8.2.2 Place the empty transfer pack on the balance and tare the balance.

8.2.3 Transfer 250 grams (g) of Dextran solution to the 300 ml transfer pack.

8.2.4 Heat seal the tubing by creating 3 seals between the bags and detach the Dextran bag by cutting the tubing at the middle seal.

8.2.5 Working in the BSC, insert a sampling site coupler to the 300 ml transfer pack containing 250 g of Dextran. Disinfect the septum top of the bottle of 25% Human Serum Albumin (HSA) and the sampling coupler with an alcohol prep pad.

8.2.6 Draw up 50 ml HSA in a syringe and inject into the 300 ml transfer pack containing 250 g of Dextran. Invert the bag several times to mix the Dextran/HSA solution (**Figure 3**).

250 ml of Dextran 40 in 0.9% NaCl

+ 50 ml of 25% (w/v) Human Serum Albumin (= 12.5 g HSA)

= 300 mls total of Dextran with 4.2% (w/v) Human Serum Albumin Buffer (12.5 g ÷ 300 = 0.0416, 0.0416 X 100 = 4.2% w/v HSA)

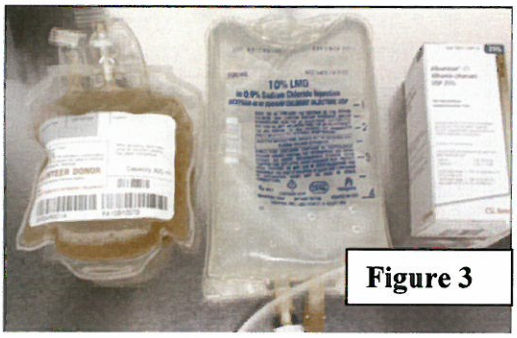


Figure 3

NOTE: Dextran-Albumin solution will be referred to as "buffer" in future steps.

8.3 Kit Preparation

8.3.1 Heat seal the tubing of a 300 ml transfer pack leaving approximately six inches of tubing. Cut the middle seal with scissors.

NOTE: *This bag is the "output bag" and will be used to collect the final washed cells from the automated wash procedure* **(Figure 4).**

NOTE: The six inches of extra tubing is used to sterile weld to another transfer pack tubing as needed to prepare the cells for infusion.

Figure 4

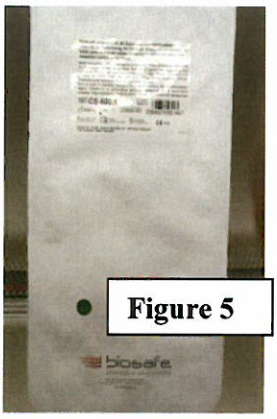
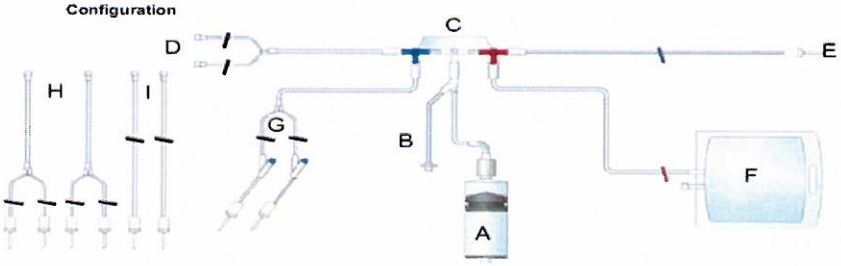


Figure 5

8.3.2 Inspect the Tyvek® cover (Figure 5) of the CS600.1 kit and note the green circle (ETO) that indicates the kit has been sterilized (If the circle is purple, do not use and report the kit lot number to Biosafe). In the BSC, remove the kit from the package. Discard both the loose extension tubing with the single spikes ("I" on kit diagram) and one of the extension tubes with the double spikes ("H" on the kit diagram). Lay the kit out on the working surface as indicated in the kit diagram

Figure 6



A: Separation chamber 220 ml
B: Line pressure monitor luer with microbial filter
C: Stopcock manifold
D: Double input line with female luer lock connectors and clamps
E: Washing solution input with spike and clamp.
F: 1000ml PVC waste collection bag
G: Double output line with spike, injection site and clamps.
H: 2 x extensions for input bag connection with double spike, male luer lock connector and clamps. For use with cryobag requiring a double connection during the thawing process.
I: 2 x extensions for input bag connection with a single spike, male luer lock connector and clamp. For use with cryobag with a single connection during the thawing process.

For use with cryobag with a single connection during the thawing process.

8.3.3 Remove the cap on one of the upper left "D" double input lines and the cap on one of the loose extension lines with two spikes ("H") and twist the connections tightly to connect the extension lines.

8.3.4 Close the all clamps on the CS600.1 kit, taking care to slide the clamps all the way across the tubing.

8.3.5 Spike the buffer to the Sepax® kit to section "E." (**Figure 6**).

8.3.6 Spike the output bag to the Sepax kit to section "G" (note that a sample syringe port is part of this section of the kit) (**Figure 7**).

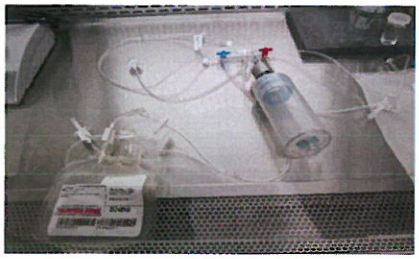


Figure 7

8.3.7 Attach an ISBT128 barcode label for the thawed unit on the output bag and one on the 1,000 ml waste collection bag attached to the kit.

8.4 Instrument preparation prior to thaw

8.4.1 Prior to thawing the unit, be sure the Sepax® 2 RM instrument power is on and has completed the autotest start-up sequence.

8.4.2 Using the touch screen choose the Washing application. On the next screen, choose CORDWASH v308.

***NOTE:** Use the current validated version of the CORD WASH program. The version number and date will be included as part of the log file generated by the Sepax® 2 RM.

8.4.3 Select "CHANGE PARAMETERS" on the touch screen. Check initial volume; if volume is incorrect, push button on the screen and manually enter the correct volume. Check the final volume; if the volume is incorrect, push button on the screen and manually enter the correct volume.

Initial Volume = 10 - 100 ml

Dilution = 1.0

Final Volume = 50 -150 ml (minimum volume is 50 ml)

8.5 Cord Blood Thawing

8.5.1 Refer to procedures in *STCL-SOP-028 Procedure for Thawing Umbilical Cord Blood Units Frozen in Two Compartment Bags Using Dextran-Albumin Solution* and *STCL-FORM-056 Cellular Therapy Infusion Request Form* to confirm the designated UCB to be removed from designated LN2 freezer.

Figure 8

8.5.2 Remove UCB unit from metal cassette (**Figure8**) and remove overwrap (**Figure 9**).

Figure 9

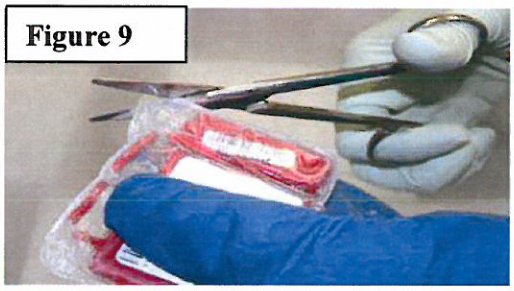
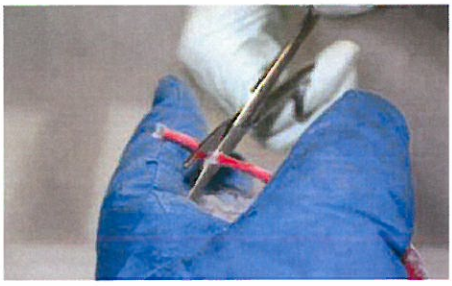


Figure 10



8.5.3 Cut the cryobag segments, if present, as shown in (Figure 10).

8.5.4 Place the segments in a cryovial pre-labeled with patient information, unit number, date, and product type. Place and keep cryovial in vapor phase until final storage spot in liquid nitrogen freezer is determined.

8.5.5 Place the cryobag inside a sterilized zip-lock bag and seal the bag securely.

8.5.6 Thaw the unit in a 37°C water bath by gently massaging the portions of the bag, until product reaches a slushy/liquid consistency.

8.5.7 Dry the outside of the zip-lock bag with paper towels.

8.5.8 Inside the BSC, remove the cryobag from the zip-lock bag and quickly clean the outside of the port covers with a Chloraprep® SEPP® applicator followed by an alcohol prep pad.

8.5.9 Using alcohol disinfected scissors (*STCL-SOP-035 Cleaning and Decontamination protocol for STCL*) cut the port covers off the 80% and 20% portions of the cryobag.

8.5.10 Disinfect the cut ports with Chloraprep® SEPP® applicator followed by alcohol prep pad.

8.6 Spiking the Cryobag to the CS600.1 kit

Figure 11

8.6.1 Insert the spikes (Figure 11), attached and extending from section "D" of the kit) one at a time into the port(s) of the cryobag, by carefully holding the bag at the port(s) and using a back and forth twisting motion. The spikes should be inserted far enough into the cryobag that the port is punctured and that the bottom of the angle on the spike is just inside the interior portion of the cryobag.

8.6.2 Place the cryobag inside a folded over (3 x 6 cell size) Phase 5™ CryoPak° gel blanket (pre-cooled for a minimum of 8 hours at 2-8° C). Slide the folded over gel blanket with the cryobag just inside the opening of a clean zip-lock bag (punctured with a hole at bottom center of bag).

Figure 12

8.6.3 Seal the zip-lock bag closed except for where the extension tubing for section "H" that attaches the cryobag to the kit comes through. Clamps on the spike tubing should be outside of the ziplock bag (**Figure 12**).

8.6.4 Before removing the CS600.1 kit with the attached buffer bag and cryobag from the BSC, ensure all clamps on the kit are closed.

NOTE: Total time from thawing the cryobag, installing the unit and the kit, and initiating the Sepax® 2 RM CORD WASH program should be approximately 5 minutes.

8.7 CS600.1 kit installation for CORD WASH

8.7.1 START PROCEDURE should be displayed on the Sepax® screen.

8.7.2 Open the two separation chamber pit covers.

8.7.3 Install the separation chamber in the pit by pushing it down firmly and verify that it is well inserted.

8.7.4 Insert the separation chamber tubing line into the optical sensor and ensure that tubing is correctly inserted.

8.7.5 Verify that the stopcocks are aligned in the T-position (**TTT**).

8.7.6 Open the stopcock holder by pushing down the two levels; install the stopcocks on the SePAX® rotary drive pins by pushing them down firmly and close the holder by pushing up the levers.

8.7.7 Close the centrifuge cover and tighten the centrifuge cover lock by screwing it clockwise.

8.7.8 Connect the pressure sensor line (luer connector/filter) to the pressure sensor port on top of the SePAX®. Tighten luer lock firmly.

8.7.9 Hang the waste and output bags on the hook provided on the SePAX.

8.7.10 Hang the washing solution bag on the back holder.

8.7.11 Press "Start procedure" to validate and to start the kit test.

8.7.12 If the traceability feature is available, enter the traceability IDs (either with the barcode reader or using the keyboard).

8.7.13 After having entered all traceability IDs, select "Input done, continue" to start the automatic kit test.

NOTE: The total processing time on the Sepax® 2 RM instrument is approximately 30 - 40 minutes.

8.8 Automated Kit Priming

8.8.1 During this operation the kit is primed and the washing solution for primary dilution is prepared in the chamber. To start, follow the instructions as displayed on the Sepax® 2 RM display:

8.8.1.1 Open the washing solution bag clamp, wash bag clamp, and output bag clamp.

8.8.1.2 Select either standard (one washing cycle) or High wash (two washing cycles).

8.8.2 Once priming is finished, the machine beeps and displays "Thaw and connect input bag". Press green √ mark and begin procedure.

8.9 Automated Procedure

8.9.1 The message "Open input bag clamp" is displayed. There are two or three clamps to open depending on the extension line that you chose.

NOTE: Avoid touching the machine, keyboard, or the kit during the automated procedure. Moving bags, tubes, stopcocks, and covers may cause errors and the process must then be restarted.

8.9.2 The washing protocol goes through the following phases:

8.9.2.1 Primary dilution (typically 1:1 volume) into initial bag and chamber (slow extraction).

8.9.2.2 Osmolarity balancing time (about 5 minutes). The product is mixed into chamber and input bag.

8.9.2.3 Chamber filling (product and washing solution).

8.9.2.4 First sedimentation and bag rinsing (two cycles).

8.9.2.5 Supernatant product extraction

8.9.2.6 In case of HIGH WASH process: chamber refilling with washing solution and back to point 8.9.2.4).

8.9.2.7 Cell resuspension

8.9.2.8 Cell extraction

8.9.2.9 Chamber rinsing (0-3 cycles).

8.9.2.10 Apply three seals on the tubing with the spike into the output bag near the attachment to the bag.

8.10 Post Procedure Actions

8.10.1 At the end of the automated procedure, with the kit still installed on the Sepax® 2 RM, the message "Remove bags and air filter" appears on the display. Follow the instructions and press the green √.

8.10.2 The message "Strip cells line" appears on the display. The cells line consists of the line from the left stopcock (blue) to the output bag. Press the green √ when stripping is done.

8.10.3 The message "Strip waste line" appears on the display. Strip the waste line and press the green √.

8.10.4 The message "Close all clamps, Validate" appears on the display. Close all clamps and press green √.

8.10.5 The message "Remove Kit, Validate" appears on the display. Remove kit and press green √.

8.10.6 Remove output bag (contains washed cord blood cells) and waste bag from used kit.

8.10.7 Apply three seals on the tubing near the waste bag.

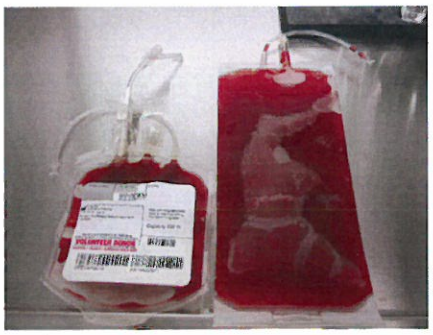
8.10.8 Cut the seal in the middle with scissors.

8.10.9 Apply three seals on the tubing near the waste bag.

8.10.10 Cut the seal in the middle with scissors

8.10.11 Place the output bag and waste bag in the biological safety cabinet (**Figure 13**).

Figure 13



8.10.12 Mix the cells in the output bag well by inverting the bag several times.

8.10.13 Wipe the syringe port on the output bag with an alcohol prep pad.

8.10.14 Draw up and expel cells several times with a needle and 3 ml luer-lok syringe before removing sample for post-thaw testing.

8.10.15 For preparation of cells for transplantation refer to procedure *STCL-SOP-028 Thawing UCB units Frozen in Two Compartment Bags Using D-A Solution* sections 8.10 and 8.11.

8.10.16 If applicable, for preparation and cryopreservation of the remaining cells as back-up from original CBU reinfusion refer to procedure *STCL-SOP-028 Procedure for Thawing UCB Units Frozen in Two Compartment Bags Using D-A Solution* section 8.13.

NOTE: The following post thaw quality control testing should be performed unless otherwise instructed by the physician or medical director:

8.10.17 Automated Hematology Cell counts

8.10.18 Trypan Blue viability staining per *STCL-SOP-022 Viability Counts via Trypan Blue Dye Exclusion*

8.10.19 CD 3, 4, 8, and 34 cell counts (and 7AAD viability, if applicable) by flow cytometry per *FLOW-GEN-012 FRM5 Stem Cell Laboratory Flow Cytometry Worksheet*

8.10.20 CFU total colonies (CFU-GM, CFU-GEMM, BFU-E) per STCL-*PROC-022 FRM1 Stem Cell Laboratory Clinical HPCA Worksheet*

8.10.21 Sterility Tests: BacT/Alert® SA & BacT/Alert® SN performed on 10 ml of supernatant from the waste bag per *STCL-EQUIP-011 Sterility Culture using the BACT/ALERT Microbiology System*

8.10.22 Restriction Fragment Length Polymorphism (RFLP): Approximately 1 x 106 cells performed upon request.

8.10.23 Endotoxin – if applicable and available

8.10.24 Mycoplasma- if applicable and available

8.11 EMERGENCY TROUBLESOOTING:

8.11.1 If the procedure must be stopped, push the Emergency STOP button on the Sepax® display. If the problem cannot be resolved and the procedure cannot be resumed, a purge and recovery process should be initiated.

8.11.2 Recovery and Purge (*if necessary*)

8.11.3 Close all clamps and remove kit from Sepax®. Transfer the kit to the biological safety cabinet. Then transfer the contents of all the bags with cells manually to the output bag (or waste bag depending on volume) through manipulation of the three stopcocks. If blood is still in the cylinder, then sterile weld a 600 ml or larger transfer bag to the "D" position tubing (or attached "H" tubing extension) on the kit and remove the original input cryobag.

8.11.3.1 Install the kit on a working Sepax® instrument and run select the PURGE protocol from the main menu of the Sepax® display to have cells and buffer in the cylinder transferred to the new larger input bag. Refer to the Sepax® 2 RM Operator's manual (pages 35- 52) as needed to complete these steps

8.11.3.2 If necessary, refer to *STCL-SOP-028 Procedure for Thawing Umbilical Cord Blood Units Frozen in Two Compartment Bags Using Dextran-Albumin Solution,* to complete the processing of the cells manually to prepare the cells in a final volume of ~ 50 mls and remove excess hemolyzed plasma and buffer.

8.12 Documentation of Wash

8.12.1 Complete all applicable forms, enter results in the database as appropriate, and file all lab-related documentation in the patient's permanent laboratory file.

8.12.2 Include the automatic Sepax Net printout of your wash process in the paperwork.

8.12.3 If additional information on the run (e.g. to document or troubleshoot error messages) is needed, you can copy the log file from the instrument to the PCMIA (smart) card in the back of the instrument.

8.13 Switching the Power Off to the Sepax® 2 RM

8.13.1 Once the procedure is completed, touch the back arrow (in the upper left hand corner) until the "Quit" box appears on the display. Touch the "Quit" button and wait for the message "Please Switch OFF your Sepax®" to be displayed on the screen. Switch power button (located on the back right corner) of the Sepax® screen.

9 RELATED DOCUMENTS/FORMS

9.1 *STCL-SOP-028 Procedure for Thawing Umbilical Cord Blood Units Frozen in Two Compartment Bags Using Dextran-Albumin Solution*

9.2 *Cryopreservation of Back-up Cells from Original UCB Reinfusion*

9.3 *STCL-FORM-056 FRM1 Hematopoietic Progenitor Cell Infusion Request Form*

9.4 *STCL-SOP-027 JA1 Thawing Job Aide*

9.5 *STCL-FORM-043 Thawing and Infusion Worksheet*

9.6 *STCL-FORM-050 Processing Lot Numbers*

9.7 *FLOW-GEN-012 FRM5 Stem Cell Laboratory Flow Cytometry Worksheet*

9.8 *STCL-PROC-022 FRM1 Stem Cell Laboratory Clinical HPCA Worksheet*

9.9 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form

9.10 *STCL-DIST-003 Cellular Product Distribution Form*

9.11 *STCL-EQUIP-011 FRM1 BacTAlert Logsheet*

9.12 *STCL-EQUIP-011 Sterility Culture using the BACT/ALERT Microbiology System*

9.13 *STCL-SOP-035 Cleaning and Decontamination protocol for STCL*

9.14 *STCL-EQUIP-019 Operation of Sterile Tubing Welder*

9.15 *STCL-SOP-022 Viability Counts via Trypan Blue Dye Exclusion*

10 REFERENCES

10.1 Sepax® Automated Wash Validation Study

10.2 Sepax® Automated Wash Validation Study Report

10.3 Kurtzberg J, Graham M, Casey J et al. The use of umbilical cord blood in a mis-matched related and unrelated hematopoietic stem cell transplantation. Blood Cells 1994; 20:275-284.

10.4 Kurtzberg J, Laughin, Graham ML et al. Placental blood as source of hematopoietic stem cells for transplantation in unrelated recipients. N. Engl. J. Med. 1996; 335:157-166.

10.5 Wagner JE, Rosental J, Sweetman R, et al. Successful transplantation of HLA-matched and HLA-mismatched umbilical cord blood from unrelated donors:

Analysis of engraftment and acute graft-versus-host disease. Blood 1996; 88:795-802.

10.6 Rubinstein P, Carrier C, Scaradavou A, et al. Outcomes among 562 recipients of placental blood transplants from unrelated donors. N. Engl. J. Med. 1998; 1565-1577.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
02	B. Waters-Pick	Section 1.1 reference Sepax® 2 RM and CORD WASH program. Section 2.1 reference Sepax® 2 RM and CORD WASH program. Section 3.1 reference Sepax® 2 RM and CORD WASH program. Section 3.2 Changed volume to 10 – 100 mls cord blood units Section 3.2 Referenced MedSep bags, Origen bag, etc. Section 5 Removed 150 ml transfer bag and added Chloraprep SEPP applicators. Section 6.1 added picture of Sepax® 2 RM instrument Section 7.1 removed face shields Section 8.3.1 removed 150 ml transfer bag reference Section 8.4.2 changed reference to CORD WASH v308 Section 8.4.3 changed wording for touch screen instructions. Sections 8.4.4 and 8.4.5 removed these sections Section 8.5.1 added STCL-SOP-028 reference to procedure name. Section 8.5.8 and 8.5.10 added ChloraPrep® SEPP® applicator Section 8.6.1 removed reference to 20% and 80% bags. Section 8.6.4 corrected kit number reference to CS600.1 Section 8.7 added CORD WASH (removed UCB washing) and updated entire section to accommodate Sepax® 2 RM Section 8.8 removed the table and entered information associated with Sepax® 2 RM in text format Section 8.9 Automated Procedure – added information throughout the section associated with Sepax® 2 RM instrument. Section 8.10 Post Procedure Actions – added information throughout the section associated with Sepax® 2 RM instrument including procedure number references. Section 8.11.3.1 added reference to Sepax® 2 RM pages 35 – 52 in the Operator's Manual troubleshooting section. Section 8.11.3.2 added STCL-SOP-028 to procedure name Section 8.13.1 modified section to include touch screen instructions for powering off the analyzer for the Sepax® 2 RM. Section 9 added procedure numbers to all documents referenced Section 11 added Revision History to this document

Signature Manifest

Document Number: STCL-PROC-036 **Revision:** 02

Title: Thawing and Washing Umbilical Cord Blood Units Using an Automated Sepax System

All dates and times are in Eastern Time.

STCL-PROC-036 Thawing and Washing UCB Units Using an Automated Sepax System

Author

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		05 May 2014, 04:58:12 PM	Approved

Manager

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		05 May 2014, 04:58:27 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		05 May 2014, 05:17:02 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Richard Bryant (RB232)		06 May 2014, 07:52:50 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		06 May 2014, 08:48:59 AM	Approved