**DOCUMENT NUMBER:** STCL-COLL-007 JA6

**DOCUMENT TITLE:**
Assembly of Collection Kits for Autologous-Directed Donations

**DOCUMENT NOTES:**

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STCL-COLL-007 JA6
Assembly of Collection Kits for Autologous and Directed Donations

1 PURPOSE
1.1 The purpose of this procedure is to provide instructions regarding how the cord blood collection kit will be assembled by the laboratory staff.

2 INTRODUCTION
2.1 The laboratory staff will assemble the collection kit when a directed or autologous cord blood collection has been approved by the medical director. The collection kit will be sent directly to the mother or delivering physician.

3 SCOPE AND RESPONSIBILITIES
3.1 The medical director, laboratory manager, and designated laboratory staff are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS
4.1 EDTA Ethylene diamine tetraacetic acid
4.2 PPT Plasma Preparation Tube
4.3 UCB Umbilical Cord Blood
4.4 ISBT International Society Blood Transfusion
4.5 CBU Cord Blood Unit
4.6 CCBB / DUMC Carolinas Cord Blood Bank / Duke Univ Medical Center
4.7 MD Medical Doctor

5 MATERIALS
5.1 Blue Box Shipper/Kit with the following labels: UN3373, “Do Not Discard” notice, “Medical Specimen/Handle with Care”, and “HPC-Cord” notice with STCL address and contact information.
5.2 2 Exogel panels
5.3 2 Absorbent pads
5.4 1 Cryopak with re-sealable bag
5.5 2 Biohazard re-sealable bags
5.6 One 4 mL red-top (serum-clot) tube
5.7 One 6 mL red-top (serum-clot) tube
5.8 Two 6 mL lavender-top (EDTA) tubes
5.9 One 5 mL PPT white-top tube
5.10 One 4 mL lavender-top (EDTA) tube
5.11 CCBB-COL-007 FRM3 Volunteer Cord Blood Donor Identification Form
5.12 1 ChloraPrep swab
5.13 1 MedSep Cord Blood Collection Unit, Code 791-08
5.14 2 cord clamps
5.15 CBU Maternal/baby identification label, STCL-COLL-007 FRM4 Auto-Directed CBU Collection Bag Label
5.16 ISBT barcode
5.17 STCL-COLL-007 JA2 Patient Instructions and Information Regarding Directed Donation and Storage of Umbilical Cord Blood
5.18 STCL-COLL-007 JA8 Blue Box Instruction Checklists
5.19 STCL-COLL-007 JA7 Packing and Shipping Diagram
5.20 STCL-COLL-007 JA1 CBU Directed Contract
5.21 STCL-COLL-007 FRM6 Billing and Claim Process Letter
5.22 STCL-COLL-007 FRM1 Autologous and Directed Collection and Processing Order Form
5.23 CCBB-COL-005 FRM2 Maternal Risk Questionnaire
5.24 CCBB-COL-005 FRM1 Family Medical History Questionnaire
5.25 CCBB-COL-005 FRM8 Maternal Risk Questionnaire Zika Virus Addendum
5.26 STCL-COLL-007 JA5 Letter to Collecting MD
5.27 STCL-COLL-007 JA3 Collection of Autologous-Directed CBU
5.28 CCBB-COL-007 FRM1 Volunteer Cord Blood Donor Identification Form
5.29 CCBB-COL-016 FRM2 Kit Program Volunteer Cord Blood Donor Identification
5.30 CCBB-COL-007 FRM3 Volunteer Cord Blood Donor Identification Form
5.31 CCBB-COL-025 FRM1 Maternal Sample Form
5.32 Return Federal Express air bill
5.33 Manila Envelope

6 EQUIPMENT
6.1 Activated electronic temperature logger in re-sealable bag.

7 SAFETY
7.1 N/A

8 PROCEDURE STEPS
8.1 Collection Kit Assembly

8.1.1 Obtain ISBT barcode from CCBB administrative staff. The CCBB administrative staff will release the barcode per procedure CCBB-QA-009 ISBT and ARC Label Release. Assign one ISBT barcode set and complete the CCBB-QA-009 FRM1 CCBB ISBT Barcode Label Release Log. Record the name of the mother and the date next to the assigned ISBT barcode on the ISBT Barcode Label Release Log and indicate direct donor UCB blue box.

8.1.2 Pre label the following with an assigned ISBT maternal barcode (see pictures below for proper placement of ISBT numbers on test tubes):
8.1.2.1  One 4 mL red-top (serum-clot) tube
8.1.2.2  One 6 mL red-top (serum-clot) tube
8.1.2.3  Two 6 mL lavender-top (EDTA) tubes
8.1.2.4  One 5 mL PPT white-top tube (NAT)
8.1.2.5  One 4 mL lavender-top (EDTA) tube

Sample tube with conventional stopper

PPT sample tube with Hemogard cap

Do Not Cover Lot Number or Expiration Date with ISBT Label

8.1.2.6  One CCBB-COL-007 FRM3 Volunteer Cord Blood Donor Identification Form, Phlebotomist’s Verification of Mother/Donor Identification
8.1.2.7  One CCBB-COL-025 FRM1 Maternal Sample Form

NOTE: Record lot number and expiration dates of maternal sample tubes on CCBB-COL-007 FRM3 Volunteer Cord Blood Donor Identification Form, Phlebotomist’s Verification of Mother/Donor Information

8.1.3  Pre label the following with an assigned ISBT barcode:

8.1.3.1  STCL-COLL-007 JA1 CBU Directed Contract
8.1.3.2  STCL-COLL-007 FRM6 Billing and Claim Process Letter
8.1.3.3  STCL-COLL-007 FRM1 Autologous and Directed Collection and Processing Order Form
8.1.3.4  CCBB-COL-005 FRM1 Family Medical History Questionnaire
8.1.3.5  CCBB-COL-005 FRM2 Maternal Risk Questionnaire
8.1.3.6 CCBB-COL-007 FRM1 Volunteer Cord Blood Donor Identification Form
8.1.3.7 CCBB-COL-016 FRM2 Kit Program Volunteer Cord Blood Donor Identification Form
8.1.3.8 STCL-COLL-007 FRM4 Auto-Directed CBU Collection Bag Label, attach to CCBB-COL-016 FRM 2 Kit Program Volunteer Cord Blood Donor Identification Form

8.1.4 Insert the following materials in the collection kit box in this order:
8.1.4.1 1 Absorbent pad
8.1.4.2 1 Exogel panel
8.1.4.3 1 Cryopak in re-sealable bag
8.1.4.4 1 biohazard Ziploc bag containing ISBT barcoded maternal sample tubes
8.1.4.5 Pall CB collection kit, 1 chloraprep swab, 2 cord clamps
8.1.4.6 Activated electronic temperature logger in re-sealable bag
8.1.4.7 1 Absorbent pad
8.1.4.8 1 Exogel panel

8.2 Place the following information in a manila envelope:
8.2.1 STCL-COLL-007 JA2 Patient Instructions and Information Regarding Directed Donation and Storage of Umbilical Cord Blood
8.2.2 STCL-COLL-007 JA 8 Blue Box Instruction Checklists
8.2.3 STCL-COLL-007 JA7 Packing and Shipping Diagram
8.2.4 STCL-COLL-007 JA1 Agreement for Directed Donation and Storage of Umbilical Cord Blood (if not previously obtained), ISBT barcoded
8.2.5 STCL-COLL-007 FRM6 Billing and Claim Process Letter, ISBT barcoded
8.2.6 STCL-COLL-007 FRM1 Autologous and Directed Collection and Processing Order Form, ISBT barcoded
8.2.7 CCBB-COL-005 FRM2 Maternal Risk Questionnaire, ISBT barcoded
8.2.8 CCBB-COL-005 FRM1 Family Medical History Questionnaire, ISBT barcoded
8.2.9 CCBB-COL-005 FRM8 Maternal Risk Questionnaire Zika Virus Addendum
8.2.10 CCBB-COL-007 FRM1 Volunteer Cord Blood Donor Identification Form, ISBT barcoded
8.2.11 STCL-COLL-007 JA5 Letter to Collecting MD
8.2.12 STCL-COLL-007 JA3 Collection of Autologous Directed CBU
8.2.13 CCBB-COL-016 FRM2 Kit Program Volunteer Cord Blood Donor Identification Form, ISBT barcoded with attached STCL-COLL-007
FRM4 Auto-Directed CBU Collection Bag Label with lot number and expiration date of cord blood collection bag and Chloraprep swab recorded on the top of form

8.2.14 CCBB-COL-007 FRM3 Volunteer Cord Blood Donor Identification Form, ISBT barcoded (Maternal)

8.2.15 Maternal Sample form, ISBT barcoded (Maternal)

8.2.16 Prepaid return Federal Express air bill

8.3 Place manila envelope on top of the silver Styrofoam lid.
# Signature Manifest

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**Revision:** 09  
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All dates and times are in Eastern Time.

## STCL-COLL-007 JA6 Assembly of Collection Kits for Autologous-Directed Donations

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