



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-COLL-007 JA6

DOCUMENT TITLE:

Assembly of Collection Kits for Autologous and Directed Donations JA6

DOCUMENT NOTES:

Document Information

Revision: 11

Vault: STCL-Collections-rel

Status: Release

Document Type: STCL

Date Information

Creation Date: 28 Sep 2021

Release Date: 17 Dec 2021

Effective Date: 17 Dec 2021

Expiration Date:

Control Information

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Owner: WATER002

Previous Number: STCL-COLL-007 JA6 Rev 10 **Change Number:** STCL-CCR-525

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 1 ChloroPrep swab
- 5.12 1 MedSep Cord Blood Collection Unit, Code 791-08
- 5.13 2 cord clamps
- 5.14 CBU Maternal/baby identification label, STCL-COLL-007 FRM4 Auto-Directed CBU Collection Bag Label
- 5.15 ISBT barcode
- 5.16 CCBB-COL-005 FRM1 Family Medical History Questionnaire
- 5.17 CCBB-COL-005 FRM2 Maternal Risk Questionnaire
- 5.18 CCBB-COL-007 FRM1 Volunteer Cord Blood Donor Identification Form
- 5.19 CCBB-COL-007 FRM2 Volunteer Cord Blood Donor Identification Delivery Information Form
- 5.20 CCBB-COL-007 FRM3 Volunteer Cord Blood Donor Identification Phlebotomist's Verification Form
- 5.21 CCBB-COL-025 FRM1 Maternal Sample Form
- 5.22 STCL-COLL-007 FRM1 Autologous and Directed Collection and Processing Order Form
- 5.23 STCL-COLL-007 FRM4 Auto-Directed CBU Collection Bag Label
- 5.24 STCL-COLL-007 FRM6 Billing and Claim Process Letter
- 5.25 STCL-COLL-007 JA1 Agreement for Directed Donation and Storage of Umbilical Cord Blood
- 5.26 STCL-COLL-007 JA2 Patient Instructions and Information Regarding Directed Donation and Storage of UCB
- 5.27 STCL-COLL-007 JA3 Collection of Autologous-Directed CBU
- 5.28 STCL-COLL-007 JA5 Letter to Collecting MD
- 5.29 STCL-COLL-007 JA7 Packing and Shipping Diagram
- 5.30 STCL-COLL-007 JA8 Blue Box Instruction Checklists
- 5.31 Return Federal Express air bill
- 5.32 Manila Envelope

6 EQUIPMENT

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

7 SAFETY

- 7.1 N/A

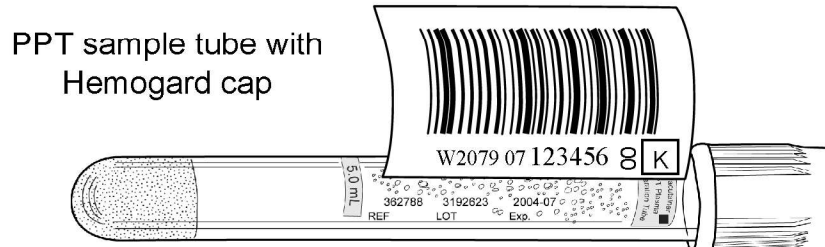
8 PROCEDURE STEPS

- 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 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



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 Phlebotomist's Verification Form*
- 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 Form*

8.1.3 Pre label the following with an assigned ISBT barcode:

- 8.1.3.1 STCL-COLL-007 JA1 *Agreement for Directed Donation and Storage of Umbilical Cord Blood (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-007 FRM2 *Volunteer Cord Blood Donor Information Delivery Information Form*
- 8.1.3.8 STCL-COLL-007 FRM4 *Auto-Directed CBU Collection Bag Label*, attach to CCBB-COL-007 FRM2 *Volunteer Cord Blood Donor Information Delivery Information 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 UCB*
 - 8.2.2 STCL-COLL-007 JA8 *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-007 FRM1 *Volunteer Cord Blood Donor Identification Form*, ISBT barcoded
- 8.2.10 STCL-COLL-007 JA5 *Letter to Collecting MD*
- 8.2.11 STCL-COLL-007 JA3 *Collection of Autologous Directed CBU*
- 8.2.12 CCBB-COL-007 FRM2 *Volunteer Cord Blood Donor Information Delivery Information 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.
- 8.2.13 CCBB-COL-007 FRM3 *Volunteer Cord Blood Donor Identification Phlebotomist's Verification Form*, ISBT barcoded (Maternal)
- 8.2.14 CCBB-COL-025 FRM1 *Maternal Sample Form*, ISBT barcoded (Maternal)
- 8.2.15 Prepaid return Federal Express air bill
- 8.3 Place manila envelope on top of the silver Styrofoam lid.

Signature Manifest**Document Number:** STCL-COLL-007 JA6**Revision:** 11**Title:** Assembly of Collection Kits for Autologous and Directed Donations JA6**Effective Date:** 17 Dec 2021

All dates and times are in Eastern Time.

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

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