STEM CELL LABORATORY (STCL)

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Auto/Directed Maternal Blood Sample Processing

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STCL-COLL-007 JA10
AUTO/DIRECTED MATERNAL BLOOD SAMPLE PROCESSING

1 PURPOSE

1.1 At the time of a cord blood collection, a peripheral maternal blood sample is collected from the cord blood donor's mother, in order to have corresponding whole blood, serum, and plasma samples available in the lab for future testing if needed.

2 INTRODUCTION

2.1 This procedure includes the instructions for processing the maternal blood samples that are collected.

2.2 Maternal samples must be collected within 30 days of CBU collection.

2.3 Whenever possible, samples should be processed within 72 hours of maternal sample collection.

3 SCOPE AND RESPONSIBILITIES

3.1 The Medical Director, Laboratory Manager and participating laboratory staff are responsible for ensuring the requirements of this procedure are successfully met.

3.2 Laboratory staff will always adhere to procedure *STCL-GEN-014 Product Safety - Minimizing Cross-Contamination* when performing the processing steps.

4 DEFINITIONS/ACRONYMS

4.1	CBU	Cord Blood Unit
4.2	EDTA	Ethylenediaminetetraacetic Acid
4.3	ISBT	International Society Blood Transfusion
4.4	HLA	Human Leukocyte Antigen
4.5	RBC	Red Blood Cells
4.6	OSHA	Occupational Safety and Health Administration
4.7	BSC	Biological Safety Cabinet
4.8	mL	Milliliter

5 MATERIALS

5.1 Disposable transfer pipettes

5.2 Maternal sample tubes

5.3 6 mL EDTA (purple top) tube

5.4 4 mL EDTA (purple top) tube

5.5 4 mL serum (red top) tube

5.6 Maternal Sample Form

5.7 Maternal sample nunc vials

5.8 Tube racks for nunc vials

5.9 ISBT cryolabels

6 EQUIPMENT

6.1 Biological Safety Cabinet (BSC)

6.2 Centrifuge

6.3 Ultra Low Freezer (-70 -80°C)

7 SAFETY

7.1 All laboratory employees who work with materials (primary and well–characterized human cells, tissues and blood) covered by OSHA's Bloodborne Pathogen Standards are to receive initial safety training and annually thereafter. Bloodborne Pathogens, General Laboratory Safety and Biosafety Level 2 (BSL2) are available as on-line training modules.

7.2 All laboratory employees need to practice the rule of Universal Precautions. It is defined as handling all human blood, body fluids and tissues as if they are infectious. This calls for the use of appropriate protective measures to reduce or eliminate the risk of occupational exposure.

8 PROCEDURE

8.1 Verify that there are barcodes on each sample tube, and that each barcode matches against the barcode provided on *CCBB-COL-025 FRM1 Maternal Sample Form* within each individual biohazard bag for each set.

8.2 If the ISBT barcodes match, continue with the next procedure step.

8.3 If the barcodes do not match or if tubes are not properly labeled, notify a laboratory manager immediately for further instruction.

8.4 Take the 4 mL serum (red top) and 6 mL EDTA (purple top) tubes from each set and place in the centrifuge. Samples must be placed in the centrifuge so that the cups are balanced. The 4 mL EDTA (purple top) tube will be placed in a holding tray while the samples spin.

8.5 Set centrifuge to spin at 3200 rpms for 20 minutes. Record Study ID step 3 on *FRM1 Maternal Sample Form* to confirm that labels were verified and that centrifugation began.

8.6 Verification of CBU status:

8.6.1 Verify the status of the CBU check box "CBU has not been excluded" and enter Study ID in step 4 on *CCBB-COL-025 FRM1 Maternal Sample Form*

8.6.2 If necessary, complete a CBU Disposition form reassigning CBU for direct donation.

8.6.3 NOTE: Maternal samples cannot be discarded until a second technician has verified the barcodes and status of the CBU to ensure correct tubes are being discarded and correctly excluded. Steps are outlined below.

8.7 For samples with collected, processed non-excluded CBU:

8.7.1 Look up the CBU RBC and Plasma nunc vial location on the *STCL-PROC-042 FRM1 CBU Processing Form* in EMMES to find the corresponding location.

8.7.2 Record the storage location and Study ID step 7 on *CCBB-COL-025 FRM1 Maternal Sample Form*.

8.7.3 Leave the sample freezer location field blank until the CBU is received and processed or the CBU is later excluded, thus maternal samples will be discarded.

8.7.4 Following centrifugation, the tubes must be kept vertical in a tube rack. Otherwise, the contents will be remixed and can't be processed without re-centrifugation. Match each spun tube set with its corresponding unspun small purple top tube in a holding rack.

8.8 Preparing samples for freezing and storage:

8.8.1 Remove any items, clean all work surfaces for this workstation, and verify that lots and expiration dates of supplies and reagents are correct and in date.

8.8.2 Select your sample to be processed. Confirm the barcodes on *CCBB-COL-025 FRM1 Maternal Sample Form*. Then confirm again that the barcodes on the sample collections tubes match their corresponding forms.

8.8.3 Transfer the three sample tubes from the holding rack into a separate tray. Use only one tray per set of samples during processing. Only barcode can be processed or in the hood at any given time.

8.8.4 Label 7 nunc vials with the provided ISBT barcode labels.

8.8.5 Using a permanent marker, write an "S" on one of the nunc vials to indicate that this is the serum vial.

8.8.6 Under the BSC, using aseptic technique, separate the serum, plasma and whole blood as follows:

8.8.7 Remove all the caps from the maternal sample nunc vials in one row while also verifying ISBT barcodes with corresponding maternal sample tube ISBT barcodes.

8.8.8 Using a transfer pipette, aspirate the clear layer of serum from the 4 mL serum (red top) tube without mixing red cells with the serum. Dispense serum into the last maternal sample nunc, labeled with "S" on the ISBT barcode. Notify a laboratory supervisor if there is hemolysis and await further instructions before continuing. Recap the nunc vial after you fill it.

8.8.9 Using a transfer pipette, aspirate the plasma from the 6 mL EDTA (purple top) tubes, without mixing red cells with the plasma. Evenly distribute the plasma into 3 maternal sample nunc vials. Notify the laboratory manager (or designee) if hemolysis is present or plasma isn't clearly separated from the red cells. Recap each nunc vial as you fill them.

8.8.10 Gently mix the whole blood from the 4 mL EDTA (purple top) using the transfer pipette and then aspirate the entire tube contents into the pipette bulb. Distribute the maternal whole blood evenly into the remaining 3 maternal sample nunc vials. Recap each nunc vial as you fill them.

8.8.11 There should be at least 0.5 ml per nunc vial. If at any time there is too little sample in either the 4 mL serum (red top) and 6 mL EDTA (purple top) tubes or if hemolysis is present, notification to a laboratory supervisor must be made. The laboratory manager (or designee) will decide whether if a request should be made for a new maternal sample to be drawn.

8.8.12 Complete step 6 of the *CCBB-COL-025 FRM1 Maternal Sample Form.*

8.8.13 Complete the date and time (using the 24 hour format) that the samples were processed in the laboratory and Study ID.

8.8.14 Whenever possible, maternal samples should be processed within 72 hours of collection.

8.9 Freezer locations and storage:

8.9.1 Locate the boxes for permanent sample storage in the STCL -80 freezer according to the location noted on the *CCBB-COL-025 FRM1 Maternal Sample Form*. Match the barcode numbers on the already stored cord blood samples to the maternal samples.

8.9.2 Within the boxes, store the vials in the following order: 3 whole blood vials, 3 EDTA plasma vials, and the serum vial.

9 RELATED DOCUMENTS /FORMS

9.1 CCBB-COL-025 FRM1 Maternal Sample Form

9.2 STCL-PROC-042 FRM1 CBU Processing

9.3 STCL-GEN-014 Product Safety Minimizing Cross-Contamination

9.4 STCL-PROC-044 CBU Processing

9.5 CCBB-LAB-005 FRM1 CBU Disposition

10 REFERENCES

10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.

10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release. Current edition.

11 REVISION HISTORY

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01	B. Waters-Pick	New procedure

Signature Manifest

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