STEM CELL LABORATORY (STCL)

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DOCUMENT TITLE:

UCB Processing Worksheet FRM2

DOCUMENT NOTES:

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STCL-PROC-042 FRM2
UCB PROCESSING WORKSHEET

Date/Time Unit Placed on Rocker: _____

Date/Time Unit Removed from Rocker:_____

Barcode Label

A. From Pre Processing/Collection Bag, Remove QC Sample:

Pre Processing Sample Removed by: Study ID: _____

B. Collection Bag Calculations:

Weight of bag = _____ mL + _____ mL CPD = _____ mL Total Volume (TV)

Study ID: _____

C. Pre Processing Sample Analysis:

$\frac{\text{\_\_\_\_\_}}{\text{(WBC)}} \times 10^6/\text{mL} \times \frac{\text{\_\_\_\_\_ mL}}{\text{(TV)}} = \frac{\text{\_\_\_\_\_}}{\text{(TNCC)}} \times 10^6$ TNCC = _____ $\times 10^8$

D. Processing: **OK to Process? ☐ YES ☐ NO** Study ID: _____

Total Volume / 5 = _____mL of Hespan needed for processing Study ID: _____

Hang Start time = _____

Manual Processing ***(if applicable)*** Spin @ 700 RPM for 10 min with NO brake

Let hang: _____ min Time Started: _____ Time Completed: _____ Study ID: _____

Removed: _____ mL Study ID: _____ Spin @ 1200 RPM for 20 min, then express and count

E. Post Processing Counts/Recoveries:

Volume Reduced/ Final Product Bag Volume = _____ mL Study ID: _____

$\frac{\text{\_\_\_\_\_}}{\text{(WBC)}} \times 10^6/\text{mL} \times \frac{\text{\_\_\_\_\_ mL}}{\text{(TV)}} = \frac{\text{\_\_\_\_\_}}{\text{(TNCC)}} \times 10^6$ TNCC = _____ $\times 10^8$

% Recovery: _____% (*If recovery is below 60%, reprocess unit*) Study ID: _____

Post processing viability (%) = _____ ABO/ Rh _____

Freezer location and number of UCB plasma nuncs: _____

Freezer location and number of RBC pellet nuncs: _____

I certify that all reagents and supplies used in processing this sample show no signs of contamination, irregularities, defects or flaws; that all heat sealed tubing and sterile welded tubing exhibit no signs of leakage, irregularities, defects, or flaws; and that all test samples related to this specific UCB unit have been identified and labeled accurately.

_____Initials/Date

Field	Requirements
Barcode Code Label	Place ISBT 128 barcode for sample
Date/Time Unit Placed on Rocker	Enter date and time unit placed on rocker
Date/Time Unit Removed from Rocker	Enter date and time unit removed from rocker for processing
Remove QC Samples	
Pre Processing Sample Removed by Study ID	Enter study ID of person removing pre processing sample
Collection Bag Calculations	
Weight of bag = __mL + ___mL CPD = ___ mL Total Volume (TV)	Perform calculations for collection bag and enter your Study ID
Pre Processing Sample analysis	
____x10^6 /mL X _____ mL = _____ x10^6 (WBC) (TV) (TNCC) TNCC = _____x10^8	Record WBC value from the automated count printout. Record Total Volume (TV) of collection bag and calculate Total Nucleated Cell Count (TNCC). Convert TNCC from x 10^6 to x10^8.
Processing OK to Process ☐YES ☐NO Study ID _____	Use unit count threshold for processing per procedure STCL-PROC-042 and indicate if unit is OK to process by marking appropriate yes or no box and enter study ID
Total Volume / 5 = _____mL of Hespan needed for processing Study ID: _____	Calculate amount of Hespan needed and enter study ID
Hang time start	Record the start time when hanging the bag.
Post processing viability / ABO/Rh	Enter viability and ABO/Rh (post processing)
Manual Processing (if applicable)	
Let hang	Enter the time the unit was allowed to hang
Time started	Enter time processing was started
Time Completed	Enter time that processing is completed
Study ID	Enter Study ID of person expressing cells
Removed/Study ID	Enter the amount of plasma removed from CBU and Study ID
Post Processing Counts/Recoveries	
Volume-Reduced Final Product Bag Volume	Enter volume from Sepax 2 S-100 printout and study ID
____ x10^6 /mL X _____mL = _____ x10^6 (WBC) (TV) (TNCC) TNCC = _____x10^8	Record WBC value from the automated count printout. Record Total Volume (TV) of final product bag and calculate Total Nucleated Cell Count (TNCC). Convert TNCC from x 10^6 to x10^8.
%Recovery	Take post TNCC and divide by pre TNCC and multiply by 100. Enter recovery % and study ID
Post processing viability / ABO/Rh	Enter viability (post processing) and ABO/Rh
Freezer location and number of UCB plasma nuncs	Enter -80 freezer storage location and number of nuncs being stored
Freezer location and number of RBC pellet nuncs	Enter -80 freezer storage location and number of nuncs being stored
Certification Statement	Initial and date to certify UCB processing

Signature Manifest

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Title: UCB Processing Worksheet FRM2

All dates and times are in Eastern Time.

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Document Release

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