STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-FORM-040

DOCUMENT TITLE:

Peripheral Blood Progenitor Cell Worksheet Adult

DOCUMENT NOTES:

Old FACT Number 7D.201

Document Information

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Control Information

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(RECIPIENT LABEL) Recipient's Name Recipient's History # Recipient's Blood Type, Recipient's DOB	(DONOR's LABEL (*if applicable*) Donor's Name (*if applicable*) Donor's History # Donor's Blood Type, Donor's DOB

Recipient's Weight: _____ **Protocol/Diagnosis** _____	**Barcode**	**N/A = Not Applicable**	**N/A = Not Applicable**
Processing (Select all #s that apply: 1- Pre-cryo, 2 - Post-conc, 3 - Direct infusion, 4 - Post plasma depletion, 5 – Post overnight storage, 6 – Other (specify)	1	2	3
Date / Time Collected			
Date / Time Received			
Date / Time Processing Started:			
Cell Count (**x10^6**)			
Hematocrit (%)			
Collection Volume (**mls**):			
Weight of bag minus "tare" weight (43.3) (*for Duke collected products*) OR use empty tare bag			
Concentrated products or NMDP product (*if applicable*) divided by correction factor of 1.06			
Final Calculated Volume – QC volume = Final VOLUME			
Volume Frozen (mls) **(w/o DMSO)**			
Total # Cells Frozen: **(x10^9)**			
Total # Cells/Kg **(x10^8)**			
Volume Frozen (mls) **(with DMSO)**			
Number of Bags Stored			
Viability %:			
Bag Storage Locations:			
Vial Storage Locations:			
CD34+ %: **(SCE Flow Assay% / Emmes %)**	/	/	/
CD34+ cells/Kg **(x10^6)**			
Other flow results:			
ABO/Rh confirmed as / by:			
Bag labels checked by ***(Two Tech confirmation)***	/	/	/
Sample processed by:			
Bags sealed by and time	/	/	/
Product placed in CRF by and time	/	/	/
Product stored in LN2 Freezer by and time	/	/	/
Heat of Fusion Data *(Temp @ _____minutes)*			

I certify that all reagents and supplies used in processing theses samples show no signs of contamination, irregularities, defects.

Date _____ Initials ____ Date _____ Initials ____ Date _____ Initials ____

I certify that all heat sealed tubing and all sterile docked tubing used in processing these samples exhibit no signs of leakage, irregularities, defects or flaws.

Date _____ Initials ____ Date _____ Initials ____ Date _____ Initials ____

Record supplies used on appropriate lot # worksheet. Record calculations and COMMENTS on the back of this worksheet in the appropriate section

NOTES Section 1:

NOTES Section 2

NOTES Section 3:

COMMENTS:

INSTRUCTIONS

Field	Requirements
Recipient's Name: History Number: ABO/Rh Donor's Name History Number: ABO/Rh	Enter the recipient's name, history number and ABO/Rh from the DHIS print outs. AFFIX LABEL) Enter the donor's name, history number and ABO/Rh from the DHIS print outs. (AFFIX LABEL)
Recipients' Weight	Enter the recipient's current weight.
Protocol / Diagnosis	Enter the recipient's protocol / diagnosis.
Barcode	Enter the ISBT 128 barcode for the product being processed.
Processing *(describe the processing involved)*	1- Pre-Cryo, 2 - Post-Conc, 3 - Direct infusion, 4 - Post Plasma depletion, 5 – Post Overnight storage, 6 – Other (specify processing involved)
Date / Time Collected	Record the date and time the product was collected.
Date / Time Received	Enter the date and time the sample was received in the laboratory.
Date / Time Processing Started	Enter the date and time processing was started on the product (for direct infusion, cryopreservation, concentrated, retested (if held overnight).
Cell Count($x10^6$)	Enter the automated cell count /ml using 10e6 notation.
Hematocrit (%)	Enter the hematocrit from the automated cell counter.
Collection Volume (**mls**):	Enter the volume of the product collected (per bag label).
Weight of bag minus "tare" weight (43.3) *(for Duke collected products)* OR use empty tare bag.	Weigh the cellular product bag using tare weight of 43.3 or using empty tare bag in designated drawer in the lab.
Concentrated products or NMDP product *(if applicable)* divided by correction factor of 1.06	Subtract the weight of the empty bag *(if product collected at DUKE)*.
Final Calculated Volume – QC volume = Final Volume	Divide weight of product using NMDP correction factor of **1.06** *(if applicable for NMDP-collected products)*along with the volume used for QC testing to yield FINAL VOLUME
Volume Frozen (mls) **(w/o DMSO)**	Record the actual volume of product cryopreserved.
Total # Cells Frozen: **($x10^9$)**	Multiply the automated cell count by the volume.
Total # Cells/Kg **($x10^8$)**	Divide the Total #Cells Frozen by the patient's weight.
Volume Frozen (mls) **(with DMSO)**	Record the total mls frozen; this volume includes the product plus DMSO.
Number of Bags Stored	Record the number of cryocyte bags frozen.
Viability:	Record the % trypan blue or 7AAD viability
Bag Storage Location:	Record the freezer locations for the bags cryopreserved.
Vial storage Location:	Record the freezer locations for the nunc vials frozen.
CD34+ %: **(SCE Flow Assay% / Emmes %)**	Record the % CD34+ reported by the SCE (Stem Cell Enumeration) flow cytometry kit; Emmes % reflects the adjusted CD34% to match the CD34+ cells/kg reported by the SCE Flow Cytometry assay.
CD34+ cells/Kg **($x10^6$)**	Record the calculated CD34+ cells/Kg by multiplying the total cells/kg by the %CD34+
Other flow results:	Record any other flow results required (ie. CD3+ cells/kg, etc).
ABO/Rh confirmed as / by:	Record the ABO/Rh of the product tested and the technologist's initials who performed the testing.
Bag labels checked by ***(Two Tech labeling Confirmation REQUIRED)***	**Record the initials of the <u>two employees</u> who are verifying the accuracy of the labels that have been prepared against the appropriate cellular product bag being processed. This labeling confirmation step should take place in the biological safety cabinet <u>before</u> labeling of bags and cryopreservation of the cellular product have been initiated.**
Sample processed by:	Record the initials of the person processing the product.
Bags sealed by and time:	Record the initials and time of the person heat sealing the product bags.
Product placed in Control Rate Freezer (CRF) by and time	Record the initials and time of the person who set up the Control Rate Freezer (CRF) and who placed the product in the CRF (for cryopreservation).
Product Stored in LN2 Freezer by and time:	Record the initials and time of the person who stored the products in the designated LN2 freezer(s).
Heat of Fusion Data: *(Temp @ x minutes)*	Record the HOF from the freezing graph *(Temperature @ x minutes)(Example = -15°C @ 44.5 minutes)*
Lot Numbers	Record lot numbers using the appropriate lot # worksheet of the supplies used to process the cellular product.
Date and Initial spaces	Date and initial to certify that all reagents and supplies used in processing the samples showed no signs of contamination, irregularities, defects and to certify that all heat sealed tubing and all sterile docked tubing used in processing the samples exhibited no signs of leakage, irregularities, defects or flaws.
Notes and Comments *(Back page)*	Enter notes and comments on page 2 (back page) of this document

Signature Manifest

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All dates and times are in Eastern Time.

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Document Release

Name/Signature	Title	Date	Meaning/Reason
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