



## STEM CELL LABORATORY (STCL)



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**DOCUMENT TITLE:**

Graft Characterization

**DOCUMENT NOTES:**

### Document Information

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### Control Information

**Author:** MGREESE

**Owner:** MGREESE

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BAR CODE LABEL



## FLOW-FORM-012 Graft Characterization

### A. Viable CD34+

1. Date of acquisition: .....   /   /      
mm dd yyyy
2. Viable CD34+ % of viable CD45+Events: .....  •
3. Viable CD34+ cell concentration (cells per  $\mu\text{L}$ ): .....     •
4. Total viable CD34+ cells in collection: ..... 

( $\times 10^3$ )  
No manual entry required

### B. Lymphocyte Population

5. Hematology analyzer WBC/ $\mu\text{L}$ ..... 

( $\times 10^3$ )  
No manual entry required
6. Record % lymphocytes of CD45+ (CD3/CD16 & 56/CD19/CD45 or equivalent):   •
7. a. Total CD45+ events acquired (CD3/CD4/CD8/CD45 or equivalent): .....
- b. Total lymphocyte events acquired (CD3/CD4/CD8/CD45 or equivalent): .....
8. CD3+ T-cells: (CD3/CD4/CD8/CD45 or equivalent)

# CD3+ Events Acquired	% of CD45+ Events	# CD3+ Cells per $\mu\text{L}$	Total CD3+ Cells in Collection
			( $\times 10^3$ )

9. CD4 and CD8: (Record % of cells per quadrant in the CD3+ gate to one decimal place)

CD4+/CD8-	CD4-/CD8+	CD4+/CD8+	Total CD4+ Cells in Collection	Total CD8+ Cells in Collection	Total CD4-/CD8- Cells in Collection
<input type="text"/> • <input type="text"/>	<input type="text"/> • <input type="text"/>	<input type="text"/> • <input type="text"/>	( $\times 10^3$ )	( $\times 10^3$ )	( $\times 10^3$ )



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10. CD45+ subpopulations: (CD3/CD16 & 56/CD45/CD19 or equivalent)  
Record % of cells per quadrant in the lymphocyte gate to one decimal place):

	CD19+/CD56- CD16-	CD19-/CD56+ CD16+	CD19+/CD56+ CD16+
	— — • —	— — • —	— — • —
Total CD19+ cells in collection	( $\times 10^3$ )	Total CD16+ 56+ cells in collection:	( $\times 10^3$ )

11. Record analyzer's laboratory certification number:

   

### C. Colony Assay Results

12. Total CFU-GM:    •   $\times 10^5$

13. Total CFU-GEMM:    •   $\times 10^5$

14. Total BFU:    •   $\times 10^5$

15. Record colony assay analyzer's certification number:

   

Comments: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Signature of Reviewer

Date

Study ID

Field	Requirements
1. Date of acquisition	mm field - require two digits between 01 and 12 • dd field - require two digits between 01 and 31, correlate to month and year to prohibit logical inconsistencies (e.g., do not allow entry of November 31 or February 29 in non-leap years) • yyyy field - require four digits
2. Viable CD34+ % of viable CD45+Events	Record flow cytometry result of testing to 2 decimal places.
3. Viable CD34+ (cells per $\mu$ L)	Record the flow cytometry result of testing to 2 decimal places.
4. Total viable CD34+ cells in collection	This value will auto-calculate and fill the field using the product volume (pulled from processing form) multiplied by the viable CD34+ cells/ $\mu$ L value recorded in 3 above.
<b>Lymphocyte Population</b>	
5. Hematology analyzer WBC/ $\mu$ L	The WBC/ $\mu$ L value auto fills from the processing form associated with the product bar code.
6. % lymphocytes of CD45+ cells	Record % of lymphocytes of CD45+ cells resulting from analysis of CD3/CD16 and 56/CD19/CD45 or equivalent
7. a. Total CD45+ events acquired b. Total lymphocyte events acquired	Enter CD45+ and lymphocyte event counts resulting from analysis of CD3/CD16 and 56/CD19/CD45 or equivalent
8. CD3+ T-cells	Enter the number of CD3+ events in the T-cell gate into the designated field. The %, per microliter, and total CD3+ T-cells will automatically calculate.
9. CD4 and CD8:	Record % of cells per quadrant in the CD3+ gate (to one decimal place) in the designated fields. The total CD4 and CD8+ T-cells will automatically calculate.
10. CD45+ subpopulations: (CD3/CD16 & 56/CD45/CD19 or equivalent)	Record % of cells per quadrant in the lymphocyte gate (to one decimal place) in the designated fields. The total CD19 and NK cells will automatically calculate.
11. Analyzer's laboratory certification number	Enter certification number for analyzer
<b>Colony Assay Results</b>	
12. Total CFU-GM	Enter total CFU-GM $\times 10^5$
13. Total CFU-GEMM	Enter total CFU-GEMM $\times 10^5$
14. Total BFU	Enter total BFU $\times 10^5$
15. Colony assay analyzer's certification number	Enter certification number for assay analyzer
Signature Date Study ID	Signature of staff reviewing form for completeness, date and four digit study ID number

**Signature Manifest****Document Number:** FLOW-FORM-012**Revision:** 01**Title:** Graft Characterization**FLOW-FORM-012 Graft Characterization****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Melissa Reese (MGREESE)		30 Aug 2012, 06:07:26 PM	Approved

**Manager Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		04 Sep 2012, 12:31:23 PM	Approved

**Medical Director Approval**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		04 Sep 2012, 02:28:50 PM	Approved

**QA Approval**

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Linda Sledge (SLEDG006)		04 Sep 2012, 02:50:38 PM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		04 Sep 2012, 03:47:20 PM	Approved

**Notification**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		04 Sep 2012, 03:47:21 PM	Email Sent
System Administrator (SYSADMIN)		04 Sep 2012, 03:47:21 PM	Email Sent
Linda Sledge (SLEDG006)		04 Sep 2012, 03:47:21 PM	Email Sent
Sharon Hartis (SH259)		04 Sep 2012, 03:47:21 PM	Email Sent
Melissa Reese (MGREESE)		04 Sep 2012, 03:47:21 PM	Email Sent