

STEM CELL LABORATORY (STCL)



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DOCUMENT TITLE:

Adult Allogeneic Donor PSC Lymphocyte Subset Results

DOCUMENT NOTES:

Document Information

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Expiration Date:

Control Information

Author: MGREESE

Owner: MGREESE

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Change Number: STCL-CCR-125

Print copy for batch file.				
FLOW-FORM-001 Adult Allogeneic Donor PSC Lymphocyte Subset Results				
Patient Name:		Recipient wt. (kg):		
MRN #:				
Product Bar Code:		Product type:		
Time of collection:		Date:		Technician initial:
Time of staining:		Date:		Technician initial:
Antibody	Lot#	Expiration date	ASR*	Passed Positive Control cell QC? Y/N
BD CD45/CD14				
BD CD3 Fitc				
BD CD56 PE			X	
BD CD19 APC			X	
BD 7-AAD				
BD CD3 PE			X	
BD CD4 APC			X	
BD CD25 Fitc			X	
BD CD8 APC			X	
Comments:				
Results				
Hematology Analyzer Cell Count			% Viability (7AAD neg. from lymph analysis tube)	
Volume (mls)			% lymphocytes	
Total viable cells	0.00E+00			
% viable CD3+CD56-				
% viable CD56+(Total)				
% viable CD3+CD56+				
% viable CD3-CD56+				
% viable CD3 (total)				
% viable CD19				
% viable CD14				
% viable CD3+CD4+				
% viable CD3+CD8+				
% viable CD3+CD4+CD25+				
		Cells/kg		
Total viable CD3+CD56-	0.00E+00	#DIV/0!		
Total viable CD56	0.00E+00	#DIV/0!		
Total viable CD3+CD56+	0.00E+00	#DIV/0!		
Total viable CD3-CD56+	0.00E+00	#DIV/0!		
Total viable CD3+	0.00E+00	#DIV/0!		
Total viable CD19	0.00E+00	#DIV/0!		
Total viable CD14	0.00E+00	#DIV/0!		
Total viable CD3+CD4+	0.00E+00	#DIV/0!		
Total viable CD3+CD8+	0.00E+00	#DIV/0!		
Total viable CD3+CD4+CD25+	0.00E+00	#DIV/0!		
Comments:				
Reviewed by:		Date:		
<p>*This test was developed and its performance characteristics determined by the Stem Cell Laboratory. It has not been cleared or approved by the U.S. Food and drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under CLIA-88 as qualified to perform high complexity clinical laboratory testing. CLIA # 34D1005310, CAP#7181142</p>				

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Adult Allogeneic	
Patient Name:	Obtain From flow worksheet
MRN #:	Obtain From flow worksheet
Product Bar Code:	Bar code number
Time of collection:	Obtain From flow worksheet
Time of staining:	Obtain From flow worksheet
Antibody	Lot#
BD CD45/CD14	Fill in with correct lot #
BD CD3 Fitc	Fill in with correct lot #
BD CD56 PE	Fill in with correct lot #
BD CD19 APC	Fill in with correct lot #
BD 7-AAD	Fill in with correct lot #
BD CD3 PE	Fill in with correct lot #

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BD CD4 APC	Fill in with correct lot #
BD CD25 Fitc	Fill in with correct lot #
BD CD8 APC	Fill in with correct lot #
Comments:	
R	
Hematology Analyzer Cell Count	Obtain From flow worksheet
Volume (mls)	Obtain From flow worksheet
Total viable cells	$=B22*B23*E22/100$
% viable CD3+CD56-	Obtain from tube 3 flow result.
% viable CD56+(Total)	Obtain from tube 3 flow result.
% viable CD3+CD56+	Obtain from tube 3 flow result.
% viable CD3-CD56+	Obtain from tube 3 flow result.
% viable CD3 (total)	Obtain from tube 3 flow result.
% viable CD19	Obtain from tube 3 flow result.
% viable CD14	Obtain from tube 2 flow result.
% viable CD3+CD4+	Obtain from tube 4 flow result.
% viable CD3+CD8+	Obtain from tube 5 flow result.

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% viable CD3+CD4+CD25+	Obtain from tube 4 flow result.
Total viable CD3+CD56-	=B25/100*B24*E23/100
Total viable CD56	=B26/100*B24*E23/100
Total viable CD3+CD56+	=B27/100*B24*E23/100
Total viable CD3-CD56+	=B28/100*B24*E23/100
Total viable CD3+	=B29/100*B24*E23/100
Total viable CD19	=B30/100*B24*E23/100
Total viable CD14	=B31/100*B24
Total viable CD3+CD4+	=B32/100*B24*E23/100
Total viable CD3+CD8+	=B33/100*B24*E23/100
Total viable CD3+CD4+CD25+	=B34/100*B24*E23/100
Reviewed by:	Reviewer's initial

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ic Donor PSC Lymphocyte Subset Results

Recipient wt. (kg):	Obtain From flow worksheet	
Product type:	Obtain From flow worksheet	
Date:	Obtain From flow worksheet	Technician initial:
Date:	Obtain From flow worksheet	Technician initial:
Expiration date	ASR*	Passed Positive Control cell QC? Y/N
Enter Exp. Date of reagent		Did reagent pass QC testing? yes or no
Enter Exp. Date of reagent		Did reagent pass QC testing? yes or no
Enter Exp. Date of reagent	X	Did reagent pass QC testing? yes or no
Enter Exp. Date of reagent	X	Did reagent pass QC testing? yes or no
Enter Exp. Date of reagent		Did reagent pass QC testing? yes or no
Enter Exp. Date of reagent	X	Did reagent pass QC testing? yes or no

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Enter Exp. Date of reagent	X	Did reagent pass QC testing? yes or no
Enter Exp. Date of reagent	X	Did reagent pass QC testing? yes or no
Enter Exp. Date of reagent	X	Did reagent pass QC testing? yes or no

Results

#Value auto calculate	% Viability (7AAD neg. from lymph analysis tube)	Value obtained from R1 % gated in lymphocyte.
	% lymphocytes	Obtain from the lymphocyte analysis.

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Cells/kg	
=B36/D4	
=B37/D4	
=B38/D4	
=B39/D4	
=B40/D4	
=B41/D4	
=B42/D4	
=B43/D4	
=B44/D4	
=B45/D4	
	Comments:

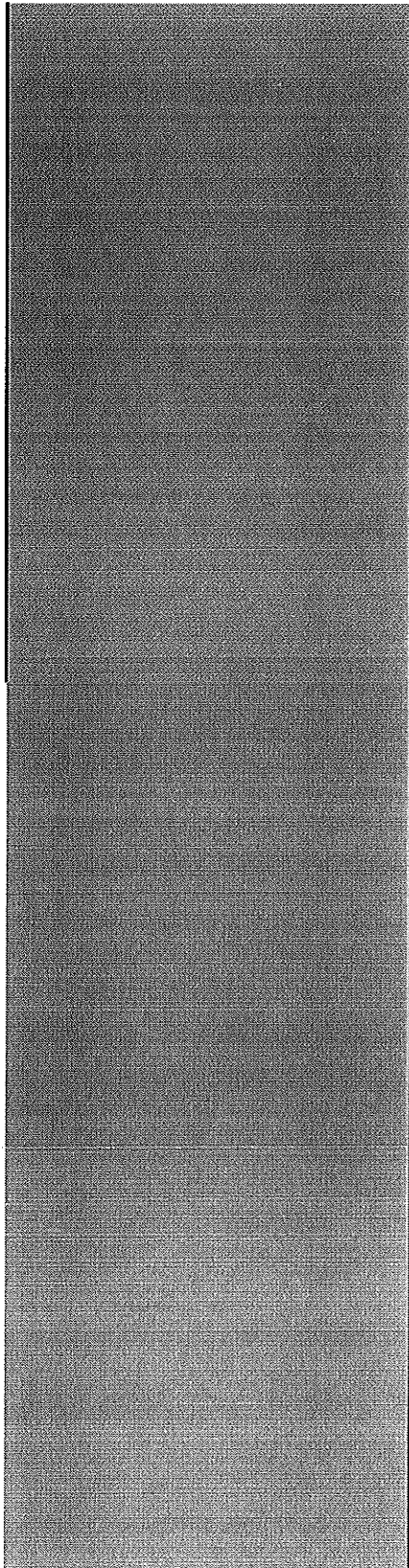
Date:	Date of review
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laboratory. It has not been cleared or approved by the U.S. Food and drug Administration. The FDA has determined this laboratory is for investigational or research use only. This laboratory is certified under CLIA-88 as qualified to perform limited testing.

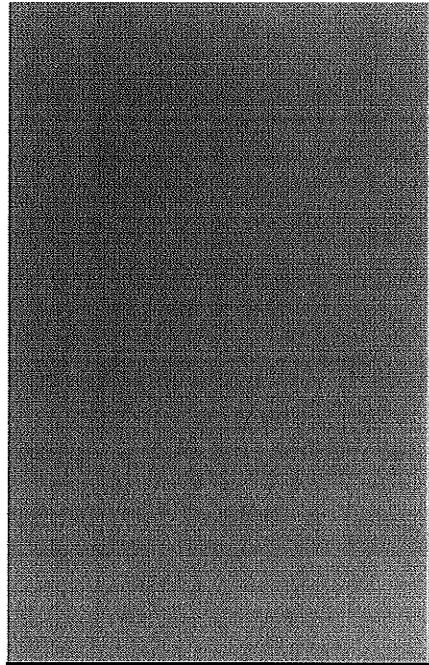
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Obtain From flow worksheet
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as determined that such clearance
high complexity clinical laboratory

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Signature Manifest**Document Number:** FLOW-FORM-001**Revision:** 03**Title:** Adult Allogeneic Donor PSC Lymphocyte Subset Results**FLOW-FORM-001 Adult Allogeneic Donor PSC Lymphocyte Subset Results****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Melissa Reese (MGREESE)		21 Mar 2013, 03:11:16 PM	Approved

Manager Approval

Name/Signature	Title	Date	Meaning/Reason
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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
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QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		03 Apr 2013, 02:18:40 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		05 Apr 2013, 04:26:51 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Sharon Hartis (SH259)		05 Apr 2013, 04:26:52 PM	Email Sent