

STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: FLOW-FORM-004
DOCUMENT TITLE:
Adult PSC CD34 Selection Product Lymphocyte Subset Results
DOCUMENT NOTES:

Document Information

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Effective Date: 08 Apr 2013 Expiration Date:

Control Information

Author: MGREESE Owner: MGREESE

Previous Number: FLOW-FORM-004 Rev 03 Change Number: STCL-CCR-127

Patient Name		-004 Adult PSC C	D34 Select	ion Product L	ymphocyte Subset Result	5	
Patient Name: MRN #: Product Bar Code: Viss: Time of collection: Time of staining: Date: Trechnician initial: Passed Positive Control cell QCP V/N Expiration ASR* 0 CD45/CD14 0	3 (3) (3)				2000 2000 2000 2000		
Product Bar Code:			Recipient				
Product Bar Code: Time of cellection: Date: Technician initial: Time of staining: Date: Technician initial: Passed Positive Control cell (CTY/M)	Patient Name:		wt. (kg):				
Product Bar Code: Type: Technician initial: Time of cellection: Date: Technician initial:							
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Time of staining: Antibody Lot# Expiration date ASR* Passed Positive Control cell QC7 Y/N					Tachnician initials	EXTENSION STATE	
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% viable CD3+CD56+				% lymphocytes			
% viable CD3-(CD56+ % viable CD19							
% viable CD3 (total)							
Washible C014							
CD3+ SOUNDS							
Cells Kg CD56+ Fix Kg CD19+ Fix CD19+							
Cells/kg				CD3+	#DIV/0I		
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Cells/kg #DIV/0 #DI						ı	
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	D3+CD4+CD25+		#DIV/01			1	
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Reviewed by: Date:			Date			1	
Reviewed by: Date: Date: Date:	his test was developed and its perform:	nce characteristics determined		Laboratory, It has not I	been cleared or approved by the U.S. Food a	nd drug	

Print copy for batch file.

Print copy for batch file.					
Selection Donor Flow W					
Patient Name:	Obtain From flow worksheet	Recipient wt. (kg):			
MRN #:	Obtain From flow worksheet				
Product Bar Code:		Product type:			
Time of collection:		Date:			
Time of staining:	Obtain From flow worksheet	Date:			
Antibody	Lot#	Expiration date			
BD CD45/CD14	Fill in with correct lot #	Enter Exp. Date of reagent			
BD CD3 Fitc	Fill in with correct lot #	Enter Exp. Date of reagent			
BD CD56 PE	Fill in with correct lot #	Enter Exp. Date of reagent			
BD CD19 APC	Fill in with correct lot #	Enter Exp. Date of reagent			
BD 7-AAD	Fill in with correct lot #	Enter Exp. Date of reagent			
BD CD3 PE	Fill in with correct lot #	Enter Exp. Date of reagent			
BD CD4 APC	Fill in with correct lot #	Enter Exp. Date of reagent			
BD CD25 Fitc	Fill in with correct lot #	Enter Exp. Date of reagent			
Comments:	I III III WICH CONTECTION #	Litter Exp. Date of Teagerit			

		Results
PRE		
Hematology Analyzer Cell Count	Obtain From flow worksheet	#Value auto calculate
Volume (mls)	Obtain From flow worksheet	According to the second
Total viable cells	#VALUE!	
% viable CD3+CD56-	Obtain from tube 3 flow result.	
% viable CD56+(Total)	Obtain from tube 3 flow result.	

<u> </u>		
0/ viable CD2 (CDEC)	Obtain from tube 3	
% viable CD3+CD56+	flow result.	
04 viable CD3 CDE6 I	Obtain from tube 3	
% viable CD3-CD56+	flow result. Obtain from tube 3	
% viable CD3 (total)	flow result.	
70 VIABLE CD3 (total)	Obtain from tube 3	
% viable CD19	flow result.	
	Obtain from tube 2	
% viable CD14	flow result.	
	Obtain from tube 7	
% viable CD3+CD4+CD25+	flow result.	
		Cells/kg
Total viable CD3+CD56-	#VALUE!	#VALUE!
Total viable CD56	#VALUE!	#VALUE!
Total viable CD3+CD56+	#VALUE!	#VALUE!
Total viable CD3-CD56+	#VALUE!	#VALUE!
Total viable CD3+	#VALUE!	#VALUE!
Total viable CD19	#VALUE!	#VALUE!
Total viable CD14	#VALUE!	
Total viable CD14	#VALUE!	#VALUE!
T. I. I. I. I. GDO. GD 4. GDOF.	Section (E)	
Total viable CD3+CD4+CD25+	#VALUE!	#VALUE!
ETNAL		
FINAL		
l	Obtain From flow	
Hematology Analyzer Cell Count		
Values a (male)	Obtain From flow	
Volume (mls)	worksheet	
Total viable cells	#VALUE!	
% viable CD2 LCDE6	Obtain from tube 3	
% viable CD3+CD56-	flow result. Obtain from tube 3	
% viable CD56+ (Total)	flow result.	
70 VIGBIC CD301 (10td1)	Obtain from tube 3	
% viable CD3+CD56+	flow result.	
	Obtain from tube 3	
% viable CD3-CD56+	flow result.	
	Obtain from tube 3	
% viable CD3 (total)	flow result.	
0/ -:	Obtain from tube 3	
% viable CD19	flow result.	
% viable CD14	Obtain from tube 2 flow result.	
10 Manie CD14	Obtain from tube 4	
% viable CD3+CD4+CD25+	flow result.	
	The state of the s	Cells/kg
Total viable CD2+CD56	#VALUE!	STREET AND ADDRESS
Total viable CD3+CD56-	# VALUE:	#VALUE!

	Reviewed by:	Enter reviewer initial
	A Committee of the Comm	
Total viable CD3+CD4+CD25+	#VALUEI	#VALUE!
Total viable CD14	#VALUE!	#REF!
Total viable CD19	#VALUÉ!	#VALUE!
Total viable CD3+	#VALUE!	#VALUE!
Total viable CD3-CD56+	#VALUE!	#VALUE!
Total viable CD3+CD56+	#VALUE!	#VALUE!
Total viable CD56	#VALUE!	#VALUE!

^{*}This test was developed and its performance characteristics determined by the Stem Cell Laboratory. FDA has determined that such clearance or approval is not necessary. This test is used for clinical pur certified uder CLIA-88 as qualified to perform high complexity clinical laboratory testing. CLIA # 34D1

rksheet/Result	S	
		0.2
Obtain From flow		
worksheet		
Obtain From flow		
worksheet		
Obtain From flow		Obtain From flow
worksheet	Technician initial:	worksheet
Obtain From flow		Obtain From flow
worksheet	Technician initial:	worksheet
	Passed Positive	
	Control cell QC?	
ASR*		
ASK	Y/N Did reagent pass QC	
	testing? yes or no Did reagent pass QC	
	testing? yes or no	
	Did reagent pass QC	
X	testing? yes or no	
	Did reagent pass QC	
x	testing? yes or no	
	Did reagent pass QC	
	testing? yes or no	
	Did reagent pass QC	
X	testing? yes or no	
	Did reagent pass QC	
x	testing? yes or no	
	Did reagent pass QC	
×	testing? yes or no	
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	PRE	
% Viablility		
(7AAD neg. from lymph	Obtain from R2 stat Tube	
analysis tube)	3	
	Obtain from tube 3 flow	
% lymphocytes	result.	
	FINAL	
% Viablility		
(7AAD neg. from lymph	Obtain from R2 stat Tube	
analysis tube)	3	
	Obtain from tube 3 flow	
<u>% lymphocytes</u>	result.	

% Recovery post selection	
TNC #VALUE!	
CD3+ #VALUE!	
CD56+ #VALUE	
CD19+ #REF!	
Log Depletion	
CD3+ #VALUE!	
CD56+ #VALUE! CD19+ #VALUE!	
Comments:	

Date of review:	Enter date of review	
It has not been cleared or	approved by the U.S. Food a	and drug Administration. The or research. This laboratory is

Signature Manifest

Document Number: FLOW-FORM-004 **Revision:** 04

Title: Adult PSC CD34 Selection Product Lymphocyte Subset Results

FLOW-FORM-004 Adult PSC CD34 Selection Product Lymphocyte Subset Results

Name/Signature	Title	Date	Meaning/Reason
Melissa Reese (MGREESE)		21 Mar 2013, 03:12:57 PM	Approved

Manager Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		23 Mar 2013, 09:51:10 AM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		24 Mar 2013, 10:05:16 AM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		03 Apr 2013, 02:35:36 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)	No.	05 Apr 2013, 04:35:23 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Sharon Hartis (SH259)			24 PM Email Sent