



STEM CELL LABORATORY (STCL)



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

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| | | | 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+CD25+ | 0.00E+00 | #DIV/0! | | | | | | | | Log Depletion | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 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+CD25+ | 0.00E+00 | #DIV/0! | | | | | | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> 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lymphocytes | | Total viable cells | 0.00E+00 | | | | | | | | | | | % viable CD3+CD56- | | | | % viable CD56+ (Total) | | | | % viable CD3+CD56+ | | | | % viable CD3-CD56+ | | | | % viable CD3 (total) |
 | | | % viable CD19 | | % Viability (7AAD neg. from lymph analysis tube) | | | % viable CD14 | | | | % 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+CD25+ | 0.00E+00 | #DIV/0! | | | | | | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | Comments: | | | | | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> | | | | | Log Depletion | | CD3+ | #NUM! | CD56+ | #NUM! | CD19+ | #NUM! | <table border="1"> <thead> <tr> <th colspan="2">Log Depletion</th> </tr> </thead> <tbody> <tr> <td>CD3+</td> <td>#NUM!</td> </tr> <tr> <td>CD56+</td> <td>#NUM!</td> </tr> <tr> <td>CD19+</td> <td>#NUM!</td> </tr> </tbody> </table> |
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Print copy for batch file.

Selection Donor Flow Worksheet		
Patient Name:	Obtain From flow worksheet	Recipient wt. (kg):
MRN #:	Obtain From flow worksheet	
Product Bar Code:	Bar code number	Product type:
Time of collection:	Obtain From flow worksheet	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:		
Results		
PRE		
Hematology Analyzer Cell Count	Obtain From flow worksheet	#Value auto calculate
Volume (mls)	Obtain From flow worksheet	
Total viable cells	#VALUE!	
% 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+CD25+	Obtain from tube 7 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!	#VALUE!
Total viable CD3+CD4+CD25+	#VALUE!	#VALUE!
FINAL		
Hematology Analyzer Cell Count	Obtain From flow worksheet	
Volume (mls)	Obtain From flow worksheet	
Total viable cells	#VALUE!	
% 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+CD25+	Obtain from tube 4 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!	#REF!
Total viable CD3+CD4+CD25+	#VALUE!	#VALUE!
	Reviewed by:	Enter reviewer initial

*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

Worksheet/Results

Obtain From flow worksheet		
Obtain From flow worksheet		
Obtain From flow worksheet	Technician initial:	Obtain From flow worksheet
Obtain From flow worksheet	Technician initial:	Obtain From flow worksheet
ASR*	Passed Positive Control cell QC? Y/N	
	Did reagent pass QC testing? yes or no	
	Did reagent pass QC testing? yes or no	
X	Did reagent pass QC testing? yes or no	
X	Did reagent pass QC testing? yes or no	
	Did reagent pass QC testing? yes or no	
X	Did reagent pass QC testing? yes or no	
X	Did reagent pass QC testing? yes or no	
X	Did reagent pass QC testing? yes or no	
% Viability (7AAD neg. from lymph analysis tube)	PRE	
% lymphocytes	Obtain from R2 stat Tube 3	
	Obtain from tube 3 flow result.	
% Viability (7AAD neg. from lymph analysis tube)	FINAL	
% lymphocytes	Obtain from R2 stat Tube 3	
	Obtain from tube 3 flow result.	

Date of review:	Enter date of review	
It has not been cleared or approved by the U.S. Food and drug Administration. The poses. It should not be regarded as investigational or for research. This laboratory is .005310, CAP#7181142		

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****Author Approval**

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)		05 Apr 2013, 04:35:23 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Sharon Hartis (SH259)		05 Apr 2013, 04:35:24 PM	Email Sent