

# STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: FLOW-FORM-0	003
DOCUMENT TITLE:	
Flow Cytometry Results	
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DOCUMENT NOTES:	
Document Information	
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Date information	
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Effective Date: 28 May 2015	Expiration Date:
Control Information	
Author: MGREESE	Owner: MGREESE
Previous Number: FLOW-FORM-003 Rev 04	Change Number: STCL-CCR-295

	FLOW-FO	RM-003 FI	ow Cytometry	/ Results	•
Patient Name:		Recipient wt. (kg):			
MRN #:		Product			
Product ID:		type:			
Time of collection: Time of staining:		Date: Date:		Technician initial: Technician initial:	
Time of Stanning.		Date.		Passed Positive Control cell	
and the dec	1-44	Expiration date	ASR*	QC? Y/N	
Antibody D CD45/CD14	Lot#	date	ASK*		
BD CD3 Fitc					
BD CD56 PE					
SD CD19 APC					-
D 7-AAD D CD3 PE					1
BD CD25 Fitc		<u> </u>			]
D CD4 APC					]
					1
					1
OC Followup:	I,	<del></del>			1433
• • • • • • • • • • • • • • • • • • •					
		Results			
Resul	t 1	1		Result 1	4
Cell Count		-	% viability		1
/olume (mls) FNC	0.00E+00	1	% lymphocytes	Result 2 (if needed)	1
.,,,	5.202100	]	% viability	(I needed)	]
% viable CD3+CD56-		]	% lymphocytes		]
% viable CD56+(Total)		]			
% viable CD3+CD56+		4	1.00		1
% viable CD3-CD56+ % viable CD3 (total)		1		3132 232	1
% viable CD3 (total) % viable CD19		]		207000000000000000000000000000000000000	]
% viable CD14		I			
% viable CD3+CD4+CD2	5+	0.11.0		1	1
		Cells/kg			1
otal CD3+CD56-	0,00E+00	#DIV/0I	3.00		1
otal CD56	0.00E+00	#DIV/01			]
otal CD3+CD56+	0,00E+00	#DXV/01			1
Total CD3-CD56+	0.00E+00	#DXV/01			l de la company
Fotal CD3+ Fotal CD19	0.00E+00 0.00E+00	#DIV/01 #DIV/01			1
Total CD14	0.00E+00	#DIV/01			]
otal CD3+CD4+CD25+	0.00E+00	#DIV/01			1
					1
Result 2 (if	needed)				
Cell Count			100000		1
/olume (mls)					
rnc	0,00E+00	1			
% viable CD3+CD56-		1			
% viable CD56+ (Total)		]			
% viable CD3+CD56+		1			
% viable CD3-CD56+		<b>∤</b>			
% viable CD3 (total) % viable CD19		1 10000		Comments:	<u> </u>
% viable CD19 % viable CD14		1			
% viable CD3+CD4+CD2	5+			1	
		4		1	
otal CD3+CD56-	0.00E+00	#DIV/0I			
otal CD56	0.00E+00	#DIV/01			
otal CD3+CD56+	0,00E+00	#DIV/01			
otal CD3-CD56+	0,00E+00	#DIV/01			
Total CD3+ Total CD19	0.00E+00 0.00E+00	#DIV/01 #DIV/01			
Total CD19	0.00E+00	#DIV/01	The second second		
Total CD3+CD4+CD25+	0.00E+00	#DIV/01			
			1000000		
		ļ		1	
		ļ		1	
Reviewed by:		Date:		· ·	

Print copy for batch file.

Print copy for batch file.				
	FLOW-FOR			
Patient Name:	Obtain From flow worksheet			
MRN #:	Obtain From flow worksheet			
Product ID:	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 #			
BD CD25 Fitc	Fill in with correct lot #			
BD CD4 APC	Fill in with correct lot #			

QC Followup:	
	and the second s
	Result 1
Cell Count	Obtain From flow worksheet
Volume (mls)	Obtain From flow worksheet
TNC	#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.
Total CD3+CD56-	#VALUE!
Total CD56	#VALUE!
Total CD3+CD56+	#VALUE!

Total CD3-CD56+

Total CD3+CD4+CD25+

Total CD3+

Total CD19

Total CD14

#VALUE!

#VALUE! #VALUE!

**#VALUE!** 

**#VALUE!** 

Result 2 (	(if needed)
Cell Count	Obtain From flow worksheet
Volume (mls)	Obtain From flow worksheet
TNC	#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.
Total CD3+CD56-	#VALUE!
Total CD56	#VALUE!
Total CD3+CD56+	#VALUE!
Total CD3-CD56+	#VALUE!
Total CD3+	#VALUE!

Total CD19	#VALUE!
Total CD14	#VALUE!
Total CD3+CD4+CD25+	#VALUE!
Reviewed by:	Reviewer's initial

<sup>\*</sup>This test was developed and its performance characteristics determined by The FDA has determined that such clearance or approval is not necessary. T

M-003 Flow Cytometr	v Results
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4-003 Flow Cytollietly Results						
	The second secon					
	Obtain From flow					
Recipient wt. (kg):	worksheet					
	Obtain From flow					
Product type:	worksheet					
	Obtain From flow					
Date:	worksheet	Technician initial:				
	Obtain From flow					
Date:	worksheet	Technician initial:				
		Passed Positive Control				
Expiration date	ASR*	cell QC? Y/N				
-		Did reagent pass QC testing?				
Enter Exp. Date of reagent		yes or no				
		Did reagent pass QC testing?				
Enter Exp. Date of reagent	X	yes or no				
		Did reagent pass QC testing?				
Enter Exp. Date of reagent		yes or no				
		Did reagent pass QC testing?				
Enter Exp. Date of reagent	X	yes or no				
		Did reagent pass QC testing?				
Enter Exp. Date of reagent	X	yes or no				
		Did reagent pass QC testing?				
Enter Exp. Date of reagent	X	yes or no				
		Did reagent pass QC testing?				
Enter Exp. Date of reagent		yes or no				
		Did reagent pass QC testing?				
Enter Exp. Date of reagent	X	yes or no				

Results		
		Result 1
#Value auto calculate	% viablility	From tube 3
	% lymphocytes	Obtain from tube 3 flow result.
		Result 2 (if needed)
	% viability	From tube 3
1.	% lymphocytes	Obtain from tube 3 flow result.

	<u> </u>	
Cells/kg		
	entrolle de la controlle de la	
#VALUE!		
	1872 1874 187	
		Comments:
#\/A111F1		
#VALUE!		

Date:	Date of review
#VALUE!	
#VALUE!	
#VALUE!	

the Stem Cell Laboratory. It has not been cleared or approved by the U.S. Food and drug Adn his test is used for clinical purposes. It should not be regarded as investigational or for research

Obtain From
flow
worksheet
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## Signature Manifest

**Document Number:** FLOW-FORM-003 **Revision:** 05

Title: Flow Cytometry Results

All dates and times are in Eastern Time.

## FLOW-FORM-003 Flow Cytometry Results

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А	ı	п	T	n	O	г

Name/Signature	Title	Date	Meaning/Reason
Melissa Reese (MGREESE)		11 May 2015, 04:05:33 PM	Approved

## Manager

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Name/Signature	Title	Date	Meaning/Reason
<ul> <li>Выпаснения и почето подавкой почето на почето не почето на поч</li></ul>		В оказывающие в поставления расправа соот меня в поставления почто от отнастива и и мето поставления положения	Conserve stages and a segment of the contract
Barbara Waters-Pick		12 May 2015, 10:21:55 AM	Approved
(WATE02)		12 May 2010, 10.21.00 / MV	Approved

## **Medical Director**

Name/Signature	Title	Date		Meaning/Reason
Joanne Kurtzberg (KURTZ001)		14 May 2015, 12:56:	30 PM	Approved

#### Quality

Name/Signature	Title	Date	Meaning/Reason	
John Carpenter (JPC27)	Mark Address on an agricologic conference construction of the cons	14 May 2015, 02:31:39	Approved	4459706755757479

#### **Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)	(in the last term of th	14 May 2015, 11:55:40 PM	Approved