STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-PROC-038 FRM2	
DOCUMENT TITLE: Certificate of Analysis for CD45RA+ Depleted Donor Lymphocytes Infusion	
DOCUMENT NOTES:	

Document Information

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Effective Date: 14 Jan 2013	**Expiration Date:**

Control Information

Author: WATE02	**Owner:** WATE02
Previous Number: None	**Change Number:** STCL-CCR-047

CERTIFICATE of ANALYSIS for CD45RA+ DEPLETED DONOR LYMPHOCYTE INFUSION

Stem Cell Lab, Duke Medical Center, Pratt Street, Durham, NC

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Date of Collection: _____
Date of Selection: _____
Volume for infusion: _____

Barcode

Donor Type: (Check ONE appropriate match)
____3 - 5/6 Matched/Related __ 6/6 Matched/Related ____ 8/8 Matched/Unrelated

Cell Dose (CD3+ cells/kg): (Check ONE)
□ 1 x 10e4/kg □ 1 x 10e5/kg □ 3 x 10e5/kg □ 1 x 10e6/kg □ 3 x 10e6/kg
□ 5 x 10e6/kg □ 1 x 10e7/kg □ 5 x 10e7/kg □ 1 x 10e8/kg

TEST	SPECIFICATION	RESULT	PASS?
VIABILITY	≥ 70%		
PURITY (CD45RA+ Cells)	≤ 10%		
ENDOTOXIN	≤ 5EU/kg/hr	Minimum infusion time _____ minutes	
GRAM STAIN	No Organisms Seen		

Technologist Completing Certificate: _____ **Date:** _____

MD Notified of release testing failure (if applicable): _____
Date and Time Notified (if applicable): _____

MD confirming / accepting product specifications prior to infusion:

_____
Print Physician's Name **Physician's Signature / Pager#**

Tech notifying physician: _____ **Date/Time:** _____

Comments: _____
_____

_____ _____
Quality or Laboratory Manager Signature **Date**

Signature Manifest

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STCL-PROC-038 FRM2 COA CD45RA+

Author Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Dec 2012, 04:24:55 PM	Approved

Manager Approval

Name/Signature	Title	Date	Meaning/Reason
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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		21 Dec 2012, 07:19:58 PM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		23 Dec 2012, 04:52:03 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		14 Jan 2013, 04:11:34 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		14 Jan 2013, 04:11:35 PM	Email Sent
Sharon Hartis (SH259)		14 Jan 2013, 04:11:35 PM	Email Sent
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System Administrator (SYSADMIN)		14 Jan 2013, 04:11:35 PM	Email Sent