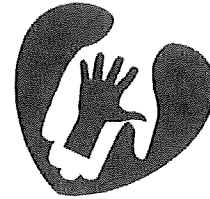


STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-PROC-019 FRM2

DOCUMENT TITLE:

CD56+ Certificate of Analysis

DOCUMENT NOTES:

Document Information

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Owner: WATE02

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**STCL-PROC-019 FRM2
CD56+ CERTIFICATE OF ANALYSIS
FOR HEMATOPOIETIC PROGENITOR CELLS, APHERESSES
CD56+ ENRICHED for DLI**

ISBT 128 Barcode

(Affix Recipient / Donor Labels)

Patient Name: _____ Donor Name: _____

History #: _____ Donor #: _____

Patient DOB: _____ Donor DOB: _____

Date of Collection: _____ Date of CD56+ Selection: _____

HLA Match (Check ONE) ☐ 8/8 ☐ 7/8 ☐ 6/8 ☐ 5/8 ☐ 4/8 OR ☐ 6/6 ☐ 5/6 ☐ 4/6 ☐ 3/6

TEST	SPECIFICATION	RESULT	PASS?
VIABILITY	> 70.0% of TNC are viable (<i>post selection</i>)		
VIABILITY	>70.0% of TNC are viable (pre-infusion) (<i>IF refrigerated overnight</i>)		
CD56+ PURITY	>70.0 % of CD56+ cells		
RECOVERY of CD56+ cells (<i>Pre vs Post</i>)	> 40% of CD56+ cells		
TOTAL CD 56+ DOSE	$\geq 1.0 \times 10^7$ cells/kg target		
CD3+ / CD56- DOSE	1.0×10^6 /kg <u>or less</u> (for 7/8 - 8/8 <u>or</u> 6/6 HLA Match)		
CD3+ / CD56- DOSE	0.5×10^6 /kg <u>or less</u> (for 4/8 - 6/8 <u>or</u> 3/6 - 5/6 HLA Match)		
GRAM STAIN	NO ORGANISMS SEEN		

This donor has been successfully screened and has been determined eligible to donate these cells.

Technologist Completing Certificate: _____ Date: _____

*In the event of criteria failure, the attending physician will be notified by e-mail, text page, or phone call so a decision can be made regarding the status of the final infusion product.*MD Notified (*if applicable*) _____ Date and Time Notified: _____Technologist Notifying ABMT MD (*if applicable*): _____

MD confirming product specifications prior to infusion: _____

Signature / Pager #

The following specifications were not met (*if applicable*): _____

Quality or Laboratory Manager_____
Date

Instructions for Completing Certificate of Analysis

Field	Requirement
Recipient name and history number	Enter name of recipient and their history # (medical record number).
Donor name and history number	Enter name of donor and their history # (medical record number).
ISBT 128 barcode #	Affix the unique identifier barcode for this product.
Date of collection	Enter the date the product was collected
Date of selection	Enter date that selection took place.
HLA Match (<i>check one</i>)	Confirm and check the HLA match of the recipient and donor
Viability result	Enter percentage of viable TNC.
Viability Pass?	Enter "Yes" or "No" for whether viability results met specifications.
Viability result	Enter percentage of viable TNC following overnight storage in the refrigerator (per protocol)
Viability Pass?	Enter "Yes" or "No" for whether viability results met specifications.
CD56 Purity	Should be > 70% purity of CD56+ cells
Purity Pass?	Enter "Yes" or "No" for whether CD56+ purity result specifications are met.
RECOVERY of CD56+ cells (<i>Pre vs Post</i>)	% recovery of CD 56+ cells/kg should be 40%
RECOVERY of CD56+ cells Pass?	Enter % recovery of CD56+ cells/kg (pre vs post processing)
TOTAL CD56+ dose	Enter the total # of CD56 + cells/kg
Total CD56 dose pass?	Enter "Yes" or "No" for whether CD56+ target cell dose met specifications.
CD3+ / CD56- DOSE (7/8 - 8/8 <u>or</u> 6/6 HLA Match)	Enter results CD3+ / CD56- results for (7/8 - 8/8 <u>or</u> 6/6/HLA Match)
CD3+ / CD56- DOSE (7/8 - 8/8 <u>or</u> 6/6 HLA Match) Pass?	Enter "Yes" or "No" for whether results met specifications for (7/8 - 8/8 <u>or</u> 6/6 HLA Match)
CD3+ / CD56- DOSE (4/8 – 6/8 <u>or</u> 3/6 – 5/6 HLA Match)	Enter results CD3+ / CD56- results for (4/8- 6/8 <u>or</u> 3/6 – 5/6 HLA Match)
CD3+ / CD56- DOSE (4/8, 5/8, <u>or</u> 6/8 HLA Match) Pass?	Enter "Yes" or "No" for whether results met specifications for (4/8, 5/8, or 6/8 HLA Match)
GRAM STAIN	Enter results of gram stain.
GRAM STAIN Pass?	Enter “Yes” or “No” for whether results met specifications.
Technologist Completing certificate and date of completion	Enter name of technologist who completed the COA and the date completed.
In the event of criteria failure, person, date, time of notification, and reason of failure.	Enter MD name, date, and time of notification of criteria failure.
Enter name of tech notifying MD	Enter tech name if results are out of specification per COA.
Signature / Pager#	MD should sign form and include pager #
Quality or Laboratory Manager	Enter signature of Quality or Laboratory Manager approving criteria reflected on the COA.

Signature Manifest**Document Number:** STCL-PROC-019 FRM2**Revision:** 07**Title:** CD56+ Certificate of Analysis

All dates and times are in Eastern Time.

STCL-PROC-019 FRM2 CD56+ Certificate of Analysis**Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		13 Mar 2017, 06:32:37 PM	Approved

Manager

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		13 Mar 2017, 06:32:49 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		14 Mar 2017, 08:03:55 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
John Carpenter (JPC27)		14 Mar 2017, 10:20:54 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		17 Mar 2017, 07:13:24 PM	Approved