



STEM CELL LABORATORY (STCL)



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DOCUMENT TITLE:

CD34+ Certificate of Analysis (COA) for Clinimacs Allogeneic Donors FRM3

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Author: WATE02

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**STCL-PROC-015 FRM3
CD34+ CERTIFICATE OF ANALYSIS (C of A)
FOR CLINIMACS ALLOGENEIC DONORS**

ISBT 128 Barcode

(Affix Recipient / Donor Labels)

Patient Name: _____ Donor Name: _____
 History #: _____ Donor #: _____
 Patient DOB: _____ Donor DOB: _____

Date of CD34+ Selection: _____ HLA Match: ___6/6 ___5/6 ___4/6 ___3/6
 Date of Infusion: _____ (Check ONE)

TEST	SPECIFICATION	RESULT	PASS?
VIABILITY	> 70.0% of the TNCs are viable		
PURITY	>70.0 % are CD34+		
CD 34+DOSE	____x10 ⁶ /kg		
Total CD 3+ DOSE/ kg (for <u>6/6</u> HLA Match)	1.0 x10 ⁶ /kg or less		
Total CD3+ DOSE/ kg (for <u>3 – 5 /6</u> HLA Match)	0.5 x 10 ⁶ /kg or less		
GRAM STAIN	Neg / No Organisms Seen		

Technologist Completing Certificate: _____ Date: _____

If any of the above criteria fail, the physician will make the final decision regarding the disposition of the product as follows: ☐ direct infusion (check if applicable)

☐ modify (with re-work) (check if applicable)

☐ long-term storage (check if applicable)

MD Notified _____ Date and Time Notified: _____

MD confirming product specifications prior to infusion:

Signature / Pager #

Tech notifying physician _____ Date/Time _____

Comments: _____

Quality or Laboratory Manager

Date

Instructions for completing Certificate of Analysis

Field	Requirement
ISBT 128 Barcode	Affix barcode assigned to the product in space allocated.
Patient name, history number, DOB	Enter name of patient, their medical history number, and date of birth.
Donor name and history number	Enter name of donor, donor's medical history number, and donor's date of birth.
Date of CD34 selection	Enter date that selection took place.
HLA Match	Select the appropriate HLA match of the recipient and the donor.
Viability result	Enter percentage of viable TNC.
Viability Pass?	Enter "Y" or "N" for whether viability results met specifications.
Purity	Enter percentage of TNC that are viable CD56+ cells
Purity Pass?	Enter "Y" or "N" for whether CD56+ viability results specifications are met.
CD 34+ dose	Enter total number of CD 34+ cells.
CD34+ dose Pass?	Enter "Y" or "N" based on the desired CD34+ cell dose/kg reflected on the orders.
CD 3+ dose/kg (6/6 or 3-5/6 HLA match)	Enter total number of CD 3+ cells/kg
CD 3+ dose/kg Pass? (6/6 or 3-5/6 HLA match)	Enter "Y" or "N" for whether CD3+/kg target cell dose results met specifications based on HLA match of patient/donor.
Gram stain	Enter results of Gram stain.
Gram stain Pass?	Enter "Y" or "N" for whether Gram results met specifications.
Technologist Completing Certificate	Technologist completing the certificate must sign COA.
Product disposition	In the event that all C of A specifications are not successfully met, the appropriate disposition categories must be selected by the physician and signature obtained.
MD Notified; Date/time notified	Record the physician's name and the date/time he/she was notified of any specifications that were NOT met on the C of A.
MD confirming product specifications prior to infusion	Physician should sign and enter pager # reflecting his/her review of C of A before infusion to the recipient.
Quality or Laboratory Manager	The quality or laboratory manager must sign the final C of A to ensure that all specifications have been met or that the physician has provided authorization for disposition category.

Signature Manifest**Document Number:** STCL-PROC-015 FRM3**Revision:** 04**Title:** CD34+ Certificate of Analysis (COA) for Clinimacs Allogeneic Donors FRM3**STCL-PROC-015 FRM3 CD34+ COA****Author Approval**

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Manager Approval

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Document Release

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