



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-PROC-015 FRM2

DOCUMENT TITLE:

Certificate of Analysis COA for Autologous CD34+ Selections

DOCUMENT NOTES:

Document Information

Revision: 03

Vault: STCL-Processing-rel

Status: Release

Document Type: STCL-Processing

Date Information

Creation Date: 11 Jul 2012

Release Date: 05 Sep 2012

Effective Date: 05 Sep 2012

Expiration Date:

Control Information

Author: WATE02

Owner: WATE02

Previous Number: STCL-DIST-004 Rev 02

Change Number: STCL-CCR-046

STCL-PROC-015 FRM2
Certificate of Analysis (COA) for Autologous CD34+ Selections
HEMATOPOIETIC PROGENITOR CELLS, APHERESIS
CD34+ ENRICHED (Post Selection)

Recipient's Name: _____
 Recipient's History #: _____ DOB: _____
 Recipient's Blood Type _____ Recipient's Sex _____
 (Affix Recipient Label)

Date of CD34+ Selection: _____

Barcode: _____

TEST	SPECIFICATION	RESULT	PASS?
VIABILITY	$\geq 70.0\%$ of TNC are viable		
PURITY	$\geq 70.0\%$ are CD34+		
CD 34+DOSE	$\geq ______ \times 10^6/\text{kg}$ target *		
CD 3+ DOSE	$< ______ \times 10^6/\text{kg}$ *		
GRAM STAIN	No Organisms Seen		
CULTURE	No Growth		

*Results vary depending on the specific protocol.

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 rework) (check if applicable)

☐ long term storage (check if applicable)

MD Notified _____ Date and Time Notified: _____

Technologist notifying physician _____ Date/Time _____

MD confirming product specifications prior to infusion:

Signature / Pager #

Comments: _____

Quality or Laboratory Manager_____
Date

Instructions for completing Certificate of Analysis

Field	Requirement
Recipient's Name, History #, DOB, Blood type, Sex	Affix label containing the recipient's name, history #, DOB, Blood type, and sex.
Date of selection	Enter date that selection was performed.
Barcode #	Affix the unique identifier barcode assigned to this cellular product.
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 CD34+ cells
Purity Pass?	Enter "Y" or "N" for whether CD34+ viability results specifications are met.
CD 34+ dose *	Enter total number of CD 34+ cells.
CD 34+ dose Pass?	Enter "Y" or "N" for whether CD34+ cell dose results met target specifications.
CD 3+ dose *	Enter total number of CD 3+ cells.
CD 3+ dose Pass?	Enter "Y" or "N" for whether CD3+ cell dose results met target specifications.
Gram stain	Enter results of Gram stain.
Gram stain Pass?	Enter "Y" or "N" for whether Gram stain results met specifications.
Culture	Enter the results of the culture.
Culture Pass?	Enter "Y" or "N" for whether culture results met specifications.
Technologist Signature /Date	Technologist completing the certificate must sign COA and enter date completed.
Criteria failure and product disposition	In the event that a selection does not meet criteria, notify physician on-call. Record the name, date and time of notification. Section the physician's decision concerning product disposition by checking the appropriate box.
Technologist Signature /Date	Technologist notifying the physician must sign and date form.
Required signatures	MD confirming product specifications prior to infusion and Quality or Laboratory Manager
Comments	Enter any pertinent information or explanations not recorded elsewhere on COA.

Signature Manifest**Document Number:** STCL-PROC-015 FRM2**Revision:** 03**Title:** Certificate of Analysis COA for Autologous CD34+ Selections**STCL-PROC-015 FRM2 COA Auto CD34+****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		05 Sep 2012, 05:14:19 PM	Approved

Manager Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		05 Sep 2012, 05:15:25 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		05 Sep 2012, 09:52:30 PM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		05 Sep 2012, 11:09:56 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		05 Sep 2012, 11:14:02 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		05 Sep 2012, 11:14:02 PM	Email Sent
System Administrator (SYSADMIN)		05 Sep 2012, 11:14:02 PM	Email Sent
Linda Sledge (SLEDG006)		05 Sep 2012, 11:14:02 PM	Email Sent
Sharon Hartis (SH259)		05 Sep 2012, 11:14:02 PM	Email Sent