



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-PROC-037 FRM2

DOCUMENT TITLE:

Certificate of Analysis for Hematopoietic Progenitor Cells, Apheresis CMV DLI CCS Enriched Post Selection, Allogeneic

DOCUMENT NOTES:

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Author: WATE02

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CMV SPECIFIC DLI (CCS) from 3-6/6 Matched Family Member Following NonMyeloablative
Allogeneic Stem Cell Transplantation
Certificate of Analysis for CliniMACs Allogeneic Donors
CERTIFICATE of ANALYSIS (C of A) for
HEMATOPOIETIC PROGENITOR CELLS, APHERESIS
CMV DLI (CCS) ENRICHED (Post Selection), ALLOGENEIC

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

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RECIPIENT:**DONOR:**

Collection Date: _____ Date of Selection Procedure: _____ Unique ID# _____
HLA Match: _____ 6/6 _____ 5/6 _____ 4/6 _____ 3/6 (Check appropriate match)

TEST	SPECIFICATION	RESULT	PASS?
VIABILITY (by Trypan Blue)	> 50.0% of TNCs are viable		
CD 3+ (CD4+ / CD8+) PURITY	> 60 % are CD3+ (CD4+/CD8+)		
CD 3+ (CD4+ / CD8+) YIELD	> 40 % CD 3+ (CD4+/CD8+)		
Total CD 3+ DOSE/ kg (for <u>6/6</u> HLA Match)	5.0 x10e5/kg or less		
Total CD3+ DOSE/ kg (for <u>3 – 5 /6</u> HLA Match)	5.0 x 10e4/kg or less		
GRAM STAIN	Neg /No Organisms Seen		
ENDOTOXIN	≤ 5 EU/kg/hour		

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

STCL-PROC-037 FRM2 Certificate of Analysis for Hematopoietic Progenitor Cells, Apheresis CMV DLI
(CCS) Enriched (Post-Selection), Allogeneic
STCL, DUMC
Durham, NC

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Instructions for completing Certificate of Analysis

Field	Requirement
Recipient name, history number, DOB, ABO/Rh, and Sex	Enter recipient's name, history number, date of birth, ABO/Rh, and sex.
Donor name, donor history number, DOB	Enter donor's name, history number, date of birth, ABO/Rh, and Sex.
Unique ID #	Affix the unique identifier ISBT 128 barcode assigned to this product.
Collection Date	Enter the date product collected
Date of Selection Procedure	Enter the date of the selection procedure
HLA Match	Selection appropriate HLA match of donor to recipient
Viability result	Enter viability of product; pass/fail.
CD3+ (CD4+ / CD8+) Dose/kg Purity	Enter the CD3+ (CD4+/CD8+) % purity; pass/fail
CD3+ (CD4+ / CD8+ Dose/kg Yield	Enter the CD3+ (CD4+ / CD8+) yield; pass/fail.
CD 3+ dose/kg (6/6 or 3-5/6 HLA match)	Enter total number of CD 3+ cells/kg; pass/fail.
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 and pass/fail
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 the entire cellular product is not infused, the appropriate disposition categories must be selected.
MD Notification	The physician responsible for the acceptance of the cellular product for infusion must sign and date/time the certificate authorizing the disposition of the cellular product.
Tech notifying physician	Enter the name of the technologist who notified the physician
Date/Time	Enter the date and time physician notified.
Comments	Enter any procedure-related comments
Quality or Laboratory Manager	The quality or laboratory manager must sign the final C of A to ensure that all specifications (when indicated) have been met.

Signature Manifest**Document Number:** STCL-PROC-037 FRM2**Revision:** 02**Title:** Certificate of Analysis for Hematopoietic Progenitor Cells, Apheresis CMV DLI CCS
Enriched Post Selection, Allogeneic**STCL-PROC-037 FRM2 COA for Hematopoietic Progenitor Cells****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Dec 2012, 05:11:08 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, 07:19:30 PM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		23 Dec 2012, 04:48:13 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		14 Jan 2013, 02:15:33 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
System Administrator (SYSADMIN)		14 Jan 2013, 02:15:34 PM	Email Sent
Linda Sledge (SLEDG006)		14 Jan 2013, 02:15:34 PM	Email Sent
Sharon Hartis (SH259)		14 Jan 2013, 02:15:34 PM	Email Sent
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