



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-PROC-047 FRM2

DOCUMENT TITLE:

CliniMACS TCR alpha beta+ T-CELL - CD19+ B-CELL C of A FRM2

DOCUMENT NOTES:

Document Information

Revision: 01

Vault: STCL-Processing-rel

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Control Information

Author: WATER002

Owner: WATER002

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STCL-PROC-047 FRM2
CLINIMACS TCR $\alpha\beta$ + T-CELL / CD19+ B-CELL
REDUCTION CERTIFICATE OF ANALYSIS

ISBT 128 Barcode

RECIPIENT DEMOGRAPHIC LABEL

DONOR DEMOGRAPHIC LABEL

Date of Collection: _____ Date of TCR $\alpha\beta$ + T-Cell / CD19+ B-Cell Depletion: _____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 % of TNC are viable (post selection)		
CD34+ x 10e6 cells/kg	> 5 x 10e6 CD34+ cells/kg		
TCR $\alpha\beta$ + T-cells/kg	\leq 1 x 10e5 cells/kg		
CD19+ cells/kg Reported		N/A	N/A
CD20+ cells/kg	<1 x 10e5 CD20+ cells/kg* <small>NOTE: *If CD20+ cells/kg is >1 x10e5 CD20+ cells/kg, MD must give patient rituximab 375 mg/m² x 1 IV on day +1; reflect MD notification in designated space below.</small>	N/A	N/A
ENDOTOXIN TESTING	< _____ EU/mL		
GRAM STAIN	NO ORGANISMS SEEN		

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

Technologist Completing Certificate: _____ Date: _____

*Attending physician informed of the need to give Rituximab 375 mg/m² x 1 IV on day +1 ☐ Yes ☐ No

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 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

Signature Manifest**Document Number:** STCL-PROC-047 FRM2**Revision:** 01**Title:** CliniMACS TCR alpha beta+ T-CELL - CD19+ B-CELL C of A FRM2**Effective Date:** 01 Sep 2021

All dates and times are in Eastern Time.

STCL-PROC-047 FRM2 CliniMACS TCR alpha beta+ T-CELL - CD19+ B-CELL C of A FRM2**Author**

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Document Release

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