



STEM CELL LABORATORY (STCL)



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Auto-Directed CBU Product Summary Report FRM3

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Author: WATER002

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STCL-COLL-007 FRM3 Auto/Directed CBU Product Summary Report

ISBT Barcode: _____

HPC-C Product Information		Maternal ID Test Results	
		Donor Testing Performed by: <input type="checkbox"/> ViroMed Laboratories, Burlington NC (Check ONE) <input type="checkbox"/> Other Testing Site _____	
		<input checked="" type="checkbox"/> Infectious disease testing included was performed at a CLIA certified and FDA registered laboratory using FDA approved testing kits for donor screening	
Collection Date		HBsAG	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Processing Date		Hepatitis C Antibody	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Received Volume	mL	HIV 1/2/O Antibody	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Final Volume	mL	Hepatitis B Core Antibody	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Total nucleated cell count:	x10 ⁸ cells	HTLV-I/II Antibody	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Total Viable CD34+ cell count:	x 10 ⁶ cells	ABO Antibodies	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
CFU-GM:	x 10 ⁵ cells	Syphilis (Treponema palidum)	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
CFU-GEMM:	x 10 ⁵ cells	CMV Immune Screen	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
BFU-E:	x 10 ⁵ cells	HIV Nat	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Viability:	%	HBV Nat	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Sterility:		HCV Nat	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
ABO/Rh		WNV NAT	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
Gender	<input type="checkbox"/> Female <input type="checkbox"/> Male	Chaga's Antibody	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
<i>HLA Test results (from the CBU, donor, and Intended Recipient) will be obtained if unit used for allogeneic transplant, prior to distribution.</i>		CMV NAT (from CORD)	<input type="checkbox"/> Non-Reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Not Tested
		Hemoglobinopathy testing	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Not Tested
Other(s) (list test and result)		Other(s) (list test and result)	

Donor Eligibility Requirements*: Have the donor eligibility requirements been met based on infectious disease risk?

1. Infectious Disease Testing: ☐ Yes ☐ No
2. Maternal Risk Assessment: ☐ Yes ☐ No

Select appropriate category below: (Reflect the reason for Donor Ineligibility in Comment section below)

- ☐ Donor Eligibility Requirements met - CBU approved for infusion for Autologous or Family Use ONLY
- ☐ Donor Eligibility Requirements **NOT** met and CBU is **NOT** approved for infusion.
- ☐ Donor Eligibility Requirements **NOT** met but CBU **approved** for infusion based on Urgent Medical Need. (Complete *STCL-QA-007 FRM1 Non-Conforming Products* form).
- ☐ Donor Eligibility Incomplete - infant donor and/or mother eligibility has not been completed. CBU **approved** for infusion based on Urgent Medical Need. (Complete *STCL-QA-007 FRM1 Non-Conforming Products* form).

Comments: _____

*HPC-C from an ineligible donor is not prohibited from use if intended for: Autologous use 21 CFR 1271.90(a) (1), Directed (1st or 2nd degree relative) 21 CFR 1271.65 (b) (i), or Documented urgent medical need 21 CFR 1271.60 (d). **The person / establishment determining eligibility of HCT/P is located at 2400 Pratt Street, Durham, NC 27705**

Donor Eligibility Determination: _____ Date _____
Medical Director SignatureQuality Systems Unit Review: _____ Date _____
Quality Signature

Signature Manifest**Document Number:** STCL-COLL-007 FRM3**Revision:** 04**Title:** Auto-Directed CBU Product Summary Report FRM3**Effective Date:** 21 Nov 2024

All dates and times are in Eastern Time.

STCL-COLL-007 FRM3 Auto-Directed CBU Product Summary Report FRM3**Author**

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Document Release

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