



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-PROC-015 FRM6

DOCUMENT TITLE:

Certificate of Analysis for CTN 1301 Protocol

DOCUMENT NOTES:

Document Information

Revision: 01

Vault: STCL-Processing-rel

Status: Release

Document Type: Processing

Date Information

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Release Date: 21 Oct 2015

Effective Date: 21 Oct 2015

Expiration Date:

Control Information

Author: WATE02

Owner: WATE02

Previous Number: None

Change Number: STCL-CCR-308

**CERTIFICATE OF ANALYSIS**

Protocol ID: **1301** Protocol Name: **A Randomized, Multi-Center, Phase III Trial of Calcineurin Inhibitor-Free Interventions for Prevention of Graft-versus-Host Disease**

Instruction: Complete one COA for each product processed on a single tubing set.

Center: _____ Patient Identifier: _____

Product: HPC, Apheresis CD34-Enriched Donation Identifier (DIN): _____

Date of Collection: _____ Date of Selection: _____ Collection No: _____

Product was: ☐ Single Selection ☐ Pooled Selection ☐ Split Selection

Infusion Product represents: ☐ Whole product ☐ Partial product

Product Release Criteria	Method	Acceptable Result	Actual Result Infusion Product
Cumulative CD3+ T cell dose	Flow Cytometry	$\leq 10^5$ /kg recipient weight. Partial product allowed.	Cumulative: This product: <input type="checkbox"/> Pass <input type="checkbox"/> Fail
Cumulative CD34 dose	Flow Cytometry	Target dose: $\geq 5.0 \times 10^6$ /kg recipient weight Minimum dose: $\geq 2.0 \times 10^6$ /kg	Cumulative: This product: <input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> Additional collection needed for target or minimum
Viability	7-AAD Flow Cytometry	$\geq 70\%$	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Sterility	Gram Stain	Negative	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Container integrity and labeling	Visual Inspection	Intact, no leakage, labeled	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Product Appearance	Visual Inspection	Slight pink to white, no aggregates	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Sterility	14 Day Cultures	Sample obtained for Culture	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Endotoxin	LAL Assay	Sample obtained for Assay	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Post Infusion Criteria Method Acceptable Result Actual Result Infusion Product

Sterility	14 Day Cultures	No Growth	<input type="checkbox"/> Pass <input type="checkbox"/> Fail Date: _____
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Endotoxin	LAL Assay	<5 EU/kg/hr infused	<input type="checkbox"/> Pass <input type="checkbox"/> Fail Date:
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Product is approved for release: ☐ Yes ☐ No

Completed by:

Date:

Title: _____

Released by:

Date:

Title: _____

Final Review by:

Date:

Title: _____

Comments:

Signature Manifest**Document Number:** STCL-PROC-015 FRM6**Revision:** 01**Title:** Certificate of Analysis for CTN 1301 Protocol

All dates and times are in Eastern Time.

STCL-PROC-015 FRM6 Certificate of Analysis for CTN 1301 Protocol**Author**

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Document Release

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