



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-FORM-071

DOCUMENT TITLE:

Certificate of Analysis for MSC, Umbilical Cord - Post Thaw

DOCUMENT NOTES:

Document Information

Revision: 03

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Date Information

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Control Information

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Owner: WATER002

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Change Number: STCL-CCR-498

CERTIFICATE of ANALYSIS

MSC, Umbilical Cord - Post Thaw

Patient Demographic Label

(PLACE HERE)

(Name, History #, DOB, Blood Type, Sex)

Product Demographic Label

(PLACE HERE)

(Lot #, Product Description, etc)

Date of Infusion: _____ Patient weight (kg): _____

Lot #: _____ Dose #: _____ Study: _____

Date of Cryopreservation: _____ ISBT 128 Barcode: _____

Date of Thawing: _____

Specifications for Final Release of MSC, Umbilical Cord for Infusion - Post Thaw

TEST	SPECIFICATION	RESULT	PASS?
VIABILITY *	$\geq 70.0\%$ Viable		
Dose: TNC/kg*	# ____ x 10e6 cells/kg		
STERILITY	14-day sterility culture is currently IN-PROGRESS . Medical team will be notified ASAP if a positive culture is identified or, at the conclusion of the culture period, when a negative report is obtained.		

* TNC and viability measured on a Nexcellom Cellometer

Select the Appropriate Infusion Dose based on the IND# listed below:

- ☐ Pro00102894 (IMPACT) IND #17313: Infusion dose = $\leq 6 \times 10^6$ cells/kg x 1 dose
- ☐ Pro00105410 (MASC) IND #19968: Infusion dose = $\leq 1 \times 10^6$ cells/kg/dose (MAX of 100 x 10e6 total cells per dose) daily x 3 doses
- ☐ Pro00106044 (MISTIC) IND #23378: Infusion dose = $\leq 2 \times 10^6$ /kg/dose (MAX dose of 100 x 10e6 total cells per dose) daily x 3 doses
- ☐ Other: _____

Technologist Completing Specifications: _____ Date: _____

Review of Final Product for Suitability - Post Thaw:Product meets or exceeds all release criteria (check ONE): ☐ YES ☐ NOProduct is released for clinical use (check ONE): ☐ YES ☐ NO

Released by: _____ Date: _____

Director, Quality Assurance (or designee)

CERTIFICATE of ANALYSIS

MSC, Umbilical Cord - Post Thaw

Patient Demographic Label

(PLACE HERE)*(Name, History #, DOB, Blood Type, Sex)*

Product Demographic Label

(PLACE HERE)*(Lot #, Product Description, etc)*

Date of Infusion: _____ Patient weight (kg): _____

Lot #: _____ Dose #: _____ Study: _____

Date of Cryopreservation: _____ ISBT 128 Barcode: _____

Date of Thawing: _____

Specifications for Final Release of MSC, Umbilical Cord

TEST	SPECIFICATION	RESULT	PASS?
STERILITY	No Growth		

Review of Final Product for Suitability:

Product previously released for clinical use meets or exceeds all release criteria *(check ONE)*:

☐ YES ☐ NO

Released by: _____ Date: _____

Director, Quality Assurance (or designee)

Signature Manifest**Document Number:** STCL-FORM-071**Revision:** 03**Title:** Certificate of Analysis for MSC, Umbilical Cord - Post Thaw**Effective Date:** 31 Dec 2020

All dates and times are in Eastern Time.

STCL-FORM-071 Certificate of Analysis for MSC, Umbilical Cord - Post Thaw**Author**

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Document Release

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