



# STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:** STCL-GEN-017 JA1

**DOCUMENT TITLE:**

Assessment of the Stem Cell Laboratory Facility Parameters JA1

**DOCUMENT NOTES:**

## Document Information

**Revision:** 02

**Vault:** STCL-General-rel

**Status:** Release

**Document Type:** STCL

## Date Information

**Creation Date:** 24 Sep 2019

**Release Date:** 27 Sep 2019

**Effective Date:** 27 Sep 2019

**Expiration Date:**

## Control Information

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**Previous Number:** STCL-GEN-017 JA1 Rev 01 **Change Number:** STCL-CCR-468

## STCL-GEN-017 JA1

### ASSESSMENT OF THE STEM CELL LABORATORY FACILITY PARAMETERS

The following parameters have been reviewed to ensure compliance with FACT standard D2.3 which requires the processing facility qualify environmental control systems and validate cleaning and sanitation procedures appropriate for the degree of manipulation being performed.

*Following a review of the parameters for the area, the document should be signed by the area Medical/Program Director, Department Manager/Supervisor, and a member from Quality.*

PARAMETER	ASSESSMENT
Contamination	<ul style="list-style-type: none"> <li>Semi-closed systems are utilized when bone marrow and/or apheresis product processing is performed</li> <li>Cellular products are sterilely docked so cellular products can be moved via gravity from one container to another</li> <li>Centrifuges are cleaned weekly with Sani-Cloth or more often if visible spills are observed</li> <li>Sterility samples are removed from each cellular product processed as per SOP or physician order; positivity rate of samples tested in the STCL is monitored and reported quarterly</li> </ul>
Cross-contamination	<ul style="list-style-type: none"> <li>Biological safety cabinets (BSCs) are cleaned before and after each cellular therapy product is processed</li> <li>Sterile zip lock bags are used when thawing cellular products</li> <li>Gloves are changed in-between each product processed</li> </ul>
Temperature, humidity	<ul style="list-style-type: none"> <li>REES monitoring system continuously records the temperature and humidity in the laboratory and supply room</li> <li>REES system will notify appropriate personnel when temperature and/or humidity are out of range</li> </ul>
Surface Contaminants	<ul style="list-style-type: none"> <li>BSC are cleaned before and after product processing.</li> <li>All surface areas are cleaned daily (or more often if visible spills) with Sani-Cloth® AF3 or equivalent germicidal wipes</li> <li>Bi-annual BSC settling plates are collected and sent for testing</li> </ul>
Air Quality	<ul style="list-style-type: none"> <li>Processing of cellular therapy products performed in the Stem Cell Laboratory (STCL) is performed using a closed system or in a BSC</li> </ul>

Based on the review of the above systems, we have determined that the methods in place are appropriate and adequate to control contamination or cross-contamination of any cellular product being processed / manipulated in the laboratory facility. Review of these systems will be repeated annually.

Reviewer Name	Job Title	Signature	Date

**Signature Manifest****Document Number:** STCL-GEN-017 JA1**Revision:** 02**Title:** Assessment of the Stem Cell Laboratory Facility Parameters JA1

All dates and times are in Eastern Time.

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**Document Release**

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