



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-PROC-015 JA1

DOCUMENT TITLE:

Auto CD34-Selected PBPCS for Treatment of Severe Crohn's Disease

DOCUMENT NOTES:

Document Information

Revision: 03

Vault: STCL-Processing-rel

Status: Release

Document Type: STCL

Date Information

Creation Date: 23 Jul 2014

Release Date: 01 Sep 2014

Effective Date: 01 Sep 2014

Expiration Date:

Control Information

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Previous Number: STCL-PROC-015 JA1 Rev 02 **Change Number:** STCL-CCR-226

STCL-PROC-015 JA1 AUTO CD34-SELECTED PBPCS FOR TREATMENT OF SEVERE CROHN'S DISEASE

1 PURPOSE

- 1.1 The CD34 Positive Selection Using the CliniMACS procedure should be followed in its entirety. This job aide will address testing parameters specific for Crohn's Disease protocol.

2 INTRODUCTION

- 2.1 This job aide will address the common practices used in the laboratory when selecting cells using the Miltenyi CliniMACS selection device.
- 2.2 When processing cellular products for transplantation, sterile technique should be used whenever possible. Additional measures, whenever possible, should be taken to minimize the possibility of contaminating cellular products.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Medical Directors, Laboratory Manager, and laboratory testing personnel are responsible for ensuring that the requirements of the procedure are successfully met.

4 DEFINITIONS/ACROMYNS

- 4.1 BSC Biological Safety Cabinet
- 4.2 N/A Not Applicable

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 N/A

7 SAFETY

- 7.1 Wear appropriate personal protective equipment whenever handling potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coat, goggles, etc.

8 PROCEDURE

- 8.1 When processing cellular products on the CliniMACS, one BSC should be designated for this procedure. No other products will be processed in that BSC during this time. Clean the BSC thoroughly before and after each use.

- 8.2 Wipe down the designated centrifuge before and after each CliniMACS selection procedure.
- 8.3 Technologists should change gloves before handling any other cellular product.
- 8.4 Technologists will only handle one cellular product at a time. This will eliminate the possibility of any mix up.
- 8.5 If more than one selection procedure is being performed by the same technologist in any given day, the technologist must remove ALL solutions, buffers, and paperwork associated with the first patient's cells before the second selection procedure is initiated.
- 8.6 When selecting cellular products for a specific study, trial, etc., complete all the necessary paperwork required by that particular study or trial to include obtaining the appropriate approval signatures on the Certificates of Analysis.
- 8.7 Testing of cellular products specific for the Crohn's Protocol is as follows:
 - 8.7.1 Pre-selection test panel should include:
 - 8.7.1.1 cell count
 - 8.7.1.2 viability (trypan blue)
 - 8.7.1.3 sterility culture (BacT Alert in Stem Cell Laboratory)
 - 8.7.1.4 CD34 count
 - 8.7.1.5 Progenitor cell assay
 - 8.7.2 Post-selection test panel should include:
 - 8.7.2.1 cell count
 - 8.7.2.2 viability (trypan blue)
 - 8.7.2.3 sterility (Per 21 CFR 610.12 regulation - which is a 14 day culture that includes a fungal culture must be sent to the Microbiology Laboratory)
 - 8.7.2.4 CD34 count + 7AAD (viability)
 - 8.7.2.5 Endotoxin testing (*if required*)
 - 8.7.2.6 Progenitor cell assay
 - 8.7.3 Post-thaw test panel should include:
 - 8.7.3.1 cell count
 - 8.7.3.2 viability (trypan blue)
 - 8.7.3.3 sterility culture (BacT Alert in Stem Cell Laboratory)
 - 8.7.3.4 CD34 count + 7AAD (viability)
 - 8.7.3.5 Progenitor cell assay
- 8.8 All associated paperwork must be included in the patient's laboratory file which will be stored indefinitely.

- 8.9 When product is issued for infusion (fresh or thawed), maintain records of the chain of custody of the product. The chain of custody will reflect the date, time, and signature of the person transporting the product for infusion and the date, time, and signature of the person accepting the product for infusion. This documentation will remain in the patient's laboratory file indefinitely.

9 RELATED DOCUMENTS/FORMS

- 9.1 *STCL-PROC-015 CD34 Positive Selection Using the CliniMACS*
 9.2 *STCL-PROC-015 FRM1 CD34+ CliniMACS Worksheet*
 9.3 *STCL-PROC-014 FRM2 Certificate of Analysis for Autologous CD34+ Selections*

10 REFERENCES

- 10.1 Circular of Information
 10.2 FACT Standards for Hematopoietic Progenitor Collection, Processing, & Transplantation, 2002
 10.3 CliniMACS Operator's Manual, Current Edition.

11 REVISION HISTORY

| Revision No. | Author | Description of Change(s) |
|--------------|----------------|--|
| 03 | B. Waters-Pick | Formatted. Section 1 – Changed wording Section 2 – Changed wording Section 9 – Added info card # to procedure referenced; added additional documents and info card #s Added Section 11 Revision History. |

Signature Manifest**Document Number:** STCL-PROC-015 JA1**Revision:** 03**Title:** Auto CD34-Selected PBPCS for Treatment of Severe Crohn's Disease

All dates and times are in Eastern Time.

STCL-PROC-015 JA1 Auto CD34-Selected PBPCS for Treatment of Severe Crohn's Disease**Author**

| Name/Signature | Title | Date | Meaning/Reason |
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Quality

| Name/Signature | Title | Date | Meaning/Reason |
|------------------------|-------|--------------------------|----------------|
| John Carpenter (JPC27) | | 18 Aug 2014, 01:53:28 PM | Approved |

Document Release

| Name/Signature | Title | Date | Meaning/Reason |
|---------------------------|-------|--------------------------|----------------|
| Sandy Mulligan (MULLI026) | | 20 Aug 2014, 08:10:46 PM | Approved |