STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-PROC-015 FRM4

DOCUMENT TITLE:

Cell Selection - Product at Receipt/Pre-Processing/Pre-Column Form

DOCUMENT NOTES:

Document Information

Revision: 01	**Vault:** STCL-Processing-rel
Status: Release	**Document Type:** Processing

Date Information

Creation Date: 15 Sep 2015	**Release Date:** 05 Oct 2015
Effective Date: 05 Oct 2015	**Expiration Date:**

Control Information

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Previous Number: None	**Change Number:** STCL-CCR-308

Blood and Marrow Transplant Clinical Trials Network
Cell Selection- Product @ Receipt/Pre-Processing/Pre-Column Form

1 Record number of apheresis performed: NUMAPHER

1 One apheresis
2 Two apheresis
3 Three apheresis

Use response for skip logic

Record date and time each apheresis was performed. Leave blank if no 2nd or third collection, Use 24 h clock:
Note: Report date and time converted to time zone of processing facility

2 Apheresis #1: (APHER1DT) (mm/dd/yyyy hh:mm)
3 Apheresis #2: (APHER2DT) (mm/dd/yyyy hh:mm)
4 Apheresis #3: (APHER3DT) (mm/dd/yyyy hh:mm)

Record Donation Identification Number (DIN) for each apheresis product collected.
Note: If ISBT128 labeling not used, indicate unique product identifier. Leave blank if no 2nd or 3rd collection.

5 DIN Apheresis #1: (DAPHER1DT)
6 DIN Apheresis #2: (DAPHER2DT)
7 DIN Apheresis #3: (DAPHER3DT)

Record date and time processing for CD34-Enrichment began. Leave blank if no 2nd or 3rd collection:

8 Apheresis #1: (APHERP1DT) (mm/dd/yyyy hh:mm)
9 Apheresis #2: (APHERP2DT) (mm/dd/yyyy hh:mm)
10 Apheresis #3: (APHERP3DT) (mm/dd/yyyy hh:mm)

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Record the following product information for each apheresis performed

APHERESIS PRODUCT#1

Record information for the product after collection and prior to processing. When availabe use day of processing data
Note: All values required. Values are absolute cell numbers NOT cells per kg

11 Total nucleated cells (TNCs): (TNC1STPR) _____ (xxx.x) x 10^9 cells
12 7-AAD flow viability: (VIA1STPR) _____ (xxx.x) %
13 #CD3+ T cells: (CD3ST1PR) _____ (xxx.x) x 10^9 cells
14 #CD34+ cells: (CD34S1PR) _____ (xxx.x) x 10^7 cells

15 Indicate conditions of processing

Use response for skip logic

1 Entire product#1 one tubing set
2 Entire product#1 two tubing sets (split)
3 Portion product#1 one tubing set, remainder pooled*
4 Portion product#1 on one tubing set, rest not processed
5 Other, describe _____

* Note record information for the non-pooled portion of product#1 in this section

For non-pooled products provide the follow data. For pooled products go to page 4.

PRE-SELECTION PRE-PLATELET AND ANTIBODY WASH PRODUCT #1, TUBING SET #1

Note: This indicates the number of collected cells undergoing platelet wash and labeling for tubing set #1

16 TNCs Product #1, Set#1 processed (TNC1S1PR) _____ (xxx.x) x 10^9 cells
17 Platelets Product#1 Set#1 processed: (PLAT1S1PR) _____ (xxx.x) x 10^{10} cells

18 Tubing set used for Product#1 Set#1 (SIZE1SET1)

1 Standard Set 161-01
2 Large Scale Set 162-01

PRE-SELECTION POST-PLATELET WASH PRODUCT#1, TUBING SET#1

19 TNCs Product #1 Post-Platelet Set#1 (TNC1POSTPLAT1) _____ (xxx.x) x 10^9 cells
20 Platelets Product #1 Post-Platelet Set#1 (PLAT1POSTPLAT1) _____ (xxx.x) x 10^{10} cells

PRE-SELECTION POST-PLATELET & ANTIBODY WASH PRODUCT#1, TUBING SET#1

21 TNCs Product #1 on Set#1 (TNC1POST1) _____ (xxx.x) x 10^9 cells

PRE-SELECTION PRE-PLATELET AND ANTIBODY WASH PRODUCT #1, TUBING SET #2

Note: This indicates the number of collected cells undergoing platelet wash and labeling for tubing set #2
Leave blank if only 1 tubing set used.

22 TNCs Product #1, Set#2 processed (TNC1S2PR) _____ (xxx.x) x 10^9 cells
23 Platelets Product#1 Set#2 processed: (PLAT1S2PR) _____ (xxx.x) x 10^{10} cells

24 Tubing set used for Product#1 Set#2 (SIZE1SET2)

1 Standard Set 161-01
2 Large Scale Set 162-01

PRE-SELECTION POST-PLATELET WASH PRODUCT#1, TUBING SET#2

25 TNCs Product #1 Post-Platelet Set#2 (TNC1POSTPLAT2) _____ (xxx.x) x 10^9 cells
26 Platelets Product #1 Post-Platelet Set#2 (PLAT1POSTPLAT2) _____ (xxx.x) x 10^{10} cells

PRE-SELECTION POST-PLATELET & ANTIBODY WASH PRODUCT#1, TUBING SET#2

27 TNCs Product #1 on Set#2 (TNC1POST2) _____ (xxx.x) x 10^9 cells

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APHERESIS PRODUCT#2

Record information for the product after collection and prior to processing
Note: All values required. Values are absolute cell numbers NOT cells per kg

28 Total nucleated cells (TNCs), Product#2: (TNC2STPR) _____ (xxx.x) x 10^9 cells
29 7-AAD flow viability, Product#2: (VIA2STPR) _____ (xxx.x) %
30 #CD3+ T cells: (CD3ST2PR) _____ (xxx.x) x 10^9 cells
31 #CD34+ cells: (CD34S2PR) _____ (xxx.x) x 10^7 cells

32 Indicate conditions of processing

1 Entire product#2 one tubing set
2 Entire product#2 two tubing sets (split)
3 Portion product#2 one tubing set, remainder pooled
4 Portion product#2 on one tubing set, remainder not processed
5 Other, describe _____

* Note record information for the non-pooled portion of product#2 in this section

For non-pooled products provide the follow data. For pooled products go to page 4.

PRE-SELECTION PRE-PLATELET AND ANTIBODY WASH PRODUCT #2, TUBING SET #1

Note: This indicates the number of collected cells undergoing platelet wash and labeling for tubing set #1

33 TNCs Product #2, Set#1 processed (TNC2S1PR) _____ (xxx.x) x 10^9 cells
34 Platelets Product#2 Set#1 processed: (PLAT2S1PR) _____ (xxx.x) x 10^{10} cells

35 Tubing set used for Product#2 Set#1 (SIZE1SET1)

1 Standard Set 161-01
2 Large Scale Set 162-01

PRE-SELECTION POST-PLATELET WASH PRODUCT#2, TUBING SET#1

36 TNCs Product #2 Post-Platelet Set#1 (TNC2POSTPLAT1) _____ (xxx.x) x 10^9 cells
37 Platelets Product #2 Post-Platelet Set#1 (PLAT2POSTPLAT1) _____ (xxx.x) x 10^{10} cells

PRE-SELECTION POST-PLATELET & ANTIBODY WASH PRODUCT#2, TUBING SET#1

38 TNCs Product #2 on Set#1 (TNC2POST1) _____ (xxx.x) x 10^9 cells

PRE-SELECTION PRE-PLATELET AND ANTIBODY WASH PRODUCT #2, TUBING SET #2

Note: This indicates the number of collected cells undergoing platelet wash and labeling for tubing set #2
Leave blank if only 1 tubing set used.

39 TNCs Product #2, Set#2 processed (TNC2S2PR) _____ (xxx.x) x 10^9 cells
40 Platelets Product#2 Set#2 processed: (PLAT2S2PR) _____ (xxx.x) x 10^{10} cells

41 Tubing set used for Product#2 Set#2 (SIZE2SET2)

1 Standard Set 161-01
2 Large Scale Set 162-01

PRE-SELECTION POST-PLATELET WASH PRODUCT#2, TUBING SET#2

42 TNCs Product #2 Post-Platelet Set#2 (TNC2POSTPLAT2) _____ (xxx.x) x 10^9 cells
43 Platelets Product #2 Post-Platelet Set#2 (PLAT2POSTPLAT2) _____ (xxx.x) x 10^{10} cells

PRE-SELECTION POST-PLATELET & ANTIBODY WASH PRODUCT#2, TUBING SET#2

44 TNCs Product #2 on Set#2 (TNC1POST2) _____ (xxx.x) x 10^9 cells

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POOLED PRODUCT PROCESSING INVOLVING PRODUCT 1 AND 2

Note: All values required. Values are absolute cell numbers NOT cells per kg

Information from product 1

45 Indicate conditions of processing

Use response for skip logic

1 Entire product pooled with entire second product
2 Entire product pooled with partial second product
3 Portion product#1 pooled with portion of product #2
4 Other, describe

Information from product 1

46 TNCs from Product#1 added to pool (TNC1ADD) (xxx.x) x 10^9 cells
47 Platelets, Product#1 added to pool (PLAT1ADD) (xxx.x) x 10^{10} cells
48 7-AAD viability Product#1 added to pool: (VIA1ADD) (xxx.x) %
49 #CD3+ T cells, Product#1 added to pool (CD31ADD) (xxx.x) x 10^9 cells
50 #CD34+ cells, Product#1 added to pool (CD341ADD) (xxx.x) x 10^7 cells

Information from product 2

51 TNCs from Product#2 added to pool (TNC2ADD) (xxx.x) x 10^9 cells
52 Platelets, Product#2 added to pool (PLAT2ADD) (xxx.x) x 10^{10} cells
53 7-AAD viability Product#2 added to pool: (VIA2ADD) (xxx.x) %
54 #CD3+ cells, Product#2 added to pool (CD32ADD) (xxx.x) x 10^9 cells
55 #CD34+ cells, Product#2 added to pool (CD342ADD) (xxx.x) x 10^7 cells

Pool data. Note: From pool flow analysis or calculated from individual products)

PRE-SELECTION PRE-PLATELET AND ANTIBODY WASH POOLED PRODUCT

56 Indicate DIN assigned to Pooled product
57 TNCs Pooled product to process (TNCPOOL) (xxx.x) x 10^9 cells
58 Platelets in pooled product (PLATPOOL) (xxx.x) x 10^{10} cells
59 7-AAD viability Pooled product: (VIAPOOL) (xxx.x) %
60 #CD3+ T cells in Pooled product. (CD3POOL) (xxx.x) x 10^9 cells
61 #CD34+ cells in Pooled product: (CD34SPOOL) (xxx.x) x 10^7 cells
62 Tubing set used for processing (SETP1SIZE)

1 Standard Set 161-01
2 Large Scale Set 162-01

PRE-SELECTION POST-PLATELET WASH POOLED PRODUCT

63 TNCs Pool Post-Platelet Wash (TNCPPOSTPLAT) (xxx.x) x 10^9 cells
64 Platelets Poo Post-Platelet Wash (PLATPPOSTPLAT) (xxx.x) x 10^{10} cells

PRE-SELECTION POST-PLATELET & ANTIBODY WASH POOLED PRODUCT

65 TNCs Pool Post Plat & Ab Wash (TNCPPOSTW) (xxx.x) x 10^9 cells

APHERESIS PRODUCT#3

Record information for the product after collection. Third products are not to be CD34-enriched

Note: All values required. Values are absolute cell numbers NOT cells per kg

66 Total nucleated cells (TNCs), Product#3: (TNC3STPR) (xxx.x) x 10^9 cells
67 7-AAD flow viability, Product#3: (VIA3STPR) (xxx.x) %
68 #CD3+ T cells, Product#3: (CD3ST3PR) (xxx.x) x 10^9 cells
69 #CD34+ cells, Product#3: (CD34S3PR) (xxx.x) x 10^7 cells

70 Indicate fate of product#3

1 Entire product infused
2 Portion of product infused, remainder cryopreserved
3 Portion of product was infused, remainder discarded
4 Other, describe

71 Indicate number of cells infused: (TNCINF3) (xxx.x) x 10^9 cells

Signature Manifest

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All dates and times are in Eastern Time.

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