STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-FORM-063

DOCUMENT TITLE:

Confirmation of Cell Dose for Infusion

DOCUMENT NOTES:

Document Information

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Control Information

Author: WATE02	**Owner:** WATE02
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Confirmation of Cell Dose for Infusion

Date of infusion: _____

Affix ISBT128 Barcode

Affix
RECIPIENT LABEL

Affix
DONOR LABEL
(if applicable)

1. Product distributed to ☐ ABMT Clinic ☐ Children's Health Center ☐ N5100 ☐ N5200 ☐ N9200 ☐ Other _____
2. Type of product distributed (***Check ONE***):
   - ☐ HPC-Apheresis
     - ☐ Unmanipulated
     - ☐ Minimally manipulated (*ie. rbc depletion, plasma depletion, etc*)
     - ☐ CD34-selection
     - ☐ CD56-selection
     - ☐ Donor Lymphocytes (DLI)
     - ☐ Other (*specify*) _____
   - ☐ HPC-Marrow
   - ☐ HPC-Cord Blood
   - ☐ Granulocytes
   - ☐ MSC
   - ☐ Other (specify): _____
3. Type of infusion (***Check ONE***):
   ☐ Fresh ☐ Thawed (***Check ONE***): ☐ *DAT* ☐ *37 degree C* ☐ Other: _____
4. Recipient's Current weight: _____ kgs
5. Desired infusion dose (***Check ONE***): ***(SEE STCL-FORM-056 Cellular Therapy Infusion Request Form for doctor's order)***
   ☐ _____ x 10e6 CD3+ cells/kg ☐ _____ x 10e6 CD34+ cells/kg
   ☐ _____ x 10e8 TNCs/kg ☐ _____ x 10e6 _____ cells/kg
6. Total Cells Available: ***(Check ONE)*** _____ x 10e6 ☐ CD3+ cells ☐ CD34+ cells ☐ TNCs
7. Total Product Volume Available to prepare infusion dose : _____ mL

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8. Calculations

(Available Cells (x 10e6) (# 6)

(A) _____ = _____ **x 10e6** ____ **cells/kg** (***Available for Infusion)***

(Current Recipient weight in kgs) (# 4)

(Cells/kg Available for Infusion (x 10e6/kg)) *(Desired Infusion Dose (_x 10e6/kg) (# 5)*

(B) _____ = _____

(Current Volume Available (mL) (# 7) X ***mL***

Solve for X; X = Volume (mL) ***(Volume needed for desired dose)***

(Tech # 1 Performing Calculations of Infusion Dose): _____ *(Initials)*_____ *(Date)/(Time)*

[redacted]

(Available Cells (x 10e6) (# 6)

(C) _____ = _____ **x 10e6** ____ **cells/kg** (***Available for Infusion)***

(Current Recipient weight in kgs) (# 4)

(Cells/kg Available for Infusion (x 10e6/kg)) *(Desired Infusion Dose (_x 10e6/kg) (# 5)*

(D) _____ = _____

(Current Volume Available (mL) (# 7) X ***mL***

Solve for X; X = Volume (mL) ***(Volume needed for desired dose)***

(Tech # 2 Verifying Calculations of Infusion Dose): _____ *(Initials)*_____ *(Date)/(Time)*

NOTE: Calculations by at least two (2) technologists confirming the Cell Dose for Infusion ordered by the designated physician MUST be completed and signed BEFORE the physician will APPROVE the distribution of the cellular product for infusion to the recipient.

EXAMPLE: - 21,181.78 x 10e6 CD3+ cells available in 377.8 mL product
- Recipient's current weight = 49.6 kgs
- 377.8 mL = Total product volume available
- 1 x 10e5 CD3+ cells/kg = Desired infusion dose

- 21,181.78 x 10e6 CD3+ cells/kg / 49.6 kgs = 427.05 x 10e6 CD3+ cells/kg (in 377.8 mL product)

- 427.05 x 10e6 CD3+ cells/kg (or *4,270.5 x 10e5 CD3+/kg*) = 1 x 10e5 CD3+ cells/kg (Desired)

377.8 mL X

- X = 0.09 mL (Desired VOLUME to meet Desired Infusion Dose of 1 x 10e5 CD3+ cells/kg

Comments: _____

☐ ***Check box and sign below to reflect APPROVAL to distribute cellular product for infusion to the designated recipient.***

(Medical Director or Designee): _____ / _____ *(Date / Time)* _____
Print Name / Signature

1. Product Distributed to	Check the location in which the product will be distributed for infusion.
2. Type of Product Distributed	Check the appropriate product type being distributed for infusion.
3. Type of Infusion	Check the appropriate type of infusion (*ie. fresh product, thawed product (specify type of thaw, etc).*
4. Recipient's Current Weight	Enter the recipient's current weight (on the day of infusion).
5. Desired infusion dose	Enter the Desired infusion dose as reflected on STCL-FORM-056 Cellular Therapy Infusion Request Form (signed by the designated physician) (*ie. 0.5 x 10e6 CD3+ cells/kg, 2.5 x 10e6 CD34+ cels/kg, etc).*
6. Total Cells Available	Enter the Total Cells Available in the product (*ie. pre-freeze, post thaw, post manipulation, post filter, etc*). Check the appropriate category to reflect (___ x 10e6 CD3+ cells/kg, ____ x 10e6 CD34+ cells/kg, etc).
7. Total Product Volume Available to prepare infusion dose (mL):	Enter the total product volume (mL) of the cellular product that is available to work when preparing the infusion dose
8. Calculations:	Two (2) technologists **MUST** show the calculations used to determine the volume of the product that is needed (mL) to meet the desired infusion dose (ordered by the physician as reflected on *STCL-FORM-056 Cellular Therapy Infusion Request Form*). Calculations **MUST** be signed including the date and time to reflect when the calculations were performed. Sign offs **MUST** be completed **BEFORE** the cellular product can be distributed for infusion to the recipient. ***EXAMPLE***: - 21,181.78 x 10e6 CD3+ cells available in 377.8 mL - Recipient's current weight = 49.6 kgs - 377.8 mL = Total product volume available - 1 x 10e5 CD3+ cells/kg = Desired infusion dose - 21,181.78 x 10e6 CD3+ cells/kg / 49.6 kgs = 427.05 x 10e6 CD3+ cells/kg (in 377.8 mL) - 427.05 x 10e6 CD3+ cells/kg (4270.5 x 10e5 CD3+/kg) = 1 x 10e5 CD3+ cells/kg (Desired) 377.8 mL X - X = 0.09 mL (*Desired VOLUME to meet **Desired Infusion Dose of 1 x 10e5 CD3+ cells/kg***)
Comments:	Enter any specific comments attributed to the product or processing of the product (ie. filtering needed, consultation w/ MDs, etc)
Check box and sign	***BEFORE*** the cellular product can be released from the STCL, the medical director (or designee) must confirm that the calculations are accurate by checking the box ☑ and signing the form to reflect APPROVAL to distribute the cellular product for infusion to the designated recipient.

Signature Manifest

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Title: Confirmation of Cell Dose for Infusion

All dates and times are in Eastern Time.

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Document Release

Name/Signature	Title	Date	Meaning/Reason
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