**DOCUMENT NUMBER:** STCL-FORM-063

**DOCUMENT TITLE:**
Confirmation of Cell Dose for Infusion

**DOCUMENT NOTES:**

### Document Information

| Revision: 01 | Vault: STCL-Form-rel |
| Status: Release | Document Type: STCL FORM |

### Date Information

| Creation Date: 21 Jan 2015 | Release Date: 30 Jan 2015 |
| Effective Date: 30 Jan 2015 | Expiration Date: |

### Control Information

| Author: WATE02 | Owner: WATE02 |
| Previous Number: None | Change Number: STCL-CCR-259 |

CONFIDENTIAL - Printed by: SH259 on 30 Jan 2015 07:24:58 am
STCL-FORM-063
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

(A) \[ \text{Available Cells (x 10e6) (\# 6)} = \text{x 10e6 cells/kg (Available for Infusion)} \]
\( \text{Current Recipient weight in kg) (\# 4)} \)

(B) \[ \text{Cells/kg Available for Infusion (x 10e6/kg))} = \text{X mL} \]
\( \text{Current Volume Available (mL) (\# 7)} \)

Solve for X; \( X = \text{Volume (mL)} \) (Volume needed for desired dose)

(Tech # 1 Performing Calculations of Infusion Dose): \( \text{Initials} \) \( \text{(Date)/(Time)} \)

(C) \[ \text{Available Cells (x 10e6) (\# 6)} = \text{x 10e6 cells/kg (Available for Infusion)} \]
\( \text{Current Recipient weight in kg) (\# 4)} \)

(D) \[ \text{Cells/kg Available for Infusion (x 10e6/kg))} = \text{X mL} \]
\( \text{Current Volume Available (mL) (\# 7)} \)

Solve for X; \( X = \text{Volume (mL)} \) (Volume needed for desired dose)

(Tech # 2 Verifying Calculations of Infusion Dose): \( \text{Initials} \) \( \text{(Date)/(Time)} \)

**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 kg
- 377.8 mL = Total product volume available
- \( 1 \times \text{10e5 CD3+ cells/kg = Desired infusion dose} \)
- 21,181.78 x 10e6 CD3+ cells/kg / 49.6 kg = 427.05 x 10e6 CD3+ cells/kg (in 377.8 mL product)
- 427.05 x 10e6 CD3+ cells/kg (or 4,270.5 x \( \times 10e5 \) CD3+/kg) = 1 x 10e5 CD3+ cells/kg (Desired)

\[ \frac{377.8 \text{ mL}}{X} \]

- \( X = 0.09 \text{ mL} \) (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): \( / \) \( \text{Print Name} \) \( / \) \( \text{Signature} \) \( \text{(Date/Time)} \)
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 (i.e. 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) (i.e. 0.5 x 10e6 CD3+ cells/kg, 2.5 x 10e6 CD34+ cells/kg, etc).

6. **Total Cells Available**
   Enter the Total Cells Available in the product (i.e. 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)

   \[
   \frac{377.8 \text{ mL}}{X} = 0.09 \text{ mL (Desired VOLUME to meet Desired Infusion Dose of 1 x 10e5 CD3+ cells/kg)}
   \]

   **Comments:**
   Enter any specific comments attributed to the product or processing of the product (i.e. 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**

**Document Number:** STCL-FORM-063  
**Revision:** 01  
**Title:** Confirmation of Cell Dose for Infusion

All dates and times are in Eastern Time.

### STCL-FORM-063 Confirmation of Cell Dose for Infusion

#### Author

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<td>(WATE02)</td>
<td>21 Jan 2015, 08:44:23 AM</td>
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#### Manager

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#### Medical Director

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#### Quality

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#### Document Release

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