



STEM CELL LABORATORY (STCL)



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Thawing and Infusion Worksheet

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Author: WATE02

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RECIPIENT'S NAME _____

DONOR'S NAME _____

RECIPIENT'S DUKE HISTORY # _____

DONOR'S DUKE HISTORY # _____

RECIPIENT'S BLOOD TYPE _____

DONOR'S BLOOD TYPE _____

Labels checked for Accuracy BEFORE thawing and distribution (Two (2) Employee Check):**(Date / initials):** _____**(Date / initials):** _____**Date of Infusion/Thaw** _____**Processed by** _____**No. Bags Thawed/infused** _____**RECIPIENT'S WEIGHT** _____ (kgs)**Volume/Bag:** 1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____

CELL COUNTS	CELLS / ML (x 10e6)	TOTAL VOLUME (mls)	TOTAL CELLS (x 10e9)	CELLS/KG (x 10e7)	% RECOVERY
CELLS FROZEN					
SUPERNATANT					
FINAL PRODUCT					
CELLS INFUSED					
TO FREEZE					

VIABILITY POST THAW _____**NUNC VIAL LOCATION** _____**STORAGE DATE(S):** _____**STORAGE LOCATIONS** BAG#1 _____ BAG#2 _____ BAG#3 _____ BAG#4 _____ BAG#5 _____

BAG#6 _____ BAG#7 _____ BAG#8 _____ BAG#9 _____ BAG#10 _____

WATER BATH TEMPERATURE START of Thaw (1" bag) _____ °C **WATER BATH TEMPERATURE END of Thaw (Last bag)** _____ °C**CERTIFICATION OF VISUAL CHECKS (✓):****N/A = Not Applicable**

Bag Number	ISBT Barcode	Freezer ✓	Pre-thaw ✓	Start Time (Product <u>IN</u> H2O Bath)	End Time (37°C Thaw) (Product <u>OUT</u> of H2O Bath)	End Time (DAT) - (End of SePAX run, End of Thaw/Dilute, or End of Thaw/Wash)	BSC ✓	Distribution ✓	Distribution Time
1									
2									
3									
4									

Bag Number	ISBT Barcode	Freezer ✓	Pre-thaw ✓	Start Time (Product <u>IN</u> H2O Bath)	End Time (37°C Thaw) (Product <u>OUT</u> of H2O Bath)	End Time (DAT) - (End of SePAX run, End of Thaw/Dilute, or End of Thaw/Wash)	BSC ✓	Distribution ✓	Distribution Time
5									
6									
7									
8									
9									
10									

I certify that all reagents and supplies used in the processing of these samples show no signs of contamination, irregularities, defects, or flaws.

Date _____ Initials _____

I certify that all heat sealed tubing and all sterile welded tubing used in the processing of these samples exhibit no signs of leakage, irregularities, defects, or flaws.

Date _____ Initials _____

I certify that the cryobag(s) thawed during this procedure exhibited no signs of leaks, cracks or irregularities.

Date _____ Initials _____

I certify that the biological safety cabinet (BSC) used to thaw these cellular products was cleaned BEFORE and AFTER the procedure.

Date _____ Initials _____

COMMENTS:

Reviewed By: _____ Date: _____

Field	Requirements
Recipient's Name	Enter Recipient's name (affix label)
Recipient's Duke History Number	Enter Recipient's Duke medical history number
Recipient's Blood Type	Enter Recipient's ABO/Rh
Donor's name	Enter Donor's name or unique ID number (affix label)
Donor's Duke History Number	Enter Donor's Duke medical history number if applicable
Donor's Blood Type	Enter Donor's ABO/Rh
Labels checked for Accuracy BEFORE distribution (date/initials)	Enter Dates and Initials of the Two (2) Employees who reviewed the labels (Recipient and Donor labels) for accuracy BEFORE thawing and distributing the product for infusion.
Date of Reinfusion/Thaw	Enter the date of thaw and/or infusion is performed
Processed by	Enter the name/initials of tech performing the thaw
No of bags thawed/reinfused	Enter total number of bags thawed or infused to Recipient
Recipient's weight	Enter Recipient's weight in kilograms
Volume/Bag	Enter the weight in grams for each bag thawed/infused
Cells counts	Enter the amount of cells/ml x10 ⁶ , total volume, total cells x 10 ⁹ and cells /kg for each of the following (when applicable): Cells Frozen, Supernatant, Final Product, Cells Reinfused, and/or To Freeze.
Viability Post thaw	Enter the viability results for the cellular product thawed
Nunc vial location	Enter the freezer location of Nunc vial stored for future use.
Storage Dates/Location	Enter the date the bag was stored in the freezer.
Water bath temperature	Record the temperature of the water bath for 1 st and last bag being thawed.
N/A (Not Applicable)	Enter <u>N/A</u> for any of the visual checks <u>NOT performed</u> (Example: If 37°C thaw is performed, enter N/A for <i>End Time (DAT)</i> column.
ISBT Barcode	Place ISBT Barcode representative of the bag to be thawed for infusion; include letter designation (ie. A, B, C, etc).
Freezer ✓	Record the initials of <u>two techs</u> or designee (ie. lab tech, Clinical Research tech, MD, Nurse not administrative staff) confirming (checking) the Recipient's name, history, and ISBT barcode on each bag to be thawed for infusion as reflected on the LIS printout and Cryopreservation Worksheet. .
Pre-Thaw ✓	Record the initials of <u>two techs</u> or designee (i.e. lab tech, Clinical Research tech, MD, Nurse not administrative staff) confirming (checking) the Recipient's name, history, and ISBT barcode on each bag to be thawed for infusion as reflected on the LIS printout and Cryopreservation Worksheet.
Start time	START TIME reflects the time the product was placed in the water bath
End time (37°C Thaw)	37°C Thaw (ONLY) – The END TIME reflects the time the product was removed from water bath (post thaw)
End time (DAT – Dextran Albumin Thaw)	1. <u>SePAX</u> - END TIME reflects completion of the thawing program on SePAX 2. <u>Thaw / Dilute</u> – END TIME reflects completion of final diluted product 3. <u>Thaw/Wash</u> – END TIME reflects completion of final product (including centrifugations, expressing supernatant, etc).
BSC ✓	Record the initials of the tech confirming (checking) the Recipient's name, history, and ISBT barcode on each bag thawed against the HPC Infusion Request Form.
Distribution ✓	Record (1) the initials of the <u>tech and the nurse</u> (receiving the cellular product) for <u>37°C thawed</u> products or (2) the initials of <u>two techs for DAT products</u> to reflect that the Recipient's name, history #, and ISBT barcode match the HPC Infusion Request Form.
Distribution Time	Enter the time the product was distributed to the nursing staff for <u>37°C thawed</u> products. For DAT products, <i>N/A</i> is entered in this column since the courier signs the bottom of the <i>Hematopoietic Progenitor Infusion Request Form</i> as the delivery person's signature.
Certification statements	Date/initial each of the certification statements listed at the bottom of the form
Comments	Enter any comments related to the thawing procedure (ie. report to clinicians of low viability, low recovery, leaking bag, etc).
Reviewed By:	Signature of lab manager (or designee) who reviewed the document

Signature Manifest**Document Number:** STCL-FORM-043**Revision:** 09**Title:** Thawing and Infusion Worksheet

All dates and times are in Eastern Time.

STCL-FORM-043 Thawing and Infusion Worksheet**Author**

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Document Release

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