STEM CELLS – THAWING

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PURPOSE

To provide instructions for thawing autologous human progenitor cells collected by apheresis (HPC-A), also known generically as stem cells, for patient infusion.

RELATED DOCUMENTS

J-W-TS-0450 Stem Cells – Receipt from CRBS

BACKGROUND

Autologous HPC products are collected and cryopreserved for future transplant to rescue a patient with a malignancy from lethal doses of chemotherapy and/or radiation. There is a risk of possibly damaging progenitor cells during the thawing process. Therefore, thawing must occur under controlled conditions to ensure viability of the progenitor cells in each product bag.

DMSO (cryoprotectant) is toxic to HPC-A cells above room temperature. The product(s) must be infused immediately after thawing. Ideally, the thawed product(s) should be infused in less than 15 minutes.

EQUIPMENT

- Water bath
- Disinfectant
- Alcohol prep pad
- 70% alcohol
- Distilled or Deionized water
- Calibrated thermometer
- Hemostat
- Sterile Ziploc bag
- Container/basin
- BMT/PSBC Thaw Record
- Sterile sampling site coupler
- 10 mL syringe
- 18 gauge needle
- 60 mL syringe
- Sterile bag
- Chain of Custody form

STEPS

Prior to the shipper being taken from the Transfusion Service to the clinical unit, the HPC-A units must be dispensed in Cerner.

Once at the clinical unit:

1. The water bath must be cleaned and prepared at least 30 minutes prior to use. (This may be done by nursing personnel prior to the arrival of the blood bank tech.)
   - Spray the water bath with an appropriate disinfectant then wipe dry with paper towels
   - Spray the water bath with 70% alcohol, then allow to air dry
   - Fill the water bath ¾ full with distilled or deionized water, then turn on the water bath
   - Insert a calibrated thermometer and allow the temperature to stabilize at 37C ± 2C.

2. Wait until a physician is present and the nurse is ready to infuse the product(s) before the thawing begins.

3. Put on PPE prior to the thaw procedure.

4. Keep the water bath covered when not in use.

5. Open the mushroom canister. Carefully blow into it to remove the fog. Frosted cassettes are empty.

5. Retrieve the first product by carefully removing the cassette from the dry shipper with a hemostat, taking the product out of the cassette and placing it in a sterile plastic Ziploc bag with the ports at the bottom of the bag. Observe for cracks, product color and intact labels. Carefully place it in a container/basin.

6. The nurse checks the information on the bag against the information on the patient's wristband (i.e., patient name and DOB) and the integrity of the component container with a second nurse and documents that they have verified this check on the "HPC Infusion Record".

7. Close the Ziploc bag and place it in the water bath. Document the time into the water bath on the BMT/PBSC Thaw Record.

8. The seal of the bag must be kept above the water. Gently agitate and knead the bag as it thaws for 3-5 minutes until "slushy". It should be cool to the touch, not warm. In the event of bag leakage/breakage, follow step 8. Otherwise proceed to Step 9.

9. Leak or break in bag:

If	Then
A leak in the bag occurs	• CLAMP THE BAG IMMEDIATELY to stop the leakage if possible • **It is up to the physician in attendance to decide if this compromised product is to be infused** • **An incident report from the transplant facility must be completed immediately after the infusion has been completed with a statement from the physician in attendance explaining the use or discard of the product, along with his/her signature** • Aseptically enter the bag with a sterile sampling site coupler cleaned with an alcohol prep pad, and remove the contents with a 60 mL syringe and 18 gauge hypodermic needle • Samples of product for sterility and fungal testing are given to the nurse for culture and copies of the final report(s) are sent to CRBS • Carefully remove the needle and replace with a clean needle • Hand the syringe to the nurse to infuse the cells directly into the line

If	Then
There is a break in the bag or along the seams of the bag prior to thawing, inform the physician. Document the conversation and approval/non-approval to infuse.	• Place the bag into a sterile bag first, then into a Ziploc bag to thaw • When the cells are thawed, remove the contents of the bag with a 60 mL syringe and 18 gauge needle • Samples of product for sterility and fungal testing are given to the nurse for culture and copies of the final report(s) are sent to CRBS • Carefully remove the needle and replace with a clean needle • Hand the syringe to the nurse to infuse the cells directly into the

	line

10. When the product has thawed to a “slushy” consistency, remove the product bag from the water bath and the outer bag. Record the in and out time of thaw and hand the product to the nurse to mix and attach to the administration tubing for infusion.

11. Note the unit number, collection date, total CD34 frozen, and total volume frozen on the “BMT/PSBC Thaw Record” and check off the unit on the shipment form.

12. Once the unit begins to flow with no hang-ups, start thawing the next unit.

12. As thawing of each product occurs, record the time the product enters the water bath, the time the product is taken out of the water bath, the time infusion is started, and the time the infusion is completed.

13. Repeat the thaw process for each bag, waiting fifteen minutes after the initiation of thawing of the first bag and before thawing the second bag to monitor for adverse reactions.

14. Thaw all remaining bags to succeed the previous bag immediately unless the patient is having difficulty and it is necessary to stop the infusion.

15. Document name, signature, date, time on the Chain of Custody form on the line “Thawed by Trained Personnel”.

16. After all products have been infused, begin to clean the area

17. Empty the water bath, clean and dry.

REFERENCES

AABB Technical Manual, current edition

AABB Standards for Blood Banks and Transfusion Services, current edition

DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**

To provide instructions for thawing stem cells in the clinical unit for patient infusion.

☐ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*

Committee Approval Date	☒ Date: 4/23/2015 ☐ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 4/22/15