

Clinical Process Instruction Manual

Tissue Cooler Usage and Validation Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) uses coolers to transport recovered tissues from a Recovery site to a Tissue Bank. The coolers serve as a means for storage and transportation of human tissues by TGLN.

Process:

1. All tissues recovered are stored in designated coolers.
2. Sterility is maintained in storage and transportation through a combination of tissue bags and jars. The coolers protect the Tissue from any environmental factors.
3. Designated coolers maintain temperature and safety throughout the interim storage and transportation processes.
4. Coolers are secured to maintain safety of tissues at all times during transport.
5. Coolers are transported through a variety of means including TGLN vehicle, courier, car service, taxis, Greyhound, and Air Canada medical desk.
6. In the case of a tissue being quarantined, the cooler provides this quarantining function, without any additional segregation or special facility/ room requirement.
7. The Tissue Recovery Coordinator (TRC) or designate is responsible for cleaning coolers that are reused.
8. On an annual basis TGLN validates as a minimum one of each cooler type to ensure that each one is capable of maintaining applicable temperature requirements.

Validation Process

9. A random sampling of each cooler type is employed to verify the coolers ability to maintain temperatures between 0°C and 10°C for a minimum of 24 hours. Ocular coolers are required to maintain temperatures between 2°C and 8°C. Coolers used to ship multi-tissue are tested for a 72-hour period. Cooler validation shall be conducted on an annual basis. A record of this activity will be maintained by the Quality Department.

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10. The following materials are required for performing a validation of each cooler type:
 - cooler and packaging materials (see tissue specific CPIs for necessary cooler and packaging materials)
 - 1 NIST traceable calibrated temperature monitoring egg (simulates HV & Skin)
 - 1 NIST traceable DIGI-SENCE digital thermometer (ocular tissue only)
 - refrigerated tap water;
 - simulated ocular tissue (any item similar in size and specific heat capacity to a human eye, a radish for example)
 - non-sterile ice
 - water softening salt (musculoskeletal tissue only, either sodium or potassium salt is acceptable)
 - 1 scale
 - Pre-drilled ocular jars (ocular tissue only)
11. The thermometers are initially tested beforehand to ensure functionality.
12. For ocular tissue cooler validation, package the simulated ocular tissue within the pre-drilled ocular jars. See *Eye Enucleation Process Instruction, CPI-9-512* for packaging instructions. Next, insert the DIGI-SENCE digital thermometer probe through the pre-drilled holes and position the tip of the probe in the center of the simulated ocular tissue.
13. For musculoskeletal tissue validation, water softening salt is used to represent the mass of bones recovered. Create a depression in the center of the mass of salt to house the temperature monitoring egg. See *Musculoskeletal Tissue Recovery Process Instruction, CPI-9-529* for packaging instructions.
14. For all other tissue, package according to the applicable CPI using the temperature monitoring egg to simulate the tissue.
15. The Quality Specialist or designate measures time zero temperature and records in log.
16. The temperature monitoring egg is set to record the temperature once every hour for a 24 – 72 hour period and record in log.
17. The Quality Specialist or designate evaluates results for all coolers and issues the *Validation of Coolers Used for Transporting Human Tissues* report to the Quality Director for review once complete.



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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Validation of Coolers Used for Transporting Tissues Report	_____	Quality Assurance Department	Quality Assurance Department	16 years

References:

- Z900.2.2 Tissues for Transplantation CSA Standard.
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D5.830, K1.200, K1.210, K1.220, K1.230