Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Tissue Critical Supply Inspection and Storage Process Instruction

Policy:

All instruments, solutions and supplies used to recover human tissue used for transplantation shall be sterile, unless otherwise indicated. Supplies must be inspected upon receipt and stored in an orderly manner that facilitates inventory rotation. This process instruction defines the process for the receipt, quarantine, inspection, release, storage, inventory and use of supplies. Inventory Coordinator (IA) or designate is responsible for performing the tissue critical supply inspection and storage process. A critical supply is defined as any material used in the pre-operative preparation, recovery, packaging, preservation or storage of a tissue that may come into direct contact with the tissue and is required to be sterile to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases. High Risk critical supplies are media. A non-critical supply is defined as any material that is used prior to pre-operative preparation or for reconstruction or does not come into direct contact with the tissue and is not required to be sterile.

Process:

The IA or designate is responsible for performing the process steps below.

General

1. It is the responsibility of the tissue processors or vendors who provide critical supplies to Trillium Gift of Life Network (TGLN) to ensure that these critical supplies meet requirements set forth in their Clinical Process Instructions (CPI), *American Association of Tissue Banks* (AATB) *Current Standards for Tissue Banking*, *Eye Bank Association of America* (EBAA), relevant *Canadian Standards Association* (CSA) *Standards* and *Health Canada's Safety of Human Cells, Tissues and Organs for Transplantation* (CTO) *Regulations*.

2. The processors or vendors shall provide to TGLN, upon request, documentation that their critical supplies have met specifications designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases.

3. TGLN shall obtain documentation that critical supplies produced and/or sterilized specifically for TGLN use have met specifications designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases (e.g., certificate of analysis, certificate of compliance or verification of sterility).

4. Critical supplies shall not be used until inspected and released for use.

5. Critical supplies shall be used and stored in accordance with manufacturers' instructions.

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Reception

6. Items shall be verified and accounted for against the attached packaging slip to ensure all the supplies have been received.

7. Items not accounted for shall be documented on the packaging slip and brought to the attention of the delivery personnel or supplier at the time the supplies are received.

8. Items that appear to have damage to the shipping container shall be documented on the packaging slip and brought to the attention of the delivery personnel or supplier at the time the supplies are received.

9. The packaging slip shall be signed by the IA or designate with the date the supplies are received.

Quarantine

10. All incoming supplies shall be stored in the designated quarantine area until inspected for integrity, sterility, and expiration.

11. Critical supplies that require storage at refrigerated temperatures shall be received, packaging inspected and placed into refrigeration on the date of receipt. This will be logged onto the *Critical Supply Receipt and Inspection Log*. See Exhibit 1.

12. Document the following information on the *Critical Supply Receipt and Inspection log* for each supply once received:
    - product name;
    - name of distributor/manufacturer;
    - date received/placed into quarantine;
    - initials of person receiving;
    - damage occurring during delivery or shipment;
    - quantity;
    - lot number and manufacturer number, if available; and
    - expiration date, if applicable.

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Release

13. A visual inspection shall be conducted upon receipt and prior to being released into inventory.

14. This visual inspection will identify evidence of:
    - compromise to the sterility of sterile items (i.e., holes in packages or broken seals);
    - color or physical changes for temperature sensitive solutions;
    - appropriate labeling with expiration dates, if applicable; and
    - name, signature, and date of person inspecting.

15. Critical supplies which are deemed high risk shall be inspected 100% while samples not deemed high risk will use the C=0 SAMPLING PLAN to determine the quantity of product requiring inspection. See Appendix 1.
    15.1. An associated Acceptable Quality Levels (AQL) index value of 10.0 shall be used.
    15.2. The lot size of the shipment to be inspected will determine the number of items randomly selected to be inspected (otherwise known as the sample size)
    15.3. If 100% of the sample size shows no defects, then the entire lot will pass inspection.
    15.4. If there is one defect within the sample size, then an associated AQL index value of 0.40 shall be used to re-inspect the lot.
    15.5. If 100% of this sample size shows no defects then the entire lot shall pass inspection. If there is one defect within the re-inspected sample size, then the entire lot shall be handled as described in 16.

16. Any critical supply with evidence of a defect shall not be placed into inventory and will be discarded, returned to the manufacturer, or labeled as “For Training Purposes Only” and placed in a designated area.

17. Document the following in the *Critical Supply Receipt and Inspection Log* for each supply released:
    - date of release;
    - sterility/integrity inspected verification (if applicable);
    - certificate of analysis is acceptable verification (if applicable);
    - initials of person releasing.

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18. For sterile solution, certificate of analysis must be received and reviewed before being released from quarantine.

19. Supply and reagent inventories not bearing expiration dates or manufacturing dates shall be labeled with the acquisition date.

20. Mechanical storage appliances used for storing tissue, reagents, media, refrigerants, or other laboratory solutions shall not be utilized for the storage of food and/or liquid for human consumption and shall be marked accordingly.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Critical Supply Receipt and Inspection Log	CSF-9-124	Tissue Department	Tissue Department	16 years

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, D5.100
- EBAA Medical Standards
- CAN/CSA-Z900.1: Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements, Canadian Standards Association
- CAN/CSA-Z900.2.4: Ocular Tissues for Transplantation
- CAN/CSA-Z900.2.2: Tissues for Transplantation
- Health Canada: Safety of Human Cells, Tissues & Organs for Transplantation Regulations,
- Squeglia, N. L. (2008). Zero Acceptance Number Sampling Plans, 5th Edition. ASQ Quality Press. References:

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Appendix 1: C=0 SAMPLING PLAN

C=0 Sampling Plan *Acceptable Quality Level (AQL)*																
LOT SIZE	**.010%**	**.015%**	**.025%**	**.040%**	**.065%**	**.10%**	**.15%**	**.25%**	**.40%**	**.65%**	**1.0%**	**1.5%**	**2.5%**	**4.0%**	**6.5%**	**10.0%**
1-8	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	5	3	2	2
9-15	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	13	8	5	3	2	2
16-25	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	20	13	8	5	3	3	2
26-50	*A*	*A*	*A*	*A*	*A*	*A*	*A*	*A*	32	20	13	8	5	5	5	2
51-90	*A*	*A*	*A*	*A*	*A*	*A*	80	50	32	20	13	8	7	6	5	4
91-150	*A*	*A*	*A*	*A*	*A*	125	80	50	32	20	13	12	11	7	6	5
151-280	*A*	*A*	*A*	*A*	200	125	80	50	32	20	20	19	13	10	7	6
281-500	*A*	*A*	*A*	315	200	125	80	50	48	47	29	21	16	11	9	7
501-1200	*A*	800	500	315	200	125	80	75	73	47	34	27	19	15	11	8
1201-3200	1250	800	500	315	200	125	120	116	73	53	42	35	23	18	13	9
3201-10,000	1250	800	500	315	200	192	189	116	86	68	50	38	29	22	15	9
10,001-35,000	1250	800	500	315	300	294	189	135	108	77	60	46	35	29	15	9
35,001-150,000	1250	800	500	490	476	294	218	170	123	96	74	56	40	29	15	9
150,001-500,000	1250	800	750	715	476	345	270	200	156	119	90	64	40	29	15	9
500,001 & Over	1250	1200	1112	715	556	435	303	244	189	143	102	64	40	29	15	9

A indicates entire lot must be inspected
Acceptance level in all cases is ZERO

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Exhibit 1: Critical Supply Receipt and Inspection Log

CSF-9-124

Trillium Gift of Life Network

Critical Supply Receipt and Inspection Log

Identification of Product	Receipt Log	Package Inspection	Item Inspection			Completion of Inspection
			N/A	YES		
Product Name: _____ Distributor/Manufacturer Name: _____	Date Received: _____ Initials of Receiver: _____ Placed directly into quarantine: ☐ Yes ☐ No Comments:	☐ Sealed/Intact ☐ Appropriate label ☐ Packing Material Quantity: _____ Lot #: _____ Expiry Date: _____ *(if applicable)* Comments:	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	Sealed Intact Appropriate labeling with expiration dates *(if applicable)* No color of physical changes to temperature sensitive solutions *(if applicable)* COA attached (*if applicable*) Comments:	Inspected by: _____ Date: _____
Product Name: _____ Distributor/Manufacturer Name: _____	Date Received: _____ Initials of Receiver: _____ Placed directly into quarantine: ☐ Yes ☐ No Comments:	☐ Sealed/Intact ☐ Appropriate label ☐ Packing Material Quantity: _____ Lot #: _____ Expiry Date: _____ *(if applicable)* Comments:	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	Sealed Intact Appropriate labeling with expiration dates (if applicable) No color of physical changes to temperature sensitive solutions (*if applicable*) COA attached (*if applicable*) Comments:	Inspected by: _____ Date: _____