



Clinical Process Instruction Manual

Environmental Monitoring at the Forensic Services and Coroner's Complex Process Instruction

Policy:

Tissue recovery is routinely practiced throughout the province in both hospital setting and at the Forensic Services and Coroner's Complex (FSCC) in Toronto. Hospitals are responsible for the design and maintenance of surgical suites in compliance with *Canadian Standards Association (CSA)* guidelines. The FSCC has designed and built a dedicated Tissue Recovery Suite (TRS) that meets the requirements of Health Canada (HC) and *American Association of Tissue Banks (AATB) Current Standards for Tissue Banking*. The TRS consists of the prep room, scrub room, and recovery room. The TRS was designed and set up to meet the requirements of the *Recovery Site Inspection Checklist* and air handling features including positive air pressurization and MERV 14 rated filters. This process instruction describes the validation methodology from an environmental monitoring perspective of the dedicated TRS for the purpose of tissue recovery.

Trillium Gift of Life Network (TGLN) has contracted an approved vendor to perform testing and analysis to ensure ongoing suitability of the FSCC for tissue recovery.

Although the TRS is not classified, TGLN adheres to the limits identified in this process instruction, which may be amended from time to time as required. TGLN works with the FSCC and tissue bank stakeholders if/when limits are exceeded or are of concern.

Process:

1. This process instruction describes the different types of testing and methodologies employed for monitoring the FSCC for tissue recovery.
2. Environmental monitoring shall be performed twice a year in the facility at rest, where "at rest" is defined as the absence of personnel and any activities immediately after routine cleaning has been performed.
3. Testing includes air and surface sampling for bacteria and fungi, and to retrieve airborne particulate counts. Sampling of bacteria and fungi was tailored to identifying viable bacteria and fungi of specific concern including *Staphylococcus aureus*, *Streptococcus pyogenes*, *Enterococcus* species, *Clostridium* species, gram negative bacilli, moulds and yeast.
4. Surface sampling will be conducted on specific areas of the TRS. These areas may be subject to change during separate environmental monitoring sessions, but will be determined by TGLN prior to each session.
5. Analyses for each type of testing is shared with applicable tissue bank stakeholders. A permanent record of environmental monitoring results shall be kept on file at TGLN head office.



Clinical Process Instruction Manual

Environmental Monitoring at the Forensic Services and Coroner's Complex Process Instruction

Particulate Counts

6. The particulate counter is factory calibrated to ISO 215-4 Calibration using NIST Traceable PSL Spheres, DMA and Condensation Particle Counter. A zero check is performed on site prior to use to ensure accuracy.
7. The device instantaneously counts particles between 0.3 to 10 microns in diameter and then calculates the concentrations of particulate at different size ranges, including particulates less than or equal to 10 microns in diameter and particulates less than or equal to 2.5 microns in diameter.
8. Measurements for airborne particulate are obtained throughout representative locations in the TRS.
9. Particulate counts are retrieved in 15 locations throughout the three areas of the TRS.

Air Sampling for Bacteria and Fungi

10. Air sampling for the determination of culture bacteria and fungi (yeasts and mould) is conducted using a multi-hole impactor. The impactor contains 400 precision drilled holes and is used in conjunction with petri plates containing specific agar media (depending on bacteria or fungi tested for) and a portable air sampling pump designed specifically to provide constant air flow.
11. Air sampling for bacteria and fungi are collected throughout the three areas of the TRS.
12. The samples and one set of blanks are submitted for identification of individual bacteria, yeast and mold.
13. Results are reported in colony forming units per cubic metre of air with bacteria, yeast and moulds identified to the species level where possible.

Settle Plate Sampling for Bacteria and Fungi

14. To evaluate the settling of bacteria and fungi on surfaces within the TRS, settle plates are placed on a specified number of representative horizontal surfaces.
15. The plates were left open for approximately one hour, then sealed for transport and delivered to the testing laboratory.
16. Results are reported as colony forming units per plate with bacteria and fungi identified to the species level where possible.



Clinical Process Instruction Manual

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Contact Plate Sampling for Bacteria and Fungi

- 17. Active microbial sampling by contact plate is utilized to monitor hard surfaces. Examples of these surfaces include sink countertops, a central area on the Operating Room (OR) table and a floor sample next to the OR table.
- 18. Results are reported as colony forming units per plate with bacteria and fungi identified to the species level where possible.

Surface Sampling

- 19. Swabs will be taken from a minimum of three identified areas of the TRS.
- 20. These areas will be finalized when the environmental monitoring is scheduled and will be determined by TGLN.

Evaluation of Results

- 21. Although the TRS is not classified, TGLN uses the maximum number of particles per meter squared for the basic environmental standards for the manufacture of sterile products listed in Appendix 1: *Particulate Counts* and Appendix 2: *Limits for Microbial Contamination*.
- 22. Although the TRS is are not classified, particulate counts are expected to remain between that of the class 10 000 and class 100 000 environments (making note that sterile packaging is opened in that area).
- 23. The limits for microbial contamination using different types of environmental monitoring techniques are listed in Appendix 2 and are expected to remain between a Health Canada Grade B and C.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Air Quality Assessment Report	-----		Tissue Department	16 years

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. J4.300 and K1.100.



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Appendix 1: Particulate Counts

Area	US/English Class	Health Canada Grade	ISO	Particles 0.5µm	Particles 5.0µm
TRS/Scrub Room	10 000	Grade B (operational) Grade C (at rest)	7	350 000	2000
TRS/Scrub Room	100 000	Grade C (operational) Grade D (at rest)	8	3 500 000	20 000



Clinical Process Instruction Manual

Environmental Monitoring at the Forensic Services and Coroner's Complex Process Instruction

Appendix 2: Limits for Microbial Contamination

Limits for Microbial Contamination			
Health Grade	Canada	Air Sample (cfu/m ³)	Settle Plates (cfu/4 hours)
B		10	5
C		100	50
D		200	100