



## Clinical Process Instruction Manual

### Microbiology and Cultures Testing Process Instruction

#### Policy:

Identification and treatment of donor infectious diseases minimizes the risk of adverse transplantation outcomes, such as transmission of infectious diseases and/or graft dysfunction or failure in the recipient. Ontario Health (Trillium Gift of Life Network (TGLN)) facilitates the testing of organ or combined organ and tissue donors, while the appropriate tissue bank(s) currently facilitate the testing of tissue-only donors. Culture and sensitivity (C&S) testing of blood is required of all organ donors. C&S testing of sputum and a bronchial alveolar lavage (BAL) is mandatory for all lung donors. If a sputum sample cannot be obtained, a BAL specimen for C&S is sufficient to meet the requirement for lung donors. C&S testing of urine is mandatory for all abdominal organ donors. See *Organ and Composite Tissue Specific Data Collection Process Instruction, CPI-9-215*. All positive cultures and their sensitivities, preliminary and final, are reported to the transplant program(s), physician(s) and/or tissue banks involved. Every TGLN donor chart is to include completed (final) culture results.

In accordance to the *Health Canada: Safety of Human Cells, Tissues and Organs for Transplantation Regulations, (SOR/2007-118)*, all testing requisitioned by TGLN will be performed by a laboratory that complies with current federal regulatory requirements as outlined in the national standards. The results of all testing will be documented in the donor chart. In the case of donations originating in Ontario, the laboratory affiliated with the referring hospital normally performs required microbiology testing, with the exception of BAL testing which is performed by an approved laboratory. Where offers of organs and/or tissues are made to Ontario from another province or country, TGLN will accept the results provided by the offering program with the understanding that the offering program is reporting results from a laboratory that meets its requirements for testing.

For the purposes of this document, the TGLN coordinator may be the Specialist, Organ and Tissue Donation Coordinator (S-OTD), Hospital Development Coordinator (HDC), Clinical Responders (CR), Clinical Services Coordinator (CSC) or Tissue Coordinator (TC) and/or Information Coordinator (IC).

#### Process:

##### Collecting Cultures:

1. The S-OTD reviews the patient's hospital record to identify any previous culture results from the current admission and documents the previous positive results with sensitivities and treatment in the donor chart. When an S-OTD is not on-site, an assigned S-OTD will provide remote phone support and collaborate with the health care providers (HCPs) to obtain the required information on previous positive culture results. When an S-OTD is not available to provide remote phone support, a CSC will obtain the above information.

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2. The S-OTD confirms if a set of cultures (blood, urine and sputum) have been drawn within the past 24 hours of obtaining consent. If a set of cultures have been drawn, the S-OTD will enter the source type and date-time collected on the “Culture Results” section of the donor chart.
3. If a set of cultures has not been drawn within the past 24 hours of obtaining consent, the S-OTD requests a new set of cultures be sent. The S-OTD facilitates the collection of the required specimens in conjunction with the HCPs. When an S-OTD is not on-site, an assigned S-OTD will provide remote phone support and collaborate with the HCPs to ensure the correct specimens are collected. The S-OTD will then assign a culture task to “Culture Assignment” with a due date of three (3) days after the date drawn with a subject of “Specimen Culture Reporting” and “Preliminary Culture Follow-up”.
4. Additional cultures may be drawn prior to the organ recovery in the following instances:
  - 4.1. If the following clinical indicators are present, it may warrant discussing repeating cultures with the Most Responsible Physician (MRP):
    - worsening shock/increasing vasopressor requirement
    - fever and/or increasing WBC with band forms/left shift (some increase in WBC with neutrophilia may be expected if methylprednisone is administered)
    - new change in chest x-ray or evolving infiltrates
    - new or worsening purulent sputum/tracheal secretions
  - 4.2. Upon request of a transplant program
  - 4.3. Upon request of a Transplant Support Physician – Infectious Disease
  - 4.4. If preliminary culture results are positive
5. If a specimen for culture cannot be obtained prior to organ recovery, the S-OTD documents in the donor chart the reason and informs the CSC. The CSC informs accepting transplant programs and applies EXD to the organ(s) offer as applicable.
6. Specimens obtained by HCP’s at the hospital are sent to the hospital microbiology lab for processing, using hospital requisition forms and labels. This includes BAL specimens obtained by HCP’s during routine bronchoscopy for lung evaluation.
7. When a bronchoscopy is arranged for potential lung donors in the recovery OR, and a BAL specimen is obtained, it is sent for culture and sensitivity (C&S) and gram stain to an approved laboratory. The TGLN Surgical Recovery Coordinator (SRC) or designate is responsible for ensuring the BAL specimen is collected in the OR, labeled and delivered with a completed requisition to the Microbiology lab at the Toronto General Hospital (TGH). Requisitions are found in the lung recovery bag.

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8. The SRC ensures the specimen and corresponding requisition are labeled with the correct TGLN # (as verified with donor identification information), the date of birth, and date and time sample obtained, when being sent to an approved laboratory. DO NOT include the donor name on samples sent to an approved laboratory. Each label is initialed to indicate that validation of the donor's identification and verification with the assigned TGLN # has been made.
9. The CSC documents the date and time each recovery culture specimen was obtained in the TGLN donor chart.

#### Obtaining Results:

10. Follow-up on culture results is the responsibility of the S-OTD, CR and HDC for Ontario donors. For out-of-province (OOP) donors, follow-up on culture results is the responsibility of the CSC.
  - 10.1. The S-OTD and HDC reviews the Task list to identify outstanding culture tasks assigned from their hospital(s).
  - 10.2. For tasks due on a weekday, the S-OTD and HDC are responsible for following up and obtaining culture results from their hospital(s). If the primary S-OTD is unavailable, their S-OTD partner (if any) or HDC are to follow up.
  - 10.3. For tasks due on a weekend or holiday, the CR or delegate is responsible for following up on all outstanding culture tasks.
11. To obtain preliminary blood, urine and sputum results, the TGLN coordinator contacts the appropriate department within the hospital as outlined in the Hospital Profile or OOP organ procurement organization (OPO), three (3) days after the culture specimen was drawn. Note: Sputum results and/or BAL results are only mandatory if lungs are retrieved.
12. The TGLN coordinator who obtained the preliminary culture results will update the "Culture Results" section in the donor chart by indicating on the '24 or 48 hr Result' section either "Positive – See report" if the result is positive, or "Negative – See report" if the result is negative. The TGLN coordinator will also upload a copy of the culture report to the corresponding entry on the "Culture Results" section in the donor chart.
13. Once the preliminary cultures have been obtained and entered into the donor chart, if obtained by the S-OTD, HDC or CR, they will notify the PRC by sending an email to #OH-TGLN\_csc@ontariohealth.ca. If there are positive culture results, the S-OTD, HDC or CR will include "POSITIVE CULTURES" in the email subject line.

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14. After the preliminary culture has been entered, the TGLN Coordinator will edit the task by adding two (2) days to the “Due Date-Time” and change the subject from “Preliminary Culture Follow-up” to “Final Culture Follow-up”.
15. To obtain final culture results, repeat the same process above for preliminary cultures. To obtain final blood, urine, and sputum results, TGLN coordinator contacts the appropriate department within the hospital as outlined in the Hospital Profile, or OOP OPO, five (5) days after the culture specimen was drawn.
16. Once final culture results are obtained and entered into the donor chart or if a case is declined for both organ and tissue, the task can be closed.
17. All final culture results, both positive and negative, are recorded in the TGLN donor chart. The TGLN coordinator ensures that a copy of all final culture reports are uploaded to the donor chart.
18. Follow-up on culture results is also required for combined organ and tissue cases where tissues were recovered.
  - 18.1. For organ and tissue cases where organs and tissues were recovered, the CSC will notify the Tissue Team Lead that results were obtained and need to be reported to the tissue banks.
  - 18.2. For organ and tissue cases where organs were declined and tissues were recovered, the IC will ask the S-OTD to follow-up on the culture results. For hospitals without a designated S-OTD, the IC will follow-up directly with the hospital lab.
  - 18.3. In cases where separate blood cultures were drawn for tissue purposes and not sent to the hospital lab, the tissue bank will alert the CSC that a positive culture has been obtained and has been uploaded to the donor chart. The CSC is responsible for reporting the results to the recipient transplant programs. Steps 22-28 are followed.
  - 18.4. The TGLN coordinator will document in the clinical notes any efforts to obtain cultures when attempt does not result in culture being entered and uploaded
19. In the event the donor management system is not available for an extended period of time, cultures will be tracked by the TGLN coordinator using a manual method.
20. If the TGLN coordinator learns that culture results are not available for an Ontario donor (i.e., lab lost culture specimens for processing, HCP did not collect samples), the TGLN coordinator informs the Manager of Hospital Programs and the TGLN Quality Director. The CSC also informs accepting transplant programs that culture results are not available.

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21. The Manager of Hospital Programs follows-up with the lab and/or S-OTD as appropriate to determine why culture results are not available. The Manager of Hospital Programs will review the case with the Quality Director and next steps will be determined.

#### Reporting results:

22. The Quality Clinical Services Senior Specialist, CSC or designate removes all identifying patient information prior to sending culture reports to transplant programs. For OPOs the culture reports do not need to be redacted. The appropriate culture fax cover sheet is completed, including
- TGLN #,
  - the recipient TGLN #,
  - CTR#, if applicable,
  - the recipient name, if known,
  - organ(s) transplanted
23. Prior to organ recovery the CSC or designate is responsible for reporting all positive cultures and may report negative cultures
24. In the event that a positive blood culture result is obtained prior to transplantation, the CSC will offer the organs out under exceptional distribution (EXD) in accordance with *Exceptional Distribution Process Instruction, CPI-9-217*. In the event that an unexpected positive blood culture is obtained post-transplantation which was not previously exceptionally distributed, the Quality Clinical Services Specialist, CSC or designate will report this as an accident in accordance with *Error/Accident Process Instruction, CPI-9-804*.
25. Reporting of culture results post organ recovery is shared between the Quality Clinical Services Senior Specialist or designate and the CSC.
26. The Quality Clinical Services Senior Specialist, CSC or designate will send a copy of all positive culture reports to all recipient transplant programs and out-of-province OPO that received organs from the donor in question. Negative culture results may also be reported. The Quality Clinical Services Senior Specialist, CSC or designate documents the date the cultures were sent in the donor chart.
27. The TC is responsible for sending culture reports to tissue banks. The culture reports do not need to be redacted. The appropriate culture fax cover sheet is completed, including:
- TGLN #,



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- tissue(s) recovered
28. The Quality Clinical Services Senior Specialist, CSC or designate may confirm with recipient transplant programs and OPOs that positive culture results were received.
  29. For tissue banks, positive culture reports do not need to be verbally reported by the TC.
  30. All confirmation of faxes (or equivalent) for culture reporting should be attached to the donor chart.

#### Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Chart	—	PRC	PRC	16 years

#### References:

- *Donor Assessment Process Instruction, CPI-9-208*
- *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*
- *Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213*
- *Organ and Composite Tissue Specific Data Collection Process Instruction, CPI-9-215*
- *Exceptional Distribution Process Instruction, CPI-9-217*
- *Error/Accident Process Instruction, CPI-9-804*
- Hospital Profiles on the Online Resource Centre
- Health Canada: Safety of Human Cells, Tissues and Organs for Transplantation Regulations, (SOR/2007-118)
- CAN/CSA-Z900.1 –22: Cells, Tissues, and Organs for Transplantation: General Requirements, Canadian Standards Association, 2022