

Clinical Process Instruction Manual

Reporting of Positive Laboratory Results and Determination of Donor Unsuitability Process Instruction

Policy:

Decisions regarding donor suitability post-tissue recovery and final disposition of tissues are based on the results of screening tests (serology, NAT and microbiology). Relevant records of positive laboratory results from a shared donor that could affect suitability determinations must be shared amongst all parties involved: referral agency, tissue bank(s), and recovery agencies. If there is a determination that a particular donor's tissue is unsuitable for transplantation for any reason (regardless of positive serology/NAT), information must be shared to other establishments that were involved with the donor, including the referral agency, the tissue bank and the recovery agency. Positive results that must be shared include but are not limited to:

- all transmissible disease tests (i.e. serology and NAT),
- ante-mortem and post-mortem blood cultures (pathogenic and non-pathogenic),
- tissue recovery cultures (pathogenic and non-pathogenic),
- tissue processing cultures (pathogenic and non-pathogenic),
- hematology performed on cadaveric donors for the purpose of determining donor suitability,
- any and all pathology reports,
- autopsy results,
- medical records from other organizations involved in the donor care outside of hospital

Identification of reportable diseases and the organization(s) responsible for reporting reportable diseases to Public Health is outlined in the *Health Protection and Promotion Act*, R.S.O. 1990, c. H.7. The applicable Public Health department determines notification and follow up of positive laboratory results for reportable diseases with the next of kin (NOK)/confidential partner. Under the Act, Trillium Gift of Life Network (TGLN) is not responsible for reporting positive reportable disease(s) results to Public Health for tissue exclusive donors, however TGLN does act as a resource to Public Health and may be contacted to facilitate sharing of pertinent information as per *Reportable Diseases Process Instruction, CPI-9-604*.

Notification of TGLN and tissue bank tissue recovery personnel is required if a donor has tested positive for infectious disease(s). This transfer of information is intended to ensure that appropriate precautions were taken prior to and during tissue recovery and to ensure that any appropriate follow up deemed necessary for recovery personnel is undertaken.

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All communications and actions taken regarding positive laboratory testing results shall be documented in the clinical notes.

This process instruction applies to Tissue Coordinators (TC), Clinical Service Coordinators (CSC) and Referral Triage Coordinators (RTC). CSCs and RTCs are responsible for notifying and transferring phone calls, related verbal reports of a positive result, to a TC for follow up.

Individual tissue bank Medical Directors shall determine how to handle discordant and positive test results.

Process:

1. This process instruction describes the procedures for receiving, investigating, evaluating and documenting information related to reports of positive laboratory findings that may impact donor suitability.

Reporting Positive Serology/NAT Results

2. Preliminary results of positive test results (verbal or documented), including screening test results and any confirmatory test results, shall be shared with all establishments who are known to have recovered or received tissues from the same donor.
3. The tissue bank provides immediate verbal notification to a TC in the Provincial Resource Centre (PRC) of all positive test results (i.e., serology/NAT) on the same business day as the test result is received.
4. The tissue bank requests the following information from the TC: the name(s) of the tissue bank(s) that received tissue from the donor.
5. The tissue bank is responsible for verbally notifying the tissue banks and recovery agencies involved with the shared donor within the same business day.
6. The tissue bank that received the positive serology/NAT results is responsible for faxing the positive results to the affected agencies within one business day of the initial verbal notification.

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7. The tissue bank that received the positive serology/NAT results is responsible for notifying the other tissue banks, recovery agency (TGLN) of a positive serology/NAT result without delay and on the same business day as verbal notification is received. The positive serology/NAT results shall be uploaded to the donor chart by the TC or the tissue bank if they have access to the electronic donor chart.
8. Positive results are faxed to all tissue bank(s) and recovery agencies involved on the same business day of receipt.
9. The TC is responsible for notifying all tissue/ocular recovery personnel involved with the recovery of the donor that had positive serology/NAT results. The notification to the recovery staff must be documented in the clinical notes.
10. For combined organ-tissue donors, the TC shall notify a CSC of the positive results.

Determination of Donor Unsuitability

11. When a tissue bank has concluded that a recovered donor is unsuitable, this information must be shared in writing with all establishments that are known to have recovered tissues or have received recovered tissue from the donor. This includes the referral agency, other tissue banks and recovery agencies.
12. The tissue bank provides immediate verbal notification (on the same business day) to the TGLN TC and requests the following information:
 - tissue bank(s) that received tissue on the same donor, and
 - recovery agency that recovered tissue on their behalf (if applicable).
13. The tissue bank provides written notice, by the preferred contact method (email or fax), within one business day of the decision to each relevant organization, as outlined in step 11 above, identifying the finding and the rationale for why the tissue was deemed unsuitable.
14. The TC documents all communication with the tissue banks including date, time and name of each individual and organization in the clinical notes. The written notice that deems the donor unsuitable must be uploaded to the donor chart upon receipt.
15. If this tissue donor is a combined organ donor, the TC must notify a CSC of the tissue bank's determination of donor unsuitability.

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16. Any positive result from a tissue test performed after decontamination/disinfection or processing (in-process or post-process microbiological testing, final cultures or graft suitability testing) is not considered to be a relevant donor record for the recovery agency and does not need to be shared with tissue banks or organ procurement organizations (OPO) who received organs or other tissues from the same donor.

Records:

- No records

References:

- Health Protection and Promotion Act, RSO 1990, c H.7.
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.232.
- Safety of Human Cells, Tissues and Organs for Transplantation Regulations S. 2004, c. 23, s. 2.
- *Reportable Diseases Process Instruction, CPI-9-604.*