Clinical Process Instruction Manual

Infectious Disease Testing – STAT Process Instruction

Policy:

In order to evaluate safety of organs for transplantation, Ontario Health (Trillium Gift of Life Network (TGLN)) facilitates infectious disease testing for potential donors using licensed Health Canada test kits (if required). STAT testing is required for: Human Immunodeficiency Virus I/II (HIV I/II), Human T-cell Lymphotrophic Virus (HTLV I/II), Syphilis , Hepatitis B surface Antigen (HbsAg), Hepatitis C Virus (HCV), antibody to Hepatitis B core Antigen (anti-HbcAb), and Cytomegalovirus (CMV). West Nile Virus (WNV) is a Health Canada recommended test, and is routinely tested as part of STAT serology between May 1st and October 31st and on donors who travelled in the preceding 56 days to areas where WNV is endemic. Exceptional distribution is applied prior to distribution of organs when hard copy documentation of the required serology results are not available prior to the distribution of organs as per *Exceptional Distribution Process Instruction*, *CPI-9-217*. Additionally, positive results do not automatically preclude donations, as exceptional distribution may be considered as per *Exceptional Distribution Process Instruction*, *CPI-9-217*. Absent, or not properly been conducted WNV testing is not subject to exceptional distribution.

If the potential donor is assessed as being an increased risk donor as per the criteria listed in *Exceptional Distribution Process Instruction*, *CPI-9-217*, Nucleic Acid Testing (NAT) may be performed. If there is a request for NAT from a donor not defined as increased risk, a discussion may occur between the requesting physician and TGLN's Transplant Chief Medical Officer (CMO) and/or Transplant Support Physician (TSP).

In addition to STAT serology listed above, potential donors will be screened and tested for Coronavirus Disease (COVID-19) as per *CSF-9-235 Emerging Infectious Disease Screening Tool (COVID-19)* and *CSF-9-236 First Person Emerging Infectious Disease Screening Tool (COVID-19)*. This process involves having STAT viral polymerase chain reaction (PCR) testing completed on samples taken from the upper respiratory tract (nasopharyngeyal swab (NPS)) and the lower respiratory tract (Endotracheal Tube (ETT) and/or bronchoalveolar lavage (BAL)).

Undiluted blood specimens are obtained for testing. See *Hemodilution Calculation Process Instruction, CPI-9-210*.

The packaging of blood specimens for transport, and the mode of transportation selected, will comply with the *Packaging and Offering for Transport: Blood Specimens Process Instruction, CPI-9-222*.

For the purposes of this document, the TGLN coordinator may be the Organ and Tissue Donation Coordinator (OTDC), Clinical Responder (CR), Surgical Recovery Coordinator (SRC), Clinical Services Coordinator (CSC) and/or Referral Triage Coordinator (RTC). Any TGLN coordinator that is responsible for packaging and offering blood specimens for transport must be trained and certified in the transport of dangerous goods by TGLN.

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Process:

Collection of Blood Specimens for Testing

1. The TGLN coordinator responsible for packaging the blood will identify and classify the specimen as per the *Packaging and Offering for Transport: Blood Specimens Process Instruction, CPI-9-222.* Any specimens classified outside of the TGLN coordinator's role specific certification will not be offered for shipment.

2. The TGLN coordinator ensures consent for donation has been obtained before blood specimens for serology testing are drawn or sent to the lab for testing. The appropriate coordinator validates the donor's identification information on relevant documentation and verifies it with the assigned TGLN donor number.

3. If an OTDC/CR is on-site at the hospital, s/he may facilitate the collection of the required specimens in conjunction with hospital staff. If an OTDC/CR is unavailable, the CSC collaborates with hospital staff by telephone to ensure the correct specimens are collected and sent to the appropriate location. See the *Laboratory Profiles* on the *Online Resource Centre* (*ORC*).

4. Archival and non-STAT serology specimens should be collected concurrently.

5. The TGLN coordinator facilitating the sampling of blood labels, all blood samples collected with the assigned TGLN number, the donor's date of birth (DOB), and the date and time sample was drawn. All blood samples collected should also have a corresponding hemodilution calculation completed and documented in the donor chart. Each label is initialed to indicate that the TGLN donor number has been verified and that validation with the donor's identification has been made.

6. The TGLN coordinator obtaining the blood samples fully completes the *Laboratory Services Requisition: STAT/Non-STAT Infectious Disease Testing of Organ Donors, CSF-9-20.* See Exhibit 1. The TGLN coordinator sends a copy with the samples to the appropriate labs and files a copy into the TGLN donor's chart.

7. The TGLN coordinator ensures that the following required STAT infectious disease tests are completed within 7 days prior to donation for all donors.
   - Syphilis (T. Pallidum or equivalent test)
   - Anti-HTLV I/II (antibody to human T-cell lymphotrophic virus)
   - Anti-HIV I/II (antibody to human immunodeficiency virus)
   - HbsAg (hepatitis B surface antigen)

- HbcAb (antibody to hepatitis B core antigen)
- Anti-HCV (antibody to hepatitis C virus)
- Anti-CMV (antibody to cytomegalovirus)

If NAT is required, the TGLN coordinator clearly indicates NAT on the requisition form and draws any additional blood tubes required for testing. Individual NAT can be done for HCV, HBV, and HIV.

8. The TGLN coordinator ensures that the following recommended STAT infectious disease test is completed within 7 days prior to donation for all donors.
   - PCR-WNV (Polymerase chain reaction (nucleic acid test)) for West Nile Virus antigen from May 1st to October 31st only, and on donors who travelled in the preceding 56 days to areas where WNV is endemic.

Pediatric Donors

9. For pediatric donors, both the donor and birth mother shall be tested if the donor is:
   - ≤ 18 months old
   - on any child less than 5 years of age who was breastfed within the last 12 months

   However, the following exceptions apply:
   - For donors ≤ 28 days old and have no obvious potential exposure to a blood-borne pathogen after birth, only birth mother STAT serology testing is required (including NAT testing).
   - For donors ≥ 29 days old, birth mother stat serology is not required if the donor has had NAT testing performed.

COVID 19 Testing

10. All donors will have viral PCR testing for COVID-19 completed as per *CSF-9-235 Emerging Infectious Disease Screening Tool (COVID-19)* or *CSF-9-236 First Person Emerging Infectious Disease Screening Tool (COVID-19)*.

11. Testing for COVID-19 will be arranged by the OTDC/CR and should be completed at Mount Sinai Hospital Microbiology Lab. Testing can be done at the local hospital lab as an alternative.

12. All COVID 19 test results should be documented in iTransplant and reported to transplant programs when results become available.

13. The Transplant Support Physician – Infectious Disease (TSP-ID) should be consulted as per *CPI 9-218 Deceased Donor Exclusion Criteria and Suitability Screening* to review any indeterminate or invalid COVID-19 results.

14. The TSP-ID should be consulted prior to moving forward if the recommended testing indicated in *CSF-9-235 Emerging Infectious Disease Screening Tool (COVID-19)* or *CSF-9-236 First Person Emerging Infectious Disease Screening Tool (COVID-19)* is not available prior to recovery.

15. For potential donors where lungs are accepted and there is no ETT or BAL COVID PCR test result available within 72 hours of recovery, a BAL sample will be collected in the donor operating room (OR). The sample will be sent to Mount Sinai Hospital Microbiology Lab. The TGLN coordinator will advise the lab that Rapid testing is required and the expected time that the sample will be dropped off, as per Exhibit 2 *TGLN Rapid COVID BAL Testing Process.*

Transporting Blood Samples for Testing

16. The TGLN coordinator involved in obtaining the blood samples coordinates the transportation and timely delivery of blood specimens to the appropriate laboratory and/or to the PRC, if applicable.

17. The TGLN coordinator ensures that the specimens are packaged, labelled and offered for transport as per the *Packaging and Offering for Transport: Blood Specimens Process Instruction, CPI-9-222.*

18. The TGLN coordinator contacts the appropriate lab to advise that the samples are to arrive. See *Laboratory Profiles* on the ORC. If STAT NAT testing is required, this can be tested at Mount Sinai Hospital Microbiology Lab 24/7. The TGLN coordinator will advise the technician that NAT is required.

19. The TGLN coordinator may document one or more of the following in the clinical notes:
    - time technician was notified
    - name of the technician who received the sample at serology lab
    - time specimen was received

Obtaining and verifying serology results

20. For Ontario Donor Cases, the Ontario serology lab(s) will enter donor serology results into the donor management system and notify the PRC that the results are available.

21. For out of province (OOP) cases, the CSC/RTC reviews the OOP donor serology results provided by the source organ procurement organization (OPO) and verifies that, at minimum, the source

OPO identification (ID) number matches the OPO ID number recorded in the TGLN donor management system. The serology results are transcribed by the RTC/CSC into the donor management system.

22. The RTC/CSC completes the independent double check process as described in CPI-9-220 Independent Double Check and Electronic Sign-off.

23. The CSC determines whether exceptional distribution circumstances exist, as per *Exceptional Distribution Process Instruction, CPI-9-217.*

24. Ontario donor serology results will be transmitted from the TGLN donor management system to the TGLN organ allocation and transplant system following the independent double check process as per CPI-9-220 Independent Double Check and Electronic Sign-off.

25. If the serology results were not entered directly by an Ontario serology lab (e.g., OOP donor serology entered by the CSC/RTC), the serology reports are uploaded to the TGLN donor chart. If a hard copy is not available prior to the distribution of organs, verbal results may be considered in accordance with Exceptional Distribution provisions, as per *Exceptional Distribution Process Instruction, CPI-9-217*.

26. The CSC will upload the redacted source OPO serology report to the Organ Allocation and Transplant System.

West Nile Virus Testing

27. In the event that a WNV test result is reported as indeterminate by an Ontario laboratory, the CSC must review the details of the indeterminate result with the TSP-ID. If the decision is made to offer out the organs, the CSC includes in the organ offer the details and rationale for offering in the context of the indeterminate WNV result that was given by the TSP-ID.

28. In the event that a WNV test result is reported as positive by an Ontario laboratory, the CSC discusses the result with the TSP-ID prior to closing the case.

Reporting STAT Serology Results

29. The CSC reports all positive and negative serology results, once available, to all relevant OPOs, transplant programs and tissue banks. The CSC documents the reporting of results in the clinical notes.

30. In certain circumstances where confirmation of these results will be conducted by Public Health Ontario Laboratory (PHOL), TGLN should inform the physician of record of the preliminary result. Refer to *Reportable Diseases Process Instruction, CPI-9-711.*

31. In the event that testing indicates that a donor is medically unsuitable for donation, the TGLN coordinator communicates this to the next-of-kin. See *Next of Kin Reporting for Medical Unsuitability Process Instruction, CPI-9-710.*

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Laboratory Services Requisition: STAT/Non-STAT Infectious Disease Testing of Organ Donors	CSF-9-20	PRC	PRC	16 years
Donor Record	————————	PRC	PRC	16 years

References:

- *Discussing Donation Opportunities and Obtaining Consent Process Instruction, CPI-9-204*
- *Donor Medical and Social History – Organ or Combined Organ & Tissue Process Instruction, CPI - 9-207*
- *Hemodilution Calculation Process Instruction, CPI-9-210*
- *Reporting Positive Communicable Disease Testing Results, CPI-9-212*
- *Independent Double Check and Electronic Sign-off – ABO and Serology Process, CPI-9-220*
- *Packaging and Offering for Transport: Blood Specimens Process Instruction, CPI-9-222*
- *Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213*
- *Exceptional Distribution Process Instruction, CPI-9-217*
- *Deceased Donor Exclusion Criteria and Suitability Screening, CPI-9-218*
- *Next of Kin Reporting for Medical Unsuitability Process Instruction, CPI-9-710*
- *Emerging Infectious Disease Screening Tool (COVID-19), CSF 9-235*

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- *First Person Emerging Infectious Disease Screening Tool (COVID-19), CSF-9-236*
- *Health Protection and Promotion Act (Ontario), Ontario Regulation 559/9, conditions requiring notification of the local Medical Officer of Health*, available at: **http://www.e-laws.gov.on.ca**
- *Health Canada: Safety of Human Cells, Tissues and Organs for Transplantation Regulations, (SOR/2007-118)*
- CAN/CSA-Z900. 1-17: Cells, tissues, and Organs for Transplantation: General Requirements, Canadian Standards Association, 2022.

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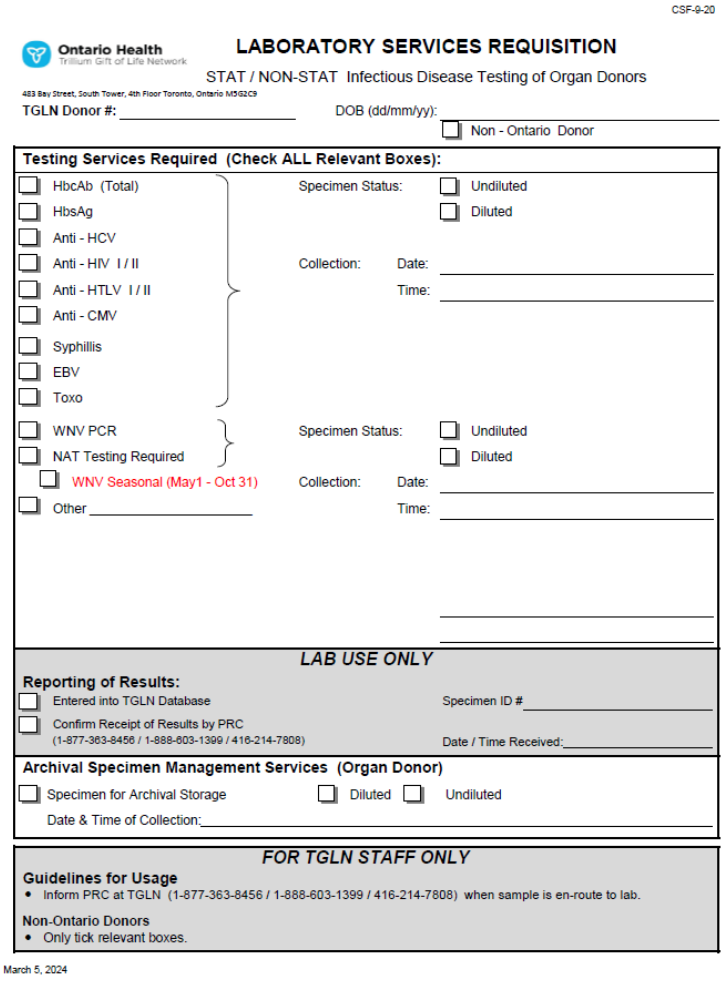
Exhibit 1: Laboratory Services Requisition: STAT/NON-STAT Infectious Disease Testing of Organ Donors



CSF-9-20

Ontario Health
Trillium Gift of Life Network

LABORATORY SERVICES REQUISITION

STAT / NON-STAT Infectious Disease Testing of Organ Donors

483 Bay Street, South Tower, 4th Floor Toronto, Ontario M5G2C9

TGLN Donor #: _____ DOB (dd/mm/yy): _____

☐ Non - Ontario Donor

Testing Services Required (Check ALL Relevant Boxes):

☐ HbcAb (Total)
☐ HbsAg
☐ Anti - HCV
☐ Anti - HIV I / II
☐ Anti - HTLV I / II
☐ Anti - CMV
☐ Syphillis
☐ EBV
☐ Toxo

Specimen Status: ☐ Undiluted ☐ Diluted
Collection: Date: _____ Time: _____

☐ WNV PCR
☐ NAT Testing Required
☐ WNV Seasonal (May1 - Oct 31)
☐ Other _____

Specimen Status: ☐ Undiluted ☐ Diluted
Collection: Date: _____ Time: _____

LAB USE ONLY

Reporting of Results:

☐ Entered into TGLN Database
☐ Confirm Receipt of Results by PRC (1-877-363-8456 / 1-888-603-1399 / 416-214-7808)

Specimen ID # _____
Date / Time Received: _____

Archival Specimen Management Services (Organ Donor)

☐ Specimen for Archival Storage ☐ Diluted ☐ Undiluted
Date & Time of Collection: _____

FOR TGLN STAFF ONLY

Guidelines for Usage
- Inform PRC at TGLN (1-877-363-8456 / 1-888-603-1399 / 416-214-7808) when sample is en-route to lab.

Non-Ontario Donors
- Only tick relevant boxes.

March 5, 2024

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Exhibit 2: TGLN Rapid COVID BAL Testing Process

Background: TGH and Mount Sinai hospital laboratory have arranged faster processing of COVID BAL samples on ***lung donors*** where no ETT or BAL COVID PCR test result is available within 72 hours of lung recovery. This process will involve collecting a BAL sample during the donor OR and testing the sample immediately after recovery using the **Luminex Aries** platform. Faster testing is required on these cases, as lung transplant will be delayed until a negative result is received.

*** Use for donors where lungs are accepted for transplant **and** no ETT or BAL COVID test is completed within 72 hours of recovery (examples: US lung offers without a Viral PCR ETT or BAL result within 72 hours of recovery, MAID donors) ***

Notification and Requisition:

- CSC to fill out a COVID sample requisition and identify on the requisition that Luminex Aries Platform is required.
- CSC to send COVID requisition to SRC and document sample requirement on the CSC to SRC reporting form.

Collection and Delivery:

- SRC to ensure an extra BAL sample is collected during the donor OR for COVID testing
- For US donors with local recovery and no SRC present where there is no Viral PCR ETT or BAL result within 72 hours of recovery, the CSC will request the US program collect a BAL sample and send it in the lung cooler to be intercepted by the SRC.
- SRC to label BAL sample and complete COVID requisition.
- SRC to attach a 'Stat' sticker to the sample bag
- SRC to deliver the sample bag directly to Mount Sinai Hospital Microbiology Lab 14th floor. (Do not leave with security at hospital entrance as this may cause a delay in processing)
- CSC to notify lab tech when sample is delivered and request stat processing using Luminex Aries Platform.
- Once results are available, CSC to notify MOTC immediately so that transplant can proceed.