Clinical Process Instruction Manual

Infectious Disease Testing – Non-STAT Process Instruction

Policy:

Retrospective (non-STAT) testing for Epstein Barr virus (EBV) is required of all solid organ donors. Retrospective Toxoplasmosis IgG (Toxo) testing of all heart donors is also required unless the heart is deemed unsuitable for transplant after recovery using licensed Health Canada test kits. If the donor is 18 months old or less, or any child less than 5 years of age who has been breast-fed in the past 12 months, a maternal blood sample must also be tested for EBV, and for Toxoplasmosis when applicable.

Test results are documented in the Trillium Gift of Life Network (TGLN) donor chart, and reported to the appropriate transplant program(s) as described below.

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 a Specialist - Organ and Tissue Donation (S-OTD), Clinical Responder (CR), Surgical Recovery Coordinator (SRC), and/or Clinical Services Coordinator (CSC). Any TGLN coordinator that is responsible for packaging and offering blood samples for transport must be certified in the transportation of dangerous goods by TGLN.

Process:

The following instruction pertains only to cases involving organ donation or combined organ and tissue donation. For cases involving tissue-only donation, all infectious disease testing is facilitated by the appropriate tissue bank(s).

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 specimen classified outside of the TGLN coordinator's role specific certification will not be offered for shipment.

2. The TGLN coordinator or designate will obtain undiluted blood specimens for non-STAT testing. See *Hemodilution Calculation Process Instruction, CPI-9-210.*

   2.1. Anti-EBV donor testing is done on all donors.

   2.2. Toxo testing is done for any donor where the heart is recovered and transplanted.

3. Non-STAT serology specimens for EBV and Toxo should be collected concurrently with archival and STAT serology specimens. If they are drawn at a later time, a separate hemodilution calculation will need to be performed. See *Hemodilution Calculation Process Instruction, CPI-9-210*.

4. **Pediatric Donors** - For pediatric donors, maternal specimens are also required for non-STAT serology testing if the potential pediatric donor is ≤ 18 months of age, or on any child less than 5 years of age who was breast-fed within the last 12 months, with the following exceptions:

   4.1. 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).

   4.2. For donors ≥ 29 days old, birth mother stat serology is not required if the donor has had NAT testing performed.

5. The SRC or designate is responsible for ensuring the correct specimens have been collected prior to, or during the organ recovery. If specimen collection done concurrently with STAT serology testing specimens is inadequate, the SRC or designate must ensure that additional specimens are collected in order to facilitate the required non-STAT serology testing.

6. The TGLN coordinator or designate will ensure that all blood samples collected are labeled with the assigned TGLN donor number (TGLN #), the donor's date of birth (DOB), and the date and time sample was drawn. Each label is initialed to indicate that the TGLN # has been verified with the donor's identification.

7. The TGLN coordinator or designate completes the *Laboratory Services Requisition* to facilitate the non-STAT serology testing. The completed requisition includes the TGLN #, the donor's DOB, the donor's sex, identification of the specific test(s) required, and instructions for reporting results to the Provincial Resource Centre (PRC). A copy of the completed requisition is placed in the TGLN donor chart. For Toxo testing at Mt. Sinai Hospital only, if there is a new donor sample (i.e., an out-of-province donor sample) or a need to add Toxo testing to a donor sample already at the lab, the TGLN coordinator must complete the *Laboratory Services Requisition* and attach it to the email sent to Microbiology.SpecialQueries@sinaihealth.ca. The subject of the email should be "Toxo testing required for Donor: ######" and the body of the email should include a statement requesting the lab staff responds to the group email when testing is complete and results have been entered into iTransplant.

   7.1. When changes or additional tests are ordered after blood specimen(s) and initial requisition(s) have been sent to the lab, the CSC sends a 2nd requisition to the lab that documents the changes or additions (verbal instructions not acceptable).

Non-Ontario Donors

8. In the event where an organ has been accepted from a non-Ontario donor, the CSC will confirm that the source establishment Organ Procurement Organization (OPO) will perform non-STAT serology testing. Otherwise, the CSC will make the necessary arrangements to have blood specimens collected and transported to an Ontario laboratory for testing.

Transporting Blood Samples for Testing

9. The TGLN coordinator or designate ensures delivery of the required blood specimen(s) to the appropriate laboratory. See *Lab Profiles.* The specimens are labeled as per item 6 above, accompanied by the completed requisition, and offered for transport as per the *Packaging and Offering for Transport: Blood Specimens Process Instruction, CPI-9-222.*

Reporting non-STAT Serology Results

10. Non-stat serology results require one (1) CSC electronic signature in the Serologies section of the donor chart, indicating that they have reviewed and forwarded the results to the relevant OPOs, transplant programs and tissue banks. If EBV and/or Toxo are resulted after the commencement of the donor OR, the CSC documents reporting activities in the donor chart.

11. Positive and negative EBV results that are received after the commencement of the donor OR are reported by the CSC as soon as they become available to all relevant OPOs, transplant programs and tissue banks.

12. Positive and negative toxoplasmosis results that are received after the commencement of the donor OR are reported by the CSC to the relevant heart transplant program as soon as the results become available.

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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

References:

- *Discussing Donation Opportunities and Documenting Consent Process Instruction, CPI-9-204*
- *Hemodilution Calculation Process Instruction, CPI-9-210*
- *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*
- Health Canada: Safety of Human Cells, Tissues and Organs for Transplantation Regulations, June 2007
- CAN/CSA-Z900.1 – 17: Cells, Tissues, and Organs for Transplantation: General Requirements, Canadian Standards Association, 2022
- *Packaging and Offering for Transport: Blood Specimens Process Instruction, CPI-9-222*
- Lab Profiles, ORC