Clinical Process Instruction Manual

Histocompatibility Testing Process Instruction

Policy:

Histocompatibility testing and virtual cross-matching is required prior to allocation of hearts, lungs, kidneys, kidney-pancreas (K-P) and pancreas transplants in order to optimize transplant outcomes. Virtual cross-match results will show up on the allocations and will be relayed to the transplant programs at time of offer. A 'STAT' cross-match may be requested by the transplant physician(s) involved in allocation, in which case a current blood sample is obtained from the chosen recipient(s) for cross-matching with the donor cells (arranged by the appropriate recipient coordinators and/or accepting transplant program). Cross-matching for heart and lungs may be requested but is often completed following transplant, unless the accepting physician indicates this is required pre-transplant. This retrospective cross-matching is completed with the use of spleen or lymph node tissue obtained during the surgical recovery.

The packaging of blood specimens for transport, and the mode of transportation selected, will maintain the safety and integrity of the specimen during transit, as required by national standards.

All testing requisitioned by Trillium Gift of Life Network (TGLN) will be performed by a laboratory that complies with current federal regulatory requirements as outlined in national standards. All test results will be documented in the TGLN donor chart.

For the purposes of this document, the TGLN Coordinator may be the Organ and Tissue Donation Coordinator (OTDC) and/or Clinical Services Coordinator (CSC) and/or Referral Triage Coordinator (RTC).

Process:

Ontario Donors:

1. The OTDC will ensure consent for organ and tissue donation is obtained before blood specimens for histocompatibility testing are drawn (this may include verbal consent).

    1.1. Due to a global blood tube shortage, TGLN has committed to limiting/decreasing the amount of blood tubes used for donor testing. For Toronto region donor hospitals where HLA typing is completed at the Toronto HLA lab, the donor HLA blood draw timing will be discussed in the case specific TGLN Team Huddle. In some circumstances, HLA blood draw may be delayed until transplant program organ interest has been established by the Provincial Resource Centre (PRC).

2. If an OTDC is on-site at the hospital, s/he may facilitate the collection of the required specimens in conjunction with hospital staff. When an OTDC is not on-site, a CSC collaborates with hospital

staff by phone to ensure the correct specimens are collected in the appropriate blood tubes. See *Lab Profiles* on the Online Resource Centre (ORC).

3. The TGLN Coordinator facilitating blood sampling will ensure that all blood samples collected are labeled with the assigned TGLN donor number (#), Canadian Transplant Registry – Donor (CTD) number if samples are being sent out of province, 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.

4. Donor blood is sent to the human leukocyte antigen (HLA) lab in the donor region by the OTDC. The OTDC will draw the required blood tubes needed for HLA typing and/or those for recipient cross-matching. See Appendix 1: Blood tube requirements.

    4.1. If donor blood is being sent just for the purposes of HLA typing, the OTDC will notify the CSC/RTC and communicate the reason why. The second set of blood tubes may be sent later for recipient cross matching to ensure optimal cell viability.

5. The CSC/RTC is responsible for contacting the HLA technician when donor samples are en route to the lab for donor testing. The CSC/RTC will document if bloods are being sent just for HLA typing or also for cross matching. The CSC/RTC may also document one or more of the following items in the clinical notes:

    - time technician was notified
    - the number and type of blood tubes being sent to the lab
    - time specimen was received by the HLA technician and name of technician

    5.1. For Toronto region donors, in certain circumstances (e.g. MAID donor or donor recovery to take place on a future day as specified by the family), it may be feasible to notify the HLA lab that donor HLA typing can be completed non-stat during normal business hours, rather than commencing expediently. See Appendix 2: Toronto Region Donor HLA Typing Commencement Algorithm.

    5.2. For donors where HLA typing is completed at the Toronto HLA lab:

        5.2.1. For stat HLA testing, if there is a new donor sample being sent to the Toronto HLA lab, in addition to contacting the lab by phone, the TGLN coordinator will email #OH-TGLN_UHNHLA <OH-TGLN_UHNHLA@ontariohealth.com> to advise that a sample is being sent. The subject of the email should be "DD Typing Request - TGLN# 123456 STAT" for stat samples that require immediate processing. The body of the email should include the ETA of the donor sample.

        5.2.2. For non-STAT testing, if there is a new donor sample being sent to the Toronto HLA lab, in addition to contacting the lab by phone, the TGLN coordinator will email #OH-

TGLN_UHNHLA <OH-TGLN_UHNHLA@ontariohealth.com> to advise that a sample is being sent. The subject of the email should be "DD Typing Request - TGLN# 123456 NON-STAT". The body of the email should include the ETA of the donor sample.

6. The CSC is notified via telephone by the HLA technician when HLA typing is complete and entered into TOTAL.

7. In the event that a kidney, kidney-pancreas (K-P) or pancreas has been allocated outside of the donor region, additional samples for testing are sent to the HLA lab of the region performing the transplant. If no OTDC is on-site, the CSC collaborates with hospital staff to complete this task.

   7.1 The CSC will determine if cell preparation (donor lymphocyte cells) is available by contacting the HLA lab in the donor region performing the HLA typing. If available, the CSC facilitates the sending of the cell preparation to the appropriate HLA lab.

   7.2 In the event that cell preparation is not available, the CSC will request the OTDC facilitate the sending of additional blood samples to the appropriate HLA lab. If no OTDC is on-site, the CSC collaborates with hospital staff to complete this task.

   The TGLN Coordinator facilitating sample collection will complete a requisition for each specimen sent for HLA testing. See Exhibit 1 for a sample of the *HLA Lab Requisition Form*.

8. If a verbal report of 'STAT' cross-match results are provided to the CSC by the HLA technician, the CSC ensures that this information has been shared with the most responsible transplant physician and/or coordinator.

9. For retrospective cross-matching, a spleen sample 1-2cm x 1-2cm (preferable) or lymph node sample is obtained during the donor recovery unless the donor is donating liver only for TGH. The Surgical Recovery Coordinator (SRC) or designate will assist in obtaining and sending samples to the appropriate lab. The SRC or designate will ensure a requisition accompanies each specimen sent to the lab for retrospective cross-matching. See Exhibit 1 for an example of a *Sample HLA Lab Requisition Form*.

10. If a verbal report of retrospective cross-match results are provided to the CSC by the HLA technician, the CSC ensures that this information has been shared with the most responsible transplant physician and/or coordinator.

11. If at any point, the organ donor recovery, or recipient organ transplant is not proceeding, the CSC notifies the HLA technician as soon as possible if testing is in progress.

Out of Province Donors:

12. For out of province (OOP) organ offers requiring a virtual cross-match, the CSC will obtain the donor HLA by hard copy (exception being HSP kidney matching where process is automated). Two CSC's and/or RTCs will verify it is for the correct donor by cross referencing, at minimum, the source establishments donor number, and will initial the hard copy document. The CSC will ensure the TGLN # is on the hard copy and will contact the appropriate HLA lab regarding the need for HLA typing data entry, and will fax or email the verified HLA results with the TGLN # to the lab.

13. The HLA technician will let the CSC know when HLA typing data entry into TOTAL is complete, and the CSC will run the allocation

14. When an organ is accepted, the CSC will make arrangements for any specimens necessary for either 'STAT' or retrospective cross-matching to be collected.

15. If a verbal report of 'STAT' or retrospective cross-matching is provided to the CSC by the HLA technician, CSC ensures that this information has been shared with the most responsible transplant physician and/or coordinator.

Donor HLA Typing Changes:

16. When a HLA lab or OPO calls to report that donor HLA typing has changed from what was initially reported, the CSC references the affected donor chart to determine:
    - if organ allocations have been run
    - if organs have been offered and/or accepted
    - if organs have already been transplanted
17. The CSC will discuss what impact the donor HLA typing change may have on allocation, virtual cross-match results (VXM), and/or for transplanted recipients with the HLA lab or OPO reporting the change using the *Donor HLA Typing Change – Decision Tree* (see Exhibit 2).

18. If the outcome of the discussion determines the donor HLA typing change will have an impact on allocation, VXM results, and/or an impact on transplanted recipients, the CSC refers to the *Donor HLA Typing Change – Decision Tree* (see Exhibit 2) to determine what action to take.

19. The CSC documents all conversations and actions taken (if any) related to donor HLA typing changes in the donor chart.

Records:

Clinical Process Instruction Manual

Histocompatibility Testing Process Instruction

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

References:

- Lab Profiles on the ORC
- 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, 2017

Clinical Process Instruction Manual

Histocompatibility Testing Process Instruction

Appendix 1: Blood tube requirements

HLA Lab	Blood Tube Requirements
Toronto	24cc EDTA (typing) 80cc ACD (crossmatches)
London	24cc EDTA (typing) 80cc ACD (crossmatches)
Hamilton	24cc EDTA (typing) 80cc ACD (crossmatches)
Ottawa	24cc EDTA (typing) 80cc ACD (crossmatches)
Kingston	24cc EDTA (typing) 80cc ACD (crossmatches)

Clinical Process Instruction Manual

Histocompatibility Testing Process Instruction

Appendix 2: Toronto Region Donor HLA Typing Commencement Algorithm

Toronto Region Donor HLA Typing Commencement Algorithm

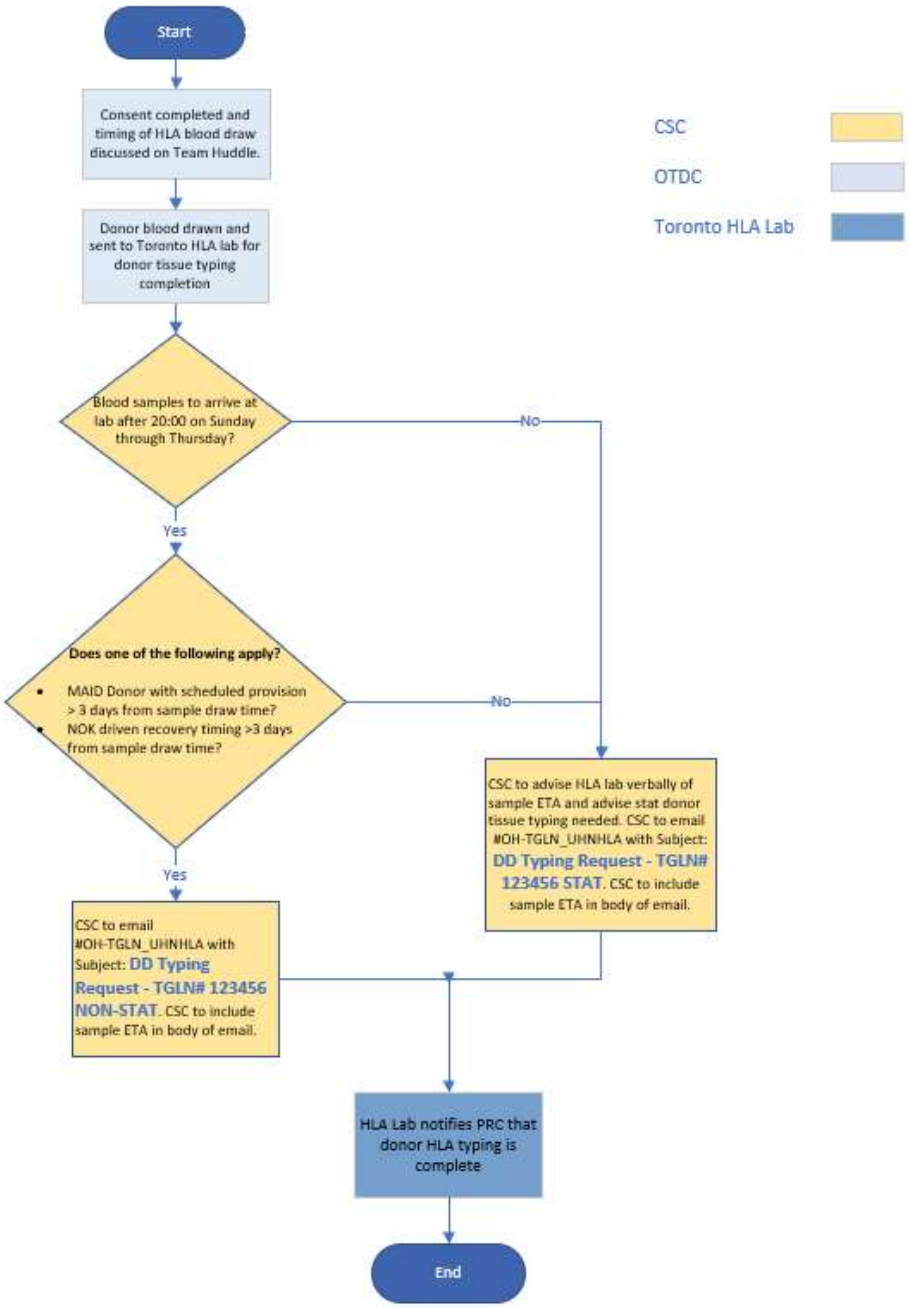

Exhibit 1: Sample HLA Lab Requisition Form

Trillium Gift of Life Network 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9

CSF-9-23

HLA Lab Requisition Form

TGLN Donor Number:		Sample Date:		
Date of Birth:		Age:	Sex: ☐ M	☐ F
Ethnicity:				
Cause of Death:				
Donor Hospital:				
Blood Type:	Subtype (if A or AB subtype required):			

Samples Sent

☐ Spleen ☐ Lymph Nodes ☐ Blood (ACD or EDTA) ☐ Cell Prep

Potential Recip. Type: ☐ Heart ☐ Lung ☐ K/P ☐ Kidney (s) ☐ Pancreas
☐ Composite Tissue ☐ Other: _____

Recipient Information

Recipient	TGLN Recip. Number	Transplant Hospital	Organ	ABO

Requested By:	
Date:	Time:
Call Results to (416) 214-7808	Pager Number:

Nov 27, 2019

Clinical Process Instruction Manual

Histocompatibility Testing Process Instruction

Exhibit 2: Donor HLA Typing Change - Decision Tree