Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Hemodilution Calculation Process Instruction

Policy:

To ensure the validity and accuracy of serology test results a hemodilution factor is calculated, prior to the drawing of blood specimens, in order to determine if the sample will be acceptable for testing in accordance with Health Canada's *Safety of Human Cells, Tissues and Organs for Transplantation (CTO) Regulations* and the *American Association of Tissue Bank* (AATB) *Current Standards for Tissue Banking.*

A hemodilution calculation is completed and testing is performed on specimens collected at the time of donation or within 7 days before or after the donation. If the donor is one month (28 days) of age or less, a blood specimen from the birth mother is collected within 7 days prior to or after the donation and is tested instead of a specimen from the donor. If the calculated hemodilution factor exceeds the threshold above which the validity of test results is compromised, an undiluted specimen from an earlier drawn sample is forwarded for testing. If an undiluted specimen is not available, tissue recovery cannot proceed, however testing can be done on the diluted specimen for organ donors. Any organ(s) donated are then offered in accordance with Trillium Gift of Life Network's (TGLN) exceptional distribution (EXD) requirements. See the *Exceptional Distribution Process Instruction, CPI-9-217*.

Tissue from a donor who is older than 12 years of age will not be suitable for transplantation if blood loss is known or suspected to have occurred and there has been a transfusion/infusion of more than 2000 mls of blood (whole blood, red blood cells) or colloids within 48 hours; more than 2000 mls of crystalloids within one hour; or any combination thereof, prior to asystole or collection of the blood specimen, whichever occurred earlier, unless:

- a pre-transfusion or pre-infusion blood specimen from the tissue donor is available for infectious disease testing; or
- an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collection of the specimen from the donor to ensure there has been no plasma dilution sufficient to affect test results.

Tissue from a donor 12 years of age or less who has been transfused or infused at all, will not be suitable for transplantation unless a pre-transfusion or pre-infusion specimen is available for infectious disease testing, or an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen to ensure there has not been plasma dilution of sufficient magnitude to affect test results.

The TGLN coordinator responsible for completing and/or verifying the hemodilution calculation may be the Organ and Tissue Donor Coordinator (OTDC), the Tissue Coordinator (TC), the Clinical Services Coordinator (CSC), or the Tissue Recovery Coordinator (TRC).

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Process:

The TGLN coordinator will:

1. Obtain the donor's weight:

    1.1. The donor's accurate weight shall be record on the hemodilution calculation section of the donor assessment or the *Eye Recovery Form* or the *Multi Tissue Recovery Form* as applicable for use in determining the donor's blood volume and plasma volume.

2. Calculate volumes:

    2.1. The volume of red blood cell products (A) infused during the 48 hours prior to collection of the blood sample for virology testing or prior to asystole, whichever came first, shall be documented.

    2.2. The volume of colloids (B) infused during the 48 hours prior to collection of the blood sample for virology testing or prior to asystole, whichever came first, shall be documented.

    2.3. The volume of crystalloids (C) infused during the one-hour period prior to the collection of the blood sample for virology testing or prior to asystole, whichever came first, shall be documented.

3. Determine the specimen's level of hemodilution:

    3.1. The TGLN coordinator will review the donor chart, and any other donor information, for all information available about transfusions and fluid infusions, which may affect the hemodilution factor, and will document the values on the applicable hemodilution forms. If the donor chart is incomplete, it is recommended that information be obtained directly from the hospital's blood bank regarding the number of units issued to the patient.

    3.2. If the total volume of colloids and crystalloids infused (B+C) is less than the plasma volume, and/or the total volume of red blood cell products, colloids and crystalloids infused (A+B+C) is less than the blood volume, the sample is acceptable for testing.

    3.3. If the total volume of colloids and crystalloids infused (B+C) is greater than the plasma volume, <u>or</u> the total volume of red blood cell products, colloids, and crystalloids infused (A+ B+C) is greater than the blood volume, the sample is considered to be diluted. Attempts should be made to obtain an undiluted sample (see section 4.1 below). If an undiluted sample is not available, then tissue recovery cannot take place. For organ donation the

diluted sample is tested, and the organs may be released in accordance with EXD requirements and documented as such on the donor assessment, in the clinical notes, on the recipient information sheet accompanying each organ to the operating room (OR) and on the *Notice of Exceptional Distribution*. See *Exceptional Distribution Process Instruction, CPI-9-217.*

3.4. In the event there is a delay between the time the hemodilution calculation is performed and the time the sample is drawn, the TGLN coordinator evaluates whether any transfusions of significance have occurred during the delay and determines if the hemodilution calculation is still valid. If it is not valid, the TGLN coordinator attempts to obtain an undiluted sample (see 4.1 below).

4. Diluted specimen:

4.1. If the specimen is excessively diluted, every attempt should be made to obtain an undiluted specimen (normally drawn at the time of admission, prior to fluid/blood administration, and obtained from the referring hospital's blood bank or biochemistry lab). If the referring hospital does not have an available sample for testing, determine if the patient was transferred to the referring hospital from another facility. If the donor was transferred, attempt to obtain an undiluted sample from the transferring facility. If the death is a coroner's case, coroner permission may be required in order for the undiluted blood to be used.

5. For sample drawn following cardiorespiratory death:

5.1. The date and time of cardiorespiratory death is used as a benchmark for the hemodilution calculation.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Assessment Form: Organ or Combined	CSF-9-15	PRC	PRC	16 years
Assessment Form: Tissue Donor	CSF-9-16	PRC	PRC	16 years
Eye Recovery Form	CSF-9-80	PRC	PRC	16 years
Multi-Tissue Recovery Form	CSF-9-146	PRC	PRC	16 years
Notice of Exceptional Distribution	CSF-9-24	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*
- *Exceptional Distribution Process Instruction, CPI-9-217*
- *Health Canada: Safety of Human Cells, Tissues & Organs for Transplantation Regulations, June 2007*
- *CAN/CSA-Z900.1 –03: Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements, Canadian Standards Association, 2003*
- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.210, D4.211, D4.220, D4.230*