2025 Accreditation Canada Diagnostics (ACD) Non-Conformances
83 Ontario Hospitals Laboratories Assessments Completed
Prepared by ORBCoN - June 18th, 2026

Total Non-Conformances n=78	ACD Requirement & TM Specific Requirement	Citations (Total # per requirement)	TM Specific ACD Requirement Statement	Summary of Findings	Available ORBCoN Resources
MAJORS n=3	VII.8 - TM011	**2**	Procedures for the control of all reagents shall be established according to the supplier's recommendations. [997]	Not all TM reagents are quality controlled (DAT)	
	VI.1 - TM096	**1**	A list of signs and symptoms of suspected transfusion reactions shall be included in the nursing and transfusion medicine manuals. [1058]	The list of signs and symptoms of suspected transfusion reactions included in the nursing manual was not consistent with the transfusion medicine manual.	Bloody Easy Blood Administration (BEBA)
MINORS n=75	I.B.10 - TM111	14	The evaluation of staff skills of those performing transfusion medicine testing may include, but is not limited to: (a) direct observation of performance: (b) monitoring of recording and reporting; (c) written tests to assess problem-solving skills; (d) assessment of knowledge of procedures and theory; (e) assessment of performance in proficiency tests. [1209]	There is no mechanism to ensure that **all staff involved in transfusion related activities** are completing the required competency evaluation program.	There are 4 editions of the Bloody Easy education book series available to your team to support Transfusion Medicine practice. There are corresponding SCORM files that can be added to your LMS that will give your team access to test questions and quizzes to maintain your team's competency. 1. Bloody Easy Lite 2. Bloody Easy Blood Administration (BEBA) 3. Bloody Easy Coagulation 4. Bloody Easy for Healthcare Professionals Bloody Easy education book series
	I.C.2 - TM182	10	There shall be a transfusion medicine committee with documented terms of reference. It shall meet at least quarterly and document its activities. [1216]	The Transfusion Medicine Committee: -Terms of reference do not included all applicable members. -Committee does not meet quarterly, as required. -Not all members have access to committee minutes to ensure they are shared with other groups that impact laboratory operations such as MAC and Leadership Team.	Transfusion Committee Toolkit
	IV.14 - TM009	4	Thawing devices used to thaw blood components/products shall be cleaned as specified as well as when required by the manufacturer. They shall not be used for incubation of tests containing biological specimens. The temperature of the thawing device shall be checked and documented at each use and be within acceptable range. [995]	Preventative Maintenance on the Plasma Thawer has not been performed at the frequency required by manufacturer.	**Consensus from Ontario's HC Blood Regulation Peer Group**: Make sure all manufacture inserts are considered when creating maintenance schedule espeically if you have equipment with various brands, models and implementation dates. Ask the Ontario Blood Regulation Peer Group
	IV.2 - TM016	4	Blood components/products shall be visually inspected upon receipt in the laboratory for leakage, discolouration, abnormalities such as clots or hemolysis, and that the blood component/product is properly labelled. Shipping boxes shall be inspected prior to opening for evidence of abnormal appearance or evidence of tampering and inspected when opened for appropriate packaging configuration. This shall be documented. [1001]	The process for receiving blood components/products does not ensure the: 1. Visual inspection is consistently documented on the packing slip. 2. Packing configuration is checked when box is opened.	There are procedures available on ORBCoN's website that can be used as templates to make sure your hospita'sl SOP captures are all relevant requirements for receiving blood components and products from CBS and other hospital sites. 1. Inter-hospital Form 2. Procedure IM006- Shipping using J82/E38 3. Procedure IM011 - Shipping using Credo/MTS
	VI.1 - TM065	4	Blood and blood components/products shall be labelled with: (a) the recipient's first and last name; (b) the recipient's unique identification number; (c) the recipient's ABO group; (d) the recipient's RhD (if applicable); (e) the unit identification number or pooled unit number; (f) the ABO group of the blood component/product (if applicable); (g) the type of blood component/product; (h) the date and time of issue (may appear on accompanying documentation); (i) volume, if different from the blood supplier and/or manufacturer (e.g., for pooled or split components); (j) the compatibility status (if applicable). [1033]	Blood components are not labelled with date and time issued	HC Regulation Self-Assessment Tools refer to Regulations # 60, 61, 65, 68
Top Non-Conformances listed above (n=36) refer to full document to review remaining 39 minor non-conformances.					
	TM112	3	Blood components/products shall be stored separately from all other substances including blood specimens, tissues for transplantation and reagents. This may involve the use of clearly identified segregated areas within the same storage equipment. [1211] Note: If using one refrigerator for blood components/products and specimens (segregated), the laboratory must ensure that a temperature of 2.0-6.0 degrees Celsius is maintained as per manufacturer's instructions to ensure the integrity of both blood components/products and samples. If refrigerator is used for recipient pre-transfusion samples only, see TM106.	The temperature range on the blood bank refrigerator does not ensure that the blood products are maintained at the recommended range of 2-6 degrees Celsius. Quarantined blood products and reagents are stored together in the same bin.	
	TM002	3	Refrigerators and freezers, when in use for storage of blood components and blood products, shall have an audible temperature alarm with a back-up power supply. The alarm and back-up power supply for the alarm shall be checked at the frequency defined by the facility and the check shall be documented. The alarm warning shall signal in a location that is continuously monitored or staffed so immediate corrective action can be taken. Alarm activation points shall be set at temperatures that allow time for appropriate corrective action before the blood components reach unacceptable temperatures. [988]	The alarm activation points on refrigerators and freezers in Transfusion Medicine are not set to allow time for appropriate corrective action before the blood components reach unacceptable temperatures. The process for the monitoring of temperature dependant equipment does not ensure the alarm and back-up power supply for the alarm are checked at least monthly (eg., fridges and freezers) and that records are maintained.	

	TM070	3	A procedure shall be established for the return of blood components/products into usable inventory. The laboratory shall ensure that: (a) visual inspection of the blood component/product is acceptable; (b) the container is intact, including ports on bags; (c) at least one sealed segment of integral donor tubing is attached to red cell components. Alternately, an identified segment must be available to the transfusing site. (d) the temperature of the blood component is acceptable as determined by one of the following: i. a suitable monitoring system indicates the unit(s) has stayed within the acceptable temperature; ii. the unit(s) has been maintained in a container validated to maintain the appropriate temperature for the period that the unit was outside the transfusion service; iii. red cells, plasma and/or cryoprecipitate have not been out of the controlled environment for more than 60 minutes from the time of issue (per occurrence, not cumulative). (e) The medical director may approve the acceptance into inventory of blood components/products that do not meet the requirements of this clause. [1038] Mechanisms to ensure component/product temperature may include: (a) the use of temperature indicator stickers on all red cells; (b) a complete physical check of temperature on returned units using calibrated equipment; (c) the implementation of strict guidelines for the control of component/product temperature outside the laboratory coupled with periodic audits of compliance; (d) the use of validated transport containers that are capable of maintaining the appropriate temperature, coupled with periodic audits.	The policy for return of blood products to inventory is supported by two conflicting procedures. The process for accepting returned blood components does not include a step to ensure the medical laboratory director approves it back in to useable inventory (i.e., thawed plasma).
	TM176	3	The package shipping label of blood components/products for external transport shall be labelled with the following information: (a) that the contents are not for transfusion if an unusable blood component/product is being shipped for investigation or disposal; (b) the site of origin; (c) the destination; (d) a notice that it contains human blood components/product; and (e) any cautions or descriptions required under provincial or federal transport regulations. [1221]	The package shipping label used for external transport of blood component/products does not include a notice that the contents are not for transfusion when the product is being shipped for investigation or disposal. When an unusable blood component/product is being externally shipped for investigation or disposal the package shipping label does not indicate it is not for transfusion.
	TM195	2	Transfusion medicine procedures shall be reviewed at least every two years. [250]	The process for document review does not ensure that Transfusion Medicine procedures are reviewed at least every 2 years.
	TM118	2	The release voucher to another facility shall accompany each shipment of blood components/products and contain the following information: (a) the name of the site shipping blood components/products; (b) the name of the site receiving blood components/products; (c) the unique serial number of the voucher; (d) a description of the type of blood components/products being shipped, including notice if quarantined blood components/products have been included; (e) the donation numbers of the blood components; (f) the total number of items; (g) the date and time of shipping; (h) the signature(s) of the designated person(s) responsible for the packing. [1223]	There is no unique serial number on the voucher for the interhospital transfer form.
	TM021	2	There shall be policies, processes and procedures documented for the transportation of blood components/products, tissue, derivatives, samples, and critical materials (including reagents) outside the facility and within the facility, including automated tube systems. These shall specify who may receive and transport blood components/products, and acceptable transit times. They shall ensure that they are stored and transported at optimal temperatures and conditions. They shall include instructions for power failures or other disruptions, maximum time for completion of transfusion, acceptable off-site processing and storage. Packaging for transport outside the facility shall be of sturdy construction and have a tamper-proof seal. [1213] Examples: - blood components are not left at room temperature for more than 60 minutes unless a suitable temperature monitoring system indicates that an acceptable temperature has been maintained; - the process ensures that the temperature of the red cell component has not exceeded 10 degrees Celsius; - blood components/products with a required storage temperature of 1-6 degrees Celsius shall be transported in a manner that will ensure maintenance of a temperature of 1-10 degrees Celsius; - blood components/products required to be stored at 20-24 degrees Celsius shall be transported at 20-24 degrees Celsius; - blood components/products required to be stored frozen shall be transported in a manner designated to maintain them in the frozen state. Note: If shipment is made using a validated box, the statement of validation would fulfill the requirement for documented evidence	There is no process to ensure that the containers used for the storage and transport of blood products/components for MHP is verified annually as per the procedure. The process for transportation of blood components/products using the Credo boxes/coolers within the facility does not ensure that optimal temperatures are maintained.
	TM126	2	There shall be a procedure defining when red cells that are negative for Hb S shall be used where required i.e., in the case of massive transfusion to a neonate including exchange transfusion or exchange transfusion to a patient with sickle cell disease. [1292]	There is no procedure to define when red cells that are negative for Hb S should be used, e.g., massive transfusions in neonate.
	TM034	2	Comparison of past testing and transfusion records with current tests shall be performed and documented prior to the issue of blood components/products for transfusion. When current sample testing does not match previous historical patient records, further investigation to solve the discrepancy shall be performed prior to the use of current testing results. [1008]	There is no procedure to describe what to do when current sample testing does not match the previous historical patient record.
	TM098	2	The transfusion reaction investigation report shall be retained in both the patient's medical chart and in the transfusion laboratory. [1060]	There is no process to ensure that the transfusion reaction investigation report is retained in the patient's medical chart.
	TM170	2	A procedure shall include instructions for the recall of any released blood components/products upon notification of any information that brings into question the safety or efficacy of the blood component/product. Procedures for recall shall: (a) include the identity of the individual responsible for recall activities; (b) allow the initiation of the recall procedure at any time; (c) describe the notification of recipients; (d) ensure that recalled blood components/products are retrieved and quarantined until final disposition is determined. [1276]	There is no procedure for the recall of released blood components/products upon notification of any information that brings into question the safety or efficacy of the blood component/product.

	TM172	2	The transfusion service shall acknowledge receipt of retrieval notification. [1278]	There is no process to acknowledge receipt of retrieval notification.
	TM157	2	Facility policies for home transfusion and infusion programs which comply with established standards shall be in place. [1266] Policies should include information about the following: - identification of person picking up product; - disposition of products not picked up; - disposition of products returned - both in date and out of date; - redistribution of products nearing expiration date; - products received from blood supplier should be documented as received.	The procedure for home infusion does not contain all the required information, i.e., disposition of products not picked up and/or returned.
	TM145	2	For perioperative collection, the collection of blood shall be performed under a program of quality control and quality assurance developed in co-operation with the other departments involved in perioperative blood collection. Quality control measurements shall address the safety and quality of the units collected for the recipient. Records of results shall be reviewed and retained. [1252] Written procedures should include criteria for acceptable performance.	The process for the quality control of perioperative blood collection devices does not ensure that records are maintained.
	TM110	1	The evaluation of staff skills of those performing transfusion medicine testing may include, but is not limited to: (a) direct observation of performance; (b) monitoring of recording and reporting; (c) written tests to assess problem-solving skills; (d) assessment of knowledge of procedures and theory; (e) assessment of performance in proficiency tests. [1209]	There is no mechanism to ensure that all staff performing transfusion medicine testing are completing the required competency evaluation program.
	TM013	1	The identity (name, initials or computer code) of the person drawing a pre-transfusion specimen, and the date and time of collection shall be recorded. This information must be retrievable for one year. [999]	There is no process to separate room temperature and frozen products for transfusion that do not meet the necessary criteria for release in a secure, quarantined location.
	TM068	1	There shall be a record of each blood component/product transfused that includes: (a) the recipient's first and last name; (b) the recipient's identification number; (c) the recipient's ABO group; (d) the recipient's RhD (only for red cells, granulocytes, and platelets); (e) the ABO and RhD group of the blood component; (f) the recipient's compatibility status (only for red cells and granulocytes); (g) the name of the component/product; (h) the unit identification number (pooled unit number if applicable)/lot number or identification number traceable to the lot number; (i) the date and time of issue; (j) the volume/dose transfused/administered; (k) the identity of the person who prepared the product for administration and the date and time of preparation; (l) the identity of the individual who administered the blood component/product; (m) date and time (both start and finish) of transfusion/administration; (n) any adverse reactions to the component/product transfused. [1036]	This was cited as a minor non-conformance in June 2023 because the identity of the person who prepared the Rhlg and IVIG product for administration and the date and time of preparation were not always recorded. This minor non-conformance is now met.
	TM058	1	For emergency transfusion, a procedure shall include instructions for the issue of blood components/products that are considered untested by the blood supplier, including documentation of authorization. [1026]	There is no procedure that includes instructions for the issue of blood components/products that are considered untested by the blood supplier.
	TM194	1	Red blood cells intended for transfusion to persons with anti-IgA, and/or IgA deficiency and a history of severe allergic reaction to transfusion, shall be from IgA deficient donors or washed with 1 to 2 litres of sterile normal saline (preferably using automated equipment) to provide sufficient washing. [1458]	There is no process in place to ensure that persons with anti-IgA, and/or IgA deficiency and a history of severe allergic reaction are transfused with appropriate donor units.
	TM050	1	A venous or capillary blood specimen shall be used for all pre-transfusion testing; cord blood shall not be used. The serum or plasma from either the mother or the infant can be used for testing for unexpected antibodies and compatibility. [1018]	The determination of what specimens are acceptable for pre-transfusion testing does not meet best practice, e.g., cord blood.
	TM103	1	The laboratory shall retain the following records for five years: (a) temperature records of refrigerators, freezers and incubators used for blood component/product storage; (b) quality control records for reagents and serological tests; (c) quality assurance reports, records of internal audits and records of product complaints; (d) external quality assessment results. [1065]	The defined retention time for quality control records does not meet the requirement of 5 years.