Transfusion Guidelines for Hospitals in Saskatchewan

Laboratory Quality Assurance Program
3475 Albert Street
Regina, Saskatchewan S4S 6X6

phone: (306) 787-8239
fax: (306) 787-7240

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INTRODUCTION

The Transfusion Guidelines for Hospitals in Saskatchewan has been developed to replace the Technical Protocol for Blood Transfusion Practice in Rural Saskatchewan Hospital Laboratories. The intent of this manual is to provide guidelines for transfusion practice in light of the current and proposed standards and is not intended to be a procedure manual.

This document covers all areas of transfusion practice. It is important to remember that standards are minimum guidelines and any lab can tailor its procedures and policies to be more stringent. The Guidelines contain references to the Draft Canadian Standards Association Z902 Blood and Blood Component Standards and the most recent Canadian Society for Transfusion Medicine Standards (6th Edition 1999). These documents are available from the Canadian Standards Association and the Canadian Society for Transfusion Medicine.

Each Transfusion Service or Region should develop their own procedures and policies using the Guideline as a reference.
MEDICAL PARTICIPATION

A transfusion service must have a medical director, who is a provincially licensed physician, qualified by training and or experience for the scope of activities performed in the facility.

The Medical Director shall be:

a) Responsible for authorizing all medical and technical policies and procedures that affect laboratory personnel and test performance.

b) Consulted and responsible for the development of all policies that relates to the care and safety of recipients.

c) Responsible for Quality Assurance and ensure compliance with standards.

d) Responsible for ensuring the appropriate use of resources in the Transfusion Service.

Standards References
CSA Draft Z902 – Section 4.3.6.1
CSTM 6th Edition – Section A1.01
POLICIES AND PROCEDURES

Standards

Standards require that an institution establish policies and procedures in consultation with a licensed physician and a qualified Medical Technologist. The policies and procedures must be reviewed on an annual basis and updated as necessary. There must be documentation of the review.

The following is a list of some policies and procedures that should be included in the Laboratory. See Appendix 3 for a summary NCCLS procedure guideline.

A. Policies

The Institution should include policies on the following:
1. Staff qualifications, assignment of responsibilities
2. Physical facilities
3. Safety – Occupational Health and Safety, and recipient safety
4. Disposal or decontamination of biological specimens
5. Record retention
6. Scope of Testing
7. Patient identification
8. Issue of unmatched blood
9. Selection of blood products
10. Specimen retention
11. Adverse event reporting and surveillance
12. Specimen referral
13. Physician notification of Abnormal results
14. Correction of erroneous results
15. Informed Consent
16. Patient Notification
17. Patients to receive Irradiated Blood Products

B. Procedures

The Institution must include procedures on the following:
1. Testing
2. Equipment use and maintenance
3. Specimen referral
4. Staff orientation
5. External and internal quality control
6. Equipment failure
7. Patient identification
8. Sample collection and labeling of specimens.
9. Quality Assurance initiatives
10. Retention of records
11. Product issue
12. Product modification
13. Emergency issue
14. Product storage
15. Investigation of Transfusion Reactions
16. Investigation and error resolution
17. Criteria for acceptance of blood and blood components into the facility
18. Selection criteria for blood and blood components
19. Recipient pre-transfusion testing
20. Blood components pre-transfusion testing
21. Massive transfusion
22. Administration of Blood

All procedures should contain corrective action instructions.

Note: These policies and procedures do not need to be Transfusion Service specific and can be included in Lab or Institutional documents.

Standards References
CSA Draft Z902 - Section 4.1 and 4.2
CSTM 6th Edition - Section A1.01
TESTING
PATIENT IDENTIFICATION

Standards

Requests for blood or blood components must identify the recipient using their family and given names and their specific ID number (i.e. PHN #). It should also contain the patient location and the blood component being requested. In emergency situations there must be policies and procedures established for identification.

Standards require that positive identification of the patient shall be made before drawing any blood specimens using the patients identification band and any discrepancies must be resolved prior to the sample being drawn. The name, initials or computer code of the person drawing the blood sample shall be documented on the request form, as well as the time and date of collection. The blood sample must be labeled in the presence of the recipient and must include recipient’s family and given names, ID number and date of collection. The person drawing the specimen will verify that the information on the label matches the identity of the recipient. A policy should be in place for specimens collected on an outpatient basis.

Recommendations

1. The use of a third identifier such as the date of birth is a good practice.
2. The lab must have procedures and policies to use when the sample identification does not match.

Standards References
CSA Draft Z902 - Section 10.2 and 10.3
CSTM 6th Edition - Section D
SPECIMEN FOR TESTING

Standards

Standards require that specimens for crossmatch must be collected within 96 hours of transfusion if:

a) the patient has been transfused with a component containing red cells (red cells and platelets) within the previous 3 months;

b) has been pregnant within the previous 3 months or;

c) if the history is questionable. Specimens for patients who do not meet these criteria may have a specimen collected during the current hospital admission (this includes a pre-admission visit). A representative sample of the patient and donor unit must be kept for 7 days post transfusion.

Recommendations

1. Each lab must define the length of time that a sample can be used for compatibility testing when a patient has not been transfused or pregnant. In most cases 14 days is adequate.

2. Where storage permits, it is preferable to keep patient specimens for 14 days because most delayed transfusion reactions occur 7 to 10 days post transfusion.

3. Each lab must have a procedure that states what specimens are acceptable for compatibility testing.

Standards References
CSA Draft Z902 – Section 10.4.1
CSTM 6th Edition – Section F2.07-2.10
COMPATIBILITY TESTING

Standards

Standards require that compatibility testing be performed before red cells are transfused except in life threatening situations. Compatibility testing shall include recipient ABO and Rh testing, antibody screening and crossmatching of recipient sample to donor red cells. Interpretations of current testing must be compared with previous results to allow for resolution of discrepancies. The following results are to be checked: ABO/Rh, grouping discrepancies, previous antibodies, transfusion reactions and special requirements.

Transfusion Medicine Issue #1 – Policy

A MLT shall monitor the accuracy of the reports of the crossmatches (compatibility tests) performed by CLXT’s who have been trained in a recognized Transfusion Medicine course as part of their training. The MLT will take appropriate action when deficiencies are identified.

Transfusion Medicine Issue #2 – Policy

Technologists performing transfusion medicine procedures must maintain a minimum of 12 documented crossmatches (compatibility tests) per year. This number may reflect a minimum of 8 patient samples/year/technologist. Proficiency testing samples may be utilized to maintain competence. This practice must be documented and available.

Standards References
CSA Draft Z902 – Section 10.4.2 to 10.4.6
CSTM 6th Edition – Section F2.01 to 2.05
Laboratory Quality Assurance Policy Manual
ABO GROUPING

Standards

Standards require ABO grouping be determined by testing the patient’s red cells with anti-A and anti-B reagents and the patient’s serum or plasma be tested with A1 and B reagent red cells. Plasma or serum testing should be omitted in children less than 4 months of age.

The results of red cell and serum tests should agree. Any discrepancy should be investigated and resolved with appropriate documentation prior to issuing red cells.

Reagents

Commercially prepared anti-A and anti-B are usually manufactured from monoclonal antibodies grown from cell cultures. Monoclonal reagents have the advantage of being very specific and stronger reacting with weakly expressed antigens.

Reagent red cells are produced from healthy donors and have been tested for disease markers.

Recommendations

1. All testing shall be performed in accordance with the manufacturer’s directions for the reagent being used.
2. ABO testing must be performed by tube method only. Slide techniques are not acceptable as the sole method of testing.
3. All patient ABO grouping must include the use of anti-A and anti-B in the forward grouping. It is recommended that these reagents be monoclonal.
4. The use of anti-A,B is the choice of the Laboratory. It is not advantageous to use a monoclonal anti-A,B reagent because it does not pick up weak subgroups of A, these are only detected with human anti-A,B and a prolonged incubation.
5. Reverse grouping testing can be performed on either a serum or plasma sample.
6. A1 and B cells must be included in the reverse grouping. The use of A2 cells, O cells and an autocontrol can be advantageous in resolution of ABO discrepancies, but are not necessary as a routine reagent.
7. Reverse grouping is not necessary in children under the age of 4 months because the ABO antibodies are not well developed.
8. All discrepancies must be investigated. The Laboratory must include in its procedure, methods to resolve ABO problems and actions to take until the problems are resolved.
9. The Canadian Blood Services performs ABO testing on all donors; it is not necessary to repeat this testing as part of confirmatory donor testing.
Standards References
CSA Draft Z902 – Section 10.4.2
CSTM 6th Edition – Section E3.00
D ANTIGEN and WEAK D TESTING

Standards

Standards require that the Rh type be determined by testing the patient’s red cells with anti-D reagent. A control system must be run that is specific to the Anti-D used and tested according to the manufacturers’ insert. If this control is positive the Rh typing must be repeated with an appropriate anti-D reagent and control.

Weak D test is not necessary when testing patients who are to receive blood products. Testing for weak D should be performed on Rh-negative infants of Rh-negative mothers with no evidence of Rh alloimmunization.

Reagents

Commercially available anti-D reagents can be of two types. High protein reagents (slide and tube) are prepared with human antisera and contain high concentrations of proteins to enhance the reactivity. Monoclonal reagents are prepared from cell cultures and are usually a low protein reagent.

The use of a control reagent is required with high protein reagents to rule out false positive reactions from the high protein media causing agglutination of protein-coated red cells. Monoclonal reagents are controlled according to the manufacturer’s instructions. It is always necessary to run a control to rule out spontaneous agglutination of red cells. For red cell specimens that show agglutination in all tubes (i.e. AB Positive patients) a negative control must be included.

Weak D testing can be performed with any reagent that the manufacturer can be used for Weak D testing, in the package insert. If weak D testing is performed appropriate controls must be included with the testing. A direct antiglobulin test or the use of Rh control treated in a manner identical to the weak D testing must be performed as part of the controls to ensure that the red cells are not covered with antibody prior to testing.

Recommendations

10. All testing shall be performed in accordance with the manufacturer’s directions for the reagent being used.
11. D antigen testing must be performed by tube method only. Slide techniques are not acceptable as the sole methodology.
12. All patient samples must be tested with anti-D reagent. It is recommended that these reagents be monoclonal.
13. A diluent control provided by the manufacturer of the anti-D must be used with high protein reagents. Monoclonal reagents must be controlled according to manufacturers direction.

14. Weak D testing must be performed on all cord samples of Rh negative babies born to Rh negative mothers.

15. It is not necessary to perform Weak D testing on transfusion recipients. It is the choice of the Laboratory to perform this testing.

16. The Canadian Blood Services performs Weak D testing on all Rh negative donors. It is not necessary to repeat this testing as part of confirmatory donor testing.

Standards References
CSA Draft Z902 - Section 10.4.4
CSTM 6th Edition - Section E 4.00
ANTIBODY SCREENS

Standards

Standards require antibody screening be performed to detect most clinically significant antibodies. This testing is done at 37°C and includes an indirect antiglobulin procedure. The use of a reagent that contains only Anti-IgG is acceptable.

Reagents

At least two cells should be used for antibody screening and these cells should express a variety of blood group antigens. The indirect antiglobulin phase must include the use of a reagent with Anti-IgG to detect clinically significant antibodies. All negative results must be confirmed by the use of IgG coated cells, unless the procedures used has manufacturer specified controls. Either plasma or serum can be used for testing. If plasma is used for testing, Anti-IgG should be used rather than a reagent containing Anti-IgG and anti-complement. See appendix 7.

No one method to detect all clinically significant antibodies is perfect. Many different procedures are available to perform antibody screening. Some of the available procedures are listed below.

1. Saline Indirect Antiglobulin – Patient serum is mixed with screening cells in a pre-determined ratio without the addition of an enhancement media.
2. Albumin Indirect Antiglobulin – 22% Bovine albumin is added to patient’s serum and mixed with screening cells.
3. LISS – A low ionic strength solution is added to patient serum and screening cells.
4. Poly Ethylene Glycol (PEG) – PEG is added to patient serum and screening cells.
5. Gel Techniques – Patient serum and cells are incubated in gel cards and centrifuged through the gel to identify agglutination.
6. Microplate Techniques – Patient serum and an enhancement media are incubated in red cell coated wells.

Each Laboratory must choose their procedure and work within the manufacturer’s guidelines for testing.
Recommendations

1. All testing must include incubation at 37°C and the use of an antiglobulin reagent.
2. It is acceptable to use Anti-IgG for testing. Most clinically significant antibodies are IgG in nature. Anti-complement can cause problems with interference from cold agglutinins and non-specific reactions.
3. If an autocontrol is used as part of the antibody screen to detect patients with positive direct antiglobulin tests, a polyspecific antiglobulin reagent must be used.
4. All testing shall be performed in accordance with the manufacturer’s directions for the reagent or product used.
5. It is acceptable to use EDTA plasma for testing if an IgG reagent is used in the antiglobulin phase. EDTA plasma has the advantage that the clotting time is not required and there are no problems with fibrin strands.
6. At least two screening cells must be used for the antibody screen.
7. It is not necessary to test at room temperature or immediate spin to avoid finding antibodies that have little clinical significance.
8. All positive antibody screens must be investigated.
9. It is not necessary to do a direct antiglobulin test (DAT) or autocontrol with all screens but all positive screens must have a DAT or autocontrol performed. If the autocontrol is positive DAT testing must be performed using a polyspecific antiglobulin reagent.

Standards References
CSA Draft Z902 – Section 10.4.5
CSTM 6th Edition – Section E6.00
CROSSMATCH

Standards

Standards require that prior to transfusion either a serological or computer crossmatch shall be performed. The method used must be capable of detecting ABO incompatibility, which is the most important function of the crossmatch. In urgent situations crossmatch may be omitted.

A serological crossmatch using an antiglobulin (or comparable) technique must be performed if the antibody screen indicates the presence of a clinically significant antibody or if the patient has a history of clinically significant antibodies. Red cells selected for transfusion should lack the corresponding antigen.

Serological Crossmatch

A serological crossmatch is performed between a sample of the recipient’s serum or plasma and a sample of donor cells from an originally attached segment from the donor unit.

There are two methodologies available for performing a serological crossmatch:

1. Immediate spin crossmatch – Can be used for patients with no history of clinically significant antibodies. The patient serum or plasma is mixed with a donor suspension and centrifuged immediately. It is designed to detect ABO incompatibilities.
2. Antiglobulin crossmatch – This method involves mixing the patient serum or plasma and donor cells together and incubating at 37°C. Once incubation is completed the mixture is taken through to antiglobulin phase with either Anti-IgG or polyspecific antiglobulin reagent. This testing can be performed using a variety of techniques including saline antiglobulin, LISS, albumin, or commercial methods such as gel or microtitre. Wherever possible this method should be the same as the method used for antibody detection.

Computer Crossmatch

Computer crossmatch can be used if the computer system being used has been validated on site to ensure that only ABO compatible red cells are selected for transfusion.

The computer crossmatch can be used only when the antibody screen is negative and there are no clinically significant antibodies in the patient’s history. Two determinations of the patient ABO/Rh must be performed, this can include either two determinations on the same sample, two different samples or a historic record. The donor units must be retyped by the hospital to confirm the donor ABO/Rh.
Recommendations

1. Each laboratory should review the use of an immediate spin crossmatch in patients with no clinically significant antibodies, as this is a faster and simpler method. A lab may choose not to do this.
2. The laboratory should have very clear guidelines as to when to use the antiglobulin method for crossmatching.

Standards References
CSA Draft Z902 – Section 10.6
CSTM 6th Edition – Section F2.11, 2.12 F3.00
DIRECT ANTIGLOBULIN TEST (DAT)

Standards

Standards require that direct antiglobulin testing be performed on an EDTA sample using a polyspecific antiglobulin reagent that contains both anti-IgG and anti-C3d. DAT testing on cord bloods may be performed using an anti-IgG reagent.

Transfusion Medicine Issue #11 – Policy

The Direct Antiglobulin Test should be performed in the following situations:

- Investigation of hemolytic disease of the newborn;
- Investigation of auto immune hemolytic anemia;
- Investigation of suspected hemolytic transfusion reactions;
- Validation of positive IAT results

Reagents

DAT performed on adults must be performed with a polyspecific antiglobulin reagent that contains anti-IgG and anti-C3d. All negative results must be confirmed using IgG sensitized cells.

DAT testing on cord blood may be performed using anti-IgG reagent because IgG antibodies coating the babies’ cells are the cause of hemolytic disease of the newborn.

Recommendations

10. Each lab should have a vial of polyspecific antiglobulin reagent available to investigate transfusion reactions even if antibody investigations are referred to a reference lab.
11. A DAT or alternate control such as Rh control must be performed to validate positive IAT reactions in testing such as weak D testing.
12. It is not necessary to perform a DAT or use an auto control as part of routine antibody screening. However when the antibody screen is positive this testing must be performed to confirm that the antibody is an alloantibody.

Standards References
CSTM 6th Edition – Section E7.00
Laboratory Quality Assurance Policy Manual
ANTIBODY IDENTIFICATION AND SPECIMEN REFERRAL

Reagents

Unexpected antibodies or red cell alloantibodies can be found in about 4% of the population. Immunization to red cell antigens may occur from pregnancy or transfusion. Antibody identification is carried out with a panel (usually 10) cells with known antigen composition from the major blood group systems. Various methodologies can be used for antibody identification but initially the same method as was used in the antibody screen should be employed. An autocontrol or DAT must be included to determine if the antibody is an autoantibody or an alloantibody.

Recommendations

1. Each Transfusion Service should have defined criteria for when a positive antibody screen is referred to a Reference Lab and under what circumstances blood can be released prior to the reference report.
2. All units that are issued prior to the identification of the cause of a positive screen should be crossmatch compatible with an antiglobulin or comparable technique. A positive screen should be crossmatch compatible with an antiglobulin or comparable technique if possible.
3. Each lab that performs antibody identification must have a procedure available for determining antibody specificity. This procedure must be performed by trained staff.
4. Whenever possible labs performing antibody identification using the “crossing out” technique should use cells that express a double dose of the antigen for exclusion.
5. Labs that are performing antibody identification should have antisera available to type the patient’s pre-transfusion cells for the corresponding antigen. It is necessary to confirm the presence of an antibody by the absence of the corresponding antigen on the patient’s cells on a pretransfusion specimen.
6. The attending physician must be notified when crossmatch compatible, antigen negative units are not available for transfusion.
PRODUCT SELECTION

Standards

Standards require that whole blood must be ABO group-specific and red blood cells must be ABO compatible for transfusion. All products should not be used after their expiration date without written approval from a physician. When possible Rh negative patients should receive Rh negative red cells. In cases of short supply, Rh positive red cells can be substituted for Rh negative red cells with the approval of the medical director.

Plasma and cryoprecipitate must be ABO compatible with the recipient red cells. The donor plasma in platelets should be ABO compatible with the recipient’s red cells. A policy should be in place to define acceptable alternatives when all products are not available.

In the presence of clinically significant antibodies or when the patient has a history of clinically significant antibodies, the red cells selected for transfusion must be crossmatch compatible and negative for the corresponding antigen. When this is not possible, the medical director must approve the transfusion.

Standards References
CSA Draft Z902 - Section 10.7
CSTM 6th Edition - Section F2.11 – 2.12 F7.00 F6.00
EMERGENCY TRANSFUSION

Standards

In situations where the recipients’ condition makes it impossible to complete testing prior to transfusion, it is sometimes necessary to release blood without pre-transfusion testing.

Standards require that previous admission records cannot be used to determine the recipient ABO and Rh. If the recipient ABO/Rh has not been completed the patient must receive group O red cells and group AB plasma products. Red cells should be Rh negative for children and women of childbearing age. If there is sufficient time to complete the recipient ABO/Rh, blood component units of the appropriate group should be issued. If the compatibility testing is not complete there must be a label affixed to the unit that clearly indicates that testing is not complete. Transfusion records must include a signed declaration by the requesting physician confirming that the clinical situation was sufficiently urgent to justify releasing the product prior to testing.

Compatibility testing should be completed as quickly as possible and if there is an incompatibility the attending physician and the medical director should be notified immediately. Compatibility should be confirmed by the use of an immediate spin crossmatch or ABO grouping the donor units prior to complete pre-transfusion testing.

When a recipient has received a volume equivalent to his blood volume within a 24 hour period it is considered to be a massive transfusion. Pre-transfusion testing may be abbreviated according to procedures and policies established.

Recommendations

1. The decision when to use Rh negative red cells for unmatched blood lies with the Transfusion Service and should be addressed in their procedures and policies. There is concern for women beyond childbearing age and men with the current presence of anti-D (this antibody is no more common than other alloantibodies). It is recommended that these decisions be made with stock shortages of O negative products in mind. If the O negative stock is depleted for an 87-year-old male they may not be available for a 23-year-old female.
2. If the Transfusion Service is not grouping all of their donor units on arrival it is a good idea to group some O positive and O negative units to hold for use in unmatched situations.
3. Each Transfusion service should determine the number of O negative red cells transfused before a patient cannot be switched back to their own
blood group. The amount of donor plasma present on A S3 red cell is small. To determine this, testing can be done between the patient serum or plasma and either A or B cells to see if there is circulating anti-A or anti-B in the patient sample.

4. Each Transfusion service should have a policy for managing Rh negative recipients who receive Rh positive blood components.

Standards References
CSA Draft Z902 – Section 10.9.3
CSTM 6th Edition – Section F6.00
CORD BLOOD TESTING

Standards

Standards require that Rh negative women who do not have evidence of immunization to D should receive Rh Immune Globulin (RhiG) at 28-32 weeks gestation and within 72 hours of delivery of an Rh positive infant, abortion, amniocentesis and any manipulation of the fetus that could cause fetomaternal hemorrhage. The RhiG should be administered within 72 hours but if this has passed it may be given up to 28 days.

A test should be performed to determine the amount of fetal-maternal bleed in non-immunized Rh negative women who deliver an Rh positive infant to determine if additional RhiG is required for effective prophylaxis. Weak D testing must be performed on all Rh negative infants of Rh negative mothers to confirm that they are not Rh positive. RhiG must be given to all Rh negative mothers who deliver a weak D positive baby.

When a Direct Antiglobulin Test (DAT) is performed, a monospecific anti-IgG reagent can be used.

Recommendations

1. It is necessary to perform blood grouping and weak D testing on all babies of Rh negative mothers to determine if the mother is eligible for RhiG.
2. Mothers with clinically significant antibodies are at risk to deliver babies with Hemolytic Disease of the Newborn (HDN). Cord bloods from these babies should be tested immediately after delivery to determine the risk. This testing should include ABO/Rh, DAT and antigen testing of the cord for the maternal antibody as well as maternal blood group and antibody testing. Additional testing should be evaluated on a case-by-case basis.
3. Cord testing should be performed when HDN is suspected or the baby is jaundiced. This can occur from an ABO incompatibility (usually a group O mother delivering a group A or B infant) and can be confirmed with a DAT. ABO/Rh grouping is not required unless the DAT is positive.
4. Additional testing that should be performed should include hemoglobin or hematocrit and a bilirubin level.
5. Cord ABO/Rh records cannot be used as previous records for ABO/Rh typing as they may be invalid.

Standards References
CSA Draft Z902 – Section 11.9
CSTM 6th Edition – Section H8.00
PRODUCT STORAGE
STORAGE

Standards

Standards require that blood components be stored according to the manufacturer’s recommendations at temperatures optimal for their function and safety. Written procedures must be available for alternate storage in the event of equipment failure.

Blood components shall be stored separately from donor samples, recipient samples, tissues for transplantation and reagents. Blood components that do not have the testing completed or do not pass inspection shall be segregated from the regular inventory. Products for disposal shall be disposed in accordance with municipal and provincial regulations.

Transfusion Medicine Issue #4 – Storage of red blood cells Policy

a) The Blood Bank refrigerator must be maintained at 1-6 degrees Celsius at all times.

b) Red blood cell products not maintained in a blood bank refrigerator must be stored at 1-6 degrees Celsius for a maximum 24 hours and monitored with a calibrated high/low thermometer.

Transfusion Medicine Issue #5 – Storage of platelets Policy

Institutions storing platelets must provide proper agitation (continuous gentle agitation) at 20-24 degrees Celsius for storage of up to 5 days from collection.

Transfusion Medicine Issue #6 – Storage of fresh frozen plasma, cryosupernatant and cryoprecipitate.

Fresh frozen blood components must be stored at -18 degrees Celsius or lower for a maximum of 12 months from the time of donation.

Transfusion Medicine Issue #7 – Storage of fractionated products

All fractionated products must be stored according to the manufacturer’s instructions.

Recommendations

1) All labs must have a current copy of Canadian Blood Services Circular of Information to use as guidance for product storage.

2) All labs must ensure that there is documentation of storage and transport of all blood components.
3) Appendix 1 has a complete listing of common components and storage and transportation temperature ranges as a reference.

Standards References
CSA Draft Z902 - Section 9.4
Laboratory Quality Assurance Policy Manual
PRODUCT PREPARATION
THAWING

Standards

Standards require that frozen plasma, cryoprecipitate and cryosupernatant plasma be thawed at 30-37°C in a waterbath. Alternately, a microwave device approved for this purpose may be used. Once thawed plasma and cryosupernatant plasma must be maintained at 1-6°C and used within 24 hours of thawing. Cryoprecipitate must be maintained at 20-24°C and used immediately or within 4 hours of thawing.

A protective over bag shall be used when thawing takes place in a waterbath. Waterbaths used to thaw blood components should not be used for incubation of tests containing biological sample.

All thawed products must be labeled with the modified expiry date immediately upon completion of the thawing process.
POOL

Standards

Standards require that a pooled product contain only units of the same ABO group. The label of the pooled product must include: component name, number of units, name of preparing facility, unique identification of the component, approximate volume and the ABO and Rh of the components in the pool.

When products are pooled the pool is now an “open system” and must be transfused with 4 hours of pooling. All pools must be labeled with the modified expiry date and time.

Recommendations

1. Platelets do not have to be pooled prior to issue. It is the decision of the transfusing facility whether to pool or not. Platelets can be administered as single units one after the other.
2. Pooling can be performed with either a specially designed pooling set or a plasma transfer set.
3. It is important that all pooling be performed in an aseptic manner to reduce bacterial contamination.

Standards References
CSA Draft Z902 - Section 10.8
CSTM 6th Edition - Section G5.00 H5.00
RECONSTITUTION OF PRODUCTS

Certain fractionation products such as Factor VIII require reconstitution prior to infusion. These should be reconstituted according to the manufacturer’s directions using aseptic technique. The transfusing facility should determine whether this is done by the laboratory or on the ward.
PRODUCT INFUSION
BLOOD AND COMPONENT INFUSION

Standards

Standards require:

1. There must be a written policy on obtaining informed consent for transfusion.
2. There must be written notification for all recipients receiving blood components.
3. Transfusions must be prescribed and administered under medical direction and the physician should specify the infusion rate.
4. Infusing hospitals must have a mechanism to trace all transfused products from receipt to infusion.
5. A transfusion should be completed within 4 hours of removing the unit from its controlled environment.
6. Red cells that have been held at room temperature for 30 minutes should not be returned to the useable inventory.
7. The recipient must be positively identified.
8. If there is a discrepancy found in the patient or blood component identification the transfusion must not be administered until discrepancy is resolved.
9. Blood components must be transfused through a sterile pyrogen-free transfusion set that has a filter designed to retain particles.
10. Before infusion the administration line and filter shall be filled with a compatible solution. A 0.9% sodium chloride solution is recommended.
11. Air must not be introduced into the blood bag or administration set.
12. Drugs or medications shall not be added to blood components. A sterile 0.9% sodium chloride solution may be added to a blood component on the order of a physician.
13. Administration sets must be changed every 24 hours or as recommended by the filter manufacturer. The set must be changed after four units of red cells have been infused or the set becomes occluded.
14. Recipient vital signs must be recorded, prior, during and after the transfusion.
15. The recipient shall be observed during and after the transfusion for suspected adverse events.
16. Following transfusion a blood transfusion record must be added to the recipient’s medical record.
17. If blood is warmed the device must be validated and meet national safety standards and be equipped with a mechanism to maintain the temperature below 42°C and must have an alarm and a visible thermometer.
18. Transfusion Services must have a policy indicating which categories of recipients are to receive irradiated blood components and a mechanism to ensure that once a patient has received irradiated products that all cellular transfusions are irradiated as long as clinically indicated.
Recommendations

1. Hospitals using perioperative collection and hospital based autologous or directed donation programs should check the CSTM and CSA standards for processing guidelines.

Standards References
CSA Draft Z902 - Section 11 and 12.5
CSTM 6th Edition - Section K3.00
TRANFUSION COMPLICATIONS AND ERRORS

Standards

The Transfusion Service must have procedures in place for documenting, reporting, evaluation and follow-up of all adverse transfusion events. A list of common signs and symptoms must be included in the nursing and transfusion service manuals. All errors and accidents must be reported to the Hospital Transfusion Committee. All clinically significant reactions must be reported to the blood supplier.

Suspected Hemolytic Reactions

When a hemolytic transfusion reaction is suspected the transfusion must be stopped immediately. The identification of the patient, the pre-transfusion specimen, the labeled blood product, the issue voucher and all other documents must be checked to exclude clerical errors. A blood specimen must be collected from the patient and a minimum investigation must include a visual inspection for hemolysis and a direct antiglobulin test. Further testing should be carried out in accordance with written procedures.

Suspected Bacterial Sepsis

When bacterial sepsis is suspected the transfusion must be stopped and the remaining blood component should have a gram stain and cultures on appropriate media incubated at both 25°C and 35°C. Blood cultures should be obtained from the recipient.

Transfusion Transmitted Diseases

The physician must notify the Transfusion Service if the patient develops a transfusion-transmitted disease following transfusion. The Canadian Blood Services must be notified to initiate a traceback investigation.

See Appendix 3 for Categories and Symptoms of Transfusion Reactions

Standards References
CSA Draft Z902 - Section 17
CSTM 6th Edition - Section M
EQUIPMENT
BLOOD STORAGE EQUIPMENT

Standards

1. Temperature records must be kept for a minimum of 5 years past the expiry date of the product or date of product use.
2. All equipment must have an emergency power supply in the event of a power failure.
3. Blood storage equipment must be cleaned on a regular maintenance schedule and documented.
4. The temperature range that the alarms ring must be checked at least every 6 months and documented with corrective action.
5. The functioning of the recording device must be checked every six months and documented with corrective action.
6. There must be a policy outlining actions to be taken when the storage temperatures exceed the allowable range.

Refrigerators and Freezers

Refrigerators and freezers should have the capacity that ensures the maintenance of the appropriate temperature throughout. They must have alarm systems with audible signals that are located in an area to allow them to be continuously monitored. Refrigerators must have the temperature-sensing device immersed in a fluid equal in volume and heat characteristic to the smallest unit of donor red cells in storage. If they do not have a continuous temperature-monitoring device, the temperature of refrigerators and freezers must be documented manually using a calibrated thermometer at least every 4 hours. The recorded temperatures must be reviewed daily and documented.

Platelet storage

Equipment for platelet storage must ensure constant gentle agitation of the platelet product. Platelets must be stored at 20–24°C, this can be accomplished by the use of a specially design platelet incubator or if stored at room temperature the ambient temperature must be checked and documented every 4 hours.

Waterbath for Thawing

Waterbath temperature must be calibrated to the required temperature and the temperature checked each time they are used. The water level should be checked daily and before use to ensure sufficient volume. Waterbaths used for thawing must not be used for test incubation.
Recommendations

1. Temperature records should be kept for 6 years, this allows for 5 years past the expiry of the longest dated product that is 1 year.
2. A 10% glycerol solution has the same thermal properties as a unit of blood; this can be prepared using 1 volume of glycerol to 9 volumes of water. This should be changed quarterly as it can be bacterially contaminated.
3. Testing for alarm ranges can be accomplished by immersing the probe in fluid with a calibrated thermometer and slowly increasing or decreasing the temperature then documenting the temperature at which the alarm sounds.
4. Equipment maintenance and malfunction records must be kept for the lifetime of the equipment.

Standards References
CSA Draft Z902 - Section 9.4
CSTM 6th Edition - Section C
TESTING EQUIPMENT

Standards

Centrifuges
The speed of rotation and timing must be calibrated on installation, following servicing and every six months.

Heating Devices
Heating devices such as a waterbath or drybath must have their temperature checked each time they are used and recorded daily. Records of corrective action must be available.
QUALITY ASSURANCE
QUALITY ASSURANCE INITIATIVE

Standards

Procedures
Operating procedures must be reviewed at least annually and updated as necessary by a knowledgeable person who has the authority to make changes. Procedure must also be reviewed when there is evidence of an adverse event or changes in regulatory requirements. The procedures should be written in a consistent format and be available to staff at all times. They must be machine printed, handwritten changes may be made temporarily when needed and these must be initialed and dated. Handwritten changes must be incorporated within 12 months of the date they were made. The procedures must include:
1. Name of facility
2. Title and Purpose
3. Unique identification number
4. Date implemented and revision dates
5. Signature and date of authorization
6. The page number and total pages
7. A clear outline of steps
8. Clearly defined responsibilities for checking, review or approval
9. Locations where the procedure is found

The facility must use document control to track all changes and revision to the procedures. All deleted procedures must be replaced and a working copy of the deleted procedure kept indefinitely.

Personnel
The facility must have staff with documented education, training and experience and skills necessary to ensure that they can perform assigned duties. There must be an organizational chart and names, qualifications and job descriptions documented. Each facility must identify training needs for all staff and develop written training programs including initial and ongoing training. Effectiveness of training must be evaluated at least annually through formal competency evaluation. This should include practical and theoretical knowledge or procedures including direct observation of performance, written tests to assess problem-solving skills, knowledge of operating procedures and theory and assessment of performance using blind specimens. Each staff must participate in proficiency testing using routine procedures and equipment.

Transfusion Committee
Each Transfusion service or region must have a Transfusion Committee. Physicians, nurses, transfusions staff and administrative personnel should be represented and their purpose is to:
1. Define and evaluated transfusion practice
2. Set criteria for evaluation of ordering practices, usage, administration policies and the ability of the service to meet the recipient needs.
3. Recommend corrective measure if necessary
4. Disseminate transfusion medicine information and education
5. Evaluate reports of adverse transfusion events and transfusion errors

Quality System
All transfusion services must have a quality system in place and should have a qualified quality assurance specialist on staff. The quality system should define the responsibility of each individual staff member, operating procedure review, internal and external audits, procedural changes and deviations from normal operating procedures.

Process Control
The Transfusion Service must have validated operating procedures in place to ensure the quality of its service. Procedures should include change control, proficiency testing program, quality control, supplier information, identification and traceability.

Standards References
CSA Draft Z902 - Section 4.0
CSTM 6th Edition - Section A General Policies
Quality Control in the Transfusion Medicine Laboratory

Questions have been raised to the Transfusion Medicine Quality Assurance Committee regarding the amount and frequency of Serologic Quality Control necessary for a safe service. The Canadian Society for Transfusion Medicine recently published the "Guidelines for Serologic Quality Control in the Transfusion Medicine Laboratory". This document presents the **minimum guidelines** for the quality control of antisera and red cell products routinely used. The Quality Assurance Committee feels that it is necessary to perform some additional testing to maintain a safe Transfusion Medicine Service.

The most effective quality control for the crossmatch test are the controls which are part of the routine testing. The forward and reverse ABO grouping must agree and these two tests actually serve to control each other, any discrepancy should be fully investigated and resolved before blood is transfused. Previous patient records are reviewed to ensure consistent grouping interpretation with previous results. The use of an Auto control, Rh control or DAT along with the Rh grouping ensures that false positive reactions will be detected. IgG sensitised red blood cells must be used for all negative testing using Anti-Human Globulin to ensure the IgG reactivity of the reagent. These controls along with some additional testing are needed to ensure a safe service.

Good Quality Control must include a mechanism to document corrective action for reagents which do not meet quality control guidelines, such as documentation of repeat testing or reagent replacement.

Upon Receipt:

**All Reagents**

1. The antisera must be visually inspected to ensure that cloudiness, turbidity and/or particulate matter are not present.
2. Each vial of reagent red cells received must be visually inspected to ensure that hemolysis and/or discoloration is not present.
3. The results of the visual inspection, reagent lot number, expiry date, date of inspection, and the individual performing the inspection must be documented.

When Used:

**All Reagents**

1. The antisera must be visually inspected to ensure that cloudiness, turbidity and/or particulate matter are not present.
2. Each vial of reagent red cells must be visually inspected to ensure that hemolysis and/or discoloration is not present.
3. Document abnormal/unusual findings.
4. The Laboratory must be able to identify the lot number and expiry date for each reagent and the date of testing as well as the individual performing the test.
Anti-A, Anti-B, A₁ cells and B cells
1. Each of these reagents should be tested against a positive and negative control.

<table>
<thead>
<tr>
<th></th>
<th>A₁ cells</th>
<th>B cells</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-A</td>
<td>2+</td>
<td>-</td>
</tr>
<tr>
<td>Anti-B</td>
<td>-</td>
<td>2+</td>
</tr>
</tbody>
</table>

Note: The reaction strength must be a minimum of 2+ positive.

Monoclonal Anti-D, SI, SII, AND SIII
1. Anti-D versus the O cells should give the following reactions.

<table>
<thead>
<tr>
<th>O cells</th>
<th>SI</th>
<th>SII</th>
<th>SIII</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2+</td>
<td>2+</td>
<td>-</td>
</tr>
</tbody>
</table>

Note: The reaction strength must be a minimum of 2+ positive.

Anti-Human Globulin
1. Anti-Human Globulin must be tested against IgG sensitised cells. The reaction must be 2+ or stronger.

Frequency of Quality Control Testing
Quality control testing should be performed when the reagents are used. The recommended Quality control protocol is easy to perform therefore it can be done at the time of testing or call back. Larger centres which are performing more testing need only run controls daily.

References:
APPENDIXES
## Appendix 1  Blood and Blood Component Storage, Transportation and Expiration

<table>
<thead>
<tr>
<th>Component</th>
<th>Storage</th>
<th>Transport</th>
<th>Expiration</th>
<th>Additional Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cells AS3</td>
<td>1-6°C</td>
<td>2-10°C</td>
<td>42 days</td>
<td></td>
</tr>
<tr>
<td>Red Blood Cells CPD/CP2D</td>
<td>1-6°C</td>
<td>2-10°C</td>
<td>21 days</td>
<td>Low volume units</td>
</tr>
<tr>
<td>Red Blood Cells CPDA1</td>
<td>1-6°C</td>
<td>2-10°C</td>
<td>35 days</td>
<td></td>
</tr>
<tr>
<td>Whole Blood CPDA1</td>
<td>1-6°C</td>
<td>2-10°C</td>
<td>35 days</td>
<td>Usually A utologous</td>
</tr>
<tr>
<td>Random platelet and Platelet pheresis</td>
<td>20-24°C</td>
<td>20-24°C</td>
<td>5 days</td>
<td>Gentle agitation during storage</td>
</tr>
<tr>
<td>Platelets pooled</td>
<td>20-24°C</td>
<td>20-24°C</td>
<td>4 hours</td>
<td>Gentle agitation during storage</td>
</tr>
<tr>
<td>Fresh Frozen Plasma</td>
<td>≤ -18°C</td>
<td>Keep frozen</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>Fresh Frozen Plasma once thawed</td>
<td>1-6°C</td>
<td>2-10°C</td>
<td>24 hours</td>
<td>Thaw at 30 – 37 °C</td>
</tr>
<tr>
<td>Frozen Plasma</td>
<td>≤ -18°C</td>
<td>Keep frozen</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>Frozen Plasma once thawed</td>
<td>1-6°C</td>
<td>2-10°C</td>
<td>5 days</td>
<td></td>
</tr>
<tr>
<td>Cryosupernatant plasma</td>
<td>≤ -18°C</td>
<td>Keep frozen</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>Cryosupernatant plasma thawed</td>
<td>1-6°C</td>
<td>2-10°C</td>
<td>24 hours</td>
<td></td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>≤ -18°C</td>
<td>Keep frozen</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>Cryoprecipitate once thawed</td>
<td>20-24°C</td>
<td>20-24°C</td>
<td>4 hours</td>
<td>Thaw at 30-37°C</td>
</tr>
<tr>
<td>Irradiated blood components</td>
<td></td>
<td></td>
<td></td>
<td>Outdate may be shortened for neonates</td>
</tr>
</tbody>
</table>

This table shows products in common use, check Circular of Information for products not listed.
Appendix 2  Specimen and Record Retention Guidelines

It is imperative to the functioning of the Transfusion Medicine Service that specimens and records are maintained for an adequate amount of time. The Canadian Society for Transfusion Medicine and Canadian Standards Association has established guidelines for the minimum retention time for specimen and records. This information can be stored electronically or hard copy.

Documents Received From the Canadian Blood Services
- Issue Vouchers Indefinitely
- Information Related to Special Access Products Indefinitely
- Lookback / Traceback Information Indefinitely
- CBS Supplier Correspondence Related to Blood Products Indefinitely

Documents Generated by the Transfusion Medicine Service
- Quality Control Records
  - Reagents and Test Controls 5 years
  - External Proficiency Testing 5 years
  - Equipment (e.g.-Serological Centrifuges) 5 years
- QA Records
  - Quality Assurance Reports 5 years
  - Internal Audit Results 5 years
  - Transfusion Committee Minutes 5 years
  - Monthly Blood Component Inventory Reports 5 years
  - Workload Reports 3 years
  - In-service Education Documentation 5 years
  - Record of blood inspection prior to release 5 years
- Copies of Revised and Deleted Procedures and Policies Indefinitely
- Employee Signatures, Initials and Computer ID 10 years*
- Temperature Monitoring Records for Blood Products 6 years
- Daily records for issue of Blood and Blood products Indefinitely
- Testing Records
  - Includes antibody investigation/resolution Indefinitely
  - Transfusion Reaction Investigation Forms
- Non-Transfusion Serological Testing Results (e.g. cord blood) 3 years

Specimens
- Segments From Donor Units 1 week post transfusion
- Serum or Plasma and cells from Transfused Patients (pre-transfusion) 1 week post transfusion
- Cord Blood 1 week
- All Other Patient Specimens 1 week
- Kleihauer-Betke Slides 1 year
*From date of last use
### Appendix 3 Categories and Symptoms of Adverse Transfusion Reactions

<table>
<thead>
<tr>
<th>Type</th>
<th>Etiology and Incidence</th>
<th>Symptoms – Presentation</th>
<th>Laboratory testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hemolytic</td>
<td>Red cell incompatibility (1:38,000 – 1:70,000)</td>
<td>Chills, fever (&gt; 1°C), hemoglobinuria, hypotension, renal failure, DIC, back pain, pain along infusion site and anxiety</td>
<td>• Clerical check&lt;br&gt;• DAT&lt;br&gt;• Visual inspection for hemoglobin&lt;br&gt;• Further tests as per policy</td>
</tr>
<tr>
<td>Febrile</td>
<td>Antibody to donor white cells (1:3 – 1:200)</td>
<td>Chills, increased temperature (&gt; 1°C), headache and vomiting</td>
<td>• Rule out hemolytic reaction</td>
</tr>
<tr>
<td>Urticarial (allergic)</td>
<td>Antibody to donor plasma proteins (1:33 – 1:100)</td>
<td>Hives, pruritis and flushing</td>
<td>• Rule out hemolytic reaction</td>
</tr>
<tr>
<td>Anaphylactic</td>
<td>Antibody to IgA and C4 (1:20,000 – 1:50,000)</td>
<td>Hypotension, urticaria, bronchospasm</td>
<td>• Rule out hemolytic reaction&lt;br&gt;• Anti-IgA and Quantitative IgA level</td>
</tr>
<tr>
<td>Transfusion Related Acute Lung Injury (TRALI)</td>
<td>Anti-WBC antibodies in donor (1:5,000 – 1:190,000)</td>
<td>Hypoxemia, respiratory failure, hypotension and fever</td>
<td>• WBC antibody screen in donor and recipient</td>
</tr>
<tr>
<td>Circulatory Overload</td>
<td>Volume Overload (&lt;1:100)</td>
<td>Shortness of breath, cough, tachycardia, hypertension and headache</td>
<td>• None</td>
</tr>
<tr>
<td>Air Embolism</td>
<td>Air infusion via line</td>
<td>Shortness of breath, cyanosis, cough, hypotension, cardiac arrhythmia</td>
<td>• None</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>Infusion of cold blood</td>
<td>Cardiac arrhythmia</td>
<td>• None</td>
</tr>
<tr>
<td>Delayed Hemolytic</td>
<td>Anamnestic immune response to RBC antigens (1:5,000 – 1:11,000)</td>
<td>Fever, jaundice, drop in hemoglobin, positive antibody screen</td>
<td>• Antibody screen&lt;br&gt;• DAT&lt;br&gt;• LDH, bilirubin</td>
</tr>
<tr>
<td>Graft-vs-Host Disease</td>
<td>Donor lymphocytes engraft in recipient and attack host tissues</td>
<td>Rash, anorexia, nausea, vomiting, diarrhea, pancytopenia, fever</td>
<td>• Skin biopsy</td>
</tr>
<tr>
<td>Posttransfusion Purpura</td>
<td>Recipient platelet antibodies destroy autologous platelets</td>
<td>Thrombocypenic purpura, bleeding 8-10 days post transfusion</td>
<td>• Platelet antibody screen</td>
</tr>
<tr>
<td>Iron Overload</td>
<td>Multiple transfusions in a transfusion dependent patient</td>
<td>Diabetes, cirrhosis and cardiomyopathy</td>
<td>• Iron studies</td>
</tr>
</tbody>
</table>
Appendix 4  Procedure Guidelines

All procedures must include the points listed in the document section of the Quality Assurance section. They should be written in the following format.

1. Title: this should clearly state the intent of the document. “Antibody Screening using the Gel Technique”
2. Purpose: This statement clearly states the documents purpose. “This procedure provides instruction for... ...”
3. Policy: If this procedure refers to a specific policy list the policy here.
4. Specimen: A list of acceptable specimens.
5. Reagents: A list of reagents to be used, can be included in table form. Procedures for preparing reagents do not need to be included unless they are prepared before each time the procedure is done. Descriptions of reagents are not required, the user can be referred to the Antisera Package Insert Manual.
7. Supplies: A list of necessary supplies
8. Quality Control: If the quality control for this procedure is included when the procedure is performed this should be included here otherwise the reader should be referred to the daily quality control procedure.
9. Procedure: This section should provide instruction for “how to do” a particular task in a clear stepwise fashion.
10. Method Limitations: This section should provide information about problems or pitfalls that may occur in the performance of this procedure.
11. Interpretations: How the test is to be interpreted.
12. Results Reporting: How to enter results into computer or onto a manual form.
13. References: A list of materials used such as manufacturers package directions or texts.
14. Related Documents: Other procedures or policies that relate to this procedure.

Refer to sample procedure on next page.
ABO GROUPING

I PURPOSE

This procedure provides instructions for determining the ABO group in human blood.

ABO blood groups are determined by testing for the presence or absence of A and B antigens on the red cells and the presence or absence of Anti-A and Anti-B in the serum.

Include a list of who is qualified to perform this procedure in your Lab. Testing is to be performed only by MLT and CLXT who have been grandfathered to perform Blood Bank procedures.

II SPECIMEN

Whatever specimen is required in your Lab for testing. Ensure that you define the rejection criteria and the age of the specimen required for testing.

III MATERIALS

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Supplies</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Isotonic Saline</td>
<td>• 12 x 75 mm test tubes</td>
<td>• Calibrated erological centrifuge</td>
</tr>
<tr>
<td>• Anti-A</td>
<td>• Pasteur pipettes</td>
<td></td>
</tr>
<tr>
<td>• Anti-B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• A1 cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• B cells</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(You don’t need actual reagent descriptions because you will have copies of the package inserts and can refer to those)
IV QUALITY CONTROL

Reagents must be tested each day with appropriate controls as per Procedure # XXX. (Describe your QC procedure)

V PROCEDURE

1. Label 4 tubes with the patient last name on all tubes and the following on each separate tube (Anti-A, Anti-B, A1c, Bc)
2. Place 1 drop of anti-A antisera in the tube labeled Anti-A
3. ...........

VI INTERPRETATION

<table>
<thead>
<tr>
<th>Anti-A</th>
<th>Anti-B</th>
<th>A1 cells</th>
<th>B cells</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>A</td>
</tr>
<tr>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>B</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>O</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>AB</td>
</tr>
</tbody>
</table>

VII RESULT REPORTING

Enter a description of how these results are to be recorded in your laboratory

VIII PROCEDURAL NOTES

1. All discrepancies must be resolved prior to the group being reported
2. Other important points

XI REFERENCES

XII DISTRIBUTION

It is important to document where copies of this procedure are in case there needs to be changes
Appendix 5  Useful References

Required References

1. Circular of Information – Most recent version; Canadian Blood Services – Saskatchewan Centre Regina
2. Canadian Standards Association Blood and Blood Component Z902; currently in draft, expected Jan 2004,
    774 Promenade Echo Drive
    Ottawa, Canada K1S 5N8
    Phone (613) 260-6198
    Fax (613) 730-1116
    www.transfusion.ca

Others

1. Canadian Medical Association Journal Guidelines for Red Blood Cell and Plasma Transfusion for Adults and Children; Supplement to CAN MED ASSOC J 1997;156(11)
    8101 Glenbrook Road
    Bethesda, MD 20814-2749
    Phone (301) 907-6977
    Fax (301) 907-6895
    www.aabb.org
Appendix 6  Transfusion Record Definitions

TRACEBACK - The name and any other available information about a transfusion recipient is supplied to the institution and it is the institution's responsibility to supply available information on all blood components, which were transfused to that individual.

LOOKBACK - The unit number, type of component, blood group and date that the unit was drawn is supplied to the institution and it is the institution's responsibility to supply either the demographic information of the person who received the product or the record of the final disposition of the product. (i.e. was it discarded?)

To facilitate either a lookback or a traceback the institution must keep records of the full name, date of birth and either the current hospital number or the Provincial Health Number for all persons receiving transfusions of any blood components. When the units are transfused to an unidentified patient the Transfusion Service must update their records with the correct information once the identity has been established. The institution must also keep a record of all units that are transferred to another institution or discarded for any reason along with the reason.

DOCUMENTS

Issue Vouchers from Canadian Blood Services (CBS) - The documentation that accompanies a shipment of blood products. Once this has been checked and verified to be correct this copy must be kept indefinitely as a record of which products were received.

Correspondence Related to Blood Components - This includes any letters or faxes that are received from CBS or other suppliers related to product information, changes, quarantine or recall of blood components.

Documents Related to Lookback or Traceback - Lookback and traceback notification is accompanied by a confirmation of Receipt of Notification that must be returned to that within 3 working days. The institution is required to keep a copy of this notification along with a copy of the lookback or traceback form. It is important to document all correspondence associated with the lookback or traceback along with the dates.

Daily Records for Issue of Blood Components/Products - All issue of blood and blood products must be documented along with the signature of the person removing the blood product from the lab. This can be accomplished by the use of a logbook system, which documents the name and identification number of the patient along with the name of the person who picked up the product from the lab.

Patient Data - This include copies of worksheets for a blood grouping and antibody screening along with antibody investigation information such as panel sheets. The lab must also keep all documentation of all testing and resolution involved with a transfusion reaction investigation.
Method Revision - Copies of all deleted procedures must be kept as a historic record in case of future questions.

Blood Components & Product Final Disposition Records - Records must be kept of the disposition of all blood products, whether the products were discarded or issued and if they were discarded the reason for discard.

Tissue & Bone Banking Donor & Inventory Records - Institutions that operate a tissue bank must keep records of all donor data including infectious disease results and documentation of donor questioning for high risk factors.
Appendix 7  Use of Plasma or Serum in Antibody Screening

The purpose of an antibody screen is to detect clinically significant antibodies that will decrease red cell survival. To facilitate the detection of these antibodies serological testing must be done at 37°C and include an indirect antiglobulin procedure. The antiglobulin reagent that has been classically used in antibody screening is a polyclonal reagent that contains Anti-IgG and Anti-C3d.

More recently the use of an Anti-IgG reagent for antibody screening has become common. Anti-IgG cannot be used for direct antiglobulin testing (DAT) by itself; it must be used in conjunction with polyclonal antihuman globulin. Anti-IgG allows for the detection of most clinically significant antibodies while screening out the nuisance cold agglutinins that bind complement and are detected in the antiglobulin phase. There have been very few clinically significant IgG antibodies described in the literature that are solely complement binding, these antibodies have mostly been in the Kidd family. The need for the Transfusion Medicine Service to supply blood products to patients in a timely manner without the nuisance of unnecessary antibody investigation has facilitated the popularity of the reagent change. Laboratories that are using gel, microtitre or Polyethylene glycol (PEG) must use the Anti-IgG reagent.

The change from polyclonal to Anti-IgG reagents has allowed Transfusion Medicine to use plasma instead of serum in testing. Anticoagulants found in plasma chelate calcium that is necessary for the complement cascade and this is the reason why serum was used for Transfusion testing when reagents containing Anti-C3d were required. The use of plasma has advantages over serum.

- Time savings from clotting and centrifugation
- No interference from fibrin strands due to improperly clotted specimens
- More flexibility in tube type

Most laboratories have found that the change from polyclonal antihuman globulin to Anti-IgG has decreased the number of pre-warm and repeat testing that is performed in the Transfusion Medicine Service.