Australian and New Zealand Society of Blood Transfusion

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GUIDELINES FOR TRANSFUSION AND IMMUNOHAEMATOLOGY LABORATORY PRACTICE

ANZSBT
Australian & New Zealand Society of Blood Transfusion

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Summary of amendments to the 1st Edition, Revised January 2020

This 2nd edition has undergone review and update. Below is a brief summary of changes however it is recommended to read each section to fully understand the intent of updates.

General changes:

There are changes to terminology to be concordant with other ANZSBT guidelines and to align with the relevant NPAAC Standards.

Written policies are now stated where required for specific circumstances – concordant with the NPAAC Requirements for transfusion laboratory practice.

The intent of national statements produced by external groups and relevant to this guideline are included.

Section 1:	Inclusion of information on patient sex and gender. Updated information on patient identification
Section 2:	The information on test controls is relocated to section 8, Quality management
Section 3:	Updated and expanded selection of products in concordance with national statements.
Section 4:	Updated selection of products in emergency bleeding in concordance with national statements. Inclusion of information for patients treated with monoclonal antibodies – previously an addendum to the guideline. Expanded information on transfusion support for allogeneic stem cell transplant. Changed ABO-mismatched renal transplants to ABO-mismatched solid organ transplants.
Section 5:	Updated information on storage and transport of blood products.
Section 6:	Updated information for investigation of transfusion reactions and reporting
Section 7:	Section renamed to Testing during pregnancy and at delivery. Updated information on availability of genotyping to include non-invasive prenatal testing.
Section 8:	The information on Governance of hospital transfusion committees is removed from this section and an informative statement is included as Appendix 2. Included section on controls for pretransfusion testing (previously in section 2). Expanded information on validation and verification processes.
Appendix 2:	Governance of hospital transfusion activities – informative. New appendix, this information was previously in section 8.

Contents

Introduction

The ANZSBT *Guidelines for transfusion and immunohaematology laboratory practice* are intended for Australian and New Zealand pathology laboratories that provide transfusion services and undertake immunohaematology testing. While describing minimum acceptable levels of practice, organisations may choose more stringent requirements.

These guidelines augment Australia's National Pathology Accreditation Advisory Council (NPAAC) *Requirements for transfusion laboratory practice*.[1] In New Zealand, they are referenced by International Accreditation New Zealand (IANZ) as requirements for accreditation of medical testing laboratories.[2]

The laboratory must have a documented quality management system that describes their organisational structure, policies, procedures, processes, and resources required for safe and appropriate laboratory and clinical practice. In this context, the provision of safe and appropriate practice requires:

- processes for patient identification that minimise clerical errors and misidentification
- correctly determining the patient's ABO group and ensuring compatibility, and performance of an antibody screen to detect clinically significant red cell antibodies
- diagnosis and management of haemolytic disease of the fetus and newborn (HDFN)
- adherence to the stringent requirements necessary for the use of information and communications technology, including laboratory information systems (LIS)
- contingency plans when routine systems are not available – these should include manual systems when there is loss of automation or the laboratory information system is offline or not functioning as it should
- suitable quality control (QC) programs for reagents, techniques, equipment and personnel
- appropriate storage and handling of blood components and products
- selection and provision of clinically safe and appropriate blood components and products
- appropriate investigation of adverse effects of transfusion
- appropriate retention of records, data and documentation as required by regulatory bodies which is vital for traceability.[3]

These guidelines acknowledge the broader transfusion and healthcare environment. Adherence to standards, guidelines, and documented policies and procedures is crucial to patient safety. The laboratory should be aware of relevant standards, requirements, or guidelines from national accreditation authorities, national blood services and other regulatory bodies. Where applicable, these will be noted in the guidelines.

Understanding recommendations

These consensus guidelines reflect the minimum acceptable level of practice. Guidance is provided in the form of recommendations, the strength of which is indicated by the following (modal) terms:

Must	Indicates a strongly recommended practice where compliance would be expected.
Should	Indicates a recommended practice where compliance would be expected but alternative practices may be acceptable.
May	Indicates a practice that is permitted within the context of the guidelines.

1. NPAAC *Requirements for transfusion laboratory practice* (5th edition; 2022) https://www.safetyandquality.gov.au/publications-and-resources/resource-library/requirements-transfusion-laboratory-practice-fifth-edition

2. AS LAB C7 *Specific criteria for accreditation: Medical testing* (ISO15189-2022) https://www.ianz.govt.nz/programmes/medical-laboratory

3. Ashford P, Butch S, Barhoush AO, Bolton W, Cusmai M, Espensen L, et al. *International Society for Blood Transfusion guidelines for traceability of medical products of human origin*. Vox Sang. 2023; 118: 587–597. https://onlinelibrary.wiley.com/doi/full/10.1111/vox.13473

1 Requests, specimens and record keeping

1.1 General principles

1.1.1 All requests must comply with these guidelines, although the laboratory may adopt more stringent requirements.

1.1.2 Specimens used for pretransfusion testing must have been collected in accordance with these guidelines. This includes specimens originally collected for other reasons; for example, prenatal or postnatal immunohaematology, haematology or biochemistry tests.

ⓘ Cord blood specimens should not be used for pretransfusion testing.

1.1.3 The laboratory should have a policy for managing requests associated with patients transferred from other hospitals, facilities or external locations outside of their jurisdiction.

1.2 Recording patient sex and gender

1.2.1 The term SEX is used when identifying the patient and recording relevant demographic details. It reflects the different biological and physiological characteristics of women, males, and intersex persons, such as chromosomes, hormones, and reproductive organs.

1.2.2 It is important to understand the distinction between **sex** and **gender** for transfusion purposes, especially in emergency situations. For example, transgender males may retain childbearing potential. Therefore, consideration should be given to following testing and transfusion requirements relevant to women.

1.2.3 It is acknowledged that sex and gender maybe used interchangeably or synonymously, and information systems may not have the provision to record them separately. Consideration should be given to capturing both sex and gender when information systems are updated. Local policies and guidelines for recording sex and/or gender for patient registration must be followed.

1.3 Electronic or ‘paperless’ systems

1.3.1 Laboratory information technology (IT) systems must comply with all applicable guidelines and standards. This includes standalone systems and those interfaced with institutional systems, such as the laboratory information system (LIS), patient admission system (PAS), hospital electronic medical record (EMR), or computerised prescriber order entry system (CPOE).

1.3.2 Electronic solutions are available that can variously integrate the LIS, EMR, mobile devices, barcode scanners, label printers, or radio-frequency identification (RFID) technology, and these can enhance safe and secure patient identification across the transfusion process.

1.3.3 All transactions within an electronic system must be securely and unambiguously recorded, with the ability to trace and attribute them to the operator performing them.

1.3.4 A unique electronic or digital signature or other appropriate system-generated identifier may be used to sign or initial a document or record (e.g. the declaration on a transfusion request) and has the same status as handwritten details.

1.3.5 The laboratory must have contingency plans, including manual systems, to manage occasions when electronic systems are unavailable and electronic patient or test records cannot be accessed.

1.3.6 Electronically stored information or records must be fully accessible for the entire regulated retention period with no changes to or loss of data and accommodating any subsequent

redundancy or changes to storage media, storage technology, or organisations responsible for maintaining storage.

1.4 Patient identification

1.4.1 Failure to correctly identify the patient (e.g. at specimen collection or before transfusion), prescribing the wrong product and transfusing the wrong patient are all causes of major morbidity and mortality.

1.4.2 Patient details, for example, provided on requests, specimens, and in laboratory records must comply with the requirements of the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for medical pathology services:*

- **three unique** identifiers must be used for requests, compatibility reports and labels, laboratory records; and
- **two unique** identifiers must be used when labelling the specimen (although three where practicable are recommended).[4]

1.4.3 The patient identifiers must include the patient's FULL NAME (surname and first name) and at least one of either DATE OF BIRTH (DOB) or a UNIQUE RECORD NUMBER such as a MEDICAL RECORD NUMBER (MRN) in Australia or NATIONAL HEALTH INDEX (NHI) number in New Zealand.

1.4.4 Other additional identifiers may be used as determined by local policies.[5]

These include:

- Unique ACCESSION NUMBER
- SEX
- PATIENT ADDRESS (for example, if the request originates outside the hospital)
- (in Australia) INDIVIDUAL HEALTHCARE IDENTIFIER (IHI)
- (in Australia) MEDICARE NUMBER (full 11 digits including the individual reference number [IRN] matched to the full name.

1.4.5 Alternative identifiers may be used in special circumstances, such as when patients are to remain anonymous.

1.4.6 The patient identifiers recorded on the request and specimen label must agree.

1.4.7 Procedures for patient identification must include the management of:

- patients without an identification wristband or who are unconscious, confused or otherwise unable to respond to direct questioning
- patients whose details change (e.g. when the identity of an unknown patient or newborn infant is subsequently established), including a procedure for linking or merging the different identities.

1.4.8 If the patient's identity is unknown or unclear (e.g. in the trauma or emergency setting), temporary or emergency identifiers must be used until the patient's identity is confirmed. Temporary medical record numbers should not be consecutive in events involving multiple casualties.

1.4.9 Temporary patient identifiers must be used for all blood components and/or product requests until the patient's identity is established and a new request (and a new specimen, if necessary) is received with the updated details.

1.4.10 Truncation of patient identifiers, for example, by laboratory and/or hospital information systems, is a potential cause of misidentification errors. The laboratory must have a policy

4. NPAAC *Requirements for medical pathology services (third edition; 2018)* https://www.safetyandquality.gov.au/publications-and-resources/resource-library/requirements-medical-pathology-services-third-edition-2018

5. National Safety and Quality Health Service Standards *Communicating for safety standard (second edition; 2021)* https://www.safetyandquality.gov.au/standards/nsqhs-standards

and procedure for handling the issues arising when long patient names (or other mandatory identifiers) are truncated or shortened.

1.5 Requests

1.5.1 A request must be received before the laboratory can undertake testing or the issue of blood components and/or products.

1.5.2 Requests that do not comply with the laboratory's requirements must not be accepted except at the discretion of the laboratory director.

1.5.3 Requests may be written, verbal, electronic (e.g., paperless systems), or any combination. A dedicated form is recommended for transfusion requests.

ⓘ The request is not a prescription, and in some organisations, practitioners other than doctors have the authority to generate requests for transfusion.

1.5.4 The request must clearly (and legibly) identify the patient with **THREE unique identifiers**).

1.5.5 When collecting specimens, the institutional policy may permit the phlebotomist to amend patient identifiers on the request to match the **confirmed details** provided by the patient.

1.5.6 Requests for immunohaematology testing must contain a declaration, like the one shown below, that has been signed by the person collecting the specimen:

> *I certify that I collected the accompanying specimens from the above patient whose identity was confirmed by enquiry and/or examination of their name band and I labelled the specimen immediately following collection and before leaving the patient.*

ⓘ The declaration may be built into electronic systems and record the collector's details using an electronic or digital identifier.

1.5.7 The request should also provide the following information:

Table 1.1: Additional information required when making a request

All requests	Requests for blood products
▪ Patient's sex ▪ Patient's location ▪ Test(s) requested ▪ Signature (or other traceable identifier) and contact details of the phlebotomist ▪ Date and time specimen was collected ▪ Name and contact details of the requesting practitioner	▪ Type of blood component and/or product(s) with number of units or dose ▪ Special requirements (e.g. irradiated or CMV seronegative products) ▪ Clinical diagnosis and indication for transfusion ▪ Date, time and location of transfusion ▪ Previous transfusions, including any adverse reactions ▪ Relevant patient history, such as red cell antibodies and obstetric history, including receipt of RhD immunoglobulin (RhD Ig)

CMV, cytomegalovirus

1.5.8 Requests for newborn/neonate testing

1.5.8.1 Requests regarding newborns/neonates, including cord blood testing, must identify the newborn/neonate as an individual and meet all expected identification and labelling criteria.

1.5.8.2 The request form should include the following information:

- either "Baby of [Mother's FULL NAME]" or the infant's FULL NAME (if this is known).

- baby's DOB
- baby's SEX

1.5.8.3 If the infant's MRN/NHI is available, this should be included in the request.

1.5.8.4 Where available, the mother's information i.e. FULL NAME and/or MRN/NHI should be included on the request in addition to the infant's details:

1.5.8.5 The request should also include:

- signature and contact details of the phlebotomist
- date and time cord blood (or infant's venous) specimen was collected
- name and contact details of the person making the request.

1.5.9 Requests for blood components and/or products

1.5.9.1 The patient must have a valid group and screen (where applicable to the blood component and/or product requested).

1.5.9.2 Requests for blood components and/or products may be made verbally, written or by electronic request.

1.5.9.3 Verbal requests must be documented by the person receiving the request and confirmed, for example, by repeating the information to the person making the request (see Table 1.2).

Table 1.2: Information required when making a 'verbal' request

Patient and requestor information	Blood component/product information
▪ Three unique identifiers: ▪ Prescribing clinician's name ▪ Requestor's name and contact details	▪ Component/product type(s) required ▪ Number of units or dose ▪ Date and time required ▪ Reason or clinical indication for request ▪ Location of intended transfusion

DOB, date of birth; MRN, Medical Record Number; NHI, National Health Index

1.5.9.4 Records of verbal and written requests must be retained according to regulatory requirements; for example, by scanning a copy of the written note or request into the LIS or EMR.

1.6 Specimens

1.6.1 Suitable specimen types for immunohaematology testing

1.6.1.1 EDTA tubes (providing plasma) or clotted tubes (providing serum) are suitable for immunohaematology tests.[6] Which is chosen will depend on the test method (e.g. automated versus manual).

1.6.1.2 The performance characteristics and suitability for immunohaematology testing of different specimen tube types may vary; therefore, tubes must be used in accordance with the manufacturer's instructions.

1.6.2 Specimen labelling requirements

1.6.2.1 Specimens for immunohaematology testing (whether pretransfusion, prenatal or postnatal) must comply with the labelling requirements in this document.

1.6.2.2 Laboratories must have a documented procedure for accepting and rejecting specimens and action to be taken if labelling is unsatisfactory.

6. EDTA: ethylenediaminetetraacetic acid

1.6.2.3 The patient (if conscious and not confused) must be asked to state and spell their FULL NAME, state their DOB and confirm their ADDRESS if used as an identifier.

1.6.2.4 For hospital patients, the details recorded on the request must also be checked against their hospital identification band.

1.6.2.5 If the patient does not have a hospital identification band, a specimen should not be collected until this situation has been remedied or the patient has otherwise been appropriately identified.

1.6.2.6 The specimen must be clearly and legibly labelled with the patient's details. Labelling must be performed immediately after collection **and** in the patient's presence; the patient's details must match those on the request.

1.6.2.7 Handwritten labelling of specimens is strongly recommended if an electronic system that securely identifies the patient and prints labels on demand at the bedside is unavailable.

ⓘ Preprinted addressograph (or similar) labels are not recommended but may be accepted at the laboratory director's discretion.

1.6.2.8 The specimen must be labelled with at least **TWO unique** patient identifiers (although three where practicable are recommended).

1.6.2.9 The specimen must also include:

- The phlebotomist's signature, such as name, initials, other simple mark, or unique employee ID number. The signature must be traceable and unequivocally belong to the person who completed the declaration on the request.
- The DATE and TIME of collection, if this is not otherwise recorded electronically and fully traceable.

1.6.2.10 Specimens received unlabelled, incorrectly labelled, or there is doubt about the integrity of labelling (e.g. evidence suggesting removal of a previous sticky label or one patient's label stuck over that of another patient) must not be used for testing.

1.6.2.11 Correction of incorrect details, relabelling or retrospective labelling of unlabelled specimens is not permitted.

1.6.3 Specimen storage

1.6.3.1 Specimens must be stored at a temperature that maintains their viability for the lifetime of the request. Table 1.3 shows the combination of permissible storage times and storage temperatures.

Table 1.3: Storage temperatures for whole blood and plasma used in pretransfusion testing

Specimen type	Storage temperature		
	18–25 °C	**2–8 °C**	**−20 °C**
Whole blood (EDTA)	Up to 48 hours	Up to 7 days	N/A
Separated plasma	Up to 48 hours	Up to 7 days	Up to 3 months[7]

EDTA, ethylenediaminetetraacetic acid; N/A, not applicable.

1.6.3.2 Laboratories choosing to use extended storage of separated plasma must understand the risks of doing so and have a documented procedure that ensures that the integrity of patient identification and labelling of the secondary tube is maintained.

7. BSH *Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories* (2012) (https://b-s-h.org.uk/guidelines)

1.6.3.3 Pretransfusion specimens from patient's red cells should be retained for up to 7 days after transfusion to allow investigation of possible transfusion reactions; separation and freezing of the plasma or serum during the storage period is not required.

1.7 Laboratory records

1.7.1 General principle

1.7.1.1 Records must comply with the requirements of the national accreditation authority or regulatory body and be retained in accordance with statutory requirements.

1.7.2 Patient records

1.7.2.1 A record containing the information shown in Table 1.4 must be held for each patient for whom pretransfusion or other testing (e.g. prenatal or postnatal) or blood components and/or products are requested.

Table 1.4: Information required for patient records

Patient information	Blood component/product information
▪ Three unique identifiers* ▪ Sex ▪ ABO/RhD blood group ▪ Date and time of specimen collection (if one collected) ▪ Antibody screen results ▪ Other testing results (e.g. antibody identification, antigen typing, DAT) ▪ Specimen or request validity/expiry ▪ Details of the person performing the testing ▪ Special requirements, warnings or other relevant information	▪ Component/product type ▪ Expiry date ▪ Donation or batch number ▪ ABO/RhD blood group (if applicable) ▪ Antigen typing (if applicable) ▪ Date of compatibility testing ▪ Compatibility testing result ▪ Date and time of issue ▪ Details of the person performing the compatibility testing

DAT, direct antiglobulin test; *i.e. full name; date of birth; Medical Record Number; NHI, National Health Index

1.7.3 Compatibility or issue report

1.7.3.1 A compatibility or issue report should be provided by the laboratory either before or with the first blood component and/or product released for the patient. The report must be placed in the patient's clinical notes or uploaded to the EMR as a record of pretransfusion testing.

1.7.3.2 The report must include the information shown in Table 1.5 and may be provided as a printed paper copy, as a removable portion of the compatibility label or electronically.

Table 1.5: Information required for the compatibility or issue report

Patient information	Blood component/product information
▪ Three unique identifiers ▪ ABO/RhD group (if applicable) ▪ Pretransfusion testing results including interpretation ▪ Special requirements, warnings or other relevant information	▪ Component/product type ▪ ABO/RhD group (if applicable) ▪ Donation or batch number ▪ Blood component/product expiry date ▪ Quantity issued (if applicable)

1.7.3.3 The compatibility or issue report must not be used as part of the pre-administration bedside identity check but may be used to check blood component and/or product information once the patient's identity is established.

1.7.4 Compatibility label

1.7.4.1 A compatibility or issue label, with the patient and component/product information listed in Table 1.6, must be securely attached to each blood component unit and/or blood product boxed bottle or vial when allocated or issued to a patient. Some elements of this information may also be presented in barcoded form.

Table 1.6: Information required for the compatibility or issue label

Patient information	Blood component/product information
▪ Three unique identifiers ▪ ABO/RhD blood group (if applicable)	▪ Donation or batch number ▪ ABO/RhD group (where applicable) ▪ Statement of compatibility or suitability ▪ Blood product expiry date Identity of the person affixing the label

1.7.4.2 Additional information may be provided on the compatibility label in accordance with local policies, for example:

- laboratory request or event number
- special patient or component requirements
- identity of the person allocating (or issuing) the component and/or product
- date and time of issue or allocation of component and/or product
- date and time of intended transfusion
- date and time after which the component and/or product must not be transfused.

1.7.5 Receipt of blood components and/or products

1.7.5.1 The laboratory must keep a record of the following information for each blood product received:

- donation or batch number
- product type
- ABO/RhD group (where applicable)
- supplier
- date and time received
- expiry date and time.

1.7.5.2 The laboratory may also record the results of antigen typing and special attributes or modifications, such as cytomegalovirus (CMV) seronegative or irradiated.

1.7.6 Issued or transfused blood components and/or products

1.7.6.1 The laboratory must keep a record of the following for each blood component and/or product issued for transfusion:

- Patient's FULL NAME (surname and first name)
- Patient's DOB; and/or patient's MRN/NHI
- date and time of issue or transfusion
- location

1.7.7 Fate of blood components and/or products

1.7.7.1 Every blood component and product must be traceable from receipt by the laboratory to its final fate, whether this is to a patient, clinical area, another facility, or disposal.

1.7.7.2 The change in status or fate of each blood component and/or product must be recorded by the laboratory, for example:

- ISSUED (i.e. from the laboratory or a remote location)
- TRANSFUSED (where this is known)
- DISCARDED (e.g. expired, out of controlled storage, damaged or recalled by supplier)
- TRANSFERRED to another laboratory or institution.

1.7.7.3 Transfused blood packs, bottles or vials should not normally be returned to the laboratory except where required for further investigation (e.g. blood components and/or products implicated in a transfusion reaction).

2 Immunohaematology testing

2.1 General principles

2.1.1 The ABO group is the most important pretransfusion test. It is crucial that the sensitivity and security of the testing system is not compromised.

2.1.2 Automated systems should be used where possible to minimise opportunities for interpretation or transcription errors.

2.1.3 A full ABO group and RhD group and antibody screen (e.g. 'group and screen' or 'G&S') must be performed on all valid specimens submitted for pretransfusion testing. For prenatal and postnatal specimens, a blood group and antibody screen are performed as required.

2.1.4 Obtaining a transfusion, drug or treatment history is important, particularly if the patient is receiving agents known to cause immune haemolysis, a positive DAT or otherwise interfere with pretransfusion testing.

2.1.5 Pretransfusion testing should be performed by directly sampling the patient's specimen.

ⓘ Aliquots created by subdividing the original specimen into separate containers/tubes of whole blood, red cells, or plasma are not recommended; the exception is plasma separated for frozen storage and subsequent use in crossmatching or other investigations.

2.1.6 For the purposes of these guidelines, when undertaking testing, 'plasma' will be used irrespective of specimen type unless otherwise stated, noting:

- If **plasma** is used, some weak complement-binding antibodies may be missed.
- If using **serum**, haemolysis can indicate a positive reaction.

2.2 Specimen acceptance criteria

2.2.1 Specimens must be checked on receipt to ensure they are appropriately labelled and the patient's details match those provided on the request.

2.2.2 Grossly haemolysed specimens should not normally be accepted for testing. Haemolysed specimens may be caused by inappropriate collection, storage or transport. When haemolysis is suspected to be due to the patient's underlying condition, for example autoimmune haemolytic anaemia, then additional testing is likely to be required.

2.2.3 The blood group and antibody screen should be completed within 48 hours of the specimen being collected unless the specimen is refrigerated.

2.2.4 When there is a delay between collection and receipt, the laboratory must ensure that transport and storage conditions maintain the specimen's viability.

2.2.5 Specimen acceptance depends on a reliable transfusion or obstetric history. The requestor is responsible for documenting and providing this information to the laboratory.

2.2.6 The results of pretransfusion testing are considered valid for the issue of red cells for the following intervals:

- 72 hours from collection: if the patient has been pregnant or transfused in the previous 3 months (or if this information is unavailable or unreliable).

  ⓘ Depending on the functionality of the LIS it is acceptable to set the expiry of specimen validity to midnight of the third day.

- **(Up to) 3 months** from collection: if the patient has not been pregnant or transfused in the previous 3 months. Before transfusion, it must be confirmed whether the patient has

been pregnant or transfused in the preceding 3 months. The supervising pathologist or delegate of the laboratory may choose to extend specimen validity for pretransfusion testing up to 7 days in certain clinical situations and the rationale documented, such as pregnant women with a high risk of transfusion (e.g. placenta praevia) or for transfusion-dependent patients with no clinically significant alloantibodies.

2.3 Automated immunohaematology instruments

2.3.1 Automated instruments must undergo appropriate validation and verification before being introduced into routine use, with records kept in accordance with national regulatory requirements.

2.3.2 If the instrument is interfaced with the LIS, validation must include the interface.

2.3.3 The laboratory must maintain a validated manual system in case of instrument failure and downtime.

2.3.4 After scheduled preventative maintenance or emergency repair, a documented 'return to service' procedure must be followed.

2.3.5 The laboratory must have a documented procedure for manual editing and authorisation of test results, including the designation of staff allowed to perform these tasks.

2.3.6 Editing and authorisation of results must require password-controlled access where possible.

2.3.7 The laboratory must have a written policy and procedure for data backup, archiving of data and recovery of data in the event of instrument failure.

2.3.8 Instruments should have in-built safeguards (with user notification) to detect system failures for example:

- failure of liquid circuits or mechanical valves
- inappropriate storage conditions for reagent red cells and other fluids
- failure to dispense or aspirate samples, reagents or wash solutions
- inappropriate level of test mixture in the reaction vessel.

2.3.9 Instruments must ensure security of patient identification between the sample and testing results; the use of barcoded laboratory accession numbers is recommended.

2.3.10 Secondary barcodes on specimens (or samples) must not obscure the primary label.

2.3.11 The laboratory must have a procedure to check that secondary labels have been applied to the correct specimen (or sample).

2.4 Labelling of secondary samples, test tubes, cassettes

2.4.1 Sample tubes, test tubes, column agglutination technology (CAT) cassettes or other media must be labelled with sufficient details of the patient (and, where appropriate, the blood component) to ensure that test results are assigned to the correct patient or blood component.

2.4.2 Initial testing should be performed by sampling directly from the primary specimen.

2.5 Blood grouping

2.5.1 ABO grouping

2.5.1.1 A full ABO group consists of both forward and reverse groups that must be agreed for a valid group to be recorded; that is:

Forward group Red cells tested with monoclonal anti-A and anti-B reagents. Anti-A,B must be used when testing newborns, otherwise use is optional.

Reverse group Plasma tested against A_1 and B reagent red cells.

2.5.1.2 The reverse group provides an important check of the forward group and can highlight ABO grouping anomalies; for example, due to transfusion, stem cell transplantation and other factors such as ABO subgroups, cold reacting antibodies or the patient's age or clinical condition.

2.5.1.3 A reverse group is not necessary for specimens from newborn infants up to the age of 4 months because any ABO antibodies are likely of maternal origin and unlikely to be informative.

2.5.2 RhD grouping

2.5.2.1 RhD grouping consists of red cells tested with a monoclonal anti-D reagent that **does not** detect RhD category VI (DVI).

2.5.2.2 Further testing of apparent RhD negatives (e.g. by IAT) is not required.

2.5.3 Confirming the ABO and RhD group

2.5.3.1 If the patient has a historical ABO and RhD group, the current typing results must match those obtained previously.

2.5.3.2 New patients must have a second confirmatory ABO and RhD group performed on either a new aliquot from the original specimen tested with the same or different reagents, or a new specimen collected independently of the original specimen:

- If confirmation is performed by a **manual** method, it should, wherever possible, be performed by a second individual having no prior knowledge of the original result; or
- If confirmation is performed by an **automated** method, there must be a procedure to independently verify the patient's identity and ensure that the correct barcode label has been applied to the specimen.

2.5.4 ABO and RhD grouping anomalies

2.5.4.1 ABO and RhD grouping anomalies should be resolved before selection of blood components for transfusion or blood products for injection (RhD Ig). Serological weak reactions are determined by local policy and in line with manufacturer's instructions – likely to be 3+ by some automated methodologies or 2+ by manual technique (0-4+ scale). Users must be aware of the variance within their laboratory test system.

2.5.4.2 If the ABO group and/or RhD group cannot be determined, they should be reported as indeterminate:

- group O red cells must be used until the ABO group is resolved
- RhD negative red cells should be used until the RhD group is resolved, particularly for women of childbearing potential, males ≤ 18 years and transfusion-dependent patients.
- A specimen may need to be sent to a specialist reference laboratory for further investigation to resolve ABO/RhD anomaly.

2.5.4.3 In emergency situations, if the ABO/RhD group has not been or cannot be determined, selection of blood components and/or products should be in accordance with 4.1.4.

2.5.5 Confirming the ABO group and RhD groups of donor red cell units and other types of donations

2.5.5.1 The ABO group of all donor red cell units and the RhD group of RhD negative units must be confirmed before use. RhD negative donor red cell units do not need to be tested for RhD variants.

2.5.5.2 Apparent RhD negative bone marrow, haemopoietic stem cells, granulocytes and other types of donations must be confirmed by testing with an RhD reagent that detects category DVI.

2.5.5.3 Group confirmation of donor units is usually performed by the laboratory undertaking pretransfusion testing. However, it is permissible for testing to be centralised; for example, at the base hospital or main laboratory of a network with 'group-confirmed' units distributed to their satellite facilities. The group confirmation results should be available (in written or electronic form) to the laboratory issuing the unit.

2.5.5.4 Group confirmation testing of donor units with subgroups of A or B (e.g. A_X, A_m, A_{el} or B_X units) may give results that contradict the primary blood group label i.e. by appearing as group O although labelled as group A or B respectively.

ⓘ ABO subgroups identified and confirmed by the blood service are printed on the unit's blood group label as a 'phenotype'. This should be considered sufficient to resolve the apparent discrepancy, allowing the unit to be accepted into the inventory and safely transfused to a patient ABO compatible with the unit's labelled blood group. Any unexpected discrepancies must be referred to the blood service.

2.6 Antibody screening

2.6.1 General principles

2.6.1.1 Antibody screening is performed to determine whether a patient has clinically significant red cell antibodies. Clinically significant red cell antibodies generally react at 37 °C in the indirect antiglobulin test (IAT).

ⓘ ABO antibodies anti-A, anti-B and anti-A,B must always be considered clinically significant.

2.6.1.2 The patient's plasma is tested against a mini-panel of two or three reagent red cells, each with a known antigenic profile.

2.6.1.3 A low ionic strength solution (LISS) IAT provides the most suitable combination of speed, sensitivity, and specificity for detecting clinically significant antibodies. The sensitivity and specificity will vary depending on whether a manual or automated method is used.

2.6.1.4 The choice between manual and automated antibody screening methods will depend on local testing requirements. Whichever technology or platform is selected (e.g. column agglutination, solid-phase) it must be fully validated before being introduced into routine use.

2.6.1.5 Other methods, such as enzyme techniques, may supplement (but not replace) the IAT technique. These may be inferior to the IAT for detecting some clinically significant antibodies.

2.6.1.6 The increased sensitivity of red cells with double-dose (homozygous) antigen expression facilitates the identification of low titre antibodies.

2.6.2 Antibody screening cells

2.6.2.1 Antibody screening cells are a complementary set of two or more group O reagent red cells (each prepared from a single donor), which between them must possess the antigens C, c, D, E, e, M, N, S, s, K, k, Fy^a, Fy^b, Jk^a, Jk^b, Le^a and Le^b. The red cells from different donors must not be pooled to achieve the desired antigen expression.

2.6.2.2 One screening cell should be R_1R_1 (or $R_1^WR_1$) and another R_2R_2.

2.6.2.3 The double-dose (homozygous) phenotypes Jk(a+b-), Jk(a-b+), Fy(a+b-) and Fy(a-b+) must be represented; the phenotypes SS and ss are also desirable.

2.7 Antibody identification

2.7.1 Laboratories must have a documented procedure for investigating a positive antibody screen,

assessing its likely clinical significance, and providing compatible blood.

2.7.2 Laboratories that do not routinely perform antibody identification should send specimens with a positive antibody screen to an appropriately accredited laboratory. It may be necessary to refer specimens to a specialist reference laboratory for further investigation or confirmatory testing.

2.7.3 Patients known to have a red cell antibody must have each new specimen tested to exclude the formation of additional antibodies.

2.7.4 The patient's plasma should be tested by IAT against a red cell identification panel capable of identifying clinically significant antibodies. Including the patient's own cells (auto control) may help determine the presence of an autoantibody or an antibody to a high-frequency antigen.

2.7.5 The specificity of an antibody can normally be assigned when it is reactive with at least two red cells carrying the corresponding antigen and non-reactive with two red cells lacking that antigen. A cross-check of the panel and initial antibody screen should be performed to ensure correlation, and that all reactivity is explained.

2.7.6 The presence of anti-Jk^a, -Jk^b, -S, -s, -Fy^a and -Fy^b should be excluded by using red cells with double-dose (homozygous) expression of the corresponding antigens.

2.7.7 Using a variety of different techniques – for example, enzyme-treated cells, polyethylene glycol (PEG)-IAT, prewarmed reagents or neutralisation – may assist in confirming the presence of antibodies weakly reactive by IAT or suspected mixtures of antibodies.

2.7.8 The patient's red cells usually lack the antigen against which the antibody is directed unless it is an autoantibody. The patient's antigen typing should be confirmed using commercial antisera (if available).

2.7.9 Where conventional serological phenotyping is inappropriate – either because the patient was recently transfused or has a positive direct antiglobulin test (DAT), or where the results are ambiguous, the specimen should be referred to the reference laboratory for additional investigation including considerations for genotyping.

Table 2.1: The clinical significance of red cell alloantibodies and selecting blood for transfusion

Antibody specificity	Clinically significant	Selection of units
Anti-A_1	Rarely	IAT crossmatch compatible at 37 °C
Anti-HI (A_1 and A_1B individuals)	Rarely	IAT crossmatch compatible at 37 °C
Anti-M (active at 37 °C)	Rarely	Antigen negative + IAT crossmatch compatible at 37 °C
Anti-N (active at 37 °C)	Rarely	IAT crossmatch compatible at 37 °C
Anti-S, -s, -U	Yes	Antigen negative
Anti-P1 (active at 37°C)	Rarely	IAT crossmatch compatible at 37 °C
Anti-D, -C, -c, -E, -e	Yes	Antigen negative
Anti-C^W	Rarely	IAT crossmatch compatible at 37 °C
Anti-Lu^a	Rarely	IAT crossmatch compatible at 37 °C
Anti-Lu^b	Yes	Antigen negative
Anti-K, -k	Yes	Antigen negative
Anti-Kp^a	Rarely	IAT crossmatch compatible at 37 °C
Anti-Le^a, -Le^b, -Le^{a+b}	Rarely	IAT crossmatch compatible at 37 °C
Anti-Fy^a, -Fy^b	Yes	Antigen negative
Anti-Jk^a, -Jk^b	Yes	Antigen negative
Anti-Co^a	Yes	Antigen negative
Anti-Co^b	Sometimes	IAT crossmatch compatible at 37 °C
Anti-Dia	Yes	IAT crossmatch compatible at 37 °C
Anti-Wr^a	Rarely	IAT crossmatch compatible at 37 °C
HTLA antibodies	Unlikely	Local policy or seek advice from reference laboratory
Antibodies to low or high frequency antigens	Depends on specificity	Local policy or seek advice from reference laboratory
Other antibodies active by IAT at 37 °C	Depends on specificity	Local policy or seek advice from reference laboratory

HTLA, High-titre, low-avidity; IAT, indirect antiglobulin test;

*Antigen negative red cells should be crossmatched by IAT at 37°C

2.8 Compatibility testing (crossmatching)

2.8.1 The laboratory must have procedures to ensure compatibility between the patient and donor.

2.8.2 Crossmatching procedures must primarily detect ABO incompatibility; suitable techniques include room temperature immediate-spin, IAT or electronic crossmatching.

2.8.3 For clinical procedures where the likelihood of red cell transfusion is low a 'group and screen' only is recommended. If transfusion becomes necessary, crossmatched blood must be available in a timely manner that is consistent with local clinical needs.

2.8.4 The laboratory should avoid unnecessarily holding or reserving crossmatched red cells by only crossmatching on demand when transfusion is required or adopting a 'maximum surgical blood order schedule' (MSBOS; Appendix 1).

2.8.5 If the patient has no clinically significant antibodies (or no history of an antibody), an abbreviated crossmatch using a room-temperature immediate-spin tube technique or an electronic crossmatch (eXM) may be used.

2.8.6 An immediate-spin crossmatch may not detect ABO incompatibility if the patient has weak Anti-A or Anti-B reactions in their reverse group. All weak reactions must be resolved.

2.8.7 If the immediate-spin technique is used, it is recommended that the donor red cells should be washed at least once to minimise the possibility of the patient's anti-A or anti-B (or both) being neutralised by soluble donor ABH substance.

2.8.8 If the patient has a clinically significant antibody (or history of an antibody), then donor red cells selected for transfusion should be typed (negative) for the corresponding antigen by the testing laboratory and must be crossmatched by IAT.

2.8.9 The antigen types of selected donor units should be confirmed using commercial antisera (if available) when the patient has history or current clinically significant antibodies.

2.8.10 The antigen typing should be undertaken by the laboratory performing the pretransfusion testing, except where typed red cells are distributed between accredited facilities of a laboratory network or organisation.

2.8.11 After testing is complete, each blood component must be labelled with a unique compatibility label.

2.8.12 The laboratory must have a mechanism to ensure the correct unit is labelled.

2.8.13 Requests for crossmatching can be made at any time during the specimen's lifetime. Once a transfusion episode has commenced, the crossmatch request becomes invalid at either the specimen's original expiry or 72 hours/midnight of the third day (as applicable) after commencing transfusion of the first unit of red cells, whichever occurs first.

2.8.14 Once a transfusion episode has commenced, subsequent specimens from the patient have an expiry of 72 hours until at least 3 months has elapsed since the last transfusion.

2.9 Electronic crossmatch

2.9.1 An electronic crossmatch (eXM) is permitted when:

- the laboratory has a comprehensively validated electronic data management system
- a valid pretransfusion specimen has been tested in accordance with the requirements given in 2.5 and 2.6
- the patient has no clinically significant antibodies or history of such antibodies.

2.9.2 The LIS must not permit the selection of ABO-incompatible red cells. When products with a different but compatible ABO/RhD group are selected the LIS should generate a warning message or flag.

2.9.3 When a patient requires 'special' modifications to a component (e.g. CMV seronegative or irradiation), the LIS must generate a warning message or flag. The system must not allow components to be released until the warning or flag is addressed by selecting suitable products or recording a reason for the non-conformance of the components selected.

2.10 Release or issue of blood components and/or products

2.10.1 Requests to release (or issue) blood components and/or products may be made by telephone or fax, on forms, electronically or in person (e.g. an orderly or nurse coming to the laboratory or accessing a remote blood refrigerator), or by other acceptable means.

2.10.2 The requestor must clearly identify the intended patient, providing (as a minimum) the patient's FULL NAME (surname and first name), DOB and/or MRN/NHI.

2.10.3 Blood components and/or products may be released directly to someone collecting them from the laboratory, delivered through a validated pneumatic tube system (PTS) or released for remote storage location (e.g. ward or theatre refrigerator, or a satellite facility). If delivered via PTS, the laboratory should be able to confirm if, and when the blood component and/or product arrived at its intended destination.

2.10.4 The identity of the person releasing the blood component and/or product from the laboratory or removing it from a remote blood refrigerator must be recorded either electronically or in a written register kept for that purpose.

2.11 Electronic remote release of blood components and/or products

2.11.1 The information system for electronic remote releasing of blood components and/or products must meet the requirements specified in 2.9.

2.11.2 All users must be appropriately trained before using electronic remote release procedures, with competency reviewed regularly; also, they must have individual passwords with designated levels of access to the IT system.

2.11.3 The remote release software must have features that ensure that:

- all requirements for computer crossmatching are met
- a patient with a clinically significant antibody (or a history of such antibodies) is excluded from remote release, with the appropriate explanatory warning message or flag.

2.11.4 The parent laboratory should be notified (in **real time** where applicable) when blood components and/or products are released or issued from remote storage to facilitate inventory management and, in particular, timely replenishment of stock.

3 Selecting blood components and/or products for transfusion

3.1 Red cell components

3.1.1 General principles

3.1.1.1 The laboratory's procedures for selecting red cell components must cover both routine and exceptional (e.g. emergency or trauma) situations.

3.1.1.2 Red cell components should be of the same ABO/RhD group as the patient.

ⓘ Selecting components with different but compatible ABO/RhD group is permissible and may assist in reducing wastage. However, this should be balanced against creating unnaturally high usage, for example the elective use of near-expiry O RhD negative red cells for non-O RhD negative recipients.

3.1.1.3 To avoid unnecessary wastage, it is preferable to maintain an appropriately representative inventory of different ABO/RhD groups that reflects the local demographics of their patients requiring transfusion.

3.1.1.4 Group O red cells must be selected when the patient's ABO group cannot be determined; similarly, RhD negative red cells should be used if an RhD group cannot be determined.

3.1.1.5 Women of childbearing potential should, in addition to receiving red cells matched for ABO and RhD, also receive red cells matched for K.

3.1.2 Selecting red cells when the patient has a clinically significant antibody or has a history of such antibodies

3.1.2.1 If the patient has (or has a history of) a clinically significant antibody, red cells negative for the corresponding antigen should be selected for crossmatching.

ⓘ If a historical antibody is **not currently detectable by IAT**, antigen-negative red cells are required and must be crossmatched by IAT.

3.1.2.2 Patients who are rr (cde/cde) with (or a history of) anti-D should where possible receive D-, C-, E- and K matched red cells.

3.1.2.3 Patients with other Rh alloantibodies should where possible receive red cells matched to their C, c, E and e antigen types (full Rh phenotype) and K to prevent further Rh alloimmunisation.

3.1.2.4 When transfusion is required before pretransfusion testing can be performed or is started but not completed, particularly in urgent situations, it may be necessary to select ABO/RhD compatible but otherwise serologically incompatible red cells.

3.1.2.5 The decision to transfuse must be based on consultation between the patient's clinician and a transfusion medicine specialist or the laboratory director, considering the clinical significance of the antibody.

3.1.2.6 For some antibodies or in complex cases, there may be a significant delay while compatible red cells are identified. The patient's clinician should be advised accordingly.

3.1.3 Selecting red cells when the patient has a positive antibody screen due to a red cell antibody not considered clinically significant

3.1.3.1 If the patient has an antibody not considered clinically significant but which is reactive by IAT at

37 °C, for example, anti-P_1, -Le^a, -Le^b, -Le^{a+b}, -HI, autoanti-I (or other cold agglutinins) then IAT crossmatch compatible red cells should be selected for transfusion; these red cells need not be antigen negative.

3.1.3.2 If the patient has a history of an antibody with no (or doubtful) clinical significance but it is **not** currently reactive by IAT (at 37 °C), it may be permissible to issue ABO compatible red cells without performing an IAT crossmatch or selecting antigen-negative red cells.

3.2 Plasma components

3.2.1 Plasma components (i.e. fresh frozen plasma [FFP], extended life plasma [ELP], cryoprecipitate or cryodepleted plasma [CDP]) should preferably be of the same ABO group as the patient. Products that are ABO compatible with the patient's red cells should be selected to avoid haemolysis due to donor anti-A or anti-B (see Table 3.1).

Table 3.1: Selection of plasma products8

	Plasma product ABO group *(in order of preference)*			
Patient ABO group	**1st choice**	**2nd choice**	**3rd choice**	**4th choice**
O	O	A	B	AB
A	A	AB		-
B	B	A (low titre anti-A/B)	AB	-
AB	AB	A(low titre anti-A/B)		-

Unknown ABO group	**Plasma product ABO group** *(in order of preference)*		
	1st choice	**2nd choice**	**3rd choice**
Emergency issue	A (low titre anti-A/B)	AB	A (titre unknown)
Neonates/Infants <1 year old	AB	A (low titre anti-A/B)	A (titre unknown)

3.2.2 Plasma products may be selected without regard to the patient's RhD status. RhD immunoglobulin (RhD Ig) is not required if RhD negative patients receive RhD positive plasma products.

3.2.3 Compatibility testing (or crossmatching) is not necessary before transfusing plasma products. However, the patient's ABO group should be determined before the first transfusion episode to establish a baseline record and to ensure that plasma with the appropriate ABO group is selected.

3.2.4 The patient's ABO group does not need to be retested before subsequent plasma component transfusions, and for neonates the ABO group does not need to be retested for the duration of their episode of care.

3.2.5 Extended life plasma (ELP)

3.2.5.1 ELP is thawed FFP that has an extended shelf life of up to 5 days after thawing, when stored at 2-6 °C. Labile coagulation factors V, VII and VIII are reduced in ELP but after 5 days of storage still remain at haemostatic levels (Table 3.2).

8. Australian Red Cross Lifeblood *Component compatibility* https://www.lifeblood.com.au/health-professionals/products/component-compatibility

*Table 3.2: Coagulation factors (IU/mL) in FFP at thawing and after extended post thaw storage**

Factor	At thawing	Day 3 (post thaw)	Day 5 (post thaw)
Factor V	0.89 ± 0.14	0.83 ± 0.17	**0.75 ± 0.13**
Factor VII	1.0 ± 0.21	0.89 ± 0.17	**0.85 ± 0.17**
Factor VIII	1.08 ± 0.33	0.63 ± 0.18	0.56 ± 0.15

* Australian Red Cross Lifeblood data used with permission (FFP n=30 / CDP n=30)

3.2.5.2 Where FFP is not transfused within 24 hours of thawing it may be converted to ELP as long as it has been maintained under appropriately controlled storage.

3.2.5.3 Each health service must consider whether ELP is applicable for use in its local setting. The decision to offer ELP should be made after due consideration of the advantages, contraindications and clinical risks of doing so and it may not be suitable for all patient groups or situations. Where a transfusion service provider only handles a small number of trauma or emergency cases holding an inventory of ELP is not recommended.

3.2.5.4 The hospital transfusion (or blood management) committee must provide guidance for the clinical indications and contraindications of plasma (including ELP).

ⓘ Appropriate clinical uses of plasma can be found in the *Patient Blood Management Guidelines* published by Australia's National Blood Authority.[9]

Table 3.3: Advantages, clinical risks and contraindication for the use of ELP

Advantages	• reduced wastage of unused thawed plasma • immediate availability of thawed plasma if required urgently, for example in trauma or major haemorrhage requiring massive transfusion • suitability for storage and use for prehospital retrieval
Clinical Risks	• reduced levels of factors V, VII and VIII • potential for increased DEHP exposure
Contraindications	• not recommended for use in neonates, freshly thawed (or less than 24hrs refrigerated) is preferred. However, in the setting of major haemorrhage or critical bleeding, do not delay provision clinical plasma when ELP (>24hrs storage) is available. • not recommended for use in patients with congenital factor V or VIII deficiency if specific factor concentrates or FFP are available

3.2.5.5 The plasticiser di(2-ethylhexyl)phthalate (DEHP) has been shown to leach into the protein and lipid rich contents of the product during storage. The consequences of transient exposure to DEHP from plasma are unclear.

3.2.5.6 The transfusion service provider must assess the risks associated with managing ELP and maintain documentation of handling, storage and requirements for use.

3.2.5.7 ELP must be clearly identifiable (and traceable) with the change in component type from FFP to ELP and the updated expiry date/time recorded in the LIS.

9. NBA *Patient blood management guidelines* https://www.blood.gov.au/patient-blood-management-guidelines

3.2.5.8 The laboratory must apply a label that obscures the original component name (FFP) and storage conditions and states the new component type (ELP), storage conditions and expiry (i.e. 5 days post-thaw).

3.2.5.9 The issue or compatibility reports must show the component type is 'Extended Life Plasma'.

3.3 Platelet components

3.3.1.1 Platelet components should preferably be the same ABO/RhD group as the patient. This may not always be possible; for example, if there are stock constraints or where special requirements such as human leucocyte antigen (HLA) or human platelet antigen (HPA) compatibility take precedence.

3.3.1.2 Platelet units with different ABO groups must not be pooled.

3.3.1.3 If ABO identical platelets are not available, then ABO nonidentical platelets may be used; the decision to use such platelets should consider the patient's age, diagnosis and available component type.

Table 3.4: Selection of platelet products[10]

	Platelet component ABO group *(in order of preference)*		
Recipient's ABO group	**1st choice**	**2nd choice**	**3rd choice**
O	O	A*	B
A	A	B# or O#	AB
B	B	A*# or O#	AB
AB	AB	A# or B#	O#
Unknown	A*# or O#	-	-

* Group A platelets that have an A_2 subgroup do not express significant amounts of A antigen and are therefore more preferable for transfusion to group O and B patients than other A platelets.

\# Apheresis platelets that have **low-titre anti-A/B** or **pooled platelets**, pose a lower risk of haemolysis when transfusing ABO incompatible components

3.3.1.4 Caution should be exercised when transfusing ABO nonidentical platelets to neonatal, paediatric and small adult patients, particularly when using apheresis platelets, due to the risk of haemolysis from donor anti-A and anti-B antibodies.

3.3.1.5 Matching of platelets for RhD group is desirable but may be considered less important than ABO matching.

3.3.1.6 RhD negative patients, especially women of childbearing potential (including female children), should receive RhD negative platelets wherever possible.

3.3.1.7 If an RhD negative patient receives RhD positive platelets, RhD Ig should be offered in accordance with institutional policy; this will be at the discretion of the patient's clinician and will depend on the patient's sex, age and diagnosis.

3.3.1.8 It is not normally necessary to offer RhD Ig to RhD negative males, postmenopausal women or those who are heavily immunosuppressed (e.g. due to haematological malignancy).

3.3.1.9 If a thrombocytopenic patient requires RhD Ig, an intravenous (IV) preparation should be considered.

10. Australian Red Cross Lifeblood *Component compatibility* https://www.lifeblood.com.au/health-professionals/products/component-compatibility

4 Use of blood components and/or products in specific clinical situations

4.1 Emergency transfusion

4.1.1 In emergency situations a pretransfusion specimen should be obtained as soon as possible and before blood components are administered.

4.1.2 Specimens must be labelled in accordance with routine pretransfusion practice.

4.1.3 Pretransfusion testing (performed as per requirements of section 2) must be completed as soon as possible, regardless of the fate of the patient.

4.1.4 Uncrossmatched group O red cells should be used only in an emergency when there is no current, valid group and screen.[11]

- red cells must not be issued based on a historical blood group
- red cells must be group O
- For women of childbearing potential (CBP) ≤ 50 years, and paediatric males ≤ 18 years (or as per local paediatric policy) – issue group O RhD negative uncrossmatched red cells
- For women ≤ 50 years, red cells that are K negative should be preferentially selected. Transfusion should not be delayed to source K negative units.
- For women > 50 years and all adult males > 18 years – issue group O RhD positive uncrossmatched red cells.
- ABO RhD compatible red cells (ideally the same group as the patient) may be issued once the patient has a confirmed ABO/RhD group
- Platelets: ABO nonidentical platelets may be given in the absence of a confirmed blood group (see table 3.4)
- Select group A clinical plasma with low anti-A/B titre, or group AB (FFP, ELP, and cryoprecipitate).. For neonates and infants < 1 year old, select group AB plasma products as first choice, where possible.[12]

4.1.5 If the patient has a positive antibody screen, the patient's clinician and the laboratory director or a transfusion medicine specialist must be informed that there may be a delay while the antibody is identified, and compatible red cells are found:

- Where transfusion is urgently required, particularly in life-threatening situations, it may be necessary to provide ABO/RhD compatible but otherwise serologically incompatible red cells until further investigations are completed.
- Compatibility testing, including an IAT crossmatch, should be performed in accordance with 2.8 and 3.1, but the degree to which this is done will ultimately be determined by the urgency of transfusion; if necessary, testing may be performed retrospectively.

4.1.6 Consult with a supervising pathologist or transfusion medicine specialist if a RhD negative patient receives RhD positive red cells to discuss the need for RhD Ig, especially in women of childbearing potential.

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11. National Blood Authority (NBA) *National statement for the emergency use of group O red blood cells* https://www.blood.gov.au/blood-products/blood-product-management/inventory-management-blood-and-blood-products

12. NBA *National statement for the emergency use of group A clinical plasma patients with critical bleeding or a major haemorrhage* https://www.blood.gov.au/blood-products/blood-product-management/inventory-management-blood-and-blood-products

4.1.7 Where a patient with an unknown blood group is receiving group O red cells, transfusion with red cells of the patient's ABO/RhD group should commence as soon as possible once a confirmed blood group is obtained.

4.1.8 For those patients that are confirmed RhD negative who have received RhD positive red cells, ABO compatible RhD positive red cells may be continued until the critical bleeding situation is resolved.

4.1.9 Red cells issued before completion of pretransfusion testing must be clearly identified; for example, as '*Uncrossmatched blood*' or '*Emergency issue – compatibility testing not completed*'.

4.1.10 When uncrossmatched red cells are issued, a crossmatch segment from the unit should be retained in case retrospective testing is required.

4.2 Major haemorrhage

4.2.1 Major haemorrhage that is life-threatening and is likely to result in the need for massive transfusion. The laboratory must have a written policy for managing major haemorrhages and critical bleeding, developed in consultation with clinicians having expertise in this area.

ⓘ The Australian NBA *Patient blood management guideline for adults with critical bleeding* provide a major haemorrhage protocol (MHP) template that can be adapted for local institutional use.[13]

4.2.2 Where a patient has received 10 or more red cell units in 24 hours, additional red cells can be issued without a serological crossmatch (where normally performed by the laboratory).

4.2.3 If the patient has a clinically significant antibody, red cell selection should be in accordance with 3.3. The supervising pathologist and patient's clinician should be consulted to guide the selection of red cell units according to the available inventory. If time is critical, antigen negative blood can be selected without IAT crossmatch or confirmatory antigen typing, but retrospective serological crossmatching is recommended with segments from issued red cell units.

4.2.4 Monitoring haemostasis is important for guiding the decision to transfuse other blood components and/or products. Viscoelastic tests (e.g. thromboelastometry or thromboelastography), full blood count and coagulation parameters - for example, international normalised ratio (INR), activated partial thromboplastin time (aPTT), and fibrinogen may be used.

4.3 Pregnancy

4.3.1 Institutions should have a written policy for managing transfusion in pregnancy. Women with clinically significant antibodies must have a valid group and screen available when they are in labour or about to undergo caesarean section.

4.3.2 K negative red cells are clinically indicated (listed in priority order) for women who:

- currently have anti-K or have a history of anti-K
- are K negative (use of K negative red cells for women who are K positive is unnecessary)
- are unable to be K typed before urgent transfusion.

4.3.3 Previously alloimmunised pregnant women typically have a greater risk of further sensitisation. If transfusion of patient, or intrauterine transfusion is planned, further phenotyping (Rh, K, Fy^a, Fy^b, Jk^a, Jk^b and Ss) of pregnant patient is recommended, and antigen negative, matched cells selected.

4.3.4 Pregnant women (but not at delivery), irrespective of CMV status, should receive CMV seronegative blood components. In critical bleeding situations, transfusion should not be delayed because of the unavailability of CMV seronegative components.

13. NBA *Patient blood management guideline for adults with critical bleeding* (http://www.blood.gov.au/pbm-guidelines) Patient blood management guideline for adults with critical bleeding | National Blood Authority

4.4 Transfusion of the fetus and newborn

4.4.1 Neonates and infants up to the age of 4 months

4.4.1.1 Initial pretransfusion testing should be performed on specimens from both the mother and neonate, as follows:

Maternal sample	ABO, RhD and antibody screen
Neonatal sample	ABO, RhD and DAT Maternal sample is recommended to identify clinically significant antibodies. If the maternal sample is not able to be collected, and transfusion requested for neonate, testing must be performed on the neonatal sample: antibody identification, elution and IAT crossmatch. **Note: cord samples are not suitable for pretransfusion testing**

4.4.1.2 If the pretransfusion antibody screen and DAT are negative, no further testing is required until the infant reaches 4 months of age; red cells may be issued by eXM.

4.4.1.3 If the infant's DAT is positive due to ABO antibodies or antenatal RhD Ig prophylaxis, electronic crossmatching is permissible.

4.4.1.4 If the maternal or infant's plasma contains a clinically significant antibody, the infant must receive red cells that lack the corresponding antigen and that are IAT crossmatch compatible with either the maternal or infant's plasma. Where antigen negative red cells are not available, the request must be discussed with the supervising pathologist and patient's clinician.

4.4.1.5 When maternal antibody is no longer detectable in specimens from the infant, antigen-negative red cells are not required.

4.4.1.6 Blood components selected for transfusion should be:

- the same ABO/RhD group as the infant or ABO/RhD compatible:
  - if the neonate has an unresolved or indeterminate RhD type, RhD negative red cells should be selected
  - red cells of the infant's blood group may be used once any passively acquired anti-A or anti-B is no longer detectable by IAT and the DAT is negative; tests for anti-A must use A_1 red cells.
- CMV seronegative (if preterm infant, up until 28 days post expected date of delivery)
- Irradiated, if the infant:
  - is having exchange transfusion(s)
  - has received an IUT; irradiated blood red cells and platelets are required until 6 months of age
  - is receiving blood components donated by a direct relative
  - Has confirmed or suspected severe congenital T lymphocyte immunodeficiency.[14]

4.4.2 Intrauterine transfusion (IUT)

4.4.2.1 Red cells for IUT are specifically manufactured by the blood supplier. Request:

- 5 days old or less
- ABO compatible with both the mother and fetus; if the fetal blood group is not known, group O should be used

14. ANZSBT *Guidelines for the Prevention of Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD)*. https://anzsbt.org.au/guidelines-standards/anzsbt-guidelines/

- K negative
- Antigen negative for the antigen/s against which the maternal antibody/antibodies are directed; it may be desirable to perform an extended maternal red cell phenotype and provide matching red cells so that the mother is not exposed to other major blood group antigens she lacks
  - ⓘ In exceptional cases, it will be necessary to give O RhD positive, c negative blood, for example, in HDFN because of anti-c alloimmunisation, where giving RhD negative blood would be harmful[15]
- CMV seronegative
- Irradiated (must be used within 24 hours of irradiation).[16]

4.4.3 Transfusion-dependent patients

4.4.4 The laboratory should be advised when a patient is expected to commence a long-term course of regular transfusions, for example, in the management of sickle cell disease, thalassaemia, or myelodysplasia.

4.4.5 The patient should have an extended phenotype (or genotype) performed, ideally before their initial transfusion. Typing should include Rh (C, c, E, e), K, Jk^a, Jk^b, Fy^a, Fy^b, S and s.

- ⓘ Red cell genotyping is available through Australian Red Cross Lifeblood and the New Zealand Blood Service.

4.4.6 Wherever possible, Rh and K matched units should be selected for transfusion. Matching for extended phenotypes is not usually required but may be recommended by laboratory directors in special circumstances.

4.5 Patients treated with monoclonal antibodies (MAb) known to interfere with immunohaematology testing

4.5.1 General Principles

4.5.1.1 Monoclonal antibodies (MAb) such as anti-CD38 and anti-CD47 may incidentally react with CD ("cluster of differentiation") antigens expressed on red cells (and platelets), causing interference in pretransfusion testing and potentially delaying transfusion:

- Anti-CD38 typically causes weak panagglutination (1+ to 2+; using 0-4+ scoring) in IAT antibody screening and, sometimes, a positive DAT.
- Anti-CD47 may cause false reactivity in the ABO reverse group (and less commonly spontaneous agglutination in the forward ABO group), moderate to strong panagglutination (3+ to 4+) in IAT antibody screening and possibly a positive DAT.

4.5.1.2 For other monoclonal antibodies refer to the recent literature.

4.5.1.3 When planning treatment, it is vital that the clinician communicates with the testing laboratory that the patient will be receiving one of the implicated MAbs, and requests a pre-treatment group and screen, an extended phenotype (or genotype if the patient has been recently transfused or has a positive DAT), and provides the patient with an alert card as per institutional policy.

15. Royal College of Obstetricians and Gynaecologists (RCOG) The *Management of Women with Red Cell Antibodies during Pregnancy* (2014) (https://ranzcog.edu.au/resources/statements-and-guidelines-directory/)

16. ANZSBT *Guidelines for the Prevention of Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD). 2nd Edition (January 2024)* (*https://anzsbt.org.au/guidelines-standards/anzsbt-guidelines/*)

4.5.2 Pretreatment (baseline) pretransfusion testing

4.5.2.1 Pretreatment (baseline) pretransfusion testing should include:

- a **blood group** (ABO/RhD) and **antibody screen** as per Section 2
- a **phenotype** if the patient has not been transfused in the last 3 months, with Rh(C, c, E, e), K (also k if K+), Jk^a, Jk^b, Fy^a, Fy^b, S, and s recommended
- a **genotype** if the patient has been transfused in the last 3 months or has a positive DAT

4.5.2.2 Enter details of the MAb treatment in the patient's LIS record noting the specific therapy, date and treating clinician.

4.5.3 Patient has commenced MAb therapy

4.5.3.1 Request a group and screen specimen to be taken prior to transfusing to allow retrospective testing and crossmatching

Blood group	• If results agree with the pre-treatment blood group, no further group testing is required on this sample. • If results differ from the patient's pretreatment group, refer below for action relevant to the specific MAb.
Antibody screen / antibody identification	• Negative results – no further investigations required • Positive result – refer to below for action relevant to the specific MAb.

4.5.4 Anti-CD38 [17]

4.5.4.1 If the patient has a positive antibody screen, the presence of an underlying red cell antibody will need to be excluded. Due to the complexity of, or difficulties associated with, pretransfusion testing in cases of MAb therapy, it may be necessary to refer specimens to a reference laboratory.

4.5.4.2 Treat the reagent red cells with DTT or trypsin (to denature the CD38 antigens) or with a neutralising reagent (e.g. which uses anti-CD38 Fab fragments to mask CD38 antigens).

ⓘ It should be noted that DTT denatures some red cell antigens, notably those in the Kell system.

ⓘ Other neutralising reagents may weaken or block antibodies or denature some red cell antigens – refer to manufacturer's instructions.

4.5.4.3 Repeat the antibody screen using treated reagent red cells or neutralised plasma. If the screen is positive, perform an antibody identification panel also using treated (or neutralised) reagents.

4.5.4.4 If the antibody cannot be identified, a haematologist or transfusion medicine specialist and the patient's clinician should be alerted to discuss transfusion requirements.

4.5.4.5 If an IAT crossmatch is required, the use of DTT or trypsin-treated donor red cells, or neutralised plasma may be necessary to avoid positive reactions due to the MAb.

4.5.5 Anti-CD47 [18]

4.5.5.1 If the patient's ABO group cannot be determined or there is a discrepancy with a previously obtained group due to MAb interference, group O red cells must be transfused until the anomaly

17. Quach H, Benson S, Haysom H, et al. *Considerations for pre-transfusion immunohaematology testing in patients receiving the anti-CD38 monoclonal antibody daratumumab for the treatment of multiple myeloma*. Internal Medical Journal 2018; 48: 210-220 https://doi.org/10.1111/imj.13707

18. Tan M, Zacher N, French R, et al. *Guidance for transfusion management in patients receiving magrolimab therapy (anti-CD47 monoclonal antibody)*. Internal Medical Journal; 2022: 1-7 https://doi.org/10.1111/imj.15934

is resolved. Other causes for grouping discrepancies should also be considered and excluded.

4.5.5.2 If the patient has a positive antibody screen, the presence of an underlying red cell antibody will need to be excluded. Due to the complexity of, or difficulties associated with, pretransfusion testing in cases of MAb therapy, it may be necessary to refer specimens to a reference laboratory.

4.5.5.3 Anti-CD47 MAbs are commonly IgG4 (but other IgG subclasses, such as IgG1, are possible). If available, using an AHG reagent that does not detect the specific IgG subclass may overcome the interfering reactivity.

ⓘ In the absence of a suitable AHG reagent, alloadsorption of the patient's plasma may assist in removing interference in the antibody screen, however this technique is not widely available in laboratories.

4.5.5.4 Repeat the antibody screen using the chosen AHG. If the screen is positive, perform an antibody identification panel using the same AHG.

4.5.5.5 If the antibody cannot be identified, a haematologist or transfusion medicine specialist and the patient's clinician should be alerted to discuss transfusion requirements.

4.5.5.6 If an IAT crossmatch is required, the AHG reagent described above should be used.

4.5.6 Selection and issue of red cells

4.5.6.1.1 For **emergency transfusion** issue blood using institutional protocols for emergency transfusion (see section 4). If time allows, select antigen negative red cells matched to the patient's phenotype (or genotype). If patient is on anti-CD38 therapy, select K negative red cells.

4.5.6.2 If the patient's ABO group is confirmed, red cells of the same ABO or compatible ABO group can be transfused. If the ABO group cannot be resolved, transfuse group O red cells in accordance with institutional policy.

4.5.6.3 If the patient's antibody screen is negative and they have no history of clinically significant red cell antibodies, provide phenotype matched red cells by the abbreviated eXM method; IAT crossmatch is not indicated. The decision to select red cells matched for only Rh and K or to the patient's extended red cell phenotype (or genotype) will depend on local policies or the availability of suitable red cells (or both).

ⓘ Patients treated with anti-CD38 should receive K negative red cells if the K type is unknown, cannot be determined prior to transfusion, or the patient is K negative.

4.5.6.4 If the antibody screen is positive, or the patient has a history of a clinically significant antibody, select red cells negative for the corresponding antigen and if able, perform an IAT crossmatch using the method described in specified MAb test section. Further matching to the patient's extended red cell phenotype (or genotype) will depend on local policies or the availability of suitable red cells (or both).

ⓘ Laboratories unable to perform specialised testing may elect to follow the institution's policy for providing extended phenotype matched red cells.

4.5.6.5 Where phenotyped matched red cells are unavailable, discuss red cell selection options with the clinical team. In the absence of alloantibodies, the priority order for phenotype matching is: Rh > Kell >Kidd > Duffy > Ss.

4.5.6.6 Laboratories should note that MAb carryover between specimens has been observed when using automated analysers.

4.5.6.7 Once MAb therapy has ended, immunohaematological interference may continue for several weeks or months after cessation. The laboratory should update the patient's LIS record and review transfusion support once MAb interference is no longer detected.

4.6 Warm autoimmune haemolytic anaemia (WAIHA)

4.6.1 General principles

4.6.1.1 If the patient has a warm (i.e. reactive at 37 °C) autoantibody, investigations should focus on obtaining a valid ABO/RhD group and establishing whether there is an underlying alloantibody.

4.6.1.2 The patient's drug history should be checked as a potential cause of the positive DAT, autoantibody or immune haemolysis.

4.6.1.3 Interpreting results and performing specialised testing, such as adsorption, requires staff with significant experience. Because of the potential complexity of, or difficulties associated with, pretransfusion testing in cases of WAIHA, referring the specimen to a reference laboratory may be necessary.

4.6.1.4 Before starting regular transfusions, an extended red cell phenotype (or genotype if the patient has been transfused within the last three months or has a positive DAT) should be performed; a minimum of Rh, K, Jk^a, Jk^b, Fy^a, Fy^b, S and s is recommended.

4.6.1.5 Phenotypically matched red cells are recommended for transfusions, with the degree of matching limited to Rh and K or an extended phenotype, according to local policy and/or availability of red cells.

4.6.1.6 Adsorption of the patient's plasma may be used to remove autoantibody activity and reveal the presence of a coexisting alloantibody:

Autoadsorption Uses the patient's own red cells (if the patient has not been transfused within the preceding 3 months).

Alloadsorption Uses phenotyped donor red cells (if the patient has been transfused in the previous 3 months or there is a limited volume of the patient's red cells).

4.6.1.7 If adsorption reveals a clinically significant alloantibody, antigen negative red cells should be selected. If an IAT crossmatch is performed adsorbed plasma should be used, where available.

4.6.1.8 If the patient is clinically stable and has formed no alloantibodies, reducing the frequency of testing (e.g. omitting regular adsorptions or serological crossmatching) may be considered. The decision to abbreviate testing should be made following discussions between a transfusion medicine specialist, the laboratory director, and the patient's clinician.

4.6.2 Positive DAT with a negative antibody screen

4.6.2.1 If the patient has not been transfused in the preceding 3 months and has no history of a clinically significant antibody, the specimen can be treated in the same way as a routine pretransfusion specimen with a negative antibody screen, and red cells can be issued using the laboratory's abbreviated crossmatch procedure.

4.6.2.2 If the patient has been transfused in the last 3 months:

- review laboratory results for evidence of haemolysis; for example, haemoglobin, reticulocytes, DAT, bilirubin, lactate dehydrogenase (LDH) and blood film
- check whether the patient has recently received ABO-mismatched blood components, intravenous immunoglobulin (IVIg), or a haemopoietic stem cell (HSCT) or solid organ transplant (SOT)
- perform an elution if a delayed haemolytic transfusion reaction (DHTR) is suspected.

4.6.2.3 If the patient has a history of a clinically significant antibody, or if an alloantibody was detected in the eluate, red cells should be issued in accordance with section 3.

4.6.2.4 If the patient has no history of a clinically significant antibody, or if no alloantibody was detected in the eluate (or elution was not indicated), the specimen can be treated as if for routine pretransfusion testing.

4.6.3 Historically positive DAT (with or without an autoantibody) now resolved

4.6.3.1 If the patient has a negative antibody screen, no history of a clinically significant antibody, and a negative DAT, then the specimen can be treated in the same way as a routine pretransfusion specimen with a negative antibody screen. Red cells can be issued using the laboratory's abbreviated crossmatch procedure.

4.7 Allogeneic haemopoietic stem cell transplant (HSCT)

4.7.1 The sources of allogeneic HSCT grafts include stem cells, bone marrow and donated cord blood. The transplant may be identical or mismatched to the ABO and/or RhD group of the recipient.

4.7.2 The institution's laboratory must be informed of the transplant plan, including details of the recipient (patient), the donor, and the confirmed infusion date, to allow the selection of appropriate blood components pre- and post-transplant transfusion support.

4.7.3 The laboratory supporting the transplant centre must have written protocols for selecting blood components for patients receiving HSCT. If the patient is transferred to another institution following the transplant, the laboratory servicing that institution must also be provided with these protocols.

4.7.4 ABO mismatched transplants may be major, minor, or both major and minor:

Major ABO mismatch	Recipient ABO antibodies against donor antigen(s)
Minor ABO mismatch	Donor ABO antibodies reactive against recipient antigen(s)

4.7.5 RhD mismatch transplants may be major or minor:

Major RhD mismatch	Recipient RhD negative / donor RhD positive
Minor RhD mismatch	Recipient RhD positive / donor RhD negative

4.7.6 The risks from ABO and/or RhD mismatch transplants include:

- haemolysis from donor antibodies infused with the transplant graft
- delayed haemolysis due to antibodies produced by the recipient's residual lymphocytes
- delayed haemolysis due to antibodies produced by donor memory B cells against recipient ABO antigens (passenger lymphocyte syndrome)

4.7.7 Other red cell antibodies, such as recipient-derived antibodies against donor antigens (major mismatch) or donor-derived antibodies against recipient antigens (minor mismatch), may also be significant and carry similar risks.

4.7.8 HSCT recipients should be monitored for haemolysis.

4.7.9 Red cells and platelets must be irradiated in concordance with the ANZSBT Guidelines for the Prevention of transfusion-associated graft versus host disease (TA-GVHD).[19]

4.7.10 Prior to transplant, the recipient must undergo a blood group and antibody screen. If the recipient has antibodies that may be directed against donor antigens, including ABO antibodies or other clinically significant red cell antibodies, baseline antibody titres should be determined, and the transplant physician informed.

19. ANZSBT *Guidelines for the Prevention of Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD)*. https://anzsbt.org.au/guidelines-standards/anzsbt-guidelines/

4.7.11 An extended phenotype for the recipient may be considered according to institutional policy.

4.7.12 Prior to transplant, the donor must have a blood group and antibody screen performed and the results provided to the laboratory.

- If the donor has a clinically significant red cell antibody, the recipient should be tested for the corresponding antigen.
- Conversely, if the recipient has a red cell antibody, the donor should be tested for the relevant antigen, and the transplant physician should be informed of the mismatch. Extended red cell phenotyping of the donor pre-transplant may also be considered based on the institution's policy.

4.7.13 The LIS should be used to record the transplant date, blood groups of the recipient and donor, and the blood components selected to support the transplant, to ensure this information is readily available at the time of blood component issue.

4.7.14 Pre-transplant selection of blood components

4.7.14.1 Select recipient-compatible red cells, platelets, and plasma components or follow the local policy for selecting blood components.

4.7.14.2 The use of "secretor plasma $Le^{(b+)}$" to reduce recipient ABO antibodies before transplant may form part of the institution's pre-transplant protocol.

ⓘ The plasma is from an $Le^{(a-b+)}$ donor and contains soluble H (and A or B antigens if the donor is group A or B). It may be effective to neutralise a recipient's ABO antibodies. [20]

4.7.15 Post-transplant selection of blood components

4.7.15.1 In the immediate post-transplant and pre-engraftment phases, the selection of blood components should follow Table 4.1 below.

4.7.15.2 A DAT may also be performed on the patient's specimen and if positive, an eluate obtained and tested against A_1 and B cells.

Table 4.1 Selection of blood components for ABO mismatched HSCT, post-transplant and pre-engraftment:[21]

	Recipient	Donor	Red Cells	Platelets	FFP / Cryo
Major ABO Incompatibility	O	A	O	A_2^* or A or $O^\#$	A or AB
		B	O	B or $O^\#$ or $A^\#$	B or AB
		AB	O	A_2^* or $O^\#$	AB
	A	B	O	B or $O^\#$	AB
		AB	A or O	$A^\#$ or $O^\#$	
	B	A	O	A	AB
		AB	B or O	B	

	Recipient	Donor	Red Cells	Platelets	FFP / Cryo
Minor ABO incompatibility	A	O	O	A	A
	B	O	O	B	B
	AB	O	O	A	AB

20. Lifeblood *Blood component information: An extension of blood component labels* https://www.lifeblood.com.au/health-professionals/learn/resource-library

21. Pawson, R. Specification SPN215/2 Selecting appropriate blood products for recipients of ABO/Rh mismatched stem cell transplants. https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/14864/d4b11163-d079-4cf7-be1d-50baa5788066.pdf

	Recipient	Donor	Red Cells	Platelets	FFP / Cryo
		A	A or O	A or O#	
		B	B or O	B or O#	

	Recipient	Donor	Red Cells	Platelets	FFP / Cryo
RhD^ incompatibility	RhD neg	RhD pos	RhD neg	RhD neg	N/A
	RhD pos	RhD neg			

* Group A platelets that have an A_2 subgroup do not express significant amounts of A antigen and are therefore preferable for transfusion to group O and B recipients receiving group A HSCT mismatch than other A platelets

\# Apheresis platelets that have low-titre anti-A/-B or pooled platelets pose a lower risk of haemolysis when transfusing ABO incompatible components

^ RhD incompatibility in the absence of immune anti-D in platelet transfusion. If RhD negative patient receiving RhD positive stem cell transplant and is transfused RhD positive platelets, the use of RhD immunoglobulin should be carefully considered as residual RhD prophylactic antibody is likely to bind to newly engrafted RhD positive stem cell donor cells. Consultation with the treating physician is advised.

4.7.15.3 If the recommended group-compatible blood components are unavailable, the treating clinician must be consulted to decide on the most appropriate alternative. The decision may be based on the time post-transplant and the patient's current blood group result.

4.7.16 Post-transplant criteria for blood group change

4.7.16.1 Prior to changing blood product groups to reflect the donor's blood group in major mismatched transplants, the following testing must be performed.

Test	Expected result
Blood group	No detectable anti-A or anti-B antibody against the donor blood group, tested by IAT using A_1 and/or B cells as indicated
Direct antiglobulin test (DAT)	Negative

4.7.16.2 Conversion of the recipient's blood group to that of the donor will be apparent when there is no evidence of mixed-field reactions in blood grouping tests. In practice, this can only usually be demonstrated if there have been no red cell transfusions in 3 months preceding testing.

ⓘ The corresponding anti-A or anti-B in the reverse group may not be detectable depending on the patient's original group.

4.7.17 Selection of blood components post-transplant and the recipient's blood group conversion

4.7.17.1 For transfusion, select blood components with the HSCT donor's blood group.

4.7.17.2 Amend the patient's LIS record and associated comments to reflect their post-transplant blood group change and new blood component requirements.

4.7.17.3 If the transplant has failed, discuss transfusion requirements with the treating clinician. The patient's blood group and transfusion support should be reviewed to ensure the continued safe and appropriate transfusion of blood components.

4.8 ABO-mismatched solid organ transplants [22]

4.8.1 The transfusion laboratory supporting the transplant centre must have written protocols for the selection of blood components, including the provision of HLA-matched red cells (where

22. NHS Blood and Transplant. Specification SPN216/7 – Management of D negative female patients with D positive: inadvertent red cell or platelet transfusion; bone grafts; solid organ transplant (SOT) or large volume fetomaternal haemorrhage (FMH). https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/25228/spn216.pdf

available) for kidney transplant recipients and for patients receiving solid organ transplants from ABO-mismatched organ donors.

4.8.2 During the transplant period, recipients from an ABO-mismatched organ donor should be transfused with blood components, and in particular plasma products, where the ABO antibodies are compatible with the ABO group of the graft.

4.8.3 For RhD negative women of childbearing potential (i.e. ≤ 50 years of age) receiving an organ from RhD positive donor, RhD Ig may be considered according to the institution's protocol. The required dose of RhD Ig will vary according to the organ transplanted. The recipient may be monitored for the ongoing presence of potentially sensitising RhD positive donor red cells using flow cytometry, with the frequency and dose of RhD Ig recommended accordingly.

4.8.4 Irradiated red cells and platelets are generally not indicated for recipients of ABO-mismatched solid organ transplants unless there are other indications for their use.

4.8.5 In choosing to transfuse, the following factors should also be considered:

- 'Passenger lymphocyte syndrome' is a rare but significant occurrence.
- Use of blood components and/or products containing ABO antibodies incompatible with the ABO group of the transplanted donor organ should be minimised.
- Renal transplant patients should remain on their transplant transfusion protocol indefinitely, with specific product requirements determined in consultation with their renal physician.

4.9 Autologous transfusion

4.9.1 Autologous blood donation is only recommended for exceptional circumstances where compatible donors are rare or difficult to find (e.g. in patients with rare blood groups or multiple red cell antibodies).

4.9.2 Laboratories performing autologous transfusions should have written protocols for managing autologous blood. Pretransfusion procedures for autologous transfusions should generally be the same as those for allogeneic transfusions.

4.9.3 Autologous units should be clearly labelled to distinguish them from allogeneic (homologous) units and stored in a designated area. Systems must be in place to prevent autologous units from being issued to a patient other than the donor.

4.9.4 A compatibility label must be attached to autologous units before release.

5 Storage and transport of blood components and/or products

5.1 Inventory management

5.1.1 The blood service (Lifeblood or NZBS) will only normally supply blood components and products to appropriately accredited pathology providers or approved health facilities in accordance with national regulations.

5.1.2 Direct supply of fresh components (red cells, platelets, and plasma) to non-approved facilities, e.g., remote healthcare facilities without on-site or local pathology providers, is only permissible in exceptional circumstances and only then under pathology provider and/or health department guidance with assurance of appropriate storage and handling, record keeping, and traceability.

5.1.3 Laboratories must have written policies that ensure proper and efficient inventory management, traceability, and minimisation of blood component and/or product wastage.

5.1.4 Laboratories must have written policies to ensure temperature-controlled storage and transport using appropriately validated equipment. This policy must include corrective actions to address deviation from specifications.

5.1.5 Laboratories must have processes to ensure the timely return into stock of unused patient-assigned blood components and/or products as determined by sample validity and blood component and/or product expiry.

5.1.6 The laboratory must (where possible) participate in a national electronic blood management and inventory tracking program.

5.1.7 Inventory practices should be reviewed at least annually, and wastage monitored against national benchmarks to ensure that appropriate inventory levels are set and wastage is minimised.

5.2 Temperature-controlled storage

5.2.1 Blood components and/or products must be stored at the relevant temperature (see Table 5.1) in appropriately monitored temperature-controlled equipment or facilities in accordance with the requirements of the manufacturer or supplier.

ⓘ Although not recommended practice, it is recognised that equipment used for storing blood components and products is also used to store (for example) donor or patient specimens, reagents, plasma derivatives, tissues and other medicines. The decision to do so must be based on a risk assessment, and items must be appropriately segregated.[23]

5.2.2 The organisation that owns or manages equipment or facilities used to store or transport blood components and products is responsible for ensuring compliance with AS3864 and all other regulatory requirements.

5.2.3 **All** refrigerators, cool rooms and freezers used to store fresh blood components i.e. red cells and plasma must comply with Part 1 (Manufacturing requirements) and Part 2 (User-related requirements for care, maintenance, performance verification and calibration) of Australian

23. New Zealand Blood Service (NZBS) *Refrigeration guidelines* (June 2019). https://www.nzblood.co.nz/clinical-information/transfusion-medicine/refrigeration-guidelines

Standard AS 3864 *Medical refrigeration equipment – for the storage of blood and blood products*.

ⓘ Although **platelet agitators** or **incubators** are not included in the standard, applicable requirements from AS3864 Part 2 should be followed. Equipment should have alarms for motion failure, open door (where relevant) and power failure. The high and low alarm points should be set at 23.5 °C and 20.5 °C, respectively. Where platelets are not stored in a platelet incubator the laboratory must demonstrate that the required room temperature is maintained.

5.2.4 Components and/or products issued by the laboratory to another location, e.g., wards, theatres, those sent with patients transferred from locations or facilities outside the jurisdiction of the receiving laboratory, or products accompanying emergency retrieval teams (e.g., in a helicopter or ambulance), are considered in **storage**.

5.2.5 If the transfusion laboratory issues blood components and/or products to a location where the laboratory is not responsible for the storage equipment or facilities, staff must be satisfied that the storage arrangements are safe and appropriate and comply with all regulatory requirements.

5.2.6 To check compliance, the issuing laboratory must obtain copies of temperature monitoring, maintenance and spatial checking records from the organisation responsible for the equipment or facility.

5.2.7 Under the following circumstances affected blood components and/or products must not be transfused (except at the discretion of the laboratory director):

- Storage at temperatures outside the specified limits; or
- Storage in nonconforming equipment; or
- Where there is any doubt regarding storage temperatures or conditions.

5.2.8 Any deviations from the required storage temperatures or conditions must be clearly documented, and the components and/or products must be quarantined until their fate is decided.

5.2.9 Policies for managing affected blood components and/or products, including the decision to return to the inventory or for subsequent transfusion, must be based on a risk assessment.

5.3 Removal from and return to temperature-controlled storage

5.3.1 General principles

5.3.1.1 Time out of controlled storage for blood components and/or products should be kept to a minimum.

5.3.1.2 If there is a short delay (or one is anticipated) before starting the transfusion, the component and/or product may be kept at ambient temperature at the patient's bedside, provided the transfusion can be completed within the total allowable duration (normally four hours).[24]

5.3.1.3 In some instances, it may be necessary to issue components (e.g. recently thawed FFP or irradiated red cells) that have not cooled to the required temperature before distribution and may still be warm on receipt. Specified temperature limits are not applicable in these instances.

ⓘ When issuing or shipping warm components and/or products, these should be segregated from any refrigerated components and/or products issued at the same time, and using a separate shipper if necessary.

24. ANZSBT *Guidelines for the administration of blood products* https://anzsbt.org.au/guidelines-standards/anzsbt-guidelines

5.3.1.4 Components and/or products issued by the laboratory to another location must be placed either into a monitored temperature-controlled device or kept in a validated shipping container able to maintain the appropriate storage temperature (see Table 5.1).

5.3.2 Red cells [25, 26]

5.3.2.1 Red cells should be issued to the clinical area for immediate transfusion.

5.3.2.2 Where possible, time out of controlled storage should be restricted to under 30 minutes

5.3.2.3 If the transfusion does not begin within 30 minutes of issue, and there is no prospect of imminent transfusion, the red cells must be returned to the transfusion laboratory or quarantined remotely using electronic blood tracking systems. The fate of the unit will be determined by the transfusion laboratory (or it's director).

5.3.2.3.1 Up to 60 minutes out of controlled temperature is acceptable provided the unit is placed in a quarantine area of a secure refrigerator for at least 6 hours, to allow it to return to 2-6 °C.

5.3.2.4 Where transfusion laboratories accept back to inventory red cells that have been out of controlled temperature storage for more than 30 and up to 60 minutes, they must have a documented process to ensure the same units of red cells are not stored outside controlled storage on more than three occasions.

5.3.3 Cryoprecipitate

5.3.3.1 Thawed cryoprecipitate must be transfused within 6 hours.

5.3.4 Fresh frozen plasma

5.3.4.1 Thawed FFP and ELP can be accepted back into the inventory if they have been out of controlled storage (2-6 °C) for 30 minutes or less on no more than one occasion.

5.3.5 Platelets

5.3.5.1 Platelets must not be stored without agitation for more than 24hours. Refer to Table 5.1

5.4 Transporting blood products

5.4.1 General principles

5.4.1.1 **Transport** is the process of shipping blood components and/or products from the supplier e.g. blood service to the hospital laboratory, from the base hospital to its satellite laboratories or between laboratories in a network.

5.4.1.2 Blood components and/or products must be transported using appropriately validated transport containers and packing configurations in accordance with the requirements of the manufacturer or supplier and the receiving laboratory.

5.4.1.3 Blood component and/or products must be maintained within the specified temperature range for the duration of transport, irrespective of mode of delivery (see Table 5.2).

5.4.1.4 Acceptance of transported blood components and/or products by the receiving transfusion laboratory is conditional on evidence of suitable storage and handling while in transit from the issuing facility.

5.4.1.5 Blood components and/or products where the temperature during transport was outside the specified limits, transported in nonconforming equipment, or where there is doubt regarding

25. Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) *Guidelines for the Blood Transfusion Services* (https://www.transfusionguidelines.org/red-book/chapter-7-specifications-for-blood-components)

26. BSH *Guidelines for the administration of blood components* (2017) (https://b-s-h.org.uk/guidelines)

the transport conditions must not be transfused (except at the discretion of the laboratory director).

5.4.1.6 Any deviations from specified transport requirements must be clearly documented and the blood component and/or products quarantined until their fate is decided.

5.4.2 Pneumatic tube system (PTS) 27

5.4.2.1 The PTS must be appropriately validated for transporting blood components and/or products.

5.4.2.2 The PTS must not expose blood components and/or products to physical forces or environmental factors including temperature and extended transit time, that could adversely affect their quality or efficacy.

5.4.2.3 The laboratory must have procedures for dealing with blockages in the PTS or for decontamination following blood component and/or product breakages or leaks during passage through the system. The procedures should include system access points and canister dumping stations.

5.4.2.4 The laboratory should ensure that the clinical area is alerted to expect delivery of the requested blood component and/or product through the PTS.

5.4.2.5 The receiving area should have a procedure for notifying the laboratory when they have received a blood component and/or product and its subsequent removal from the PTS (or failure of the blood component and/or product to arrive as expected).

27. Association for the Advancement of Blood and Biotherapies. *AABB guide to pneumatic tube delivery systems – Validation and use to transport blood components*. https://www.aabb.org/aabb-store/product/aabb-guide-to-pneumatic-tube-delivery-systems-validation-and-use-to-transport-blood-components---digital-15175121

Table 5.1: Blood component storage temperatures

Product	Storage temperature	Maximum storage duration
Red cells	2 °C to 6 °C	42 days
Paediatric red cells	2 °C to 6 °C	35 days
Washed red cells	2 °C to 6 °C	28 days
Irradiated red cells	2 °C to 6 °C	14 days post irradiation 24 hours post irradiation for IUT or exchange transfusion 48 hours for neonatal or infant small volume transfusions
Frozen red cells	-60 °C to -80 °C or below	30 years[28]
Thawed red cells	2 °C to 6 °C	24 hours post thawing
Platelets	20 °C to 24 °C In a room at ambient temperature or platelet incubator with continuous gentle agitation, preferably on a flatbed agitator	7 days
Frozen plasma (FFP, CDP, cryoprecipitate)	–25 °C or below	12 months If storage temperature is between –18 °C and –25 °C expiry should be reduced to 3 months
Thawed plasma (FFP, CDP)	2 °C to 6 °C	24 hours
Extended life plasma (ELP)	2 °C to 6 °C	5 days from thawing
Thawed cryoprecipitate	20 °C to 24 °C	6 hours
Plasma derivatives and recombinant products as per manufacturer or supplier instructions		

CDP, cryodepleted plasma; ELP, extended life plasma; FFP, fresh frozen plasma; IUT, intrauterine transfusion

Table 5.2: Blood component and product transport temperatures

Product	Transport temperature
Red cells	2 °C to 10 °C
Frozen plasma (FFP, CDP, cryoprecipitate)	–25 °C or below If transport temperature is between –18 °C and –25 °C expiry should be reduced to 3 months
Thawed plasma (FFP, CDP), ELP	2 °C to 10 °C
Thawed cryoprecipitate	20 °C to 24 °C
Platelets	20 °C to 24 °C Time without agitation should not exceed a total of 24 hours
Plasma derivatives and recombinant products	As per manufacturer or supplier specifications

CDP, cryodepleted plasma; FFP, fresh frozen plasma; ELP, extended life plasma

28. European Directorate for the Quality of Medicines & Healthcare of the Council of Europe (EDQM). Guide to the preparation, use and quality assurance of blood components. 19th edn. Strasbourg: EQQM Publications, 2017 (https://www.edqm.eu/en/blood-guide)

6 Management of adverse transfusion events

6.1 Notification of transfusion reactions

6.1.1 Transfusing institutions must have systems and procedures in place to identify, manage, investigate and report adverse transfusion reactions and other transfusion-related adverse events.

6.1.2 Adverse transfusion events should be discussed with a suitably experienced pathologist (e.g., laboratory director, haematologist, or transfusion medicine specialist) to ensure appropriate haemovigilance reporting and patient management, particularly regarding ongoing or future transfusions.

6.1.3 Events with component and/or product safety, quality or donor implications must be reported as soon as possible such as suspected cases of transfusion-transmitted bacterial, viral or parasitic infections or transfusion-related acute lung injury (TRALI). The supplying blood service may require immediate follow-up action, for example, recalling potentially bacterially contaminated components prepared from the same donation or where further patient or donor investigations are necessary (e.g. suspected TRALI).

6.1.4 All issued but non-transfused components must be returned immediately to the blood service or quarantined by the laboratory to prevent further transfusion before the investigation is completed.

6.2 Investigation of transfusion reactions

6.2.1 The laboratory must have a documented procedure for investigating a suspected transfusion reaction.

6.2.2 Transfusion reactions must be appropriately investigated to exclude haemolytic transfusion reactions if clinically considered possible before any further blood components and/or products are issued. If further blood components and/or products are required urgently, refer to the laboratory's suitably experienced pathologist to support clinical decision making.

6.2.3 Not all reactions require investigation. For example, minor allergic or febrile non-haemolytic reactions may not need investigation. ANZSBT Guidelines for the Administration of Blood Products provide advice on when investigation may not be required.

6.2.4 If a further transfusion is required before the investigation is completed, it must be authorised by a suitably experienced pathologist (e.g. laboratory director, haematologist, or transfusion medicine specialist).

6.2.5 The patient's identification and blood component and/or product compatibility labels must be confirmed at the bedside to rule out clerical or administration errors or ABO incompatibility.

6.2.6 Where a possible haemolytic transfusion reaction or bacterial contamination is clinically suspected, or needs to be excluded, the following should be sent to the laboratory as soon as possible after the reaction:

- a 'transfusion reaction investigation request' providing details of the clinical signs and symptoms of the reaction
- FBC & blood film, DAT, biochemistry for renal function, LDH and bilirubin, reticulocytes and haptoglobins a sample of the first urine produced post-transfusion for haemoglobin, urobilinogen (may be done on point of care strip testing) and urinary haemosiderin

- If the patient is febrile, blood cultures and request remnants of the blood component and/or product being transfused, and its administration set to be returned to the laboratory, as well as Any empty bags or bottles from blood components and/or products transfused before the implicated unit (if available).
  - ⓘ When returning used or empty blood components and/or products to the laboratory, local occupational health and safety policies (in particular, those for handling clinical waste) must be observed. Sharps must not be returned.

6.2.7 The following checks should be performed by the laboratory:

- patient's identity on the request form(s), pretransfusion and post-transfusion specimen(s), compatibility label(s) and the pretransfusion testing records
- the blood component and/or product donation or batch number(s) - when received
- the ABO/RhD groups of the patient and blood components
- visual check of returned components and/or products, for evidence of deterioration such as clots, or particulate matter, haemolysis or discolouration.

6.2.8 The laboratory investigations shown in Table 6.1 should be performed.

Table 6.1: Transfusion laboratory investigations following transfusion reactions

Patient or product	Investigations
Patient's specimens	• Visual examination of the post-transfusion plasma for haemoglobinaemia and haemolysis • ABO/RhD group, antibody screen and DAT on pretransfusion and post-transfusion specimens **Note:** a negative post-transfusion DAT does not exclude a severe haemolytic transfusion reaction • Review pre- and post-transfusion results to confirm compatibility
Red cells	• Determination of the ABO/RhD group of the unit being transfused at the time of the reaction, and any previously transfused units, where available • IAT crossmatch of the patient's pretransfusion and post-transfusion specimens against the red cell unit being transfused at the time of the reaction and any previously transfused units (where available)
Platelets or plasma	• Consider anti-A, anti-B in the plasma of the transfused unit(s)

DAT, direct antiglobulin test; IAT, indirect antiglobulin test; XM, crossmatch

6.3 Additional laboratory testing for transfusion reactions

6.3.1 Additional patient or donor investigations may be indicated or considered for specific reactions, as shown in Table 6.2.

Table 6.2: Additional laboratory investigations associated with transfusion reactions

Suspected reaction	Tests
TRALI	HLA and HNA typing and antibodies
TACO	BNP or N-terminal pro-BNP may be useful for distinguishing TACO from TRALI
Anaphylaxis	Pretransfusion IgA levels or anti-IgA (other plasma proteins if indicated), tryptase

BNP, brain natriuretic peptide; FNHTR, febrile non-haemolytic transfusion reaction; HLA, human leucocyte antigen; HNA, human neutrophil antigen; HPA, human platelet antigen; IgA, immunoglobulin A; TACO, transfusion-related circulatory volume overload; TRALI, transfusion-related acute lung injury.

Note that TRALI is a clinical diagnosis. Antibody studies are performed on the donor and may lead to donor exclusion, but positive results are not required to diagnose TRALI.

6.4 Other reportable transfusion-related adverse events

6.4.1 Laboratories and hospitals must have processes for detecting, investigating and reporting adverse events and non-conformances. These include the provision of incorrect blood components or components with unintended non-compliance with special requirements. These events may represent transfusion process failures and should be investigated even if there was no associated harm.

6.5 Laboratory reporting of transfusion reaction investigations

6.5.1 The transfusion laboratory should provide a report of the findings from investigation of the adverse reaction (or adverse event) to the patient's clinician, with a copy of the report must be available to be placed in the patient's clinical notes (if required).

6.5.2 The report should include details of the event and recommendations for managing future transfusion requirements.

6.5.3 Moderate or severe acute transfusion reactions should be referred to the local blood management committee to assess:

- appropriateness of the transfusion
- appropriateness of patient management and laboratory investigations
- identify strategies to improve transfusion practice and to provide feedback to the relevant clinical team
- identify trends in transfusion practice
- reporting to relevant state or national haemovigilance programs and to the blood service

6.5.4 A report should be sent to the state/territory or national haemovigilance programme in accordance with jurisdictional requirements.

7 Antenatal and postnatal testing

7.1 General principles

7.1.1 The aim of pretransfusion testing during pregnancy and at the time of birth is to identify pregnancies at risk haemolytic disease of the fetus and newborn (HDFN), as well as to provide appropriate transfusion support (if required) to the mother, fetus or newborn. The scope and timing of routine antenatal pretransfusion testing is shown in Table 7.3.

7.1.2 Patient identification, requests, specimens and testing should be treated in the same way as those in the pretransfusion setting.

7.1.3 Pretransfusion testing during pregnancy, and at the time of birth provides information to the healthcare provider regarding:

- RhD status to identify RhD negative women who may be offered prophylactic RhD Ig if predicted to be carrying an RhD positive fetus, or *RHD* NIPT screening is not available
- antibody screening to identify women with clinically significant red cell alloantibodies
- monitoring of clinically significant red cell antibodies, either by titration or quantitation, to identify pregnancies at risk of Haemolytic Disease of the Fetus and Newborn (HDFN)
- identifying and quantifying fetomaternal haemorrhage (FMH) using the Kleihauer-Betke test or flow cytometry to determine the appropriate dose of RhD Ig to prevent RhD alloimmunisation

7.1.4 Identification, and management of women with RhD variants including serological weak reactions (in line with manufacturer's instructions for automated methodologies or 2+ by manual technique (0-4+ scale)) or inconclusive RhD grouping. Patients should be treated as RhD negative until the RhD status has been confirmed by a reference laboratory.

7.1.5 Women with RhD variants known to produce anti-D may be offered RhD Ig prophylaxis, depending on the specific RhD variant. Conversely, women with an RhD variant not known to produce anti-D can be treated as RhD positive and do not require RhD Ig.

7.1.6 For RhD negative women, specimens must be collected prior to giving RhD Ig. If RhD Ig has been given for a prior potentially sensitising event, an antibody screen must be performed. To assist with the interpretation of results, the date RhD-Ig was given should be provided on the request.

7.1.7 It is acceptable for RhD Ig to be given immediately after taking the blood specimen, before antibody screen results are available.

7.1.8 Determining if the fetus carries the relevant red cell antigen (e.g. by non-invasive prenatal testing) may be clinically appropriate where a clinically significant maternal antibody is identified, or where the mother has a history of HDFN, and the father is heterozygous for the relevant antigen (or a paternal phenotype is unavailable).

7.1.9 Paternal phenotyping or genotyping can assist in predicting the likelihood of fetal inheritance of the implicated red cell antigen, and therefore the risk of HDFN.

7.2 Routine antenatal testing

7.2.1 An ABO/RhD group and IAT antibody screen should be performed as early as possible during each pregnancy, preferably at the first antenatal visit (ideally within the first trimester).

7.2.2 All women should have an ABO/RhD group and IAT antibody screen performed at 28 weeks. For RhD negative women requiring RhD Ig prophylaxis the specimen should be collected before this is administered.

7.2.3 When a red cell antibody is detected, its specificity must be identified, clinical significance determined and risk of HDFN assessed. If the antibody is clinically significant, antibody titration or quantitation should be performed to assess the risk of HDFN.

7.3 Alloimmunisation in pregnancy

7.3.1 To ensure appropriate management of the patient, all relevant information and history must be available, for example:

- previous history – for example, transfusion, pregnancies and RhD Ig prophylaxis
- previously affected pregnancies – for example, IUT, neonatal exchange transfusion and jaundice
- paternal blood group and Rh phenotype.

7.3.2 The clinical significance of antibodies detected during routine antenatal testing should be assessed (see Table 7.4). Antibody prevalence can vary between countries or regions, reflecting geographical or ethnic variations in blood group gene frequencies and transfusion practices.

7.3.3 Antibodies that cause HDFN are immunoglobulin G (IgG) and reactive by IAT. Anti-D, anti-c and anti-K are the most common antibodies resulting in severe haemolytic disease that may require antenatal intervention, referral to a specialist fetal medicine unit is recommend.

7.4 Fetal genotyping

7.4.1 Fetal genotyping using non-invasive prenatal testing (NIPT) should be considered for all RhD negative women in pregnancy who have not formed an anti-D to predict the RhD status of the fetus to allow target use for RhD Ig in accordance with national guidelines.

7.4.2 Fetal genotyping should also be considered for all at-risk pregnancies, that is the women is alloimmunised with a clinically significant red cell antibody to which there is a NIPT assay available to predict if the fetus is at risk of HDFN in accordance with national guidelines.

7.5 Women with anti-D

7.5.1 Distinguishing between passive and immune anti-D

7.5.1.1 When anti-D is detected, the laboratory should discuss the likely origin of the antibody with the patient's clinician and try to ascertain whether the antibody is immune (stimulated by pregnancy or transfusion) or passive as the result of RhD Ig prophylaxis.

7.5.1.2 It is important for the patient's management to ensure that passive antibody (i.e. residual RhD Ig) is not misinterpreted as immune anti-D, causing further prophylaxis to be withheld.

ⓘ RhD Ig prophylaxis should continue unless it is unequivocally confirmed that the anti-D is immune.

7.5.1.3 Currently, passive anti-D cannot definitively be differentiated from immune anti-D. Serological differentiation based on the reaction strengths from antibody screening is not reliable.

- If there is no record or it is unknown whether RhD Ig has been given, an antibody titration should be performed, and specimen should be sent for quantitation, where available. The patient should be treated as sensitised until the results of the above investigations are available.
- The post-prophylaxis concentration of RhD Ig would not be expected to exceed 0.1 IU/mL (following a standard 625 IU intramuscular dose) or 0.4 IU/mL (following a 1500 IU IV dose) unless multiple doses were given.

- Passive anti-D is *likely* if it is shown that RhD Ig was given in the previous 8–12 weeks. The patient should be treated as unsensitised, and further prophylaxis should be offered as recommended.
- If the anti-D is no longer detectable by IAT or the antibody level is falling, this suggests probable RhD Ig; conversely, a stable at repeat testing in 4 weeks or the antibody titre increased then this suggests immune anti-D.

7.5.1.4 Further testing after 28 weeks is not necessary if anti-D is not detectable in a specimen taken before giving RhD Ig, or if RhD Ig has recently been given (in the previous 8–12 weeks) or the anti-D quantification concentration is < 0.1 IU/mL.

7.5.2 Women with immune anti-D

7.5.2.1 A baseline antibody strength should be determined either by titration or quantitation (against the international anti-D standard) when the anti-D is first detected, with testing repeated every 4 weeks until 28 weeks, and every 2 weeks thereafter. Each specimen should be tested in parallel with the previous specimen.

7.5.2.2 If a specimen with anti-D is referred for routine antibody screening or pretransfusion testing, a selected panel of RhD negative cells (an 'RhD negative set') that possesses all other relevant red cell antigens should be used to detect (or exclude) the formation of other antibody specificities.

7.5.2.3 An antibody detected using the 'RhD negative set' should be fully investigated.

7.5.2.4 Laboratories should provide guidance on the test method used and the significance of the results.

7.5.2.5 The patient should be referred to a specialist fetal medicine unit for assessment and monitoring if they have an anti-D quantification ≥ 4 IU/mL or titre ≥ 32 (or a significant rise in titre).

Table 7.1: Clinical significance of anti-D quantification

Concentration (IU/mL)	Risk of HDFN
< 4	Unlikely; continue to monitor
4–15	Moderate risk; refer to a specialist fetal medicine unit
> 15	High risk; refer to a specialist fetal medicine unit

HDFN, haemolytic disease of the fetus and newborn; IU, international units

7.5.3 Clinical interpretation and reporting of anti-D

7.5.3.1 Laboratory results should be reviewed in conjunction with the patient's clinical history including potential sensitising events and recent (i.e. in the previous 8–12 weeks) administration of RhD Ig.

7.5.3.2 Reports to the patient's clinician should interpret the results in the context of the patient's clinical history and offer an assessment as to whether the antibody is presumed to be residual RhD Ig or immune in origin.

7.5.3.3 Paternal phenotyping recommended to predict the fetus' risk of expressing the RhD antigen.

7.5.3.4 Maternal samples should be sent for RHD NIPT to predict the RhD status of the fetus, and its risk of HDFN.

7.6 Women with anti-c

7.6.1 A baseline antibody strength should be obtained either by titration or quantitation (against the international anti-c standard) at the time the anti-c is first detected, with testing repeated every 4 weeks until 28 weeks, and every 2 weeks thereafter.

7.6.2 Each specimen should be tested in parallel with the previous specimen.

7.6.2.1.1 Laboratories should provide guidance on the test method used and the significance of the results.

7.6.2.1.2 Paternal phenotyping recommended to predict the fetus' risk of expressing the c antigen.

7.6.2.1.3 Maternal samples should be sent for c NIPT to predict the c status of the fetus, and its risk of HDFN.

7.6.3 The patient should be referred to a specialist fetal medicine unit for assessment and monitoring if they have an anti-c level ≥ 7.5 IU/mL, or titre ≥ 32 (or significant rise in titre) or the fetus is predicted to express the c antigen.

Table 7.2: Clinical significance of anti-c quantification

Concentration (IU/mL)	Risk of HDFN
< 7.5	Unlikely; continue to monitor
7.5–20	Moderate risk; refer to a specialist fetal medicine unit
> 20	High risk; refer to a specialist fetal medicine unit

HDFN, haemolytic disease of the fetus and newborn; IU, international units

7.7 Women with apparent anti-C+D (possible anti-G)

7.7.1 Some examples of apparent anti-C+D antibodies may be anti-G (or anti-C+G).

7.7.2 It is important that the correct antibody specificity is assigned in cases of apparent anti-C+D because women with anti-G (or anti-C+G) but not anti-D may form anti-D and are therefore eligible for both prophylactic and post-partum RhD Ig.

7.7.3 Confirming the presence of anti-G requires specialist techniques, and specimens may need to be referred to a reference laboratory.

7.8 Women with anti-K (or other Kell system antibodies)

7.8.1.1 If anti-K (or other Kell blood group system antibodies) are detected, paternal K phenotyping is recommended to predict the fetus' risk of expressing the K antigen.

7.8.1.2 Maternal samples should be sent for K NIPT to predict the K status of the fetus, and its risk of HDFN. If the fetus is K negative, the mother should be treated as an unaffected pregnancy.

7.8.1 If the K NIPT or paternal phenotype predicts the fetus will express the K antigen, referral to a maternal fetal medicine unit is recommended, regardless of the antibody titre.

7.8.2 Anti-K impairs haematopoiesis as well as causing haemolysis and peripheral sequestration. Previous obstetric history is not predictive of the likely severity of disease related to anti-K antibodies.

7.8.3 Anti-K titres do not correlate with clinical severity but a baseline antibody titre should be obtained when the antibody is first detected and can be repeated every 4 weeks until 28 weeks and every 2 weeks at the discretion of the treating clinician.

7.9 Women with other red cell antibodies

7.9.1 Antibodies that cross the placenta and potentially cause HDFN are IgG and are reactive by the IAT. Refer to table 7.4. Women with antibodies not implicated in HDFN do not need to be monitored.

7.9.1.1 If clinically significant antibodies other than anti-D, anti-c, and anti-K are detected during prenatal testing before 28 weeks gestation, an antibody titre should be obtained when the antibody is first detected (for the baseline level) and repeated during routine screening at 28 weeks gestation.

7.9.1.2 Paternal phenotyping recommended to predict the fetus' risk of expressing the antigen to which the women is alloimmunised.

7.9.2 Maternal samples should be sent for NIPT, if the assay is available, to predict the antigen expression of the fetus, and its risk of HDFN.

7.9.3 If the titre is ≥ 32 (or other critical titre defined by the laboratory), the patient should be referred to a maternal fetal medicine unit for further assessment and testing.

7.10 Pretransfusion testing in the peripartum

7.10.1 Maternal testing

7.10.1.1 If the maternal ABO/RhD group is not known, a pre- or post-delivery specimen should be tested to determine if the mother is RhD negative and therefore offered RhD-Ig.

7.10.1.2 The decision to request a group and screen before delivery should be based on the risk of maternal bleeding and of factors that may delay transfusion, such as availability of emergency blood products or presence of clinically significant antibodies.

7.10.1.3 If the newborn shows clinical evidence of HDFN (e.g. a positive DAT) but the maternal antibody screen is negative and there is no fetomaternal ABO incompatibility, an antibody in the maternal serum to a low incidence antigen should be considered. A crossmatch between maternal plasma and paternal red cells (if ABO compatible) may be informative.

7.10.2 Neonatal testing

7.10.2.1 If the mother is RhD negative and/or has a clinically significant antibody or was not tested during pregnancy, a cord specimen should be collected and ABO/RhD typing and DAT performed.

7.10.2.2 Cord blood specimens not needed for testing may be stored (as per Table 1.3) in case testing is required at a later stage.

7.10.2.3 A DAT is indicated when there are clinical signs of jaundice or anaemia in the neonate and where the mother is known to have a clinically significant antibody. Haemoglobin and bilirubin may also be assessed. Antigen typing of the baby for the relevant antigen(s) should be performed where the mother is known to have a clinically significant antibody.

7.10.2.4 A positive DAT indicates that the neonate's cells are coated with antibody but does not predict severity of haemolysis. An elution may be performed to confirm the identity of the antibody coating the cord red cells.

7.10.2.5 In ABO HDFN, the DAT may be negative. In some cases, although the causative ABO antibody is not detectable by DAT, it may be demonstrable by elution.

7.10.2.6 Newborns of RhD negative mothers should be tested by a technique that detects **clinically significant RhD variants** to ensure that RhD Ig is offered to the mother when indicated. Monoclonal anti-D typing reagents should detect most significant RhD variants.

7.10.2.7 It is unlikely that newborns with the DVI antigen will cause maternal sensitisation; therefore, it is not necessary to group the newborns with reagents specifically capable of detecting DVI.

7.11 Testing for fetomaternal haemorrhage (FMH) to determine the dose of RhD Ig

7.11.1 FMH can occur at any time during pregnancy but particularly at the time of birth, potentially leading sensitisation of RhD negative mothers by RhD positive fetus/neonate and subsequent alloimmunisation

7.11.2 It is important to estimate the volume of FMH following a potentially sensitising events to ensure that the appropriate and timely dose of RhD Ig is given (ideally within 72hrs)) to prevent RhD sensitisation.[30]

7.11.3 Before 20 weeks, the fetal blood volume is small so an FMH will be covered by the standard dose of RhD Ig; there is no need to quantity the FMH.[30]

7.11.4 All RhD negative women without evidence of anti-D who gives birth to an RhD positive baby should have a test for FMH as soon as practical. It is recommended that a specimen is collected 30-45 minutes following the sensitising event and ideally within 2 hours.

7.11.5 Two assays are used for the detection and quantitation of FMH including the Kleihauer-Betke test (acid elution) and flow cytometry. Flow cytometry is considered more precise and reproducible.

7.11.6 A single 625 IU dose of RhD Ig will protect against an FMH of up to 6 mL of fetal red cells; for FMH > 6 mL, a dose of 100 IU/mL is recommended. Depending on the estimated volume of FMH, more than one dose of RhD Ig may be necessary.

ⓘ Calculations for determining the volume of FMH can be found in the ANZSBT *Guidelines for laboratory assessment of fetomaternal haemorrhage*.[29]

7.11.7 If large doses of RhD Ig are indicated or intramuscular injections are inappropriate or unsuitable, an IV RhD Ig preparation should be considered.

[29] https://anzsbt.org.au/pages/anzsbt-guidelines.html

Table 7.3: Routine antenatal testing

Test	Circumstances	Timing
Blood group (ABO/RhD)	All pregnant women	Initial antenatal visit 28 weeks
	Pretransfusion testing	As required
Antibody screen	All pregnant women	Initial antenatal visit 28 weeks Collect blood specimen before administration of RhD Ig
	RhD negative women receiving RhD Ig following a sensitising event	As required; collect blood specimen prior to administration of RhD Ig
	Pretransfusion testing	As required
Antibody identification	Positive antibody screen	Following initial detection of antibody and repeated as necessary
Antibody levels (by titration or quantitation)	All alloimmunised women during pregnancy	At first detection of antibody, phenotype partner or NIPT to determine fetus risk of HDFN. Referral for appropriate clinical management advised.
	Anti-D, anti-c or anti-K	At first detection of antibody, phenotype partner or NIPT to determine fetus risk of HDFN. Every 4 weeks until 28 weeks gestation, then every 2 weeks. Referral for appropriate clinical management advised.
	Other antibodies likely to cause HDFN detected during routine prenatal testing	At first detection of antibody, phenotype partner or NIPT (if available) to determine fetus risk of HDFN. Every 4 weeks until 28 weeks gestation, then every 2 weeks. Referral for appropriate clinical management advised
Testing for FMH	RhD negative women following a potentially sensitising event (> 20 weeks gestation) if carrying an RhD positive fetus or RHD NIPT not available.	As required
	RhD positive neonate born to a RhD negative women without immune anti-D	As required

Test	Circumstances	Timing
Fetal RhD genotyping using non-invasive prenatal testing	Routine testing for RhD negative women where available.	Performed as per testing laboratory requirements
Fetal genotyping using non-invasive prenatal testing for alloimmunised patients	At-risk pregnancy: • With no history of HDFN but elevated titre of clinically significant red cell antibody; or • Previous pregnancy complicated by HDFN with unknown or heterozygous paternal blood group; or Paternal K positive or unknown phenotype	As per national guidelines - performed ≥ 12 weeks gestation

FMH, fetomaternal haemorrhage; HDFN, haemolytic disease of the fetus and newborn; IUT, intrauterine transfusion; RhD Ig, RhD immunoglobulin

Table 7.4: Red cell antibodies and the risk of haemolytic disease of the fetus and newborn

		HDFN	
Blood group System	**IgG**	**Likelihood**	**Severity**
ABO	Some	Yes	No to moderate (rarely severe)
M	Most	Rare	No to severe
N	Some	No	
S, s, U	Most	Rare	No to severe
P_1	Rare	No	
Rh	Most	Yes	Mild to severe
Lutheran	Most	Rare	Mild
Kell	Most	Yes	Mild to severe
Lewis	Some	No	
Duffy	Most	Rare	Mild to severe
Kidd	Most	Rare	Mild to moderate (rarely severe)
Diego	Most	Rare	Mild to severe
Yt	Most	No	
Xg	Most	No	
Scianna	Most	Yes	Mild to severe (only anti-Sc3, anti-Rd)
Dombrock	Most	No	
Colton	Most	Rare	Mild to severe
LW	Most	No	
Chido/Rogers	Most	No	
H	Some	Rare	No to severe
Gerbich	Most	Yes	Mild to severe (only anti-Ge3)
Cromer	Most	No	
Knops	Most	No	
Indian	Most	No	
JMH	Most	No	
I	Rare	No	
Vel	Yes	Rare	Severe
Other antibodies active by IAT at 37 °C (including antibodies to low or high frequency antigens)		Depends on specificity; May need to seek advice from reference laboratory	

HDFN, haemolytic disease of the fetus and newborn; HLA, human leucocyte antigen; IAT, indirect antiglobulin test; IgG, immunoglobulin G

8 Quality management

8.1 Laboratory quality management system

8.1.1 The laboratory must have a Quality Management System (QMS) in accordance with national accreditation and regulatory requirements.

8.1.2 All policies, procedures, and methods must be documented and kept in a designated 'Quality manual', which must be readily accessible to all staff.

The quality manual should be periodically reviewed (e.g., annually) to ensure that it remains current. Electronic document control systems facilitate continual document review and timely updates.

8.2 Accreditation of medical testing laboratories

8.2.1 Medical testing laboratories are accredited in Australia by the National Association of Testing Authorities/Royal College of Pathologists of Australasia (NATA/RCPA) and in New Zealand by International Accreditation New Zealand (IANZ) against the respective national standard: AS ISO 15189:2023 *Medical laboratories – Requirements for quality and competence* or NZS ISO 15189:2022 *Medical laboratories – requirements for quality and competence*. [30, 31, 32]

8.2.2 In New Zealand, accreditation of transfusion medicine laboratories is further supported by the New Zealand Blood Service *Te Whatu Ora Clinical Oversight Programme*, which provides formal clinical and technical oversight of blood banks through a combination of site visits, clinical audits and regional blood bank meetings.

8.2.3 Governance of hospital transfusion activities is accredited according to National Standards. For information on activities of a hospital transfusion governance committee, refer to Appendix 2 Informative

8.3 Quality control (QC)

8.3.1 General principles

8.3.1.1 All equipment (instruments, reference materials, consumables, reagents and analytical systems) must be validated and subjected to regular maintenance and calibration programs to ensure reliability.

8.3.1.2 Equipment performance must be monitored at regular intervals in accordance with the manufacturer's recommendations and relevant national accreditation guidelines.

8.3.1.3 The manufacturer's instructions must be followed, although more stringent testing may be performed if desired.

8.3.1.4 Records of all QC performed by the laboratory must be maintained in line with national regulatory requirements.

8.3.1.5 The laboratory should record all batch numbers and expiry dates of reagents, and the time span over which they were used. It should be possible to link each test to the reagents used.

8.3.1.6 The laboratory must regularly assess the performance of its test system(s), including staff proficiency, by including control specimens and comparing results with those previously obtained.

30. National Association of Testing Authorities (NATA) www.nata.com.au
31. Royal College of Pathologists of Australasia (RCPA) www.rcpa.edu.au
32. International Accreditation New Zealand (IANZ) www.ianz.govt.nz

8.3.1.7 Controls must be specific and sensitive and monitor critical points in the test procedure.

8.3.1.8 In automated systems, controls should detect unexpected dilution of the testing environment (and therefore loss of ionic strength); for example, due to leaks, backflow contamination (e.g. valve leaks) within the fluidic system or sample carryover.

8.3.1.9 Weak IgG-coated red cells should be used to control the washing phase of tube or microplate IAT methods. These are added to all negative IAT results, with a positive result indicating a valid test. A negative result suggests incomplete washing, and the test run is invalid.

8.3.2 Acceptance testing of reagents

8.3.2.1 The laboratory must have documented procedures for assessing the suitability of reagents before they are introduced into routine use.

8.3.2.2 Acceptance testing must specify criteria against which reagents are assessed and the action required if these criteria are not met. Any item failing the acceptance criteria should not be used in testing.

8.3.2.3 Transport conditions of the reagents (for example must be delivered on dry ice) must be verified on delivery, if transport conditions have not been met, reagents should be quarantined/discarded and the quality incident reported to supplier and documented locally via (QMS).

8.3.2.4 Once transport conditions of reagents have been accepted, reagents must be quarantined in an area according to their storage conditions until pre-acceptance testing can be completed.

8.3.2.5 A visual inspection of reagents should also form part of the acceptance testing.

8.3.2.6 Inspection of the product insert for updates to instructions for use and Certificates of Analysis/Conformity, if applicable.

8.3.2.7 When defining acceptance criteria, it is recommended that laboratories refer to the manufacturer's instructions for expected haemagglutination reaction strength of red cells or expected titres of antisera.

8.3.2.8 Acceptance testing provides a baseline against which ongoing performance of reagents can be assessed.

8.3.2.9 A base laboratory may choose to perform centralised acceptance testing of the reagents it distributes to networked satellite or regional laboratories for use.

8.3.2.10 The decision to omit further acceptance testing at the networked laboratories will be based on an assessment of potential risks to reagent performance that include:

- transit time
- reagent stability at ambient temperatures
- potential damage during transit
- suitable control or monitoring of transport conditions (e.g. use of temperature data loggers).

8.3.3 Frequency of reagent QC

8.3.3.1 Reagent performance must be regularly checked against the manufacturer's specifications or performance criteria set by the laboratory (or both).

8.3.3.2 Reagent QC checks should be performed at least **once per day** (of use). For high throughput laboratories, the testing frequency should provide timely detection of failure in the test system. Longer testing intervals may be acceptable if recommended by the manufacturer or if the laboratory has undertaken a risk assessment and robust validation demonstrating that a single QC check is adequate to assure reagent quality and performance over an extended interval.

8.3.4 Controls for ABO/RhD grouping

8.3.4.1 Positive and negative controls must be included at regular intervals during testing, when reagent lots change, and when the analyser is started up.

8.3.4.2 The frequency of when controls are used depends on work patterns, methods used and the manufacturer's instructions. At a minimum, controls should be included once per day or on each day the laboratory undertakes testing when this is not daily.

Table 8.1: Controls for ABO/RhD grouping

	Control cells	
Reagent	**Positive**	**Negative**
Anti-A	A	B
Anti-B	B	A
Anti-D	RhD positive	RhD negative

8.3.5 Controls for antibody screening

8.3.5.1 A weak positive antibody control, such as anti-D at a concentration of ≤0.1 IU/mL (or another weak antibody specificity at a comparable concentration), should be run at least once per day or on each day that the laboratory undertakes testing when this is not daily, to monitor the efficacy of the test procedure.

8.3.5.2 Controls for antibody screening should be chosen so that both positive and negative results are obtained for each reagent screening cell.

8.3.5.3 The specificity of controls should be reviewed against the antigen profile of any new lot of screening cells.

8.3.5.4 The antibody screening control pass or fail criteria should ensure that each cell gives the expected reaction (positive or negative) with the chosen control material. Reaction strength should be checked to detect any adverse changes, e.g. weaker reactions due to loss of antigen expression. Limits for acceptable reaction grades can often be set within the automation, e.g. pass if the reaction strength is > 1 (0-4 scoring).

8.3.5.5 The acceptable reaction strength for each control batch will depend on the manufacturer's specifications, technique used and scoring system (i.e. 0–4 or 0–12).

8.4 Internal QC

8.4.1 The intervals at which controls are included should be set to provide timely detection of deteriorating performance or failure of the test system and should be based on a documented risk assessment of the consequences of this occurring. A variety of factors will influence the frequency, for example:

- the number of patient specimens tested
- the workflow of the laboratory
- the scope of testing (in particular, whether crossmatching is performed)
- the storage requirements and the usage patterns of reagents.

8.4.2 Laboratories that primarily provide blood grouping and antibody screen and are not associated with an acute care facility may choose to run controls only once per day because the consequence of test failure may simply be repeating the testing of all affected specimens.

8.4.3 Control specimens containing weak antibodies (e.g., anti-Fy^{a} or anti-Jk^{a}) should be regularly included to monitor both the sensitivity of the test system and the stability of red cell antigens

on reagent red cells. Obtaining weaker-than-expected reaction strengths will help detect deteriorating test performance, particularly changes in antigen expression.

ⓘ Including controls with mixed cell populations or a weak positive DAT is also recommended.

8.4.4 Controls should be validated under the laboratory's normal testing conditions. New controls should be tested in parallel with the current controls using the same reagent red cells to establish new QC limits.

8.4.5 Control failures require documented corrective action as well as the repeat of all patient tests performed since the control material last returned expected results.

8.4.6 Internal QC results must be regularly reviewed by a senior staff member with outcome of the review documented.

8.5 External quality assurance (EQA)

8.5.1 The laboratory must participate in an accredited external quality assurance program (QAP) appropriate to the range of immunohaematology testing undertaken and relevant to the scope of its accreditation.

8.5.2 Where laboratories use both manual and automated techniques, they must undertake (internal or external) quality assurance for each and review the comparability of performance and techniques.

8.5.3 All staff must participate in EQA, ideally undertaking at least two exercises a year. Where the number of staff precludes regular individual participation in the chosen QAP, the laboratory must provide an internal proficiency testing program to supplement external QAP participation.

8.5.4 The laboratory should choose QAPs accredited to ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing*.[33]

8.6 Validation, verification, modification and upgrades

8.6.1 A written policy must clearly define the validation and qualification process and its purpose within the laboratory. The policy must commit to maintaining critical processes, equipment, facilities, and systems in a valid state and mention applicable regulations, standards, and guidelines that underpin the laboratory's approach to validation.

8.6.2 Validation

8.6.2.1 All critical processes, equipment, facilities, reagents or systems must undergo appropriate validation or verification before use, with records held in accordance with national regulatory requirements.

8.6.2.2 A validation process involves defining the requirement for the test or process and proving that it can perform that function. Validation is required for tests developed in house, tests without regulatory approval, or tests performed in a manner or for a purpose not intended by a manufacturer.

8.6.2.3 Verification is the process of showing that a test or procedure performs in accordance with claims by the supplier where the supplier has already shown suitability for the intended purpose.

8.6.2.4 Automated equipment must be shown to:

- be capable of achieving the required performance (fit for purpose)
- comply with the specifications associated with the tests performed, transport or storage

33. ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing* https://www.iso.org/obp/ui/en/#iso:std:iso-iec:17043:ed-2:v1:en

- comply with the laboratory's requirements
- comply with regulatory requirements.

8.6.2.5 Where a laboratory is associated with other laboratories in a network that are, for example, using the same processes, equipment and reagents, a single validation performed at one of the sites may be acceptable. Each laboratory should have a mechanism for ensuring that its test results are comparable to the other sites in the network.

8.6.2.6 All validation failures or non-conformances must be fully investigated to determine the root cause and to resolve the problem. Investigation and subsequent corrective or remedial action must be fully documented, and records retained according to accreditation requirements. Any subsequent variation to a manufacturer's recommended solutions must be validated by the user.

8.6.3 Verification

8.6.3.1 Performance of automated equipment must be regularly checked (verified) by testing a suitable combination of the following, chosen to challenge the expected range of sensitivity and specificity:

- specifically formulated QC material
- previously analysed samples
- commercial controls
- reference material.

8.6.3.2 All verification failures or non-conformances must be fully investigated to determine the root cause. All findings, including resolution of the problem, must be documented.

8.6.4 Modifications and upgrades

8.6.4.1 A risk assessment must be undertaken before equipment is modified or upgraded (or changes are made to the operating software) to identify critical control points and areas where failure could cause harm to a patient.

8.6.4.2 All changes, modifications or upgrades to critical processes, equipment, facilities or systems must be documented and managed by revalidation of the system before being returned to service/use.

8.6.4.3 Following modifications or upgrades to the equipment or changes to operating software, operators should receive relevant retraining, and performance must be verified and documented to show that any change has not had an adverse effect.

8.6.5 Software validation

8.6.5.1 Transfusion LIS must undergo a documented validation process prior to installation and following modifications or upgrades.

8.6.5.2 Software used by the laboratory must undergo a documented validation. The following information must be recorded and kept in accordance with regulatory requirements:

- software version
- date of validation
- identity of the person performing the validation
- evidence of an independent check of all the validation documentation.

8.6.5.3 Validation must ensure that software performs as expected and required (irrespective of the source and manufacturer's prior testing) and should include both destructive testing of individual modules (to test their robustness) and integrated testing of the complete system and logic paths using correct and incorrect data.

8.6.5.4 A validation checklist should be prepared that provides a series of challenges to the software to ensure that the appropriate responses are generated and to demonstrate the following:

- ABO-incompatible units cannot be issued
- expired blood components and/or products cannot be issued
- unambiguous warning flags or messages (that cannot be inappropriately overridden) highlight special transfusion requirements or other locally applied protocols
- the software correctly and appropriately handles all expected donor and recipient ABO and RhD group combinations when determining compatibility (or incompatibility) of each blood component.

8.6.6 Software modifications or upgrades

8.6.6.1 Before undertaking modifications or upgrades to software, a risk assessment must be performed to identify critical control points and areas where failure could cause harm to a patient.

8.6.6.2 All software modifications or upgrades must be fully documented, and records kept.

8.6.6.3 Modified or upgraded software must be fully validated (unless the changes are considered minor) to show that any changes have not had an adverse effect. Even minor changes to software may affect the functionality or operation of the system; therefore, extra vigilance is required to ensure the system is operating as expected.

8.6.6.4 Electronic release of blood components and/or products or computer crossmatching is prohibited until any validation is completed.

8.6.6.5 Operators should receive appropriate retraining following any software modifications or upgrades

8.7 Maintenance and calibration

8.7.1 Laboratory equipment must be regularly maintained in accordance with the manufacturer's instructions. Where appropriate, calibration of equipment must be undertaken by an accredited provider. Any reference instruments used to calibrate the equipment must be in date and calibrated for use according to relevant standards (e.g. ISO 9001/AS9100).

8.7.2 Equipment storing blood components and/or products must be maintained in accordance to AS3864 Medical refrigeration equipment – for the storage of blood and blood products.

8.7.3 Table 8.2 shows the recommended maintenance or calibration intervals for equipment. These are only guidelines and are intended for use where requirements have not been set by the supplier, or where the supplier's requirements are less stringent than those required by regulatory standards.

8.7.4 Equipment requalification (e.g. calibration or performance verification) must be performed following repair or a significant change in location. If equipment relocation is minor, the level of requalification should be based on a risk assessment of the impact.

8.7.5 There should be a record of equipment failure and subsequent corrective actions. There should be a process for recognising and correcting equipment with recurrent failures and for returning equipment to use after corrective action.

Table 8.2: Maintenance and calibration schedules [34]

Device	Requirement	Interval
Thermometer – digital	Calibration	2 years
	Checking (against reference device at temperature of use or ice point)	6 months
Thermometer - liquid in glass	Calibration	5 years
	Check (at ice point or against reference thermometer at one point in range)	6 months
Centrifuge	Calibration	Annually
Cell washer	Tube fill and Wash check	Monthly or more frequently as per manufacturer instruction
Timer	Timer accuracy	6 months
Blood component and/or product Refrigeration[35]	Temperature check (digital and chart recorders)	Daily
	Chart recorder change	Weekly
	Alarm backup battery check	Monthly
	Cleaning (as required)	Monthly
	Temperature monitoring and alarm system accuracy	6 months
	High/low temperature	6 months
	Power failure alarm	6 months
	Mechanical inspection	6 months
	Temperature monitoring and alarm system calibration	Annually
	Alarm reactivation test	Annually
	Spatial temperature check	On receipt, after moving or significant repair
	Defrosting	As required
	Download electronic monitoring data	As required
Platelet rotator/agitator	Temperature check	Daily
	Calibration	Annually
	Spatial temperature check	On receipt, after moving or significant repair
	Rotation rate or agitation frequency (as per manufacturer's specifications)	On receipt, after moving or significant repair
	Alarm checks	6 months

34. NATA *General accreditation guidance* https://nata.com.au/files/2021/05/General-Equipment-Table.pdf
35. Standards Australia *AS3864 (2012) Medical refrigeration equipment - For the storage of blood and blood products. Part 2: User-related requirements for care, maintenance, performance verification and calibration*

Device	Requirement	Interval
Plasma thawer	Temperature check	Daily
	Cleaning	Weekly
	Calibration	Annually
Heat blocks, water bath, incubator	Temperature check	Daily
	Cleaning	As required
	Calibration	Annually
	Spatial temperature check	3 years
Pipette	Volume dispensed (requirements for calibration and/or checking based on criticality and/or reproducibility of dispensing volume	According to local policy

Abbreviations

AABB	American Association of Blood Banks
ACSQHC	Australian Commission on Safety and Quality in Health Care
ANZSBT	Australian and New Zealand Society of Blood Transfusion
aPTT	Activated partial thromboplastin time
AS	Australian standard
BMI	Body mass index
BNP	Brain natriuretic peptide
BSH	British Society for Haematology
CAT	Column agglutination technology
CDP	Cryodepleted plasma
CMV	Cytomegalovirus
CPOE	Computerised prescriber order entry
C:T	Crossmatch to transfusion (ratio)
DAT	Direct antiglobulin test
DOB	Date of birth
DVI	RhD category VI
EDTA	Ethylenediaminetetraacetic acid
ELP	Extended life plasma
EMR	Electronic medical record
EQA	External quality assurance
eXM	Electronic crossmatch
FFP	Fresh frozen plasma
FMH	Fetomaternal haemorrhage
FNHTR	Febrile non-haemolytic transfusion reaction
G&S	Group and screen
GVHD	Graft versus host disease
HDFN	Haemolytic disease of the fetus and newborn
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HPA	Human platelet antigen
HSCT	Haemopoietic stem cell transplant
HTC	Hospital transfusion committee
HTLA	High titre, low avidity
IAT	Indirect antiglobulin test
IgA	Immunoglobulin A

IgG	Immunoglobulin G
IHI	Individual Healthcare Identifier
INR	International normalised ratio
ISO	International Organization for Standardisation
IT	Information technology
IU	International units
IUT	Intrauterine transfusion
IV	Intravenous
IVIg	Intravenous immunoglobulin
IVF	Invitro fertilisation
LIS	Laboratory information system
LISS	Low ionic strength solution
MDS	Myelodysplastic syndrome
MRN	Medical record number
MSBOS	Maximum surgical blood order schedule
NATA	National Association of Testing Authorities
NBA	National Blood Authority
NPAAC	National Pathology Accreditation Advisory Council
NHI	National health index
NZS	New Zealand standard
NIPT	Non-invasive prenatal testing (also known as Non-invasive prenatal assay)
PCR	Polymerase chain reaction
PEG	Polyethylene glycol
PT	Prothrombin time
PTS	Pneumatic tube system
RhD Ig	RhD immunoglobulin
QAP	Quality assurance program
QC	Quality control
QMS	Quality management system
RFID	Radio-frequency identification
TACO	Transfusion-associated circulatory overload
TA-GVHD	Transfusion-associated graft versus host disease
TRALI	Transfusion-related acute lung injury
WAIHA	Warm autoimmune haemolytic anaemia

Glossary

Australian Standard (AS)	Precedes document number of standards issued by Standards Australia
Blood components	Red cells, platelets, fresh frozen plasma, cryoprecipitate and white cells derived from human blood
Blood product	Plasma derivatives and recombinant products
Blood Service	Australian Red Cross Lifeblood or New Zealand Blood Service
Brain natriuretic peptide (BNP)	Test for BNP levels used to distinguish TACO from TRALI
Childbearing potential (reproductive age)	Defined by the World Health Organisation as women between the aged 15-49
Daratumumab	Human monoclonal antibody with anti-CD38 specificity used to treat myeloma
Destructive testing	Destructive software testing attempts to cause a piece of software to fail in an uncontrolled manner, in order to test its robustness
Ethylenediaminetetraacetic acid (EDTA)	Anticoagulant, chelating agent
Extended life plasma (ELP)	Thawed plasma with a 5-day post-thaw shelf life
GATA mutation	A mutation in the promoter region of the FYB gene that disrupts a binding site for the erythroid transcription factor GATA-1, resulting in the loss of FY expression on red cells. Found in individuals of African descent with a Fy(a-b-) phenotype. The presence of FYB means these individuals do not produce anti-Fy^b, making it easier to find antigen-matched blood.
Group and screen (G&S)	A shorthand description for pretransfusion blood group (ABO/RhD typing) and antibody screening of the recipient
Hospital	The hospital, health-care facility or other organisation under whose direction requests for pretransfusion testing are made
IgA, IgD, IgE, IgG, IgM	The five classes of immunoglobulin; glycoprotein molecules that are produced by plasma cells in response to an immunogen and which function as antibodies
Individual Healthcare Identifier (IHI)	A nationally unique 16-digit number allocated to all individuals enrolled in Medicare, or who hold a Department of Veterans' Affairs treatment card and others who seek health care in Australia
International Accreditation New Zealand (IANZ)	New Zealand's national authority for accreditation which includes accreditation of medical testing laboratories
International Organization for Standardisation (ISO)	International standard-setting body composed of representatives from national standards bodies
Kleihauer-Betke test	Test used to detect and quantify fetomaternal haemorrhage

Laboratory	The blood bank or pathology laboratory responsible for performing pretransfusion testing on behalf of the hospital
Laboratory director[36]	The pathologist, transfusion medicine specialist, medical officer or Clinical Scientist with responsibility and authority for the clinical and scientific oversight of the laboratory.[37]
National Association of Testing Authorities (NATA)	Australia's national laboratory accreditation authority
Neonate	Newborn infant aged under 1 month
National Pathology Accreditation Advisory Council (NPAAC)	Australian body that advises the Commonwealth, state and territory health ministers on matters relating to the accreditation of pathology laboratories. NPAAC has a key role in ensuring the quality of Australian pathology services and responsible for the development and maintenance of standards and guidelines for pathology practices.
National Health Index (NHI)	A unique identifier that is assigned to every person who uses health and disability support services in New Zealand
New Zealand standard (NZS)	Precedes document number of standards issued by Standards New Zealand
Plasma derivatives	Plasma proteins fractionated from large pools of human plasma under pharmaceutical conditions (e.g. coagulation factors, albumin and immunoglobulins)
Recombinant product	Nonhuman-derived replacement for specific clotting factor deficiency
Remote release of blood	Issuing blood products directly from a satellite refrigerator at a physically distinct location from the supplying laboratory, such as a ward or other clinical area or facility
RhD variant	RhD antigen with fewer antigen sites or missing epitopes leading to weak(er) or absent reactions with anti-D sera
Radio-frequency identification (RFID)	The process of using an electrical transponder that stores information that can be used to identify the item to which the transponder is attached
Transfusion dependent	Any patient with a long-term hereditary or incurable condition (with expected survival > 12 months) who requires regular and ongoing transfusion support

36. AS ISO 15189 *Medical laboratories – requirements for quality and competence (2013)*

37. NPAAC *Requirements for supervision in the clinical governance of medical pathology (2018)*

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Appendix 1:
Maximum surgical blood order schedule

The maximum surgical blood order schedule (MSBOS) is a tool for the laboratory, surgeons and anaesthetists, to assess the typical red cell requirements for each procedure performed in their hospital(s), based on historical experience. However, the MSBOS is only meant as a guide, and the transfusion needs of individual patients should always be guided by clinical judgement.

Specialised surgical procedures (e.g. cardiac, hepatic and neurosurgery) usually employ standard protocols developed in consultation with the laboratory.

When creating an MSBOS, consideration should be given to the availability of local pathology services, and adjustments may be required to accommodate regional facilities without an on-site laboratory. When establishing additional surgical services or contemplating unusual or complex surgery, a local risk assessment should consider the following:

- availability of transfusion support (location, inventory level and time for resupply)
- laboratory capability for managing additional pretransfusion testing and crossmatching that may delay the availability of blood, e.g. patients with clinically significant red cell antibodies
- scope or complexity of surgical procedures
- distance from tertiary support services, availability of evacuation or retrieval services and associated blood product inventory.

Following a risk assessment, laboratories may opt to only provide blood on demand following a group and screen (G&S) to minimise unnecessary crossmatching and potential wastage. A G&S policy is preferable when there is a 24/7 on-site transfusion laboratory at the transfusing institution.

The crossmatch (C) to transfusion (T) ratio (C:T ratio) is a useful measure for the appropriateness of crossmatch requirements; procedures with a C:T ratio > 1.8 are normally considered suitable for G&S only.

Table A1: Generic example of a maximum surgical blood order schedule (MSBOS)

Clinical specialty	Procedure	Requirements
General surgery	Abdominoperineal resection	G&S
	Amputation (below or above knee)	G&S
	Anterior resection	G&S
	Appendectomy	Nil
	Apronectomy (mini-abdominoplasty)	G&S
	Bowel resection	G&S
	Breast surgery (lumpectomy)	G&S
	Burns debridement	Individual assessment
	Cholecystectomy (open)	G&S
	Cholecystectomy (laparoscopic)	G&S
	Colectomy (formation or closure)	G&S
	Ethmoidectomy	Nil
	Gastrectomy	2
	Gastric stapling	G&S
	Haemorrhoidectomy	Nil
	Hiatus hernia repair (abdominal)	G&S
	Hiatus hernia repair (transthoracic)	G&S
	Incisional hernia repair	Nil
	Laparotomy	G&S
	Lipectomy	G&S
	Lumbar sympathectomy	G&S
	Mastectomy (simple)	G&S
	Mastectomy (radical)	G&S
	Mastoidectomy	Nil
	Pancreatectomy	G&S
	Parotidectomy	G&S
	Rhinoplasty	G&S
	Splenectomy	2
	Thyroidectomy	G&S
	Tonsillectomy	Nil
	Tracheostomy	G&S
	Vagotomy and drainage	G&S
	Varicose veins stripping	Nil

Clinical specialty	Procedure	Requirements
Gynaecological surgery	Caesarean section	Nil
	Colposuspension	Nil
	Cone biopsy	Nil
	D&C	Nil
	Ectopic pregnancy	G&S
	Hysterectomy	G&S
	Laparoscopy	Nil
	Myomectomy	G&S
	Ovarian cystectomy	G&S
	Termination of pregnancy	Nil
	Tubal ligation	Nil
	Vaginal repair	Nil
	Vulvectomy	Nil
Orthopaedic surgery	Arthroscopy	Nil
	Arthrotomy	Nil
	Femoral nail removal	Nil
	Fractured femur	G&S
	Harrington's rods	4
	Hip replacement	G&S
	Hip replacement – redo	G&S
	Knee replacement	G&S
	Laminectomy	G&S
	Meniscectomy	Nil
	Putti-Platt	Nil
	Spinal fusion	G&S
	Synovectomy (knee)	Nil
Thoracic surgery	Lobectomy	G&S
	Pleurectomy	G&S
	Pneumonectomy	G&S
	Thymectomy	G&S
Urological surgery	Cystectomy	G&S
	Cystoscopy or cystotomy (vesicotomy)	Nil
	Nephrectomy	G&S

Clinical specialty	Procedure	Requirements
Urological surgery *continued*	Nephrolithotomy	G&S
	Prostatectomy (open)	G&S
	Prostatectomy (transurethral resection; TURP)	Nil
	Pyelolithotomy	G&S
	Ureterolithotomy	G&S
Vascular surgery	Aortic aneurysm (elective)	2
	Aorto-femoral bypass graft	G&S
	Aorto-iliac bypass graft	G&S
	AV shunt	Nil
	Carotid endarterectomy	G&S
	Femoropopliteal bypass graft	G&S
	Ilio-femoral bypass graft	G&S
	Sympathectomy lumbar	G&S

Appendix 2: Governance of hospital transfusion activities – informative

Health service organisations must have governance and systems in place for the safe and appropriate prescribing and clinical use of blood products in accordance with the Australian National Safety and Quality Health Service (NSQHS) Standards *Blood Management Standard* or a similar quality and safety framework.

The New Zealand Blood Service produces a *Transfusion Medicine Handbook* that provides guidance on the clinical use of blood components, products, and blood transfusion in New Zealand.

In many organisations, a *Hospital transfusion committee* (HTC) or *Patient blood management committee* (PBMC) provides governance and oversight of patient blood management and transfusion-related activities.

The HTC/PBMC brings together a cross-functional or multidisciplinary group of health professionals and plays a critical role in ensuring that blood products are used appropriately, safely and efficiently. In some locations, particularly small health service organisations, this function may be incorporated into other committees or roles that oversee medicines or broader clinical practice.

The HTC/PBMC is responsible for ensuring that transfusion-related activities comply with relevant local and national guidelines and standards, for example, in:

- disseminating national or local guidelines within the institution
- developing local policies and protocols for blood use and collection
- auditing use and wastage, and developing related performance indicators
- risk management
- communication with internal and external bodies about quality assurance matters.

The HTC/PBMC provides support to haematologists and transfusion laboratory staff in enforcing policies relating to non-laboratory aspects of transfusion practice, for example:

- informed consent
- documentation of transfusion
- identification of patients
- collection of pretransfusion specimens
- correct prescribing of blood products.