

Australian & New Zealand Society of Blood Transfusion Ltd

5th Edition, March 2007

**GUIDELINES for PRETRANSFUSION
LABORATORY PRACTICE**



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GUIDELINES FOR PRETRANSFUSION LABORATORY PRACTICE

5th Edition

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Foreword

The ANZSBT Council takes great pleasure in publishing the 5th edition of the '**Guidelines For Pretransfusion Laboratory Practice**' [formerly the '*Guidelines For Pretransfusion Testing*'].

This edition represents not only revision of the guidelines but, as you will have noted, a small but perhaps significant name change.

The ANZSBT has always issued guidelines rather than prescriptive standards although this distinction has often become blurred when they are used in the process of accrediting laboratories. Accordingly ANZSBT has been approached by, and is now working with, the National Pathology Accreditation Advisory Council [NPAAC] on developing a pretransfusion laboratory standard which these guidelines will complement.

In addition the Australian Commission for Safety and Quality in Healthcare is currently reviewing accreditation processes in Australia, and there are other joint Australian / New Zealand initiatives on other blood related matters. Consequently further changes to guidelines and standards may ensue.

Once again a group of ANZSBT members from Australia and New Zealand has undertaken the task of revising the Pretransfusion Guidelines with energy and enthusiasm. The participation of the general membership has also been important in arriving at the content of the 2007 edition.

Whilst, as in the past, it is impossible to incorporate every single submission and point of view, this document again represents a consensus of views as to those that can ensure current best and safe practice in pretransfusion testing.

Previous editions of the Guidelines have been widely accepted and we are confident that this new edition will once again prove to be extremely valuable to the medical and scientific community.

Ken Davis
President ANZSBT
March 2007

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The aim of this document is to provide guidelines for safe and appropriate pretransfusion laboratory practice.

Consequently the provision of safe transfusion practice requires:

- documentation and patient identification systems that minimise clerical errors and patient misidentification.
- determination of the recipient ABO and Rh(D) group and the performance of an antibody screen to detect clinically significant red cell antibodies.
- adherence to the stringent requirements necessary for the use of information technology in the Transfusion Laboratory.
- suitable quality control programs for reagents, techniques, equipment and personnel.
- selection and provision of compatible blood and blood products.
- appropriate storage and handling of blood and blood products in accordance with AS 3864 and the requirements of the national blood supplier.
- appropriate investigation of adverse effects of transfusion.
- appropriate retention of records, data and documentation as required by regulatory bodies.

These guidelines should be considered in conjunction with the requirements of national accreditation authorities, national blood services and other regulatory bodies. However, where coexisting material exists such as ANZSBT guidelines or associated national standards, regulations or otherwise related documents, it is not intended to duplicate this [except where inclusion aids interpretation of these guidelines]. Such material includes ISO 15189 *Medical Laboratories – Particular requirements for quality and competence* [issued in Australia as AS 4633 and New Zealand as NZS/ISO 15189], the NATA *Supplementary requirements for accreditation in the field of medical testing* and AS 3864 *'Medical refrigeration equipment – for the storage of blood and blood products'*.

Finally it is important to maintain an awareness of the literature [and current thinking] in the areas of transfusion medicine, laboratory technology, and safety & quality, as a guide to best practice.

This document is intended for use with complementary guidelines in relation to transfusion medicine that ANZSBT has published:

- Testing during pregnancy and the perinatal period
- Administration of blood products
- Gamma irradiation of blood products
- Leucocyte-depleted blood products
- Autologous transfusion

or will be publishing:

- Paediatric transfusion
- Critical bleeding [Massive transfusion]
- Management of transfusion reactions

The recommendations in the '*Guidelines for Pretransfusion Laboratory Practice*' are primarily educative and represent what Council and the Scientific Subcommittee believe is best or acceptable practice.

In this edition of the guidelines the following directive terms are used:

- Must** indicates a practice which is advised
- Should** indicates a practice which is recommended where compliance would be expected for good laboratory practice, but for which alternative practices may also be acceptable
- May** indicates a practice is permissible within the limits of these guidelines

To aid interpretation of these guidelines the following terms are also used:

- Hospital** the hospital, healthcare facility or other organisation under whose direction requests for pretransfusion testing are made
- Laboratory** the blood bank or pathology laboratory facility responsible for performing pretransfusion testing on behalf of the Hospital
- Laboratory Director** the Pathologist, Transfusion Medicine Specialist, Medical Officer or Senior Scientist responsible for the clinical / scientific oversight of the Laboratory in accordance with ISO 15189:2003 '*Medical Laboratories – Particular requirements for quality and competence*'
- Blood Product** To assist in the clarity of these guidelines the term '**Blood Product**' has been used generically to describe the following:
- Blood component**
 - Plasma derivative**
 - Recombinant product**

Please see glossary on pages 26 - 27 for further definitions of the above.

1. Sample, Request Form and Record Requirements

This aspect of transfusion practice is crucial to patient safety. Failure to correctly identify the patient at sample collection, prescribing the wrong product or transfusion of the wrong patient all remain significant causes of patient morbidity and mortality.

1.1 REQUEST FORMS AND SAMPLE COLLECTION

1.1.1 General Principles

1.1.1.1 All pretransfusion requests, irrespective of origin, must meet the requirements of these guidelines, along with the requirements of the receiving laboratory. This includes patients transferred from hospitals or other facilities or locations outside of the jurisdiction of the testing Laboratory.

1.1.1.2 Request forms for transfusion should be designed for this purpose alone.

1.1.1.3 Request forms should contain a declaration similar to that below, which must be signed by the person collecting the patient's sample:

I certify that I collected the accompanying sample from the above patient, whose identity was confirmed by inquiry and/or examination of their name-band, and that I labelled the sample immediately following collection

1.1.1.4 The hospital laboratory and/or requestor must have a written policy for identifying patients who, at the time of sample collection, are found to be:

- (i) unconscious, irrational or unable [for some other reason] to respond to direct questioning; and
- (ii) without an identification wristband

1.1.1.5 The patient's details should be handwritten on the sample tube. It is strongly recommended that pre-printed labels are not be used; if used they must conform to the requirements of 1.1.3.5.

Hand-held computers in conjunction with barcode scanners and label printers or radio-frequency identification [RFID] systems are available which facilitate security in patient identification at the time of sample collection. The use of such systems must be in accordance with the requirements of 1.1.3.

1.1.1.6 The laboratory must have a written policy for the management of inadequately labelled samples and/or incomplete request forms.

1.1.1.7 Request forms and samples must be received together and must be checked on receipt.

1.1.1.8 Request forms and samples must carry identical patient identification information.

1.1.1.9 Unlabelled samples must be discarded.

1.1.2 Request Forms [Written/Electronic]

1.1.2.1 A formal request for pretransfusion testing [or issue of blood products] must be made. This may be handwritten or in an electronic form.

1.1.2.2 The request form must clearly [and legibly] identify the patient. The following information must be provided:

- (i) family name
- (ii) given name in full
- (iii) unique hospital record [or national health index] number and/or date of birth
- (iv) gender
- (v) signature [and contact details] of the sample collector

1.1.2.3 For electronic requests an electronic 'signature' or other system identifier must uniquely identify the person making the request, in the absence of a written signature.

1.1.2.4 The request form** should also include [in addition to the requirements of 1.1.2.2]:

- (i) date and time of sample collection
- (ii) name and signature of the practitioner completing the form
- (iii) details of the test(s) requested and/or type of blood product required
- (iv) clinical diagnosis and indications for blood product
- (v) date and time required
- (vi) transfusion history
- (vii) known red cell antibodies
- (viii) obstetric history [including RhD-Immunoglobulin administration]
- (ix) location

**It should be noted that the request form is not a prescription and in some organisations staff other than doctors have authority to complete the request form]

1.1.2.5 In emergency situations, where the patient's identity is unknown, an alternative method of uniquely identifying the patient must be used. These details must be reliably linked to the patient's proper name once available.

1.1.3 Sample Requirements

1.1.3.1 All pretransfusion samples must comply with the minimum labelling requirements specified in this document.

1.1.3.2 Clotted or EDTA samples should be used for pretransfusion testing. The performance characteristics of different sample tube types vary, limitations identified by the tube's manufacturer must therefore be observed.

1.1.3.3 Grossly haemolysed samples should not be used for testing [as this may indicate a problem with collection or transport].

1.1.3.4 The patient's identity must be positively confirmed at the time of sample collection:

- (i) by direct questioning:

The patient must be asked [if conscious and rational] to state their family name, given name(s) and date of birth.

- (ii) by checking [where available] the patient's hospital identification wristband. It is recommended that hospital patients without an affixed hospital identity label are not bled

1.1.3.5 Following collection and before leaving the patient, the sample tube(s) must be legibly labelled [see 1.1.1.5] with the:

- (i) patient's family name, first name in full, and hospital record [or national health index] number or date of birth. For unidentified patients see 1.1.2.5.
- (ii) date and time of collection
- (iii) signature [or initials] of the collector

1.1.4 Verbal Requests For Blood Products

1.1.4.1 Verbal requests for blood products [either face-to-face or by telephone] may be accepted. Local policies or other relevant regulations may require the requestor to retrospectively provide a [signed] request form.

1.1.4.2 Patients must have a valid group and screen [where applicable].

1.1.4.3 Verbal requests must be documented in accordance with laboratory policy. A telephone message pad or other similar means should be used to record the required information [and provide documentary evidence of the request].

1.1.4.4 Records of verbal requests must be retained according to regulatory requirements.

1.1.4.5 The names of the person making the request, the person receiving the request and the name of the requesting clinician must be recorded.

1.1.4.6 The following information should be obtained and confirmed [for example by reading back to the person giving the information]:

- (i) family name
- (ii) given name in full
- (iii) date of birth
- (iv) hospital record [or national health index] number
- (v) location
- (vi) number/volume and type of product
- (vii) reason for request
- (viii) date and time required

1.1.5 Request For Release/Issue of Blood Products

1.1.5.1 Requests for the release [or issue] of blood products may be made via the telephone, by facsimile, in person [for example by an orderly or nurse presenting at the laboratory] or other acceptable means.

1.1.5.2 The intended patient must be clearly identified by the requestor before the laboratory releases blood products. The laboratory must be provided [as a minimum] with the patient's name and hospital record [or national health index] number.

1.1.5.3 Blood products may be released to a person physically collecting them from the laboratory, delivered through a pneumatic tube system direct to the clinical area or 'remote release' from a satellite storage location [see also 2.1.6].

1.2 PRETRANSFUSION LABORATORY RECORDS

1.2.1 General Principles

1.2.1.1 Laboratory records relating to transfusion practice must comply with the requirements of national accreditation authorities or regulatory bodies. Records must be retained in accordance with statutory requirements.

- 1.2.1.2 Where pretransfusion record management is computerised it is recommended that the laboratory information system [LIS] complies with the requirements of the BCSH guidelines 'The Specification And Use Of Information Technology (IT) Systems In Blood Transfusion practice' (2006) which ANZSBT endorses.

1.2.2 Patient Records

- 1.2.2.1 A record must be held for each patient from who a pretransfusion sample is received and/or for whom blood products are required. It should contain the following information:

Patient [Recipient]

- (i) family name and given name(s) in full
- (ii) hospital record [or national health index] number
- (iii) date of birth
- (iv) date [and time] of sample collection
- (v) ABO/Rh(D) blood group
- (vi) antibody screen results
- (vii) expiry date of sample or request

Blood Product

- (i) product type
- (ii) donation/batch number
- (iii) ABO/Rh(D) blood group [where applicable]
- (iv) compatibility testing result [where applicable]
- (v) date of compatibility testing [where applicable]
- (vi) date and time of issue

1.2.3 Compatibility or Issue Report

- 1.2.3.1 A compatibility or issue report should be provided before or with the first blood product released from the laboratory.

- 1.2.3.2 This report should include the following:

- (i) family name and given name(s) in full
- (ii) hospital record [or national health index] number and/or date of birth
- (iii) ABO/Rh(D) blood group
- (iv) product details including type, donation or batch number, blood group and expiry date
- (v) pretransfusion testing results including relevant interpretation and clinical comments
- (vi) details of any special requirements, warnings or other relevant information

- 1.2.3.3 The report should be placed in the patient's notes as a record of pretransfusion testing.

1.2.4 Compatibility or Issue Label

- 1.2.4.1 A compatibility or issue label must be securely attached to each blood product once pretransfusion testing [or selection] is completed and the product is allocated to the patient. It must contain the following information:

Patient [Recipient]

- (i) family name and given name(s) in full
- (ii) hospital record [or national health index] number and/or date of birth
- (iii) ABO/Rh(D) blood group

Blood Product

- (i) donation number / batch number
- (ii) ABO/Rh(D) blood group [if applicable]
- (iii) statement of compatibility [or selection]
- (ii) quantity issued [if applicable]
- (iv) expiry date

1.2.5 Inventory Management

1.2.5.1 The laboratory must record the following information in relation to each blood component / product it receives [according to national or jurisdictional policy]:

- (i) donation or batch number
- (ii) blood component/blood product type
- (iii) ABO/Rh(D) group [where applicable]
- (iv) date and time received
- (v) expiry date and time
- (vi) recipient's family name, given name(s) in full, hospital record or national health number or date of birth, date of transfusion
- (vii) the fate of the blood product [issued, expired, transferred]
- (viii) date and time of transfusion

1.2.5.2 The laboratory must ensure that systems are in place to trace every blood component or blood product to its final destination, whether this is to a patient, clinical area, another facility or disposal.

2. Pretransfusion Protocols

2.1 PRETRANSFUSION TESTING

2.1.1 ABO And Rh(D) Grouping

2.1.1.1 An ABO and Rh(D) group must be determined for samples submitted for pretransfusion testing.

2.1.1.2 The ABO group must be determined by testing the patient's red cells with anti-A and anti-B [and anti-A,B if desired] reagents.

2.1.1.3 A reverse group [of the patient's serum/plasma tested against A1 and B red cells] must be performed. Note: this is not required for samples from newborn infants [less than 4 months of age].

2.1.1.4 In the absence of a reverse group the patient's red cells should be tested against a reagent diluent control or AB serum/plasma.

2.1.1.5 The Rh(D) group must be determined by direct agglutination using an anti-D reagent. A test for weak or partial D phenotypes [and in particular D^{VI}] is not required for pretransfusion testing.

[Requirements for testing cord blood in relation to administration of anti-D immunoglobulin are described in the ANZSBT *Guidelines for Blood Grouping & Antibody Screening in the Antenatal & Perinatal Setting 3rd Ed. (2007)*]

2.1.1.6 An Rh(D) diluent control should be used where specified by the reagent manufacturer.

2.1.1.7 The ABO and Rh(D) group must be confirmed before red cell products are transfused by:

- (i) comparing the current findings with those recorded for previous samples; or
- (ii) performing a second test [manual or automated]:
 - i. on the same sample by re-sampling on a separate occasion to the first test; or
 - ii. testing a second sample collected separately to the original sample

Where possible in manual testing, a second worker, having no prior knowledge of the initial result, should perform the second test. A reverse ABO group is not mandatory when performing this check group.

2.1.1.8 ABO or Rh(D) group anomalies should be resolved prior to selection of blood products for transfusion. In emergency situations where unresolved grouping anomalies remain O Rh(D) Negative red cells and AB plasma must be issued for transfusion.

2.1.1.9 The ABO group of all donor red cell units and the Rh(D) group of those labelled as Rh(D) negative must be confirmed by the laboratory undertaking the pretransfusion testing, except where group-confirmed red cell units are distributed between the accredited facilities of a laboratory network or organisation.

2.1.1.10 Confirmatory weak D testing is not required for allogeneic red cell donations. However testing for weak D must be performed on previously untested bone marrow, stem cells and other types of donation [for example directed donations, granulocytes.

2.1.1.11 Positive and negative controls must be tested on a regular basis:

Reagent	Positive control	Negative control
Anti-A	A	B
Anti-B	B	A
Anti-D	D positive	D negative
A1 grouping cells	Anti-A	Anti-B
B grouping cells	Anti-B	Anti-A

2.1.1.12 The frequency at which controls are included depends on work patterns, methods used and the manufacturer's instructions. As a minimum controls should be included once per day, or on each day the Laboratory undertakes testing where this is not daily [see 4.2.3].

2.1.2 Antibody Screening

2.1.2.1 Pretransfusion testing must include an antibody screen capable of detecting potentially clinically significant red cell antibodies. Clinically significant antibodies are generally those, which are reactive in the indirect antiglobulin test [IAT] performed at 37°C. However, anti-A, -B and -A,B must always be regarded as clinically significant.

2.1.2.2 The antibody screen must be capable of detecting anti-D at a concentration of 0.1 IU/mL or lower.

2.1.2.3 Column agglutination technology [CAT], liquid-phase and solid-phase methods are all suitable for IAT testing. However careful consideration should be given to which method is chosen, as there are differences in the robustness or reliability of each.

2.1.2.4 Alternative methods such as enzyme techniques or Polybrene® methods may be used in addition to [but not instead of] an IAT technique, if the method has been appropriately validated and documented. However these alternative methods may be inferior to the IAT for some clinically significant antibodies.

2.1.2.5 The reagent red cells used for screening must come from at least two separate group O donors and between them express the following antigens: C, c, D, E, e, M, N, S, s, K, k, Fy^a, Fy^b, Jk^a, Jk^b and Le^a. The cells from different donors must not be pooled to achieve the desired range of antigen expression.

2.1.2.6 One cell should be of R1R1 and another of R2R2 phenotype.

2.1.2.7 The following phenotypes must be represented in the screening cells: Jk(a+b-), Jk(a-b+), Fy(a+b-), Fy(a-b+); SS and ss phenotypes are also desirable. The higher sensitivity from using reagent red cells with double-dose antigen expression is particularly important for the prevention of delayed transfusion reactions, especially those due to Kidd antibodies.

2.1.2.8 Anti-Kp^a and anti-C^w are rarely of clinical significance, consequently Kp^a(+) and C^w(+) screening cells are not essential.

2.1.2.9 A weak positive antibody control serum/plasma or reagent [such as anti-D at a concentration of <0.1 IU/mL or other antibody specificities with an equivalent concentration] should be used at least once per day to test the efficacy of the test procedure.

2.1.2.10 Additional control reagents containing weak, clinically significant antibodies [such as anti-Fy^a or anti-Jk^a] should also be regularly used to ensure both the sensitivity of the test procedure and the integrity of antigen expression of reagent red cells during storage.

2.1.2.11 An autologous control or DAT is not required as part of the antibody screening process.

2.1.3 Antibody Identification

- 2.1.3.1 The specificity of antibodies detected during antibody screening must be determined and clinical significance assessed [see table 1]. Referral to a reference laboratory may be necessary for definitive identification or confirmatory testing.
- 2.1.3.2 A laboratory that does not perform antibody identification should send samples that have positive antibody screens to an appropriate referral Laboratory.
- 2.1.3.3 If the patient is known to have a red cell antibody, testing to exclude formation of additional antibodies should be undertaken for each new sample received.
- 2.1.3.4 Antibody identification should be performed using a reagent red cell panel employing at least the method by which the antibody is detectable. The panel should be able to resolve as many likely antibody mixtures as possible. Inclusion of the patient's own cells [auto control] may be helpful, e.g. in recognising the presence of an autoantibody or an antibody to a high-frequency antigen.
- 2.1.3.5 The specificity of an antibody [including each individual antibody in multiple antibody mixtures] can normally be assigned when it is reactive with at least two reagent red cells carrying the corresponding antigen and non-reactive with two reagent red cells lacking the antigen.
- 2.1.3.6 The presence of anti-Jk^a, anti-Jk^b, anti-S, anti-s, anti-Fy^a and anti-Fy^b should be excluded using red cells with double-dose expression of the corresponding antigens.
- 2.1.3.7 A panel of enzyme-treated cells, or other sensitive techniques, may be useful, particularly when an antibody weakly reactive by IAT, or where a mixture of antibodies, is suspected.
- 2.1.3.8 The patient's red cells should be shown to lack the antigen against which their antibody is directed.

2.1.4 Crossmatching

- 2.1.4.1 The laboratory must have procedures in place to exclude incompatibility between the recipient and donor using suitable crossmatching techniques such as immediate-spin, IAT or computer crossmatching. The crossmatching procedures must be able to detect ABO incompatibility.
- 2.1.4.2 The laboratory should minimise the requirement to hold crossmatched red cells in reserve for patients by adopting a Maximum Surgical Blood Order Schedule [MSBOS] [see page 28].
- 2.1.4.3 It is recommended that a 'Group and Screen' protocol be used for those clinical procedures where the likelihood of red cell use is minimal. If transfusion is subsequently required following this protocol, crossmatched blood must be available in a timely manner [consistent with local clinical needs].
- 2.1.4.4 Red cells negative for the corresponding antigen(s) should be selected when the patient has a clinically significant antibody or has a history of a clinically significant antibody. The selected red cells should be crossmatched by an IAT technique.
- 2.1.4.5 An abbreviated crossmatch consisting of a computer crossmatch or an immediate-spin crossmatch [performed by a tube technique] may be used:
- (i) if the patient has no clinically significant red cell antibodies; and
 - (ii) no known history of clinically significant antibodies
- 2.1.4.6 An immediate-spin crossmatch must not be used where clinically significant antibodies are present and/or the recipient exhibits weak anti-A and/or anti-B reactions in their reverse group.
- 2.1.4.7 A crossmatch is initially valid for the lifetime of the sample [see 2.1.7]. Once transfusion is commenced the crossmatch will cease to be valid either at the original expiry date/time of the sample or 72 hours from starting transfusion of the first unit of red cells, whichever eventuates first.

2.1.4.8 Once a transfusion episode has commenced, subsequent samples from the patient will have an expiry of 72 hours until a gap of three months between transfusions has occurred [see 2.1.7.5].

2.1.5 Computer Crossmatching [Electronic Issue]

Computer crossmatching procedures should comply with the BCSH guidelines 'The Specification And Use Of Information Technology (IT) Systems In Blood Transfusion practice' (2006).

2.1.5.1 A computer crossmatch is permissible when:

- (i) a comprehensive, validated, electronic data management system is in place
- (ii) a valid pretransfusion sample has been tested in accordance with the requirements of 2.1.1 and 2.1.2
- (iii) there are no clinically significant antibodies detectable in the current sample and no history of clinically significant antibodies.

2.1.5.2 It must be ensured that:

- (i) group specific red cells cannot be released electronically unless there is an ABO group obtained on a current sample
- (ii) group specific red cells cannot be released solely on the basis of historical records
- (iii) only group O red cells are released in an emergency situation where there is no current group and screen
- (iv) release of red cells for patients with special requirements [e.g. autologous, CMV-antibody negative, irradiated], is flagged [or precluded] by messages informing the user if these requirements are not met
- (v) a unique compatibility label is generated during the release and that the software checks to ensure that the group of the labelled unit is compatible with the patient's group
- (vi) a electronic mechanism exists to ensure the correct unit is labelled
- (vii) a transfusion record is produced with the released unit to maintain documentation of the transfusion

2.1.6 Remote Release of Blood

2.1.6.1 The information system for remotely releasing blood products must meet the requirements specified in 2.1.5

2.1.6.2 All users must be formally trained prior in using remote release, with regular competency reviews, and must have individual passwords with designated levels of access to the program.

2.1.6.3 Features of the software must ensure that:

- (i) all requirements for computer crossmatching have been met
- (ii) any patient with a history of a clinically significant antibody detected at any time is excluded from remote release, with appropriate explanatory messages

2.1.6.4 Different systems perform remote release in varying manners and notification processes may also vary. Where applicable, the parent Laboratory must be notified in 'real time' when remote release occurs, enabling the maintenance of stock levels.

2.1.7 Sample Validity

2.1.7.1 The group and screen should be completed within 48 hours of sample collection [see 2.1.8.1]. If a delay in receipt is expected the laboratory must ensure that transport and storage conditions are adequate for preventing deterioration of the sample in transit.

2.1.7.2 Sample validity times depend on an accurate transfusion or obstetric history being available. It is the responsibility of the requestor to ensure that this information is obtained and documented.

2.1.7.3 Subject to storage in accordance with 2.1.8 sample validity times may be as follows:

Criteria	Sample Validity
Patient has been transfused, is pregnant [or has been in the previous 3 months]	72 hours
Patients not pregnant or transfused in the previous 3 months	7 days
Sample collected in advance of elective surgery ['preadmission' samples] and where the patient's history clearly excludes transfusion or pregnancy in the previous 3 months	1 month for serum/plasma that has been separated and stored frozen at [or below] -20°C [see 2.1.8.1]

2.1.7.4 Validity times may be varied at the discretion of the Laboratory Director.

2.1.7.5 Where a patient is being repeatedly transfused antibody screening should normally be performed every 72 hours. However for some who have been repeatedly transfused over several years and who have not produced antibodies, then a more relaxed approach may be taken at the discretion of the Laboratory Director.

2.1.8 Sample Storage

2.1.8.1 The following are suggested as working limits for sample storage:

	18–25 °C	4 °C	-20 °C
EDTA whole blood	Up to 48 hrs	Up to 7 days	N/A
Separated plasma/serum	Up to 48 hrs	Up to 7 days	Up to 1 month

2.1.8.2 Although antibodies remain stable in frozen-stored samples, the risk of intervening transfusion or pregnancy and the risk associated with the identification and labelling of separated samples should be assessed before considering the use of these for crossmatching.

2.1.8.3 Samples from patients to whom blood has been transfused should be retained for at least 7 days post-transfusion for the purpose of investigation of reported transfusion reactions.

2.2 SELECTION OF RED CELL PRODUCTS FOR TRANSFUSION

2.2.1 General Requirements

2.2.1.1 There must be clearly written policies on the selection of red cells for both routine and exceptional transfusion situations.

2.2.1.2 Red cell products should be of the same ABO and Rh(D) type as the patient whenever possible.

2.2.1.3 Group O red cells must be selected when the patient's ABO group cannot be determined. Similarly if a conclusive Rh(D) group cannot be obtained Rh(D) negative red cells should be used until a confirmed result is obtained.

2.2.2 Selection Of Red Cells When The Antibody Screen Is [Or Has Previously Been] Positive

2.2.2.1 Red cells should be selected which are negative for the relevant antigen where the antibody is clinically significant [Table 1]. Antigen typing should be confirmed by the laboratory performing the pretransfusion testing.

2.2.2.2 If there is historical evidence of a clinically significant antibody but it is not currently detectable by IAT, antigen negative red cells are required.

2.2.2.3 When transfusion is unavoidable and serologically compatible units are not available, incompatible units may be given after consultation between the responsible medical officer and the Laboratory Director. Assessment of the clinical significance of the antibody is essential in such situations [see table 1].

2.2.2.4 For patients with antibodies of no or doubtful clinical significance such as anti-A1, -P1, -Le^a, -Le^b, -Le^{a+b}, auto-anti-I, -HI or other cold agglutinins reactive by IAT, select IAT crossmatch compatible red cells. The red cells need not be antigen negative.

Table 1: SELECTION OF RED CELLS: ALLOANTIBODIES REACTIVE BY IAT AT 37°C
Where 'antigen negative' red cells are specified these should be IAT crossmatch compatible [at 37°C].

Specificity	Clinical significance	Selection of units*
Anti-A1	Rarely	IAT crossmatch compatible
Anti-HI [in A1 and A1B patients]	Rarely	IAT crossmatch compatible
Anti-D, -C, -c, -E, -e	Yes	Antigen negative
Anti-C ^W	Rarely	IAT crossmatch compatible
Anti-K, -k	Yes	Antigen negative
Anti-Kp ^a	Rarely	IAT crossmatch compatible
Anti- Jk ^a , -Jk ^b	Yes	Antigen negative
Anti-M	Sometimes	Antigen negative
Anti-N	Sometimes	IAT crossmatch compatible
Anti-S, -s, -U	Yes	Antigen negative
Anti-Fy ^a , -Fy ^b	Yes	Antigen negative
Anti-P1	Rarely	IAT crossmatch compatible
Anti-Le ^a , -Le ^b , -Le ^{a+b}	Rarely	IAT crossmatch compatible
Anti-Lu ^a	Rarely	IAT crossmatch compatible
Anti-Wr ^a	Rarely	IAT crossmatch compatible
High titre low-avidity antibodies [HTLA]	Unlikely	Local Laboratory policy or seek advice from reference Laboratory
Antibodies against low or high frequency antigens	Depends on specificity	Local Laboratory policy or seek advice from reference Laboratory
Other antibodies active by IAT at 37°C	Seek advice from Reference Laboratory	

2.3 SELECTION OF NON RED CELL PRODUCTS

2.3.1 Fresh Frozen Plasma And Cryoprecipitate

2.3.1.1 Plasma products should be compatible with the ABO group of the recipient's red cells [to avoid haemolysis caused by the infusion of donor anti-A or anti-B antibodies]. The preference is for plasma of the same ABO group as the recipient:

Recipient's ABO Group	ABO Group of Donor Plasma [In Order Of Preference]				Notes
	1st	2nd	3rd	4th	
O	O [1]	A	B	AB [3]	
A	A	AB [3]	B [2]		1. Group O FFP should only be given to group O recipients
B	B	AB [3]	A [2]		2. Tested and negative for high-titre ABO antibodies
AB	AB [3]	A [2]	B [2]		3. AB plasma although suitable for patients of any ABO group is often in short supply
Unknown	Issue AB if urgent [3]				

2.3.1.2 Plasma products of any Rh(D) type may be given without regard to the recipient's Rh(D) status. RhD-immunoglobulin is not required if Rh(D) negative recipients receive Rh(D) positive FFP or cryoprecipitate.

2.3.1.3 Plasma of different blood groups must not be pooled.

2.3.1.4 Pretransfusion testing is not required prior to transfusion of plasma products. However an ABO group should be performed before the first transfusion episode to establish a baseline ABO group.

2.3.2 Platelet concentrates

2.3.2.1 Platelet concentrates should be of the same ABO group as the recipient.

2.3.2.2 If platelets of the same group are not available a decision on whether to give ABO-antigen or ABO-antibody incompatible platelets is required. The choice will depend on, for example, the patient's age, diagnosis/therapy as well as the product type available. In order of preference the platelets chosen should be as follows:

- (i) ABO/Rh(D) antigen compatible [but plasma incompatible]; or
- (ii) ABO/Rh(D) antigen incompatible

2.3.2.3 Requirements for HLA compatibility may take precedence over ABO typing.

2.3.2.4 Individual units of different ABO blood groups must not be pooled. Matching for Rh(D) type is desirable [as platelet products may contain small or minimal numbers of red cells], but may be less important than ABO matching. Platelets do not carry Rh antigens.

2.3.2.5 Rh(D) negative platelet concentrates should be given, where possible, to Rh(D) negative patients especially women of child-bearing potential.

- 2.3.2.6 If Rh(D) positive platelets are transfused to women of child-bearing potential RhD-immunoglobulin should be considered. It is not necessary to give RhD-immunoglobulin to Rh(D) negative men or post-menopausal women who have haematological disorders and who receive Rh(D) positive platelets.

2.4 EMERGENCY TRANSFUSION

2.4.1 Pretransfusion Testing

- 2.4.1.1 In an emergency, pretransfusion samples should be obtained as soon as possible.
- 2.4.1.2 Samples must be labelled in accordance with routine pretransfusion practice and standard pretransfusion testing performed [see 2.1].
- 2.4.1.3 Pretransfusion testing must be completed as soon as possible
- 2.4.1.4 If the antibody screen is positive or a subsequent crossmatch incompatible, the treating medical officer and the Laboratory Director must be informed. If blood is still required urgently, indicate that there may be a delay in the issue of compatible blood, stressing that [possibly incompatible] blood is available if required, until investigations are completed.

2.4.2 Issue Of Blood Products

- 2.4.2.1 Where blood products are required before pretransfusion testing can be performed and until an adequately identified sample has been received and a confirmed group obtained [see 2.1.1.7]:
- (i) red cells must be group O; and
 - (ii) plasma should be group AB
- **Red Cells must not, under any circumstance, be issued on the basis of a historical blood group.
- 2.4.2.2 If there is insufficient time to complete full pretransfusion testing, ABO and Rh(D) compatible red cells [preferably group specific] may be issued once the patient's ABO and Rh(D) blood group has been determined on two occasion [as per 2.1.1.7].
- 2.4.2.3 Where stocks of Rh(D) negative cellular products are limited, criteria for the issue of Rh(D) positive products should be developed by the laboratory. It is important to ensure that Rh(D) positive cellular products are not given to Rh(D) negative females with child bearing potential.
- 2.4.2.4 When a patient of undetermined group receives group O red cells, transfusion with group specific blood should commence as soon as possible after a confirmed group is obtained. It is recommended that the absence of anti-A or -B be confirmed [by IAT] prior to any decision to revert to products of the patient's confirmed group.
- 2.4.2.5 Red cells issued prior to pretransfusion testing being completed must be clearly labelled for example 'Uncrossmatched Blood' or 'Emergency Issue - Compatibility Testing Not Completed'.

2.5 CRITICAL BLEEDING / MASSIVE TRANSFUSION

2.5.1 Definition

- 2.5.1.1 Massive transfusion is [arbitrarily] defined as transfusion of a volume equivalent to the patient's total blood volume within 24 hours] or transfusion of more than 6 units of blood [in an adult] within a 6-hour period. Other definitions do exist and the use of these may be acceptable. Critical bleeding is not always related to number of red cells transfused.
- 2.5.1.2 The laboratory must have a written policy for management of massive transfusions. It is recommended that this is developed in consultation with the clinicians responsible for managing these events.

2.5.2 Crossmatching Requirements

- 2.5.2.1 In a massive transfusion event, where the patient has received red cells of their own ABO group, further red cells can be issued without a serological crossmatch [where this would otherwise be routinely performed]. ABO incompatibility must still be excluded through appropriate serological confirmation of the blood groups of both patient and selected red cell units. A computer crossmatch [or electronic issue] may be used as long as the criteria in 2.1.5 are met.
- 2.5.2.2 If ABO non-identical red cells have to be transfused, a return to red cells of the same group as the patient should occur soon as possible. It is recommended that absence of anti-A or -B be confirmed [by IAT] prior to any decision to revert to products of the patient's confirmed group.
- 2.5.2.3 If the patient has a clinically significant antibody the selection of red cells should be in accordance with 2.2.2.
- 2.5.2.4 Monitoring of platelet count and coagulation parameters [INR, APTT and fibrinogen] is essential in determining the requirement for other blood products.

2.6 TRANSFUSION IN PREGNANCY

2.6.1 General Requirements

- 2.6.1.1 The requirements for pretransfusion testing during pregnancy are as per 2.1. It is recommended that samples for antenatal testing should be treated in the same way as pretransfusion samples in respect of patient identification, collection and labelling.
- 2.6.1.2 The use of CMV-antibody negative or CMV 'safe' [i.e., leucocyte depleted] blood products should be dictated by local or national policies.
- 2.6.1.3 Most alloimmunised women undergoing intrauterine top-up transfusion for fetal anaemia are antibody responders with a high likelihood of further antigen sensitisation. It is therefore recommended that red cells matching the Rh, Kell, Duffy, Kidd, and S status of the mother be selected.

2.7 TRANSFUSION OF THE FETUS AND NEONATE

2.7.1 General Requirements

- 2.7.1.1 Fetal [intra-uterine] and neonatal [top-up or exchange] transfusions should comply with ANZSBT Paediatric Transfusion guidelines. [Currently in preparation].
- 2.7.1.2 Cellular products selected for neonates should be CMV-antibody negative and/or leucodepleted. [Similar requirements as 2.6.1.2].
- 2.7.1.3 Cellular products for infants that are immunocompromised, low birth weight [<1500 g], recipients of intrauterine transfusion or recipients of blood from relatives must be irradiated.

2.8 CHRONICALLY TRANSFUSED PATIENTS

2.8.1 General Requirements

- 2.8.1.1 Patients undergoing long-term transfusion regimens should have an extended phenotype of their red cells [for example Rh, K, Kidd, Duffy, Ss] before their initial transfusion.
- 2.8.1.2 Consideration should be given to providing red cells matched to the patient's Rh and K types where this is readily available.
- 2.8.1.3 Where possible red cell units <14 days old should be provided.

2.9 TRANSFUSION OF PATIENTS WITH WARM AUTOIMMUNE HAEMOLYTIC ANAEMIA [WAIHA]

2.9.1 General Principles

- 2.9.1.1 Serological investigations in patients with warm autoantibodies [reactive at 37 °C] should focus on obtaining the correct ABO and Rh(D) type and determining whether or not the patient has an alloantibody.
- 2.9.1.2 An autoantibody may mask the presence of alloantibody therefore adsorption of the patient's serum/plasma may be required to remove autoantibody activity:
- (i) autoadsorption using the patient's own red cells [providing patient has not been transfused within the preceding 3 months]; or
 - (ii) allogeneic adsorption using selected phenotyped donor red cells [if patient transfused within the previous 3 months or where there is a limited amount of patient's cells]
- 2.9.1.3 A full phenotype should be performed [by reagents not affected by a positive DAT] on the patient before commencing a regular transfusion regimen. This provides a baseline phenotype as well as an indication of what alloantibodies might be produced. [A minimum of Rh, K, Fy, Jk, Ss is recommended]. If monoclonal typing reagents are not available the sample should be forwarded to a reference laboratory.
- 2.9.1.4 The interpretation of results and need for adsorption should be made by staff with significant experience in performing such procedures. Referring samples to a Reference Laboratory may be necessary.
- 2.9.1.5 The frequency of repeat testing should be determined by the Laboratory Director in consultation with the patient's physician.

2.9.2 Positive DAT [Anti-IgG With/Without Anti-C3] And Negative Antibody Screen

- 2.9.2.1 If the patient has not been transfused in the last three months and has no history of a clinically significant antibody then the sample can be treated in the same way as a normal sample with negative antibody screen. Red cells, if required, can be issued by the laboratory's routine abbreviated crossmatch procedure [see 2.1.4.5].
- 2.9.2.2 If the patient has been transfused in the last three months
- (i) check if the patient has recently received ABO-mismatched products, intravenous immunoglobulin or has received a transplant in the last three months
 - (ii) perform an elution to rule out a delayed haemolytic transfusion reaction
- 2.9.2.3 If the patient has a history of a clinically significant antibody or an alloantibody is found following elution and red cells are required, these should be issued in accordance with 2.2.2.
- 2.9.2.4 If the patient has no history of a clinically significant antibody or no alloantibody is found following elution or elution was not indicated [in accordance with (i) above] red cells, if required, can be issued by the Laboratory's routine abbreviated crossmatch procedure [see 2.1.4.5].

2.9.3 Positive DAT [Anti-IgG With/Without Anti-C3] And Autoantibody Present

- 2.9.3.1 Perform an autoadsorption [or alloadsorption if patient transfused within the last three months] to ascertain if underlying alloantibody present.
- 2.9.3.2 Perform an extended phenotype on the patient's red cells [see 2.9.1.3].
- 2.9.3.3 If transfusion is required issue red cells crossmatched [by IAT] using the patient's adsorbed serum/plasma. If long term transfusion support is anticipated select phenotype-matched red cells.
- 2.9.3.4 Perform an elution as indicated [see 2.9.2.2 (ii) above].

2.9.4 Historically Positive DAT [With/Without Autoantibody] Now Resolved

- 2.9.4.1 If the patient has a negative antibody screen, no history of a clinically significant antibody and the DAT is now negative, then the sample can be treated in the same way as a normal sample with negative antibody screen.
- 2.9.4.2 Red cells, if required, can be issued by the laboratory's routine abbreviated crossmatch procedure [see 2.1.4.5]. Phenotype-matched red cells are not required.

2.10 RECIPIENTS OF ALLOGENEIC HAEMOPOIETIC STEM CELL GRAFTS

2.10.1 General Requirements

- 2.10.1.1 These patients often present unusual grouping and crossmatching problems. The transplant may introduce a new ABO antigen [major mismatch] or a new ABO antibody [minor mismatch] or both.
- 2.10.1.2 The laboratory should have clear protocols on the selection of blood products with respect to ABO and Rh(D) groups of recipient and donor in these scenarios.
- 2.10.1.3 All cellular products must be irradiated to prevent graft versus host disease [GVHD] and should be CMV-negative where indicated.

2.11 AUTOLOGOUS TRANSFUSION

2.11.1 General Requirements

- 2.11.1.1 Reference should be made to ANZSBT Autologous Guidelines (2002) before undertaking an autologous collection program.
- 2.11.1.2 Autologous units should be clearly labelled to distinguish them from allogeneic [homologous] units and stored in a separate designated area.
- 2.11.1.3 Pretransfusion records for autologous transfusion should be as for allogeneic transfusion [see 1.2].
- 2.11.1.4 Pretransfusion testing should be performed in accordance with 2.1.
- 2.11.1.5 A compatibility label must be attached to autologous units prior to release [see 1.2.4.1].

3. Management Of Transfusion Reactions

3.1 MANAGEMENT OF TRANSFUSION REACTIONS

3.1.1 Notification Of Transfusion Reactions

- 3.1.1.1 The laboratory must have systems in place to identify reactions or other adverse events associated with transfusion.
- 3.1.1.2 The laboratory must have written procedures for the management and investigation of suspected transfusion reactions or other transfusion-related adverse events.
- 3.1.1.3 Serious reactions [and other transfusion-related adverse events] should be discussed with a Transfusion Medicine Specialist, to ensure appropriate management of the patient, particularly in regard to continuing transfusion requirements.
- 3.1.1.4 Other significant events and in particular suspected cases of transfusion-transmitted bacterial or viral infection should be reported to the relevant regulatory authority via the manufacturer of the blood product. In particular, notification of suspected bacterial infections should be notified URGENTLY to the blood service/supplier since other components may be at risk.

3.1.2 Investigation Of Transfusion Reactions

- 3.1.2.1 Suspected serious transfusion reactions should be investigated prior to further transfusion.
- 3.1.2.2 Patient identification and compatibility labels must be rechecked at the bedside.
- 3.1.2.3 The following should be immediately sent to the laboratory accompanied by a request form giving full clinical signs and symptoms of the reaction:
 - (i) the remains of the product being transfused at the time of reaction, IV administration set and empty bags from previously transfused products [these should be returned in a way which complies with the principles of safe handling of clinical waste, and occupational health and safety practices]
 - (ii) EDTA, clotted and other samples, as necessary, collected immediately post-reaction and from the opposite arm to the infusion site
 - (iii) the first sample of urine collected post-transfusion
- 3.1.2.4 The following clerical checks must be performed:
 - (i) checking the identity of the patient on the request form(s), pre- and post-transfusion sample(s), compatibility label(s) and the pretransfusion testing records
 - (ii) checking the product donation number(s)
 - (iii) checking the ABO/Rh(D) types of the patient and products
 - (iv) visual inspection of unit and segments for signs of clots, haemolysis or discolouration

3.1.2.5 The following laboratory testing should be performed:

- (i) visual examination of the patient's post-transfusion serum/plasma for haemoglobinaemia / haemolysis
- (ii) ABO/Rh(D) typing, antibody screen and DAT on patient's pre- and post-transfusion samples. [A negative DAT post-transfusion does not exclude a severe haemolytic transfusion reaction]
- (iii) checking the ABO/Rh(D) type of the unit being transfused at the time of the reaction, and any previously transfused units where available [for platelets and plasma products a reverse group only is required]
- (iv) IAT crossmatch of all red cell units given against the patient's pre- and post-transfusion samples

3.1.3 Additional Testing

3.1.3.1 It may be difficult, clinically, to distinguish haemolytic or simple non-haemolytic febrile transfusion reactions from those due to bacterial contamination. If the tests in 3.1.2 are inconclusive the following further testing may be informative:

- (i) determination of plasma haemoglobin, serum bilirubin and haptoglobin levels
- (ii) determination of urinary haemoglobin and urobilinogen
- (iii) Gram stain and culture of samples from blood remaining in packs or tubing from transfusions given prior to the reaction .
- (iv) blood cultures taken from the patient
- (v) checking the contents of the original red cell pack [following centrifugation if necessary] for pretransfusion haemolysis due to incorrect storage

3.1.3.2 Testing the patient for HLA, platelet and neutrophil antibodies may be necessary in the event of non-haemolytic transfusion reactions.

3.1.3.3 If the reaction is severe with pulmonary involvement and Transfusion Related Acute Lung Injury [TRALI] is suspected, the implicated donors should be screened for HLA and neutrophil antibodies.

3.1.3.4 In suspected anaphylactic or anaphylactoid reactions the possibility of antibodies to plasma proteins [particularly IgA] should be considered.

3.1.4 Reporting Of Other Transfusion-Related Adverse Events And Reactions

When a person receives an inappropriate transfusion, blood intended for another patient or products where special requirements such as CMV-negative or irradiation are not met, unless there is a major incompatibility the patient may not experience [or show] any obvious side effects.

However these events represent failures in the transfusion process which need to be identified and subsequently corrected to prevent similar events happening in the future. It is essential that any such event is firstly recognised, then reported to the Laboratory. The cause of the event should be investigated by root cause analysis and appropriate corrective action taken and recorded.

4. Quality Aspects

4.1 QUALITY ASSURANCE

4.1.1 General Principles

- 4.1.1.1 A consistently high standard of pretransfusion testing depends on close attention to detail and quality assurance of the laboratory functions involved.
- 4.1.1.2 The laboratory must have a quality system in place that conforms to national accreditation or regulatory requirements.
- 4.1.1.3 Methods and procedures manuals must be available within the laboratory. All methods undertaken within the laboratory must be clearly documented.
- 4.1.1.4 The methods and procedures manual should be reviewed at least annually.

4.1.2 Accreditation And Clinical Oversight Of Medical Testing Laboratories

- 4.1.2.1 Medical testing laboratories are accredited by NATA/RCPA [Australia] and IANZ [New Zealand] under the requirements of quality standard ISO 15189:2003 Medical Laboratories – Particular requirements for quality and competence [issued in Australia as AS 4633 and New Zealand as NZS/ISO 15189].
- 4.1.2.2 In New Zealand accreditation of transfusion medicine laboratories is further supported by the complementary activities of the NZBS ‘DHB Clinical Oversight Programme’. This programme provides formal clinical and technical oversight of blood banks through a combination of site visits, clinical audits and regional blood bank meetings.
- 4.1.2.3 All hospitals should establish a hospital transfusion committee [HTC] to implement and oversee quality assurance of transfusion medicine activities. Alternatively these functions may be incorporated within the role of another appropriate quality assurance or risk management committee as the local situation demands.
- 4.1.2.4 The provision of safe and effective transfusion practice requires multidisciplinary collaboration. The HTC can help with areas covered by these guidelines, as follows:
 - (i) disseminating national or local guidelines within the institution
 - (ii) developing local policies and protocols for blood use and collection
 - (iii) auditing use and wastage, and developing related performance indicators
 - (iv) risk management
 - (v) communication with internal and external bodies about quality assurance matters
 - (vi) training of medical and nursing staff and phlebotomists in generating requests and collection and labelling of samples

- (vii) supporting haematologists and transfusion laboratory staff in enforcing policies relating to non-laboratory aspects of transfusion practice, e.g. documentation of transfusion, identification of patients, collection of pretransfusion samples and correct prescription of blood products.

4.1.3 Internal Quality Assurance Programs

- 4.1.3.1 All staff must participate in regular [preferably quarterly] internal quality assurance programs, such as the inclusion of quality assurance samples into the routine workload.
- 4.1.3.2 The inclusion of samples with weak antibodies or red cells with weakly positive DATs are recommended for assessing whether or not weak reactions can be detected. The provision of samples with mixed cell populations is also recommended.

4.1.4 External Quality Assurance Programs

- 4.1.4.1 The laboratory must participate in a recognised external quality assurance program in areas appropriate to their range of testing.
- 4.1.4.2 All staff must participate in external QA programs at least twice annually.

4.2 QUALITY CONTROL

4.2.1 General Principles

- 4.2.1.1 All equipment [instruments, reference materials, consumables, reagents and analytical systems] must be subjected to regular maintenance and calibration programmes to ensure reliability.
- 4.2.1.2 Equipment performance must be monitored at regular intervals in accordance with the manufacturer's recommendations and relevant national accreditation guidelines.
- 4.2.1.3 The manufacturer's instructions must be followed although more stringent testing may be performed where this is felt to be beneficial.
- 4.2.1.4 Records must be maintained of all quality control performed by the laboratory in accordance with national regulatory requirements.

4.2.2 Pre-acceptance Testing Of Reagents

- 4.2.2.1 The laboratory must assess the suitability of reagents before they are introduced into routine use [pre-acceptance testing]. This is an important step, which provides a baseline against which on-going performance of the reagent can [and should] be monitored.
- 4.2.2.2 The laboratory must have documented procedures for pre-acceptance testing of reagents. These must include the criteria against which reagents are assessed for suitability and what steps are taken if reagents do not meet these criteria.
- 4.2.2.3 It is recommended that assessment criteria using comparison of grades of reaction, e.g. testing antisera of known antibody concentration or titre, be used.
- 4.2.2.4 Any item not meeting the defined acceptance criteria should not be used.

4.2.3 Frequency Of Reagent QC

- 4.2.3.1 The following table provides an indication of the required frequency of QC testing. Longer intervals between testing may be acceptable if mandated by the manufacturer or the laboratory can show that the extended interval has been appropriately validated.

Reagent	Frequency
ABO Antisera	Each day of use
Rh Antisera	Each day of use
Other Antisera	Each day of use
AHG	Each day of use
ABO Reagent red cells	Each day of use
Antibody Screening cells	Each day of use

4.2.4 Maintenance And Calibration

4.2.4.1 The table below shows recommended maintenance and/or calibration intervals. These are general guidelines only and are intended for use where requirements have not been set by the supplier, or where the supplier's requirements are less than those required by the relevant regulatory standard.

Device	Maintenance and/or Calibration requirement	Frequency
Temperature Measuring Devices – Digital	Calibration	Annual 2 point calibration over required range.
Temperature Measuring Devices – Liquid in Glass – Reference	Calibration	Full calibration every 5 years 6 monthly ice point checks.
Temperature Measuring Devices – Liquid in Glass – Working	Calibration	Initial full calibration 6 monthly checks [working range $\leq 5^{\circ}\text{C}$ - single point check within the working range; Working range $> 5^{\circ}\text{C}$ - several points should be checked within the working range]
Centrifuges	Calibration	Annual
Timers	Calibration	Annual
Refrigeration equipment	Temperature check Spatial checks	Daily Annual
Platelet incubators/rockers	Temperature check Spatial checks	Daily Annual
Alarms	Function check	Monthly
Heat blocks, water baths, incubators	Temperature check Calibration	Daily Annual
Pipettors	Dispensed volume check	6 monthly

4.2.4.2 Equipment must also undergo calibration after it is repaired or undergoes a significant change in location.

4.3 AUTOMATED TESTING EQUIPMENT

4.3.1 Validation

4.3.1.1 A documented validation must be performed on all automated equipment, prior to formal implementation. Validation records must be held in accordance with national regulatory requirements.

4.3.1.2 Automated equipment must be shown to:

- (i) be capable of achieving the required performance
- (ii) comply with the specifications associated with the tests performed
- (iii) comply with the laboratory's requirements
- (iv) comply with regulatory requirements

4.3.1.3 All validation failures or non-conformances must be fully investigated to determine the root cause. All findings including resolution must be documented.

4.3.1.4 All findings including resolution must be documented.

4.3.2 Verification

4.3.2.1 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 :

- (i) specifically formulated QC material
- (ii) previously analysed samples
- (iii) commercial controls
- (iv) reference material

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

4.3.3 Modifications and Upgrades

4.3.3.1 A risk assessment must be undertaken before undertaking modifications or upgrades to equipment [or changes to the operating software]. The assessment must:

- (i) identify critical control points
- (ii) identify areas where if there is a failure, harm to a patient or donor may occur

4.3.3.2 The equipment's performance must be verified following modifications or upgrades to equipment or changes to operating software, to show that any change has not adversely affected performance.

4.3.3.3 Appropriate operator training must follow equipment [and software] modifications.

4.3.4 Data Backup

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

4.3.5 Routine Testing

- 4.3.5.1 The laboratory must maintain a full audit trail of all testing steps, cross-referenced to controls, amendments, authorisations and staff conducting the testing.
- 4.3.5.2 Automated equipment must ensure positive patient identification is maintained between the sample and testing results. The use of bar-coded laboratory accession numbers is recommended.
- 4.3.5.3 The laboratory must maintain a validated manual system to be used during instrument failure or downtime.

4.3.6 Editing Results

- 4.3.6.1 The laboratory must have a documented policy that describes the access levels for staff permitted to enter, validate, alter and verify test results.

4.4 SOFTWARE VALIDATION

4.4.1 General Principles

- 4.4.1.1 The laboratory must undertake a documented validation of software with records held in accordance with national regulatory requirements. The documentation should record the following:
 - (i) the software version
 - (ii) the date of validation
 - (iii) the identity of the person performing the validation
 - (iv) an independent check of all the validation documentation by a senior member of the transfusion laboratory staff
- 4.4.1.2 Validation must ensure that the software performs appropriately in the environment in which it is to be used [irrespective of the source and prior manufacturer testing], and should include:
 - (i) destructive testing of individual modules
 - (ii) integrated testing of the complete system and all logic paths using both correct and incorrect dataThe validation must be clearly documented
- 4.4.1.3 A validation checklist should be used which show that, under a series of challenges, the program generated the appropriate responses. It is particularly important to demonstrate that the software:
 - (i) does not allow the issue of ABO-incompatible units
 - (ii) does not allow issue of expired blood products
 - (iii) provides clear warning flags for special transfusion requirements or other locally applied protocols
 - (iv) appropriately handles the various combinations of donor and recipient ABO and Rh(D) types in determining compatibility [or not] of each blood product.

4.4.2 Modifications Or Upgrades

- 4.4.2.1 A risk assessment must be undertaken before undertaking modifications or upgrades to software [or associated hardware]. The assessment must:
 - (i) identify critical control points
 - (ii) identify areas where if there is a failure, harm to a patient or donor may occur
- 4.4.2.2 All changes to software must be fully documented and records kept.

4.4.2.3 Further validation must be performed [unless any change is minor]:

- (i) when the software is modified or upgraded
- (ii) following preventative maintenance on the software [or system hardware], or changes to interfaces with the system

Even minor changes to the software [or hardware] system may cause unexpected effects on the system's functionality, requiring extra vigilance to ensure correct operation of all aspects of the system.

4.4.2.4 Appropriate operator training must follow software modifications.

4.4.2.5 After any software [or hardware] modification impacting on the electronic release of blood, computer crossmatching is prohibited until any validation is completed.

4.5 BLOOD PRODUCTS

4.5.1 Temperature Controlled Storage

4.5.1.1 Blood products must be stored in an appropriate temperature controlled [and monitored] environment.

4.5.1.2 Refrigerators and deep freeze cabinets used to store blood products must conform to Australian Standard AS 3864 *Medical refrigeration equipment – for the storage of blood and blood products*. This applies not only to blood banks but also the external locations that they supply within their hospital campus(es), other satellite locations and private healthcare facilities. Compliance with the standard is the responsibility of the organisation that owns the equipment.

4.5.1.3 The following storage temperatures must be used:

Product	Storage Temperature
Red blood cells	2 - 6 °C
Platelets **	20 - 24 °C [with gentle agitation]
Frozen plasma [FFP or Cryoprecipitate]	-25 °C or below
Cryoprecipitate	-25 °C or below
Manufactured blood products	As per manufacturer's instructions

***Platelets may be stored in any room with the appropriate ambient temperature. To avoid fluctuations in room temperature, platelet 'incubators' offering a controlled temperature environment are recommended in which a platelet agitator can be placed.*

4.5.1.4 Blood products, which during storage, have reached a temperature outside of specification, have been stored in nonconforming equipment or where there is any doubt regarding the conditions of storage, must not be used for transfusion [except at the discretion of the Laboratory Director]. Any such occurrences must be clearly documented and the product held in quarantine until a decision is made regarding its fate.

4.5.2 Transporting Blood Products

- 4.5.2.1 Blood products must be transported within the specifications of the supplier along with the requirements of the receiving laboratory. This applies to all products irrespective of origin including those accompanying patients transferred from hospitals, facilities or other locations outside the jurisdiction of the receiving laboratory.
- 4.5.2.2 The temperature of products during transport must be maintained within the range specified by the supplier for the duration of transit.
- 4.5.2.3 Acceptance of products into the inventory of the receiving facility and/or subsequent transfusion is conditional on evidence of suitable storage and handling whilst in transit from the issuing facility.
- 4.5.2.4 Any products where there is any doubt regarding the conditions of storage during transport must not be used for transfusion. Any such items must be held in secure quarantine until a decision regarding their fate is made. Acceptance [or use] of products where suitable storage conditions have not been maintained is at the discretion of the Laboratory Director.

Glossary

AHG	Anti-human globulin
APTT	Activated partial thromboplastin time
ARCBS	Australian Red Cross Blood Service
AS	Australian Standard; precedes document number of standards issued by Standards Australia
AV	Arterio-venous [shunt]
BCSH	British Committee for Standards in Haematology; Sub-committee of the British Society for Haematology. Provides up to date advice on the diagnosis and treatment of haematological disease by the production of evidence based guidelines
Blood components	Red cells, platelets, fresh frozen plasma, cryoprecipitate and white cells derived from human blood
CAT	Column agglutination technology
CMV	Cytomegalovirus
C:T	Crossmatch to transfusion [ratio]
DAT	Direct antiglobulin test
D&C	Dilation and curettage
DHB	District Health Board
EDTA	Ethylene-diamine-tetra-acetic acid; anticoagulant, chelating agent
FFP	Fresh frozen plasma
Group and screen [G&S]	Collective description of the following procedures: ABO and Rh(D) grouping of the recipient. Antibody screening of the recipient [or mother in the case of neonatal transfusion]
GVHD	Graft versus host disease
HLA	Human leucocyte antigen
HTC	Hospital transfusion committee
IAT	Indirect antiglobulin test
INR	International normalised ratio
IT	Information technology
IU	International units
IUT	Intrauterine transfusion
ISO	International Organisation for Standardisation; International standard setting body composed of representatives from national standards bodies
IV	Intravenous
Laboratory Director	The Pathologist, Transfusion Medicine Specialist, Medical Officer or Senior Scientist responsible for the clinical / scientific oversight of the Laboratory in accordance with ISO 15189:2003 'Medical Laboratories – Particular requirements for quality and competence'.
LIS	Laboratory information system
LISS	Low ionic strength solution

MSBOS	Maximum surgical blood order schedule
NATA	National Association of Testing Authorities; Australia's national laboratory accreditation authority
Neonate	Newborn infant less than one month of age
NPAAC	National Pathology Accreditation Advisory Council; advises the Commonwealth, State and Territory Health Ministers on matters relating to the accreditation of pathology laboratories. 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.
NZBS	New Zealand Blood Service
NZS	New Zealand Standard; 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, immunoglobulins
PT	Prothrombin time
RCPA	Royal College Of Pathologists Australasia
Recombinant product	A product from a non human source which provides an activate replacement of a deficiency of a specific clotting factor
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
PEG	Polyethylene glycol
QA	Quality assurance
QC	Quality control
RFID	Radio-frequency identification; The process of using an electrical transponder which stores information that can be used to identify the item to which the transponder is attached.
TRALI	Transfusion-related acute lung injury
WAIHA	Warm Autoimmune Haemolytic Anaemia

Maximum Surgical Blood Order Schedule [MSBOS]

MAXIMUM SURGICAL BLOOD ORDER SCHEDULE (MSBOS)

The MSBOS provided below is intended as a guide only. The laboratory will need to assess the usual red cell requirements for each procedure in the hospital(s) that they serve, in conjunction with the surgeons performing the procedures.

The crossmatch:transfusion [C:T] ratio is a useful guide and those procedures with a C:T ratio >2 can normally be considered suitable for a group and screen [G&S] protocol. Specialised surgical procedures e.g. cardiac, hepatic and neurosurgery usually employ standard protocols developed in consultation with the laboratory.

General Surgery

Procedure	Crossmatch Requirements
Abdomino-perineal resection	2
Amputation [below or above knee]	G&S
Anterior resection	2
Appendectomy	Nil
Apronectomy [mini-abdominoplasty]	G&S
Bowel resection	2
Breast surgery [lumpectomy]	G&S
Burns debridement	Individual Assessment
Cholecystectomy	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]	2
Incisional hernia repair	Nil
Laparotomy	G&S
Lipectomy	G&S
Lumbar sympathectomy	G&S
Mastectomy [simple]	G&S
Mastectomy [radical]	G&S
Mastoidectomy	G&S
Pancreatectomy	2
Parotidectomy	G&S
Rhinoplasty	G&S

Splenectomy	2
Thyroidectomy	G&S
Tonsillectomy	G&S
Tracheostomy	G&S
Vagotomy and drainage	G&S
Varicose veins stripping	Nil

Gynaecological Surgery

Procedure	Crossmatch Requirements
Caesarean section	G&S
Colposuspension	G&S
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	G&S
Tubal ligation	Nil
Vaginal repair	G&S
Vulvectomy	G&S

Orthopaedic Surgery

Procedure	Crossmatch Requirements
Arthroscopy	Nil
Arthrotomy	Nil
Femoral nail removal	Nil
Fractured femur	2
Harrington's rods	4
Hip replacement	3
Knee replacement	G&S
Laminectomy	G&S
Meniscectomy	Nil
Putti-Platt	G&S
Spinal fusion	2
Synovectomy [knee]	G&S

Thoracic Surgery

Procedure	Crossmatch Requirements
Lobectomy	2
Pleurectomy	2
Pneumonectomy	4
Thymectomy	2

Urological Surgery

Procedure	Crossmatch Requirements
Cystectomy	4
Cystoscopy or cystotomy [vesicotomy]	Nil
Nephrectomy	G&S
Nephrolithotomy	G&S
Prostatectomy [open]	2
Prostatectomy [transurethral resection; TURP]	G&S
Pyelolithotomy	G&S
Ureterolithotomy	G&S

Vascular Surgery

Procedure	Crossmatch Requirements
Aortic aneurysm [elective]	4
Aorto-femoral bypass graft	4
Aorto-iliac bypass graft	4
AV shunt	Nil
Carotid endarterectomy	G&S
Femoro-popliteal bypass graft	2
Ilio-femoral bypass graft	4
Sympathectomy lumbar	G&S

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