

NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

**REQUIREMENTS FOR TRANSFUSION
LABORATORY PRACTICE**
(Fourth Edition 2019)

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Australian Government Department of Health

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The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate standards and initiate and promote education programs about pathology tests.

Publications produced by NPAAC are issued as accreditation material to provide guidance to laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a risk to public health and patient safety.

Scope

The *Requirements for Transfusion Laboratory Practice (Fourth Edition 2019)* is a Tier 4 NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services*. The latter is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific standards in that document are provided for assistance under the headings in this document.

The role of transfusion laboratories in pathology services, pharmacies and those commercial suppliers of blood products who supply direct to patients are critical to patient safety. The *Requirements for Transfusion Laboratory Practice* are for use by laboratories providing pre- transfusion and antenatal and post-natal immunohaematology testing and issuing of blood and blood products. They are also for use in **patient testing** where it is conducted by the Australian Red Cross Blood Service. The document provides a risk based approach to provision of these services.

This Standard also applies in the context of **donor testing** conducted by the Australian Red Cross Blood Service, who, by agreement with the Australian Government, are the sole supplier of fresh blood related components and products in Australia. Additional requirements that are applicable to the testing of donor blood specimens are outlined in Standard 5.

Current Australian and New Zealand Society of Blood Transfusion (ANZSBT)¹ and National Blood Authority (NBA)² documentation provide further guidance and must be used in conjunction with this document.

Abbreviations

Abbreviation	Description
ANZSBT	Australian and New Zealand Society of Blood Transfusion
Blood Service	Australian Red Cross Blood Service
AS	Australian Standard
DAT	Direct Antiglobulin Test
GVHD	Graft Versus Host Disease
HDFN	Haemolytic Disease of the Foetus and Newborn
HSCT	Haemopoietic Stem Cell Transplantation
HTC	Hospital Transfusion Committee
IAT	Indirect Anti-globulin Test
ISO	International Organization for Standardization
IVD	In Vitro Diagnostic Medical Device
LIS	Laboratory Information System
NATA	National Association of Testing Authorities, Australia
NBA	National Blood Authority
NPAAC	National Pathology Accreditation Advisory Council
QA	Quality Assurance
QAP	Quality Assurance Program
RCPA	Royal College of Pathologists of Australasia
TGA	Therapeutic Goods Administration

Definitions

Term	Definition
Allogeneic	means cells and noncellular elements obtained from a human donor who is genetically different from the intended human recipient.
Blood components	means generically in this document, red cells, platelets, fresh frozen plasma, cryoprecipitate, cryodepleted plasma and whole blood derived from human blood.
Blood donor	means a person who provides blood for manufacture of a blood component or a blood derived product, through the Australian Red Cross Blood Service.
Blood products	means generically in this document, plasma derivatives and recombinant product.
Cold-chain	means the maintenance of appropriate storage and transport conditions under which blood and blood products are handled within the safe temperature range of appropriate to that product to guarantee their suitability for clinical use and patient safety, from the place of manufacture to the point of administration.
Computer Crossmatch	means application of computer software to allow electronic issue of compatible red cells without serological crossmatch.
Confirmatory or check group or forward group	means testing of red cells for ABO and RhD status using commercial reagents.
Donor	means a person who provides the source cells for a product.
External Quality Assessment	means a program in which specimens are periodically sent to laboratories for analysis and/or identification, in which each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and others. Such a program may also compare an individual's results with their peer group.
Haemovigilance	means a program to identify and prevent occurrence or recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient. The system should include monitoring, identification, reporting, investigation and analysis of adverse events near-misses and reactions related to transfusion and manufacturing.

Term	Definition
In vitro diagnostic medical device (IVD)	<p>means the same as the definition in the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> and is a medical device that is:</p> <ul style="list-style-type: none"> (a) a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and (b) intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for: <ul style="list-style-type: none"> (i) giving information about a physiological or pathological state or a congenital abnormality; or (ii) determining safety and compatibility with a potential recipient; or (iii) monitoring therapeutic measures; and (c) not a product that is: <ul style="list-style-type: none"> (i) intended for general laboratory use; and not manufactured, sold or presented for use as an IVD medical device.
In-house IVD	<p>means the same as the definition in the <i>Therapeutic Goods (medical Devices) Regulations 2002</i> and is an IVD medical device that is:</p> <ul style="list-style-type: none"> (a) within the confines or scope of an Australian laboratory or Australian laboratory network: <ul style="list-style-type: none"> (i) developed from first principles, or (ii) developed or modified from a published source; or (iii) developed or modified from any other source; or (iv) used for a purpose, other than the intended purpose assigned by the manufacturer; and not supplied for use outside that laboratory or laboratory network.
LIS	means Laboratory Information System.

Term	Definition
Patient	means a person who is receiving healthcare services or is an outpatient.
Quality Control	means operational techniques and activities that are used to fulfil requirements for quality. Internal Quality Control means operational techniques and activities at the point of use that are used to fulfil requirements for quality of Medical Pathology Services.
Remote release	means issuing blood products directly from a blood storage facility at a physically distant location from the supplying laboratory, such as a ward or other clinical area or facility.
Requirements for Medical Pathology Services	means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.
Reverse group	means testing of plasma or serum for the presence of anti-A and/or anti-B to confirm results of a forward group.
Transfusion related Adverse Event/Incident	means an adverse event in which a person receiving health care was harmed. In the case of blood and blood products the resulting harm was from the transfusion of blood and blood products. An incident is an event or circumstance that resulted, or could have resulted, in unintended and/or unnecessary harm to a person and/or a complaint, loss or damage.
Transfusion record	means for the purpose of this document, the patient's transfusion laboratory record.

Introduction

Transfusion medicine is an essential part of medical practice and is critical to patient care. The use of blood products and blood components provides essential therapeutic support in a broad range of medical and surgical settings, and is associated with recognised risks.

The *Requirements for Transfusion Laboratory Practice (Fourth Edition 2019)* outlines practice standards that assure the safety, quality and efficacy of transfusion testing, associated transfusion laboratory practice, and non-transfusion related blood group immunohaematology testing. This document must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services*.

These Requirements also apply to donor testing conducted by the Blood Service. Standard 5 outlines the specific requirements applicable for blood donor testing.

Transfusion testing includes terms specific for this area of practice, and these are defined in the *Definitions* section of this document. Importantly, to assist in the interpretation of the requirements, the terms ‘blood component’ and ‘blood product’ have been used to distinguish between components produced within donor collection centres, and fractionated plasma derivatives.

The practice of transfusion medicine continues to evolve. The priorities in reviewing the *Requirements for Transfusion Laboratory Practice* were to use a risk based approach and ensure safeguards were in place for patients undergoing transfusion or immunohaematology testing, and for the standard to support contemporary practice. There are new standards to address the introduction of automated immunohaematology testing platforms and other technologies, the electronic laboratory environment, and a focus on storage and transport to support the management of inventory and minimisation of wastage of blood. The standard also recognises the importance of patient blood management and haemovigilance programs and defines the role that transfusion laboratories play in stewardship of both patients and the blood supply. NPAAC has produced these mandatory Requirements, in conjunction with ANZSBT¹ for the accreditation of transfusion laboratories.

The ANZSBT is the specialist society in laboratory and clinical transfusion practice. The NPAAC *Requirements for Transfusion Laboratory Practice* must be read in conjunction with the ANZSBT *Guidelines for Pretransfusion Laboratory Practice*.¹

These Requirements have been developed with reference to Australian regulations and standards from the International Organization for Standardization including:

AS ISO 15189 *Medical Laboratories – Requirements for quality and competence*

AS 3864.2 *Medical Refrigeration Equipment - For the Storage of Blood and Blood Products*

These Requirements should be read within the national pathology accreditation framework in conjunction with the current version of each of the following NPAAC documents:

All Tier2 and 3 Documents

Tier 4 Document

- *Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells*
- *Requirements for Medical Testing of Human Nucleic Acids*

In addition to these standards, laboratories must comply with all relevant state and territory legislation.

In each section of this document, points deemed important for practice are identified as either ‘Standards’ or ‘Commentaries’.

- A standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a laboratory can attain accreditation – standards are printed in bold type and prefaced with an ‘S’ (e.g. **S2.2**). The use of the word ‘**must**’ in each standard within this document indicates a mandatory requirement for pathology practice.
- A Commentary is provided to give clarification to the standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a ‘C’ (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a standard or not. Note that when comments are expanding on a standard or referring to other legislation, they assume the same status and importance as the standards to which they are attached. Where a Commentary contains the word ‘**must**’ then that Commentary is considered to be **normative**.

Please note that any Appendices attached to this document may be either **normative** or **informative** in nature and should be considered to be an integral part of this document. Please note that all NPAAC documents can be accessed at [Department of Health](#).

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

NPAAC Secretariat
Diagnostic Imaging and Pathology Branch
Medical Benefits Division
Department of Health
GPO Box 9848 (MDP 851)
CANBERRA ACT 2601

Phone: (02) 6289 4017
Fax: (02) 6289 4028
Email: [NPAAC Secretariat](#)
Website: [Department of Health](#)

1. Clinical Governance of Transfusion Laboratories

(Refer to Standard 4 in *Requirements for Medical Pathology Services*)

S1.1 The laboratory must be part of a quality system that provides clinical governance and oversight of patient blood management and transfusion-related activities.

C1.1 The clinical governance system should actively manage patient safety, transfusion safety, and the appropriate prescribing and clinical use of blood components and blood products.

2. Patient Identification and Labelling

(Refer to Standard 8A in *Requirements for Medical Pathology Services*)

Accurate patient identification and specimen labelling are crucial to patient safety. Labelling of the primary pretransfusion sample tube **must** occur in the presence of the patient after positive identification of the patient.

Failure to comply with these requirements remains a significant cause of patient morbidity and mortality.

S2.1 All transactions must be securely and unambiguously recorded with the ability to trace and attribute all transactions to the operator performing them.

C2.1 The use of a unique electronic/digital signature or other appropriate system generated identifier in an electronic system is acceptable.

C2.2 Requestor, patient and the collector must be identified.

S2.2 The request must include a specimen collector declaration similar to that below.

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

S2.3 The collector must be identified in the form of a signature or a unique electronic/ digital signature.

S2.4 Specimen labelling must be correct, adequate and unambiguous.

C2.4(i) The patient's details on the specimen tube **must** comply with the *Requirements for Medical Pathology Services*.

C2.4(ii) The specimen label **must** include the patient identifiers and collector identifier that **must** be traceable in the medical pathology service records.

C2.4(iii) Patient identity **must** be confirmed at the bedside prior to labelling of the specimen.

C2.4(iv) The specimen label and patient details must match.

S2.5 The date and time of collection of specimens must be traceable.

C2.5 If the date and time of collection is not recorded electronically, it must be handwritten on the request and/ or specimen label.

S2.6 If there is a discrepancy between the patient request and specimen, this must be resolved and documented in accordance with the laboratory's protocol before proceeding with testing.

Verbal Requests

S2.7 **The laboratory must have a protocol for accepting verbal requests to issue blood to patients for whom the laboratory holds a request for Group and Hold (or pre-transfusion blood group/antibody screen) and for the issue of other blood components/ products.**

C2.7 These requests **must** be recorded by the laboratory.

Requests and specimen labelling for Neonates and Cord Blood Testing

S2.8 **The request must clearly identify the neonate as an individual and meet the standard specimen labelling requirements.**

C2.8 Where available, the mother's details i.e. full name and date of birth and/or medical record number should be included in addition to the neonatal details on the request.

3. Transfusion Laboratory Records

(Refer to Standard 8 in *Requirements for Medical Pathology Services*)

Laboratory records

S3.1 Where pretransfusion record management is computerised, the Laboratory Information System must comply with the relevant NPAAC requirements.#

S3.2 For each blood component issued, the patient's laboratory transfusion record must contain the following information:

Patient (recipient):

- (a) three unique identifiers#**
- (b) date and time of specimen collection and expiry date**
- (c) ABO/RhD blood group**
- (d) antibody screen results or antibody specificity where applicable**
- (e) antigen typings where applicable**
- (f) any special requirements where applicable, for example CMV seronegative, irradiated**
- (g) identification of the person performing the compatibility testing.**

Blood component:

- (a) component type**
- (b) donation/batch number**
- (c) ABO/RhD blood group (where applicable)**
- (d) expiry date of the component**
- (e) date and time of issue**
- (f) antigen typings where applicable**
- (g) any special requirements where applicable, for example CMV seronegative, irradiated.**

S3.3 For blood products issued to individual patients the record must include:

- (a) three unique identifiers#**
- (b) product type**
- (c) donation/batch number and quantity**
- (d) expiry date of the product**
- (e) date and time of issue.**

Refer to NPAAC *Requirements for Medical Pathology Services* and *Requirements for Information Communication*

For blood products issued to a clinical area, the record must include:

- (a) component type**
- (b) donation/batch number and quantity**
- (c) clinical area sent to**
- (d) date and time of issue**
- (e) expiry date of product.**

Compatibility record

S3.4 A permanent record of each unit of blood component issued must be incorporated into the patient's medical record and must contain the following:

- (a) three unique identifiers[#]**
- (b) ABO/RhD blood group and antibody screen of patient**
- (c) component details including type, donation number, blood group and expiry date of the component**
- (d) details of any special requirements, warnings or other relevant information.**

Labelling

S3.5 A label must be securely attached to each unit of blood component or product allocated to a patient. It must contain the following information:

Patient details:

- (a) three unique identifiers[#]**
- (b) ABO/RhD blood group (if applicable).**

Blood component/product:

- (a) donation or batch number**
- (b) ABO/RhD blood group (if applicable)**
- (c) statement of compatibility/selection**
- (d) blood component/product expiry date and time**
- (e) identity of the person affixing the label.**

[#] Refer to NPAAC *Requirements for Medical Pathology Services and Requirements for Information Communication Requirements for Transfusion Laboratory Practice*

Traceability

S3.6 The laboratory must have systems in place to trace every blood component or product which it issues, whether this is to a patient, clinical area, another facility or disposal, including the return of the component or product to the laboratory.

C3.6(i) The laboratory **must** record the following information in relation to each blood component or product it receives:

- (a) source/supplier
- (b) donation or batch number
- (c) blood component or product type
- (d) ABO/RhD group (where applicable)
- (e) date and time received
- (f) expiry date
- (g) recipient's family name, given name(s), medical record number or date of birth or responsible clinical area
- (h) date and time of issue
- (i) the fate of the blood component or product (issued, recalled, expired, transferred, or discarded).

C3.6(ii) Transfer of components/products in bulk should be discouraged. Where this occurs, they **must** be tracked to the receiving clinical areas.

C3.6(iii) Clinical users are responsible for recording the ultimate fate of the product in the relevant clinical area.³

4. Pretransfusion Testing of Patients

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

Pretransfusion testing may be undertaken by means of automated, semi-automated or manual techniques.

S4.1 An ABO and RhD group must be determined for all specimens accepted for pretransfusion testing.

C4.1 Forward and reverse groups **must** be performed for all specimens for pretransfusion testing. For neonates and confirmatory groups, only the forward group is required.

S4.2 When performing blood grouping, all discrepancies whether technical or clerical must be resolved and documented in accordance with the current ANZSBT Guidelines.¹

S4.3 The ABO and RhD group must be confirmed on all specimens and prior to transfusion by:

- (a) comparing the current findings with those recorded for previous specimens where available; or
- (b) repeating the test (manual or automated) on the same specimen by re-testing on a separate occasion to the first test; or
- (c) testing a second specimen collected separately from the original specimen.

C4.3 Where possible in manual testing, a second staff member who has no prior knowledge of the initial result, should perform the second test.

S4.4 The ABO group of all donor red cell component units and the RhD group of those labelled as RhD negative must be confirmed by the laboratory undertaking the pretransfusion testing.

C4.4(i) Blood group confirmation of donor red cell component units **must** be performed by a forward group check.

C4.4(ii) Laboratories are not required to repeat donor red cell component unit group checks, if they have accepted red cell component units from another laboratory within the same network and using the same LIS.

C4.4(iii) Confirmatory weak RhD testing of donor red cell component units is not required.

S4.5 Pretransfusion testing must include an antibody screen capable of detecting potentially clinically significant red cell antibodies.

C4.5(i) Clinically significant red cell antibodies are generally considered to be those, which are reactive by the indirect antiglobulin test (IAT) performed at 37°C. Note that anti-A, -B and -A, B **must** always be regarded as clinically significant (refer to *Appendix A*).

C4.5(ii) If the patient is known to have a red cell antibody/ies, testing to

exclude formation of additional antibodies **must** be undertaken for each new pretransfusion testing specimen received if it is to be used for further cross matching.

- S4.6 The reagent red cells used for antibody 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, Fya, Fyb, Jka, Jkb and Lea.**
- S4.7 Red cells from different donors must not be pooled to achieve the desired range of antigen expression.**
- C4.7(i) One cell **must** be of R1R1 and another of R2R2 phenotype.
- C4.7(ii) The following phenotypes **must** be represented in the screening cells: Jk(a+b-), Jk(a-b+), Fy(a+b-) and Fy(a-b+).
- C4.7(iii) It is also desirable to include SS and ss phenotypes in the screening cells.
- C4.7(iv) Anti-Kpa and anti-Cw are rarely of clinical significance; consequently Kpa+ and Cw+ screening cells are not essential.
- S4.8 Antibody identification must be performed using a reagent red cell panel employing the method(s) by which the antibody is known to be detectable.**
- S4.9 The specificity of an antibody/ies detected during antibody screening must be investigated.**
- C4.9 Antibody identification **must** be confirmed by typing the patient's red cells for corresponding antigen(s) (if not transfused in the past 3 months), if antisera are available or by genotyping. Antibody identification may need to be referred to a reference laboratory.
- S4.10 The clinical significance of any red cell alloantibody(ies) must be identified to determine if antigen negative red cell component unit are needed for transfusion or if there is a risk of HDFN in the pregnant patient and where appropriate, discussed with the managing clinician should a delay to blood provision or risk of HDFN be identified (refer to *Appendix A* and *Appendix B*).**
- S4.11 The laboratory must have procedures in place to determine compatibility between the recipient and requested blood component.**
- C4.11(i) Group specific red cell component units **must not** be released solely on the basis of historical patient blood group records.
- C4.11(ii) Only group O red cell component units are to be released in an emergency situation where there is no current blood group and screen testing result available.

- S4.12** If electronic cross matching is used the following conditions must be met:
- (a) a comprehensive, validated, electronic data management system is in place
 - (b) a valid pretransfusion specimen that has been tested in accordance with the requirements of S4.1 and S4.5
 - (c) there are no clinically significant antibodies detectable in the current specimen and there is no known history of clinically significant antibodies (refer to *Appendix A*).
- S4.13** Specimens must be stored at a temperature that maintains their suitability for serological testing for the lifetime of the pretransfusion request.
- C4.13(i) Whole blood samples may be stored at 2-8°C for up to 7 days.
- C4.13(ii) Separated plasma may be stored at 2-8°C for up to 7 days, or at -20°C for up to 3 months.
- S4.14** The results of pretransfusion testing (on appropriately stored specimens) must be valid for the issue of red cells as follows:
- (a) 72 hours from collection: if the patient has been pregnant or transfused in the previous 3 months (or if this information is not available or is unreliable).
 - (b) 7 days from collection: if the patient has not been pregnant or transfused in the previous 3 months.
 - (c) Up to 3 months from collection: specimens taken in advance of elective surgery if the patient has not been pregnant or transfused in the previous 3 months. At the time of admission, it must be confirmed whether the patient has been pregnant or transfused in the preceding 3 months.
- C4.14 Depending on the functionality of the LIS, it is acceptable to set validity time to midnight of the third day.
- S4.15** For patients who have been transfused and/ or pregnant in the previous 3 months, red cell component units must not be issued more than 72 hours after collection of the specimen used for pretransfusion testing.

5. Immunohaematology Testing of Blood Donors

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

This section applies specifically to the testing of donor specimens by the Blood Service and must be read in conjunction with the other requirements set out in this Standard.

Blood Donor Identification

S5.1 Where a blood specimen is collected solely for the purpose of blood donation testing, the donor's sample must be labelled in accordance with the relevant regulatory requirements for blood collection and manufacture.

C5.1 Evidence of compliance **must** be maintained.

Donor Blood Group Testing and Antibody Screening

S5.2 Testing of donor specimens must meet relevant regulatory standards for blood collection and manufacture.

C5.2(i) In first time blood donors, the ABO and RhD group **must** be determined and **must** be based upon the results of two independent ABO and RhD tests. A reverse group is only required to be performed once on the initial donation.

C5.2(ii) At subsequent donations, the ABO group and RhD blood group **must** be tested and **must** be the same as the historically determined group. A reverse group is not required to be performed.

C5.2(iii) If a discrepancy or variant reaction is found, the applicable blood components **must** not be released until the clinical significance of the discrepancy is unequivocally resolved.

C5.2(iv) Where antibody screening is conducted in blood donor specimen testing, red cell reagents may be pooled provided that the assay is in accordance with the relevant regulatory standards for blood collection and manufacture.

C5.2(v) The purpose of antibody testing in this setting is to assure blood component quality and minimise the chance of a transfusion reaction in a patient who receives a blood or high volume plasma transfusion.

6. Automated Immunohaematology Instruments

(Refer to Standard 6B in *Requirements for Medical Pathology Services*)

S6.1 Prior to introduction into routine laboratory use, automated immunohaematology instruments must undergo validation and verification.

C6.1 If the instrument is interfaced (either unidirectionally or bidirectionally) with the LIS the equipment validation **must** include testing and challenge of the interface.

S6.2 The laboratory must maintain a validated manual system to be used during system/instrument failure or downtime.

S6.3 When automated instruments undergo preventative maintenance or emergency repair, there must be a documented ‘return to service’ procedure, including appropriate validation/ verification before the equipment is brought back into service.

S6.4 The laboratory must have a policy for the manual editing and authorisation of test results.

C6.4 This **must** include the designation of staff allowed to edit results.

S6.5 Automated equipment must ensure patient identification is maintained between the sample and testing results.

C6.5 The use of bar-coded laboratory accession numbers is recommended.

7. Antenatal and Postnatal Testing

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

The objective of immunohaematology testing during pregnancy and at delivery (i.e. pre and postnatal testing) is to manage the risk of haemolytic disease of the fetus and newborn (HDFN) in the current or future pregnancies, and (if required) provide appropriate transfusion support to the mother and fetus or neonate.²

- S7.1 Pre and postnatal specimens must be treated in the same way as other pretransfusion specimens in respect of patient identification, collection and labelling in accordance with Standard 2.**
- S7.2 The request form and specimen labelling, transfusion laboratory records and pretransfusion testing must be in accordance with Standard 3 to Standard 4.**
- C7.2(i) If it is known that RhD-Ig has been given for a sensitising event, the request form should include the date of the RhD-Ig administration.
- C7.2(ii) All RhD negative women without evidence of immune anti-D delivering an RhD positive baby should have a test for fetomaternal haemorrhage (FMH) as soon as practical and within 72 hours of delivery. The report should provide advice on the appropriate dose of RhD-Ig.
- S7.3 Antibody screening and identification of detected antibodies must be performed consistent with the requirements in Standard 5.**
- S7.4 When clinically significant red cell allo antibodies are identified in antenatal testing, the result and its significance must be communicated to the clinician.**
- C7.4 The report should include advice regarding:
- (a) the potential for clinically significant HDFN (refer to *Appendix B*)
 - (b) requirements for follow-up testing
 - (c) recommendation for referral for specialist obstetric management where appropriate
 - (d) the potential for the maternal alloantibody to limit the availability of compatible red cell transfusion.

8. Cord Blood and Neonatal Pretransfusion Testing

(Refer to Standard 6A in *Requirements for Medical Pathology Services*)

S8.1 The request and specimen must clearly identify the neonate as an individual and meet the patient identification and labelling requirements in Standard 2.

C8.1 Where available, the mother's details i.e. full name and date of birth and/ or medical record number should be included in addition to the neonatal details on the request form.

S8.2 Laboratories must have a written protocol in relation to pre-transfusion testing and transfusion management of mothers and their babies in the following settings:

- (a) RhD negative women
- (b) women with current or historical clinically significant antibody/ies
- (c) women presenting at delivery without prior pretransfusion testing during the pregnancy.

S8.3 Laboratories must have a written protocol for cord blood testing.

C8.3(i) Cord blood must not be used for pretransfusion testing.

C8.3(ii) If the fetus is at risk of HDFN a cord blood specimen should be taken for ABO/RhD typing, DAT.

C8.3(iii) Where the mother is RhD negative and has no pre-formed anti D, newborns should be tested by a technique that detects common RhD variants of clinical significance.

S8.4 Laboratories must have a written protocol for neonatal pretransfusion testing.

C8.4(i) Initial pretransfusion testing in the four postnatal months should include:

- (a) Maternal ABO/RhD and antibody screen
- (b) Neonatal ABO/RhD and DAT performed on a capillary or venous blood sample and the results compared with cord blood ABO RhD, if available.

C8.4(ii) If maternal plasma is not available an IAT antibody screen and IAT crossmatching (as required) should be performed on the infant's plasma.

C8.4(iii) If the initial maternal pretransfusion antibody screen performed at the time of delivery and neonatal DAT are negative, no further specimens are required until the infant reaches 4 months of age and ABO RhD compatible red cells can be provided without serological crossmatching.

S8.5 If a clinically significant antibody is (or antibodies are) detected in the

maternal (or infant's) plasma, the infant must receive red cells lacking the corresponding antigen/s.

- C8.5(i) These red cells should be crossmatched by IAT using either maternal or neonatal plasma.
- C8.5(ii) If, when testing subsequent specimens from the infant, the maternal antibody is no longer detectable, the use of antigen negative red cells is not required.

9. Selection of Blood Components

(Refer to Standard 6B in *Requirements for Medical Pathology Services*)

Selection of red cell component units for transfusion

S9.1 There must be written policies on the selection of red cells for:

- (a) routine transfusion
- (b) critical bleeding¹
- (c) use of K negative red cells [#]
- (d) use of CMV negative red cells
- (e) use of irradiated blood components
- (f) washed blood components
- (g) special circumstances where no compatible red cell units are available.

S9.2 Red cell components must be ABO compatible with the patient's sample. If the ABO group cannot be determined, Group O red cells must be selected.

- C9.2(i) Wherever possible, red cells should be the same ABO and Rh type as that of the patient.
- C9.2(ii) Women of child bearing potential who are RhD negative should, wherever possible, be given RhD negative red cells.
- C9.2(iii) Women of child bearing potential who are K negative should, wherever possible, be given K negative red cells.
- C9.2(iv) If the Rh group is not able to be determined, RhD negative red cells should be given until a definitive result is available.
- C9.2(v) Patients that may require long-term transfusion regimens should have an extended phenotype performed (for example C, c, E, e, Jk^a, Jk^b, Fy^a, Fy^b, K, S and s) at the earliest practical time ideally before their initial transfusion. Consideration should be given to providing red cells of the patient's Rh and K types where readily available. If the phenotype cannot be identified, genotyping should be considered.
- C9.2(vi) If the patient has a clinically significant antibody/ies, or a history of a clinically significant antibody/ies, the patient should be given antigen negative red cells. If circumstances do not allow this, incompatible red cells may be transfused after consultation between the responsible treating medical officer and the senior medical specialist from the transfusion laboratory.

[#] Consensus statement on use and allocation of Kell negative red cells ([ANZSBT website](#))

Selection of non-red cell blood components

Fresh frozen plasma, extended life plasma and cryoprecipitate

S9.3 Plasma components of different ABO blood groups must not be pooled.

- C9.3(i) Plasma components should be ABO-compatible with the recipient.
- C9.3(ii) Where Group A FFP is used in critically bleeding patients in whom their blood group is unknown, or it is given to blood group B or AB patients, then the A FFP should be low anti-A/B titre.
- C9.3(iii) Plasma components of any RhD type may be given without regard to the recipient's RhD status. Anti-D immunoglobulin is not required if RhD negative recipients receive plasma components from RhD positive donors.

Platelet concentrates

S9.4 Individual units of different ABO blood groups must not be pooled.

- C9.4(i) Platelet concentrates should be of the same ABO group as the recipient, although if they are not available or near expiry stocks are being used, then either ABO-antigen compatible or ABO-antibody incompatible platelets with low anti-A/B titre may be given with the decision based on the recipient's age, diagnosis and product type.
- C9.4(ii) Wherever possible, platelets from RhD positive donors should not be given to RhD negative females of child bearing age. If this occurs, then administration of RhD immunoglobulin at the recommended dosage may be considered to limit the risk of sensitisation.

10. Transfusion in Special Circumstances

(Refer to Standard 8 in *Requirements for Medical Pathology Services*)

In the following clinical settings the following conditions also apply.

Critical bleeding/emergency transfusion

- S10.1 Specimens must be labelled in accordance with routine pretransfusion practice (Standard 2) and standard pretransfusion testing performed as per Standard 4.**
- C10.1 For provisions relating to unconscious patients refer to S6.3 of the *Requirements to the Medical Pathology Services* and Standard 2 of this document.
- S10.2 Red cells must not be issued in emergency situations on the basis of a historical blood group alone.**
- C10.2(i) If blood components are required before transfusion testing can be undertaken, the red cells **must** be group O. If the patient is a female of child bearing potential, red cells should be RhD negative wherever possible. Group A low titre anti A/B plasma should be issued if group AB is not available.
- C10.2(ii) If there is insufficient time to complete full pretransfusion testing, ABO and RhD compatible red cells (preferably at least ABO group specific) may be issued once the patient's ABO and RhD blood group has been determined (see S4.1 and S4.3).
- C10.2(iii) RhD positive red cells and platelets should not be given to RhD negative females of child bearing potential, except in life-threatening circumstances. If this occurs, then administration of RhD-Ig may be considered to limit the risk of sensitisation.
- S10.3 Red cells issued before completion of pretransfusion testing must be clearly labelled as such, for example 'Uncrossmatched blood' or 'Emergency issue - compatibility testing not completed'.**
- S10.4 If the antibody screen is positive or a subsequent crossmatch incompatible, the treating clinician must be informed immediately.**
- S10.5 The laboratory must have criteria for the issue of RhD positive red cells and platelets when RhD negative stocks of these components are limited.**

Transfusion of patients with Autoimmune Haemolytic Anaemia (AIHA)

S10.6 The laboratory must have a written procedure for the serological investigation and for the provision of red cells for the patient found to have autoantibodies due to autoimmune haemolytic anaemia.

C10.6(i) Prior to the provision of red cells, consultation with the referring medical officer **must** occur.

C10.6(ii) Transfusion of phenotypically matched red cells is recommended. The degree of matching (e.g. limited to Rh and K or to the extended type) will depend on local policies or availability of suitable red cells (or both).

C10.6(iii) If the phenotype cannot be identified, genotyping should be considered.

Recipients of autologous and allogeneic haemopoietic progenitor cell transplants

S10.7 Laboratories must have written protocols on the selection of blood components with respect to ABO and RhD groups of recipient and donor for transfusion of haemopoietic progenitor cell transplants (HPCT) patients who are to undergo or have undergone HPCT.

C10.7 Guidance relating to the use of blood components in these setting should be sought from the NPAAC *Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells* and from the ANZSBT Guidelines.¹

S10.8 Red cells and platelets used in patients following Allogeneic HSCT must be irradiated to prevent Transfusion associated GVHD.

Recipients of ABO-mismatched solid organ transplants

S10.9 Laboratories must have written protocols for the selection of blood components for transfusion to patients receiving a solid organ transplant from an ABO- mismatched donor.

C10.9(i) For non-red cell products, the plasma should be ABO-compatible with the graft (i.e. donor ABO group).

C10.9(ii) The patient does not need to receive irradiated components.

C10.9(iii) In choosing to transfuse the following factors should be considered:

- (a) the use of blood components/products containing ABO antibodies incompatible with the ABO group of the transplanted donor organ should be minimised
- (b) donor exposure should be minimised to reduce the risk of HLA sensitisation
- (c) if possible, transfusion of platelets which are ABO incompatible with recipient plasma should be avoided as ABO incompatible platelets have shortened survival
- (d) renal transplant patients should remain on their transplant related transfusion protocol indefinitely.

Transfusion in pregnancy

S10.10 Pre and postnatal specimens must be treated in the same way as pretransfusion specimens in respect of patient identification, collection and labelling in accordance with Standard 2.

C10.10 Women with current or historical clinically significant antibodies should have a valid group and antibody screen available when they are in labour or about to undergo caesarean section.

S10.11 Selection of blood components for transfusion in pregnancy must be in accordance with Standard 10.

C10.11(i) Red cells selected for transfusion in pregnancy should be matched for ABO and RhD.

C10.11(ii) The use of K negative red cells must be used in the transfusion of K negative women or where there is insufficient time to determine K status. K negative red cells are not required in K positive women.

C10.11(iii) The use of K negative red cells in women who are K positive is not necessary.

C10.11(iv) Pregnant women, irrespective of their CMV status should receive CMV seronegative blood components, where available.

C10.11(v) Where CMV seronegative blood components are not available, leucodepleted components are a suitable substitute.

C10.11(vi) CMV seronegative red cells or platelets are not required post-partum.

C10.11(vii) In critical bleeding situations transfusion should not be delayed because of the unavailability of antigen matched or CMV seronegative blood components.

Intrauterine and neonatal transfusion

S10.12 Laboratories must have written protocols for the selection of blood components for neonatal transfusion:

- (a) red cells must be the same ABO/RhD type as the infant or ABO/RhD compatible**
- (b) red cells of the infant's blood group may be used once any passively acquired anti-A or -B antibodies are no longer detectable by IAT; tests for anti-A must use A1 red cells**
- (c) red cells and platelets should be CMV seronegative**
- (d) red cells and platelets must be irradiated, if the infant:⁵**
 - (i) is having exchange transfusion(s)**
 - (ii) has previously received an IUT (with irradiated blood components required until 6 months of age)**
 - (iii) is receiving blood components donated by a direct relative**
 - (iv) has a low birth weight (<1500 g)**
 - (v) is immunocompromised**
- (e) apheresis ABO mismatched platelets should be avoided in neonates and paediatric patients because of the risk of haemolysis from donor ABO antibodies.**

S10.13 Laboratories must have written protocols for the selection of blood components for intrauterine transfusion.

C10.13 Red cells selected for Intrauterine Transfusion (IUT) should be:

- (a) less than 5 days old
- (b) K negative if the mother is K negative
- (c) ABO/RhD compatible with both the mother and fetus and negative for the antigen(s) against which the maternal antibody/ies is/are directed
- (d) it may be desirable to perform an extended maternal red cell phenotype (C, c, E, e, K, Fy^a, Fy^b, Jk^a, Jk^b, S and s) and provide phenotype matched red cells so the mother is not exposed to other blood group antigens she lacks, where readily available.
- (e) CMV seronegative
- (f) irradiated (**must** be used within 24 hours of irradiation).

Transfusion Dependent or Frequently Transfused Patients

Transfusion dependence occurs as a result of ongoing anaemia associated with reduced erythropoiesis and where a person regularly requires ≥ 1 RBC-transfusion over a specified interval in conditions such as sickle cell disease, thalassaemia or myelodysplasia.

S10.14 Laboratories must have a written protocol on the selection of blood components for transfusion dependent or frequently transfused patients.

- C10.14(i) Patients should have an extended red cell phenotype determined (including C, c, E, e, K, Fy^a, Fy^b, Jk^a, Jk^b, S and s) before their initial transfusion if clinically feasible.
- C10.14(ii) Transfusion of phenotypically matched red cells is recommended. The degree of matching (e.g. limited to Rh and K or to the extended type) will depend on local policies or availability of suitable red cells (or both).

11. Autologous Transfusion

(Refer to Standard 8A in *Requirements for Medical Pathology Services*)

Autologous blood (red cell) donation is only recommended for exceptional circumstances such as patients with rare blood groups/antibodies or multiple red cell antibodies where it can be difficult to find compatible donors.²

- S11.1 All laboratories involved in the provision of a pre-donation autologous blood service must have clear protocols for the collection, testing, storage and issue of these units.**
- S11.2 All autologous red cell units must be clearly labelled to distinguish them from allogeneic (homologous) units and stored in a separate designated area.**
- S11.3 Autologous red cell units must only be used for the patient from whom they were collected.**
- S11.4 Pretransfusion testing, labelling and documentation must be performed in accordance with Standard 2, Standard 3 and Standard 4.**

12. Transfusion Reactions and Transfusion Related Adverse Events

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

- S12.1 The laboratory must have written procedures for the investigation and reporting of suspected transfusion reactions or other transfusion-related adverse events.**
- S12.2 Suspected transfusion transmitted infections, transfusion associated acute lung injury or other sentinel transfusion events must be reported to the relevant provider of the blood component or product.**
- S12.3 The laboratory must have a written procedure for managing notifications and recalls of blood components or products, including notification to clinicians, where relevant.**
- S12.4 The laboratory must participate in an internal, local or state haemovigilance program for the collection and management of information of reactions and adverse events associated with transfusion.**

13. Storage, Transport and Inventory Management of Blood Components and Products

(Refer to Standard 7 in *Requirements for Medical Pathology Services*)

Storage and Transport

S13.1 The laboratory must have written policies to ensure correct temperature controlled storage and transport of blood components and products.

C13.1(i) Red cells, frozen blood components and blood products **must** be stored in an appropriate temperature controlled monitored environment that is managed in accordance with AS3864 *Medical Refrigeration Equipment*.⁴

C13.1(ii) Platelets **must** be stored at 20-24°C with continual agitation to maintain their viability and haemostatic potential. Refer to *Appendix C*.

C13.1(iii) Where the transport is longer than 30 minutes, blood components and products **must** be packed for transport in a validated and locally verified shipper with specific packing configurations to maintain the specified temperature range for the duration of transit and expected environmental conditions.

C13.1(iv) Blood components and products **must** be stored and transported in accordance with the manufacturers' specifications.

C13.1(v) Blood components and products **must** not be issued or re-issued where they have been stored or transported outside of the temperature specifications, unless at the discretion of the supervising Pathologist or delegate. This decision **must** be documented with a comprehensive rationale.

C13.1(vi) Laboratories should not issue blood components or products to a non-compliant refrigerator.

S13.2 Laboratories that accept blood components from satellite refrigerators must have access to monitoring and maintenance documentation for the refrigerator and be assured that the cold chain has been maintained.

C13.2(i) Accredited laboratories **must** share monitoring and maintenance records for refrigerators where legitimately requested by other users.

C13.2(ii) Laboratories should advise users of its service of the relevant requirements to minimise any wastage of blood components or products.

Transport by pneumatic tubes

S13.3 Prior to use for distribution of blood components and products pneumatic tube systems must be validated to ensure:

(a) **the integrity of the blood component or product is not compromised by transportation**

(b) **the transit times are appropriate for the clinical service**

(c) **the components or products arrive at the intended destination.**

- S13.4** The laboratory must have a protocol to deal with blockages in the pneumatic tube system.
- S13.5** The laboratory must have a protocol for decontamination following breakages of component bags during transport.
- S13.6** The laboratory must have a blood tracking system in place to ensure the confirmation of blood component and product receipt when transported via a pneumatic tube system. This includes transportation to and from the laboratory and clinical areas.

Inventory management

- S13.7** Laboratories must have written policies that ensure proper and efficient inventory management and traceability that minimises wastage of blood components and products.
- C13.7(i) The laboratory **must** participate in a national electronic blood management tracking inventory program.
- C13.7(ii) Inventory practices should be reviewed at least annually and wastage monitored against national benchmarks to ensure appropriate inventory levels are set and wastage monitored and minimised.⁷

14. Quality Assurance and Quality Control

(Refer to Standard 5 and Standard 8 in *Requirements for Medical Pathology Services*)

External Quality Assurance (EQA)

S14.1 All laboratories must participate in suitable External Quality Assurance programs relevant to the scope of their accreditation.#

- C14.1(i) Those laboratories performing red cell phenotyping **must** participate in red cell phenotyping QAP whether as part of a general QAP or specialised phenotyping QAP.
- C14.1(ii) Where laboratories are deploying manual and automated techniques they **must** undertake (internal or external) quality assurance for both techniques and review performance and comparability of techniques.
- C14.1(iii) All staff involved in immunohaematology testing **must** participate in external QAP on a rotational basis and ideally at least twice annually.
- C14.1(iv) Where a large number of staff may preclude regular individual participation in the QAP, the laboratory must develop an internal QA program to supplement the external QAP participation.

Quality Control

S14.2 The laboratory must have documented procedures for assessing the suitability of reagents before they are introduced into routine use.

- C14.2 The procedure for acceptance testing of reagents **must** include the criteria against which reagents are assessed for suitability and what steps are taken if reagents do not meet these criteria.

S14.3 The performance of reagents must be checked on a regular basis against the manufacturer's specifications and/or performance criteria set by the laboratory.

- C14.3(i) The laboratory **must** regularly assess performance of its test system(s) by the inclusion of control specimens and comparing results with those previously obtained.
- C14.3(ii) Ethnic diversity of the population under investigation **must** be considered when choosing control materials for the test procedure.
- C14.3(iii) Control material **must** be specific and sensitive in order to detect deterioration of blood group antigens present on screening cells.
- C14.3(iv) Records **must** be maintained of all quality control performed by the laboratory.
- C14.3(v) The control testing frequency should provide timely detection of failure in the test system.

NPAAC *Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 2018)*

Maintenance and calibration

- S14.4 All equipment must be subjected to regular maintenance and calibration programs.**
- S14.5 Equipment performance must be monitored at regular intervals in accordance with the manufacturer's recommendations.**
- S14.6 Performance of automated equipment must be regularly verified by testing a suitable combination of the following, chosen to challenge the expected range of sensitivity and specificity including:**
- (a) external QAP**
 - (b) specifically formulated QC material**
 - (c) previously analysed samples**
 - (d) commercial controls**
 - (e) reference material.**

Validation, Verification and Changes

- S14.7 All critical processes, equipment or systems must undergo appropriate validation before use.**
- S14.8 All changes to critical processes and equipment must be validated/ verified before the system is brought back into use.**
- S14.9 Transfusion LIS must undergo a documented validation process prior to installation and following modifications or upgrades.**

Appendix A The Clinical Significance of Red Cell Alloantibodies in Relation to Blood Selection for Transfusion (Normative) ⁸

Antibody Specificity	Clinically Significant	Selection of Units
Anti-A ₁	Rarely	IAT crossmatch compatible at 37°C
Anti-HI (A ₁ and A ₁ B individuals)	Rarely	IAT crossmatch compatible at 37°C
Anti-M (active at 37°C)	Rarely	antigen negative
Anti-N (active at 37°C)	Rarely	IAT crossmatch compatible at 37°C
Anti-S, -s, -U	Yes	Antigen negative
Anti-P ₁	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

Antibody Specificity	Clinically Significant	Selection of Units
Anti-Co ^b	Sometimes	IAT crossmatch compatible at 37°C
Anti-Wr ^a	Rarely	IAT crossmatch compatible at 37°C
High titre low-avidity antibodies (HTLA)	Unlikely	Local policy or seek advice from reference laboratory
Antibodies to low/high frequency antigens	Depends on specificity	Local policy or seek advice from reference laboratory
Other antibodies active by IAT at 37°C		Local policy or seek advice from reference laboratory

Antigen negative red cells should be cross matched by IAT at 37°C

For rare antisera IAT, crossmatch compatible blood is appropriate if antisera is not available.

Appendix B Red Cell Antibodies and the Risk of HDFN (Informative)⁸

Antibody Specificity	HDFN Likelihood	HDFN Severity
Rh	Common	Mild to severe
Kell	Common	Mild to severe
S	Rare	Mild to severe
s	Rare	Mild to severe
U	Rare	Mild to severe
Colton	Rare	Mild to severe
Diego	Rare	Mild to severe
ABO	Common	Mild to moderate
Kidd	Rare	Mild
Duffy	Rare	Mild
M	Rare	Mild
Lutheran	Rare	Mild
Dombrock	Rare	Mild
LW	Rare	Mild
Le ^a	None	
Le ^b	None	
P1	None	
N	None	
Yt ^a	None	
I	None	
Ch, Rg	None	
JMH	None	
Knops	None	

Antibody Specificity	HDFN Likelihood	HDFN Severity
Xg ^a	None	
High titre low-avidity antibodies (HTLA)	Unlikely	
Antibodies to low/high frequency antigens	Depends on specificity	
Other antibodies active by IAT at 37°C	Seek advice from reference laboratory	

Appendix C Storage of Platelets (Informative)

Storage

- Platelets should be continually agitated on a platelet agitator in a room with an ambient temperature of between +20 °C and +24 °C or within a platelet incubator (+20°C and +24°C).
- The recommended type of agitator is a flatbed agitator and it should be operated according to manufacturer's instructions.
- Platelet agitators that are integrated into an incubator should:
 - be fitted with a temperature monitoring device to ensure that the temperature is maintained within 20-24°C
 - be fitted with alarm systems:
 - for motion failure
 - temperature failure (alarm points 20.5°C and 23.5°C)
 - door open
 - power failure
 - include temperature display and recording devices for a permanent record of the temperatures reached.

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Members of the NPAAC Document Review and Liaison Committee (DRL)

Members of the National Pathology Accreditation Advisory Committee (NPAAC)

Further information

Other NPAAC documents are available from:

The Secretary
NPAAC Secretariat
Department of Health
GPO Box 9848 (MDP 851)
CANBERRA ACT 2601

Phone: +61 2 6289 4017
Fax: +61 2 6289 4028
Email: [NPAAC Secretariat](#)
Website: [Department of Health](#)

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