National Guidelines

QUALITY CONTROL IN TRANSFUSION MEDICINE

Islamabad, Pakistan

Fourth Edition 2026

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4th Edition – 2026

BBMT
Bring Brilliant Minds of Transfusion
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Abbreviations and Acronyms

AABB	American Association of Blood Banks
AFIP	Armed Forces Institute of Pathology
AFIT	Armed Forces Institute of Transfusion
AIDS	Acquired Immunodeficiency Syndrome
AJK	Azad Jammu and Kashmir
ATR	Adverse Transfusion Reaction
BBMT	Bring Brilliant Minds of Transfusion
BTA	Blood Transfusion Authority
BTS	Blood Transfusion Service
CoA	Certificate of Analysis
CC	Check Cells
CCC	Coombs Check Cells
CCP	Critical Control Point
CLIA	Chemiluminescence Immuno Assay
ELISA	Enzyme Linked Immunosorbent Assay
DRAP	Drug Regulatory Authority of Pakistan
EQAS	External Quality Assurance Scheme
EU	European Union
FEFO	First Expiry, First Out
FFP	Fresh Frozen Plasma
FIFO	First In, First Out
FNHTR	Febrile Non-Haemolytic Transfusion Reaction
GB	Gligit Baltistan
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
Hb	Haemoglobin
HBB	Hospital Blood Bank
HBV	Hepatitis B Virus
HCT	Haematocrit
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTC	Hospital Transfusion Committee
KP	Khyber Pakhtunkhwa
IBTA	Islamabad Blood Transfusion Authority
IBTS	Institute of Blood Transfusion Services
IMDC	Islamabad Medical & Dental College
IMTC	Islamabad Medical Technology College
ISO	International Organization for Standardization
JPMC	Jinnah Postgraduate Medical Centre
M/o NHSR&C	Ministry of National Health Services, Regulations and Coordination
NACP	National AIDS Control Programme
NAT	Nucleic Acid Testing
NIH	National Institute of Health
PCV	Packed Cell Volume
PPM	Planned Preventive Maintenance
PTP	Post-Transfusion Purpura
QA	Quality Assurance
QC	Quality Control
RBC	Regional Blood Centre
RBC	Red Blood Cell
Rh	Rhesus
SBTP	Safe Blood Transfusion Programme
SOP	Standard Operating Procedure
TACO	Transfusion-Associated Circulatory Overload
TA-GVHD	Transfusion-Associated – Graft Versus Host Disease
TNA	Training Need Assessment
TQM	Total Quality Management
TRALI	Transfusion-Related Acute Lung Injury
TTI	Transfusion Transmitted Infection
WBC	White Blood Cells
WHO	World Health Organisation

Preface to the Fourth Edition

Pakistan has a long and distinguished legacy in the field of blood transfusion medicine. The country's formal engagement with transfusion services dates back to 1942, when the National Blood Transfusion Programme was established (in Lahore) during British colonial rule, decades before the World Health Organization (WHO) advocated for the institutionalization of organized blood services. Over the years, Pakistan's blood transfusion system has evolved remarkably, guided by successive generations of dedicated professionals who recognized the importance of standardization, safety, and quality in transfusion practices.

The formulation of national standards and guidelines has remained central to this evolution. The first comprehensive National Standards and Guidelines were developed in 1999, largely through the vision and technical input of Dr. Birjees Mazhar Kazi, drawing upon templates from the British Blood Transfusion Society and the British Society of Haematology. In subsequent years, these documents underwent systematic refinement, leading to the independent development of the National Standards (2012, updated in 2015), National Quality Control Guidelines (2007, updated in 2017 and 2020), and Guidelines on the Clinical Use of Blood (2012, updated in 2015, 2018, and 2024). Additionally, the Standard Operating Procedures Manual was first launched in 2007, with successive updates in 2011-2012 and 2014, followed by its Urdu edition in 2016, marking an important step toward accessibility and implementation.

In December 2024, recognizing the growing scope of transfusion medicine and the need for continuous improvement, the Bring Brilliant Minds of Transfusion (BBMT-Pakistan) convened a national consultative meeting during its 5th annual conference in Langkawi, Malaysia. This gathering of experts unanimously endorsed the revision of the National Quality Control Guidelines for Transfusion Medicine. It is a matter of pride to see how this platform has matured into the national voice for transfusion medicine, bringing together professionals, regulators, and academicians under one collective vision for blood safety in Pakistan.

After a year-long, collaborative, and rigorous process, this new edition has come to fruition. I am deeply grateful to the provincial and regional editors whose leadership ensured a broad-based and inclusive approach: Dr. Dure Naz Jamal (Sindh), Prof. Shabnam Bashir (Punjab), Dr. Noor e Saba (Khyber Pakhtunkhwa), Dr. M. Afzal Zarqoon (Balochistan), Dr. Naveed Ahmed (AJK), and Dr. Farwa Sijjeel (Islamabad).

Having been part of the previous three editions, I have personally witnessed the growth of awareness, expertise, and institutional capacity in transfusion medicine across the country. The first edition (2007-08), compiled under the National AIDS Control Programme, was led by Dr. Umar Farooq and the late Dr. Syed Abdul Mujeeb, under the guidance of Prof. Masood Anwar, then Executive Director of the National Institute of Health. The second (2017) and third (2020) editions, developed under the Safe Blood Transfusion Programme, were led by Prof. Hasan Abbas Zaheer with valuable technical contributions from Dr. Saeed Ahmed, Dr. Akhlaaq Wazeer, and myself, alongside strong international support.

This fourth edition benefits from the input of both national and international experts, including collaborators from Germany, the Netherlands, Spain, Iran, Sri Lanka, Saudi Arabia, Lithuania, and Luxembourg. It represents a unified, evidence-based, and forward-looking framework that aims to elevate the quality of transfusion services in Pakistan to global benchmarks.

It is my sincere hope that this edition will serve as a practical and authoritative reference for all stakeholders, from policymakers and regulators to laboratory professionals and clinicians. The provincial blood transfusion authorities now carry the responsibility of ensuring its effective implementation within their respective jurisdictions. Together, through adherence to these standards, we can ensure that every unit of blood collected, tested, and transfused in Pakistan meets the highest standards of safety, efficacy, and quality.

I extend my heartfelt gratitude to all contributors, reviewers, and institutional partners, both national and international, whose dedication, technical insight, and collective vision made this edition possible. Their commitment stands as a testament to Pakistan's continuing progress toward a safer, quality-assured blood transfusion system.

(Dr. Usman Waheed)

January 2026

Preface to the Third Edition

The Safe Blood transfusion Programme, Pakistan is pleased to present the third edition of the National Guidelines for Quality Control in Transfusion Medicine. The first edition of the document was formulated by the National AIDS Control Programme in 2007. The second edition was developed in 2017 by the Safe Blood Transfusion Programme with significant revisions and additions of new chapters. The second edition was disseminated to all national stakeholders in capacity building workshops across the country by the SBTP team. The implementation of the document was made mandatory, through the Islamabad Blood Transfusion Authority, and a prerequisite for licensing in the Islamabad Capital Territory.

With the practical implementation of these guidelines in the blood centres the need for a revision was felt by many eminent national experts who provided valuable input that was incorporated in the second edition. The second edition of the guideline document for Quality Control in Transfusion Medicine was therefore revised and a third edition is being published in an effort to ensure the maximum safety of all procedures for donors, recipients and staff in transfusion services. Blood transfusion is an excellent therapeutic intervention for patients provided stringent yet simple quality control measures are followed thoroughly in order to ensure transfusion efficacy and safety, and so to protect the donor and the patient against the possible risks. A quality system is a documented system. Written procedures and records, checked at planned intervals with proper auditing, provide evidence that quality requirements have been met and the blood is safe. This is why documentation is so important, it is a health care issue, it is not an administrative question.

It is pertinent to mention here the invalable support from eminent international experts; Prof. Cees Th. Smit Sibinga (Netherlands), Prof. José Manuel Cárdenas (Spain), Dr. Sedigheh Amini (Iran), Dr. Jean-Claude Faber (Luxembourg) and Dr. Ralf Knels (Germany) who have been guiding the Programme since its early stages and in some cases even the conceptual phase. The Programme is also very fortunate to avail the professional guidance and expertise from provincial blood programmes, public health specialists and well-reputed blood centres from across the country who have contributed and reviewed this document.

Dr. Saeed Ahmed, Dr. Usman Waheed and Akhlaaq Wazeer need a special mention for developing this document and whose diligence and hard work have made the finalization of this document possible. The Programme earnestly anticipates that this document will serve the purpose for which it was developed – to introduce standardization and strengthen the culture of quality in the Blood Transfusion Services in Pakistan.

(Prof. Hasan Abbas Zaheer)

February 2020

Preface to the Second Edition

The Safe Blood Transfusion Programme is pleased to present the second edition of the National Guidelines for Quality Control in Transfusion Medicine initially developed by the National AIDS Control Programme (NACP) in 2007. The revision of the guidelines was necessitated due to the new technological developments in the field and the sector reforms being initiated in the country. In 2008, the government established the Safe Blood Transfusion Programme as an independent vertical health programme, outside the confines of the NACP, with the mandate to implement the blood safety systems reforms including the utilization of the German government support for the creation of an independent centrally coordinated blood transfusion system in Pakistan. The ambitious reform process is now well underway and the first phase of the German government funded project has been successfully completed in which a network of Regional Blood Centres (RBCs) linked to existing Hospital Blood Banks (HBBs) have been established all over the country in addition to a lot of technical preparatory work. The Phase II of the project has now started in which the scope and coverage of the project will be expanded in addition to strengthening the gains of the first phase particularly the smooth operationalization of the newly developed infrastructure.

The RBCs are a new entity in the country's blood transfusion system. To obtain blood, they must link to the blood donor community and to dispense blood components, it has to create links to the HBBs. The RBCs will co-operate with the blood transfusion authorities and be linked to the provincial blood transfusion service organization. As such, a centralized blood banking system is a very new concept in Pakistan with only few people from the private and NGO sector having prior experience with this model.

Under the GIZ funded Technical Cooperation component, in the first phase, a large number of documents were developed for utilization in the new system as well as the existing system. The most relevant for the operation of RBCs are the Functional Brief of RBCs describing features and functions, business plan and manual of operation for RBCs; SOPs for the blood transfusion services; the quality manual; and the national blood policy. This guideline document will supplement and compliment the TC component technical documents and help improve the standard of services in the existing system as well as in the new project infrastructure.

Keeping in view the significance of strict quality control at every step in blood transfusion service, this guideline document for Quality Control in Transfusion Medicine was revised and is being published in an effort to ensure the maximum safety of all procedures for donors, recipients and staff in transfusion services. It is hoped that the document will encourage blood banks and transfusion services to develop strong quality assurance programmes, organize scheme of management and employ training and competency evaluation programmes. Standardized forms developed by the Programme are also provided which must be routinely used in the blood centres. The guideline draws from the documents of the World Health Organisation, European Union, International Haemovigilance Network and Technical Manual of American Association of Blood Banks.

It is pertinent to mention here the invaluable support from eminent international experts namely Prof. Cees Th. Smit Sibinga (Netherlands), Prof. José Manuel Cárdenas (Spain), Dr. Jean-Claude Faber (Luxembourg) and Dr. Ralf Knels (Germany) who have been guiding the Programme since its conceptual phase. The revision of this document was enabled with the outputs of the Missions of these eminent international experts. Prof. Sibinga conducted the first WHO Quality Management Training course through GIZ support in 2008, which was aimed to assist the blood transfusion services to implement effective quality systems. The Programme is also very fortunate to avail the professional guidance and expertise of eminent national experts within the country who have contributed effectively in reviewing this document.

Dr. Saeed Ahmed, Usman Waheed and Akhlaaq Wazeer need a special mention for their valuable efforts with the drafting of this document. The Programme is grateful for their diligence and hard work in the finalization of this document.

(Prof. Hasan Abbas Zaheer)

January 2017

Preface to the First Edition

Blood Transfusion is an essential part of modern health care. Used correctly, it can save life and improve health. There has been a growing awareness about quality in blood transfusion services with the objective of releasing only those blood products and blood which fulfill the desired standards in terms of efficacy and safety. Keeping in view the vital importance of strict quality control at each stage of each procedure, this first National Guidelines for Quality Control in Blood Banking is being published in an effort to ensure the maximum safety of all procedures for donors, recipients and staff of the transfusion services.

It is hoped that the guidelines will encourage blood banks and transfusion services to develop strong quality assurance programmes, organize scheme of management and employ training and competency evaluation programmes.

This first edition will get revised periodically in the future and consolidate by incorporating suggestions, guidance and critique from the working specialists in the field of transfusion medicine.

(Maj. Gen. (R) Prof. Masood Anwar, H.I.)

June 2007

1. Introduction

Blood transfusion services are an integral part of the healthcare system. It is an essential function of the health services to provide safe blood in an efficient, coordinated, quality assured and cost-effective manner. Safety of blood assumes greater significance and relevance in developing countries where hepatitis B, C and HIV are diseases of greater public health importance.

The World Health Organisation defined Quality, in 1993, as: "The consistent and reliable performance of services or products in conformity with specified standards". This definition means that the "products" are blood and blood components and plasma derived products, which are both safe and effective for clinical transfusion, or other specified uses and that a quality based approach in all procedures ensures maximum safety for recipients, donors and staff, and results in maximum clinical effectiveness. Quality is not for sale, it has to be created and carefully maintained. That can be achieved individually, but also group or team wise. It is often seen as something expensive to create and maintain. However, the opposite is true, as quality improves life, prevents unnecessary costs and allows efficacy, consistency and safety.

Transfusion medicine has evolved rapidly from an intervention mainly perceived as a laboratory prepared product to save life, to the recognition that blood and blood components for clinical use must meet the highest standards of quality, safety and efficacy. Only over the last quarter, quality and its structured management started to grow, ultimately changing the emphasis from the narrow product orientation to the broad chain and customer orientation – the integration of blood transfusion in the national health care system.

To ensure the continued safety of the national blood supply, it is essential that blood centres implement effective control over manufacturing processes and systems. This can be accomplished by each blood centre developing a well-planned, documented, and managed Quality Assurance (QA) programme designed to recognize and prevent the causes of recurrent deficiencies in performance. QA is the sum of activities planned and performed to provide confidence that all systems and their elements that influence the quality of the product are functioning as expected and relied upon. The goals of QA are to significantly decrease errors, ensure the credibility of test results, implement effective manufacturing process and system controls, and ensure continued product safety and quality. Quality Assurance also includes measures to prevent, detect, investigate, assess, and correct errors. The emphasis is on preventing errors rather than detecting them retrospectively.

The purpose of these guidelines is to assist manufacturers of blood and blood components, i.e., blood centres and transfusion services, in developing a QA programme in their effort to be consistent with recognized principles of quality assurance and current Good Manufacturing Practice (cGMP). The effort is aimed at inculcating quality concepts and quality thinking in transfusion services and shall lead to training of their staff along these lines. There are several good reasons for a blood centre to develop and implement quality control at every step of transfusion process, e.g. it is an important aspect of standardizing the blood centres performance of critical tasks.

There are two key concepts in the quality control; one is testing and the other is monitoring. QC testing is performed to ensure the proper functioning of material, equipment and methods during operations. Testing provides feedback to operational staff about the state of a process that is in progress, and whether to continue or to stop the release of the results until a problem is resolved. Some examples of QC testing include reagent QC, equipment QC (temperature readings on refrigerator), components QC (cell counts performed on finished blood components), clerical checks, visual inspections, etc. QC monitoring on the other hand is the responsibility of both the staff and the management. Staff should document the results of control samples and events that do not meet specified criteria as part of their routine job assignments. The management should regularly review the performance of quality indicators and compare performance to standards.

Quality control should be carried out according to a defined sampling plan, and the results subjected to periodic review. All QC procedures should be validated before use and acceptance criteria based on a defined set of specifications for each blood unit and blood component. QC test results that do not satisfy the specified acceptance criteria should be clearly identified to ensure that blood components of that donation remain in quarantine and the relevant samples held for further testing.

The frequency of analysis or how often quality control should be done depends on the operations within the blood centres. The quality principles have migrated from inspection to QC which focuses on testing of product to ensure that product complies with national standards. This sense of quality in transfusion medicine has strengthened the blood supply and is now viewed as its foundation. As a result, the blood supply continues to improve towards a safety system.

2. Quality Management in Transfusion Medicine

Quality management in transfusion medicine is concerned with every aspect of transfusion practice and applies to all its activities. The word quality began its journey as the understanding of a laboratory quality control measurement. However, as the clinical practice of blood transfusion evolved through the discovery that transfusion can transmit infectious agents and can also cause harm to the recipient, clinicians, transfusionists and researchers recognized the importance to fully understand, define and implement quality in all facets of transfusion medicine. The quality management involves identification and selection of prospective blood donors, adequate collection of blood, preparation of blood components, laboratory testing and ensuring the appropriate clinical use of blood and blood components. The objective is to ensure availability of a sufficient supply of high quality blood and blood components for transfusion with maximum efficacy and minimum risk to both donors and recipients.

Quality management can be achieved by adopting good manufacturing practice, good laboratory practice and good clinical practice through establishing a comprehensive and co-ordinated approach of total quality management (TQM). All those who are involved in blood transfusion-related activity must be aware of the importance of quality management for its successful implementation. Good record-keeping, documentation, use of standard operating procedures (SOPs) and laboratory worksheets, and implementation of safety guidelines will further improve the quality performance of the services. Under a quality management system, the blood centre is able to demonstrate that the components that are made and the services that are offered are of a good, consistent and reliable quality and safety. Recent developments in quality management system paradigms have placed an increased emphasis on standardized documentation that allows continuous traceability and standardized procedures. There has been a shift toward focusing on customer satisfaction and relationships, and this will likely continue to develop and mature.

2.1 Quality Indicators in Blood Centre

These indicators are meant to monitor quality at each and every step of blood transfusion chain. These should be monitored on monthly basis and corrective and preventive actions should be taken.

- **Donor Satisfaction**

All donors should be satisfied with the blood centre staff and procedures (no double prick, unnecessary deferrals, etc.)

- **Donor Adverse Reaction**

Presence of untrained staff in donation area may lead to high ratio of donor adverse reactions. Trained staff may prevent mild reactions by reassurance and moderate to severe reactions by early intervention. This may have impact on other blood donors.

- **Rejected Donors**

Untrained / unqualified staff deputed in donor selection may defer donors for unnecessary reasons leading to less number of donations and psychological disturbances among donors. The supervisor should check records on daily basis and corrective and preventive action should be taken.

- **Rejected Units**

Untrained phlebotomist may give multiple pricks which will lead to "unit rejection" due to haemolysis, clots, low volume, etc. The supervisor should check records on daily basis and corrective and preventive action should be taken.

- **Labeling Errors on Patient Request and Samples**

Wrong labeling of donor samples and donor bag may lead to discard of unit which is wastage. Further wrong labeling on the patient sample/form may lead to adverse reaction and mortality.

- **Blood Administration at Bed Side**

Before transfusing blood to the patients, unit number and patient should be verified along with blood group, cross match, expiry date, etc. to prevent wrong administration of the unit. A transfusion check list, like the one in the operation theater should be available and verified for blood administration.

- **Discarded Units**

All un-screened blood should have valid reasons to discard, e.g. quantity not sufficient in blood bag, reactivity for hepatitis, etc. milky white plasma, haemolyzed unit, direct Coombs positive on donor bag, antibody screening positive of donated bag, etc. Further all screened units should have valid reasons for discard. Rule of FIFO (First In & First Out) should be strictly followed except in by-pass and neonate exchange cases. This FIFO rule prevents unnecessary wastage of units.

- **Availability of Blood and Blood Components**

Blood centre should be able to fulfill the hospital demand. Cell separator for collection of Mega Unit platelet concentrates may provide large number of platelets in short time. Hospital blood bank should have

close liaison with central blood centre.

- **Crossmatch to Transfusion Ratio (C:T Ratio)**

Clinicians may prescribe/generate unnecessary crossmatch requests. This practice decreases the blood centre stock inventory, less laboratory safety, more work and more staff is required, financial loss, wastage of unit, etc. The standard ratio is 2:1. This means for each 2 blood requests, clinicians must transfuse one unit or transfuse 50% of their request.

2.2 Quality System

Every blood centre should develop an effective quality system to ensure the implementation of quality strategies. The quality system should cover all aspects of its activities and ensures traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood components to recipients. It should also reflect the structure, needs and capabilities of the blood centre, as well as the needs of the hospitals and patients that it serves. This should provide a framework within which blood transfusion service activities are established, performed in a quality focused way and continuously monitored to improve outcomes.

2.3 Key Elements of Quality System

The key elements of a quality system include organizational management, standards, data management and documentation, training, assessment, and resources.

2.3.1 Organizational Management

An effective quality system requires the commitment and support from management at all levels, including:

- Clearly defined organizational structure that describes accountability, authority and responsibility.
- Appointment of a quality manager, with the necessary skills and expertise, in each blood centre and hospital blood bank.
- Formation of a quality section or identified work area in each blood centre and hospital blood bank from where quality activities can be coordinated.
- Development of a culture of quality through a management focusing on building quality into all activities.
- Motivation of staff to ensure their commitment and support for the quality system.
- Identification of specific processes and procedures and their critical control points (CCP).

2.3.2 Standards for Quality Systems

Relevant and appropriate standards are required to provide the framework for development of quality system:

- The existence of relevant legislation or regulations must be acknowledged and incorporated into the framework of quality systems.
- Standards may be national or international, e.g. national standards and guidelines for blood banks and transfusion services and AABB standards, etc.

2.3.3 Data Management and Documentation

An effective and accurate data management and documentation system that ensures traceability of all transfusion (vein-to-vein) activities is the foundation of a good quality management. Important activities include:

- Development of a quality manual: a document describing the quality system, including the organization's quality policy, standards and procedures.
- Production and use of appropriate, comprehensive documents for all activities, including standard operating procedures, forms, labels and any other documents required.
- Generation and maintenance of complete and accurate records.
- Development of a system to manage the issuance, use and retrieval of documents.

2.3.4 Training

Comprehensive, appropriate and effective training is required for all staff and other health care professionals involved in blood transfusion service. Important activities include:

- Training policy and plan.
- Training need assessment.
- Training for all BTS staff in general principles of quality, the quality system, documentation and the use of quality monitoring tools.
- Training programmes for other health care professionals involved in blood transfusion service.
- Clear understanding of the role of individuals in the quality system and the consequences of quality failures.
- Ongoing monitoring and evaluation of training and its impact.

2.3.5 Assessment

Ensuring quality is a continual process. Ongoing assessment of the effectiveness of the quality system is essential through:

- Validation of all processes, procedures, equipment and reagents.
- On-going collection and analysis of data generated from key activities and their use in quality improvement.
- Establishment of haemovigilance through a system of monitoring, reporting and investigation of adverse

incidents related to all blood transfusion activities.

- Regular review of all activities to assess the overall effectiveness of the quality system and ensure continuous improvement by taking corrective and preventive actions.
- Programme of regular internal and external audits of the quality system.
- Reporting and analysis of errors with effective corrective and preventive action.
- Active participation in appropriate external quality assessment schemes to improve laboratory performance.

2.3.6 Resources

Availability, safety, quality and accessibility of blood and blood components for transfusion are a global concern. In resource limited countries, blood transfusion services often struggle against competing demands for increasingly scarce resources. As a result blood transfusion often receives low priority. The limited resources necessitate optimizing the cost of delivering quality service. It is therefore essential to be able to have accurate information on the cost of provision of blood transfusion service. This analysis of data will justify the funding and help in evaluating and monitoring cost effectiveness. As the funding of the BTS system is ultimately the responsibility of the government in the public sector, cost recovery or cost sharing strategies should be implemented to lighten the burden on the government. For carrying out cost analysis and budget requirements, data must be available for cost indicators. The broad categories for which costs could be itemized include costs of organizing blood donation campaigns, including material development and printing; collection, storage and processing of blood units; cost of testing and screening of blood; and distribution and transportation charges. Other costs would include managing the programme at national and provincial levels; staff salaries; costs of training health care workers and blood transfusion personnel; office supplies and equipment; maintenance of a quality assurance programme; and support for research and development in the area of blood transfusion services.

3. Quality Control of Reagents

3.1 Introduction

Reagents quality control must be performed and documented every day and whenever a new vial is opened. After opening the new vial, its QC must be compared against the old vial which is about to finish/expire (run QC samples on both new and old lot) and ensure the results of the new vial are equal/same or better than the old ones before placing them in use (lot to lot QC). QC is performed to check that certain critical control points in testing are within specific parameters and reagents are used according to facility's SOPs and according to manufacturer's instructions. All the staff should be trained in performing quality control.

Every day, a technologist must confirm that the reagents react as expected when used. If a reagent does not give the expected results, the known controls must be repeated with the same reagent. If the results are still incorrect, the reagent vial should be discarded and a new vial must be opened and tested. The QC of any reagent is done to get the expected results, its sensitivity, specificity, continuous reproducibility of same results till the reagent ends, etc. Titer and avidity are checked by the manufacturer before the lot number is released but individual titer should also be checked by the blood centre before opening the vial and when the reagent is about to finish/expire. The titer should remain the same till expiry. Results of daily QC must be recorded on the quality control form. All the information written on the QC forms should be filled in clearly, correctly and completely.

The QC should be checked by all staff and in each shift. Blood centre supervisor and manager, should review and sign all the QC results on weekly basis. Corrective and preventive action should be taken immediately whenever required. All such actions must be documented and reviewed by the blood centre supervisors and managers.

3.2 ABO and RhD Blood Grouping

ABO and RhD blood grouping must be determined on every patient and blood donor. Forward and reverse ABO grouping must be performed on all routine blood samples except in newborn upto the age of six months (perform only forward grouping) by tube/gel (ID-microtyping system)/solid phase/microplate technique, etc.

In emergency situations, the blood centre should be informed as quickly as possible of the quantity of blood needed and the time when it is needed. Each blood centre should establish SOPs for emergency release of uncrossmatched blood and following should be adhered:

- In class 1 emergency, e.g. gun shot, there is no time to send blood sample or written request to the blood centre, blood order can be given by phone call, etc. and blood centre has to issue O-Negative packed red cells to patients under 18 years (male or female) or women under 50 years of age (child bearing age) OR blood bank will issue O-Positive packed red cells to males above 18 years or women above 50 years of age) irrespective of the patient's ABO blood group.
- If there is time (at least 10 minutes) to determine ABO and Rh type, then uncrossmatched group specific blood will be released.
- If there is more time available, rapid spin method (saline phase) should be followed to demonstrate ABO compatibility between donor cells and recipient serum.

These three types of emergency issuance of blood should be followed keeping in mind the nature of emergency, time available and availability of the written request of medical officer incharge.

3.2.1 Quality Control of ABO Blood Grouping

- Only monoclonal and high titer anti A and anti B should be approved for use in blood centre for the blood donors and recipients in normal or routine cases. Human anti A and anti B antisera are used to resolve ABO blood group discrepancies because of their low titer.
- The titer of monoclonal anti A and anti B antisera should be 1:256 or above and should give 4+ results with A1 and B cells.
- Anti AB antisera is used to detect weak antigens, subgroups and for confirmation of O group.
- Manufacturer's instructions should be followed for all reagents.
- All equipment, pipettes, etc. should be calibrated in proper working condition and have regular PPM (planned preventive maintenance) before running the patient and donor samples on them.
- Before a new blood grouping reagent vial is used, serial dilution testing with control cells should be performed (anti A and anti B titer should be 1:256).
- The control cells should be prepared by pooling three ABO group red blood cell samples of the same blood group. Make sure the ABO cells used for reverse grouping or control cells are not weak or sub

groups of A or B like A2, A3, Ax, or B3, Bx, etc. They will give weak reaction with high titered antisera.

- The minimum controls required for ABO blood grouping tests are as follows:

Reagent	Control Cell
Anti A (Titer 1:256)	A1 and O Cells
Anti B (Titer 1:256)	B and O Cells
Anti AB (1:28 each with A and B cells)	A1, B and O Cells

- All reagents when not in use should be stored at 2-6 °C.

3.2.2 Quality Control of RhD Grouping

- Only monoclonal high titered approved reagents should be used.
- The recommended titer for anti D should be 1:128. Anti D containing low protein media (6% albumin) are usually preferred for tube technique because it does not give false positive results while high protein media, e.g. 30% albumin can give false positive results, and (Rh controls are recommended if anti D with high protein media is used).
- For tube technique, anti D IgM antisera is preferred because it gives reaction at saline phase, this anti D should not be used for D variant testing. Alternatively a combination of IgM and IgG should be used for tube technique having the advantage to perform D variant test with this antiserum. Anti D antisera with IgG only (anti D human IgG type) should not be used for RhD testing of patient or donor because IgG is a sensitizing antibody and will not give agglutination. This human anti D IgG type is used for making coombs control cells or check cells. All blood centres should have human anti IgG type of anti D for making check cells or coombs control cells.
- Manufacturer's instructions should be followed for allreagents.
- All equipment, pipettes, etc. should be calibrated in proper working condition and haveregular PPM (planned preventive maintenance)before running the patient and donorsamples on them. Before a new blood grouping reagent vial is used, serial dilutiontesting with control cells should be performed.
- Routine anti D antisera should give positive reaction with RhD positive cells (e.g. O positive cells) and negative reaction with RhD negative red cells (e.g. O negative cells).
- Appropriate reactivity with control red blood cell samples expressing weak D should also be confirmed regularly during use, although not necessarily with each series of tests.
- When the blood grouping is not performed in batches, the appropriate reactivity of ABO and RhD reagents should be checked at least once in the morning of every working day before testing the donor or patient sample.
- RhD control should be run in parallel because of possibility of auto antibodies (auto control positive).
- All reagents when not in use should be stored at 2-6 °C.

3.2.3 Check Cells (IgG coated cells)

IgG coated check cells are used to validate all tests using antihuman globulin reagent (AHG). Check cells ensure that the washing was complete (all unbound proteins removed), AHG reagent was added and active.

3.2.3.1 Requirements

- Test tubes (size 13 x 100)
- Anti D, human, incomplete IgG type
- 0.9% Normal saline
- Calibrated centrifuge
- Water bath
- Alsever's solution (suspending media for storage of check cells 21-28 days)
- Sterilized dropper
- Paper tape and pen (for labeling)
- Pipettes
- 5 segments from known non haemolysed O positive donor units

3.2.3.2 Procedure

- Label one clean test tube with CC (Check Cells) or CCC (Coombs Control Cells).
- Take 100 microliters O Positive red cells from each segment into this tube. Wash one time with normal saline. Discard supernatant.
- Add 4-5 drops of IgG (human) anti D reagent to this tube.
- Mix gently and incubate at 37 °C for 30 minutes. During incubation, mix gently after every 5 minutes.
- Wash tube thoroughly six times with normal saline, removing as much of the saline as possible after the last wash.
- Prepare a 3-5% dilution in another tube with normal saline (shelf life 12-24 hours) or in Alsever's solution (shelf life 21-28 days).
- Ensure that, these check cells should give 1+ or 2+ agglutination with Polyspecific or Monospecific coombs IgG sera before storage.
- Label as follows:
  - 3-5% check cells in Alsever's or normal saline
  - Date prepared:
  - Expiry date:
  - Made by:

- Document preparation of the check cells at the bottom of the daily reagent QC form. Run a positive and negative control as follows and document on the daily reagent QC form:
- Positive Control: Add two drops of AHG reagent and one drop of check cells. Spin and read. Result should be 1 + or 2 + . 2 + is preferred.
- Negative Control: Add two drops of normal saline and one drop of check cells. Spin and read. Results should be negative (0).

3.3 Quality Control of Anti Human Globulin Testing

- Since Coombs antisera (Polyspecific or Monospecific) is highly sensitive and can easily be neutralized by contamination within seconds (contaminated tip, no or improper washing, etc.), so it is recommended to test every Coombs test tube (cross match, antibody screening and identification, D variant, minor group phenotyping, etc.) with Coombs Control Cells for its efficacy.
- For QC of Coombs Control Cells, Group O red blood cells sensitized with IgG and C3d (if available) should be used as positive controls for Coombs antisera. Usually only IgG coated red cell suspension is used as positive control and un-sensitized O positive or O negative cells are used as negative control. In case of a negative result, the test must be repeated.
- Blood and blood components from DAT positive donation should not be used for transfusion.
- Donors with positive DAT for more than one year should be removed from the donor list and referred to physician. One in 1,000 donors may have Positive DAT without any cause.
- There are two type of Coombs antisera, (1) Polyspecific Coombs reagent containing anti IgG and anti C3d, (2) Monospecific Coombs reagent containing either anti IgG or anti C3d. First line of testing for Coombs phase should be with Polyspecific and if incompatibility is observed then Monospecific reagents should be used to know the cause of reacting antibodies. Monospecific anti IgG Coombs detects clinically significant IgG antibodies in patients sera which is responsible for extravascular haemolysis. Monospecific anti C3d Coombs detects antibodies against C3d complement component in the patient which usually react with cold blood group antibodies like M, N, Lutheran, etc. and can also react with warm clinically significant antibody of Kidd blood group system in which the reactionis solely due to complement mediating antibodies. All blood centres should have both Polyspecific and Monospecific Coombs antisera.
- Follow the manufacturer's instructions and SOPs.

3.4 Quality Control of Compatibility Testing

- All equipment, pipettes, etc. should be calibrated, in proper working condition and have regular PPM (planned preventive maintenance) before running the patient, donor and QC samples on them.
- Use Coombs control cells with each Coombs compatible test tube (cross match, antibody screening and identification, D variant, minor group phenotyping, etc.) for validation of Coombs reagent.

3.5 Quality Control of Copper Sulphate

- Copper Sulphate solution is used to test donor haemoglobin. The specific gravity of the solution is adjusted to 1.053 which is the specific gravity of whole blood having 12.5 g/dl haemoglobin.
- The accuracy of this test is upto 90% and may give false high haemoglobin reading in diseases like multiple myeloma, Waldenstorm macroglobulinaemia, etc. where there are high abnormal protein in the serum.
- The solution is prepared by mixing 17 grams of anhydrous (dry) Copper Sulphate to 100 ml of distilled water. This will be stock solution (blue colour)
- The working solution is prepared by taking 51 ml of stock solution and mixing in 49 ml distilled water. Adjust specific gravity to 1.053 by adding stock solution or distilled water.
- Working solution should be prepared on daily basis.
- 50 ml fresh working solution should be prepared for 25 tests after which new solution should be prepared. A new working solution may also be prepared if the
  solution becomes turbid even after one or more tests.
- Check the physical quality of the Copper Sulphate solution against a light source for the presence of any precipitate or cloudiness. If it is cloudy or have precipitates, then discard the solution and prepare new solution.
- Volume of Copper Sulphate working solution should be sufficient, i.e. at least 50-60 ml to allow the drop to fall approximately three inches down. The drop of blood will sink to the bottom within 10 seconds if the donor haemoglobin value is more than 12.5 g/dl. If the donor haemoglobin is less than 12.5 g/dl then the drop of blood will not sink to the bottom.
- Movement of the drop after 10 seconds should be ignored as all drops will eventually sink to the bottom of the container.

- This is not a quantitative test, but a qualitative one, and will show only if the haemoglobin is above or below the minimum limit.
- Only those, whose drops of blood sink within 10 seconds, should donate.
- Copper Sulphate solutions should be stored away from light, in clean containers at room temperature and tightly capped to prevent evaporation.
- The solution should be kept at room temperature or brought to room temperature before use.
- Used solution should be considered a bio-hazard and discarded as per policy.
- Copper Sulphate solutions should not be frozen or exposed to very high temperatures.
- The specific gravity should be checked every day befor use. Check specific gravity of the working solution by refractometer. It should be 1.053 which corresponds to haemoglobin of 12.5 g/dl.
- Specific gravity should be checked daily with at least three samples per day with haemoglobin above, below and at 12.5 g/dl of haemoglobin.
- Copper Sulphate powder is highly carcinogenic and should not be touched without gloves. If touch without gloves can rapidly be absorbed into the skin and can be very harmful.

Form 3.1: Quality Control Transfusion Service Reagent Rack

Reagent specificity	Lot #	Expiry Date	Reagent Appearance Satisfactory √ Not Satisfactory X							Date Placed in Use
			1	2	3	4	5	6	7	
Anti A										
Anti B										
Anti AB										
Lectin A1										
Anti -D										
Rh Control (6% B. Albumin)										
3%-5% A1, B & O Cells										
Screening Cells										
Check Cells IgG coated										
Polyspecific Coombs reagent (anti IgG & anti C3d)										
22% Bovine Albumin										
Anti -c										

Tube #	Reagent Specificity		Expected Date	Day 1 Date:		Day 2 Date:		Day 3 Date:		Day 4 Date:		Day 5 Date:		Day 6 Date:		Day 7 Date:	
				Reaction	OK?	Reaction	OK?	Reaction	OK?	Reaction	OK?	Reaction	OK?	Reaction	OK?	Reaction	OK?
1	Anti-A Plus A1 Cells	IS	≥3+														
2	Anti-A Plus B Cells	IS	0														
4	Anti-B plus B Cells	IS	≥3+														
5	Anti-B plus A1 Cells	IS	0														
6	AHG plus IgG Coated Check Cells	IS	1+ to 2+														
7	AHG plus O Cells	IS	0														
8	Check Cells plus Normal Saline	IS	0														
9	Anti-D Plus O POS Cells	IS	≥3+														
10	Anti D Plus O Neg Cells	IS	0														
11	Anti-D Plus SC1	IS	≥2+														
12	Anti-D Plus SC11	IS	≥2+														
13	Anti-D plus SC III	IS	0														
		AHG	0														
		CC	≥1+														
14	22% Albumin Plus SC1	IS	0														
14	RH CTRL Plus SC11	IS	0														
15	Anti c Plus SC 111	IS	≥2+														
Q.C. testing performed by and time:																	

Routine Testing	A1 Cells (Prepared in Alsever's Sol.)		B Cells (Prepared in Alsever's Sol.)		O Pos Cells (Prepared in Alsever's Sol.)		Check Cells (Prepared in Alsever's Sol.)	
	1st	2nd week	1st week	2nd week	1st week	2nd week	1st week	2nd week
Preparation Date								
Prepared By								
Expiry Date								

Form 3.2: Copper Sulphate Quality Control Form

QC Date	Technician Name	Working Solution Preparation Date	Working Solution Expiry Date	Specific Gravity (1.053)	Control/ Known Hb Level (12.5g/dl)	Drop of Blood Sink (Pass) Float (Fail)	Tech. Signature
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
31							

Corrective and Preventive action: _____

_____

Reviewed by _____ Date_____

4. Quality Control of Blood Components

4.1 Introduction

Ensuring safe and efficacious supply of blood and blood components requires applying the principle of quality assurance to all aspects of components collection, preparation, testing, storage and transport. All procedures and equipment in use must be validated prior to their implementation and periodically monitored thereafter. The contents of final blood components should be periodically assessed to make sure they meet the QC standards of blood components. 1% of the total components prepared should be checked for their quality. If the work load is < 500 donors per month then a minimum of 4 per month should be checked for components quality.

FFPs and platelets should be prepared only from those whole blood bags which are filled within 15 minutes of aseptic phlebotomy. The whole bag (including red cells) should be discarded if the collection exceeds 15 minutes. Components should be prepared and stored within 8 hours from the blood collection time. This usually happen in blood camps, so ensure that the components are prepared within time.

The haematocrit (HCT) of packed cells must be 55-79% to ensure sufficient nourishment and anticoagulant is available to keep the red cells viable for 35 days.

Sometimes platelet bag contains red cells; if 2 ml or more red cells are present in the platelet bag than unit should be cross matched before issuance. The formula to calculate red cells volume in the bag: Volume of red cells = Platelet bag HCT multiplied by plasma in bag. For example, plasma volume is 55 ml and HCT is 1%. To remove % we divide 1 by 100 which is equal to 0.01. So 55 x 0.01 = 0.55 ml red cells are present in platelet bag.

The count and pH of platelets must be > 5.5×10^{10} per unit and $\geq$ 6.2 respectively, to ensure proper platelet function in the recipient. The pH of > 6.2 indicates proper storage conditions as platelets secrete lactic acid under stress, therefore lowering the pH in the surrounding plasma. The FFPs are tested for factor VIII which should be 0.7 IU/ml and fibrinogen level >140 mg/unit. Cryoprecipitate is tested for factor VIII and fibrinogen level which should have minimum of 80 IU of Factor VIII and $\geq$150 mg of fibrinogen in 100% of the tested units. Low level of factor VIII is seen in FFP and cryoprecipitate bags if the total FFP volume is less than 200 ml. Therefore only those bags should be selected for preparation of cryoprecipitate which have a minimum volume of 200 ml (after deducting the weight of plastic bag which is usually 26-32 grams).

4.2 Specimen Collection

QC should be checked of those components which have completed their shelf life. For packed red cells collected in CPDA-1, the QC should be checked on the 35th or 36th day of their shelf life, for platelets early morning of the 6th day of their shelf life. If in-date units are selected, they must be given a final disposition and documented as "used for quality control".

- For packed red cells, a segment is required after thorough mixing from each blood unit with the appropriate segment number (segments must be made after the preparation of the packed cells, before making the segment strip the tubing by mixing blood and remaining plasma very well).
- For platelets, a segment is required from each platelet unit with an appropriate segment number (leave at least two segments with number on platelet unit).
- For FFPs, a segment is required from each FFP unit with an appropriate segment number (at least one segment will be sufficient).

4.3 Procedure

4.3.1 Packed Red Cells

- Every 100th bag (1 % of the collected donations) should be checked or minimum of 4 bags per month should be checked for quality control.
- For packed red cell haematocrit testing, detach one segment (newly made, from packed red cell not the original segment made from whole blood) from three or four donor units of different types, made on different shifts if possible.
- Take the contents of each segment and place into a 12" x 75" test tube which is properly labeled with each unit number and mix well.
- Run these samples on the haematology analyzer and record the results on the QC form.
- Specific gravity of packed red cells is 1.080.
- Acceptable results for packed RBCs QC: at least 100% of units tested should have HCT percentage

less than 80% when collected in CPDA-1.

- For leucodepleted packed red cells, all pecifications are the same except residual WBC count which should be $< 5x10^6$/l.
- Store at 2-6°C for up to 35 days (with CPDA-1).
- Visually inspect packed cells for physical haemolysis, clots, grossly lipemic (milky white colour) or signs of bacterial contamination of units by observing colour (brownish/purplish/murky or greyish) and consistency. Further, bag segment should also be looked for signs of haemolysis (pinkish or reddish colour plasma).
- Record results on QC form.

4.3.2 Platelet Concentrates

- Minimum 1% or 4 bags per month should be checked for quality control.
- After their expiry date, i.e. on the morning of 6th day, the random platelet concentrate unit should have at least $\geq 0.55 \times 10^{11}$ platelet yield and pH should be $\geq$ 6.2 in at 90% of the tested donor units.
- Document the unit numbers of platelet concentrate to be tested for QC.
- Weigh the platelet bag and calculate plasma volume, e.g. total weight of platelet bag = 90 grams, and the weight of empty plastic bag = 30 grams. Then plasma in this bag would be 90-30 = 60 ml because 1 gm plasma is approximately equal to 1 ml.
- Then after thorough gentle mixing, aspirate 10 ml of platelet concentrate in a syringe from platelets bags, incubated at 20-24 °C for 12 - 24 hours at continuous agitation.
- Fill two plain tubes labelled with the donor number (approximately 3 ml each). Send one tube to the haematology laboratory to have a platelet count and the other to chemistry laboratory to have a pH measurement (if the departments are separate).
- For platelet count, run the sample on the haematology analyser and the platelet countfor each donor on QC form.

Calculate the platelet yield of each unit by the following formula:

1) Yield of the unit = platelets count x weight of unit in gm (or volume ml) x 1,000 x 1,000 OR

2) Platelet Yield = $\frac{\text{Platelet count x Plasma volume in platelet bag}}{100,000}$ = ____

For example, platelet count is 1,200/ul and plasma volume is 55 ml then;

$\frac{1200 \times 55}{100,000} = 0.66 \times 10^{11}$ Yield which is more than the required yield, i.e. $\geq 0.55 \times 10^{11}$

- Note down the yield on the QC form. Yield should be $\geq 0.55 \times 10^{11}$ in 90 % of the donor units tested (single donor unit).
- For aphaeresis platelets units, the yield should be $\geq 3.0 \times 10^{11}$ in 90 % of the aphaeresis donor units tested.
- Check the pH of each platelet unit which must be $\geq$ 6.2 in 90% of donor units tested.
- Perform swirling test which must be positive.
- Positive Swirling Test is because of discoid shape of the platelets. They move in circulardirection when the bag is tilted upward and downward in light.
- Negative Swirling Test is when the platelets are not moving in circular direction rather moving straight upward and downward indicating they are functionless and should not be transfused to the patients.
- Also check for physical haemolysis or any bacterial contamination, by observing colour and consistency.
- Record results on QC form.

4.3.3 Fresh Frozen Plasma

- Minimum 1% or 4 bags per month should be checked for quality control.
- Allow FFP segments to thaw at 37 °C.
- Transfer 3 ml plasma from the segment to a properly labelled 3 ml plastic serum tube.
- Immediately send the tube to test for Factor VIII level and Fibrinogen.
- Factor VIII level should be $\geq$ 0.7 IU/ml or $\geq$ 700 IU/L (if chromogenic Factor VIII kit is used for testing) and Fibrinogen level should be $\geq$140 mg/unit.
- FFP volume should be 150 – 250 ml (Specific gravity of FFP = 1.026).
- FFP should be stored at minus 18°C for one year and at minus 65 °C for seven years.
- Record results on QC form.

4.3.4 Cryoprecipitate

- Every 100th bag (1 % of the collected donations) or minimum 4 bags per month should be checked.
- Examine physical appearance of cryoprecipitate for abnormal colour, clots, precipitate, etc.
- Volume should be 10-15 ml.
- Factor VIII level should be $\geq$ 80 IU per ml (with chromogenic Factor VIII kit).
- Fibrinogen should be $\geq$150 mg/unit.
- Cryoprecipitate should be stored at less than minus 18°C for one year.
- Record results on QC form.

Form 4.1: Blood Components Quality Control Form

Blood Component	Parameter	Specification	Result
Red Cell Concentrates (RCC)	Volume	230 -250 ml	
	%Hct	55 -79%	
	Haemolysis	<0.8%	
	Sterility	Sterile	
	Clot	Absent	

Blood Component	Parameter	Specification	Result
Platelet Concentrates	Volume	45 -65 ml	
	Swirling	Present	
	Platelet yield	≥ 5.5×10^{10}/unit or ≥ 0.55×10^{11}/unit	
	pH	≥ 6.2	
	Sterility	Sterile	

Blood Component	Parameter	Specification	Result
Platelet Concentrates (Aphaeresis)	Volume	150 -300 ml	
	Swirling	Present	
	Platelet yield	≥ 3.0×10^{11}/unit	
	pH	≥ 6.2	
	Sterility	Sterile	

Blood Component	Parameter	Specification	Result
Fresh Frozen Plasma (FFP)	Volume	150 -250 ml	
	F VIII	≥ 0.7 IU/ml	
	Fibrinogen	≥140 mg/unit	

Blood Component	Parameter	Specification	Result
Cryoprecipitate (Single Donor Pack)	Volume	10-15 ml	
	F VIII	≥ 80 IU/ml	
	Fibrinogen	≥ 150 mg/unit	

Reviewed by _____ Date_____

Form 4.2: Single Donor Platelets Quality Control Form

S. No	Date	Unit #	Donors Platelet Count	pH (Expected pH 6.2) in 90% units	Product Volume (150-300 ml)	Product Count	Product Yield * (Expected 3.0×10^{11} in 90% units)	Procedure Done By	Culture & Sensitivity (negative)	QC by Tech	Remarks

Reviewed By: _____ * Platelet Yield = Product Volume (ml) x Product Count (platelets/ul) x Conversion Factor (1000ul/ml) Date: _____

5. Quality Control of Screening for Transfusion Transmitted Infections

5.1 Introduction

Screening for transfusion transmitted infections (TTIs) to exclude blood donations at risk of transmitting infection from donors to recipients is a critical part of the process of ensuring that transfusion is as safe as possible. Effective screening for evidence of the presence of the most common and dangerous TTIs can reduce the risk of transmission to very low levels.

Quality systems are crucial for the overall effectiveness of all aspects of the screening programme and in assuring the quality, safety and efficacy of all blood and blood components. All screening tests should be performed in accordance with defined quality requirements and all blood donations and blood components prepared from them should be handled appropriately before, during and after laboratory testing. If the daily screening of a blood centre is 100 or more tests, then run the controls with every 100th test (1%), if the number is 30 – 100, then once every day and if the number is less than 30, then run the controls once a week or batch to batch.

5.2 Procedure

- Follow the manufacturer's instructions and blood centre's SOPs.
- Only approved kits should be used for screening of TTIs which should meet predefined criteria for specificity and sensitivity.
- In addition to the manufacturer's controls provided with the kit, additional internal quality control measures, e.g weak positive sample can be run with each series of tests to ensure acceptable sensitivity of the method.
- No series of the tests should be validated unless the results of the manufacturer's and additional quality control samples are satisfied.
- All these activities should be periodically reviewed and recorded.
- FDA approved or CE marked or nationally approved control needs to be run with every batch of screening of Hepatitis B surface antigen, anti HCV and anti HIV-I/II.
- No pooling of serum should be done for screening.

5.2.1 Quality Control of Tests for Malaria

- Standard approved stains should be used to demonstrate the presence of malarial parasites in the thick blood smear of the blood donation.
- Quality control measures should be taken to demonstrate the acceptability of the procedure.
- If immuno-chromatographic or other technique is used, an additional quality control (weak positive sample) should also be run to validate the method and kit.

5.2.2 Quality Control of Tests for Syphilis

- For RPR test, positive and negative controls (animal serum in sodium azide) are included in the kit and must be run parallel to every test performed.
- The test is non-specific and must be confirmed by specific treponemal tests.
- If immuno-chromatographic or other technique is used, an additional quality control (weak positive sample) should also be run to validate the method and kit.

5.2.3 Quality Control of Tests for HBV, HCV and HIV

- The common standard screening tests for HBV, HCV and HIV are ELISA and CLIA. Both tests utilize positive and negative controls provided in the kit with every batch of testing.
- The manufacturer of the system also supply additional controls for external quality testing.
- To evaluate the quality of the kits, sensitivity, specificity, positive predictive value and negative predictive value are calculated.
- The sensitivity of a test is the probability that it will produce a true positive result when used on an infected population (as compared to a reference or "gold standard").
- Sensitivity is calculated as under:

$$\text{Sensitivity} = \frac{\text{Number of true positive specimens (TP)}}{\text{TP} + \text{Number of false negative specimens (FN)}} \times 100$$

$$\text{e.g. } \frac{4}{4+1} \times 100 = 80\%$$

- The specificity of a test is the probability that a test

will produce a true negative result when used on a non-infected population (as determined by a reference or "gold standard"). It is calculated as under:

$$\text{Specificity} = \frac{\text{Number of true negative specimens (TN)}}{\text{TN + Number of false positive specimens (FP)}} \times 100$$

e.g. $\frac{94 \times 100}{94+1} = 98.947\%$

- The positive predictive value of a test is the probability that a person has a proven infection when a positive test result is observed. It is calculated by the formula:

$$\text{Positive predictive value} = \frac{\text{Number of true positive specimens (TP)}}{\text{TP + Number of false positive specimens (FP)}}$$

- The negative predictive value of a test is the probability that a person is not infected when a negative test result is observed. It is calculated by the formula:

$$\text{Negative predictive value} = \frac{\text{Number of true negative specimens (TN)}}{\text{TN + Number of false negative specimens (FN)}}$$

5.3 Quality Control of ELISA, CLIA & NAT

5.3.1 ELISA

- Never use expired reagents and kits.
- All hardware to be used must be standardized and calibrated.
- Every run must include positive and negative controls.
- The standards must be of good quality and properly working.
- Chemicals must be purchased from suppliers who guarantee the purity and suitability for the desired application. Critical chemicals must be tested before purchase of large quantities.
- The suppliers must ensure the good quality for next lots.
- Buffers for QC of reagents must be tested according to SOP for large-scale use. Buffer preparations must be registered. Fresh buffers can be used after specific time period.
- All procedures must be well documented and log books must be up to date.

5.3.2 CLIA

- Never use expired reagents and kits.
- Always use recommended reagents and kits according to test demand.
- The technicians must be trained and well aware of troubleshooting. All the reagents and kits must be standardized and optimized.
- Regularly check instrument status and status of previous run.
- It is necessary to make a log sheet for each step of manual handling.
- The system and reagents/kits log sheets must be updated regularly.
- Chemicals must be purchased from suppliers who guarantee the purity and suitability for the desired application. Critical chemicals must be tested before purchase of large quantities.
- All hardware to be used must be standardized and calibrated.
- Always run controls.

5.3.3 NAT

- Never use expired reagents and kits.
- Nucleic Acid Testing (NAT) ensures early detection of transfusion-transmissible infections (TTIs) such as HIV, HBV, and HCV.
- NAT directly detects viral nucleic acids, making strict QC essential for maintaining assay sensitivity and specificity.
- QC programme must include daily equipment checks, thermal cycler verification, calibration of pipettes, and monitoring of laboratory environmental conditions.
- Strict contamination-control procedures are mandatory, including unidirectional workflow, dedicated areas, and use of aerosol-resistant tips.
- Every NAT run must include internal controls (ICs), positive controls, and negative controls to confirm assay reliability.
- Lot-to-lot verification of NAT kits and reagents is necessary before routine use.
- Verification of nucleic acid extraction efficiency and detection of PCR inhibitors should be performed routinely.
- Comprehensive record-keeping, including run logs, QC charts, maintenance records, and deviation reports, is essential.
- Participation in External Quality Assessment (EQA) programmes helps monitor long-term performance and inter-laboratory comparability.
- Regular staff training, competency assessments, and adherence to SOPs ensure consistent high-quality testing.
- QC processes must align with ISO 15189, WHO guidelines, and national blood safety standards.
- Effective QC reduces diagnostic window periods, thereby improving overall blood safety.

5.4 Documentation

The following must be documented for every QC test performed:

- The date on which the test is run
- Name of the kit used
- Lot number and expiry date of the kit
- Signatures of the technician
- Signature of the supervisor
- Reactive units are marked in red and are separated from the stock

5.5 Algorithm for TTIs Screening

1. Initial Screening Test

Positive reaction (Hold the donation) | Negative reaction (Release to stock)

2. Repeat Screening (Serum x 2)

Positive results	Negative and Intermediate results
Flag donor, record as permanent deferral not to be bled for clinical use. Arrange counselling and investigation of donor.	Donation not to be used. Defer donor for six months and if found negative, reinstate as active donor.

Any repeat test positive (Label not for transfusion) | Both repeat test negative (Release to stock)

3. Screening test on plasma from donation (If plasma gives the only clear cut negative result, an investigation according to local SOPs to explain the discrepancy)

4. Send the sample to reference laboratory for confirmatory testing (NAT).

5.6 Levey Jennings Chart

Levey-Jennings (LJ) chart is a simple graph on which values of quality control are plotted to see the pattern of quality control. This graph is always plotted against X-axis (horizontal line) and Y-axis (vertical line). Usually X-axis consists of intervals of run (date, month, etc) while Y-axis contains the values of control. Normally 7 horizontal lines emerge from Y-axis, 1 central and 3 on either side (above and below). Central line is denoted as Mean (X) and upper 3 lines are ascendingly tilted as +1SD, +2SD and +3SD while lower 3 lines are numbered as -1SD, -2SD and -3SD. SD is Standard Deviation that measures how close or far is the value of your quality control from the Mean.

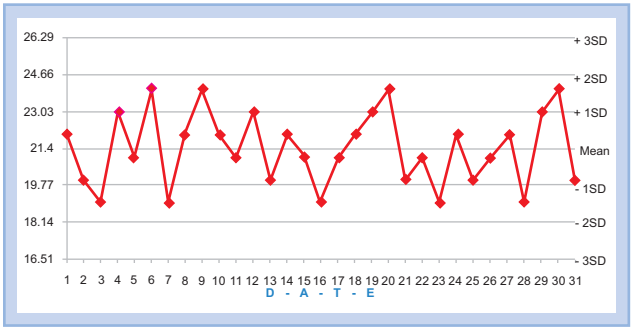

Fig 5.1: A template of a simple LJ Chart

LJ Chart is interpreted by certain rules termed as Westgard Rules or Multirules. These rules are purely based on basic statistical concept. These rules are also subcategorized into a) Warning Rules and b) Rejection Rules and are applicable when two levels of control material are analyzed in one run.

The following table explicitly describes the commonly used Westgard Rules along with their interpretation;

Table 5.1: Commonly used Westgard rules with interpretation

No.	Rule	Interpretation
1	**12S**	Warning Rule, no need to reject the analysis but must check for 13S rule. When ONE of two observation falls outside ±2SD limit.
2	**13S**	Rejection Rule. When ONE observation falls outside the ±3SD limit.
3	**22S**	Rejection Rule. When TWO consecutive observations of the same level fall outside ±2SD limit in same direction, OR, Both controls in the same run exceed ±2SD.
4	**R4S**	Rejection Rule. When consecutive ONE observation exceeds the +2SD and other exceeds -2SD limit. Total difference between controls is 4S.
5	**41S**	Rejection Rule. When FOUR consecutive observations fall outside 1SD on either side of Mean.
6	**10x**	Rejection Rule. When TEN consecutive observations fall on either side of Mean.

6. Quality Control of Equipment

6.1 Introduction

Quality system essentials define that qualification, calibration, maintenance and monitoring of equipment should be performed. There should be a schedule for equipment monitoring, calibration and preventive maintenance which provides a framework to conduct and review these activities, which is how one can assure consistent performance. A preventive maintenance programme is essential to ensure that equipment is well-maintained and any potential problems are detected and corrected prior to the machine's breakdown and subsequent downtime.

All equipment used for blood banking should be maintained and calibrated regularly and correctly. All refrigerators, platelet agitators and freezers that are used for the storage of blood and blood components must have a means of monitoring and recording any temperature fluctuation. Alarm system (audio visual system) is placed in the cross match area or where the staff is present 24 hours and 365 days a year to monitor the temperature and hear the alarm before the temperature reaches in unacceptable ranges and take appropriate action. For example, for red cells storage the lowest temperature limit is 1^0C and upper temperature is 6^0C. At these limits the alarm should beep.

There must be adequate space for storage of all components and these components must be stored in a manner that prevents damage, limits deterioration. Specific groups must be stored in FIFO (First In & First Out) order and in separate shelves to prevent wrong issuance of units.

The centrifuges used should have the desired speed and are able to perform the function in a quality assured manner. For example, using table top centrifuge for Coombs phase and immediate spin, i.e. 3400 rpm for 15 or 20 seconds one should get clear supernatant, no free cells, clear round button and cell button can easily be dispersed. For washing phase the calibrated centrifuge should give clear supernatant, straight cell trail, no free cells and clear settling of red cells at 90/120/150 seconds, etc. If these criteria are attained, it means now the centrifuge is calibrated. This should be done on yearly basis.

6.2 Procedure

- For new equipment, policies and procedures should include a requirement to define the criteria for selection and requirement for installation, calibration and qualification. Parallel testing must be performed with the old adopted and the new system for 100-500 samples or as approved mutually. These samples should include normal, abnormal, discrepant, etc. If the desired results are obtained then QC samples must be run and if again the desired results are achieved the machine is approved for use with continuous monitoring, etc.
- After installation, there must be a documentation of any problem and regular follow up must be done.
- Maintenance can be divided into maintenance performed by users and the maintenance requiring professional service personnel.
- All maintenance activities should be planned and completed on schedule and should be fully recorded.
- In case of any repair of instrument, recalibration and re-qualification should be done.
- The calibration should also be considered when existing equipment is relocated.
- The centre must develop a mechanism to uniquely identify and track all the critical equipment.
- There should be listing of all equipment and its unique identifying number as a tool to assist in control function of scheduling and performing monitoring, calibration and preventive maintenance.
- Evaluation of equipment will assist in assessing the functionality of the equipment and identify the equipment that may need replacement.
- For daily quality control, temperature of all the freezers and refrigerators should be checked and recorded.
- Speed and time of the centrifuges should be checked with taco-meter and stopwatch.

6.3 Calibration of Serologic Centrifuges

6.3.1 Principe

First, calibrating of a centrifuge evaluates the behavior of RBCs in solutions of different viscosity; it does not test the reactivity of different antibodies. The optimal spin time should be determined for the most reproducible and accurate results of agglutination grading.

Secondly, AHG phase reagents are added directly to a dry cell button and therefore may have different requirements than saline or albumin phase reactants.

Third, since AHG is inactivated readily by unbound immunoglobulin it becomes necessary to monitor and ensure that RBCs are washed free of all proteins and suspended in a protein-free medium.

6.3.2 Reagents and Equipment: Saline Phase

- Serofuge to be calibrated
- For saline reactive antibodies:
- Serum from group A person (anti-B), diluted with 6% Albumin to give 1 + reaction strength
- Negative control: 2-5 % cell suspension of A1 cells
- Positive control: 2-5 % cell suspension of B cells
- Test tubes: 12 x 75
- Calibration worksheet for recording results

6.3.3 Procedure

6.3.3.1 Saline Phase

1. Dilute the serum from a group A person with 6% albumin to give a 1 + reaction.
2. Label 10 tubes as follows: 10 POS, 15 POS, 20 POS, 30 POS and 45 POS, 10 NEG, 15 NEG, 20 NEG, 30 NEG and 45 NEG.
3. Add two drops of diluted serum (anti-B) to each tube labeled 10 Positive and 10 Negative (quantity that corresponds to routine patient testing).
4. Add one drop of B cells to 10 pos tube, and one drop of A cells to 10 neg tube (quantity that corresponds to routine patient testing).
5. Spin the two tubes, one positive and one negative for 10 seconds.
6. Gently re-suspend cell buttons using the microscope / lighted agglutination viewer, grade and record reaction results on the calibration worksheet.
7. Continue testing in pairs (one positive and one negative), adding cells just before spinning, until all 10 tubes have been tested. (Steps 4 – 6), increasing the time of spin with each set (15 sec, 20 sec, 30 sec, and 45 sec).
8. Select the optimal time of centrifugation, which is the shortest time required to fulfill the following criteria:
   a. Agglutination in the positive tubes is as strong as determined in preparing reagents.
   b. There is no agglutination or ambiguity in the negative tubes.
   c. The cell button is clearly delineated and the periphery is sharply defined, not fuzzy.
   d. The supernatant fluid is clear.
   e. The cell button is easily re-suspended.
   f. Record the centrifuge identification, the time selected, the date and the identity of the person performing the calibration.

6.3.3.2 Manual Cell Washing Phase

Tests in which antihuman globulin (AHG) serum is added to red cells may require centrifugation conditions different from those for immediate spin agglutination. Centrifugation conditions appropriate for both washing and AHG reactions can be determined in one procedure.

Note: Check cells (Coombs Control Cells) must be added to the negative tubes and test 1+ or greater to ensure the completeness of washing.

Reagents and Equipment

- AHG reagent (unmodified)
- Saline (large volumes)
- Test tubes 12 x 75
- Calibration worksheet for recording results
- Negative control: 2-5 % suspension of D-negative red cells, incubated for 15 minutes at 37°C with 6% albumin
- Positive control: 2-5% suspension of D-positive red cells incubated for 15 minutes at 37°C with anti-D which has been diluted to give 1 + reaction strength after addition of AHG
- IgG-coated check cells (Coombs Control cells)

- Procedure

1. Prepare negative and positive controls as above.
2. Label 10 tubes as follows: AHG 10 POS, AHG 10 NEG, AHG 15 POS, AHG 15 NEG, AHG 20 POS, AHG 20 NEG, AHG 30 POS AND AHG 30 NEG, AHG 45 POS AND AHG 45 NEG.
3. Add one drop of positive control to all POS tubes and one drop of negative control to all NEG tubes.
   a. Fill all tubes with saline and centrifuge in pairs, one POS and one NEG, for different times:
      i. Pair one: 30 seconds, pair two: 45 seconds, pair three: 60 seconds, pair four: 90 seconds and pair five: 120 seconds.
      ii. The red cells should form a clearly delineated button, with no cells trailing up the side of the tube.
      iii. After saline has been decanted, the cell button should be easily re-suspended in the residual fluid.
      iv. The optimal time for washing is the shortest time that accomplishes these goals.
      v. Record all observations on the calibration worksheet.
4. Repeat washing process on all tubes three more times, using time determined to be optimal in step
5. After the final wash, decant the saline completely, tapping the rim of the tubes on paper to obtain a dry cell button.
6. Add 2 drops of AHG to each pair of tubes and centrifuge for different times:
   a. Pair one: 10 seconds, pair two: 15 seconds, pair three: 20 seconds, pair four: 30 seconds, and pair five: 45 seconds.
   b. Gently re-suspend cell buttons using the lighted agglutination viewer, grade and record reaction results on the calibration worksheet.
7. Select the optimal time of centrifugation, which is the shortest time required to fulfill the following criteria:
   a. Agglutination in the positive tubes is as strong as determined in preparing reagents
   b. There is no agglutination or ambiguity in the negative tubes.

c. The cell button is clearly delineated and the periphery is sharply defined, not fuzzy.
d. The supernatant fluid is clear.
e. The cell button is easily re-suspended.

8. Add check cells to the negative tubes, spin and read.
   a. Check cells must be positive, as this assures the completeness of washing.

9. Record centrifuge identification, the times selected, the date, and the identity of the person performing the calibration.

Note: It is ideal to use only one centrifuge speed and alter the time (in seconds) for different testing conditions/phases.

Form 6.1: Red Cell Concentrate Refrigerator Temperature Record Form

Normal Range	Upper	Lower
	6^0C	1^0C

No.:_____ Description:_____Month/Year:_____

	08:00 am			12:00 pm			04:00 pm			08:00 pm			12:00 am			04:00 am		
Date	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
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25																		
26																		
27																		
28																		
29																		
30																		
31																		

Reviewed By: _____

Date:_____

Corrective and Preventive Action:_____

Form 6.2: Platelet Agitator Temperature Record Form

Normal Range	Upper	Lower
	24^{0}C	20^{0}C

No.:_____ Description:_____ Month/Year:_____

	08:00 am			12:00 pm			04:00 pm			08:00 pm			12:00 am			04:00 am		
Date	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10																		
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27																		
28																		
29																		
30																		
31																		

Reviewed By: _____

Date:_____

Corrective and Preventive Action:_____

Form 6.3: Fresh Frozen Plasma Freezer Temperature Record Form

Normal Range	Upper	Lower
	-18^0C	-65^0C

No.:_____ Description:_____ Month/Year:_____

	08:00 am			12:00 pm			04:00 pm			08:00 pm			12:00 am			04:00 am		
Date	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By	Inner	Chart	Observed By
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
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26																		
27																		
28																		
29																		
30																		
31																		

Reviewed By: _____

Date:_____

Corrective and Preventive Action:_____

Form 6.4: Serofuge/Centrifuge Maintenance/Cleaning Log

Month/Year:_____ **Model:** _____ **Serial #**_____ **Location:**_____

Clean Weekly Use hospital – approved all-purpose cleaner hospicidspray, remove and soak carriages in cleaner solution for at least 15 minutes, use centrifuge brush to clean thoroughly, rinse with water and allow to dry wipe bowl inside cover and external surfaces with cleaner solution then wipe with water – soaked gauze and allow to dry. Enter date in boxes initial below.

Month	January					February					March					April					May					June					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Clean Bowl																															
Carriages																															
Inside cover																															
External surfaces																															
Surrounding areas																															
Initials																															

Month	July					August					September					October					November					December					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Clean Bowl																															
Carriages																															
Inside cover																															
External surfaces																															
Surrounding areas																															
Initials																															

Date	Problems	Corrective Actions	Comments	Initials
	Service Log			

Reviewed By: _____ Date:_____

Form 6.5: Daily Quality Control Recordings of Refrigerated Centrifuge

To be recorded once each day of use

Month/Year: _____ Serial Number:_____

Date	Temp Set (°C)	Temp Read (°C)	RPM Set	RPM Read	Suitable for use (Yes / No)	Tech
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						
21.						
22.						
23.						
24.						
25.						
26.						
27.						
28.						
29.						
30.						
31.						

Corrective and Preventive Action: _____

Reviewed By: _____ Date:_____

Form 6.6: Cryofuge Maintenance Log

Month/Year:_____ **Model:** _____ **Serial #**_____ **Location:**_____

Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean surface area																															
Clean centrifuging chamber																															
Clean accessories (containers & hangers)																															
Initials																															
Weekly																															
Clean rotors																															
Clean accessories (containers & hangers)																															
Grease lightly (containers & hangers)																															
Grease lightly (angle rotors)																															
Clean Packing ring & sealing ring																															
Firm seating of rotor																															
Initials																															

Monthly	Date	Initials		Problems/Corrective Actions/Comments
Clean rotors and motor shaft				
Grease motor shaft				
Check: swing out rotors, hangers, groves and base, lifting lugs.				

Reviewed by:_____ **Date**_____

Form 6.7: Gel Card Centrifuge Maintenance Log

Month/Year:_____ **Model:**_____ **Serial #**_____ **Location:**_____

Month	January					February					March					April					May					June					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Clean housing																															
Check movement of ID cards holder																															
Inspection of seal and covers																															
Initials																															

Month	July					August					September					October					November					December					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Clean housing																															
Check movement of ID cards holder																															
Inspection of seal and covers																															
Initials																															

Date	Problems	Corrective Actions	Comments	Initials

Reviewed by:_____ **Date**_____

Form 6.8: Gel Card Incubator Maintenance Log

Month/Year:_____ **Model:**_____ **Serial #**_____ **Location:**_____

Month	January					February					March					April					May					June					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Clean the tub, lid and outer housing																															
Check the O ring for damage																															
Initials																															

Month	July					August					September					October					November					December					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Clean the tub, lid and outer housing																															
Check the O ring for damage																															
Initials																															

Date	Problems	Corrective Actions	Comments	Initials

Reviewed by:_____ **Date**_____

Form 6.9: Plasma Thawer

Month/Year:_____ **Model:**_____ **Serial #**_____ **Location:**_____

Month	January					February					March					April					May					June					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Fully drain the existing water																															
Clean the housing & inside using a soft cloth with disinfectant copatible with stainless steel																															
Refill with distilled water and add 30 drops of Helmer cleaner																															
Quality lubircation																															
Sign/ID																															

Month	July					August					September					October					November					December					Supervisor Review
Week	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Fully drain the existing water																															
Clean the housing & inside using a soft cloth with disinfectant copatible with stainless steel																															
Refill with distilled water and add 30 drops of Helmer cleaner																															
Quality lubircation																															
Initial																															

Date	Problems	Corrective Action	Comments	Sign/ID

Reviewed by:_____ **Date**_____

Form 6.10: Platelet Incubator

Month/Year:_____ **Model:** _____ **Serial #**_____ **Location:**_____

Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Clean shelves																														
Clean base																														
Clean glass door																														
Initial																														
Weekly																														
Change temperature chart																														
Initial																														

Monthly	Date	Initial

Monthly	Date	Initial

Problems/Corrective and Preventive Actions/Comments

Reviewed by:_____ **Date**_____

Form 6.11: Refrigerator Decontamination

Serial No:_____ **Month**_____ **Year**_____

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Refrigerator # 1 unscreened blood units Clean Shelves (monthly) Clean Floor (monthly) Rotate Stock/Organize shelves Ensure stock is in date and organized by blood group and expiry date												
Refrigerator # 2 Reagent Clean Shelves Clean Glass Doors Remove not released units and (Daily) realocate to Ref # 1 (Daily) Remove expiry units organized by blood group and expiry date												
Week 1 (Initial and date)												
Week 2 (Initial and date)												
Week 3 (Initial and date)												
Week 4 (Initial and date)												
Review Date												

Cleaning solution: Equipment cleaning solution/10% bleech

Corrective and Preventive Action:_____

_____

Reviewed by:_____ **Date**_____

Form 6.12: Serologic Centrifuge/Seroguge Calibration Work Sheet

Month:_____ **Year:**_____ **Serial No:** _____

Criteria	Reaction Phase	Time in Seconds				
	Immediate/Saline Phase	10	15	20	30	45
Supernatant Fluid Clear?						
Cell Button Round/Irregular						
Cells Easily Re-suspended?						
Agglutination Grade?						
Remarks: Optimal Time for this Phase is: seconds						

Washing Phase	Tube Pairs	
Time of spin: 30 Sec.	AHG 10 Pos	
Clearly delineated button?		
Cell trailing up side of tube?		
Cells easily re-suspended?		

Washing Phase	Tube Pairs	
Time of spin: 45 Sec.	AHG 15 Pos	AHG 15 Pos
Clearly delineated button?		
Cell trailing up side of tube?		
Cells easily re-suspended?		

Washing Phase	Tube Pairs	
Time of spin: 60 Sec.	AHG 20 Pos	AHG 20 Pos
Clearly delineated button?		
Cell trailing up side of tube?		
Cells easily re-suspended?		

Washing Phase	Tube Pairs	
Time of spin: 90 Sec.	AHG 30 Pos	AHG 30 Pos
Clearly delineated button?		
Cell trailing up side of tube?		
Cells easily re-suspended?		

Washing Phase	Tube Pairs	
Time of spin: 120 Sec.	AHG 45 Pos	AHG 45 Pos
Clearly delineated button?		
Cell trailing up side of tube?		
Cells easily re-suspended?		
Optimal time for washing is: _____Seconds.		

Phase of Reaction	Coombs Phase	Time In Seconds				
Criteria:		10	15	20	30	45
Supernatant Fluid Clear?						
Cell Button Clearly Delineated?						
Cells Easily Re-suspended?						
Agglutination Grading						
Negative Control tube is Negative?						
Remarks: Optimal Time For This Phase is: sec						

Criteria:

- Clearly delineated button: Yes/No
- Few cells trailing up the side of the tube: Yes/No
- Cell button easily re-suspended in residual fluid: Yes/No **Reviewed by:**_____**Date:** _____

Form 6.13: Weighing Scale Daily QC Form

Month/Year:_____ **Model:**_____ **Serial #**_____ **Location:**_____

Jan	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Problem/ Corrective Action	Supervisor Review
Reference Mass	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g		
Scale Reading																																	
Deference Daily Cleaning **Initial**																																	

Feb	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Problem/ Corrective Action	Supervisor Review
Reference Mass	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g		
Scale Reading																																	
Deference Daily Cleaning **Initial**																																	

Mar	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Problem/ Corrective Action	Supervisor Review
Reference Mass	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g		
Scale Reading																																	
Deference Daily Cleaning **Initial**																																	

Apr	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Problem/ Corrective Action	Supervisor Review
Reference Mass	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g	500g		
Scale Reading																																	
Deference Daily Cleaning **Initial**																																	

Acceptable Deference +/- 5g

Corrective and Preventive Action:_____ **Reviewed by:**_____ **Date:** _____

Form 6.14: Quality Control of Water Bath

Daily 4 hourly temperature of water bath should be recorded. Water should be clean and tubes should be 2/3rd immersed in water. Alarm and timer are checked quarterly.

Month/Year:_____ **Model:**_____ **Serial #**_____ **Location:**_____

Date	Shift	Digital Temp	Manual Temp	Timer	Technician
1	08:00 am				
	12:00 pm				
	04:00 pm				
	08:00 pm				
	12:00 am				
	04:00 am				
2	08:00 am				
	12:00 pm				
	04:00 pm				
	08:00 pm				
	12:00 am				
	04:00 am				
3	08:00 am				
	12:00 pm				
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4	08:00 am				
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7	08:00 am				
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	08:00 pm				
	12:00 am				
	04:00 am				

Reviewed By: _____ Date:_____

Form 6.15: Log Sheet for Quarterly Alarms Checks (Platelet Incubator)

Month/Year:_____ **Model:**_____ **Serial #**_____ **Location:**_____

	Temperature of Activation					General Alarm System			Senior Review		QA Review
Month	High	Low	Date	Init.	OK?	Date	Init.	Date	Init.	Date	Init.
January											
April											
July											
October											

Comments:_____

Corrective and Preventive Action:_____

Reviewed By: _____ Date:_____

Form 6.16: Log Sheet for Quarterly Alarms Checks (Refrigerator)

Take a small bottle of 50-100 ml and fill it with water of known temperature, i.e. 8-10°C. Insert the refrigerator sensor into this. After a few minutes, the refrigerator will give alarm. This is high alarm check (above 6°C). Similarly for low temperature alarm check (1°C), take ice water with known temperature of 0 to 1. Put the refrigerator temperature sensor to it. After a few minutes it will alarm.

Month/Year:_____ **Model:** _____ **Serial #**_____ **Location:**_____

	Temperature of Activation					General Alarm System			Senior Review		QA Review
Month	High	Low	Date	Init.	Remarks	Date	Init.	Date	Init.	Date	Init.
January											
April											
July											
October											

Comments: _____

Corrective and Preventive Action: _____

Reviewed By: _____ Date:_____

Form 6.17: Log Sheet for Quarterly Alarms Checks (Freezer)

Take a small bottle of 50-100 ml and fill it with ice water. Insert the freezer sensor into this. After a few minutes the freezer will give alarm. Note the temperature, this is high alarm check OR open the door of the freezer for few minutes and note gradual decline in freezer temperature. When the temperature reaches minus 17°C or minus 16°C, freezer should give alarm. For freezers, there is no need to check for low alarm at minus 18 0C or below.

Month/Year:_____ **Model:** _____ **Serial #**_____ **Location:**_____

	Temperature of Activation					General Alarm System			Senior Review	QA Review
January										
April										
July										
October										

Comments:_____

Corrective and Preventive Action:_____

Reviewed By: _____ Date:_____

Form 6.18: Storage Unit Alarm Activation Record Form

In case of Refrigerator/Freezer/Platelet Incubator Fault

Storage Unit Name:_____ Asset #:_____Upper Thermometer:_____

Location:_____Lower Thermometer:_____

Date and Time of Alarm Sound: _____

	Temp.	Time	Tech.
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			
Upper			
Lower			

Refrigerator/Freezer/Platelet Incubator Contents Transferred?:_____

Temporary Storage Area:_____

Supervisor Informed of Transfer: Date: _____ Time: _____

QA Review: _____ Date: _____

Reviewed By: _____ Date:_____

Form 6.19: Suggested Quality Control Performance Intervals

Equipment and Reagents	Frequency
1. Refrigerators/Freezer/Platelets Incubator	
A. Refrigerators	
1. Recorder	Daily
2. Manual temperature	Daily
3. Alarm system board (if applicable)	Daily
4. Temperature Charts (review daily)	weekly
5. Alarm activation	Quarterly
B. Freezers	
1. Recorder	Daily
2. Manual temperature	Daily
3. Alarm system board (if applicable)	Daily
4. Temperature Charts (review daily)	weekly
5. Alarm activation	Quarterly
C. Platelet Incubators	
1. Recorder	Daily
2. Manual temperature	Daily
3. Temperature Charts (review daily)	weekly
4. Alarm activation	Quarterly
D. Ambient Platelet Storage area	Every 4 –8 hours
2. Laboratory Equipment	
A. Centrifuge/cell washers	
1. Speed	Quarterly
2. Timer	Quarterly
3. Function	Yearly
4. Tube Fill Level (serologic)	Day of use
5. Saline fills volume (serologic)	Weekly
6. Volume of antihuman globulin dispensed (if applicable)	Monthly
7. Temperature check (refrigerated centrifuge)	Day of use
8. Temperature verification (refrigerated centrifuge)	Monthly
B. Heating blocks/Water baths/view boxes	
1. Temperature	Day of use
2. Quadrant/area checks	Periodically
C. Component thawing devices	Day of use
D. pH meters	Day of use
E. Blood irradiators	
1. Calibration	Yearly
2. Turntable (visual each time of use)	Yearly
3. Timer	Monthly/ Quarterly
4. Source decay	Dependent on source
5. Leak test	Twice Yearly
6. Dose delivery check (with indicator)	each irradiator use
7. Dose delivery verification	
a. Cesium-137	Yearly
b. Cobalt-60	Twice Yearly
c. other source	As specified by manufacturer
F. Thermometers (vs NIST-certificated or traceable)	
1. Liquid-in-glass	Yearly
2. Electronic	Monthly
G. Timer/Clocks	Yearly
H. Pipette recalibration	Yearly

I.	Sterile Connecting device	
1.	Weld check	Each use
2.	Function	Yearly
J.	Blood warmers	
1.	Effluent temperature	Quarterly
2.	Heater temperature	Quarterly
3.	Alarm activation	Quarterly

3. Blood Collection Equipment

A.	Whole blood equipment	
1.	Agitators	Day of use
2.	Balance/scales	Day of use
3.	Gram weight (vs NIST-certified)	Yearly
B.	Microhematocrit centrifuge	
1.	Centrifuge timer check	Quarterly
2.	Calibration	Yearly
C.	Cell counters/hemoglobinometers	Day of use
D.	Blood pressure cuff	periodically
E.	Apheresis equipment Checklist requirements	As specified by manufacturer

4. Reagents

A.	Red cells	Day of use
B.	AntiSera	Day of use
C.	Antiglobulin Serum	Day of use
D.	Transfusion-transmissible disease marker testing	Each test run

5. Miscellaneous

A.	Copper sulphate specific gravity	Day of use
B.	Shipping containers for blood transport (usually at temperature extremes)	Twice yearly

Form 6.20: Room Temperature and Humidity Check Log

Month/Year:_____ **Model:**_____ **Serial #**_____ **Location:**_____

Record thermometer or digital reading in °C each day if temperature exceeds acceptable range notify supervisor if contents may be compromised take action to preserve record observations actions and service below

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Alarm Check	Supervisor Review
Jan	Temp																																	
	Humidity																																	
	Initials																																	
Feb	Temp																																	
	Humidity																																	
	Initials																																	
Mar	Temp																																	
	Humidity																																	
	Initials																																	
Apr	Temp																																	
	Humidity																																	
	Initials																																	
May	Temp																																	
	Humidity																																	
	Initials																																	
Jun	Temp																																	
	Humidity																																	
	Initials																																	
Jul	Temp																																	
	Humidity																																	
	Initials																																	
Aug	Temp																																	
	Humidity																																	
	Initials																																	
Sep	Temp																																	
	Humidity																																	
	Initials																																	
Oct	Temp																																	
	Humidity																																	
	Initials																																	
Nov	Temp																																	
	Humidity																																	
	Initials																																	
Dec	Temp																																	
	Humidity																																	
	Initials																																	

Date	Problems	Corrective Action	Comments	Initials

Reviewed By: _____ Date:_____

Form 6.21: General Cleaning Log-Bench

Month/Year:_____ **Model:**_____ **Serial #**_____ **From** _____ **To**_____ **Location:**_____

Clean Sinks, ID Centrifuges, ID Incubator, Plasma Thawer, Bench tops and all Surfaces with Hospital approved Cleaner, Hospicidspray or Alcohol Swabs.

Month			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Supervisor Review
Jan	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Feb	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Mar	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
April	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															

Reviewed By: _____ Date:_____

Form 6.22: General Cleaning Log-Bench

Month/Year:_____ **Model:** _____ **Serial #**_____ **From** _____ **To** _____ **Location:** _____

Clean Sinks, ID Centrifuges, ID Incubator, Plasma Thawer, Bench tops and all Surfaces with Hospital approved Cleaner, Hospicidspray or Alcohol Swabs.

Month			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Supervisor Review
May	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Jun	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Jul	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Aug	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															

Reviewed By: _____ Date:_____

Form 6.23: General Cleaning Log-Bench

Month/Year:_____ **Model:**_____ **Serial #**_____ **From** _____ **To**_____ **Location:**_____

Clean Sinks, ID Centrifuges, ID Incubator, Plasma Thawer, Bench tops and all Surfaces with Hospital approved Cleaner, Hospicidspray or Alcohol Swabs.

Month			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Supervisor Review
Sep	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Oct	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Nov	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															
Dec	Counter Tops																																
	Initials	1st Shift																															
		2nd Shift																															

Reviewed By: _____ Date:_____

Form 6.24: Quality Control of Empty Blood Bags

Single, double and triple blood bags are used for collection of whole blood from the blood donor. The blood bag contains 63 ml CPDA1 which is sufficient for collection of 450 ml ± 10% whole blood. After opening the aluminum foil the blood bags should be used within 14 days (or follow manufactures advice). Before issuance of blood bag, each bag should be looked for its quality. The blood bag needle should be properly sealed, there should be no leakage and they should be within expiry date. QC of atleast one bag should be checked in each shift.

Month:_____ **Year:**_____

Date	Company Name	Bag Type	Intact Needle seal (Yes / No)	Leakage (Yes No)	Anticoagulant Transparency Yes / No	Lot #	Expiry Date	Sign.
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
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31.								

Reviewed By: _____ Date:_____

Form 6.25: Quality Control of Blood Bag Shaker

Blood bag shakers are used to mix the incoming blood from the blood donor with the anticoagulant CPDA1. The speed of the shaker varies from 10 rpm to 40 rpm. There should be homogenous mixing / colour of the blood. Blood is collected within 8-12 minutes. If whole blood is collected in more than 15 minutes then fresh plasma should not be separated for making FFP, in such cases only red cell concentrates and platelets should be separated from collected whole blood.

Month:_____ **Year:**_____

Date	Shaker Speed	Proper Mixing of Blood Yes / No (homogenous colour)	Alarm (optional)	Sign.
1.				
2.				
3.				
4.				
5.				
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29.				
30.				
31.				

Corrective and Preventive Action:_____

_____

Reviewed By: _____ Date:_____

7. Quality Control of Donor Management

The most important strategy to ensure a safe and adequate supply of blood and blood products is motivation, recruitment, selection and retention of voluntary non-remunerated blood donors. The implementation of quality system is a pre-requisite for a consistent approach to donor selection. Essential elements of a quality system in the donor selection process include:

- An organizational structure that defines the authority, responsibility and reporting channels of all personnel, including written job specifications.
- Donor selection criteria, as part of the national guidelines for the BTS, to ensure uniform application in every facility in which blood donations are collected.
- Standard operating procedures (SOPs) that guide every process, procedure and task to ensure consistency, accuracy and donor adherence, including information on the necessary staff, facilities, forms, worksheets and references, such as:
    - Donor interview and assessment based on a standardized donor questionnaire
    - Basic health check, including haemoglobin screening
- Staff training and competency assessment, including a training curriculum and training records.
- Records system (electronic or manual) that ensures traceability and confidentiality, including:
    - Donor records associated with each donation, including completed donor questionnaires
    - Results of basic health check and haemo-globin screening
    - Donor deferrals and reasons for deferral
    - Adverse donor reactions
- Periodic monitoring and evaluation of the donor selection process.

The confidentiality of donor records and the traceability of donations should be assured at all times through the use of unique identification numbers for donors and donations, and a mechanism linking donors to donations. The education and training of staff and regular quality monitoring are necessary for continual quality improvement.

7.1 Activities to Ensure Safe and Regular Blood Donation

- Identify low-risk donors and encourage self-exclusion by donors with risk behaviour.
- Develop effective education and motivation campaigns to recruit voluntary donors.
- Develop and maintain effective donor selection procedures.
- Provide high standard of comprehensive donor care.
- Maintain efficient donor records.
- Develop systems to retain voluntary and non-remunerated donors (VNRBD).

7.2 Monitoring

The process of donor selection requires on-going monitoring and evaluation to ensure that it achieves its objectives of ensuring donor and patient health and safety and a sufficient supply of safe blood and blood components. The main parameters to be monitored include:

- Donor demographics and characteristics
- Donor deferrals
- Donor adverse reactions
- Confidentiality, including facilities, procedures and documentation
- Complaints
- Blood screening results
- Transfusion reactions in recipients of blood and blood products
- Errors and untoward events
- Staff competency assessment and training needs.

7.3 Information to be Provided to Prospective Donors of Blood or Blood Components

- Accurate educational materials, which are understandable by the general public, explaining the essential nature of blood, the blood donation procedure, the components derived from whole blood and aepheresis donations, and the important benefits to patients.
- For both allogenic and autologous donations, the reasons for requiring an examination, health and medical history, and the testing of donations and all the significance of 'informed consent'.

- For allogenic donations, self-deferral, and temporary and permanent deferral, and the reasons why individuals are not allowed to donate blood or blood components if there could be a risk for the recipient.
- For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individuals whether as donor or recipient of the autologous blood or blood components.
- Information on the protection of personal data: no unauthorized disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed.
- The reasons why individuals are not allowed to make donations which may be detrimental to their health.
- Specific information on the nature of the procedures involved either in the allogenic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the indented transfusion requirements.
- Information on the option of donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during the donation process, without any undue embarrassment or discomfort.
- The reasons why it is important that donors inform the blood centre of any subsequent event that may render any prior donation unsuitable for transfusion.
- Information on the responsibility of the blood centre to inform the donor, through an appropriate mechanism, if test results show abnormality of significance to the donor's health.
- Information why unused autologous blood and blood components will be discarded and not transferred to other patients.
- Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood TTIs agents, will result in donor deferral and discarding of the collected unit.
- Information on the opportunity for donors to ask questions at any time.

7.4 Information to be Obtained from Donors by Blood Banks at Every Donation

- Identification of the donor.
- Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.
- Health and medical history of the donor health and medical history, provided on a questionnaire and through a personal interview performed by a qualified healthcare professional that includes relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves.
- Signature of the donor, on the donor questionnaire, counter signed by the health blood centre staff member responsible for obtaining the health history confirming that the donor has:
  - Read and understood the educational materials provided;
  - Had an opportunity to ask questions;
  - Been provided with satisfactory response to any question asked;
  - Given informed consent to proceed with the donation process;
  - Been informed in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements; and
  - Acknowledged that all the information provided by the donor is true to the best of his/her knowledge

7.5 Donor Selection Process

The purpose of donor selection is to assess the suitability of an individual to be a blood donor so that blood donation is safe for the donor and the blood components derived from this donation are safe for the recipients.

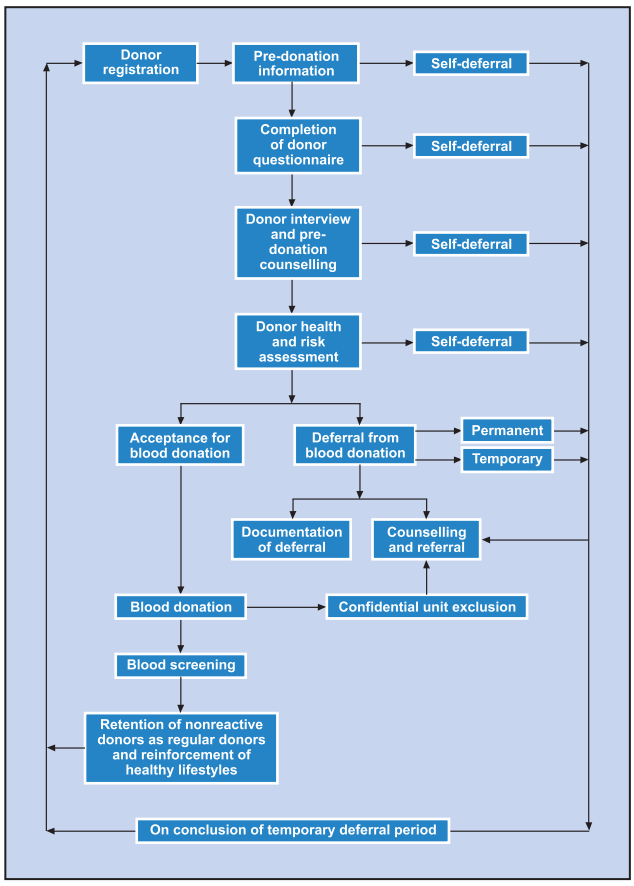

Figure 7.1 Flow chart for donor selection

The donor selection process should be carried out in accordance with written standard operating procedures. The steps involved in the donor selection process, prior to blood collection, are shown in following figure. Compliance with all donor selection criteria is crucial to ensure a safe blood donation process and outcomes. All potential and existing donors should be asked to adhere to the blood donor selection criteria by providing accurate information and answers to all questions asked, both for the protection of their health and that of patients who receive transfusion.

7.6 Donor Haemovigilance

Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence.

Donor haemovigilance is a continuous process of data collection and analysis of adverse donor events and reactions in order to investigate their causes and outcomes. Haemovigilance data should be utilized for clinical and public health decision making. All adverse events and reactions in donors should be identified, documented and reported. These data should be regularly analysed in order to undertake possible corrective and preventive actions. The goal of donor haemovigilance is to reduce the occurrence of adverse events and reactions and improve the outcomes both for donors and patients.

All donors should be advised to inform the blood centre of any side effects they suffer after donating, such as a delayed faint, or if they recall an illness or information that should have been declared before donation. Donors should also be asked to notify the blood centre if they become unwell within 28 days of donation, particularly with an illness that they may have been incubating at the time of donation. This is especially important with an infection such as hepatitis A where prompt action may prevent infection in the recipient.

Donor haemovigilance is a requirement of the quality system and contributes to:

- Improved donor safety through the implementation of corrective and preventive actions to avert the occurrence or recurrence of adverse donor events and reactions
- Tracing of donors and withdrawal of donations that may have or could contribute to serious adverse reactions in recipients
- Improved patient safety through better donor selection criteria and processes
- Epidemiological follow-up of the donor population

Adverse reaction is defined as any unintended response in donor or patient associated with the collection or transfusion of blood or blood components. The reporting of adverse reaction should be performed using a standard form, either by a paper or electronic system. Reports should be scrutinized to ensure that they are correctly categorized, and that all relevant information has been documented.

A rapid response system should be in place to share any relevant information related to adverse donor events and reactions for appropriate action to be taken for improving donor and patient safety. Information about any adverse effects in the recipients of transfusion should also be fed back into the donor haemovigilance system to improve donor selection.

7.7 Definitions of Donors Adverse Events

These definitions have been developed (2008) and revised (2014) by the ISBT Working Party on Haemovigilance in collaboration with the International Haemovigilance Network and the AABB Donor Haemovigilance Working Group. These have been endorsed by the Word Health Organization, the European Blood Alliance and the Alliance of Blood Operators.

The great majority of blood donors experience no complications. By monitoring complications, blood establishments can take measures to further reduce them.

7.7.1 Complications mainly with Local Symptoms

These complications are directly caused by the insertion of the needle. Some of these are mainly characterized by occurrence of blood outside vessels, whereas others are mainly characterized by pain.

- Adverse event is any undesirable or unintended occurrence associated with transfusion or donation. It includes all adverse reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents.
- Adverse reaction is any unintended response in donor or patient associated with the collection or transfusion of blood or blood components.
- Corrective action is taken to eliminate the cause of a detected nonconformity or other undesirable situation.
- Imputability is the probability that an identified probable cause was the actual cause of an adverse event after the investigation of the adverse transfusion event is completed.
- Incident is any untoward occurrence associated with an activity or process, such as the collection, testing, processing, storage and distribution of blood and blood components, or in the transfusion or administration.
- Near miss is an error or deviation from standard procedures or policies which, if undetected, could result in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognized before the transfusion took place.
- Preventive action is taken to eliminate the cause of a potential nonconformity or other potential undesirable situation.

7.7.1.1 Complications mainly characterized by the occurrence of blood outside the vessels

- Haematoma (Bruise)

Definition: A haematoma is an accumulation of blood in the tissues outside the vessels.

Mechanism: The symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues. For apheresis procedures, haematomas may also be caused by infiltration of the soft tissues by red cells during the return phase of the procedure. Large haematomas, particularly those in deeper layers of the forearm, put pressure on surrounding tissues and may contribute to other complications such as nerve irritation and injury and more rarely compartment syndrome.

Signs and Symptoms: Bruising, discolouration, swelling and local pain. Accumulation of blood in deeper tissues may result in more serious pain and pressure syndromes listed below.

- Arterial Puncture

Definition: Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding the donor.

Mechanism: Because of the rapid blood flow, the risk of a large haematoma is increased and thereby risks of more serious pain and pressure syndromes listed below.

Signs and Symptoms: A lighter red colour than usual of the collected blood can be seen. The needle and tubing may appear to pulsate; the blood bag fills very quickly. There may be weak pain localized to the elbow region.

- Delayed Bleeding (re-bleeding) - optional category

Definition: Leakage of blood from the venipuncture site after the initial bleeding has stopped.

Mechanism: Re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal of the bandage. After the donor has left the clinic, re-bleeding may be related to heavy lifting or strain to the donor's arm. Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk to re-bleed.

Signs and Symptoms: Spontaneous recommencement of bleeding from the venipuncture site, after pressure has been applied and the initial dressing has been removed, or leaking through the dressing.

7.7.1.2 Complications mainly characterized by pain

- Nerve Injury/Irritation

Definition: Injury or irritation of a nerve

Mechanism: A nerve may be hit directly by the needle at insertion or withdrawal, or there may be pressure on a nerve due to a haematoma or inflammation of the soft tissues. Include medically diagnosed cases, as well as cases reported on the basis of documented 'nerve' type symptoms.

Signs and Symptoms: Radiating, often 'electrical' sharp pain moving away from the venepuncture site, and/or paraesthesias such as tingling, burning sensations in the hand, wrist or shoulder area but away from the venepuncture site. Symptoms may arise immediately when the needle is inserted or withdrawn. In cases associated with a haematoma, pain may not be apparent at the time and may start when the haematoma has reached a sufficient size, sometime after insertion of the needle. Symptoms may be worse in certain positions or with certain arm motions. Rarely, weakness of the arm may develop.

Optional split by duration of symptoms:

Symptoms resolving within 12 months: Symptoms usually resolve within days, but rarely may persist for months or become permanent.

Symptoms lasting more than 12 months.

- Other Painful Arm – optional category

Definition: Pain in the arm is the primary symptom, without the characteristics of nerve irritation outlined above, or the presence of a large hematoma or other defined complications that may be painful.

Mechanism: Pain may be related to tissue injury, possibly due to hematoma in the deeper tissues.

Signs and Symptoms: Pain in the arm, without characteristics of nerve irritation. May be described as an ache or heaviness in the arm, similar to that experienced after vaccination. Include all cases where arm pain is the main symptom, unless a diagnosis of nerve injury/irritation is suspected in the presence of nerve type symptoms recognised by trained staff.

7.7.1.3 Localised infection/inflammation

- Localised infection/inflammation

Definition: Inflammation along the course of a vein, which may progress to localised infection several days after phlebotomy. There may be clotting in the vein.

Mechanism: Tissue damage and introduction of surface bacteria into the deeper tissues with venepuncture. The superficial vein itself (thrombophlebitis) or the surrounding subcutaneous tissue (cellulitis) may be predominantly affected.

Signs and Symptoms: Warmth, tenderness, local pain, redness and swelling at the site of phlebotomy. The site and the vein may feel tender, firm, and warm to the touch. Fever may be present.

Optional split into 2 categories:

Thrombophlebitis: The redness, swelling, and tenderness extend along the course of the vein.

Cellulitis: The redness, swelling and tenderness affect the soft tissues, and are not localised to the course of the vein.

7.7.1.4 Other major blood vessel injury

These rare, serious conditions must always be medically diagnosed.

- Deep Venous Thrombosis (DVT)

Definition: Thrombosis of a deep vein in the donor's phlebotomy arm.

Mechanism: Superficial venous thrombosis may progress into the deeper veins of the donor's arm. DVT may also rarely occur without previous signs and symptoms of superficial thrombosis. An additional risk factor for thrombosis, in particular, the use of oral contraceptives, may be present in these donors.

Symptoms and Signs: Swelling and pain in the upper arm. May be accompanied by symptoms of superficial inflammation and thrombosis (see above).

- Arteriovenous Fistula

Definition: Acquired connection between the vein and artery due to venepuncture lacerations.

Mechanism: A channel forms between the lacerated vein and artery immediately post-venepuncture, or in the healing process. May be related to arterial puncture.

Signs and Symptoms: Pulsating mass with a palpable thrill and associated bruit. The affected area may be warm, and the distal part of the arm may be cool if significant shunting of blood is present. The distal veins may be dilated and may pulsate.

- Compartment Syndrome

Definition: Increased intra-compartment pressure leading to muscle and soft tissue necrosis.

Mechanism: Blood may accumulate in the frontal deep areas of the forearm, closing small blood vessels and resulting in muscle and nerve tissue necrosis. May be related to arterial puncture.

Signs and Symptoms: Painful arm, particularly on movement; swelling, paresthesias and partial paralysis.

- Brachial Artery Pseudoaneurysm

Definition: Collection of blood outside an artery, contained by adventitia or the surrounding tissues alone.

Mechanism: After a traumatic arterial puncture, blood may leak out of the artery and accumulate in the surrounding space.

Signs and Symptoms: Pulsating mass in the arm. May be accompanied by pain and paraesthesias. May be preceded by a large haematoma following arterial puncture.

7.7.2 Complications mainly with Generalized Symptoms: Vasovagal Reactions

Definition: A vasovagal reaction (VVR) is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). It is the most common acute complication related to blood donation.

Mechanisms: Both physiologic and psychological factors may be important. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed, relative to the donor's total blood volume.

Signs and Symptoms: Usually several of the following: discomfort, weakness, anxiety, lightheadedness/dizziness, nausea, chills, sweating, vomiting, pallor, hyperventilation, rapid or a slow pulse. Hypotension and loss of consciousness (LOC) may occur and can be accompanied by loss of bladder or bowel control or convulsive movements. Reactions may occur before phlebotomy (rare), during phlebotomy or immediately after phlebotomy, when the donor stands up, in the refreshment area, or after the donor has left the collection site. Most reactions occur within 12 hours of phlebotomy. Reactions accompanied by LOC carry a risk of injury, particularly if they occur once the donor has left the collection site (delayed vasovagal reactions).

Vasovagal reactions are divided in two main subgroups:

Without loss of consciousness (LOC) - the donor does not faint

With loss of consciousness (LOC) - the donor faints for a period of time

Optional subdivision for donors with LOC:

LOC < 60 seconds - without other signs and symptoms

LOC ≥ 60 seconds - or with complications of convulsive movements, urinary or faecal incontinence

Optional subdivision:

With injury - Injury caused by falls or accidents in donors with a vasovagal reaction

Without injury

Optional subdivision:

Location of reaction:

On collection facility*- Symptoms occurred before donor has left the donation site

Outside collection facility - Symptoms occurred after donor has left the donation site

*in area within which staff can observe the donor and be responsible for the care of donors with complications

7.7.3 Complications related to Aphaeresis

- Citrate Reaction

Definition: Neuromuscular hyperactivity related to reduced ionized calcium levels.

Mechanism: Infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrhythmias, including cardiac arrest. Operator error with mix up of saline and citrate bags may occur with some apheresis equipment, and lead to rapid citrate infusion.

Symptoms and Signs: Numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, metallic taste, chills, shivering, lightheadedness, feeling of tightness, muscle twitching, rapid

or slow pulse, shortness of breath.

Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle contractions (tetany), shock, irregular pulse and cardiac arrest.

- Haemolysis

Definition: Donor red cells may be damaged, releasing haemoglobin.

Mechanism: There may be malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids, such as dextrose D5W, may be used in error.

Signs and Symptoms: Pink or red plasma, blood in lines or filter may appear dark. The donor may notice pink or red urine after collection.

- Air Embolism

Definition: Air bubble introduced into the donor's circulation.

Mechanism: Air may enter into the lines due to incomplete priming of lines, as a result of a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect, and reduce blood flow to the brain.

Signs and Symptoms: Bubbling sound or feeling at the venipuncture site. Cough, dyspnoea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea and vomiting.

- Infiltration: Optional Category

Definition: Intravenous solute (saline solution) enters the extravascular tissues during volume replacement (generally only applicable to double red cell procedures).

Mechanism: The needle is no longer positioned in the intravascular space, so fluids enter the surrounding tissues.

Signs and Symptoms: Swelling of the tissues at the venipuncture site.

7.7.4 Allergic Reactions

- Allergy (Local)

Definition: Red or irritated skin at the venipuncture site.

Mechanism: Reaction caused by allergens or irritants in solutions used for disinfection of the arm (such as iodine or chlorhexidine) or in manufacture of the collection set. Irritation may also occur due to application of the adhesive bandage (bandage adhesive dermatitis). An allergic reaction to latex that may be in supplies such as gloves may also occur.

Signs and Symptoms: Itching and redness at the venepuncture site, the bandage site, or the entire skin disinfection area. In a true allergic reaction, there may be a raised rash or hives in these areas that may expand to cover a larger area of the arm. The reaction may occur soon after donation or in the hours to days post-donation.

- Generalised Allergic Reaction (Anaphylactic Reaction)

Definition: Anaphylactic type reactions usually starting soon after the procedure is begun and may progress rapidly to cardiac arrest.

Mechanism: Extremely rare reactions, attributed to donor sensitivity to ethylene oxide gas used to sterilize some collection kits.

Signs and Symptoms: Apprehension, anxiousness, flushing, swelling of eyes, lips or tongue, cyanosis, cough, wheezing, dyspnoea, chest tightness, cramps, nausea, vomiting, diarrhoea, tachycardia, hypotension, and altered mentation.

Severity Grading Scale
0 = no sign
1 = immediate signs without vital risk and resolution
2 = immediate signs with vital risk
3 = long term morbidity
4 = death

Form 7.1: Notification of a Complication or an Adverse Reaction in a Blood Donor

Name of Blood Centre_____

Reported by_____Donor Name_____Donor ID_____

Date complication/adverse reaction occurred (day/month/year)_____

Type of donation: ☐ Whole Blood ☐ Plateletphaeresis ☐ Plasmaphaeresis ☐ Others (specify)

Type of Donor Complication or Adverse Reaction (s)	Severity Level			
	1	2	3	4
Vasovagal				
— Without loss of consciousness (LOC)				
— With loss of consciousness (LOC)				
Haematoma				
Arterial puncture				
Nerve injury				
Localized infection/inflammation				
— Thrombophlebitis				
— Cellulitis				
Deep venous thrombosis				
Arteriovenous fistula				
Compartment syndrome				
Brachial artery pseudoaneurysm				
Specific aphaeresis complications				
— Allergic reaction (generalized)				
— Anaphylactic reaction				
— Haemolysis				
— Air embolism				
— Citrate reaction				
— Infiltration				
— Hypotension (induced due to hypovolaemia)				
— Clotting				
Other reactions (specify)				

Remarks_____

_____

Date complication/adverse reaction notified (day/month/year)_____

Form 7.2: Periodic Reporting of Complications or Adverse Reactions in Blood Donors

Name of Blood Centre_____

Reported by_____Donor Name_____Donor ID_____

Reporting period *from* (day/month/year)_____*to* (day/month/year)_____

Total number of donations in the reporting period (including aphaeresis)_____

Type of Donor Complication or Adverse Reaction (s)	Severity Level				
	1	2	3	4	Total number reported
Vasovagal					
— Without loss of consciousness (LOC)					
— With loss of consciousness (LOC)					
Haematoma					
Arterial puncture					
Nerve injury					
Localized infection/inflammation					
— Thrombophlebitis					
— Cellulitis					
Deep venous thrombosis					
Arteriovenous fistula					
Compartment syndrome					
Brachial artery pseudoaneurysm					
Specific aphaeresis complications					
— Allergic reaction (generalized)					
— Anaphylactic reaction					
— Haemolysis					
— Air embolism					
— Citrate reaction					
— Infiltration					
— Hypotension (induced due to hypovolaemia)					
— Clotting					
Other reactions (specify)					

Remarks_____

_____

Reported by_____to_____

Date of submission (day/month/year)_____

Form 7.3: Deferral List for Medication

Class	Chemical Name	Trade Name	Action to be taken
Age-related Macular Degeneration (AMD) medication	Bevacizumab Pegatanib Sodium Ranibizumab	Avastin Macugen Lucentis	Defer for 3 months from cessation of treatment
Alcohol Deterrent	Disulfiram	Antabuse	Must not donate if less than 4 weeks from taking Disulfiram (Antabuse).
Alpha Blockers	Alfuzosin Doxazosin Prazosin Tamsulosin Terazosin	Xatral Doxatan; Doxane; Cardura Atodel Omnic; Tamnic; Combodart (in combination with Dutasteride) Hytrin	Blood Pressure must be checked for all donors on Alpha-Blockers. If normal, accept. In the case of Combodart defer for 6 months from last dose as for Dutasteride
Analgesic/Antithrombic	Acetylsalicylic Acid	Aspirin	Consider condition for which the medication is being taken otherwise defer for five days from last dose.
Antacids-including H_2 receptor antagonists and Proton Pump inhibitors			If symptoms are relieved by regular or sporadic use of medication and donor is in good health, accept Remember to ask re endoscopy
Anti-Acne medication	Tetracycline/erythromycin/other antibiotic	Dalacin; Zineryt	Defer for 4 weeks from last dose of systemic or local antibiotic (in view of infected skin)
Anti-Acne medication	Isotretinoin/Tretinoin	Roaccutane; Retin-A	Defer for 4 weeks from last dose
Anti-Acne medication	Acitretin	Neotigason	Defer for 24 months from last dose
Anti-Acne medication	Etretinate	Tigason	Must not donate if has ever taken Etretinate (Tigason)
Anti-androgens	Dutasteride	Avodart; Combodart (in combination with Tamsulosin)	Defer for 6 months from last dose
Anti-androgens	Finasteride	Propecia; Proscar	Defer for 4 weeks from last dose
Anti-androgens	Bicalutamide Cyproterone Acetate Flutamide	Tosadex Androcur Flutan	Must not donate if taken for a malignant condition
Antibiotics			Defer for 4 weeks from cessation of treatment
Anticoagulants			Permanently exclude if treatment is for cardiovascular disease, axillary vein thrombosis, repeated thrombophlebitis or thrombosis. Accept after isolated deep vein thrombosis (other than axillary vein thrombosis) and/or pulmonary embolus with specific cause and off all anticoagulant therapy for 3 months
Anticonvulsants			Permanently exclude anyone on medication for epilepsy. If has not required anticonvulsants for 3 years and has not had a seizure may, with discretion, be accepted.
Anticonvulsants used for Neuropathic pain	Pregabalin Gabapentin	Lyrica; Pragiola	Defer donors on this medication for 4 weeks after cessation of treatment.
Anti-D			Defer for 6 months if anti-D was given 'routinely' but for 12 months if the pregnancy was complicated. Otherwise allow to donate. (Anti-D used locally has always been from US sources. No risk of v-CJD).

Class	Chemical Name	Trade Name	Action to be taken
Antidepressants			If on SSRI's and SSNRI's only defer for 4 weeks following cessation of treatment. If off other antidepressants and in stable condition for at least 4 weeks, may donate.
Antifungals			If topical, allow if infection resolved. If systemic, defer for 4 weeks from cessation.
Antihelmintics	Mebendazole	Vermox	Defer for 3 weeks from completion of treatment
Antihistamines			If a donor has a history of a mild to moderate allergy which is not a drug allergy and may be on medication including antihistamines but is otherwise fit and well, accept.
Antihypertensives			Known hypertensive who has been on stable medication (not Beta Blockers) for a minimum of 4 weeks and has an acceptable blood pressure recorded at the donor session, accept. Donors on Beta Blockers (oral or eye drops) who reveal no episode of postural hypotension, whose pulse is at least 60 per minute and blood pressure is acceptable, accept. Otherwise defer permanently.
Anti-inflammatory drugs-Non-steroidal			Defer for 5 days
Anti-inflammatory drugs - Steroids			Local / Intra-articular: defer for 1 week from injection. See also underlying condition. Systemic / Oral (Short term): defer for 4 weeks after completion. Consider underlying condition.
Anti-Fibrinolytic	Tranexamic Acid	Cyklokapron	Defer if prescribed for any type of bleeding tendency or disorder. Defer if on long-term treatment. Accept if prescribed on an intermittent basis to prevent spotting and bleeding associated with the contraceptive implant or to decrease menstrual bleeding, as long as at least 48 hours have elapsed since taking the drug.
Anti-obesity Drugs			Accept if donor is taking anti-obesity drugs as long as he/she is well, has no complications thereof and treatment does not contain ephedrine, pseudo ephedrine or ephedrine-like substances in which case a deferral period of one week from cessation of treatment should be applied.
Anti-oestrogens	Tamoxifen	Nolvadex; Novofen	Permanently exclude if history of carcinoma. If prophylactic use defer for as long as the individual is receiving treatment and for 6 months after cessation.
Antipsoriatics	Acitretin	Neotigason	Defer for 24 months from last dose
Anti-smoking medication	Nicotine replacement	Nicorette Niquitin	Defer while on treatment
Anti-smoking medication	Varenicline	Chiampix	Defer for 1 month following cessation
Anti-smoking medication	Bupropion	Zyban	Defer for 1 month following cessation
Antithyroid Drugs	Carbimazole	Neomercazole	Defer for 2 years following cessation of treatment
Anti-vertigo medication	Betahistine Prochlorperazine	Betaserc; Vertimed Stemetil	Defer for 4 weeks from cessation of treatment and then allow only if asymptomatic

Class	Chemical Name	Trade Name	Action to be taken
Antivirals			Accept two weeks after recovery and completing all treatment.
Anxiolytics			If donor is well and off all medication for the past 4 weeks, accept.
Asthma medication			Accept provided asymptomatic on maintenance dose of non-steroid and/or inhaled steroid medication. Defer for 14 days after full recovery from acute exacerbation. Defer for 14 days after completion of a short course (less than 3 weeks) of oral or injected steroids.
Beta-blockers	Propranolol Sotalol Metoprolol Atenolol Nebivolol Labetolol Carvedilol	Emforal Sotalol Metoprolol Velorin; Atenomel; Tenormin; Tredol Nebilet; Nebol Trandate Avernol; Carvidex	Permanently exclude if used for the treatment of cardiovascular disease. Defer if used to control symptoms of thyroid disease. Otherwise, for donors who reveal no episode of postural hypotension and whose Heart Rate is at least 60/min: Accept if used for: 1. treatment of controlled hypertension. 2. prophylaxis of migraine. 3. Anxiety – if not experiencing symptoms 4. Glaucoma in the form of eyedrops.
Bisphosphonates	Alendronic Acid Ibandronic Acid Risedronate Sodium Zoledronic acid	Lendrate; Bone-Aid; Tevanate; Osteomel. Osbonelle Actonel; Ristonel Zolendronic Acid	May donate if cause of osteoporosis is not of itself a reason to defer. Permanent deferral if used for malignancy.
Coagulation Factor Concentrates			Permanently exclude current or past treatment with Coagulation Factor Concentrates.
Contraceptive Pill/implant			Accept, if possible do not use the arm with the implant for donation.
Diuretics			Accept if treatment is taken for pre-menstrual tension. If taken for hypertension accept, provided that Blood Pressure is well controlled, donor is on a stable dose of medication and has no complications due to hypertension. Consider other use on basis of underlying condition.
Erectile Dysfunction Medication	Prostaglandin E1 injection (Vasodilator)-Alprostadil	Caverject	Enquire about any underlying causes. Accept after 12 hours if no local infection. If less Than 12 hours defer till next day. Must Not Donate if: Oral or injectable therapy has been obtained abroad or from the Internet from a non registered medical practitioner.
Erectile Dysfunction Medication	Phosphodiesterase Type 5 (PDE_5) inhibitors -Tadalafil	Zenvil; Vixantus; Qizerz; Tadafil	Enquire about any underlying causes. Accept 3 days from last dose. Must Not Donate if: Oral or injectable therapy has been obtained abroad or from the Internet from a non-registered medical practitioner.
Erectile Dysfunction Medication	Phosphodiesterase Type 5 (PDE_5) inhibitors-Sildenafil, Vardenafil	Pulmopresil; Sidena	Enquire about any underlying causes. Accept next day after last dose. Must Not Donate if: Oral or injectable therapy has been obtained abroad or from the Internet from a non-registered medical practitioner.

Class	Chemical Name	Trade Name	Action to be taken
Hormone replacement therapy			Must not donate if: a) Used for malignancy. b) A recipient of human gonadotrophin of pituitary origin. c) A recipient of human pituitary growth hormone. d) A recipient of replacement adrenal steroid hormones. Discretionary: a) If treatment is for the menopause, its symptoms, or for osteoporosis prevention, accept. b) If treatment is for a shortage of sex hormones, e.g. in some cases of erectile dysfunction and is not related to the treatment of malignancy, accept. c) If treated with growth hormone that was exclusively recombinant, accept. d) If treated with gonadotrophins that were exclusively non-pituitary derived, accept
H_2 Receptor Antagonists	Cimetidine Ranitidine	Tagamet Timet Zantac Asyran	Must not donate if waiting for investigations or results. If symptoms are relieved by regular or sporadic use of medication and donor is in good health, accept
Lithium Salts	Lithium Carbonate	Camcolit Priadel	Persons requiring anti-psychotic medication should be permanently excluded.
Morning After Pill	Levonogestrel	Levonelle Escapelle	Accept, provided the high risk exclusions do not apply
Nasal Decongestants	Nasal Spray/Drops: Oxymetazoline Benzalkonium Chloride Xylometazoline Hydrochloride Beclomenthasone Diproprionate Budesonide Fluticasone Proprionate Mometasone Furoate Triamcinolone Acetonide Oral preparations: Pseudoephedrine Pseudoephedrine in combination with antihistamines	 Utabon Balkis Otrivin Beconase Rhinocort Flixonase Nasonex Nasacort Sudafed Cirrus; Clarinase; Actifed	It is primarily the reason for taking nasal decongestants, rather than the medication itself which determines eligibility to donate. If taken for viral or bacterial infection, defer for 2 or 4 weeks respectively. If on nasal spray/drops for controlled allergy, allow. For oral preparations taken for allergy defer for 48 hours from last dose if donor is asymptomatic.

Class	Chemical Name	Trade Name	Action to be taken
Oral Hypoglycaemic Drugs	Metformin (Biguanide)	Glucophage; Sophamet; Glyformin	If diabetes is well controlled, there are no complications and the medication has not been altered in the last four weeks, donor may be accepted. Also, this has to be viewed in the context of the donor's age and other co-existing medical conditions, such as obesity, hypertension and dyslipidaemia, increasing the pre-disposition to cardiovascular disease.
	Glibenclamide (Sulphonylurea)	Glitisol; Glibomet	
	Gliclazide (Sulphonylurea)	Medoclazide; Diamicron; Normodiab; Zicron; Azildor	
	Glimipride (Sulphonylurea)	Amaryl	
	Vildagliptin (Dipeptidyl peptidase-4 inhibitor)	Daltex	
	Sitagliptin (Dipeptidyl peptidase-4 inhibitor)	Jimandin	
	Acarbose (Alpha-glucosidase inhibitor)	Glucobay	
	Repaglinide (Meglitinide)	Ilgaper	
Pineal Gland Hormones	Melatonin		Permanently exclude.
Pituitary and Hypothalamic Hormones	Desmopressin		Permanently exclude donors who have been treated with Human Desmopressin
Prolactin Inhibitors	Bromocriptine	Medocriptine	Must not donate if on prolactin inhibitors such as Bromocriptine or Cabergoline for prolactin secreting pituitary adenoma.
	Cabergoline	Dostinex	
Proton-Pump Inhibitors and other drugs for acid related disorders	Omeprazole	Medoprazole; Losec; Ulcesep; Lomex-T; Eselan; Omranyt; Sopral; Losamel.	Must not donate if waiting for investigations or results. If symptoms are relieved by regular or sporadic use of medication and donor is in good health, accept
	Pantoprazole	Panrazol; PantoMylan; Panto-TAD; MAALOX REFLUSSO	
	Lansoprazole	Lasoprol; Lanzol	
	Esomeprazole	Nexium; Nepramel	
	Rabeprazole	Pariet	
Radioactive Iodine			Must not donate if: a) For malignancy. b) Administered in the preceding six months for a non-malignant condition.

Class	Chemical Name	Trade Name	Action to be taken
Radionuclides			1.Radioactive iodine therapy: Must not donate if: a) For malignancy. b) Administered in the preceding six months for a non-malignant condition. 2.Other treatments or investigation: apply rationale
Sedation for minor procedure			Must not donate if: The underlying condition for which the anaesthetic or sedation was given is not acceptable. Less than 24 hours since the anaesthetic or sedation was administered.
Sedatives			Enquire about medical history and underlying condition. Medication alone may not contraindicate donation.
Selective oestrogen receptor modulators	Raloxifene	Evista	Defer while on treatment. Following cessation of treatment may donate after 2 weeks given that the majority of a dose of raloxifene and glucuronide metabolites are excreted within 5 days and are found primarily in the faeces, with less than 6 % excreted in urine.
Steroid Therapy			a) Topical Steroid therapy - Consider underlying condition. Assess venepuncture site. Allow if occasional use of steroid cream over small areas. Defer for 6 months after using steroid cream over large areas for more than 3 weeks. b) Steroid Inhaler - Accept if using steroid inhalers for prophylaxis and condition is well controlled. c) If on long-term oral steroid therapy - defer permanently. If on short-term oral steroid therapy – Consider underlying condition defer for 7 days after completion or course. d) Intra-articular use – consider underlying condition. Otherwise defer for one week from injection.
Vasoprotectives	Hesperidin/Diosmin	Daflon	May donate as long as reason for taking medication is not in itself a reason for deferral.
Vitamins and other nutritional supplements			Must not donate if: On prescribed medication to treat a deficiency. Discretionary: a) Medication to prevent recurrence, as opposed to treat a deficiency (e.g. B12 for treated pernicious anaemia or folic acid for treated

Form 7.4: Deferral List for Vaccines and Diseases

Vaccines

S. No.	Vaccine	Deferral Period
1.	Hepatitis B	48 hours
2.	Cholera, Typhoid, Tetanus, Whooping Cough, influenza, diphtheria	1 week
3.	BCG and Rubella	3 weeks
4.	German Measles (Rubella)	4 weeks
5.	ATS	4 weeks
6.	Rabies	12 months
7.	HBIG (hepatitis B immune globulin)	12 months

Diseases

S. No.	Disease	Deferral Period
1.	Acne	2 years if taking Ruoaccutine or Tagison
2.	Acupuncture	12 months
3.	Alcoholism	Accepted when sober
4.	Angina	Permanently unfit
5.	Asthma	Acceptable if not taking any medicines
6.	Biopsy	Acceptable if benign and healed
7.	Blood disease	Unfit to donate
8.	Cerebrovascular disease	Permanently unfit
9.	Common cold	Acceptable if no temperature
10.	Dengue fever	Acceptable after 6 months of complete recovery
11.	Dermatitis Eczema and Psoriasis	Acceptable if healed. Refer to Doctor
12	Diabetes Mellitus	Acceptable when diet controlled. Unfit if taking Insulin and oral drugs Insulin and oral drugs
13	Epilepsy	Permanently unfit
14	Fracture	Major fracture 6 months Minor fracture 3 months
15	Gonorrhea	Acceptable after treatment
16	Gout	Acceptable after treatment
17	Hemorrhoids	Acceptable after complete healing and not taking any iron therapy or other medications
18	Hepatitis A infection	Acceptable after one year
19	Hepatitis B	Permanently unfit
20	Hepatitis C	Permanently unfit

21	Hypertension	Defer or refer to doctor
22	Hyperthyroidism	Unfit to donate
23	Hypothyroidism	Unfit to donate
24	Influenza	Acceptable after recovery
25	Malaria	Acceptable after three years
26	Menstruation	Acceptable after menstrual period is over
27	Migraine	Acceptable
28	Polycythemia Vera	Permanently unfit
29	Pregnancy	Acceptable after 6 months
30	Scabies	Acceptable after treatment and symptom free
31	Surgery	One year after major and minor surgeries
32	Syphilis	Unfit
33	Tooth extraction	Three months after complete recovery and healing
34	Tuberculosis	Acceptable after 5 years of recovery provided no relation with HIV/AIDS

Form 7.5: Donor History Form

Name:_____ Donor No: _____

ID No: _____ Age:_____ Sex:_____

Occupation: _____ Address: _____

_____

Telephone No._____ E-mail address: _____

1. HEALTH ASSESSMENT

Please tick the appropriate answer to each question	Yes	No
1.1 Are you feeling well and in good health today?	☐	☐
1.2 Have you had a meal or snack in the last 4 hours?	☐	☐
1.3 Have you already given blood in the last 12 weeks?	☐	☐
1.4 Have you got a chesty cough, sore throat or active cold sore?	☐	☐
1.5 Are you pregnant or breast feeding?	☐	☐
1.6 Do you have or have you ever had:		
a Chest pains, heart disease/surgery or a stroke?	☐	☐
b Lung disease, tuberculosis or asthma?	☐	☐
c Cancer, a blood disease, an abnormal bleeding disorder, or a bleeding gastric ulcer or duodenal ulcer?	☐	☐
d Diabetes, thyroid disease, kidney disease, epilepsy (fits)?	☐	☐
1.7 In the last 7 days, have you seen a doctor, dentist or any other healthcare professional or are you waiting to see one (except for routine screening appointments)?	☐	☐
1.8 In the past 12 months:		
a Have you been ill, received any treatment or taken any medication?	☐	☐
b Have you been under a doctor's care, undergone surgery, or a diagnostic procedure, suffered a major illness, or been involved in a serious accident?	☐	☐
1.9 Have you ever had jaundice (excluding jaundice at birth), hepatitis or liver disease or a positive test for hepatitis?	☐	☐
a In the past 12 months, have you had close contact with a person with yellow jaundice or viral hepatitis, or have you been given a hepatitis B vaccination?	☐	☐
b Have you ever had hepatitis B or hepatitis C or think you may have hepatitis now?	☐	☐
c In the past 12 months, have you been tattooed, had ear or body piercing, acupuncture, circumcision or scarification, cosmetic treatment?	☐	☐
1.10 In the past 12 months, have you or your sex partner received a blood transfusion?	☐	☐
1.11 Have you or your sex partner been treated with human or animal blood products or clotting factors?	☐	☐
1.12 Have you ever had injections of human pituitary growth hormone, pituitary gonadotrophin (fertility medicine) or seen a neurosurgeon or neurologist?	☐	☐
1.13 Have you:		
a Ever had malaria or an unexplained fever associated with travel?	☐	☐
b Visited any malarial area in the last 12 months?	☐	☐
1.14 When did you last travel to another region or_____country (in months / years)?	☐	☐

2. RISK ASSESSMENT

2.1 Is your reason for donating blood to undergo an HIV test?	☐	☐
2.2 Have you ever been tested for HIV?	☐	☐
2.3 If "Yes" what was the reason? ☐ Voluntary ☐ Employment ☐ Insurance ☐ Medical advice Other:_____		
2.4 Have you ever had casual, oral or anal sex with someone whose background you do not know, with or without a condom?	☐	☐
2.5 Have you ever exchanged money, drugs, goods or favours in return for sex?	☐	☐
2.6 Have you suffered from a sexually transmitted disease (STD): e.g. syphilis, gonorrhoea, genital herpes, genital ulcer?	☐	☐

		Yes	No
2.7	In the past 12 months:		
	a Has there been any change in your marital status?	☐	☐
	b If sexually active, do you think any of the above questions (2.1–2.6) may be true for your sexual partner?	☐	☐
	c Have you been a victim of sexual abuse?	☐	☐
2.8	Have you or your sexual partner suffered from night sweats, unintentional weight loss, diarrhoea or swollen glands?	☐	☐
2.9	Have you ever injected yourself or been injected with illegal or non-prescribed drugs including body-building drugs or cosmetics (even if this was only once or a long time ago)?	☐	☐
2.10	Have you been in contact with anyone with an infectious disease or in the last 12 months have you had any immunizations, vaccinations or jabs?	☐	☐
2.11	Have you ever been refused as a blood donor, or told not to donate blood?	☐	☐
2.12	Have you been prisoner in last six months?	☐	☐
2.13	Do you have history of traveling abroad in last 12 months?	☐	☐

3. DECLARATION

Please do not sign until you have answered all the questions and read the declaration below.

a I confirm that, to the best of my knowledge, I have answered all the questions accurately and consider my blood safe for transfusion to a patient.

b I understand that any willful misrepresentation of facts could endanger my health or that of patients receiving my blood and may lead to litigation. I am aware that my blood will be screened for, among others, HIV, hepatitis B, hepatitis C, syphilis and malaria. I understand that these screening tests are not diagnostic and may yield false-positive results. If any of the tests give a reactive result, I will be contacted using the information I have provided, and offered counselling.

c I understand the blood donation process, and I have been counselled regarding the importance of safe blood donation.

d I confirm that I am over the age of 18 years.

e I undertake that should there be any reason for my blood to be deemed unsafe for use at any stage, I will inform the Blood Transfusion Service.

Donor's signature:_____

Decision: ☐ Accept ☐ Defer

Donor weight:____kg

Blood pressure:___/___mmHg, Haemoglobin/haematocrit:_____

Deferral period:_____

Reason for deferral:_____

Interviewed by (name and signature):_____

Venepuncture performed by (name and signature):_____

Date:_____

8. Quality Control of Clinical Transfusion Chain

8.1 Hospital Transfusion Committee

Every hospital and health care facility responsible for the transfusion of blood components should have a transfusion committee in place. Hospital Transfusion Committees (HTCs) play a pivotal role in promoting safety and efficiency in blood transfusion therapy. They formulate appropriate local policies and procedures in accordance with the National Blood Policy and CUB Guidelines, regularly review and revise them and monitor hospital transfusion practices against them. HTC establish and diffuse guidelines for requisition, handling, issuing, storage, and transfusion of blood and components as well as their traceability. HTC are a watchdog for promoting safe and appropriate transfusion of blood and components.

Transfusion Committees are an organizational concept and structure which can be set up with the proper resources of the hospital. They provide leadership and advocacy for good transfusion practices. Corresponding to the complexity of blood transfusion, Transfusion Committees are a multi-disciplinary team, involving all departments prescribing and providing blood products. They are using Clinical, Quality, and Risk Management Tools. They develop indicators of good practices at local level.

Hospital Transfusion Committees are a part of the Quality System for the Management of the transfusion of blood and blood products. They are the moral authority at hospital for the implementation of good transfusion practices, haemovigilance and all required corrective actions within the hospital.

The HTC concept was born in the US at the end of the seventies, when quality management strategies began to be introduced for the management of the health care units and hospitals. From the start, HTC was a quality tool to implement, at the hospital level, quality standards and practices in routine blood transfusion practices.

A Hospital Transfusion Committee has to promote the establishment of:

- Rules governing good transfusion practices at the hospital level,
- Policies, guidelines, and procedures covering all the aspects of the day to day practices in transfusion medicine.
- Initial and continuous training of all staff regarding safe blood transfusion practices.
- Audits to follow-up on the implementation of safe blood transfusion practices.

HTC has been also the structure through which haemovigilance concept has been put to practice, and promoted, among all the health care units where blood transfusions are prescribed and used. HTCs first began to be set up at the end of the nineties.

Thus, a HTC is the best way to implement, at the hospital level, quality and safety in the blood transfusion. This also forms the basis of the WHO recommendation that a Transfusion Committee should be established in every hospital to:

- Implement the national blood policy, standards and guidelines
- Monitor the use of blood and blood components at the local level

8.2 Patient Haemovigilance

Haemovigilance was established in the mid-1990s in response to concerns regarding transfusion-transmitted viral infections. Since then, haemovigilance programmes have drawn attention to the importance of many previously unrecognized and potentially preventable adverse events, including incorrect blood component transfused, transfusion-related acute lung injury and bacterial contamination of platelets, etc.

As per agreed definition, the Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence.

The haemovigilance system should include root cause analysis and corrective and preventive actions as part of a continuing improvement cycle. Haemovigilance should be fully integrated into the quality systems of hospitals involved with clinical transfusion, to ensure patient safety at all levels.

Form 8.1: Hospital Transfusion Committee TOR

Terms of Reference

1. To ensure safe procedures in vein to vein transfusion chain.
2. To develop policies for the use of blood and blood products.
3. To ensure the dissemination and implementation of national guidelines on Clinical Use of Blood to avoid unnecessary transfusions and rational use of blood.
4. To promote best practice through local protocols based on national guidelines.
5. To set up a surgical blood ordering schedule and also regularly review it.
6. To ensure that adverse transfusion events/reactions are investigated and corrective actions are taken.
7. To ensure that adverse transfusion events/reactions are reported to the haemovigilance system.
8. To support training and education in Clinical Use of Blood.
9. To promote audits of the use of blood components.
10. To consider the legal implications of clinical transfusion practice.
11. To address issues relating to patients' religious and cultural choices.
12. To be aware of factors which might affect short and long term demands for blood.
13. To promote techniques such as Autologus Transfusion for preventing the use of donor blood.
14. To support the blood bank to optimize stock management.
15. To communicate with internal and external quality assurance bodies (if necessary) regarding transfusion quality assurance matters.
16. To monitor the blood transfusion budget and maintain a cost effective service.

Frequency of Meetings

- Meetings may be held on quarterly or bi-annual basis.

Membership

- Medical Superintendent
- Haematologist
- Clinician from major specialities consuming blood and blood components, e.g.
  - Surgery
  - Obstetrics and gynaecology
  - Medicine
  - Paediatrics
  - Thalassaemia units
- Nursing Head
- Pharmacist
- Blood Bank Incharge
- Other members to be co-opted as needed

Form 8.2: Blood Request Form

Patient's Name_____

W/O, S/O, D/O_____ Hospital ID_____

Age/Sex_____/_____ Ward_____ Bed No._____

Diagnosis _____

Indication for transfusion_____

History of transfusions_____

Any transfusion reaction_____

Previous pregnancies_____

Haemoglobin_____ Platelet count (if platelets required)_____

Blood components required:

Red Cell Concentrates ☐	**Fresh Frozen Plasma** ☐	**Platelet Concentrates** ☐
Cryoprecipitate ☐	**Leuko-reduced** ☐	**Irradiated** ☐
Washed ☐	**Whole Blood** ☐	**Others** ☐

No. of units required_____Blood group (if done earlier)_____

Date and time when required _____

Name and signatures of requesting doctor_____

Form 8.3: Signs and Symptoms of Adverse Transfusion Reaction

Sign/Symptom	Type of Reaction	Comment
Fever (temperature of ≥ 38ºC and rise of 1-2 ºC from baseline)	FNHTR, AHTR, TRALI (respiratory symptoms), bacterial contamination, can be unrelated to the blood transfusion.	Can coexist with other signs such as chills, rigors, myalgia, nausea or vomiting, dyspnea, hypotension (≥30 mmHg below the baseline) and tachycardia (HR >40 bpm above the baseline)
Urticaria, hives, pruritus	Allergic transfusion reaction, anaphylaxis	Can be mild and localized or more severe with generalized urticaria
Angioedema	Allergic transfusion reaction	May be preceded by tingling around the face and lips
Dyspnoea or hypoxia	TRALI, TACO, TAD, Severe Allergic transfusion reaction,	Severe dyspnea without shock may occur in TRALI or TACO. TAD is a diagnosis of exclusion, and therefore patients should be assessed for other causes of dyspnoea before making this diagnosis
Stridor, bronchospasm	Allergic/anaphylaxis	
Pulmonary oedema	TACO, TRALI	
Hypotension (fall in systolic and/or diastolic BP by greater than 30 mmHg and systolic blood pressure of 80 mm or less)	AHTR, severe allergic reaction, anaphylaxis, bacterial contamination, TRALI, Hypotensive reaction (Bradykinin mediated hypotension), can be unrelated to transfusion	Patients on ACE inhibitors are at risk. Risk is higher with bedside leukofiltration. Isolated hypotensive reactions are a diagnosis of exclusion, and occur within an hour of transfusion, in the absence of allergic or anaphylactic symptoms. These reactions usually require no/minor intervention.
Pain	FNHTR (generalized aches), AHTR (pain at the infusion site, abdomen, chest, loins), Anaphylactic reaction (chest pain)	
Severe anxiety or 'feeling of impending doom'	AHTR, bacterial contamination	Mild anxiety is common in patients on transfusions, especially for the first time. However, patients should be assessed for any transfusion reaction if anxiety develops.
Bleeding diathesis with acute onset	DIC can be associated with AHTR, bacterial contamination or massive transfusion	

This list can be used as a guide and may not be inclusive.

DIC: Disseminated Intravascular Coagulation
FNHTR: Febrile Non-Haemolytic Transfusion Reaction
AHTR: Acute Haemolytic Transfusion Reaction
TRALI: Transfusion Related Acute Lung Injury
TACO: Transfusion Associated Circulatory Overload
TAD: Transfusion Associated Dyspnoea

Form 8.4: Notification of Adverse Transfusion Reaction

Please complete ALL details below. Return completed form, any implicated pack(s) plus a 10ml clotted and 6-10ml EDTA patient post transfusion blood sample to Blood Bank

Requesting Doctor: Reported by: Date: (day/month/year)

1. Patient's Information

Name		Age/DOB		Gender	
Hospital ID		Ward		Bed No.	
Diagnosis					
Previous history	Transfusion ☐ (Recent date .....) Transfusion reaction ☐ Pregnancy ☐ Transplantation ☐				

2. Vital Signs

	Time	Temp (°C)	Pulse (/min)	RR (/min)	SBP/DBP (mmHg)
Pre-transfusion					/
During the reaction					/
Post-transfusion					/

3. Reaction Information: Signs & Symptoms (tick as appropriate)

General	Pain	Muco-cutaneous	Respiratory	Others
chills/rigors ☐	abdomen ☐	facial flushing ☐	hypoxemia ☐	nausea/vomit ☐
sweating ☐	flank/back ☐	jaundice ☐	dyspnoea/wheeze ☐	diarrhoea ☐
anxious/restless ☐	loin ☐	cyanosis/pallor ☐	orthopnoea ☐	dark urine ☐
flushing ☐	chest discomfort ☐	peripheral edema ☐	stridor/bronchospasm ☐	oliguria ☐
loss of consciousness ☐	heat in vein ☐	hives/urticarial (<1/3 body) ☐	cough ☐	Change in pulse/bp ☐
oozing/bleeding ☐	myalgia ☐	hives/urticarial (<1/3 body) ☐	pink sputum/ pulmorary edema ☐	Others (specify) ☐
	headache ☐	throat/eye/tongue swelling ☐	cyanosis ☐	_____

4. Implicated Transfusion Details & Information for Fluids and Medications

Blood product(s) : Whole Blood ☐ Red Cells ☐ FFP ☐ Platelets ☐ Cryoprecipitate ☐ Leuko-reduced ☐
Irradiated ☐ Washed ☐

Pack (donor) number ( ) sequence of units 1._____ 2. _____ 3. _____

Time: Transfusion commenced_____Signs & Symptoms noted_____Transfusion stopped_____

Rate of infusion_____Volume given_____ml

Non-blood IV fluid given within 12 hours before start of transfusion:

Fluid_____ Input_____ml Output_____ml

Medications given: During / immediately prior to reaction:_____

Pre-transfusion:_____

5. Other information

Bilateral pulmonary infiltration on chest X-ray	☐	Jugular venous distension	☐
PaO2/FiO2≤300 mmHg	☐	Elevated central venous pressure	☐
SpO2=90% on room air	☐	Drug infusions in same line as blood products	☐
History of warming of blood pack	☐	Request of blood culture	☐
Presence of clerical error	☐	Use of angiotensin-converting enzyme inhibitors	☐

Other specific findings: _____

Form 8.5: Investigation of Adverse Transfusion Reaction

1. Patient's Information	
Patient's name:	Date/time received:
Reviewed by:	Date: (day/month/year)

2. Test Results

		Pre-transfusion	Post-transfusion	Tested by/date
Blood bank tests	ABO/Rh			
	ABO/Rh (of blood bag)			
	IAT cross-match			
	Antibody screening test			
	DAT			
Tests for haemolysis	LDH			
	Haptoglobin			
	Plasma Hb			
	Urine Hb			
	Bilirubin			
	Fibrinogen			
	Spherocytes in blood smear			
	BUN/Creatinine			
Tests for allergy	Tryptase			
	IgA			
Tests for dyspnoea	BNP			
Tests for fever/infection	Blood culture of blood bag			
	Blood culture of patient			
	Complete blood count			

3. Reaction Classification

Immunological haemolysis due to ABO incompatibility ☐	Transfusion-transmitted viral infection (HCV) ☐
Immunological haemolysis due to other allo-antibody ☐	Transfusion-transmitted viral infection (HIV-1/2) ☐
Non-immunological haemolysis ☐	Transfusion-transmitted viral infection, other (specify) ☐
Febrile non-haemolytic transfusion reaction ☐	Transfusion-transmitted parasitic infection (malaria) ☐
Anaphylaxis/hypersensitivity ☐	Transfusion-transmitted parasitic infection, other (specify) ☐
Transfusion-associated circulatory overload (TACO) ☐	Post-transfusion purpura (PTP) ☐
Transfusion-related acute lung injury (TRALI) ☐	Transfusion-associated – graft versus host disease (TA-GVHD) ☐
Transfusion-transmitted bacterial infection ☐	Other reactions (specify) ☐
Transfusion-transmitted viral infection (HBV) ☐	

4. Severity

Non-severe ☐ Severe ☐ Life threatening ☐ Death ☐ Not determined ☐

Blood supplier notified if necessary ☐ Date……..

Future transfusion recommendations

Incharge Blood Bank (Name)…… Date……..... Signed: ……..

Form 8.6: Reporting of Adverse Transfusion Reaction

Name of Hospital_____

Reported by_____Date adverse reaction occurred (day/month/year)_____

Name of recipient_____Hospital ID_____

Age of recipient _____ years Sex of recipient ☐ M ☐ F Date of transfusion (day/month/year)_____

Adverse reaction in relation with ☐ Whole Blood ☐ Red Cell Concentrates ☐ FF P

☐ Platelets ☐ Others (specify)

Type of Recipient Adverse Reactions	Severity Level			
	1	2	3	4
Immunological haemolysis due to ABO incompatibility				
Immunological haemolysis due to other allo-antibody				
Non-immunological haemolysis				
Febrile non-haemolytic transfusion reaction				
Anaphylaxis/hypersensitivity				
Transfusion-associated circulatory overload (TACO)				
Transfusion-related acute lung injury (TRALI)				
Transfusion-transmitted bacterial infection				
Transfusion-transmitted viral infection (HBV)				
Transfusion-transmitted viral infection (HCV)				
Transfusion-transmitted viral infection (HIV-1/2)				
Transfusion-transmitted viral infection, other (specify)				
Transfusion-transmitted parasitic infection (malaria)				
Transfusion-transmitted parasitic infection, other (specify)				
Post-transfusion purpura (PTP)				
Transfusion-associated – graft versus host disease (TA-GVHD)				
Other reactions (specify)				

Remarks_____

_____

Date adverse reaction notified (day/month/year)_____

Form 8.7: Periodic Reporting of Adverse Transfusion Reactions

Name of Hospital_____

Reported by_____

Reporting period from (day/month/year)_____to (day/month/year)_____

Total number of patients transfused in the reporting period (including aphaeresis)_____

Total number of transfusions Whole blood_____Red Cell Concentrates_____FFP_____

Platelets_____Cryoprecipitate_____Others_____

(Use separate table for each blood component)

Type of Donor Complication or Adverse Reaction (s)	Severity Level				
	1	2	3	4	Total number reported
Immunological haemolysis due to ABO incompatibility					
Immunological haemolysis due to other allo-antibody					
Non-immunological haemolysis					
Febrile non-haemolytic transfusion reaction					
Anaphylaxis/hypersensitivity					
Transfusion-associated circulatory overload (TACO)					
Transfusion-related acute lung injury (TRALI)					
Transfusion-transmitted bacterial infection					
Transfusion-transmitted viral infection (HBV)					
Transfusion-transmitted viral infection (HCV)					
Transfusion-transmitted viral infection (HIV-1/2)					
Transfusion-transmitted viral infection, other (specify)					
Transfusion-transmitted parasitic infection (malaria)					
Transfusion-transmitted parasitic infection, other (specify)					
Post-transfusion purpura (PTP)					
Transfusion-associated – graft versus host disease (TA-GVHD)					
Other reactions (specify)					

Remarks_____

_____

Reported by_____to_____

Date of submission (day/month/year)_____

9. Purchase and Inventory Management

Efficient purchase and inventory management are critical components of a quality management system (QMS) in transfusion medicine. They ensure continuous availability of validated materials, reagents, and consumables required for safe blood collection, testing, storage, and distribution. Poor procurement practices can lead to reagent shortages, compromised testing reliability, and interruption of blood supply services.

In hospital blood banks (HBBs) and transfusion services, contract and purchasing issues are usually handled by the hospital's purchasing department. Blood centre personnel may or may not have control over the specific vendors with which the organization has agreements to purchase reagents, kits for testing, equipment, and other important supplies and materials. At a minimum, the blood centres need to have a process by which critical supplies are inspected and tested, where required. In addition, there should be effective processes for managing inventories of reagents and other supplies. Blood centres need to have specified processes for selecting vendors of equipment, supplies and services, and for entering into amending agreements. In addition, blood centres must also have processes for receipt, inspection, and testing (where required) of incoming critical materials such as blood bags, antiseras, and kits for TTI screening.

9.1 Procurement Process

Vendor Qualification and Selection

- Only approved suppliers/vendors meeting quality and regulatory standards should be used.
- Maintain a Vendor Approval Register with documentation on supplier evaluation, audits, and certification (e.g., ISO 9001, GMP).
- Prefer vendors with a consistent supply record and valid DRAP registration (for IVDs, bags, and kits).

Purchase Requisition and Authorization

- Each department (collection, testing, component preparation) should generate purchase requisitions based on consumption trends and minimum stock levels.
- All purchases must be authorized by the Quality Manager or Head of Transfusion Services before processing.

Purchase Orders

- Clearly specify item name, catalog number, manufacturer, lot number, expiry, quantity, storage requirements, and delivery schedule.
- Include clauses for non-conformance return if items fail quality acceptance testing.

Receipt and Acceptance Testing

- Upon delivery, check for:
  - o Integrity of packaging, labeling, and expiry dates.
  - o Manufacturer's certificate of analysis (CoA) or quality control certificate.
  - o Compliance with order specifications.
  - . Perform lot-to-lot verification for new reagent lots before routine use.
- Record acceptance in the Goods Receipt Logbook and update inventory.

9.2 Inventory Management

Inventory Control Systems

- Maintain a centralized inventory register (manual or digital LIMS).
- Apply First Expiry, First Out (FEFO) or First In, First Out (FIFO) principles.
- Monitor minimum and reorder levels for critical supplies.
- Conduct monthly physical stock verification and reconcile discrepancies.

Stock Classification

- Critical items: Blood bags, reagents for mandatory TTI testing (HBsAg, anti-HCV, anti-HIV, syphilis, malaria, NAT).
- Supportive items: PPE, disinfectants, glassware, plasticware, stationery, etc.
- Capital equipment: Refrigerators, centrifuges, analyzers — with preventive maintenance schedules.

Storage and Handling

- Store all reagents and supplies under manufacturer-specified conditions (temperature, humidity, light exposure).
- Maintain temperature logs and alarms for refrigerators/freezers.
- Separate quarantine areas for expired or rejected materials.
- Implement color-coded labeling (e.g., Green = In use, Yellow = Quarantine, Red = Rejected).

Traceability and Documentation

- Assign unique batch/lot numbers to every reagent and supply.
- Maintain traceability from procurement to each test run and patient report.
- Document:
  - Purchase requisition forms
  - Delivery notes
  - Lot verification records
  - Usage logs
  - Disposal records (for expired or rejected items)

Disposal of Expired/Recalled Items

- Expired reagents must be segregated and disposed of as per biohazard waste management protocols.
- In case of product recall, immediate notification and quarantine must occur; document all actions taken.

Quality Indicators and Auditing

- KPIs:
  - Stock-out incidents per quarter
  - % of reagents failing lot verification
  - Turnaround time from purchase request to delivery
  - % of expired items discarded before use
- Conduct internal audits annually to assess compliance with procurement and inventory SOPs.

Risk Management

- Maintain a Risk Register identifying supply chain vulnerabilities.
- Develop contingency plans for critical reagents (e.g., maintain dual suppliers).
- For national programmes, ensure framework agreements and pooled procurement for cost efficiency.

9.3 Disaster Management and Continuity Planning in Procurement and Inventory

- Natural disasters, pandemics, civil unrest, and other emergencies can disrupt the supply chain for blood and laboratory materials, severely compromising transfusion services. A proactive disaster management and continuity plan ensures uninterrupted access to essential reagents, blood bags, and equipment critical for patient care. Preparedness minimizes downtime, prevents reagent shortages, and supports national emergency response.

Risk Identification and Assessment

Potential disruptions should be mapped through a supply chain vulnerability assessment, identifying:

- Natural hazards (earthquakes, floods, landslides).
- Man-made events (conflict, power failure, strikes, terrorism).
- Logistic breakdowns (fuel shortages, blocked transport routes, supplier insolvency). Each risk must be rated for probability and impact, guiding mitigation and preparedness actions.

Preparedness Measures

- Buffer Stocks: Maintain at least three months of critical inventory (blood bags, test kits, reagents, anticoagulants, PPE) at each regional or national center.
- Alternative Suppliers: Pre-qualify at least two vendors for every critical item, ensuring redundancy in case of disruption.
- Cold Chain Continuity: Equip refrigerators/freezers with backup power, voltage stabilizers, and temperature monitoring systems connected to alarm alerts.
- Emergency Kits: Prepare portable emergency stock boxes containing essential supplies for field operations or mobile collection units.
- Data Backup: Maintain duplicate inventory and procurement records (both digital and paper) stored off-site or in cloud systems.

Response Phase

When a disaster occurs:

- Activate the Emergency Supply Chain Plan under the direction of the Transfusion Service Disaster Coordinator.
- Prioritize supplies for critical hospitals and trauma centers.
- Utilize mutual aid agreements with nearby regional blood centers to share resources.
- Maintain clear communication with suppliers, transport authorities, and health department logistics units.
- Document all response actions, including consumption rates and shortages.

Recovery and Post-Disaster Review

- Conduct an inventory damage assessment and restock essential items immediately after the event.
- Review supplier performance, transportation reliability, and system weaknesses.
- Prepare a post-incident report summarizing gaps, corrective actions, and future recommendations.
- Update standard operating procedures (SOPs) and training based on lessons learned.

Key Quality Indicators

- Number of days critical stock remained available during disaster.
- Time taken to restore normal inventory operations.
- Number of alternative vendors activated successfully.
- Percentage of losses mitigated through preparedness

plans.

Integration with National Emergency Systems

- Link the transfusion service's disaster plan with the National Disaster Management Authority (NDMA) or Provincial Health Emergency Operations Centres (HEOCs).
- Participate in joint simulation exercises and emergency drills.
- Ensure that procurement and logistics officers are part of the national Health Cluster Response during crises.

Fig. 9.1: Disaster Response and Continuity Flow

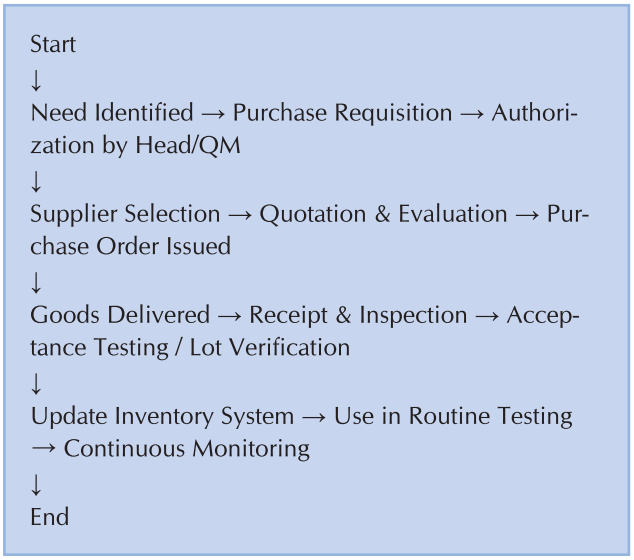

Fig. 9.2: Procurement Process Flow

Fig. 9.3: Stock Verification & Reconciliation Flow

Form 9.1: Inventory Control Checklist

Item Category	Item Name / Description	Lot No.	Expiry Date	Stock on Hand	Reorder Level	Supplier	Storage Temp (°C)	Remarks
Blood Bags	Single / Double / Triple / Quad						2–6 °C	
Test Kits	HBsAg, anti-HCV, HIV, Syphilis, Malaria, NAT						2–8 °C	
Reagents	Anti-A, Anti-B, Anti-D, Coombs Reagent, Saline						2–8 °C	
Consum-ables	Gloves, Needles, Vacutainers, Disinfectants						Room Temp	
Controls & Calibrators	QC sera, positive / negative controls						-20 °C	

Verify stock monthly, apply FIFO/FEFO, document lot verification results, and note any damaged/expired items

Form 9.2: Supplier Evaluation and Approval Form

Evaluation Parameter	Criteria	Score (1–5)	Remarks / Evidence
Regulatory Compliance	DRAP license, ISO 9001, GMP certification		
Product Quality	Certificate of Analysis, stability data, batch consistency		
Delivery Performance	Timeliness, accuracy of orders delivered		
Technical Support	Availability of training, troubleshooting assistance		
Pricing & Value	Competitive pricing, cost-benefit analysis		
After-Sales Service	Replacement policy, recall management		
Communication & Responsiveness	Ease of contact, complaint handling		

Rating Scale:
1 = Poor 2 = Fair 3 = Good 4 = Very Good 5 = Excellent
Minimum qualifying score: ≥ 3.5 average.
Evaluated by: Procurement Officer / Quality Manager /Head of Transfusion Service.
Review Cycle: Annually or after major supply issues.
To be reviewed monthly.

Form 9.3: Emergency Stock Register (Disaster Preparedness)

Critical Item	Minimum Emergency Stock	Current Stock	Buffer Days of Use	Last Verification Date	Responsible Person	Backup Supplier / Region	Remarks (Action Taken)
Blood Bags	1000 units						
TTI Reagents	3 complete lots						
NAT Kits	1 month supply						
PPE (Kits, Masks, Gloves)	500 sets						
Disinfectants	50 litres						

Stock must be secure, labeled “Disaster Reserve,” and rotated (FEFO) to avoid expiry.

9.4 Model Specifications for Procurement of Blood Grouping Antisera

General Requirements

All antisera used in blood grouping and typing must be:

- Approved by the Drug Regulatory Authority of Pakistan (DRAP) or equivalent national regulatory body.
- Manufactured under Good Manufacturing Practices (GMP).
- Supplied with a Certificate of Analysis (CoA) from the manufacturer, stating lot number, expiry date, potency, and specificity results.
- Compatible with the testing methodology used in the laboratory (slide, tube, microplate, gel card, or column agglutination).

Scope of Antisera

Table 9.1: Antisera considered essential for blood grouping and compatibility testing

Basic Typing Antisera	Extended Typing / Special Use
Anti-A	Anti-C
Anti-B	Anti-c
Anti-AB	Anti-E
Anti-D (IgM or blend IgM + IgG)	Anti-e
Control Serum	Anti-K (Kell)
	Anti-Fya, Anti-Fyb, Anti-Jka, Anti-Jkb (if applicable)

Table 9.2: Technical Specifications

Parameter	Specification / Requirement
Formulation	Ready-to-use liquid reagents, preferably monoclonal or monoclonal blend.
Origin	Human monoclonal or recombinant source preferred; animal-derived allowed if validated and DRAP-approved.
Potency (Titer)	Minimum 1:256 for tube tests; higher titers preferred for slide or microplate methods.
Specificity	Must react specifically with target antigen; no cross-reactivity or false positives.
Clarity	Free from visible turbidity, flocculation, or contamination.
Preservatives	Contain sodium azide or equivalent bacteriostatic agent at safe concentration (<0.1%).
Color Coding	As per international convention:

Anti-A: Blue
Anti-B: Yellow
Anti-AB: Colorless
Anti-D: Clear/Colorless or Green
Control: Colorless |
| **Packaging** | Leak-proof, labeled dropper bottles (5 mL, 10 mL, or 20 mL), tamper-evident caps, resistant to freezing. |
| **Labeling** | Clearly state:
Product name and antigen specificity
Manufacturer and country of origin
Lot/batch number
Expiry date
Storage conditions (2–8 °C)
Precautions and intended use |
Shelf Life	Minimum 12 months from date of delivery; stability validated for 2–8 °C storage.
Storage Conditions	Maintain cold chain at all times (2–8 °C, avoid freezing or heat exposure).
Compatibility	Compatible with both manual and automated grouping platforms.
Quality Control Requirements	Each lot must be tested with known positive and negative control red cells upon receipt and at regular intervals (weekly/monthly).
Documentation	Manufacturer's CoA, safety data sheet (SDS), performance validation data, and instruction for use (IFU) must accompany every shipment.

Acceptance Criteria at Receipt

Upon delivery, each consignment must be checked for:

- Physical condition (no leakage, no freezing).
- Integrity of labeling and packaging.
- Matching lot number with accompanying CoA.
- Temperature monitoring (if shipped with cold packs).
- Internal lot verification testing before release for routine use.

Table 9.3: Recommended QC Panel for Verification

Test	Positive Control Cell	Negative Control Cell	Expected Reaction
Anti-A	Group A1 cells	Group B cells	3+ to 4+ / 0
Anti-B	Group B cells	Group A1 cells	3+ to 4+ / 0
Anti-AB	Group AB cells	Group O cells	3+ to 4+ / 0
Anti-D	Rh(D) positive cells	Rh(D) negative cells	3+ to 4+ / 0
Control	Any red cells	—	No agglutination (0)

Rejection Criteria

Reject antisera if:

- Containers are broken, frozen, or turbid.
- Labels are missing or illegible.
- Lot numbers or expiry dates are inconsistent.
- Lot fails initial QC testing (weak or nonspecific

reactions).

- CoA or regulatory documents are not provided.

Documentation and Traceability

- Record all details in Reagent Receipt and Verification Register.
- Maintain Lot Verification Log with test results, date, and verification officer's initials.
- Trace each reagent lot to every batch of patient testing for full accountability.

9.4.1 Specification Sheet 1: Anti-A Blood Grouping Reagent

Product Name:
Anti-A (Monoclonal) Blood Grouping Reagent

Intended Use:

For the identification of the A antigen on human red blood cells by agglutination in slide, tube, or microplate techniques.

Principle:

The reagent contains monoclonal antibodies directed gainst the A antigen that agglutinate red cells xpressing the A antigen.

Composition:

- Monoclonal Anti-A antibody (IgM or IgM + IgG blend)
- Buffered saline solution with preservatives (≤ 0.1 % sodium azide)
- pH 6.8 – 7.2
- May contain inert dye (blue) for identification

Formulation:

Ready-to-use liquid reagent, supplied in leak-proof dropper bottles (5 mL – 20 mL).

Table 9.4: Performance Requirements

Parameter	Specification
Titer	1:256 (tube method)
Reaction Strength	3 + to 4 + with known A1 cells
Specificity	No agglutination with B or O cells
Shelf Life	12 months from delivery
Storage	2 –8 °C (do not freeze)

Labeling:
Must indicate reagent name, lot number, expiry date, manufacturer, storage conditions, volume, and color code (Blue).
Documentation Required:

- Certificate of Analysis (CoA) with lot number
- DRAP registration proof / Free Sale Certificate
- Manufacturer's Instructions for Use (IFU)
- Safety Data Sheet (SDS)

Quality Control:
Each new lot must be verified with:

- Positive control: Group A1 red cells
- Negative control: Group B or O red cells
  Expected results: 3 + to 4 + / 0

General Note:

- Maintain cold-chain transport (2–8 °C) with temperature log.
- Minimum residual shelf life at delivery: 12 months × 80 % remaining.
- Lot verification testing mandatory before routine use.

Document all details in Reagent Receipt and Verification Register and retain CoA for two years post-expiry.

9.4.2 Specification Sheet 2: Anti-B Blood Grouping Reagent

Product Name:
Anti-B (Monoclonal) Blood Grouping Reagent
Intended Use:
For detection of B antigen on human red blood cells by agglutination methods.
Principle:
Monoclonal Anti-B antibodies agglutinate red cells carrying the B antigen.
Composition:

- Monoclonal Anti-B antibody (IgM)
- Buffered saline with preservatives
- pH 6.8 – 7.2
- Inert dye (Yellow)

Formulation:
Ready-to-use reagent, stable between 2–8 °C.

Table 9.5: Performance Requirements

Parameter	Specification
Titer	1:256 (tube method)
Reaction Strength	3 + to 4 + with known B cells
Specificity	No agglutination with A or O cells
Shelf Life	12 months
Packaging	5 mL–20 mL dropper bottle, tamper-proof

Labeling:

Include reagent name, manufacturer, lot number, expiry, storage, volume, color code (Yellow).

Documentation Required:
CoA, IFU, SDS, DRAP approval / import license.

Quality Control:

- **Positive control:** Group B red cells
- **Negative control:** Group A or O red cells
  Expected: 3 + to 4 + / 0

General Note:

- Maintain cold-chain transport (2–8 °C) with temperature log.
- Minimum residual shelf life at delivery: 12 months × 80 % remaining.
- Lot verification testing mandatory before routine use.
- Document all details in Reagent Receipt and Verification Register and retain CoA for two years post-expiry.

9.4.3 Specification Sheet 3: Anti-AB Blood Grouping Reagent

Product Name:

Anti-AB (Monoclonal Blend) Blood Grouping Reagent

Intended Use:

For detection of A and B antigens on red blood cells; used as a confirmatory reagent to identify group AB or O.

Principle:

Contains a blend of monoclonal Anti-A and Anti-B antibodies that agglutinate red cells expressing either A or B antigens.

Composition:

- Monoclonal Anti-A + Anti-B antibodies
- Buffered saline with preservatives
- pH 6.8 – 7.2
- Colorless solution

Formulation:

Ready-to-use reagent, liquid form, 2–8 °C storage.

Table 9.6: Performance Requirements

Parameter	Specification
Titer	1:128 (tube method)
Reaction Strength	3 + to 4 + with A, B, AB cells
Specificity	No agglutination with group O cells
Shelf Life	12 months
Container	Clear, tamper-evident dropper bottles

Labeling:

Name, lot number, expiry, storage, manufacturer, colour code: Colourless.

Documentation:

CoA, IFU, SDS, DRAP compliance certificate.

Quality Control:

- Positive controls: A1 and B cells
- Negative control: O cells
  Expected: 3 + to 4 + / 0

General Note:

- Maintain cold-chain transport (2–8 °C) with temperature log.
- Minimum residual shelf life at delivery: 12 months × 80 % remaining.
- Lot verification testing mandatory before routine use.
- Document all details in Reagent Receipt and Verification Register and retain CoA for two years post-expiry.

9.4.4 Specification Sheet 4: Anti-D (Rh) Blood Grouping Reagent

Product Name:

Anti-D (Rh) Blood Grouping Reagent – Monoclonal Blend

Intended Use:

For detection of D (Rh) antigen on red blood cells by slide, tube, or microplate method.

Principle:

Monoclonal Anti-D (IgM and/or IgG blend) antibodies agglutinate D-positive red cells. The blend improves sensitivity and detects weak D variants.

Composition:

- Monoclonal Anti-D antibodies (IgM or IgM + IgG)
- Buffered saline solution with preservatives
- pH 6.8 – 7.2
- Colorless or light-green solution

Formulation:

Ready-to-use liquid reagent, 5–10 mL dropper bottles, suitable for tube, slide, and gel methods.

Table 9.7: Performance Requirements

Parameter	Specification
Titer	1:128 (tube method)
Reaction Strength	3 + to 4 + with Rh(D) positive cells
Specificity	No agglutination with Rh(D) negative cells
Detects Weak D	Yes (if IgG + IgM blend)
Shelf Life	12 months
Storage	2–8 °C, avoid freezing

Labeling:

Include product name, "Anti-D (Rh)", lot number, expiry, manufacturer, volume, colour code = Green or Clear.

Documentation:

CoA, IFU, SDS, DRAP registration, stability data, performance validation.

Quality Control:

- Positive control: Rh(D) positive cells
- Negative control: Rh(D) negative cells

Expected result: 3 + to 4 + / 0

General Note:

- Maintain cold-chain transport (2–8 °C) with temperature log.
- Minimum residual shelf life at delivery: 12 months × 80 % remaining.
- Lot verification testing mandatory before routine use.
- Document all details in Reagent Receipt and Verification Register and retain CoA for two years post-expiry.

9.5 Model Specifications for Procurement of Blood Bags

9.5.1 General Requirements

- All plastic blood bags shall conform to ISO 3826-1 standards, except 5 days platelet storage bag, and be licensed by the Drug Regulatory Authority of Pakistan (DRAP).
- The bag material must be biocompatible, non-toxic, non-pyrogenic, non-haemolytic, and phthalate (DEHP) plasticized PVC or equivalent approved polymer.
- Closed, sterile, disposable system with integrally attached tubes and satellite bags to prevent contamination and air embolism.
- Shelf life: minimum 3 years from manufacturing; residual shelf life at the time of supply should be at least 3/4 of the total shelf life.
- The manufacturer must provide ISO13485 certification, EU Quality Management System Certificate, Certificate of Analysis (CoA), and stability data (not older than 3 years).

9.5.2 Biocompatibility and Performance Certification

Documentary evidence of the following tests must accompany each tender lot:

- Cell-culture cytotoxicity
- Haemolysis rate (≤ 0.8 % at expiry)
- Systemic toxicity / pyrogen test
- Sensitization and intracutaneous irritation
- Sterility (no growth in aerobic/anaerobic conditions)
- Biochemical stability at day 28 / 35 / 42 for CPD, CPDA-1, CPD-SAGM bags:
  - Plasma pH ≥ 6.8
  - ATP ≥ 70 % of initial
  - 2,3-DPG ≥ 50 % of initial
  - K^+ ≤ 40 mEq/L
  - ≥ 75 % viable RBC 24 h post-transfusion
  - DEHP leaching ≤ 0.01 % w/v

9.5.3 Design and Construction

Table 9.8: General specifications of blood bag

Parameter	Specification / Requirement
Material	DEHP-plasticized PVC, transparent, flexible, non-collapsible under vacuum, non-vented.
Capacity	Single/Double/Triple/Quad configurations (600 mL ± 10 %).
Primary Bag	450 mL whole-blood collection; marked graduations at 50 mL intervals.
Satellite Bags	400 mL each for plasma and platelet storage (5-days platelets storage bag - TOTM plasticizer - which ensure the platelet could preserve up to 5-7days)
Tubing	Transparent, non-kinking, minimum 100 cm from bag to needle; printed ID/segment numbers; integral break-off closure.
Needle	double layer siliconization 17 G ultra-thin wall, rust-proof stainless steel, beveled tip, hermetically sealed, fitted with protective cover and needle-safety shield to prevent sharps injury. Needle system should haveindicator for bevel up
Needle Cap	The protective coverings (needle cap) on the blood taking needle must be is easily removable and tamper proof without be re-capped.
Needle Guard	The needle guard (needle-safety shield) should prevents accidental needle-stick injuries after use. Once the blood collection is completed, needle must be smoothly pulled by the operator into the needle protector device (NPD) and lock. Must be signalled to personnel by an audible click or tactile indication. the entrance surface of NPD must extend at least 8mm beyond the tip of the needle. The collection needle should not slide out from the NPD .The needle protection should be welded.
Ports	Tamper-proof, resealable, sterile access ports for component transfusion and additive transfer.
Slits for Hanging	Adequate for safe suspension during transfusion.
Sampling Device	Integrated diversion pouch (up to 50 mL) with multiple-sampling Luer adapter for pre-donation sampling. It should be easy to insert vacuum tubes for blood sampling. The barrel should be transparent, and the barrel must extend at least 18mm beyond the tip of the sampling needle. The vacuum tube holder should have a cap. The cap must not fully detach from the vacuum tube holder barrel when opened, in order to ensure it remains "in situ" for closing following sample collection. The cap can be opened by one hand.
Resistance to Distortion	Must withstand 5,000 g for 30 min at 4–24 °C without leakage or deformation.
Temperature Resistance	Integrity maintained up to −80 °C for component freezing.

9.5.4 Anticoagulant and Additive Solutions

Table 9.9: Anticoagulant and Additive Solutions

Type	Composition / Volume	Appearance	Remarks
CPDA-1	63 mL per 450 mL blood volume	Clear, colourless	Manufacturer must supply CoA for composition and sterility.
SAGM	100 mL ± 5 mL per satellite bag	Clear, colourless	For red-cell preservation up to 42 days. Volume of SAGM solution in related to the whole blood collection and generally is assigned like this; 350ml – 78ml / 450ml – 100ml / 500ml –110ml
No discoloration or precipitation allowed during storage at 25 °C.			

9.5.5 Packaging and Labeling

- Primary packaging: individual sterile plastic pouch; secondary: aluminum foil pack (1–6 bags).
- Label must state: product name, capacity, lot number, date of manufacture, expiry, storage (≤ 28 °C), anticoagulant type, and manufacturer details.
- The label cannot be peeled off from bag even at subzero temperature during centrifugation
- Temper proof labels
- Labeling information in compliance to ISO 3826
- Aluminum pack to bear note: "Use within 15 days after opening."
- Tertiary packaging: corrugated carton (10-12 foil packs) clearly marked with quantity, weight, consignee, and handling instructions.
- Each carton must contain:
  - o Manufacturer's CoA and test reports
  - o Declaration: "Blood may be collected up to the expiry date marked on the label."

9.5.6 Storage, Transport, and Sterility

- Must arrive moisture-free and externally sterile.
- Transport under temperature-controlled conditions (≤ 28 °C) with records of each shipment.
- Conform to Hospital Waste Management Rules 2022, National Hazardous Waste Management Policy, 2022. for safe disposal post-use.

9.5.7 Evaluation and Documentation

- Minimum five sample bags to be submitted for technical evaluation per tender.
- Supplier to provide satisfactory user performance reports from at least two reputable public institutions (last 3 years).
- All quality-assurance reports must be current (≤ 5 years old).

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