Guidelines For Quality Control In Blood Banking

2007

National AIDS Control Programme
Ministry of Health - Government of Pakistan
www.nacp.gov.pk

Model Standard Operating Procedures For Blood Transfusion Service

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Foreword

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 fulfil 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.

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Acknowledgements

The first draft of these guidelines was formulated during the course of a three day consultative workshop held at Islamabad under the auspices of the National AIDS Control Programme. It was participated by the Programme Managers of BTS from the four provinces and AJK namely, Prof. Dr. Yasmin Lodhi (Punjab), Prof. Dr. Fazale Raziq(NWFP), Prof. Dr. Nadeem Samad Sheikh(Balochistan), Dr. Zahid Hasan Ansari(Sindh) and Dr. Irum Gilani, besides prominent haematologists from the public and private sector including Prof. Dr. Khalid Hasan(PIMS), Dr. Hasan Abbas Zaheer(PIMS), Dr. Tahir Shamsi (BITS), Dr. Rafi Ahmed(IBTS), Dr. Shagufta Hussain(PIMS) and Dr.Shaheen Kauser(BITS).Their valuable efforts need to be acknowledged gratefully.

The draft was reviewed by various experts notably Prof. Dr. Khalid Hasan(PIMS) and Dr. Tassadaq Farooq(DHQ Rawalpindi).We were fortunate to avail the professional guidance and expertise of Maj. General(r) Masood Anwar, the Executive Director of NIH, himself an eminent hematologist of the country.

These documents are adapted for use in Pakistan and draw from the Quality control documents of the European Union and Technical Manual of American Association of Blood Banks.

Dr. Tasneem Shahid (NACP) needs a special mention for his valuable efforts with the editing of this document. The Programme is particularly grateful to Dr. Umar Farooq, Quality Assurance Officer and Incharge BT component, whose diligence and hard work made the finalization of this document possible.

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Introduction

Blood transfusion services have become an integral part of the health-care system. It is an essential function of the health services to provide safe blood to all those who need it in an efficient, coordinated and cost-effective manner. Safety of blood has assumed greater importance and relevance in developing countries where HIV, hepatitis B and hepatitis C are becoming diseases of greater public health importance and the HIV/AIDS pandemic is growing at an alarming pace.

To ensure the continued safety of the nation's blood supply, it is essential that blood establishments implement effective control over manufacturing processes and systems. This can be accomplished by each blood establishment developing a well planned, written, and managed Quality Assurance program designed to recognize and prevent the causes of recurrent deficiencies in blood establishment 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 Quality Assurance 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 this guideline is to assist manufacturers of blood and blood components, i.e., blood banks and transfusion services, in developing a quality assurance (QA) program 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 blood establishment personnel along these lines. Moreover, it is to be emphasized that this is meant to be a living document and will be adopted periodically to reflect the lessons learnt.

Quality Management In Blood Transfusion Service

Quality Management in blood transfusion service is concerned with every aspect of transfusion practice and applies to all its activities. It involves identification and selection of prospective blood donors, adequate collection of blood, preparation of blood components, laboratory testing and ensuring the most appropriate use of blood/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. 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 and documentation, use of standard operating procedures and laboratory worksheets, and implementation of safety guidelines will further improve the quality performance of the services.

Responsibilities & Implementation:

Quality System

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Requirements For Quality Systems In Blood Transfusion Services

It is the responsibility of governments to ensure that the blood and blood products provided for clinical use by the national blood program are safe, adequate, effective and produced consistently to the appropriate standards. To achieve this, the blood transfusion service must develop an effective quality system. This should provide a framework within which BTS activities are established, performed in a quality-focused way and continuously monitored to improve outcomes. Prerequisites for developing a quality system within the national blood program include:

- Nationally-coordinated blood transfusion service
- Commitment and support of management at all levels
- Recognition of the importance of quality in the national blood policy
- National quality policy and quality plan detailing the strategy, mechanism and resources for their implementation
- Designation of a national quality manager with the necessary responsibility and authority for the development, implementation and monitoring of the quality system
- Provision of appropriate, adequate and sustainable resources to support the development and maintenance of the quality system.

Organizational Management

Central to an effective quality system is commitment and support from management at all levels, including:

- Clearly defined organizational structure that defines accountability, authority and responsibility
- Designation 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 which quality activities can be coordinated
- Development of a culture of quality through a management focus 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.

Standards for Quality Systems

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

- The existence of any relevant national legislation or regulations must be acknowledged and incorporated into the framework for quality
- Standards may be national or international: e.g. International Organization for Standardization (ISO) and Good Manufacturing Practice (GMP)
- The standards adopted must be relevant to the BTS and its activities.

Documentation

An effective and accurate documentation system that ensures traceability of all BTS activities is the foundation of good quality management. Important activities in this regard include:

- Development of a quality manual: a document describing the qualitysystem, 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 issue, use and retrieval of documents.

Training

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

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

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
- Ongoing collection and analysis of data generated from key activities and their use in quality improvement
- Establishment of haemo-vigilance 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
- 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.

Financial Resources

A careful planning of budget is necessary for adequate financial support for academic, research and service components. The limited resources necessitate optimizing the cost of delivering quality service. Therefore it is important to carry out a cost analysis for BTS which will help in the planning of a budget. This analysis will justify the funding and help in evaluating and monitoring cost effectiveness.
Funding of the BTS system is ultimately the responsibility of the national authorities. Where possible, 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 program at national, state and local levels; staff salaries; costs of training health care workers and blood transfusion personnel; office supplies and equipment; maintenance of a quality assurance program; and support for research and development in the area of blood transfusion services.

Quality Control of Procedures in Blood Banking

Scope:
Standard Operating Procedures.

SOPs constitute an important parameter for quality control; these are specific procedures which are written by the in-charge of the blood unit. There use is compulsory every time an activity is performed in the blood bank.

Test Reagents & Equipment.

- After proper validation, all the test reagents & kits should be stored and used according to manufacturer's instructions.
- Test procedures to be documented and kits & reagents stock inventory maintained.
- Every test donation should be traceable for batch number, manufacturer of kit & reagents.
- Record should be maintained of the test equipment, its validation, calibration & repair etc.
- Control samples should be run with every batch / series of tests.

Reporting Results

The laboratory test reports should be reported and recorded either manually or by computer.

Release of tested components

Standard procedures must ensure that blood/blood components should only be released for issue after performing all mandatory & additional tests.

Test results should be issued by a designated person either computerized or manually.

Routine Procedures Performed in Blood Banks

- ABO & Rh Blood Grouping Mandatory
- Anti Globulin Tests
- Screening for TTIs Mandatory
- Compatibility Testing Mandatory
- Component Preparation
- Transportation of Blood/Components
- Infectious Waste Disposal Mandatory

ABO & RhD Blood Grouping

- ABO & RhD Blood Grouping must be determined on each blood donation. The primary and any derived component be labeled.
- Forward and reverse grouping must be performed on previously unknown ABO group.
- Only forward ABO grouping is sufficient for previously known ABO blood groups.

Quality Control of ABO Blood Grouping

- Only approved reagents should be used.
- QC of procedures recommended by reagent and equipment manufacturer should be followed.
- Before a blood grouping reagent is used, appropriate reactivity with control cells should be performed.

The following minimum controls are required for ABO blood grouping tests:

Reagent	Control
Anti-A	A**1** , A**2** & O Cells
Anti-B	B, & O Cells
Anti-AB	A**1** , A**2** , B & O Cells

The control cells should be prepared by pooling of 3 red cell samples of the same blood group.

Quality Control of RhD Grouping

- Only approved reagents should be used.

- QC of procedures recommended by reagent and equipment manufacturer should be followed.
- Before a b/g reagent is used, appropriate reactivity with control red cell samplesshould be confirmed. For each series of RhD b/g tests unequivocal appropriate reactions must be obtained with R1r red cells as a +ve control and rr or r1r as ve control.
- Appropriate reactivity with control red cell samples expressing weak D should also be confirmed regularly during use, although not necessarily with each series of tests.

NOTE:

When the blood grouping is not performed in batches or series the appropriate reactivity of ABO & RhD reagents should be checked at leastonce in the morning of each working day.

Quality Control of Anti Globulin Testing (Optional)

- DAT is optional test on collected blood donations.
- Group O red cells sensitised with IgG antibody should be used as positive control.
- Blood & Blood components from DAT +ve donation should not be used.
- FFP of DAT +ve donation may be used for fractionation if the fractionator's specifications allow.
- Donors with +ve DAT for more than 1 year should be removed from donor list and referred to physician.

Quality Control of Screening for TTIs

Mandatory Screening Tests for TTIs

1. HBsAg
2. Anti HCV
3. Anti HIV 1&2
4. Syphilis
5. Malaria

Quality Control of HBsAg, Anti HCV, Anti HIV 1&2 and Syphilis Screening Tests

Follow the Manufacturer's instructions and SOPs.

- Only approved kits should be used for screening of TTIs which should meet predefined criteria for specificity & sensitivity.
- In addition to the manufacturer's controls provided with the kit, additional internal quality control measures (weak positive sample) should 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.

Quality Control of Tests for Malaria

Follow the Manufacturer's instructions and SOPs

- Standard stains {*Only approved* }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 immunchromatographic or other technique is used an additional quality control (weak +ve sample) should also be run to validate the method and kit.

Q/C Schedule for TTIs

- If the daily screening for TTIs is 100 or more tests then run the controls withevery 100 tests.
- If the number is 30 to 100 then once every day.
- If the number is less than 30 then once a week

Documentation

a) The date on which the test is run.
b) Name of the kit used.
c) Lot No. and Expiry date of the kit.
d) Signatures of the technician.
e) Signature of the Supervisor.
f) Reactive units are marked in red and are separated from the stock.

Algorithm for TTIs

Initial Screening Test

1. Positive Reaction (Hold the donation) — No Reaction (Release to Stock)

2. Repeat Screening (Serum X 2)

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 lab (NACP for HIV)

Positive Result:	Negative or Indeterminate Result:
Flag donor record as permanent deferral not to be bled for clinical use. Arrange counseling and investigation of donor.	Donation not to be used. Defer donor for six months and if found negative, reinstate as active donor.

Blood and Blood Components

- Label on Bag
- Name of the product.
- Donation Number/Donor Number.
- ABO & Rh Group.
- TTIs Screening Result.
- Volume of the Product.
- Expiry Date.
- Storage Temperature.

Whole Blood

1 % of the collected donations be tested for the parameter given below. A minimum of 75% of those donations tested for parameter should meet the specification.

Volume	450 ± 45 ml + Anticoagulant Volume	RBC

Concentrate

1 % of the collected donations be tested for the parameters given below. A minimum of 75% of those donations tested for parameters should meet the specification.

Parameter	Frequency of Test	Specifications
Volume	1 %	350 ± 70 ml
Hct	1 %	0.50 to 0.70

Fresh Frozen Plasma

1 % of the prepared products should be tested for the parameters given below. A minimum of 75% of those donations tested for parameters should meet the specification.

Parameter	Frequency	Specifications
Volume	1 %	350 ± 70 ml
Hct	1 %	0.50 to 0.70

Cryoprecipitate

1 % of the prepared products should be tested for the parameters given below. A minimum of 75% of those donations tested for parameters should meet the specification.

Parameter	Frequency	Specification
Volume	1 %	35-50 ml
Factor VIIIc	1 %	> 0.7 IU / ml
Fibrinogen	1 %	> 140 mg/unit

Platelet Concentrate

1 % of the prepared products should be tested for the parameters given below. A minimum of 75% of those donations tested for parameters should meet the specification.

Parameter	Frequency of Test	Specifications
Volume	1 %	50 to 80 ml
Pltcount	1 %	≥ 55 X 109/unit
pH on day 5	1 %	6.4 to 7.4

Pooled Platelet Concentrate

1 % of the prepared products should be tested for the parameters given below. A minimum of 75% of those donations tested for parameters should meet the specification.

Parameter	Frequency of Test	Specifications
Volume	1 %	200to 300 ml
Plt count	1 %	≥ 220 X 109/unit
pH on day 5	1 %	6.4 to 7.4

Apheresis Platelet Concentrate

(Equivalent to10 units of Plt Conc)
1 % of the prepared products should be tested for the parameters given below. A minimum of 75% of those donations tested for parameters should meet the specification.

Parameter	Frequency of Test	Specifications
Volume	1 %	200to 300 ml
Plt count	1 %	? 55 X 1010/unit
pH on day 5	1 %	6.4 to 7.4

Q/C of Compatibility Testing

- Follow the manufacturer's instructions and SOPs.
- Use Group O red cells sensitized with IgG antibody as +ve control**('O' Rh D+ve RBCs + IgG anti-D)**
- Use +ve control cells with every compatibility testing.

Quality Control of Reagents

I. INTRODUCTION

Reagent quality control must be performed and documented each day of use and whenever a new vial is opened during the day. Q.C. is performed to check that certain critical control points in both patient and donor unit testing will be performed within specific parameters if reagents are used according to both this facility's S.O.P. and reagent manufacturer's instructions.

All the staff should be trained in performing quality control. At any one time one technician should be assigned this task.

II. PRINCIPLE

Each day, a technologist must confirm that the reagents react as expected when used. If a reagent does not give the expected results, the control must be repeated. If the results are still incorrect, the vial should be discarded and a new vial must be tested.

The QC is done to test the quality and specificity of reagents. Titer and avidity are checked by the manufacturer before the lot number is released.

Results of daily QC must be recorded on the quality control form. All the information written on the sheet shall be filled in correctly and completely.

QC forms attached at ANNEX I.

III.MATERIALS, EQUIPMENT AND REAGENTS

1.Anti-A
2.Anti-B
3.Anti AB
4.A_1 cells
5. B cells
6. O cells
7. Anti-D
8. SC I
9. SC II
10. SC III
11. Antiglobulin reagent (Coomb's)
12. IgG coated red cells (Check cells)
13. Anti-c, or Anti-e antisera
14. 22% Albumin
15. 6% Albumin
16. Isotonic saline
17. 12X75mm Test tubes
18. Markers
19. Disposable pipettes
20. Agglutination viewer
21. Centrifuge
22. Dry heat block/Water bath

IV. PROCEDURE

1) Label tubes 1 through 15 with numerals for the following according to exact sequence of negative and positive controls as given below:

1. Anti-A + A_1 cells
2. Anti-A + B cells
3. Anti-B + A_1 cells
4. Anti-B + B cells
5. AHG + Check cells
6. AHG + O cells

7. Check cells + normal saline
8. Anti-D + O positive cells
9. Anti-A + O positive cells
10. Anti-D + SC. I
11. Anti-D + SC. II
12. Anti-D + SC.III
13. 22% Bovine Albumin + SC. I
14. 6%Bovine Albumin (Rh control) + SC. II
15. Anti-c (or Anti-e) + SC. III

(Note: Procedures from 10-15 are Optional)

(2) Place 1 drop of required antisera (as mentioned above) appropriately to each tube except in tubes 5 and 6 where 2 drops of AHG will be placed and in tube #13 three drops of 22% Albumin will be added.

(3) Check all the tubes to make sure that antisera have been added.

(4) Add 1 drop of cell suspension as designated in the Q.C. form (mentioned above) into respective tubes.

(5) Perform an immediate spin on all the tubes.

(6) Read the results macroscopically with the agglutination viewer after the tubes have been spun.

(7) Grade and record results on the Q.C. form.

(8) Place tube # 12 at 37°C for 15 minutes.

(9) Wash tube # 12 three times with normal saline using 'n wash' program in the cell washer after incubation. If performing manually, decant supernatant completely.

(10) Add 2 drops of AHG.

(11) Use 'mix and centrifuge program' on cell washer. Otherwise mix well and centrifuge at 2500rpm for 20 seconds.

(12) Spin, grade and record results on Q.C. form.

(13) Add 1 drop of check cells to negative tubes.

(14) Spin, grade and record results.

(15) The expected results are listed on the left hand side of Q.C. form and all reactions should be qualified against the expected results.

(16) Each reaction will be judged by the technologist as ok ($\surd$), indicating that the reaction is satisfactory.

(17) Any unacceptable results should be repeated at least once and must be documented for the corrective action on the backside of Q.C. form.

(18) If a new vial is opened during the day, Q.C. for the reagent must be performed and documented on a separate new Q.C sheet with date, time and initials of the technologist.

- Use best judgment when troubleshooting why a reagent may not react as expected.

V. RESULTS

With the help of grading system for agglutination, grade and record reactions. All the reactions should be interpreted as acceptable or unacceptable.

Satisfactory: if the reaction meets or exceeds the expected reaction.

Unsatisfactory: if results are not within the expected limits.

NOTES:

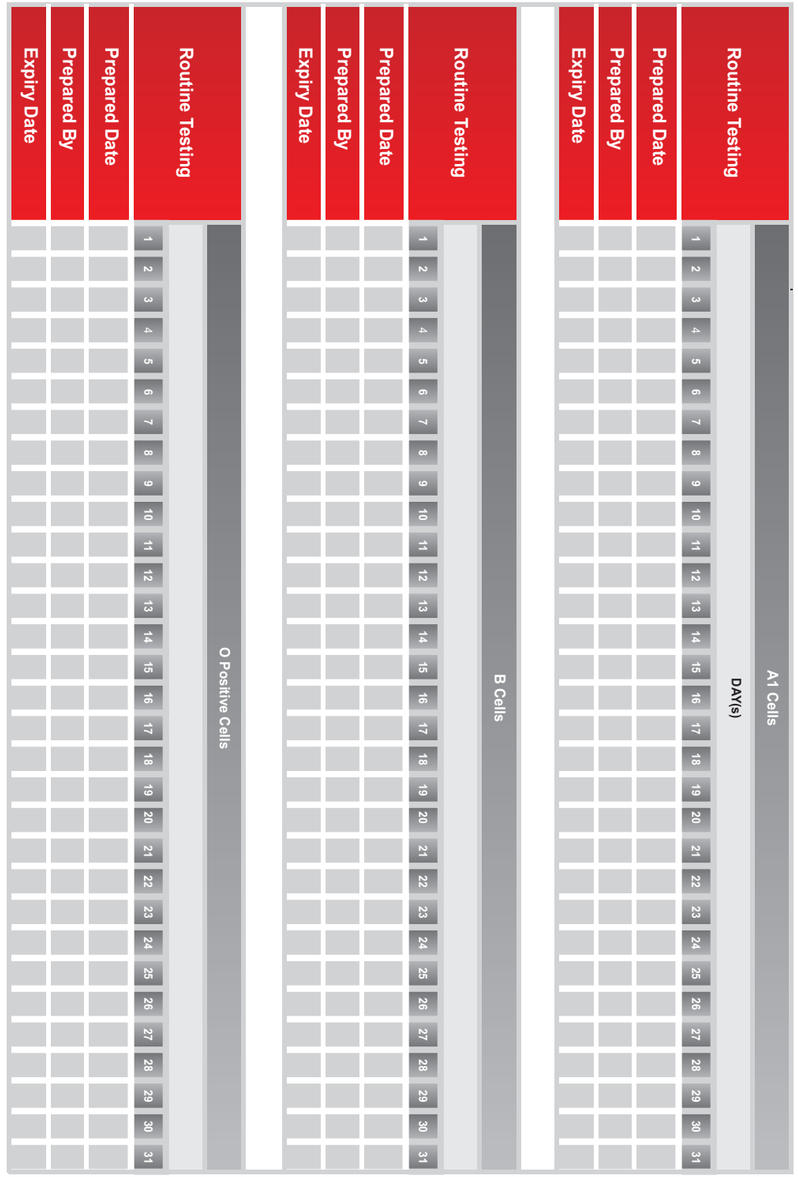
- Q.C. of the reagent rack is the first step justifying the validity of patient and donor results.
- The reagent rack should be kept out of extreme temperatures and should optimally be stored between 2-8 °C when not in use.

VI. DOCUMENTATION

- Refer to Quality control form for guidance and to log results.
- Record the lot# of all reagents required in reagent rack in appropriate space next to the corresponding reagent specificity on the bottom of the Q.C. form on day 1 of respective week. Also record expiration date of each reagent.
- The reagents should be checked against the logged lot# and expiration to make sure that no new lots have been opened without documentation in respective week.
- When a new bottle of reagent is placed in rack to use, check to see if the lot number has been changed, if so, then complete the appropriate change of reagent in the lower right half of the Q.C. form with new lot#, manufacturer name, date when reagent was placed in the rack and expiration date.
- All bottles of reagents should be inspected daily for appearance. The reagents appearance should be documented as satisfactory (√) or unsatisfactory (X) in the appropriate space on the bottom of the Q.C. form each day of use.
- A notation of unsatisfactory would require an explanation in the space provided at the back of Q.C. sheet.

ANNEX-1

Quality Control- Reagents



Quality Control of Components

I. PRINCIPLE:

Ensuring safe and efficacious 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 there after. The contents of final blood products should be periodically assessed to make sure they meet the QC standards on blood products: QC testing on packed cells and platelets is performed twice a month.

Component production should be done within 6 hours after blood collection. The Hematocrit on packed cells must be < 80% because the ratio of red cells to preservative must be correct to ensure the viability of the red blood cells. A HCT of < 80% ensures the presence of adequate glucose for red cell metabolism for up to 35 days of storage. The frequency of testing is every 100th bag.

The count and pH of platelets must be > 5.5 x 1010 and > 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. Store at 22 °C (room temperature) on continuous agitation.

II. SPECIMEN:

- For packed red cells: a segment is required from each donor unit with the appropriate segment # (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 (for segment leave at least 2 segments with number on platelet unit
- Specimen for culture.

III. REAGENT'S AND EQUIPMENT:

- Hematology Analyzer
- Hitachi cup
- Scissors
- pH meter
- Component QC form
- Pen

IV. PROCEDURE:

A. For red cell or packed cell: HCT Testing

i. Detach 1 segment (newly made, from P/C not the original segment made from W/B) from three donor units of different types, made o different shifts if possible.
ii. Take the contents of each segment and place into a 12 x 75 test tub or Hitachi cup, which is properly labeled with each unit number, an mix well.
iii. Run these samples on the hematology Sysmex analyzer and record the results on the QC log sheet on each unit.
iv. HCT of each unit must be ≤ 80%.
v. Send for culture & Enter culture results.

b. Leucodepleted Red Cell Concentrates:

i. Apart from all specifications of A i-v., residual WBC count should be $<5x10^6$/l.
ii. Stored at 4 +/- 2 °C for up to 35 or 42 days according to the bag and whether S AG-M solution is added in the final product bag.

C. For Platelet: PLT Count and pH:

i. Examine three units prepared on different shifts if possible, on the 5th day from collection.

ii. Detach a segment from each unit and collect the contents into a properly labeled Hitachi cup.

iii. Run the sample on the hematology analyzer.

iv. Note the platelet count for each donor on QC sheet.

v. Weigh empty bag unit.

vi. Weigh each platelet bag in gm (record on sheet). (gm = ml)

vii. Calculate the yield of each unit by the following formula:

Yield of the unit = count of platelet of unit x weight of unit in gm (or volume ml) x 1000

viii. Note down the yield on the QC log sheet. Yield should be > 5.5 x 1010 in 90 % of the donor units tested. (single donor unit)

ix. Yield should be > 30 x 1010 in 90 % of the apheresis donor units tested. (Plateletpheresis unit equivalent to 6 – 10 single donations of platelets).

x. Also check the pH of each platelet unit; which must be > 6.2 in 90% of donor units tested. The pH meter is located in Histopathology.

xi. Record results on worksheet.

D. For Fresh Frozen Plasma:

i. Examine physical appearance of FFP for colour.

ii. Volume should be 150 – 200 ml.

iii. Every 100th bag should be checked for factor VIII level. It should be >0.71 units/ml.

iv. FFP should be stored at < -18 °C up to one year.

E. For Cryoprecipitate:

i. Examine physical appearance of Cryo for colour.

ii. Volume should be 30 – 50 ml.

iii. Every 100th bag should be checked for:

i. Factor VIII C level. It should be >0.71 units/ml.

ii. Fibrinogen >140 mg/unit

iv. Cryo should be stored at < -30 °C up to one year.

F. For Cryosupernatant:

i. Examine physical appearance of Cryosupernatant for colour.

ii. Volume should be 130 – 180 ml.

iii. Every 100th bag should be checked for factor IX level. It should be >0.71 units/ml.

iv. Cryosupernatant should be stored at < -18 °C up to one year.

NOTE:

- Make sure that the units tested are prepared by different shifts, if possible.
- Choose those platelet units that expire the same day (5 days old).
- Also check for physical hemolysis or any bacterial contamination of units, by observing color and consistency.

Quality Control of Equipment

Quality System Essentials defines that qualification, calibration, maintenance and monitoring 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.
- For new equipment policies and procedures should include a requirement to define the criteria for selection and requirement for installation, calibration and qualification.
- After installation there must be a documentation of any problem and regular follow up must be done.
- 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.
- Facility or authority 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.
- All these activities should be periodically reviewed and recorded.
- Evaluation of equipment and trend 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.
- F.D.A approved or authority approved control needs to be run with every batch of screening of Hepatitis B surface antigen, anti HCV and HIV-I and HIV-II.
- No pooling of serum should be done for screening.
- Quality Control Charts are placed at the end of this section.

Blood Bank Serofuge Maintenance Plan

Daily maintenance (For 31 days)

Date	CLEANED	INSPECTION.	TECH.

Pick (√) under respective column if the procedures mentioned above have been performed.

Supervised By ..... Date .....

Refrigerator Temperature Log Sheet
Range (1-6 Degrees Celsius)

Month: _____ Year: _____ Month: _____ Year: _____

Date	Digital Temp	Internal Temp	Chart (ok?)	Initials	Date	Digital Temp	Internal Temp	Chart (ok?)	Initials
1					1				
2					2				
3					3				
4					4				
5					5				
6					6				
7					7				
8					8				
9					9				
10					10				
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18					18				
19					19				
20					20				
21					21				
22					22				
23					23				
24					24				
25					25				
26					26				
27					27				
28					28				
29					29				
30					30				
31					31				

Date	Corrective Action/Alarms/Comments

Supervised By: _____ Supervised By: _____

Log Sheet For Quarterly Alarm Checks of Blood Bank Refrigerator

Year_____

High Activation

Date	Temp. Alarm activates > 6°C	satisfactory Unsatisfactory

Low Activation

Date	Temp. Alarm activates ≥ 1°C	Satisfactory Unsatisfactory

Supervised By: _____ Supervised By: _____

Freezer Temperature Log Sheet

Temperature Range: (-18˚c To -87˚c)

Date	Shift	Digital Temp	Internal Temp	Tech
1	M			
	E			
	N			
2	M			
	E			
	N			
3	M			
	E			
	N			
4	M			
	E			
	N			
5	M			
	E			
	N			
6	M			
	E			
	N			
7	M			
	E			
	N			
8	M			
	E			
	N			
9	M			
	E			
	N			
10	M			
	E			
	N			
11	M			
	E			
	N			
12	M			
	E			
	N			
13	M			
	E			
	N			
14	M			
	E			
	N			
15	M			
	E			
	N			
16	M			
	E			
	N			
	M			
	E			
	N			

Date	Shift	Digital Temp	Internal Temp	Tech
17	M			
	E			
	N			
18	M			
	E			
	N			
19	M			
	E			
	N			
20	M			
	E			
	N			
21	M			
	E			
	N			
22	M			
	E			
	N			
23	M			
	E			
	N			
24	M			
	E			
	N			
25	M			
	E			
	N			
26	M			
	E			
	N			
27	M			
	E			
	N			
28	M			
	E			
	N			
29	M			
	E			
	N			
30	M			
	E			
	N			
31	M			
	E			
	N			

Date	Corrective action	Tech

QUARTERLY ALARM

Date: _____ Red Light on [y] [N] Tech:

Serologic Centrifuge Calibration Work Sheet

Instrument Identification: _____

Date calibration/performance testing: _____ Technologist initials: _____

Phase of Reaction	Saline	AHG	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							
MANUAL WASHING CHECK	TUBE PAIRS						
TIME OF SPIN: 30 SEC	AHG 10 SEC POS			AHG 10 SEC NEG			
CLEARLY DELINEATED BUTTON?				CRITERIA: ▪ Clearly delineated button yes ▪ Few cells trailing up the side of the tube –yes ▪ Cell button easily resuspended in residule fluid- yes			
CELLS TRAILING UP SIDE OF TUBE?							
CELLS EASILY RE-SUSPENDED?							

TIME OF SPIN: 45 SEC	AHG 15 SEC POS		AHG 15 SEC NEG
CLEARLY DELINEATED BUTTON?			
CELLS TRAILING UP SIDE OF TUBE?			
CELLS EASILY RE-SUSPENDED?			

TIME OF SPIN: 60 SEC	AHG 20 SEC POS		AHG 20 SEC NEG
CLEARLY DELINEATED BUTTON?			
CELLS TRAILING UP SIDE OF TUBE?			
CELLS EASILY RE-SUSPENDED?			
CLEARLY DELINEATED BUTTON?			
CELLS TRAILING UP SIDE OF TUBE?			
CELLS EASILY RE-SUSPENDED?			
CLEARLY DELINEATED BUTTON?			
CELLS TRAILING UP SIDE OF TUBE?			
CELLS EASILY RE-SUSPENDED?			
TIME OF SPIN: 90 SEC	AHG 30 SEC POS		AHG 30 SEC NEG
CLEARLY DELINEATED BUTTON?			
CELLS TRAILING UP SIDE OF TUBE?			
CELLS EASILY RE-SUSPENDED?			
TIME OF SPIN: 120 SEC	AHG 45 SEC POS		AHG 45 SEC NEG
CLEARLY DELINEATED BUTTON?			
CELLS TRAILING UP SIDE OF TUBE?			
CELLS EASILY RE-SUSPENDED/			
OPTIMAL TIME FOR WASHING IS: SEC:			

PHASE OF REACTION	SALINE	AHG	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							

Supervised By: _____ Date: _____

COMPONENT TRANSFUSION COMPATIBILITY CHARTS

FOR PACKED RED CELL TRANSFUSIONS									
PATIENT BLOOD GROUP		**B POS**	**O POS**	**A POS**	**AB POS**	**B NEG**	**O NEG**	**A NEG**	**AB NEG**
DONOR BLOOD GROUP	B POS	YES	NO	NO	YES	NO	NO	NO	NO
DONOR BLOOD GROUP	O POS	YES	YES	YES	YES	NO	NO	NO	NO
DONOR BLOOD GROUP	A POS	NO	NO	YES	YES	NO	NO	NO	NO
DONOR BLOOD GROUP	AB POS	NO	NO	NO	YES	NO	NO	NO	NO
DONOR BLOOD GROUP	B NEG	YES	NO	NO	YES	YES	NO	NO	YES
DONOR BLOOD GROUP	O NEG	YES	YES	YES	YES	YES	YES	YES	YES
DONOR BLOOD GROUP	A NEG	NO	NO	YES	YES	NO	NO	YES	YES
DONOR BLOOD GROUP	AB NEG	NO	NO	NO	YES	NO	NO	NO	YES

FOR FRESH FROZEN PLASMA (FFP) TRANSFUSIONS									
PATIENT BLOOD GROUP		**B POS**	**O POS**	**A POS**	**AB POS**	**B NEG**	**O NEG**	**A NEG**	**AB NEG**
DONOR BLOOD GROUP	B POS	YES	YES	NO	NO	YES	YES	NO	NO
DONOR BLOOD GROUP	O POS	NO	YES	NO	NO	NO	YES	NO	NO
DONOR BLOOD GROUP	A POS	NO	YES	YES	NO	NO	YES	YES	NO
DONOR BLOOD GROUP	AB POS	YES	YES	YES	YES	YES	YES	YES	YES
DONOR BLOOD GROUP	B NEG	YES	YES	NO	NO	YES	YES	NO	NO
DONOR BLOOD GROUP	O NEG	NO	YES	NO	NO	NO	YES	NO	NO
DONOR BLOOD GROUP	A NEG	NO	YES	YES	NO	NO	YES	YES	NO
DONOR BLOOD GROUP	AB NEG	YES	YES	YES	YES	YES	YES	YES	YES

FOR WHOLE BLOOD TRANSFUSIONS									
PATIENT BLOOD GROUP		**B POS**	**O POS**	**A POS**	**AB POS**	**B NEG**	**O NEG**	**A NEG**	**AB NEG**
DONOR BLOOD GROUP	B POS	YES	NO	NO	NO	NO	NO	NO	NO
DONOR BLOOD GROUP	O POS	NO	YES	NO	NO	NO	NO	NO	NO
DONOR BLOOD GROUP	A POS	NO	NO	YES	NO	NO	NO	NO	NO
DONOR BLOOD GROUP	AB POS	NO	NO	NO	YES	NO	NO	NO	NO
DONOR BLOOD GROUP	B NEG	YES	NO	NO	NO	YES	NO	NO	NO
DONOR BLOOD GROUP	O NEG	NO	YES	NO	NO	NO	YES	NO	NO
DONOR BLOOD GROUP	A NEG	NO	NO	YES	NO	NO	NO	YES	NO
DONOR BLOOD GROUP	AB NEG	NO	NO	NO	YES	NO	NO	NO	YES

PLATELET TEMPERATURE LOG SHEET

Range (20-24 degrees Celsius)

Month: _____ Year: _____ Month: _____ Year: _____

Date	Digital Temp	Internal Temp	Chart (ok?)	Initials	Date	Digital Temp	Internal Temp	Chart (ok?)	Initials
1					16				
2					17				
3					18				
4					19				
5					20				
6					21				
7					22				
8					23				
9					24				
10					25				
11					26				
12					27				
13					28				
14					29				
15					30				
					31				

Date Corrective Action/Alarms/Comments Initials

Date_____

Supervised by_____

Date_____

Supervised by_____

Copper Sulphate Quality Control

Date	Tech.	Date CuSo4 Made	Specific Gravity	Known Hb level	Drop of blood float or sink	Accept Yes or No

Supervised by_____ **Date**_____

Quality Control Transfusion Service Reagent Rack

Reagent specificity	Lot #	Expiry Date	Reagent Appearance Satisfactory√ Not Satisfactory X 1234567	Date Placed in Use	Lot#	Expiration Date
DIACLON ANTI-A						
DIACLON ANTI-B						
DIACLON ANTI-D						
RH CONTROL(6% ALBUMIN)						
A1,B & O Cells						
SCREENING Cells						
CHECKS Cells						
DIACLON POLY AHG						
DIACLON 22% ALBUMIN						
DIACLON ANTI-c						

Tube#	Reagent Specificity	Phase	Expected Date	Day1 Date Reaction	OK?	Day2 Date Reaction	OK?	Day3 Date Reaction	OK?	Day4 Date Reaction	OK?	Day5 Date Reaction	OK?	Day6 Date Reaction	OK?	Day7 Date Reaction	OK?
1	Anti-A Plus A1 Cells	IS	≥3+														
2	Anti-A Plus B Cells	IS	0														
3	Anti-A Plus O POS Cells	IS	0														
4	Anti-B plus B Cells	IS	≥3+														
5	Anti-B plus A1 Cells	IS	0														
6	AHG plus Check Cells	IS	1+ to 3 +														
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 SC1	IS	≥2+														
11	Anti-D Plus Sc11	IS	≥2+														
12	Anti-D plus SC III	IS	0														
		AHG	0														
		CC	≥1+														
13	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 &Time:

Routine Testing	A1 Cells		B Cells		O Pos Cells		Check Cells	
	1st week	nd week	1st week	2nd week	1st week	2nd week	st week	2nd week
Prepared Date								
Prepared By								
Expiry Date								

DONOR SCREENING TESTING WORKSHEET

Date:_____

KIT LOT#: _____ EXPIRY DATE: _____

DONOR RANGE TESTED: _____

POSITIVE QC RESULT: _____ ACCEPTABLE? _____

NEGATIVE QC RESULT: _____ ACCEPTABLE? _____

TECH. SIGNATURE: _____

Date:_____

KIT LOT#: _____ EXPIRY DATE: _____

DONOR RANGE TESTED: _____

POSITIVE QC RESULT: _____ ACCEPTABLE? _____

NEGATIVE QC RESULT: _____ ACCEPTABLE? _____

TECH.SIGNATURE:_____

Date:_____

KIT LOT#: _____ EXPIRY DATE: _____

DONOR RANGE TESTED: _____

POSITIVE QC RESULT: _____ ACCEPTABLE? _____

NEGATIVE QC RESULT: _____ ACCEPTABLE? _____

TECH.SIGNATURE:_____

Date:_____

KIT LOT#: _____ EXPIRY DATE: _____

DONOR RANGE TESTED: _____

POSITIVE QC RESULT: _____ ACCEPTABLE? _____

NEGATIVE QC RESULT: _____ ACCEPTABLE? _____

SUPERVISED by:_____ DATE: _____

TECH.SIGNATURE:_____

Quality Control of Donor Handling

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.

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

Information to be provided to prospective donors of blood or blood components

1. Accurate educational materials, which are understandable for members of the general public, about the essential nature of blood, the blood donation procedure, the components derived from whole blood and apheresis donations, and the important benefits to patients.
2. 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 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

3. 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.
4. The reasons why individuals are not to make donations which may be detrimental to their health.
5. 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.
6. 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.
7. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion.
8. Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show abnormality of significance to the donor's health.
9. Information why unused autologous blood and blood components will be discarded and not transferred to other patients.
10. Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit.
11. Information on the opportunity for donors to ask questions at any time

Information to be obtained from donors by blood establishments at every donation

1. Identification of the donor

   Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.

2. 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.

3. Signature of the donor

   Signature of the donor, on the donor questionnaire, countersigned by the health care staff member responsible for obtaining the health history confirming that the donor has:

   a. read and understood the educational materials provided;
   b. had an opportunity to ask questions;
   c. been provided with satisfactory response to any question asked;
   d. given informed consent to proceed with the donation process;
   e. 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
   f. acknowledged that all the information provided by the donor is true to the best of his / her knowledge.

Eligibility Criteria For Donors Of Whole Blood And Blood Components

1. Acceptance Criteria For Donors Of Whole Blood And Blood Components

Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorized by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions.

The following criteria do not apply to autologous donations.

1.1 Age and body weight of donors

Age	18 to 65 years	
	17 – 18 years	Unless classified as a minor by law, or with written consent of parent or legal guardian in accordance with law.
	First time donors over 60 years	At the discretion of the physician in the blood establishment
	Over 65 years	With permission of the physician in the blood establishment, given annually.
Body weight	≥ 50 kg for donors either of whole blood or apheresis blood components	

1.2 Haemoglobin levels in donor's blood

Haemoglobin	For females ≥ 125 g/l	For males ≥ 135 g/l	Applicable to allogeneic donors of whole blood and cellular components

1.3 Protein levels in donor's blood

Protein		The protein analysis for apheresis plasma donations must be performed at least annually

1.4 Platelet levels in donor's blood

Platelets	Platelet number greater than or equal to 150 x 10^9/l	Level required for apharesis platelet donors

2 Deferral Criteria For Donors Of Whole Blood And Blood Components

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure
Central nervous system disease	A history of serious CNS disease
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy
Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any reoccurrence of convulsions
Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease
Diabetes	If being treated with insulin
Infectious disease	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune
	Hepatitis C HIV-1/2
	HTLV I/II
	Babesiosis
	Kala Azar (visceral Leischmaniasis)
	Trypanosomiasis cruzi (Chagas'disease)
Malignant disease	Except in situ cancer with complete recovery
Transmissiblespongiform encephalopathies (TSEs) (e.g. Creutzfeldt Jakob Disease variant Creutzfeldt Jakob disease)	Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jakob disease, further precautionary measures may be recommended.
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood.

2.2 Temporary deferral criteria for donors of allogenic donations

2.2.1 Infections

Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

2.2.2 Exposure to risk of acquiring a transfusion-transmissible infection

■ Endoscopic examination using flexible instruments ■ Mucosal splash with blood or needle stick injury ■ Transfusion of blood components ■ Tissue or cell transplant of human origin ■ Major surgery ■ Tattoo or body piercing ■ Acupuncture unless performed by a qualified practitioner and with sterile single use needles ■ Persons at risk due to close household contact with persons with hepatitis B.	Defer for 6 months, or for 4 months provided a NAT test for hepatitis C is negative.
Persons whose behavior or activity places them at risk of acquiring infectious diseases that may be transmitted by blood	Defer after cessation of risk behavior for a period determined by the disease in question, and by the availability of appropriate tests.

2.2.3 Vaccination

Attenuated viruses or bacteria	4 weeks
Inactivated / killed viruses or rickettsiae	No deferral if well
Toxoids	No deferral if well
Hepatitis A or hepatitis B vaccines	No deferral if well and if no exposure
Rabies	No deferral if well and if no exposure If vaccination is given following exposure defer for one year
Tick-borne encephalitis vaccines	No deferral if well and if no exposure

2.2.4 Other temporary deferrals

Pregnancy	6 months after delivery or termination, except in exceptional circumstances and at the discretion of a physician
Minor surgery	1 week
Dental treatment	Minor treatment by dentist or dental hygienist – defer until next day (NB: tooth extraction, root filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action and the disease being treated

2.4 Deferral criteria for donors of autologous donations

Serious cardiac disease	Depending on the clinical setting of the blood collection
Persons with or with a history of: hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune hepatitis C HIV-1/2 HTLV I/II	Member states may, however, establish specific provisions for autologous donations by such persons
Active bacterial infection	

The Quality Assurance personnel shall daily fill out the proforma for the donors entertained the previous day. The data generated should be reviewed periodically, weekly / monthly, and necessary corrective measures adopted.

All the information parameters in the proforma should be part of the SOPs of the Donor Handling session. Any abnormal occurrence / accident should be recorded in the information sheet.

Donor Handling Proforma

Donor Serial Number	Registration	Questionnaire	Phy. Exam	Bag Filling Duration	Single / smooth Phlebotomy	Bag Shaker	Tube Sealer	Donation Counseling		Post Donation Care	Reaction
								Pre	Post		

Purchases and Inventory

- Availability of dependable and reliable test kits and supplies is essential. This requires a national plan for procurement and distribution, as well as careful management of supplies and reagents at the testing site.

Responsibilities at the national level

Most countries use a tender process for procurement of reagents and supplies for all laboratories and testing sites managed through the Ministry of Health. It is important that supplies and reagents be carefully selected and that they are ordered in sufficient quantity to last until the next tender.

- Purchased kits must have an expiration date far enough into the future to allow for efficient use and to prevent waste. A policy of "first expired, first out" will also help to assure minimize wastage.

- The Ministry of Health/national reference laboratory must have means of assessing the quality of the kits, reagents, and supplies as they are received by the central purchasing body, to ensure that standards and specifications are met. It is recommended that each lot number should be checked by the national reference laboratory before distribution.

  A distribution plan that allows these reagents and supplies to reach all testing sites within the appropriate time frame and prior to expiration will be needed. The plan must take into account emergency or unexpected needs.

Responsibilities at the testing site

- An inventory record for kits and supplies should be maintained. Each site should determine re-order levels for each item in the inventory based on workload and usage. This will allow for ordering in a timely manner, so that the testing site always has the necessary reagents and supplies and no interruption in testing will occur.

- On receipt of new supplies and reagents, the inventory record should be updated and all of the new material stored under the appropriate environmental conditions.

- To avoid wastage, sites should follow the concept of "first expired, first out". Kits that expire earliest must be used before kits with a longer expiration date.

Stock Card

Item Name: _____ Unit: _____

Manufacturer: _____

Kit Lot Number: _____ Expiration Date: _____

**Minimum Stock (Re-Order Level): _____

Date	Received From	Issued to	Quantity Received	Quantity Issued	*Balance	Lot #	Signature

Signature of the Incharge_____

Date_____

**Minimum Stock = Maximum lead time in weeks times (x) maximum usage
Maximum lead time is 2 weeks
Maximum usage / 3 months = 3 kits
Minimum Stock = 2 x 3 = 6 kits
*Balance – Perform physical inventory count each month. If physical count does not equal balance,consider causes for discrepancies, e.g., theft, expired kits

Stock Book

Item Name	Manufacturer's Name	Qty (units) Requested	Date Requested	Qty Received	Date Received	Lot #	Expiry Date	Received by

Signature of the Incharge _____ Date_____