NATIONAL STANDARDS FOR BLOOD TRANSFUSION SERVICE

Edition 1-2013

Blood Safety Program, Health Care and Diagnostic Division
Department of Medical Services
Ministry of Health
Thimphu: Bhutan

FOREWORD

Ministry of Health over a period of time has been focusing on consolidation of health care services by improving quality, enhancing sustainability, improving accessibility and strengthening human resource development and deployment.

Based on the principle of delivering quality health care services, the Blood Safety Program under the Department of Medical Services has developed a manual on "National Standards for Blood Transfusion Service" based on "Good Manufacturing Practices" (GMP) with objective to maintain and enhance the quality and safety of blood transfusion in the health facilities. The standards address the entire low risk population; selection of donor, blood collection; testing/screening services, equipment, reagents, and human resources. The efforts of the program are commended and appreciated since this standard has come at a critical juncture where our efforts are geared towards providing quality health care services.

Besides adhering to blood transfusion standards I would urge all health care providers to make use of this and other clinical standards, guidelines, standard operating procedures, handbook on universal precaution, etc., while delivering services to the clients. Your little bit of extra efforts will definitely go a long way in improving health care services to our people.

Our quest is to improve quality of health care services to the people of Bhutan. I wish all health family members "TASHI DELEK" in our common endeavour.

(DR. UGEN DOPHU)
Director General

PREFACE

Blood transfusion is a life saving intervention that has an essential role in the total patient management within health care delivery. It is therefore important that the health authority takes appropriate and adequate measures to ensure that the blood banks in the country have the basic requirements in terms of human and financial re-sources and the necessary infrastructure and other support to provide service in accordance with the set standards.

For better adherence to the standards, special areas to focus on are self-sufficiency in blood and blood products, based on voluntary non-remunerated blood donation; continued medical education of all the health personnel involved in the blood transfusion chain; periodic auditing of blood banks and development of quality management system in the blood transfusion service.

Keeping in mind the guiding principle of consistency, the manual on 'National Standards for Blood Transfusion Service' has been prepared on the basis of Good Laboratory Practice and Good Manufacturing Practice, with the objective of ensuring quality and safety of blood and blood products in the face of known and emerging threats to public health in the country.

The standards address the entire transfusion chain from donor to recipient, encompassing the selection of blood donors from low-risk population, safe blood collection, testing of donated blood for transfusion transmissible infections and blood group serology, preparation, storage, issue and transportation of blood components for appropriate clinical use and lastly safe administration of blood to the recipients.

In this document, the technical standards appear at the beginning followed by quality requirements for processes and procedures carried out in a center's day to day operations.

Some terms are specifically designed for the purpose of these standards. The term '**SHALL**' is used to indicate a mandatory statement and describes the single acceptable activity or method.

The term '**SHOULD**' is used to indicate a commonly accepted activity which may have an effective alternative that can be used also.

A glossary is included in the manual for the purpose of defining terms to reflect their usage in the context of these standards.

REFERENCES

While preparing the document guidance has been taken from:

1. Standards on Blood banks/Blood centers and Transfusion Services, 1st edition 2007, NABH, India
2. WHO Recommendations on Basic Requirements for Blood Transfusion Services, WHO/EHT/06.05 advanced draft
3. AABB Standards for Blood Banks and Transfusion Services, 21st edition
4. Manual on the management, maintenance and use of the blood cold chain equipment, WHO, Geneva, 2005.
5. 'Framework for standard of practice and service standards' developed by QASD, Ministry of Health

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GLOSSARY

Autologous blood: The blood drawn from the patient/recipient for re-transfusion into him /her at later date.

Apheresis: Procedure whereby whole blood is separated by physical means into components and one or more of them returned to the donor.

Blood: Human blood drawn from a donor and mixed with anti-coagulant.

Blood center: A facility or centre that performs all the following functions:
- Recruiting blood donors
- Screening and selecting blood donors
- Blood collection
- Testing, and processing of blood units
- Transportation, receiving, and storage of blood units
- Pre-transfusion tests on patients blood samples
- Issue of blood or blood components for clinical transfusion

Blood storage center: A center that is involved in the following functions only:
- Receiving and storing screened blood and blood components from another authorized blood establishment
- Performing compatibility tests
- Blood issue for transfusion

Blood component: Any therapeutic constituent of blood that is separated by physical or mechanical means (e.g. red cells, platelets, plasma). It is not intended to capture plasma derived products.

Blood collection: A procedure whereby a single donation of blood is collected in an anticoagulant solution.

Blood product: Any therapeutic substance derived from human blood, including whole blood, blood components and plasma derived products.

Calibrate: To set measurement of equipment against a known standard.

Clinically Significant Antibody: Any allogenic or autologous antibody that is capable of producing a significant adverse reaction to transfused blood or component.

Closed System: A system for collecting and processing blood in containers that have been connected together by the manufacturer before sterilization, so that there is no possibility of bacterial or viral contamination from outside after collection of blood from the donor.

Corrective Action: An activity performed to eliminate the cause of an existing nonconformance, or other undesirable situation in order to prevent recurrence.

Competence: Ability of an individual to perform a specific task according to standard procedure.

Conformance: Fulfillment of requirements as defined by standards.

Critical: Capable of affecting quality.

Document (noun): Written or electronically generated information involved in providing a product or service. Examples are policies, standards, standard operating procedures, work instructions, reports and records.

Document (verb): To capture information for use in documents through writing or electronic media.

Donor: A person who gives whole blood or one of its components.

Donor-Patient: A person whose blood or tissue is collected for possible autologous transfusion or transplantation.
Expiry: The last day on which blood, component, or tissue is considered suitable for transfusion or transplantation.

Equipment: A durable item, instrument or device used in a process or procedure.

Evaluation: It is a specific selection process to determine the suitability of a procedure or material (equipment, blood bags, or reagents).

Guidelines: Documented recommendations.

Good Laboratory Practice: Ensuring that laboratory functions are carried out in accordance with requirements and may include planning, performance, monitoring, recording and reporting of laboratory functions.

Good Manufacturing Practice: Ensuring that products are consistently produced and controlled in accordance with appropriate standards and regulatory requirements.
Issue: To release for clinical use /transfusion.

Internal Quality Control: Testing that's routinely performed on material and equipment to ensure their proper function.

Label: An inscription affixed to a unit of blood, component or sample for identification.

Labeling: Information that is required or selected to accompany a unit of blood,

component or sample, which may include content, identification, and description of process, storage requirements, expiration date, cautionary, or indication for use.

Maintain: To keep in the current state.

Material: A good or supply item used in manufacturing process. Materials are a type of input product. Reagents are a type of material.

Neonates: A young child less than 4 months of age.

Organization: An institution, or part thereof that has its own functions and administration.

Open System: A system, the contents of which are exposed to air and outside elements during preparation and separation of components.

Policy: A written statement which guides present and future decisions. It determines the future course of action to be established.

Process: A set of related task and activities, often performed by one person according to instruction.

Processing of blood: Any procedure that takes place after the blood is collected.

Process Control: The efforts to standardized and control process in order to produce predictable out-put.

Procedure: A series of task usually performed by one person according to instructions.
Pre-donation procedure: It includes mandatory process and activity done before proceeding with bleeding a donor.

Post-donation procedures: All procedures and activities done after bleeding a donor.

Preventive action: An action taken to reduce the potential for an error to occur.
Product: A tangible result of a process.

Quality: Characteristics of a unit of blood, component, sample, or service that bear on its ability to meet requirements. Fit for its purpose.

Quality System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Quarantine: To isolate nonconforming blood, component or materials.

Reaction: In reference to a transfusion, a suspected or proven, unexpected response to a blood transfusion, manifested by signs and/or symptoms.

Reagent: A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a product) because of is biological or chemical activity.

Replacement /family donation: donation given by an individual who gives blood when it is required by a member of the patient's family or community. This may involve a hidden paid donation system in which the donor is paid by the patient's family.

Service: An intangible result of a process or procedure.

Shall: A term used to indicate a requirement.

Supplier: Individual or organization that provides an input material or service.

Supplier Qualification: An evaluation method designed to ensure that input materials and services (e.g., materials, blood component, patient blood sample) obtained from a supplier meet specified requirement.

Traceability: The ability to follow all steps of a process or procedure from the beginning to end.

Unit: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.

Urticarial Reaction: The development of hives, maculopapular rash, or similar allergic manifestation.

Validation: Establishing recorded evidence that proves a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specification and quality attributes.

Verification: Evaluating the performance of a system with regard to its effectiveness based on intended use.

Voluntary non-remunerated donation: Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his / her own free will and receives no payment for it, either in cash or kind which could be considered a substitute for money. Small tokens, refreshments are compatible with voluntary, non-remunerated donation."

Whole blood: Blood collected in an anticoagulant solution with or without additives.

ACRONYMS

AIDS:	Acquired Immunodeficiency Syndrome
BC:	Blood Centre
BMB:	Bhutan Medicines Board
BMHC:	Bhutan Medical and Health Council
CPDA:	Citrate Phosphate Dextrose Adeninine
CCC:	Coombs Control Cells
DMS:	Department of Medical Services
DoPH:	Department of Public Health
DRA:	Drug Regulatory Authority
DVED:	Drugs Vaccine and Equipment Division
ELISA:	Enzyme Linked Immuno-Assay
EQAS:	External Quality Assessment Scheme
FFP:	Fresh Frozen Plasma
GSH:	Group Screen and Hold
Hb%:	Hemoglobin
HBsAg:	Hepatitis B Surface Antigen
HBV:	Hepatitis B Virus
HCV:	Hepatitis C Virus
HIV:	Human Immunodeficiency Virus
HR:	Human Resource
IAT:	Indirect Antiglobulin test
IEQAS:	International external quality assessment scheme
IQC:	Internal Quality Control
MT:	Medical Technologist

MLT:	Medical laboratory technician
MoH:	Ministry of Health
NEQAS:	National External Quality Assessment Scheme
NBTC:	National Blood Transfusion Committee
NBTS:	National Blood Transfusion Service
NBC:	National Blood Center
OFID:	OPEC Fund for International Development
PHL:	Public Health Laboratory
PRC:	Packed Red Cell
PC:	Platelet Concentrate
QA:	Quality Assurance
QM:	Quality Manager
QS:	Quality System
RBC:	Regional Blood Centre
RGoB:	Royal Government of Bhutan
SOP:	Standard Operative Procedure
TPHA:	Treponema Pallidum Hemagglutination
TTI:	Transfusion Transmissible Infections
VBD:	Voluntary Blood Donation
VCT:	Voluntary Counseling and Testing
VNRBD:	Voluntary Non-remunerated Blood Donors
WHO:	World Health Organization
WB:	Whole Blood

Chapter 1: INTRODUCTION

Blood transfusion is a key component of modern day health care and therefore it is of utmost importance to ensure that blood and blood products meet the appropriate national standards of safety and efficacy for transfusion and benefit blood recipients in their clinical management process.

National Blood Policy, 2007

Mission Statement:

1. Ensure adequate, timely and easily accessible supply of safe and quality blood and blood products through the establishment of a National Blood Transfusion Service (NBTS).
2. Ensure adequate resources for the operation of a sustainable National Blood Safety Program.
3. Develop effective legislation and a national regulatory body to oversee the operation of the blood service in the country.
4. Blood transfusions shall be advised and carried out under the supervision of a registered medical practitioner or other suitably qualified and authorized health care professional

Present scenario and future plans

The blood supply system in the country functions as part of the laboratory service in all the hospitals and BHU-I, whereby the individual hospital blood bank is obliged and responsible to undertake the task of recruitment of blood donors, blood collection, screening of blood units for infections, storage and making it available for trans-fusion to the respective clinical departments of the hospital. Such a fragmented organizational structure poses many challenges and constraints.

Therefore, in line with the blood policy and the vision, national blood safety program has proposed consolidation of the service in its medium to long-term strategic plan. In this proposal, critical functions like donor recruitment, blood collection, screening for transfusion transmitted infections (TTIs), processing and distribution shall be limited to few strategic blood banks that shall be referred to as 'blood centers' in each region; rest of the blood banks shall function as 'blood storage centers' and the service to be collectively termed as 'Blood Transfusion Service' (BTS).

Hence, this document reflects the minimum requirements, the service and quality standards based on the new organizational and functional structure of BTS in line with the proposed consolidation strategy.

Vision:

To have a well organized, coordinated, standardized and quality national blood transfusion service that ensures adequate, safe and timely blood supply to all the health facilities practicing clinical blood transfusions.

Goals:

1. To provide the best possible care to the donor before, during and after donation.
2. To ensure that the best rational use of the donated blood is made by the prescribers.
3. To implement quality management system in the service.

Chapter 2: CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

Blood transfusion service and hospital transfusion practice established by national health authority shall function in compliance with the below mentioned code of ethics.

Blood donors and blood donation:

2.1 All matters related to blood donation should be in accordance with the National Blood Policy 2007.

2.2 Blood donation shall be on a voluntary basis and no-remuneration shall be given to the donors.
There shall be no compulsion made on an individual to donate blood.

2.3 The donor should understand the risks of donating infected blood to others and his/her ethical responsibility to the recipient.

2.4 The donor should provide informed consent to the donation of blood and to the subsequent use of the blood by the transfusion service.

2.5 Blood donation shall be based on the donor selection criteria laid down and must not entail discrimination of any kind including gender, nationality or religion.

BTS personnel:

2.6 The BTS personnel shall explain the donor of the risks connected with the donation procedure. The donor's health and safety shall be the ethical responsibility of the staff.

2.7 Blood should be collected under the overall responsibility of either a registered medical practitioner or an authorized BTS personnel who can manage a donor adverse reaction.

2.8 Anonymity between the donor and the recipient must be ensured and the confidentiality of donor information assured.

2.9 Blood is a public resource and access should not be restricted. Wastage of blood and blood components should be avoided at all times.

2.10 A profit motive shall not be the basis for the establishment and running of future private blood banks or blood service in the country.

Hospital transfusion practice:

2.11 There should be no financial incentive, or motive of personal gain nor any coercion from the patient's party to prescribe a blood transfusion. Rational clinical needs should be the basis of prescribing blood transfusion.

2.12 The prescribing clinician shall inform the patient of known risks and benefits of blood transfusion and of alternative therapies. The patient's decision to accept or refuse the procedure must be respected.

2.13 In the event that the patient is unable to give prior informed consent or in case of a minor, the clinician shall discuss with the patient's family and decide to transfuse blood in the best interest of the patient.

2.14 Transfusion therapy must be carried out under the overall responsibility of a registered medical practitioner or other qualified and authorized health care professional.

2.15 As far as possible only those components (cells, plasma or plasma derivatives) shall be prescribed that are need based, clinically appropriate and provide optimal safety to the patient.

Chapter 3: THE BLOOD DONOR

3.1 Donor recruitment:

3.1.1 All blood establishments in the country shall collect blood from voluntary, non-remunerated donors recruited from low risk, safe and healthy population within the community. No payments shall be made to any donor.

3.1.2 Pre-donation information shall be provided. Basic information on following topics shall be included:

- Blood science.
- Importance of voluntary blood donation.
- General information about blood donation process and pre and post-donation care.
- Importance of honest answers during the donor interview procedure.
- The tests conducted on donor and donated unit.
- HIV transmission and HIV risk reduction.

3.1.3 Pre-donation counseling shall be provided to all potential donors by authorized staff in a private and confidential manner.
It shall include information on:

- High risk behaviors and mode of transmission of infections like HIV and hepatitis.
- Signs and symptoms of HIV/AIDS, hepatitis and other sexual transmitted infections.
- Importance of true answers and self exclusion or self deferral by unsuitable donors.
- Mandatory tests done on all donated blood.
- Confidentiality of test results.
- Obtaining an 'Informed Consent'.
- Available testing options or sites for HIV test.

3.2 Donor selection

3.2.1 All potential blood donors shall be assessed before blood donation by authorized BTS personnel Assessment of blood donors shall include the following steps:

a. Donor interview. Refer to Annex 2 for 'Donor questionnaire and consent form'.
b. Physical examination for any jaundice, swollen glands, skin rashes, tattoos, needle or body piercing marks.
c. Check for body weight, temperature, and blood pressure.
d. Check for hemoglobin content and ABO/Rh blood group.

The interviewer then decides on the fitness of the donor based on the national donor selection criteria.

3.2.2 Criteria for blood donor acceptance:-

3.2.2.1 The donor shall be in the age group of 16 to 60 years.
For 16 or 17 aged individuals, a written consent from parents / guardians should be obtained before blood donation. Elderly donors between 60- 65 age group must be assessed by a doctor for suitability to donate.

3.2.2.2 Minimum acceptable body weight shall be 45 kg for 350ml and 50 kg for 450ml blood collection. In an case, blood volume collected should not exceed 10ml/ kg body weight.

3.2.2.3 Minimum hemoglobin level must be 12.0 gm%

3.2.2.4 Blood pressure: -Systolic reading between 90 mmHg and 180mmHg
- Diastolic reading between 50 mmHg and 100mmHg

3.2.2.5 The donor shall be having normal body temperature on the day of donation

3.2.2.6 The donor shall be free from any skin disease at the phlebotomy site on the arm.

3.2.2.7 The last blood donation must be at least three months ago.

3.2.2.8 The donor shall be in good health and mentally alert on the day of donation.

3.2.2.9 The donor shall not be a jail inmate or a drug/ alcohol addict.

3.2.2.10 The donor should have eaten something in the last 8 hours and had 5 hours sleep.

3.3 Donor Deferral

Donors shall be deferred based on national donor deferral guidelines. Refer to Annex 3.

3.3.1 The following individuals must not be allowed to donate blood as they are at risk of contracting
HIV/AIDS, Hepatitis B, Hepatitis C or syphilis due to their risky lifestyles:

a. Intravenous drug users or individuals sharing sharp injectable objects.
b. Persons with multiple sex partners.
c. Commercial sex workers.
d. Persons who had paid, casual or unsafe sex.
e. Individuals with homosexual behaviors.
f. Sex partners of all the above.

3.3.2 The following steps shall be followed when a donor is not accepted for donation:

a. The donor shall be explained in a clear and understandable language the reason for deferral.
b. The donor shall be informed whether the deferral is temporary or permanent. If temporary, encourage the donor to come after the deferral period is completed.
c. The donor shall be referred to a doctor for consultation if required.
d. All records of deferred donors shall be maintained.
e. Reassure the donors and encourage them to ask questions or clarify any doubts before they leave the blood center.

3.4 Blood collection/donor phlebotomy procedure

3.4.1 This procedure shall be conducted by only trained and authorized personnel.

3.4.2 Donor identification and blood unit identification must be confirmed before blood collection

3.4.3 Each blood unit shall be assigned a unique unit number which shall be used as an identifier on all blood components, blood samples and for documentation purpose.

- For donations from voluntary blood donors, the alphabet letter 'V' shall be prefixed to the unit number.
- For donations from replacement blood donors, the alphabet letter 'R' shall be prefixed to the unit number.
- For donations collected at mobile sites, the alphabet letter 'M' shall be prefixed to the unit number.
- Donor's name shall not appear anywhere on the blood bag.

3.4.4 Equipment/supplies for phlebotomy

3.4.4.1 Blood bags fulfilling the standard specifications shall be used for blood collection. All blood bags and sample collection tubes shall be checked before use for sterility, expiry date, appearance of the anti-coagulant solution, any leakage or any defects in the bags.

3.4.4.2 Quality control of all blood collection equipment shall be carried out as per the standard operating procedures and documented.

3.4.5 Preparation of the veni-puncture site:
The veni-puncture site shall be cleaned and prepared with locally available anti-septic agent to minimize risk of bacterial contamination.

3.4.6 Veni-puncture
Successful veni-puncture must be carried out at first attempt. If the first veni-puncture fails, a second veni-puncture shall be attempted only if the donor permits. In some cases a new blood bag may have to be used.

3.4.7 Anti-coagulant
CPDA1 shall be the anticoagulant used in the blood bag. The volume of anti-coagulant shall be in the proportion of 1:7 to the volume of blood collected for adequate anticoagulation.

3.4.8 Blood collection time
Total blood collection time should be between 8 to 12 minutes. If the time exceeds 12 minutes, the blood collected shall not be used for platelet preparation.

3.4.9 Pilot samples

3.4.9.1 Pilot samples are blood donor samples collected at the time of donation for conducting laboratory tests.

3.4.9.2 Pilot samples shall be taken when the needle is in-situ and not from the blood bag.

3ml of blood shall be collected in EDTA tube and 6ml in plain tube.

3.4.9.3 The tubes containing pilot samples shall be appropriately labeled immediately after blood collection.

3.4.9.4 Hermetic sealing of the blood bag tubing shall be done to ensure sterility of the blood collected.

3.4.10 Blood volume collected:

a. 350ml in single bags for whole blood transfusion.
b. 450ml in double or triple bags for preparation of packed red cells, fresh frozen plasma and platelet concentrates.

3.4.11 Therapeutic phlebotomy:

It shall be performed when ordered by a physician. Units drawn shall not be used for transfusion.

Records of therapeutic phlebotomy should be maintained.

3.5 Post –donation care

All blood donors shall be made to rest for at-least 15 minutes post-donation and shall be provided with oral fluids and post donation advice and instructions in the form of 'Information note'.

3.6 Donor adverse event

3.6.1 All the BTS personnel shall be trained in identification and management of donor adverse event.

3.6.2 Standard procedures shall be followed to identify and manage donor adverse reactions.

3.6.3 In the advent of a severe reaction, a doctor should be informed urgently

3.6.4 Records of all donor adverse events shall be maintained

3.7 Autologous transfusion procedure

3.7.1 Preoperative autologous donation:

a. Done prior to elective surgery.
b. All the donor screening criteria has to be applied as in a homologous donor. Minimum Hb% should be 11gm%.
c. 1 unit can be collected every 5-7 days.
d. First donation should be 35 days prior to surgery and last donation 72 hours before surgery date.
e. Oral iron supplement to be given to the donor-patient.

f. Prior consent from the donor–patient should be taken for the blood units to be used as homologous do-nation if unused by him/her.
g. All screening tests shall be carried out on all autologous blood units.

3.8 Donor and donation records

Following records shall be maintained:-

a. Name of the donor, age, gender and records of all donations.
b. Contact details-present address, telephone numbers and email address.
c. Date of blood collection, volume of blood collected and time taken.
d. ABO, Rh blood group.
e. Hemoglobin result of each donor at each time of donation.
f. Medical history records.
g. TTI results of all donations of each donor.
h. Donor deferral records.
i. Donor adverse reaction records.
j. Records of blood discards (if any) of a donor.

3.9 Quarantine and discard of blood units

Until TTI testing is completed and reported as non-reactive, no unit of blood or blood component shall be used for transfusion.

3.9.1 The blood bank shall have a process of physical separation of all un-screened blood and blood component units.

3.9.2 Quarantined units shall be stored in appropriate equipment at required storage temperatures.

3.9.3 All blood and blood components declared as 'Screen Reactive or 'Indeterminate' on TTI testing shall be disposed in accordance with 'Hospital infection control and waste management' guidelines.

3.10 Transportation of blood

3.10.1 Un-processed, whole blood units shall be cooled and maintained at +10°C while transporting from mobile sites to the blood center .The blood units for platelet preparation shall be cooled up to +20°C and transported within 6 hours to the blood center.

3.10.2 Processed blood shall be stored using appropriate storage equipment in the appropriate temperature range until the date of expiry.

Table 1: Transportation and Storage Requirements

Blood	Condition	Temperature range	Transportation /Storage time	Storage equipment
Whole blood and Packed red cell	For transportation to another center	+2°C to +10°C	Transportation time should be less than 24 hours	Well insulated container with ice packs
Whole blood and Packed red cell	For storage in blood center	+2°C to +6°C	35 days	Blood bank refrigerator
Platelet concentrates	For transportation to another center	+20°C to +24°C	24 hours	Well insulated container without ice packs
Platelet concentrates	For storage in blood center	+20°C to +24°C	5 days	Platelet agitator with incubator
Fresh Frozen Plasma	For transportation to another center	Frozen state	Transported until maintained in frozen state	Well insulated container with ice packs

3.11 Storage of donor blood samples

Long-term archiving of the donor's serum samples can be useful for look back facility in case of an adverse transfusion event. 2ml of serum or plasma sample shall be stored at -20ºC or below in a froze state for a year. Records of archiving should be maintained.

3.12 Labeling of blood units

3.12.1 Each blood bag shall be labeled with following information:

a. Unique unit number
b. ABO blood group
c. Rh blood type
d. Date of collection
e. Date of expiry
f. Type of blood component
g. Volume of the unit
h. TTI results

3.12.2 A colored label shall be put on every blood bag. The following color scheme for the said label shall be used for different ABO groups of blood:

Blood group	Color of label	Color of Letters
'A'	Yellow	Black
'B'	Pink	Black
'O'	Light Blue	Black
'AB'	White	Black

3.13 Release of blood units for clinical transfusion

Only blood units screened "Non-reactive" for all TTI markers and with confirmed ABO, Rh blood group shall be suitable for storing in blood inventory and future release for transfusion purpose.

3.14 Post-test counseling

It is recommended that all blood donors are provided with post-test counseling.

3.14.1 Screened non-reactive donors

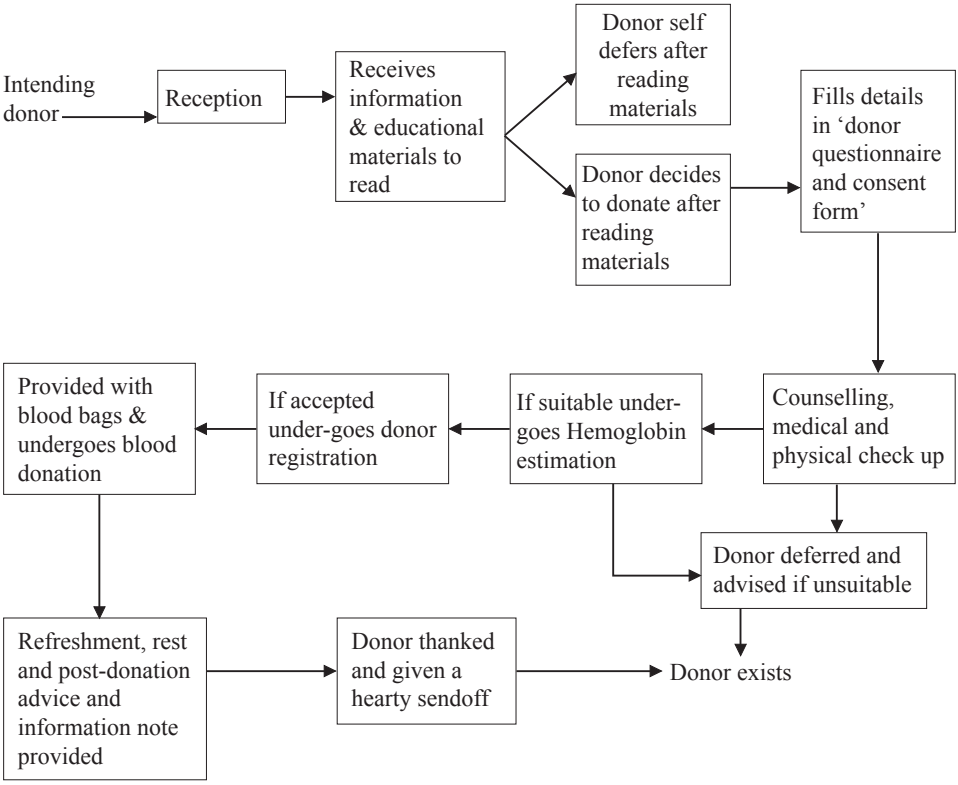
Donors, who test non-reactive to all TTIs, shall be encouraged to donate blood regularly and lead low-risk lifestyles.

3.14.2 Screen reactive donors

Whenever a screening test is reactive to anti-HIV, anti-HCV or/and HBsAg markers, information to be Provided to the blood donor shall include:-

a. Explanation to the donor on the screen results, the non-specific reactivity detected by highly sensitive screening assays to ensure blood safety to the recipients.
b. Information on the discard of the reactive unit and the deferral advice on future blood donation.
c. Referral to a VCT center for further counseling and information and consenting for confirmatory testing.

FLOW DIAGRAM OF A POTENTIAL BLOOD DONOR SHALL BE AS FOLLOWS



Chapter 4: TESTING OF DONATED BLOOD

4.1 Blood Group Serology

All tests shall be performed in accordance with the standard operating procedures developed.

4.1.1 Determination of *ABO group* of all blood units collected.

4.1.1.1 ABO blood group shall be determined by both cell and serum grouping methods.

4.1.1.2 Cell grouping shall be done with anti-sera anti-'A', anti-'B' and anti-'AB' by tube method.

4.1.1.3 Serum grouping shall be done with standard 'A' cell, 'B' cell and 'O' cell.

4.1.2 Determination of *Rh type* of all blood units collected.

4.1.2.1 This shall be carried out with anti-'D' IgM+IgG reagent. If the initial test is negative, IAT method to detect weak 'D' shall be carried out. If Weak D test is positive, the unit shall be labeled as Rh D Positive.

4.2 Blood screening for Transfusion Transmissible Infections (TTIs)

4.2.1 All donated blood units shall be tested mandatory for four infections transmissible by transfusion.

4.2.1.1 Screening for HIV shall include anti-HIV-1/2 antibodies as the minimum required screening target.

4.2.1.2 Screening for viral hepatitis shall include Hepatitis B surface antigen (HBsAg) for Hepatitis B and anti-HCV anti-body for Hepatitis C as the minimum required screening targets.

4.2.1.3 Test for Syphilis shall include specific treponemal antibodies as the minimum required screening target.

4.2.1.4 Test for malaria antigens to all four species shall be done on all donations collected in endemic districts.

Table 2: TTIs and Serological Markers

Mandatory TTI s	Serological Markers
Human Immunodeficiency Virus	Antibodies to HIV-1 and 2
Hepatitis B	Hepatitis B surface antigen (HBsAg)
Hepatitis C	Anti-HCV antibody
Syphilis	Specific treponemal antibody
Malaria	Malaria antigen

4.3 Screening assays

All blood centers shall screen 100% blood units for TTIs using ELISA assays. In emergency situations when blood is needed urgently but not readily available in

inventory, screening with rapid assays could be done. But the unit shall be retested with the ELISA assay.

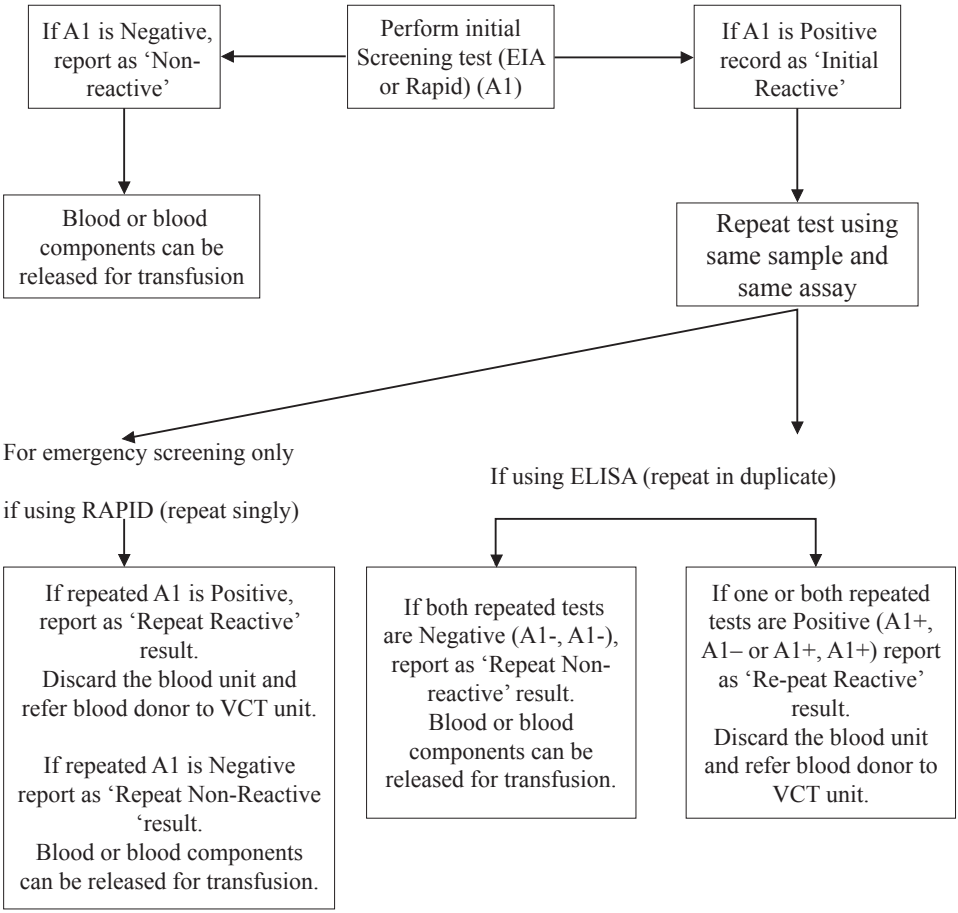
4.4 National screening algorithm

All blood centers shall follow the screening algorithm shown in Figure1 when screening blood units for HIV, HBV and HCV infections.

4.5 Personnel

TTI testing shall be done by only authorized laboratory personnel and 'National Guidelines on screening donated blood for TTIs' shall be followed.

Figure 1: Screening Algorithm



Chapter 5: BLOOD AND BLOOD COMPONENTS

General principles

5.1 All blood components shall be prepared from whole blood from donors who meet national donor selection criteria.

5.2 The volume of whole blood collected for blood component preparation shall be 450ml.

5.3 Sterility of all components shall be maintained during processing and storage.

5.4 Fresh frozen plasma shall be prepared within 8 hours after collection.

5.5 Platelet concentrates shall be prepared within 8 hours after collection of whole blood that is stored at temperature of +22ºC ± 2ºC.

5.6 Once the sterility of the component is compromised by use of open system, packed red cells prepared from that unit must be transfused within next 24 hours and platelet concentrates prepared must be transfused within next 6 hours from the time of compromised sterility.

5.7 All the prepared components shall have integrally connected segments filled with the final product for subsequent compatibility testing and quality checks.

5.8 All the components prepared from whole blood shall bear the same unit number as that of the whole blood unit. The final label on the blood component unit shall have all the details as mentioned in standard 3.5 ‘Labeling of a blood unit’.

5.9 The blood bank shall develop SOPs to perform periodic quality control checks on prepared components.

5.10 The national standards for quality control of blood and blood component including testing parameters frequency of testing and quality requirements have been developed and shall be followed. Principles of good manufacturing practice must be followed to provide blood components of required specifications.

Table 3: Standard requirements for storage, transport, expiry of blood and blood components

Components	Properties	Storage	Transport	Expiry
Whole blood	Vol: 350 ml +/- 10% Hct: 35-50% Dosage:10ml/kg body wt Increases Hb by 1-1.5gm%	In a blood bank refrigerator at +2ºC to +6ºC	Can be transported For next 24hrs. if maintained at +1ºC to +10ºC	35 days in a closed system 24 hours if open system
Packed Red Cells	Vol:250ml± 30ml Hct: 60 to 70% Dosage:5ml/kg body wt Increases Hb by 1-1.5gm%	Same as above	Same as above	Same as above
Fresh Frozen Plasma (FFP)	Vol: 200-220ml Contains stable & 70% unstable clotting factors Dosage:15ml/kg body wt	In a plasma freezer at below -30ºC	Transported in frozen state	1 year
FFP Thawed	Same as FFP	+2ºC to +6ºC in a blood bank refrigerator	Maintain between +1ºC to +10ºC	4 -6 hours
Liquid Plasma	Vol: 200-220ml Contains only stable clotting factors	+2ºC to +6ºC in a blood bank refrigerator	Maintain between +1ºC to +10ºC	40 days
Platelet concentrate	Vol: 50 to 70ml Contains 3.5-4.5x10^{10} platelets/ unit Dosage:1unit/10 kg body wt Increases the platelet count by 10,000 to 20,0000/ul blood	In a platelet incubator with agitator at +20ºC to +24ºC with continuous gentle agitation	+20ºC to +24ºC	5 days if closed system. 6 hours if open

Chapter 6: CLINICAL USE OF BLOOD AND BLOOD COMPONENT

6.1 Transfusion requests

6.1.1 Transfusion of blood and blood components shall be advised by authorized health personnel based on definite clinical benefits to the patient's health. Administration of blood and blood components shall be under the supervision of a health staff trained in clinical transfusion process who can manage adverse events appropriately.

6.1.2 'National Guidelines on Clinical Use of Blood for Clinicians and Nurses' shall be followed by all prescribing and administering blood.

6.1.3 All requests shall be sent to the blood centre using standard 'Blood Request Form' and accompanied by the recipient's blood sample. Refer to Annex 4.

6.1.4 Patient identification must be done using his full name, age/sex and hospital registration identification number (OPD or inpatient hospital registration number).

6.1.5 No telephonic requests shall be entertained by blood centres except in a dire EMERGENCY situation.

6.2 Pre-transfusion tests shall include:

6.2.1 Determination of ABO group of the patient.

- ABO blood group shall be determined by both cell and serum grouping methods
- Cell grouping shall be done with anti-sera anti-'A', anti-'B' and anti-'AB' by tube method
- Serum grouping shall be done with standard 'A' cell, 'B' cell and 'O' cell

6.2.2 Determination of *Rh 'D' type* group of the patient

- This shall be carried out with anti-'D' IgM+IgG reagent. If the initial test is negative, the patient shall be typed as Rh 'D' negative.

6.2.3 Major cross-match test between patient's serum/plasma and donor red cell.

6.2.4 National and regional blood centers shall perform additional antibody screening, identification and antigen tests on the patient's sample. Group Screen Hold (GSH) protocol shall be followed for all elective surgical cases as outlined in the national guidelines document.

6.3 Blood issue

6.3.1 The blood center shall have a process for EMERGENCY issuing of blood/blood components before completion of the pre-transfusion tests if the treating doctor decides that delay in administering blood transfusion can be detrimental to the patient's survival.

6.3.2 Blood and blood components that have been returned to the blood center shall be reused only if certain specific criteria have been met. These criteria shall be developed by each center.

6.3.3 Records of patient's details, the tests results and issues must be maintained at all times.
All tests shall be performed in accordance with the standard operating procedures developed.

6.4 Clinical transfusion process (CTP)

6.4.1 Only trained and authorized health personnel shall administer blood/blood components to patients.

6.4.2 A written informed consent shall be obtained from all patients before each transfusion is started. Refer to Annex 5.

6.4.3 Procedures and protocols for clinical transfusion process as reflected in the national guidelines document shall be followed.

6.4.4 Positive patient identification check, correct blood unit identification pre-, during and post-transfusion monitoring of the patient are essential elements of CTP and contributes in minimizing adverse transfusion events. These elements shall be followed.

6.4.5 All transfusions shall be documented using the 'Transfusion Report' form. Refer to Annex 6.

6.4.6 All transfusion reactions shall be reported by the attending nursing staff to the concerned doctor, recorded and investigated by the blood center. Refer to Annexes 7A and 7B for 'Transfusion Reaction form' and 'Transfusion Reaction Investigation form' respectively.

Chapter 7: QUALITY SYSTEM

7.1 Executive Management

In order to provide the required level of safety in blood donation and transfusion service, the principles of quality, good manufacturing and laboratory practice shall be implemented through a quality management system.

The new organogram proposed under consolidated BTS is shown in Annex 8.

7.1.1 National Blood Transfusion Committee

The National Blood Transfusion Committee (NBTC) shall be the highest decision making body on all matters related with blood transfusion service, blood and blood products. It shall serve as a legal advisory committee to the Bhutan Medicines Board (BMB) on the above matters. Refer to Annex 9 for the composition, roles and responsibilities of the committee.

7.1.2 Ministry of Health

The national blood transfusion service (NBTS) under the Department of Medical Services (DMS), Ministry of Health shall be the key planning agency. The department shall be responsible to make available to NBTS all the necessary resources-human and financial for the operations of the NBTS.

NBTS shall define clear lines of authority, responsibility and accountability for all health personnel involved in blood safety and blood transfusion. It shall work in co-ordination with clinical services for appropriate use of blood for patient care.

The composition and roles of NBTS are reflected in Annex 10.

The composition and functions of various levels of consolidated BTS are reflected in Annex 11, 12 and 13.

7.2 Personnel

The BTS shall have adequate number of personnel qualified by education, training and or experience. The blood center should have a written dated and signed organogram (organisational structure), clearly defining the reporting structures and hierarchies of the management and staff.

7.2.1 BTS technicians shall be competent and full time possessing a certificate/diploma /degree of medical laboratory technology and blood banking.

7.2.2 The head of major blood centers shall be a doctor with post graduate qualification in transfusion medicine with responsibilities including professional, consultative or advisory, organizational, administrative and educational matters.

7.2.3 The quality manager shall be designated staff responsible for directing and

coordinating the quality system and directly reporting to the head of the center.

7.2.4 The technical in-charge/supervisor of each section shall be responsible for the technical operation and to ensure quality assurance.

7.2.5 The staff shall receive on the job orientation/induction briefing and training specific to quality assurance and quality management for services offered

7.2.6 Personal records of all staff shall be maintained with details on educational qualifications, job description, trainings received and competency evaluation reports.

7.2.8 All staff shall participate in continued medical education programs and regular updates on recent advances in blood banking and clinical transfusion as mandated by Bhutan Medical and Health Council.

7.2.9 All staff performing TTI testing and processing blood units shall undergo a periodic competency evaluation. This activity shall enable in deciding the training needs of the staff.

Table 4: Human Resource requirement for consolidated BTS until 2023

Blood center	Position Title	Qualification	Designation	HR requirement	Remarks
National Blood Center	Transfusion Medicine specialist	PG qualification in Transfusion Medicine	Head	1	
	Technologist	B. Sc Medical Laboratory Technology with training in Quality Management in BTS	Quality Manager	1	
	Donor recruitment personnel	Medical Laboratory Technician or Health Assistant trained in health education, blood science and donor recruitment	Donor Recruiter	2	
	Medical Laboratory technicians	Certificate in general Medical Laboratory Technology	Blood center staff	15	

Regional Blood Center	Transfusion Medicine specialist	PG qualification in Transfusion Medicine	*Head	1	*Atleast at Monggar and Gelephu RBCs
	Technologist	B. Sc Medical Laboratory Technology with 6 months training in blood banking and clinical transfusion	*Head	1	*At other RBCs
	Technologist	B. Sc Medical Laboratory Technology with training in Quality Management in BTS	Quality Manager	1	
	Medical Laboratory technicians	Certificate in general Medical Laboratory Technology	Blood center staff	10	
	Donor recruitment personnel	Medical Laboratory Technician or Health assistant trained in health education, blood science and donor recruitment		1	
Blood storage center	Medical Laboratory technicians	Certificate in Medical Laboratory Technology		1	Rotated from general laboratory

7.3 Premises

Requirements:

7.3.1 The premises shall be of suitable size, construction and location to facilitate its proper operation, cleaning and maintenance and at the same time minimize the risk of occupational injury to the personnel.

7.3.2 The following standards shall be followed and kept in mind while constructing a blood center:

a) The space shall be hygienic and safe, away from open sewerage, public lavatory.
b) Adequate ventilation and lighting shall be provided for all technical activities that take place.
c) The lay-out of the service shall take into account the work flow for registration of donors, blood donation, processing, testing of blood and allocate sufficiently large rooms.

d) Adequate size and number of rooms for storage of blood and blood components in their respective equipment shall be designed.
e) Access to all functional areas except the donor area shall be restricted to authorized personnel only.
f) A continuous water supply and un-interrupted power supply round the clock shall be made available at all times.
g) The walls and floors of the rooms shall be smooth and capable of being easily washable and kept clean.

7.3.3 Each blood center shall have provision of a room for the following activities:
a) Registration of blood donors.
b) Donor interview, counseling and medical examination in private to determine their fitness as donors blood and to provide an opportunity for self exclusion of unsuitable potential blood donors.
c) Blood collection with minimum risk of contamination or errors.
d) Refreshment cum post donation care of donors, including management of donors with adverse events.
e) Laboratory for screening of blood units for transfusion transmitted infections (TTIs).
f) Laboratory for blood group serology and immunohematology testing.
g) Processing of whole blood into components in a manner that prevents contamination and loss of potency.
h) Separate storage of quarantined and finished products.
i) Separate storage of reagents, supplies and equipment.
j) Sterilization cum washing (optional) room.
k) Documentation, recording and storage of data on the donor, the blood units and the blood recipients.
l) Quality control and assurance activities.
m) Administrative room with computer, internet connection and printer.

It shall cover a minimum area of 100 sq.m for its above operations and an additional area of 50 sq.m for having facilities for blood component preparation. An area of10 sq.m shall be included for aphaeresis services.

7.3.4 Mobile blood donation: The premises used may not comply with the above requirements, they must be adequate to ensure safety of the donor, collected blood and the staff participating in the camp and the subsequent users of the premises.

For holding a mobile blood donation camp, the following requirements shall be fulfilled:
a) The premises shall have sufficient space and shall be hygienic
b) Electric supply made available for equipment used in the blood donation camp.
c) Adequate lighting.

d) Facilities for confidential examination of donors.
e) Hand washing facilities.
f) Basic furniture like chairs and tables.
g) Couches /beds that can be arranged within the available space.
h) Refreshment facilities for donors and staff.
i) Proper disposal of waste.

7.4 Standard tests, equipment and reagents

7.4.1 Each center shall perform the required tests as shown in Annex 14. The list of standard equipment and standard reagents are provided in Annex15 and Annex 16 respectively.

7.4.2 Standard specifications developed for all BTS equipment and reagents shall be used for floating quotations to registered suppliers. Only those that meet the criteria shall be selected and purchased. Annex 19 and Annex 20 provide the specifications for blood bank equipment and reagents respectively.

7.4.3 Prior to selection, all immuno-hematology reagents and supplies shall be evaluated by national blood center and TTI test kits by Public Health Laboratory (PHL).

7.4.4 All BTS equipment shall be validated on installation and before use jointly by manufacturer, competent technical staff, Quality Assurance and Standardization Division and Bio-Medical Engineering unit.

7.4.5 Equipment control process shall be in place for periodic calibration, and maintenance.

7.4.6 Quality controls of reagents and test kits shall be performed periodically.

7.4.7 All BTS personnel shall be trained on the use and maintenance of the equipment.

7.4.8 Records of all installed equipment shall be maintained. Refer to Annex 17 for details.

7.5 Quality Assurance (QA)

Blood and blood components are intended for use in the cure, treatment or prevention of diseases in humans and have been classified as medicinal products by the Bhutan Medicines Board. Hence all blood products shall be regulated and controlled under the Medicines Act of the Kingdom of Bhutan 2003.

In-order to ensure that blood and blood components maintain consistent quality and safety standards, all blood centers shall implement the following elements of QA:

7.5.1 Quality Control (QC)

It refers to all the activities undertaken by the staff at periodic intervals to monitor the

quality of the materials, reagents, equipment, methods, blood and blood components prepared to assure that they meet their minimum requirements.

Quality control (QC) shall be conducted for:-

- o Reagents
- o Equipment
- o Techniques
- o Whole blood and blood components

7.5.1.1 Quality control of reagents (anti-sera) shall include:

a. Checks for titer, antibody specificity and avidity on every new batch or lot received.

b. These checks shall be conducted as below:

Table 5: Frequency of testing for reagents and solutions

Reagents and supplies	Frequency of testing with controls
Blood grouping anti-sera	Each day of use
Standard cells for serum grouping	Each day of use
Anti-Human Globulin	Each day of use
Coombs control cells	Each day of use
Bovine albumin	Each lot
Syphilis serology assays	Each run
HIV test assays reagents	Each run
Hepatitis test assays	Each run
Normal saline	Each day of use

c. Minimum quality requirements for anti-sera and red cell reagents are as follows:-

Table 6: Anti-sera (anti-A, anti-B and anti-AB)

Parameters	Quality requirement
Appearance on visual inspection	No turbidity, no particle or precipitates
Specificity with positive and negative controls and required strength of reactions	For Anti-A : hemolysis or positive reaction of grade 3+/ 4+ with A cell : negative reaction with B cell For Anti-B : hemolysis or positive reaction of grade 3+ /4+ with B cell : negative reaction with A cell For Anti-AB: hemolysis or positive reaction of grade 3+ /4+ with A cell and B cell : negative reaction with O cell

Avidity	Macroscopic agglutinates seen in 10 seconds with whole blood on slide test
Acceptable titer	3+ reaction at 1:256 titer (to be carried out with every new lot , and with new annual procurement supply)

Table 7:Anti-D anti-sera

Parameters	Quality requirement
Appearance on visual inspection	No turbidity, no particle or precipitates
Specificity with positive and negative controls and required strength of reactions	positive reaction of 3+ /4+ with D +ve cell negative reaction with D negative cell
Avidity	Macroscopic agglutinates seen in 10 seconds with whole blood on slide test
Acceptable titer	3+ reaction at 1:64 titer (to be carried out with every new lot , and with new annual procurement supply)

Table 8: Anti-Human Globulin (AHG)

Parameters	Quality requirement
Appearance	No turbidity, no particle or precipitates.
Specificity and strength of reactions	positive reaction of 2+/3+ / 4+ with CCC negative reaction with any standard cell

Table 9: Bovine Albumin

Parameters	Quality requirement
Appearance	No turbidity, no particle or precipitates. (to be done daily)
Reactivity with negative control only	Negative reaction with any standard cell (to be done with each new lot)

Table 10: Red cell preparations (A cell, B cell, O cell and Coombs Control Cells)

Parameters	Quality requirement
Appearance on visual inspection	No hemolysis in the supernatant. If a single saline wash removes the hemoglobin-stained supernatant fluid, the red cells are appropriate for use. Otherwise, they must be discarded.

Specificity with positive and negative controls and required strength of reactions	A cell : positive reaction of grade 3+ /4+ with anti-A : negative reaction with anti-B B cell : positive reaction of grade3+/ 4+ with anti-B : negative reaction with anti-A O cell : negative reaction with anti-A and anti-B CCC : Grade 2+/3+ / 4+ reaction with AHG : negative reaction with normal saline

7.5.1.2 Quality control of BTS equipment

a. For all new equipment, installation and operational qualification must be performed. After it is qualified for use, an ongoing quality control checks should be performed.

b. All critical equipment must be calibrated and adjusted:

- before use- that is on installation
- after activities that may affect the calibration
- at prescribed intervals.

c. Safeguards are to be implemented to prevent adjustments that would invalidate the calibration setting and calibration equipment must have adequate accuracy and precision.

Table 11: Quality Control Performance Intervals

Equipment	Performance	Frequency
Blood collection monitor with shaker	Agitation Time displayed Volume displayed	Day of use Monthly Monthly
Spring balance for blood collection	Volume displayed	Day of use
Electronic balance for blood bags	Weight/Volume displayed	Monthly
Di-electric tube sealer	Adequate sealing	Day of use
Hemoglobinometer	Hb value with known control sample	Day of use

7.5.1.4 Quality control of blood and blood components

Table 13: Whole blood (100% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	350ml /450ml (± 10%)	Minimum of 4 units per month
Hct	30% to 40%	Minimum of 4 units per month
Sterility	No growth	Minimum of 4 units per month

Table 14: Packed red cell (100% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	280ml (±50ml)	Minimum of 4 units per month
Hematocrit value	65% to 75 %	Minimum of 4 units per month
Sterility	No growth	Minimum of 4 units per month

Table 15: Platelet concentrate (75% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	50 to 70 ml	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher
Platelet count	$\geq 3.5 \times 10^{10}$ platelet per bag in at least 75% of the units tested at the end of the storage period	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher
pH at the time of expiry	6 to 7	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher
Sterility	No growth	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher nits before issue
Physical examination	Swirling phenomenon demonstrated	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher

Table 16: Fresh frozen plasma (75% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	220 to 250ml	Minimum of 4 units per month
Factor VIIIc	0.7 IU/ml	Minimum of 4 units per month
Fibrinogen	200 to 400 mg	Minimum of 4 units per month
Visual inspection	No leakage, no clots, no abnormal color	All units before issue

7.5.2 Documentation

All BTS activities shall be documented including all the tests performed and quality data. Confidentiality of both blood donors and blood recipients shall be ensured.

Different sets of documents that shall be developed and controlled are reflected in Annex 18. All records shall be maintained for period of 5 years. Accessibility to the information shall be restricted and a document control system wherein development, approval, validation, review, revision and authorization shall be done by authorized personnel only.

7.5.3 Proficiency testing

Proficiency testing scheme shall assess and monitor the ability of laboratories to perform immune-hematological and TTI test procedures with accuracy, through the analysis of unknown samples provided by an external source. The national scheme called National External Quality Assessment Scheme (NEQAS) shall be co-ordinated by the National Blood Center for immuno-hematology tests and by Public Health Laboratory for TTI tests wherein known samples of undisclosed nature shall be distributed at regular intervals to all the blood centers in the country.

7.5.4 Deviations, non-conformances, and complications

7.5.4.1 Each BTS management shall review at regular intervals the effectiveness of the quality assurance activities and introduce corrective measures if necessary.

7.5.4.2 It shall identify, assess, investigate and monitor events that deviate or fail to meet the accepted standards

7.5.4.3 This shall include discovery of nonconforming services and products as well as adverse reactions to blood donation and blood transfusion.

7.5.4.4 All BTS personnel shall be trained how to:

- Recognize, classify, analyze the root cause, and document any such occurrence.
- Prioritize the necessary corrective action needed.
- Verify that the corrective action is performed.
- Take preventive action where possible to reduce the likelihood of future recurrence.
- Report to immediate higher authority when required.

7.5.5 Assessment

7.5.5.1 Internal Assessment

The operations of all blood centers shall be assessed through periodic internal audits or self-inspection conducted by trained team or designated staff headed by the Quality Manager. The methodology, frequencies, and areas to be audited as well as quality indicators set shall be made known to the concerned unit at each center. At the end of each audit, a feedback or an audit report consisting of the findings, recommended corrective measures and stipulated time frame to improve shall be provided to the auditees.

7.5.5.2 External Assessment

It shall be the mandate of the national regulatory authority to oversee the operations of BTS within the legal framework developed. This is necessary in-order to protect the health of blood donors and blood recipients and to monitor the compliance of blood centers to national standards and good manufacturing and laboratory practices.

Chapter 8: BIOSAFETY AND WASTE MANAGEMENT IN BLOOD TRANSFUSION

The waste management in the blood transfusion service deserves special consideration as:

- Large volume of blood is collected and handled from apparently healthy asymptomatic donors
- Large volume of blood needs to be discarded due to various reasons like reactive, contaminated units outdated or unsuitable units.
- A greater degree of potential hazard among health workers through the use of wide-bore needles for blood collection.

Therefore following standards shall apply:

8.1 All BTS personnel shall be trained in national bio-safety guidelines, handling blood and well informed of the hazards including transmission of viral infections.

8.2 Incidental exposures to infected samples like bag breakage, splash, and needle stick injury shall be immediately reported and recorded with the concerned authorities and action taken as per the guidelines on post –exposure prophylaxis.

8.3 Immunization against hepatitis B infection shall be mandatory before joining service after which their immune status will be determined.

8.4 The following safety instructions shall be followed at all times:-

8.4.1 All staffs are adequately trained in safety measures.

8.4.2 Staff must behave in a safe and responsible manner.

8.4.3 Access to the blood bank must be restricted to authorized personnel only.

8.4.4 Appropriate protective clothing must be worn including apron, mask and gloves.

8.4.5 Eating must be prohibited inside the laboratory.

8.4.6 Care must be taken to avoid formation of aerosols or splashing of materials.

8.4.7 All work surfaces must be decontaminated before and after the routine work is begun and after any spillage.

8.4.8 All contaminated waste or reusable materials must be appropriately decontaminated before disposal or reuse.

8.4.9 In-case of needle stick injury, squeeze out the blood, wash the hand with soap and water or anti-septic and prepare an incident report.

8.4.10 National guidelines on waste management and infection control are strictly followed.

8.4.11 All the waste produced at the mobile blood donation camps is also to be segregated at source and then transported back to the BTS for proper treatment and disposal.

8.5 The waste that generated within the BTS should always follow an appropriate and well-defined process from its point of generation until its final disposal referred to as “cradle to grave” concept.

This process should consists of following steps:-

a. Generation
b. Segregation at source of generation of waste
c. Collection
d. Storage
e. Transportation
f. Treatment
g. Disposal

Table 17: Example of waste generated in a BTS

Non-risk waste	Infectious waste	Sharps	Chemical waste
Packages, boxes Wrappings	Gloves, gauze, swabs, used cuvettes contaminated with blood. Blood and blood component units discarded due to TTIs, expired and unsuitability. Used blood bags, transfer bags and accessories for component preparations. Segments from blood bag tubing. IV sets, used test tubes, micro-capillary tubes, and glassware, used syringes. Liquids from cell washers. Blood and serum samples. Red cell suspension for blood group serology testing	Needles from blood collection bags, blood administration sets and other disposable needles. Broken test tubes, glass slides. Broken glassware and ampoules, lancets, scissors wafers for sterile connecting devices	Anticoagulant solutions, Copper Sulfate, disinfectants, reagents, anti-sera, buffer solutions

Table 18: Waste segregation

Types of Waste	Colour of container/ markings	Type of container
Infectious waste	Red polyethylene bag, marked "INFECTIOUS" or alternatively in plastic bins labelled with the international biohazard symbol.	Strong, leak proof plastic bags or containers capable of being autoclaved
Sharps	Yellow plastic containers, marked "SHARPS" Yellow Cardboard boxes	Puncture-proof and leak-proof containers, fitted with covers and made of plastic, dense cardboard or metal
General domestic waste	Green	Plastic bags

8.6 Treatment and disposal of infectious waste like blood units tested reactive for TTIs

8.6.1 Autoclaving in a waste autoclave operating at a minimum temperature of 121º C for 30 minutes or at 138°C for 18 minutes is the recommended method.

8.6.2 After the sterilization, the waste should be buried in a secure landfill.

8.6.3 The other option is the use of double chamber pyrolytic incinerator with temperatures higher than 1200ºC.

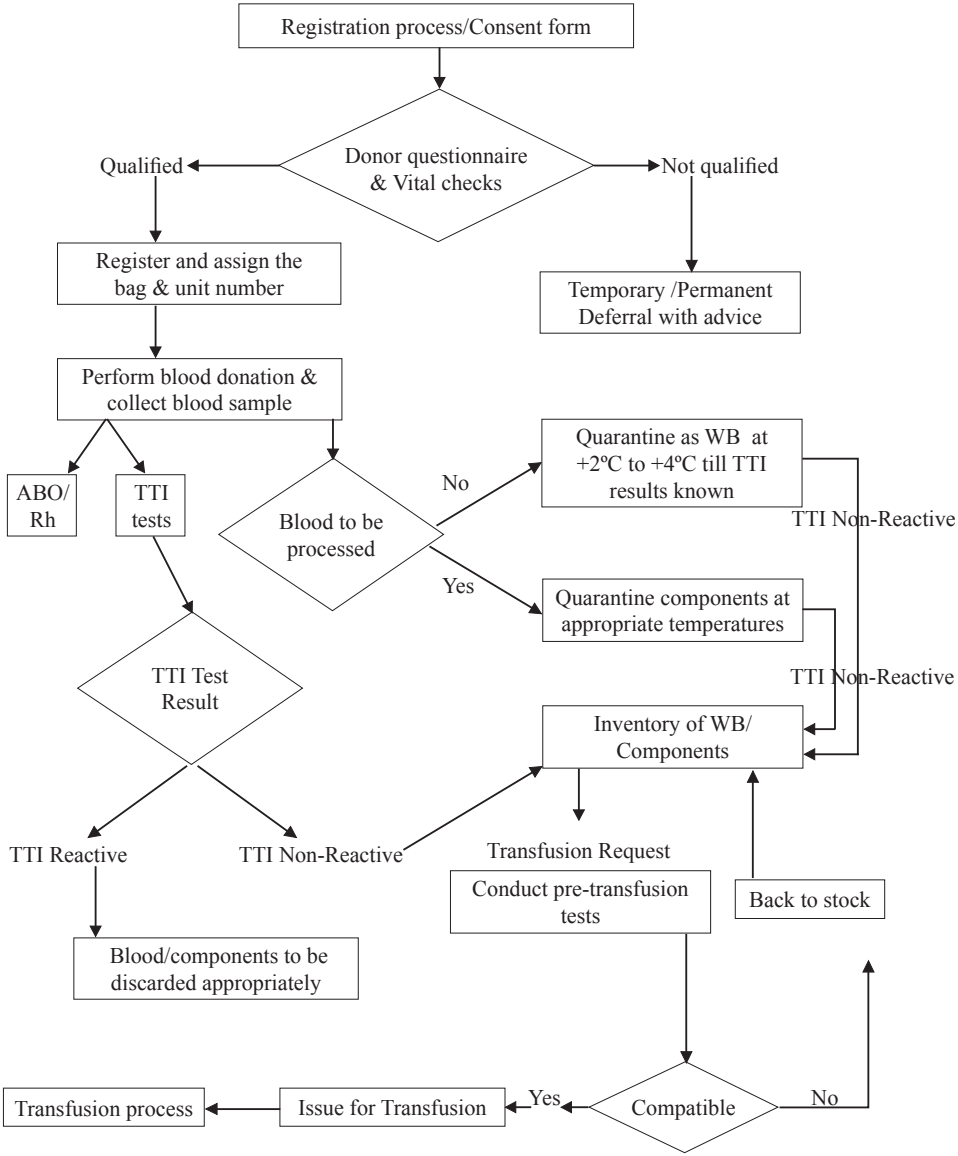
8.6.4 Where autoclave or incinerator is not available, burying of the infectious waste in a secured landfill is the method of choice.

8.6.5 Filled blood bags that are to be discarded should never be opened and the contents poured into the sink or bucket. Also never intend to inject disinfectant solution into the blood bags.

ANNEXURE

Annex 1

PROCESS FLOW



BLOOD DONOR QUESTIONNAIRE AND CONSENT FORM
NAME of BLOOD CENTER (indicate here)

Thank you for coming forward to donate blood

To ensure your safety as a blood donor and safety of the recipients of your blood, please read the information leaflet and answer the questions correctly. In case of any queries please seek help from the blood center staff. All information provided by you shall be kept confidential

Name of Donor: _____Age/Sex: _____

QUESTIONS	YES	NO	Remarks
Have you been feeling well today? Have you eaten some food in the last 8 hours?			
Have you donated blood before? If Yes, when was your last donation? Have you been advised not to donate blood for some reason?			
In the last three days have you taken medicines like aspirin, antibiotics or any vaccines like TT, hepatitis B or had any tooth extraction done?			
Have you ever suffered from major disease of the heart, lungs, kidney, thyroid, skin, liver, jaundice, epilepsy, high blood pressure, allergy, stomach ulcers, swollen glands, continuous fever, unexplained weight loss, continuous diarrhea, continuous cough, TB? If Yes, please provide details. Have you undergone any operation in last 6 months? If Yes, please give details			
In last one year, have you had a tattoo, ear or body piercing done? In last one year, have received rabies vaccination or blood transfusion?			
Has your blood ever been tested **'POSITIVE'** for Hepatitis B / Hepatitis C or for any Sexually Transmitted Disease? OR In last one year have you been treated for syphilis, gonorrhea or any sexually transmitted disease?			
In the last one year, have you been in sexual contact with anyone having jaundice, or anyone with HIV, Hepatitis B, Hepatitis C or had sex with a commercial sex worker, a drug addict or done any payment in return for sex? In last one year, have you had casual, unprotected sex with one or multiple partners?			

In the last three years, have you suffered from malaria or taken treatment for malaria? In the last six months, have you visited high malaria risk region?			
Have you suffered from any abnormal bleeding tendency like easy bruising or heavy blood loss after minor cuts?			
In case you are a woman are you pregnant, breast feeding a child of less than one year old or had an abortion in the last six months?			
Statement of consent: I, the undersigned have understood the importance and have given the correct answers to the best of my knowledge. I also give consent to screen my blood for infections like HIV, Hepatitis B and C and syphilis. Blood donor's signature:_____			

Hb% :_____ ABO/Rh:___Body weight:_____Température:_____BP:_____

Alcohol smell : Yes/No ; IV drug use marks : Yes/No ; Infected wounds : Yes/No ; Jaundice :Yes/No

Outcome: Donor accepted/ Temporary deferred/ Permanently deferred (Tick appropriate answer)

Date of donation :_____, Blood unit no :_____,

Type of blood bag : Single/Double/Triple bag ; Blood volume collected:_____
Time Taken:_____

Any reaction during/after blood donation? Yes/No. If yes, please mention the type of reaction:_____

Name of the blood center staff: _____
_____
_____

Information Note (to be provided to donor)

Name of donor:_____ Age/Sex:_____/____

Date of donation:_____, Unit No.:_____

You should follow the instructions mentioned below after donating blood:

- Take plenty of oral fluids on the day of donation.
- Continue your routine work; avoid any type of heavy or risky activity on that day.
- Do not smoke for the next one hour.
- Keep the band-aid/plaster on the donation arm for the whole day.
- In case after donating blood if you feel that your blood may be unsafe to the patient who receives it, you may please inform the concerned blood bank at the earliest for its timely discard.

Donated blood shall be screened for HIV, Hepatitis B, Hepatitis C, syphilis and if indicated for malaria

Thank you for your support. Kindly come again and donate the "GIFT of BLOOD"

Your next date of donation is around :_____

Name and Signature of the blood center staff: _____

Date: _____

Annex 3

DONOR DEFERRALS

A. LIST OF TEMPORARY DEFERRALS

CONDITIONS	*PERIOD OF DEFERMENT*
• Abortion	• Accept after 6 months
• Antibiotics	• Accept after completion of antibiotics
• Allergies	• Accept if mild seasonal allergy
• Anemia	• Accept only if it is iron deficiency anemia after it is treated
• Alcoholism	• Accept if donor is sober and not under the influence of alcohol
• Arthritis	• Accept after acute phase
• Asthma	• Accept after drug therapy
• Blood transfusion history	• Accept 6 months after the date of blood received
• Bronchitis	• Accept after 1 month of recovery
• Breast feeding	• Defer for 12 months after child birth
• Chest pain/shortness of breath	• Accept only if cleared by a medical doctor
• Common cold	• Accept if there is no fever
• Cystitis (Urinary Tract Infection	• Accept 3 weeks after recovery
• Dermatitis/skin infection	• Accept if venipuncture site is clear of any infection and not on any oral medication like antibiotics
• Dengue	• Defer until 4 weeks after recovery
• Diabetes	• Accept only if diet controlled, or taking single antidiabetic oral drug.
• Dysentery	• Accept 1 month after recovery
• Epilepsy	• Defer for 3 years after completion of treatment • No deferral needed if H/o epilepsy in childhood
• Fractures	• Minor accept after 3 months • Major accept after 6 months
• Fever, flu like illness	• Accept after 2 weeks
• Gall stones	• Accept if no symptoms of acute attack
• Gastro enteritis	• Accept after 1 month
• Gout	• Accept if asymptomatic and not on treatment

• H/o Malaria or taken anti-malarial drugs	• Accept after 3 years
• Visited an endemic area	• Accept after 6 months of return from malaria area
• Hypertension/high BP	• Defer temporarily and refer to a doctor
• Hypothyroidism	• Accept if 6 months of therapy have passed and thyroid levels are within normal limits
• H/o jaundice	• Accept after 12 months
• Menstruation	• Accept after menstruation is over
• Migraine	• Acceptable
• Peptic Ulcer / gastritis	Accept if on diet control or on antacid treatment
• Surgery	• Minor surgeries like appendicectomy, hernia repair, tonsillectomy accept after 3 months • Major surgeries like, gall stone removal, uterus removal, thyroidectomy accept after 6 months
• Syphilis or gonorrhea	• Accept after 12 months of completion of treatment
• Sexual contact with HIV/ Hepatitis B /C individual, drug addict, prisoner, homosexual	• Defer for 6 months
• Sexual contact with multiple partners or with commercial sex worker	• Defer for 6 months
• Tattoo, body piercing with unsterile sharps	• Defer for 6months
• Tonsillitis	• Defer till completion of treatment with antibiotics
• Tooth extraction	• Defer for 1 week
• Typhoid	• Accept after 1 month
• Tuberculosis	• Accept 5 years after recovery

B. LIST OF CONDITIONS FOR PERMANENT DEFFERAL

1	Abnormal bleeding tendency
2	Anemia's other than iron deficiency anemia
3	Asthma on steroid treatment
4	Cancers
5	Diabetes on treatment with insulin or with complications
6	Epilepsy

7	Hypertension with complications or heart diseases
8	Individuals with Hepatitis B, Hepatitis C or HIV/AIDS
9	Hyperthyroidism or thyrotoxicosis
10	Chronic kidney diseases or liver diseases

C. SPECIAL CONDITIONS

SPECIAL CONDITIONS	ACCEPT
1.Medicines/ Antibiotics/Aspirin	Accept three days after stoppage
2.Vitamins, contraceptive pills	Accept the donor on same day
3.Vaccines • Hepatitis A, Hepatitis B (recombinant), Rabies (Human diploid), Tetanus Toxoid • Rubella Vaccine • Hepatitis B immunoglobulin	• Accept after 48 hours • Accept after four weeks • Accept after 12 months
• Tattooing, ear piercing or any body part piercing	• Accept after 12 months
• History of syphilis or gonorrhea	• Accept after 12 months from completion of treatment
• Any individual who has been in a correction institution like jails or prisons for more than 72 hours	• Accept after 12 months

Annex 4 (SAMPLE ONLY)

BLOOD REQUEST FORM

NATIONAL BLOOD TRANSFUSION SERVICE, BHUTAN

Hospital: _____ Date of request: _____

PATIENT DETAILS

Name: _____ /Age/Sex: _____Wt:_____

Hospital reference no.: _____ Ward: _____

Blood group (documented earlier): ABO _____, Rh_____

HISTORY

Diagnosis: _____ Previous transfusion : Yes/No _____

Reason for transfusion: _____ Any reactions : Yes/No _____

Hemoglobin result (if WB/PRC requested): _____Previous pregnancies : Yes/No ____

Platelet count (if Platelets requested):_____

	REQUEST FOR:		URGENCY	
		1. Cross matched Blood		
Whole blood	☐ units	a) Routine	☐	
Packed Red Cells	☐ units	b) Urgent	☐	(blood needed in one hour)
Plasma	☐ units	c) Hold for surgery	☐	(GSH Protocol/CrossMatch)
Platelets	☐ units	**2. Un-Cross matched blood (tick in the blank space)**		

Date/time required: _____ a) Group 'O' PRC_____

b) Group specific blood_____

c) Abbreviated cross matched blood_____

Name of the doctor requesting blood: _____

LABORATORY USE ONLY

Compatibility testing

Patient's Reference. No: _____Patient's Blood Group: _____,

Antibody Screening : POSITIVE / NEGATIVE

Unit No.	PRC FFP/ PC/ WB	ABO/ Rh	Date & time of cross match	IS	37°C	IAT	CCC	Result of cross match	Name of staff cross matching unit	Date & time of issue and name of staff

Annex 5 (SAMPLE ONLY)

INFORMED CONSENT FORM FOR

TRANSFUSION OF BLOOD & BLOOD COMPONENTS

National Blood Transfusion Service
Bhutan

Patient Information

Name: …….

Age: …… Sex: ……..…

ID No: ……..……....

Parent Name: ……..

Hospital Reg. No……....

I. PATIENT STATEMENT:

I, the undersigned CONSENT to undergo the procedure of transfusion of blood or blood components with full knowledge of the need, the benefits, possible risks, side effects and the alternatives to a transfusion.

I have also been informed about the risks and consequences of not receiving this therapy and been given an opportunity to ask questions regarding transfusion and have received answers to my questions and concerns in a language understandable to me.

_____
(Signature/Thumb Imprint & Name)

II. PATIENT REPRESENTATIVE / INTERPRETER'S STATEMENT:

1. The patient is unable to consent because (where applicable): _____
_____

2. I, therefore, consent for the patient:

_____ _____
(Signature and Name) (Relationship to Patient)

3. Interpreter's attestation (where applicable):

The translation has been provided by me: _____
(Signature and Name)

III. DOCTOR'S AFFIRMATION:

I declare that I have personally explained the above information in detail to the patient and/or the patient's representative and have answered the entire patient's questions to the best of my knowledge.

_____
(Signature and Name)

Annex 6 (SAMPLE ONLY)

TRANSFUSION REPORT

(to be filled for each transfusion)

Name of patient: _____, Hospital: _____

Age / Sex: _____

Registration No: _____ Ward: _____

Pt's Blood Bank Ref No. _____ Pt's blood group: _____

Unit No: _____ Blood group of the unit: _____ Compatibility label checked: Y /N (circle)

Type of component (circle one): PRC /WB / FFP / Platelet concentrate /Pooled platelets

Volume of the unit: _____ml.

Name of the doctor advising: _____

Details of the nursing staff performing the checks and starting the transfusion:

Name: _____ Signature:_____

Date / time of starting the transfusion: _____

Any IV Fluid joined? Y/N _____ Any pre-medication given? Y/N _____

Vitals to be noted as below:

Time	Vitals			
	Temperature	Pulse rate	Blood Pressure	Respiratory rate

Outcome of the transfusion: Completed / Transfusion reaction occurred /(tick the appropriate)

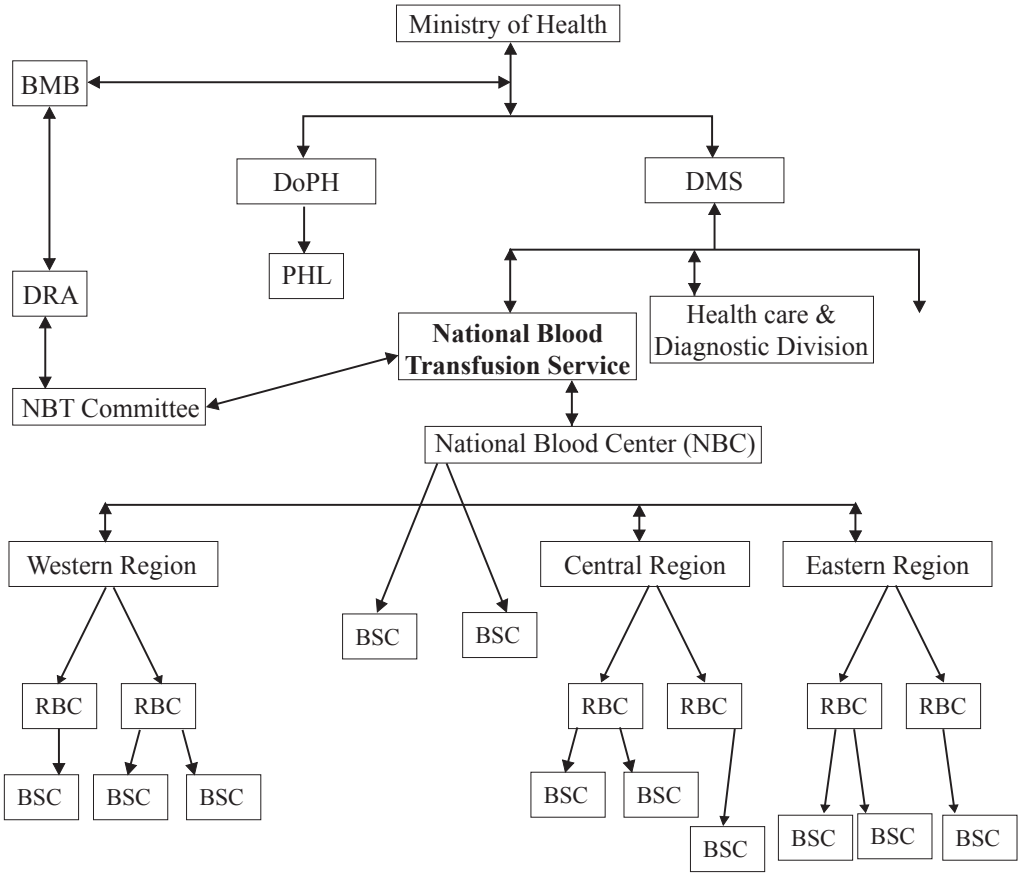
If reaction occurred, is it reported and are blood samples sent to the Blood Center? Y / N _____

Is the blood bank in-charge or blood center staff informed? Y / N _____
Details of the nursing staff completing the transfusion / reporting the reaction:

Name: _____Signature: _____

Annex 8

Figure:1 ORGANOGRAM OF CONSOLIDATED BLOOD TRANSFUSION SERVICE



Annex 9:

National Blood Transfusion Committee (NBTC)

1. *The National Blood Transfusion Committee (NBTC) shall comprise of the following members:*

1.1 Chairman- Director General, Department of Medical Service (ex officio)

1.2 Dy Chairman – Drug controller / Chief Regulatory Officer, DRA

1.3 Secretary – Director/Head of NBTS

1.4 Transfusion medicine specialist (ex officio)

1.5 Head, Public Health Laboratory (ex-officio)

1.6 Chief Program Officer –QASD (ex-officio)

1.7 Gynecologist (nominated by MOH)

1.8 Medical specialist (nominated by MOH)

1.9 Emergency medicine specialist (nominated by MOH)

1.10 Microbiologist (nominated by MOH)

2. *Roles and Responsibilities* of NBTC shall:

2.1 Serve as an advisory committee to the Bhutan Medicines Board on matters related to blood and blood products and blood transfusion service.

2.2 Guide Bhutan Medicines Board and the Ministry of Health in reviewing and revising the National Blood Policy and in all policy related matters.

2.3 Provide technical advice and guidance to Ministry of Health and other relevant agencies on establishment of a national blood program and development of a strategic blood plan.

2.4 Review, recommend changes and revise the national guidelines and standards for BTS for better implementation by the relevant agencies and enforcement.

2.5 Recommend the board for institution of subcommittees as and when required.

Annex 10

NATIONAL BLOOD TRANSFUSION SERVICE (NBTS)

1. *Staff at NBTS:*

1.1 Director /Head

1.2 Quality manager

1.3 Programme officer

1.4 Administrative staff and Support staff

2. *Functions of NBTS*

2.1 Secure annual budget from MoH for all BTS operations.

2.2 Perform strategic planning and develop actions plan and implement activities.

2.3 Coordinate all operations of Blood Transfusion Service in the country.

2.4 Develop national guidelines, standard procedures, and donor educational materials

2.5 Create national awareness and conduct multi-media campaigns on voluntary blood donations (VBDs).

2.6 Co-ordinate with relevant agencies on human resource development, capacity building through in-service trainings and CMEs for doctors, laboratory technicians, technologists, nurses, ACOs and other relevant health personnel.

2.7 Co-ordinate with DVED in the procurement of equipment, reagents and supplies.

2.8 Coordinate with DRA.

2.9 Monitor blood centers' by conduct periodic supervisory visits/audits.

2.10 Manage blood safety data through collection, compilation and analysis of reports from all blood Centers.

2.11 To co-ordinate with national blood center to organize National External Quality Assurance scheme in blood group serology and TTIs.

2.12 Organize National Hemovigilance System.

Annex 11

NATIONAL BLOOD CENTER (NBC)

1. *Staff at National Blood Center*

1.1 Head

1.2 Quality Manager

1.3 In-charge -Donor section and dedicated staff

1.4 In-charge -Red cell serology and dedicated staff

1.5 In-charge- TTI laboratory and dedicated staff

1.6 In-charge –Blood Component section and dedicated staff

2. *Functions of National Blood Center*

2.1 Perform all routine operations of a blood center

2.2 Provide technical advice to NBTS

2.3 Assist NBTS in national awareness and multi- media campaigns for Voluntary blood donations (VBD)

2.4 Preparing all technical documents

2.5 Introduction of new technologies

2.6 Support NBTS in procurement of reagents, consumables and equipment

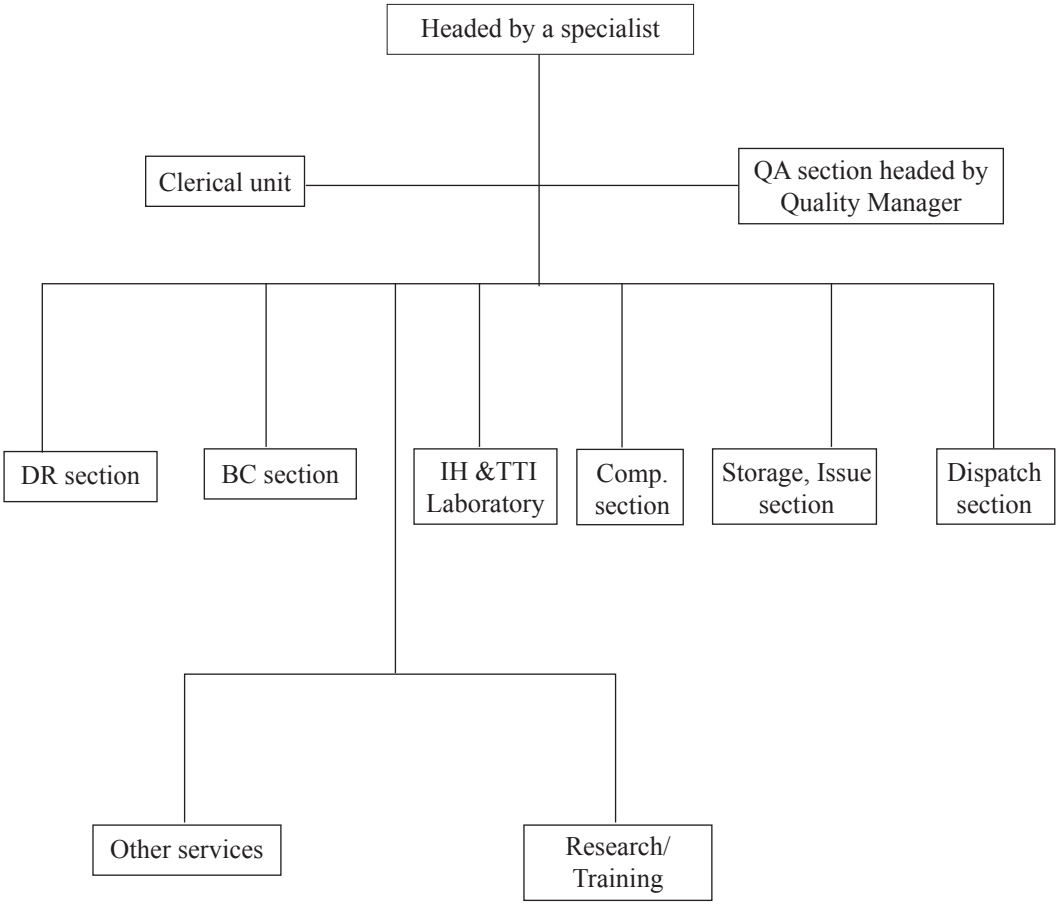
2.7 Conduct training of all categories of staff involved in blood transfusion chain

2.8 Organize National External Quality Assessment Schemes (NEQAS)

2.9 Participate in International External Quality Assessment Schemes (IEQAS)

2.10 Conduct Hemovigilance system

FUNCTIONAL STRUCTURE OF NATIONAL BLOOD CENTER



QA : Quality assurance
DR : Donor Recruitment
BC: Blood Collection
IH & TTI: Immuno-hematology and Transfusion Transmitted Infection
Comp. section: Blood component preparation

Annex 12

REGIONAL BLOOD CENTER (RBC)

1. *Staff at Regional Blood Center*

1.1 Head

1.2 Quality Manager

1.3 I /C -Donor section and full time dedicated staff

1.4 I/C -Red cell serology and full time dedicated staff

1.5 I/C -TTI laboratory and full time dedicated staff

1.6 I/C- Component section and full time dedicated staff

2. *Functions of a Regional Blood Center*

2.1 Blood Donor recruitment

2.2 Blood donor selection

2.3 Blood collection

2.4 Blood component preparation

2.5 Red cell serology testing

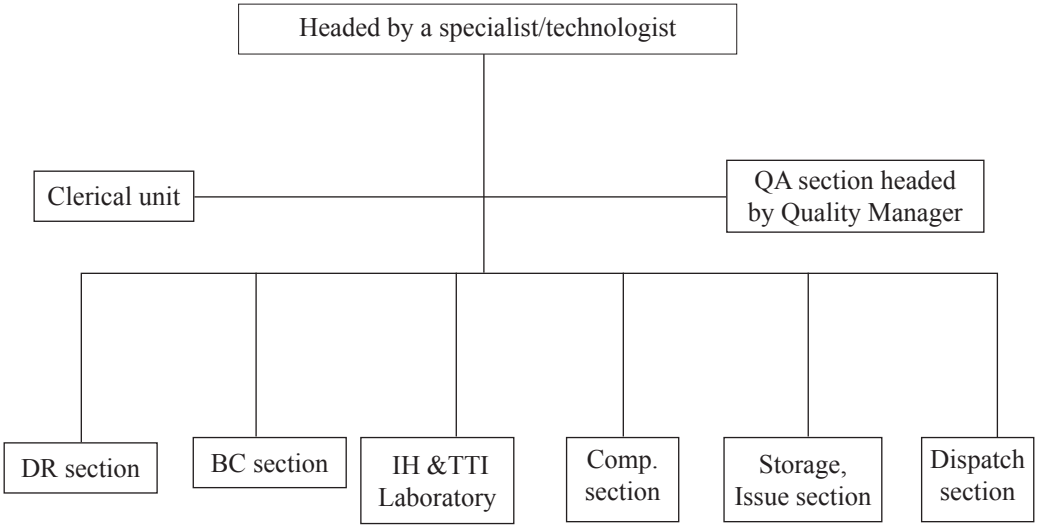
2.6 TTI Testing

2.7 Issue / Transport & distribution of blood and components to blood storage centers

2.8 Hemovigilance

2.9 Transfusion audits & monitoring

FUNCTIONAL STRUCTURE OF REGIONAL BLOOD CENTER



QA: Quality assurance
DR : Donor Recruitment
BC: Blood Collection
IH & TTI: Immuno-hematology And Transfusion Transmitted Infection
Comp. section: Blood component preparation

Annex 13

BLOOD STORAGE CENTERS (BSC)

1. *Staff at Blood Storage center*

1.1 Technicians from laboratory service on rotation

2. *Functions of a Blood Storage Center*

2.1 Receipt and storage of screened blood & components

2.2 Blood inventory management

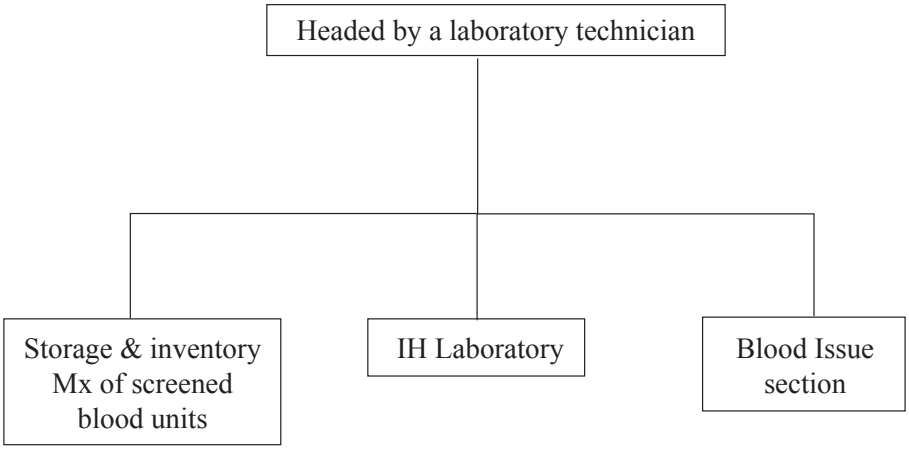
2.3 Maintenance of storage equipment

2.4 Grouping & cross-matching (compatibility tests)

2.5 Issue of blood

2.6 To participate in Hospital Transfusion Committee (HTxC) meetings

FUNCTIONAL STRUCTURE OF A BLOOD STORAGE CENTER (BSC)



IH : Immuno-hematology laboratory

Mx: Management

Annex 14

STANDARD TESTS AT CENTERS

Tests	NBC	RBC	BSC
Blood Donor Management Area			
ABO grouping	+	+	x
RhD typing	+	+	x
Weak D test	+	+	x
Test for Donor Hemoglobin	+	+	x
Screening of donated blood for HIV, HBV, HCV, syphilis and malarial (for all malarial endemic regions)	+	+	x
Donor Red cell phenotyping	+	+	x
Compatibility tests			
ABO grouping	+	+	+
Rh typing	+	+	+
Cross-matching test	+	+	+
Antibody screening test to detect unexpected anti-bodies	+	+	x
Antibody identification test	+	+	x
Recipient Red cell phenotyping	+	+	x
Quality Control tests			
QC tests on blood group serology reagents	+	+	+
QC tests on TTI reagents	+	+	x
QC tests on blood components	+	+	x
Other tests			
Tests for transfusion reaction investigation	+	+	+
Prenatal testing	+	+	+

ANNEX 15

BASIC EQUIPMENT REQUIREMENT AT CENTERS

S/No	Name of the equipment	NBC	RBC	BSC
	Blood donor management section			
1	Automatic Blood Collection Monitor with Shaker:	+	+	x
2	Blood collection spring scale	+	+	+
3	Portable Hemoglobin testing machine-Hemocue machine	+	+	x
4	Donor Couch	+	+	x
5	Hand tube stripper with roller and cutter	+	+	+
6	Dielectric tube sealer	+	+	+
7	Apheresis machine	+	x	x
	Immunohematology laboratory			
8	Blood Bank Bench top centrifuge (serofuge)	+	+	+
9	Automatic Cell Washer	+	+	x
10	Microscope	+	+	+
11	Dry Incubator	+	+	+
12	Column Agglutination Test system (Incubator Centrifuge and work station)	+	x	x
	Blood component preparation & storage section			
13	Refrigerated blood processing centrifuge	+	+	x
14	Double pan blood bag weighing balance	+	+	x
15	Standard blood bank refrigerator	+	+	+
16	Platelet agitator and incubator	+	+	x
17	Plasma Storage freezer	+	+	x
18	Plasma thawing bath	+	+	x
19	Manual Plasma expresser	+	+	+
20	Sterile connecting device	+	+	x
21	Cryobath	+	x	x
22	Laminar air flow	+	+	x
23	pH meter	+	+	x
	TTI laboratory			
24	ELISA system (washer and reader)	+	+	x

25	Micropipettes	+	+	x
	Blood cold chain			
26	Blood transport boxes with data loggers	+	+	x
27	Cool boxes	+	+	+

ANNEX 16

BASIC REAGENTS REQUIREMENTS AT CENTERS

S/No	Name of the reagents	NBC	RBC	BSC
1	Combi-pack of pre-diluted monoclonal Anti – D IgG antibody reagent and red cell preservative	+	+	+
2	Alsevers Solution for preservation of red blood cell	+	+	+
3	Anti - A, monoclonal antibody	+	+	+
4	Anti - A1, lectin, monoclonal antibody	+	+	+
5	Anti - AB, monoclonal antibody	+	+	+
6	Anti - B, monoclonal antibody	+	+	+
7	Anti - C, monoclonal antibody	+	+	x
8	Anti - c, monoclonal antibody	+	+	x
9	Anti - D, IgG antibody	+	+	+
10	Anti - D, IgM and IgG antibody	+	+	+
11	Anti - E, monoclonal antibody	+	+	x
12	Anti - e, monoclonal antibody	+	+	x
13	Anti - Fy^a antibody	+	+	x
14	Anti - Fy^b antibody	+	+	x
15	Anti - H lectin, monoclonal antibody	+	+	x
16	Anti - Human Globulin, poly-specific anti – IgG and anti- $C3^d$	+	+	+
17	Anti - Jk^a, monoclonal antibody	+	+	x
18	Anti - Jk^b, monoclonal antibody	+	+	x
19	Anti - K, monoclonal I antibody	+	+	x
20	Anti - Le^a monoclonal antibody	+	+	x
21	Anti - Le^b monoclonal antibody	+	+	x
22	Anti - $Lutheran^a$ antibody	+	+	x
23	Anti - $Lutheran^b$ antibody	+	+	x
24	Anti - M, monoclonal antibody	+	+	x
25	Anti - Mi^a, antibody	+	+	x
26	Anti - N, monoclonal antibody	+	+	x
27	Anti - P1, antibody	+	+	x
28	Anti - S, antibody	+	+	x
29	Anti - s, antibody	+	+	x
30	Antibody panel cells for antibody identification	+	+	x

31	Antibody screening cells	+	+	x
32	Adult blood administration set	+	+	+
33	Blood bag – single,CPDA1, 350ml	+	+	+
34	Blood bag – double, CPDA1, 450ml	+	+	x
35	Blood bag – triple, CPDA1, 450ml	+	+	x
36	Blood bag - quadruple, top and bottom	+	x	x
37	Bovine serum Albumin 22% solution	+	+	+
38	Column Agglutination Technology ID cards or cassettes for ABO, Rh and DAT test for newborns	+	x	x
39	Column Agglutination Technology, ID cards cassettes for Coombs Cross-match	+	x	x
40	Column Agglutination Technology, ID cards for antibody screening and antibody identification	+	x	x
41	Hemocue micro-cuvettes for Hb estimation specific to equipment	+	+	x
42	Plasma Over wrap	+	+	x
43	Platelet administration set	+	+	x
44	Printed sticker for Blood group- 'A' positive in yellow	+	+	+
45	Printed sticker for Blood group 'AB' positive black	+	+	+
46	Printed sticker for Blood group 'B' positive in pink	+	+	+
47	Printed sticker for Blood group 'O' positive in blue	+	+	+
48	Rh Control	+	+	+
49	Transfer bag, capacity 300ml	+	+	+
50	Volumetric Blood administration set for pediatric patients	+	+	+
51	Temperature recorder chart equipment specific (if required)	+	+	+
52	Temperature recorder pen for chart equipment specific (if required)	+	+	+
53	Rapid test kits for HIV antibody	+	+	+
54	Rapid test kits for HCV antibody	+	+	+
55	Rapid test kits for Hepatitis B surface antigen	+	+	+
56	ELISA test kits for HIV antibody	+	+	x
57	ELISA test kits for HCV antibody	+	+	x
58	ELISA test kits for Hepatatis B surface antigen	+	+	x
59	Treponema Pallidum Hemagglutination test kit	+	+	x
60	RPR test kit	+	+	+
61	Rapid test kits for blood donor screening for malaria antigens	+	+	x

ANNEX 17

EQUIPMENT RECORD

1. Name of the equipment:_____
2. Name and contact details of the manufacturer:_____
3. Name and contact details of the supplier:_____
4. Funded by:_____
5. Cost of the equipment (if known):_____
6. Date of installation: _____
7. Installation certificate: _____
8. Serial Number of the equipment: _____
9. Designated area for installation: _____
10. Electrical Requirement: _____
11. Intended use or purpose of the equipment: _____
12. Operation manual & Service manual available with: _____
13. Basic Principle on which the equipment works: _____
14. Calibration details: _____
15. Details of preventive maintenance: _____
16. Signature /Name of the person performing the QC: _____

ANNEX 18

STANDARD OPERATING PROCEDURES

Sr. No	Names of the test procedures
	Blood donor management
1	Donor selection criteria
2	Hb estimation of donors by Hb colour scale method
3	Hb estimation of donors by HaemoCue method
4	Preparation for phlebotomy
5	Selection of blood bags
6	Blood collection procedure
7	Management of donor adverse reaction
8	Relating product to donor
Immuno-hematology	
9	Washing of red cell (manual method)
10	Preparation of 3-5 % red cell suspension
11	Reading ,grading and recording reactions
12	Preparation of Std Ac, Bc and Oc for serum grouping
13	Preparation of Coombs Control cells
14	ABO blood grouping
15	Rh 'D' typing
16	Weak 'D' test
17	Direct Antiglobulin test
18	Antibody Screening test for unexpected antibodies(optional)
19	Antibody Identification test (optional)
20	Red cell antigen testing against the identified antibody
21	Patient sample acceptance and registration
22	Compatibility testing
23	Investigation of a transfusion reaction
24	Antibody titration
Labeling, storage, issue of blood and blood components	
25	Labeling of blood bags
26	Proper Storage of blood and blood components
27	Inventory of blood and blood components

28	Issue of blood and blood components
29	Reissue of returned, unused blood
30	Storage of reagents
31	Supply of safe blood for transfusion
32	Use of Sterile connecting device
	Blood Component preparation
33	Blood component preparation
34	Thawing of Fresh Frozen Plasma
	Screening of donated blood for TTIs
35	ELISA testing for HBsAg
36	ELISA testing for Anti-HIV antibody 1/2
37	ELISA testing for Anti-HCV
38	Rapid testing for HBsAg
39	Rapid testing for Anti-HIV antibody 1/2
40	Rapid testing for Anti-HCV antibody
41	RPR testing
42	TPHA testing
43	Malaria screening
44	Referral of screen reactive donors to VCT
	Quality control tests
45	QC of reagents-anti-sera
46	QC of reagents- red cell reagents
47	QC of equipment -Blood collection monitors -Blood bank refrigerator -Plasma freezer -Platelet agitator and incubator -Blood bank centrifuge -Plasma thawing device
48	QC of blood component -Platelet concentrates -Packed red cells -FFP
	Bio-hazard
49	Management of blood spill
50	Antigen Phenotyping test worksheet
51	Antibody titration worksheet

LIST OF FORMS AND WORKSHEETS

Forms/Sheets	Worksheets	Registers
Blood donor registration form	Hemocue QC sheet	Blood donor registers
Blood donor questionnaire and consent form	Worksheet for cell grouping and serum grouping for donors	Patient sample and crossmatching register
Blood donor deferral sheet	Worksheet for cell grouping and serum grouping for patients	DAT register
Unit collection sheet	Worksheet for Rh typing	Weak D test register
Donor reaction sheet	Daily QC of blood grouping reagents	District blood receipt register
Blood request form	Antibody screen test worksheet	Blood discard register
Transfusion report	Antibody identification test worksheet	Blood inventory register
Transfusion reaction form	Worksheet for QC of equipment	Blood component preparation register
Blood bank report	Worksheet for QC of antisera	Blood issue register
Temperature record charts	Worksheet for QC of blood components	Register for manual preparation of red cell units
VCT referring form	Worksheet for transfusion reaction investigation	TTI record register
Consent form for blood transfusion	Worksheet for sterile connecting device	VCT register
Six monthly blood bank report	Worksheet for ELISA -HIV, -HCV and HBsAg	
Monthly stock usage form	Worksheet for rapid test -HIV, -HCV and HBsAg	
Stock control card	Worksheet for rapid malaria test	
Equipment condemnation form		

ADMINISTRATION DOCUMENTS

Quality manual
Quality Policy document
Incident report
Records for blood bags, reagents and test kits
Equipment record
Personnel records

ANNEX 19

EQUIPMENT SPECIFICATIONS

Sl. no	Name of the Equipment	Description of Function	Operational Requirements
1	Laboratory Incubator	For dry heat treatment of test samples at 37°C ±2°C during the immunohematology procedures (incubation of biological agents)	***Specifications:*** • Dimensions (WxHxD): Housing:552mm x 685mm x700mm Chamber:408x459x390mm Useful space: 326x367x312mm • Volumes: Inside:73 litres Useful sapce:37.4litres Steam space:78litres Weight:40kg • Trays: Maximum tray load: Lumped: 15kg Surfaec:20kg Total :50kg • Number Standard/Max:2/9 piece • Dimensions (WxD):356x350mm • Thermal data: operating temperature: +2 5 °C to70°C Temperature deviations at 37 °C ±1°C • Warm up times when unit is empty to 37°C:37minutes • Cool down times from 37°C to when unit is empty to 30°C is 80min • Heat radiation to surrounding areas of 25°C at operating temperature of IS 37°C0.03kW • Rated voltage : 1/PE AC, 230V • Rated frequency : 50/60 Hz • Power consumption:0.32kW • Current load 0.35kVA • Current input1.4A • Reaction after power failure of more than 20 min to 2 hours and return of power: Control unit regulates on set temperature. Programme will be stopped, inside temperature will be flashing

			• Display accuracy:≤±1°C • Materials used: Outer casing :galvanized sheet steel Heat sink: aluminum Inner chamber, shelves and components fitted in the inner chamber: stainless steel Glass door toughened with sodium silicate Door seal: Seasoned silicone rubber Door handle: PA, glass fiber reinforced Control unit: ABS Thermal insulation: Mineral fiber wool Leads: PVC sheathed copper wire Filling medium-over-temperature protection device: polydimethyldisiloxane, equipped with an electronic upper –limit cut –out device of protection class 3.1
2	Blood Bank Centrifuge (Serofuge)	1.For spinning the test samples to detect antigen-antibody reactions during the immunohematogy testing	***Specifications*** • Silent centrifuge head for 12 tubes of dimensions 10 x 75 mm and 12 x 75mm. • Max RCF: 3000 rpm,/ 1006g • Adjustable parameters: 10 different parameters. • Time display in seconds. • Voltage requirement: 220 to 240 V 50 Hz. • Dimensions:260mm width,305mm depth , 175mm height • Weight: 4 to 5 kg ***Accessories required*** • Centrifuge head for 12 tubes of dimensions 10 x 75 mm and 12 x 75mm • Centrifuge head for 6 tubes of 15 x 100mm • Necessary stabilizer to be included with the equipment

3	Blood collection monitor with shaker	1.Accurate collection of blood volume during the blood donation process	***Specifications:*** • Type of mixing: Linear with central support • Volume weighing range : 10ml – 990ml (with minimum variation of 10ml) • Accuracy :±2% within the range of 300 to 500 ml • Weight display range: 10 – 990gms. • Weight accuracy: -1gm to +2gm. • Time display accuracy: 1second. • Power consumption 35VA • Line frequency 50/60 Hz • Power supply 115/230VAC with optional battery pack • Alarming conditions audible and visual. • Automatic mixing of the blood with anticoagulant preferably three dimen-sions. • Voltage input: 220 to 240 V 50Hz • Rechargeable battery pack • Weight of the machine: 3 kg without battery ***Accessories required:*** • Re-chargeable battery pack • Calibration mass of 500gm
4	Di-electric tube sealer	Hermetic sealing of the PVC tubing containing blood and blood components ensuring sterility of the blood in the blood bag	***Specifications*** • Sealing time: 1 to 3 seconds • Indication lamps for power, ready and sealing. • Maximum diameter of the tube that can be sealed :6mm • Tube detection: automatic • Power source: 220- 240 V, input frequency 50-60 Hz. • Power consumption: operating-170W, standing-20W • Operating temperature : +5 to +40 °C • RF output power:20W

			• RF output frequency; 40.68MHz • Compliance: EN61010-1 • Classification: Class I • Installation category: Category II • Operation: Continuous • Provided with a splash guard • The sealer to be equipped with a reliable process control that ensures leakage detection. • Weight: Approx 5 to 6 kg ***Accessories:*** Fuse: 250V, 3.15A 5' 20mm Type A Exhaust Fan,12volts DC Appropriate Voltage stabilizer
5	Platelet agitator and incubator	Storage of platelets for five days at the required temperature of +22°C±2°C in an incubator with continuous agitation of the platelet units for an even suspension of platelets in plasma , thereby maintaining the quality of the platelet unit .	***Specifications*** • •Type of equipment: Flatbed agitator fitted inside a temperature-controlled incubator operating in a CFC free refrigerant gas and insulation material and electricity from the national grid • Operation: Continous • Power:60W • Construction: Internal: Stainless steel • External: Corrosion resistant , at least 1mm thickness • Designed to hold a load of random platelet packs (300ml bag size) or • apheresis platelet packs (500ml) or a mixture of both types. • Glass door for easy inspection from outside • Design of shelves: Shelves are made of corrosion resistant material with sufficient clearance to minimize noise. • Easy loading and withdrawal of platelet packs. • Shelves cannot be pulled out in error. • The agitator holding the shelves is

			• suspended in such a way as to ensure minimum noise for the life of the agitator. • Amplitude 3.6 to 4.0cm; 65 to 75 strokes /minute • Electrical characteristics: Nominal input voltage 220/240V 50Hz. Equip-ment meets electrical safety specifications such as that of the IEC • Internal Temperature Control: Fan cooling, Electronic temperature control to maintain even temperature +22°C ± 2°C at all shelves and temperature display unit at 0.1°C graduation. • Microprocessor controlled LCD display of the inside tempearture at any given time • Audiovisual alarm when temperature out of range, open door,low battery and power failure warning, with battery backup. • External Ambient temperature: Incubator performs in an ambient tempera-ture of +43ºC+/- 1ºC and relative humidity of 60% • Capacity: for storage of approximately 24 to 36 bags of platelet concen-trates. • Temperature recording mechanism like a seven day recorder chart or an in-built printer ***Accessories:*** i. Seven day temperature recorder chart for continuous temperature re-cording (optional) ii. Ink stylus pens (optional)

6	Upright Plasma freezer	Rapid freezing process of the liquid plasma and subsequent storage of the plasma in the frozen state for 6months to 1 year at below -20°C	**Plasma Freezers** Equipment meets internationally accepted electrical safety speci-fications such as that IEC. ***Specifications:*** Type of equipment: Compression freezer with CFC free refrigerant gas and elec-tricity supply from the national grid • Construction: Internal: Stainless steel. External: corrosion resistant • Upright type • Solid door with roll out type drawers • Electrical Characteristics: Nominal input voltage 220V/240V 50 Hz. • Internal temperature Control: Electronic temperature control • Operating temperature: -35° C to -40°C with setting accuracy of +/- 1°C what-ever the load. • Fan air cooling, automatic defrost within safe temperature control • External ambient temperature: Performs in an ambient temperature of +10 to +43°C. • Hold over time: A full load of plasma packs at -36°C takes atleast 1 hour to rise to above -20°C. A full load of plasma packs at -36°C takes atleast 32 hours to rise above -5°C • Capacity: To store 200 approx plasma bags of 250 ml volume • Temperature Monitoring: Digital temperature (LED) display with 0.1 □C graduation • Temperature recording device • Visual and audible alarm system indicating unsafe temperatures • Battery back up for alarm and temperature recording device ***Accessories:*** Transparent poly carbonate material rack to hold 25 units of frozen plasma per rack Dimension of the rack are: 105x125x648mm

7	Incubator	As above Sr.No 1	
8	Plasma thawing device	Thawing (liquefaction) of the frozen plasma at controlled temperature of +37°C ±2°C and controlled time duration thus maintaining the properties of clotting factors in the plasma.	***Specifications:*** • Type of equipment: At 37°C water bath. Plasma packs held in special containers and constantly agitated uniformly in the bath until thawing is complete. Packs remain dry. • Construction: Internal: Corrosion resistant material, easy to clean and no staining. Easy loading and removal of the plasma packs. Easy to empty water when • Electrical Characteristics: Nominal input voltage 220V/240V 50 Hz. • Equipment meets internationally accepted electrical safety specifications such as that IEC. • Internal Temperature Control: Tamper resistant temperature control set at 37°C (+_1°C.) • External Ambient Temperature: Performs in an ambient temperature of 10°C to 30°C. • Thawing Time: A full load of flat plasma packs (approx 250ml volume) with a core temperature of -30°C is thawed completely in less than 20 minutes. • Warning Systems: Digital temperature (LED) display with 0.1°C graduation. • Visual and audible alarm system indicating temperature outside range. • Audible /visual alarm if water level drops.. • Audio/visual alarm if plasma pack leaks during thawing if pack is not in a leak proof container. • Capacity: To thaw 8 plasma bags at a time. ***Accessories:*** voltage stabilizer to be included with the equipment plastic wraps for holding the bags during thawing

9	Standard upright blood bank refrigerator	• Heavy insulation for storage of the whole blood and packed red cells at +4°C±2°C • with special features of alarm alerts, • continuous temperature monitoring and display, • uniform temperature mainatianence throughout the equipment. • longer holdover time in the event of power failure	***Specifications:*** • Type : Compression type ,CFC free refrigerant gas • Construction: Internal: Stainless steel. External: Corrosion Resistant. • Glass door and roll out stainless steel drawers. • Electrical Characteristics: Input voltage: 220 /240 V 50 Hz. • Internal temperature Control: Electronic temperature control: range +2°C to +6°C with setting accuracy +-1°C. • Fan air cooling. • External ambient temperature: Performs in an ambient temperature of +10ºCto +43ºC. • Hold –Over time: A full load of blood packs at +4 °C takes at least 30 minutes to rise to above +6 °C • Cooling down time: A full load of blood packs at +25°C takes a maximum of 13 hrs for all the packs to reach below +6°C • Temperature monitoring: Digital temperature LED display with 0.1ºC graduation • Temperature recording device. • Audible and visual alarm system indicating unsafe temperatures. • Battery back up for alarm and temperature recording device. • Mounted on castor wheels • Minimum compressor starting voltage: 22% below nominal voltage Capacity of three different BBRs are: i. Terumo penpol : 300 litres (144 blood bags of 450ml volume or 168 bags of 350 ml) ii. Revco I : 300 litres

			iii. Revco II: 500 litres ***Accessories:*** Seven day circular chart paper for range of 0 to +40°C, chart resolution:±1°C Stylus ink pen
10	Automated Cell Washer	Multi-functions in medical analysis : 1. Centrifuging of test samples to detect antigen-antibody re-actions in immune-hematology tests. 2. Automatic washing of the test samples with normal saline.	***Specifications:*** • Fast acceleration and deceleration. • Compact and light weight. • Agitates automatically after each decant; agitate cycle also manually operable. • Digital display of time and wash cycle. • Single distributor for standard 10mm x 75mm or 12mm x 75mm test tubes. (12 test tubes) • Speed and RCF:500 to 3000rpm and decant speed at 600rpm • Controls for Mode, Cycle; Time and Command • Brushless system---no need to replace worn brushes • Lifetime lubrication of all moving arts. • Saline level detection/alarm system • Electrical Requirements:220 V • Easy-to-clean housing. ***Accessories required:*** 1. Centrifuge head with No 1 to 12 test tube holders of 12mm tube diameter 2. Aspiration tube (1 meter) 3. PVC tube between saline pump and NaCl detector (1 meter) 4. Ballast for tube NaCl =H2O 5. Polypropylene connector (right angled connecting piece for tubes) 6. Waste tube(1 meter) 7. Fan filter 8. Replacement fuses 100-240VAC

11	Electronic Blood measuring scale	To determine the weight /volume of various blood components during the process of blood component preparation	***Specifications:*** • Input supply 220 to 240 V 50 Hz • Weighing range: up to 1 kg • Resolution: 1Gm • Zero set provision to account for weight of the empty bag • Alarm when the programmed volume is reached • Provisions for six key keyboard for power on/off; weight/volume conversion; zero set. • Led indications for zero set and volume measurement
12	Blood collection spring scale	Special spring scale for measuring the blood volume (from 0 to 500ml) collected in the bag. Used during mobile blood donation camps	Special spring scale for measuring the blood volume (from 0 to 500ml) with accuracy
13	Hemocue Blood Hb	Hemocue machine is used for quantitative determination of Hb in whole blood using a specially designed analyzer with specially designed microcuvettes containing dried reagents. It is the method of choice for measuring Hb of blood donors in blood banks, mobile camps for its eay to use machine, consumables and quick measuring time .	***Specifications:*** • Measuring range: 0-25.6gm/dl • Samples can be capillary, venous or arterial blood for Hb estimation • Battery operable and with power supply. • Voltage: 6-9 VDC • Current input: 100mA • Pollution degree 2 • Over voltage category II • Weight :350gm • 4 batteries type AA • Dimensions: 85x 160x43mm Transformer CE marked 230VAC, 50 Hz, output is 6VDC, 350 mA ***Consumables required:*** • Microcuvettes specific to the machine • Liquid Hemocue controls (High, Low and normal range) • Hemocue cleaner

14	Hand tube stripper	A multi functional instrument for squeezing tubing and cutting the tubing.	Hand Tube stripper, roller cutter
15	Donor couch	Ensuring safety and comfort to the donor and the phlebotomist. Enables the phlebotomist to tilt the couch by operating a simple switch	***Specifications:*** • Width of the arm rest: 15cm • Length of arm rest : 60cm • Lifting capacity : 135 kg • Power : 230V, 50Hz • Weight : 80 kg • Seat height : 56cm • Length of seat and rest : 100 cm leg • Length of back rest : 90 cm • Width : 67 cm • Upholstery : Soft upholstery of 2.5inch thickness • Base adjustments: Back rest tilt 0° to 75° Seat rest tilt 0° to 20° Leg rest tilt to 35° • Castor wheels to be provided. • Tray and stands to be provided. • Interface for blood collection monitor • Confirms to standard and specifications of ISO 9001 CE, WHO, IDCA.
16	Sterile connecting device	The system is used for automatically connecting in a sterile manner of the PVC tubing of the blood bags	***Features:*** • The SCD connects PVC tubing of the blood bag of same diameter, maintaining a functionally closed system. During the wielding process, the sterility of cells or fluid in tubes and bags is maintained. • PVC tubing is connected using wafers that are heated to a high temperature. This maintains sterility during wielding. • The wielding temperature is

			controlled by a sensor, assuring the accurate heating and sterility of the SCD wafer. • There is no physical contact with the wafer from application to disposal. By using the wafer cassette, wafer replacement is carried out by pulling the wafer replacement lever. Wafers are automatically disposed off after use. They are used for single use only. • An LCD display indicates operating status, guidance for the operators and error messages. • Specifications: • Tubing sizes: Outer diameter:3.9-4.5mm Inner diameter :2.9-3.1mm • Tubing material: Polyvinyl Chloride (PVC) that is the tubing of the blood bags, Leukocyte reduction filters, apheresis kits . • Operating conditions: Temperature +10 to +40ºC, humidity :10% to 80% • Storage conditions: Temperature:-10 to +50ºC • Electrical requirements: AC 100 to 240V, 50 to 60 Hz • Weight: 5 to 7 kg approx • External dimensions: W224 x H177 X D342mm ***Consumables required*** • TSCD II Wafers (model number SC*W017) Pack size: one cassette contains 70 number of wafers

17	Refrigerated blood processing centrifuge	For separation of blood by centrifugation into various blood components under controlled temperature speed and time	***Specifications:*** • High –capacity floor standing centrifuge with temperature controlled refrigeration. • Microprocessor driven and programmable memory up to minimum 20 programmes for speed, RCF, acceleration, deceleration, temperature and time and functions: like RCF pre-selection, quick run, automatic rotor recognition, imbalance detection and soft touch lid lock • Maintenance free induction motor • Should have provision or capacity to centrifuge 8 blood bags of 450ml volume (double, triple and quadruple blood bags). • Power :220, 50 Hz • Speed range: 300 to 10,000 rpm, adjustable in 10 rpm increments. • Max RCF: 15,320g. • Drive: Brushless induction drive. • Acceleration/deceleration: 9/9 profiles • Program memory: 9 + 1 centrifugation programs • Run time: 0 to 99minutes, plus load. • Temperature range: -9°C to +40°C, CFC refrigerant free • Temperature: 2 digit adjustable in 1°C interval • Safety Features: Lid lock and lid interlock, automatic imbalance cut –out and steel armored chamber and provision for unlocking the lid incase of power failure and quick stop at any time using a special key also during the deceleration phase

			• Should display the error of lid not closed, imbalance, malfunction of the centrifuge, operating errors, over temperature. ***Accessories Required:*** ROTOR: Windshield and double blood bag buckets (6 pieces) For centrifuging capacity of 8 blood bags x 450ml. 1. Maximum Speed: 4,400 rpm 2. Maximum RCF: 5,480g 3. Maximum Capacity: 8x 500 ml 4. Adapter for 450/500ml quad, triple "XL" set of 6 5. Volume Adjustment Plates: blue rubber (set of 12) 6. Taring sticks: 4 each of 6gm and 15gm
18	Manual plasma expresser	The stand is used to extract manually blood components from a blood collection bag, or from a satellite bag to a transfer bag.	***Specifications:*** • Spring loaded • Fitted with 8mm plexiglass plate to give strength while operating the function of expression • To accommodate bags to up to 500ml volume • Rear base designed to wash the blood stains
19	Ice-lined blood bank refrigerator (optional)	A refrigerator for storage of whole blood or red cells in blood banks with a limited electric supply. They should hold the temperature below +10°C for up to 72 hours following a power cut and at +4°C in presence of power supply	***Specifications:*** • Type of equipment: Compression refrigerator that uses CFC free gas and at least 8 hours /day of electricity • Construction: Internal: Stainless steel. • External corrosion resistant • Chest type with CFC gas free insulation. Upright trays. • Solid door. • Net Volume: 180 litres. Lockable lid

			• Electrical Characteristics: Input voltage: 220 /240V 50 Hz. • Equipment meets electrical safety specifications such as that of IEC • Minimum Compressor starting voltage: 22% below nominal voltage. • Internal temperature Control: Electronic temperature control, range + 2°C to+6°C in refrigerator section with setting accuracy of +/- 1°C whatever the load. In freezer section temperature range -20°C to -40°C. fan air cooling. • External Ambient temperature: Performs in an ambient temperature of +10°C to +43%. • Hold-Over Time during power cut out: at +32°C ambient should be 60 hours. • Cooling Down Time: A full load of blood packs at +37°C takes a maximum of 8 hours for all the packs to reach below +6°C. • Temperature Monitoring: Digital temperature LED display with 0.1&C graduation. • Temperature recording device\. Audible and visual alarm system indicating unsafe temperatures. Battery back up for alarm and temperature recording device. • Capacity: 100 to 150 blood bags of 450ml volume. • Necessary Spare parts to be made available. • Voltage stabilizer is needed then to be provided with the equipment

20	Semi Automatic ELISA	For blood screening using ELISA assays	***Specifications:*** • Open System for programming any ELISA test • UV Screening , Advanced kinetics, End point, curve fit, shaking • Programmable time and speed • Measurement channels & Ref. channel present • Variable Wave length and filters present • Absorbance range – 0 to 4.0 OD • Accuracy and precision - +- 0.005 OD • Resolution – 0.001 OD • Throughput to suite Lab. Requirement • Software capable for self test and calibration • Help menu available • Residual volume per well – 2 l • Suitable for U,V & flat bottom microplates etc • Printer attachable • Software capable for self test and calibration • Many methods stored for easy recall • Crosswise operation, overflow washing, bottom washing • Vacuum power – software adjustable • Software capable for self test and calibration
21	Cool boxes	Features: To carry whole blood from one blood bank to another	***Specifications:*** • Robustness: Fitting 2, casing 2 • Net capacity: 10 to 12 bags • Cold life: Maintenance of under +10ºC for minimum of 130 hours in an ambient temperature of +43ºC

			• Minimum Ice Melting Rate: More than 10 hours per 1 kg ice melted during 43ºC cold life test • Cold packs: To confirm specification E5/IP1 or IP2. Sufficient water filled ice packs for freezing at -20ºC are provided to surround blood bags on all sides • Means of handling: Two handles for easier lifting, carrying by vehicle • Optional specifications: The transport box may be designed to operate from the direct current of a motor vehicle battery during long transportation hours

Annex 20

REAGENTS SPECIFICATIONS

SL. No	Items	Function	Vol. & storage	Remarks.
1	Combi-pack of pre-diluted monoclonal Anti - D, IgG antibody reagent and red cell preserving solution	To prepare Coombs control cells	2 vials of 10 ml each and storage at +2 to +8°C	Coombs Control cells prepared should give 2+,3+,4+reaction with AHG and have stability of 4 weeks post preparation
2	Alsevers Solution for preservation of red blood cell antigenicity	To prepare standard cells	vial of 20ml each and storage at +2 to +8°C	Standard cells prepared should have stability of 4 to 6 weeks post preparation
3	Anti - A, Monoclonal blood grouping IgM antibody for slide and tube method.	For ABO blood group ing	vial of 10 ml and storage at +2 to +8°C	Titre ≥ 1:256 with A cell and negative with B cell
4	Anti - A1, lectin, monoclonal IgM antibody for tube method	To detect A1 red cell antigen from A2	vial of 5ml each	
5	Anti - AB, Monoclonal blood grouping IgM antibody for slide and tube method	For ABO blood group ing	vial of 10ml each and storage at +2 to +8°C	Titre ≥ 1:256 with A cell and negative with B cell
6	Anti - B, Monoclonal blood grouping IgM antibody for slide and tube method	For ABO blood group ing	vial of 10ml each and storage at +2 to +8°C	Titre ≥ 1:256 with B cell and negative with A cell
6	Anti - C, Monoclonal Rh/hr typing IgM antibody for tube method	For typing antigen (C)	vial of 2ml each and storage at +2 to +8°C	

7	Anti - c, Monoclonal Rh/hr typing IgM antibody for tube method	For typing antigen (c)	vial of 2ml each and storage at +2 to +8°C	
8	Anti - D, IgG only, antibody only for tube method	For a weekly D testing	vial of 10 ml each	
9	Anti - D, IgM and IgG combination, Monoclonal IgM and IgG blood typing antibodies for slide and tube method	For Rh blood typing	vial of 10ml each and storage at +2 to +8°C	Titre ≥ 1:256 with D positive cell
10	Anti - E, Monoclonal Rh/hr typing IgM antibody for tube method	For typing antigen (E)	vial of 2ml each and storage at +2 to +8°C	
11	Anti - e, Monoclonal Rh/hr typing IgM antibody for tube method	For typing antigen (e)	vial of 2ml each and storage at +2 to +8°C	
12	Anti - Fy^a antibody	For phenotyping the respective red cell antigens	vial of 2ml each and storage at +2 to +8°C	
13	Anti - Fy^b antibody	For phenotyping the respective red cell antigens	vial of 2ml each and storage at +2 to +8°C	
14	Anti - H lectin, monoclonal IgM antibody for tube method		vial of 5ml each and storage of +2 to +8°C	

15	Anti - Human Globulin (Green), polyspecific, containing anti - IgG and anti $C3^d$	To detect IgG antibodies as in Crosmatching, DAT and IAT tests	vial of 10ml each and storage at +2 to +8°C	AHG should give 2+/3+/4+ reaction with CCC and negative reaction with any std cell
16	Anti - Jk^a, monoclonal IgM antibody for tube method	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	
17	Anti - Jk^b, monoclonal IgM antibody for tube method	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	
18	Anti - K,monoclonal IgM antibody for tube method	For phenotyping the respective red cell antigens	vial of 5ml each and storage at +2 to +8°C	
19	Anti - Le^a monoclonal IgM antibody for tube method	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	
20	Anti - Le^b monoclonal IgM antibody for tube method	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	
21	Anti - Lutheran ^{a}	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	

22	Anti - Lutheran [b]	For phenotyping the respective red cell antigens	vial of 5ml each and storage of +2 to +8°C	
23	Anti - M, monoclonal IgM antibody for tube method	For phenotyping the respective red cell antigens	vial of 5ml each and storage of +2 to +8°C	
24	Anti - Mi[a], antibody for tube method	For phenotyping the respective red cell antigens	vial of 5ml each and storage at +2 to +8°C	
25	Anti - N, monoclonal IgM antibody for tube method	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	
26	Anti - P1, antibody for tube method	For phenotyping the respective red cell antigens	vial of of 1ml each and storage at +2 to +8°C	
27	Anti - S, antibody for tube method	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	
28	Anti - s, antibody for tube method	For phenotyping the respective red cell antigens	vial of 3ml each and storage at +2 to +8°C	

29	Antibody panel cells for antibody identification for conventional tube method (a set of 11cells of 3% suspension). Together the three cell set must possess all the antigens on their red cells for Rh, Kidd, Duffy, P1, MNS, Kell, Lewis , Lutheran blood group system	To identify all unexpected red antibodies	11X4ml/pack and storage at +2 to +8°C	To be procured on monthly basis maintaining cold chain and have a shelf ife of 4 weeks
30	Antibody screening cells for conventional tube method. (A sets of 3cells of 3% suspension) .Together the three cell set must possess all the antigens on their red cells for Rh, Kidd, Duffy, P1, MNS, Kell, Lewis , Lutheran blood group system	To detect unexpected antibodies	3X10ml/pack and storage at +2 to +8°C	To be procured on monthly basis maintaining cold chain and have shelf life of 4 weeks
31	Bovine serum Albumin 22% solution for serological applications ,protein concentration and pH should be adjusted to 22% and 7.1 respectively	To enhance immunological reactions and increase test sensitivity	vial of 10ml each and storage at +2 to +8°C	

32	Rapid test kit for blood donor screening for Malarial Antigens to all four species ,It should comprise of monoclonal anti Pan specific pLDH IgG antibody conjugated with gold sol in conjugate pad which facilitate high specificity and monoclonal anti Pan specific pLDH IgM antibody in test line area of chromatography membrane which facilitate high sensitivity for the antigen (pLDH) detection	Rapid test kit for blood donor screening for Malarial Antigens to all four species which detects pan specific pLDH , High sensitivity for antigen detection, should detect very less parasitaemia. (150 parasites/ ul), have no cross reactivity	25 test kits in one pack and storage at +2 to +8°C	
33	Rh-hr Control fortified with Bovine serum Albumin	To be used in parallel to confirm the specific reaction with Rh antigen and Rh antibody	vial of 5ml each and storage of +2 to +8°C	
34	Rapid test kits for anti-HIV antibody			WHO evaluated Sensitivity: ≥99.5 % and specificity : >98%
35	Rapid test kits for anti HCV antibody			WHO evaluated Sensitivity: ≥99.5% and specificity : >98%

36	Rapid test kit for Hepatitis B Surface Antigen			WHO evaluated Sensitivity: ≥99.5% and specificity : >98%
37	ELISA test for anti-HIV 1 / 2 antibody			WHO qualified, sensitivity: ≥99.5% and specificity: >99.8%, Antibody (IgG and IgM) detection
38	ELISA test for anti HCV antibody			WHO qualified, sensitivity: ≥99.5% and specificity: >99.8%, Antibody (IgG and IgM) detection
39	ELISA test for Hepatitis B Surface Antigen,			WHO qualified, sensitivity: ≥99.5%, specificity: 99.8% Antibody (IgG and IgM) detection
40	TPHA rapid immunochromatography test kit			Sensitivity: 100%, specificity: 99.8% Antibody (IgG and IgM) detection
41	RPR flocculation test kits,			Sensitivity: 100%, and specificity: 99.8%Directions for both qualitative and quantitative method (serial dilution)

42	Rapid test kits for blood donor screening for malaria antigens	Test that can detect pan specific pLDH which facilitate to detect active infection i.e. viable parasites of all malaria		It should be highly sensitive – antigen detection- (should be able to detect very less parasitaemia. (150 parasites/ul) and NO Interference protected from heterophile antibodies – no cross reactivity. It should be a double antibody sandwich assay for detection of active malaria infection comprising of monoclonal anti Pan specific pLDH IgG antibody conjugated with gold sol in conjugate pad which facilitates high specificity and monoclonal anti Pan specific pLDH IgM antibody in test line area of chromatography membrane which facilitates high sensitivity for the antigen (pLDH) detection.