Standards for

Blood Bank Services

Version 1

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Health Policies and Standards Department

Health Regulation Sector (2022)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018 to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector;
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice;
- Managing patient complaints and assuring patient and physician rights are upheld;
- Governing the use of narcotics, controlled and semi-controlled medications;
- Strengthening health tourism and assuring ongoing growth; and
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for Blood Bank Services aims to fulfil the following overarching DHA Strategic Priorities (2022-2026):

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Leading global efforts to combat epidemics and infectious diseases and prepare for disasters.
- Pioneering prevention efforts against non-communicable diseases.
- Become a global digital health hub.
- Foster healthcare education, research and innovation.

- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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EXECUTIVE SUMMARY

The purpose of this document is to assure the provision of the highest levels of safety and quality during collection of blood from voluntary blood donors, processing, screening, storing and transportation. This standard has been developed to align with the evolving healthcare needs and international best practice in transfusion medicine. It includes several aspects which are required to provide effective, efficient, safe and high quality of blood and blood components. This standard includes the process of collecting blood from voluntary blood donors including and not limited to: blood donors' education, registration, eligibility criteria, questionnaire and consent, medical assessment pre-blood donation, blood donation and post blood donation care and instructions. In addition to blood processing, labelling, screening, storing and issuing and distributing blood and components. Laboratory equipment use and maintenance, safety requirements, management of blood donor & related blood and components records and quality assurance. It also addresses the facility and healthcare professional requirements, staffing requirements, Medical Director responsibilities, staff training and competency assessment, infection control, quality control and reporting key performance data.

At Blood Banks, a thorough assessment is required which includes and not limited to the donor eligibility criteria, a minimum physical examination, laboratory testing, providing utmost safety to the blood donors and collecting the highest quality blood for use for needy patients in hospitals. Blood Banks shall provide services such as but not limited to:

- Donor Education
- Donor Registration

- Filling of Donor History Questionnaire.
- Donor Medical Assessment (Screening)
- Phlebotomy
- Post Donation Care
- whole blood units processing to components. Pathogen reduction technology
- Screening blood donors' samples for infectious diseases according to UAE, national screening program.
- Conducting ABO, Rh typing and screening donors' samples for unexpected Red Cells Antibodies.
- Storing of blood and components
- Transportation of blood and components under pre-defined controlled temperature.
- Daily quality control procedures.
- Maintaining and updating related records.

Blood donation process shall require a certified nurse to perform donor registration, assess eligibility and carry out medical assessment. While blood collection (phlebotomy) can be carried out by trained phlebotomist. Blood and components collection, preparation, screening, storing and distribution can be performed by a qualified medical laboratory technologist and under the supervision of laboratory Medical Director who should be qualified by training and education to direct blood facility. The concerned technical team who are trained, competent, experienced and privileged by the Clinical Privileging Committee should perform specified tasks within the confinements of permitted licensure and specialization.

This standard is aligned with the following Federal, DHA and international standards:

1. Cabinet Resolution No. (28) of 2008 regarding the Blood Transfusion System
2. Cabinet Decision No. (40) of 2019 regarding the executive regulations regarding medical Liability
3. Law no. (4) of 2015 on Private Health Facilities and related ministerial decision (29) of 2020.
4. Unified National Standards for Hospitals (2018).
5. Unified Healthcare Professional Qualification Requirements (PQR)
6. National Guidelines for Biosafety 2020.
7. Federal: Unified National Standards for Hospitals.
8. Dubai Design Code.
9. DHA Health Facility Guidelines, Part B - Health Facility Briefing and Design, Laboratory Unit
10. DHA Clinical Laboratory Accreditation Policy
11. DHA Facility Licensing Policy.
12. DHA Role and Responsibilities of Medical Director Policy.
13. DHA Communicable Disease Notification Policy.
14. Standards for Medical Advertisement Content on Social Media.
15. DHA Guidelines for Managing Health Records.
16. Association for the Advancement of Blood and Biotherapies (AABB) current standards.

ETHICAL CONSIDERATION

1. Blood donation is voluntary act. The Blood Banks are strictly prohibited from giving any commission to the blood donors.

2. Blood & components are considered as pharmaceutical products where GMP, GLP & GCP are applied.
3. Personnel working in the Blood Banks shall be aware of their ethical responsibilities and comply with the DHA Code of Conduct for Healthcare Professionals.
4. Personnel working in the Blood Banks shall maintain donor's information confidentiality at all times.
5. Donor' confidentiality to be maintained through the whole journey of the donation. Notification of abnormal finding should be addressed to the concerned donor only.

DEFINITIONS

Accreditation: is the process of officially evaluating clinical laboratory to maintain satisfactory standards, conducted by international accreditation organizations.

Adverse Event: is a complication in a donor or patient. Adverse events may occur in relation to a donation, a transfusion, or a diagnostic or therapeutic procedure.

Allogeneic Donor: is an individual from whom products (blood) intended for another person are collected.

Autologous Donor: is a person who acts as his or her own product donor.

Backup: is a digital data and/or physical storage containing copies of relevant data.

Blood Bank (BB): is a DHA licensed medical site, building or place in which procedures for collecting blood and blood component from eligible, voluntary and non-remunerated blood donor, blood component preparation and processing, screening, storage and supply intended for transfusion, is performed by trained and skilled healthcare professional according to current DHA Standards for Blood Bank services.

Blood Components: are therapeutic products prepared from a whole blood collection or produced through an automated collection, e.g., red cells, plasma, and platelets.

Blood Donation Collection Site (BDCS): is a DHA licensed medical site, building or place in which procedures for collecting blood and blood component from eligible and voluntary and no remunerated donor is carried out, ensuring required pre and post donation care is performed by trained and skilled healthcare professional.

Blood Donor: is any individual (age 18 to 65 years) who fulfils the eligibility criteria for whole blood and/or component donation, and is voluntarily willing to donate, without any remuneration.

Clinical Audit: is a systematic examination to review and determine whether actual activities and results comply with standards of care.

Closed System: is a system of which the contents are not exposed to air or outside elements during collection, preparation, and separation of components.

Competence: is the ability of an individual to perform a specific task according to standardized procedures.

Conformance: is fulfilment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or laws.

Corrective Action: is an activity performed to eliminate the cause of an existing Non-conformance or other undesirable situation in order to prevent recurrence.

Critical Equipment/Materials/Tasks: is a piece of equipment, material, service, or task that can affect the quality of the facility's products or services.

Cytapheresis: is a collection of procedure where whole blood is removed and separated into components. One or more of the cellular components may be retained, while the remaining elements are combined and returned to the donor or patient.

Deviation: is a departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Directed donor: is an individual who donates blood components intended for and used solely by a single identified recipient.

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

Final inspection: is to measure, examine or test one or more characteristics of a unit of blood or a blood component, a tissue or a service and compare results with specified requirements in order to establish whether conformance is achieved before distribution or issue.

Health Care Worker: is an individual employed by the health facility, whether directly or by contract with another entity, who provides direct or indirect donor care, this includes but not limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the health facility site.

Healthcare professional: is a person who is authorized and licensed by the Dubai Health Authority (DHA) to practice any healthcare professions as per the unified prequalification's requirements for the United Arab Emirates.

Hemovigilance: is the systematic surveillance of adverse reactions and adverse events related to transfusion' with the aim of improving transfusion safety. Transfusion reactions and adverse events should be investigated by the clinical team and hospital transfusion team and reviewed by the hospital transfusion committee.

Hospital based Blood Banks: are units available within the laboratory of the hospital and under direct supervision of the laboratory director. The Blood Banks is responsible for storage of blood component, inventory management, pre and post required transfusion related testing.

Informed Consent: refers to an agreement and permission accompanied by full information on the nature and risks of whole blood donation procedure. Consent is taken in a written form. Informed consent also refers to the consent given by the parent or legal guardian, in case the donor is a minor (17 years).

Irradiated: is the exposure of blood and components to x-rays or gamma rays at a specific dose to prevent proliferation of T Lymphocytes and prevent related post transfusion complications. .

ISBT 128: is a standard for the identification, terminology, coding, and labelling for blood, cellular therapy, and tissue products. When linear bar codes are used, Code 128 symbology is utilized.

Label: is an inscription affixed or attached to a unit of blood or a blood component, an issue, a derivative, or a sample for identification.

Labelling: is information that is required or selected to accompany a unit of blood or a Blood component, a tissue, a derivative, or a sample, which may include content, Identification, description of processes, storage requirements, expiration date, cautionary Statements, or indications for use.

Licensure: is issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

Lived with: is resided in the same dwelling (e.g., home, dormitory room or apartment).

Non-conformance: is the failure to meet requirements.

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

Pathogen Reduction: is exposure of blood components to a method designed to reduce the risk of transfusion-transmitted infections. The selected method should be FDA or equivalent approved to ensure efficiency and safety of end product.

People of Determination: are people with special needs or disabilities, under the National Policy for Empowering People with Special Needs. The UAE law defines a person with special needs as

someone suffering from a temporary or permanent, full or partial deficiency or infirmity in his physical, sensory, mental, communication, educational or psychological abilities to an extent that limits his possibility of performing the ordinary requirements as people without special needs.

Permanent Deferral: is a deferral applied to a donor who will never be eligible to donate blood for someone else.

Product: is a tangible result of a process or procedure.

Quality Control: is a testing, which is routinely performed on materials and equipment to ensure their proper function.

Quality Indicator Data: is information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

Quarantine: is to isolate nonconforming blood, blood components, tissue, derivative or materials to prevent their distribution or use.

Release: is the removal of product from quarantine or in-process status for distribution.

Safety: is the condition of being protected against physical, psychological, or other types or consequences of failure, error, or harm, which could be considered non-desirable. This can take the form of being protected from the event or exposure to something that causes health losses, such as using a drug, a procedure, or risk in the care environment.

Standard Operating Procedure (SOP): is a document, which contains detailed, written instructions for both operational and analytical procedures. It describes the stepwise process and technique of performing a test or procedure in the laboratory.

Supplier Qualification: is an evaluation method designed to ensure that input materials and services (e.g. Materials, blood, blood components, tissue, derivatives, patient blood samples) obtained from a supplier meet specified requirements.

Supplier: is an entity that provides an input material or service.

Temporary Deferral: is a deferral placed on a donor who is not eligible to donate for a specified period.

Traceability: is the ability to follow the history of a product or service by means of recorded identification.

Transfusion Related Acute lung injury (TRALI): is a new lung injury within 6 hours of completed transfusion.

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

Validation: is establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

ABBREVIATIONS

AABB	:	Association for the Advancement of Blood and Biotherapies.
BB	:	Blood Bank
BDCS	:	Blood Donation Collection Site
CAP	:	College of American Pathologist
DBDC	:	Dubai Blood Donation Centre
DHA	:	Dubai Health Authority
DHQ	:	Donor History Questionnaire
DRBC	:	Double Red Blood Cell
EQA	:	External Quality Assessment
FDA	:	Food & Drug Administration
GCP	:	Good Clinical Practice
GLP	:	Good Laboratory Practice
GMP	:	Good Manufacturing Practice
H/O	:	History of
HRS	:	Health Regulation Sector
IDT	:	Infectious Disease Testing
IQC	:	Internal Quality Control
NAT	:	Nucleic Acid Test
QA	:	Quality Assurance
QAP	:	Quality Assurance Program
SOP	:	Standard Operating Procedures

UAE	:	United Arab Emirates
V/S	:	Vital Signs

1. BACKGROUND

Blood transfusion is an essential part of patient care and life-saving support within the health care system. Unsafe blood transfusions have significantly contributed to the global burden of new hepatitis and HIV infections. An important part of blood safety is collecting blood from only voluntary non-remunerated blood donors fulfilling donation eligibility criteria. As per UAE. Blood transfusion policy, AABB and FDA, Blood Banks are considered as pharmaceutical industry where GMP, GLP and GCP are applicable.

Blood collection, processing, screening and storage services are critical steps in manufacturing therapeutic products. Blood Bank services are committed to providing safe and adequate blood and blood product to all the needy patients in all the government and private hospitals. A Blood Bank (BB) shall be DHA licensed facilities for practising whole blood and or component collection, components preparation, screening, storage and distribution. DHA should serve as a regulatory and auditing body for such services.

While DHA licensed Blood Bank is responsible for formulating related policies and procedures pertaining to whole blood collection, components preparation, screening, storing, issuing and transportation of blood; DHA licensed Blood Donation Collection Site (BDCS) is responsible for formulating related policies and procedures pertaining to whole blood and or component collection from voluntary donors, temporary storage and then transportation of collected blood and components from the blood collection sites to laboratory unit to DHA main blood donation center to carry out the required procedures that will include processing and preparation of components, screening , storage and distribution.

New Blood Collection sites shall obtain accreditation within eighteen (18) months from the issuing date of the health facility license for whole blood collection.

NOTE: For further details, refer to the DHA Clinical Laboratory Accreditation Policy.

2. SCOPE

2.1. Blood Bank services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality Blood Bank services in Dubai Health Authority (DHA) licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing Blood Bank services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing Blood Bank services shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. The Blood Bank shall be:

5.2.1. Independent/Stand-alone service; OR

5.2.2. Part of a DHA licensed Hospital.

5.3. The health facility must obtain a license from DHA to operate as Blood Bank for production and distribution of blood and components in the Emirate of Dubai. This applies to governmental, semi-governmental, and private under DHA jurisdiction.

5.4. Health facilities aiming to provide Blood Bank services shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae.

5.5. Licensed health facilities opting to add Blood Bank services shall inform Health Regulation Sector (HRS) and apply to HRS to obtain permission to provide the required service.

5.6. The health facility should develop the following policies and procedure; but not limited to:

5.6.1. ABO, Rh typing and un expected red cells antibody testing.

5.6.2. Blood & components storage & transportation.

5.6.3. Blood and/or component Collection from allogenic and autologous blood donors.

5.6.4. Blood component preparation and processing

5.6.5. Donor confidentiality & privacy.

5.6.6. Donor data management.

5.6.7. Donor education, communication and Informed consent.

5.6.8. Donor eligibility management.

5.6.9. Donors blood samples screening for infectious diseases

5.6.10. Emergency action plan

5.6.11. Hemovigilance

5.6.12. Incident reporting

5.6.13. Infection control measures and hazardous waste management

5.6.14. List of services performed in the Blood Collection site.

5.6.15. Look Back

5.6.16. Proficiency testing procedures

5.6.17. Quality control procedures

5.6.18. Service Description and Scope of Services.

5.7. The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premise in two languages (Arabic and English).

5.8. Obtain accreditation within eighteen (18) months from the issuing date of the health facility license and Ensure maintaining valid accreditation (AABB or CAP).

5.9. The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets and communications.

5.10. Based on the onsite assessment and after meeting the DHA requirements and recommendations, Health Regulation Sector (HRS) will issue a DHA license valid for one year.

5.11. At any time and upon reasonable cause, HRS, Clinical Auditors may conduct random inspections to audit the Blood Bank to determine compliance and take appropriate action if required.

5.12. The onsite inspections may be scheduled or unannounced.

5.13. After every inspection, the health Inspector shall issue an inspection report stating the identified, non-compliance and violation(s).

5.14. The management of the Blood Bank shall submit to the HRS, Clinical Audit and Control Department (CACD) a written plan of correction of violations cited within fifteen (15) days after receiving the noncompliance letter stating the identified violations.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. The licensed Blood Bank shall meet the health facility requirement as per the DHA Health facility Guidelines 2019 and specifically the Functional Planning Units. It provides specific design requirements for the following areas:

6.1.1. Pre-donation

a. Donor registration, filling of DHQ, Donor medical assessment and maintaining confidentiality and privacy.

6.1.2. Collection of blood/component

6.1.3. Post donation care

a. Observation of donors and refreshment.

6.1.4. Medical laboratory

a. For components preparation, processing, labelling, storage and shipping

b. Screening tests:

I. ABO and Rh testing, Unexpected Red Cell antibody testing.

II. Infectious Disease testing that includes Serology and NAT according to National screening programme for donors and donor sample testing shall be separated from patient testing.

6.1.5. Medical store

6.1.6. Support areas

c. Waste storage including sharp safe

d. Equipment and critical items Storage

e. Area for Administrative activities.

f. Refreshment storage

6.2. Special consideration should be given to the choice of fireproof construction for the buildings aligned to the building and design codes of DM and Dubai Civil Defence (DCD) requirements.

6.3. Special consideration should also be given to climate and ventilation control.

6.3.1. The temperature and humidity within the Blood Bank should be maintained within proper limits for effective performance of tests performed and maintained according to manufacturer's specifications.

6.3.2. A comfortable working environment is considered 20 to 25°C with relative humidity of 35 to 50%.

6.4. The Blood Bank should install and operate equipment required for provision of the proposed services in accordance to the manufacturer's specifications.

6.5. Facilities and safety:

6.5.1. The Blood Bank shall have policies, processes, and procedures to ensure the provision of safe environmental conditions. The facility shall be suitable for the activities performed. Safety programs shall meet local state and federal regulations, where applicable.

6.5.2. The Blood Banks shall have processes to minimize and respond to environmentally related risks to the health and safety of employees, donors, volunteers, patients, and visitors. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

6.5.3. Collected blood units shall be handled or discarded in a manner that minimizes the potential for human exposure to infectious agents.

6.6. The Blood Banks shall provide documented evidence of the following; but not limited to:

6.6.1. Equipment maintenance services.

6.6.2. Laundry services.

6.6.3. Medical waste management as per Dubai Municipality (DM) requirements.

6.6.4. Housekeeping services.

6.6.5. The Blood Banks shall be designed to easily accommodate People of Determination and aligned with the Dubai Universal Design Code.

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS

7.1. All healthcare professionals in the Blood Banks must hold an active DHA professional license and work within their scope of practice.

7.2. Appropriate and adequate number of DHA licensed healthcare professionals shall be present on duty during the working hours of the Blood Banks to meet the functional program.

7.3. Management of the Blood Banks shall determine the number of DHA licensed healthcare professionals employed and assigned to each service, and shall be consistent with type the of services provided.

7.4. All healthcare professionals should maintain a valid training/certification in basic Cardiopulmonary Resuscitation (CPR) or Basic Life Support (BLS) or Advanced Cardiac Life Support (ACLS), as required.

7.5. For qualifications, training, experience and Continuing Professional Development (CPD) requirements of healthcare professionals employed by a DHA Blood Banks refer to the Healthcare Professionals Licensing.

7.6. Staff of the Blood Banks shall follow the policies and procedures to ensure high quality results.

7.7. All staff shall ensure confidentiality of information, and should ensure security and safety of data.

7.8. The Blood Banks shall have a Medical Director who is a full-time or part-time DHA licensed physician, qualified by training and experience and facility defined relevant training and continuing education.

7.9. The Medical Director may delegate responsibilities to another qualified physician; however, the Medical Director shall retain ultimate responsibility for Medical Director duties.

7.10. To ensure safe and high-quality care is upheld within Blood Banks. the Medical Director/laboratory director shall abide by the DHA Policy for Role and Responsibilities of Medical Director.

7.11. The Blood Banks shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.

7.12. Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience.

7.13. The Blood Collection site shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.

7.14. Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals. Action shall be taken when competence has not been demonstrated.

7.15. Personnel records for each employee shall be maintained.

7.16. For those authorized to perform or review critical tasks, records of names, signatures initials or identification codes, and inclusive dates of employment shall be maintained.

8. **STANDARD FOUR:** MANAGEMENT RESPONSIBILITIES

8.1. Blood Banks shall have a Medical Director who is a licensed physician, qualified by training, experience, and facility-defined relevant continuing education in activities required in the Blood Banks.

8.2. The Medical Director shall have responsibility and authority for all medical and technical policies, processes, and procedure including those that pertain to laboratory personnel

and test performance and for the consultative and support services that relate to the care and safety of donors and/or transfusion recipients.

8.3. The Medical director shall ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

8.4. To guarantee the smooth operation and ensure safe and quality services are provided in the Blood Banks the management lead by the Medical/Laboratory Director has certain responsibilities which include, but not limited to the following:

8.4.1. Comply with all federal and local laws and regulations.

8.4.2. Apply current DHA Blood Bank standards in daily operations.

8.4.3. Ensure maintaining valid accreditation from AABB or CAP.

8.4.4. Collaborate with DHA Blood transfusion services in term of unifying important and critical policies and procedures related to donors and patient's safety.

8.4.5. Take necessary measures to distribute new DHA circulars and announcements among all staff.

8.5. Assess the effectiveness of the quality system through assessments and scheduled management reviews.

8.6. Ensure all healthcare professionals employed have a current DHA license, are privileges as per the Clinical Privileging Policy and work within their scope of practice.

8.7. Maintain the recommended immunizations for health professionals working at the BDCS and BB.

8.8. Support Continuous Professional Development (CPD) of the staff members by allocation of time for these activities.

8.9. Document ongoing assessment activities including corrective action, effectiveness reviews, and policy and procedure revisions made to prevent recurrence of a problem and discuss assessment reviews with staff.

8.10. Cooperate with HRS inspectors and/or any duly authorized representative when they visit the health facility and/or request for any material.

8.11. Avoid giving misleading information and false statements, which may lead to legal action against any employed DHA, licensed healthcare professionals or the health facility.

8.12. Settle any violation fines related to employed healthcare professionals or the health facility.

8.13. Maintaining malpractice insurance for all licensed healthcare professionals as per article Cabinet Decision no. (40) of 2019 concerning UAE Federal Law concerning Medical Liability.

8.14. Use the DHA Infectious Diseases Notification Service online portal (IDNS) through HP-DHA@dha.gov.ae to report communicable disease required by the Cabinet Decision no. (24) of 2020 concerning Publication and exchange of health information on communicable diseases and epidemics and misinformation related to human health, and keep a log of it, aligned with DHA Communicable Disease Notification Policy.

8.15. Submit to the Health Data and Information Analysis Department in DHA the required statistical data of the health facility.

8.16. Obtain prior approval from the Ministry of Health and Prevention (MOHAP) for media and advertisement materials, for further information regarding the media and advertisement materials approval procedures and requirements please visit the MOHAP website.

9. **STANDARD FIVE:** MANAGEMENT OF EQUIPMENT

9.1. The Health facility management shall identify the equipment that is critical to the provision of blood, blood components and/or services in the Blood Bank. This includes policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these current CAP and or AABB Standards.

9.2. Selection of Equipment

9.2.1. The Blood Banks shall have a process to define the selection criteria for equipment.

9.3. Qualification of Equipment

9.3.1. All equipment shall be qualified for its intended use.

9.3.2. Equipment repairs and upgrades shall be evaluated and equipment prequalified, as appropriate, based on the manufacturer recommendations.

9.4. Installation Qualification

9.4.1. Equipment shall be installed per the manufacturer's specifications

9.5. Operational Qualification

9.5.1. The functionality of each piece of equipment and each component of an information system shall be verified before actual use and shall meet the manufacturer's operational specifications.

9.6. Performance Qualification

9.6.1. The Blood Banks shall demonstrate that equipment performs as expected for its intended use. Performance specifications established by the manufacturer shall be met.

9.7. Use of Equipment

9.7.1. Equipment shall be used in accordance with the manufacturer's written instructions.

9.7.2. Equipment used for Infectious disease screening for Blood donor sample shall not be used concurrently for testing patient samples.

9.8. Unique Identification of Equipment

9.8.1. Equipment shall have unique identification.

9.9. Equipment Monitoring and Maintenance

9.9.1. The Blood Banks shall have a process for scheduled monitoring and maintenance of equipment that at a minimum is in accordance with manufacturer's written instructions.

9.9.2. The process shall include frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.

9.10. Calibration of Equipment

9.10.1. Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision.

9.10.2. At a minimum, calibrations and/or adjustments shall be performed as described below, unless otherwise indicated by the manufacturer:

a. Before use.

b. After activities that may affect the calibration.

c. At prescribed intervals.

9.11. There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting.

9.12. Calibration procedures shall follow the manufacturer's written instructions and shall include:

9.12.1. Instructions for performing calibrations.

9.12.2. Acceptance criteria.

9.12.3. Actions to be taken when unsatisfactory results are obtained.

9.13. Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

9.13.1. Assessment of blood, blood components, tissue, derivatives, and services provided since the equipment was last known to be functioning per manufacturer's written instructions, or facility-defined specifications.

9.13.2. Assessment of the effect on donor eligibility and donor and patient safety.

9.13.3. Steps to ensure that the equipment is removed from service.

9.13.4. Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected.

9.13.5. Steps for requalification of the equipment.

9.13.6. Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

9.14. Storage Devices for Blood, Blood Components, Reagents, and Derivatives Storage devices shall have the capacity and design to ensure that the proper temperature is maintained.

9.14.1. Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored.

9.14.2. For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every four (4) hours.

9.15. Alarm Systems

9.15.1. Storage devices for blood, blood components, tissue, derivatives, and reagents shall have alarms and shall conform to the following standards:

a. The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, derivatives, or reagents reach unacceptable conditions.

b. Activation of the alarm shall initiate a process for immediate action, investigation, and appropriate corrective action.

9.16. Information Systems

9.16.1. The Blood Bank shall use DHA Blood services software for donor's management to have unified donor's and donation data within the Emirate of Dubai.

9.16.2. An alternate system, including any required forms, shall be maintained and readily available for use to ensure continuous operation in the event that computerized data and Computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.

9.16.3. Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use.

9.16.4. The system shall be designed to prevent unauthorized access to computers and electronic records shall be established and followed.

10. **STANDARD SIX:** PROCESS CONTROL

10.1. The Blood Banks shall have policies and validated processes and procedures that ensure the quality of the services and shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

10.2. Change Control

10.2.1. The Blood Banks shall have a process to develop new processes or procedures or to change existing ones. This process shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated.

10.3. Quality Control

10.3.1. A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected. Improvement through Corrective and Preventive Action, applies.

10.3.2. The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.

10.3.3. Quality control failures shall be investigated before release of test results, products, or services.

10.4. Use of Materials

10.4.1. All materials (including containers and solutions used for collection, processing, preservation, and storage of blood and blood components, and all reagents used for tests) shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements and meet the accreditation requirements of AABB and/or CAP.

10.5. Sterility

10.5.1. Aseptic methods shall be employed to minimize the risk of microbial contamination of blood and blood components. Equipment and solutions that come into direct contact with blood or blood components shall be sterile and pyrogen-free. Single-use equipment shall be used whenever possible.

10.5.2. The Blood Banks must have methods to limit introduction of bacteria during collection, processing, and sampling.

10.5.3. The Blood Banks shall have methods to detect bacteria or use pathogen reduction technology in all platelet components stored at 20 – 24 ^{0}C.

10.5.4. Detection methods shall use devices cleared or approved by the FDA or Competent Authority. Pathogen reduction technologies shall be cleared or approved by the FDA or Competent Authority.

10.5.5. If a true-positive culture result is obtained and a sample is available, additional testing to identify the organism shall be performed. Additional testing and follow-up shall be defined.

10.6. Identification and Traceability

10.6.1. Process or Procedure Steps; for each critical step in collection, processing, screening and transportation of blood, there shall be a mechanism to identify who performed the step and when it was performed.

10.6.2. Traceability; The Blood Banks shall ensure that all blood and critical materials used in their processing, as well as laboratory samples and donor and patient records, are identified and traceable.

10.7. General Labelling Requirement

10.7.1. The labeling system shall make it possible to trace any unit of blood, from source to final disposition. The system shall allow recheck of records applying to the specific unit or tissue, including investigation of reported adverse events.

10.7.2. Labeling of blood and blood components containers shall be in conformance with the most recent version of ISBT 128 system.

10.7.3. The BDCS may use the ISBT label as same as that of DHA blood service center. The Blood Bank must have a unique identifier in the ISBT label for traceability.

10.7.4. A unique identification shall be affixed by the collecting or pooling facility to each unit of blood, blood component, and attached container, or lot. This identification shall not be obscured, altered, or removed by facilities that subsequently handle the unit.

10.8. Donor Identification

10.8.1. Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.

10.9. Inspection

10.9.1. The Blood Banks shall have a process to ensure that blood, blood components, tissue, derivatives, and services are inspected at facility-defined stages to verify that specified requirements are met.

10.10. Handling, Storage and Transportation

10.10.1. The Blood Banks shall have a process to ensure that blood units, samples, and critical materials (including reagents) are handled, stored, and transported in a manner that prevents damage, limits deterioration, as per manufacturer instruction and meeting UAE Blood Transfusion Policy and current AABB/CAP requirements for storage, transportation, and expiration. Refer to **Appendix 1** for storage, transportation and expiration requirements.

10.11. Transportation

10.11.1. Blood units shall be inspected immediately before packing for shipment to DHA Blood services and/or shipped for transfusion.

10.11.2. Containers (e.g., portable coolers) shall be qualified to transport blood to ensure that they maintain temperatures within the acceptable range for the expected duration of transport or shipping. (Refer to **appendix 1)**

10.12. Proficiency Testing

10.12.1. Blood Banks shall participate in an external proficiency-testing program, if available, for each analyte.

10.12.2. When an external proficiency-testing program is not available, there shall be a system for determining the accuracy and reliability of test results.

10.12.3. Proficiency testing shall include comparison of test results from an outside laboratory.

10.12.4. Results shall be reviewed and when expected results are not achieved, investigation and corrective action shall be taken where appropriate.

10.12.5. BDCS shall share all proficiency testing results with DHA Blood Service periodically.

11. **STANDARD SEVEN**: DONOR EDUCATION, CONSENT, NOTIFICATION AND ELIGIBILITY

11.1. Donor Education

11.1.1. The Blood Banks shall have procedures to ensure that the following requirements are met for all donors before donation:

a. Donors are given educational materials regarding the donation process.

b. Donors are given educational materials regarding relevant transfusion-transmitted infections

c. Donors are informed of the importance of providing accurate information.

d. Donors are informed that they should not donate blood in order to obtain infectious disease testing services and that there are circumstances in which testing is not performed.

e. Donors are given education materials regarding the risks of post donation iron deficiency and mitigation strategies.

f. Donors are informed of the importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.

g. Donors acknowledge that the educational materials have been read.

11.1.2. When parental permission is required, the collection facility shall have a process to provide information to parent(s) or legally authorized representative(s) of the donor concerning the donation process, and potential adverse effects related to the donation.

11.2. Donor Consent

11.2.1. The consent of all donors shall be obtained on the day of donation and before collection.

11.2.2. Elements of the donation procedure shall be explained to the prospective donor in understandable terms.

11.2.3. The explanation shall include information about risks of the procedure, tests performed to reduce the risks of relevant transfusion-transmitted infections to

the allogeneic recipient, and requirements to report donor information, including test results, to state or local health departments.

11.2.4. The donor shall have an opportunity to ask questions and have them answered and to give or refuse consent for donation.

11.2.5. In the case of a minor or a legally incompetent adult, consent shall be addressed in accordance with applicable law.

11.3. Donor Notification of Abnormal Findings and Test Results.

11.3.1. The medical director of the Blood Banks shall establish a process to notify all donors (including autologous donors) of any medically significant abnormality detected during the pre-donation evaluation or because of laboratory testing or recipient follow-up. In the case of autologous donors, the referring physician shall also be notified. Appropriate education, counseling, and referral shall be offered. Refer to **Appendix 2**; flow chart for donor's notification.

11.3.2. Blood Banks qualified medical physician should notify the donor with any abnormal results found during pre-donation testing or screening.

11.3.3. Donor notification for abnormal infectious disease results must be done within eight (8) weeks from the date of collection.

11.4. Care of Donors

11.4.1. The collection facility shall have a policy to ensure that the donor qualification process is private and confidential.

11.4.2. The donor shall be observed during the donation and for a length of time thereafter, as defined by the facility's policies and procedures

11.4.3. The collection facility shall have a process for treating donor adverse events and providing for emergency medical care as necessary. Immediate assistance and the necessary equipment and supplies shall be available. (Refer to **Appendices 3 and 4)**

11.4.4. Adverse events related to the blood donation process shall be assessed, investigated and monitored.

11.5. Post phlebotomy Instructions

11.5.1. The collection facility shall provide the donor with written instructions about Post phlebotomy care, including actions to take, about adverse events that may occur after donation. (Refer to **Appendix 5**)

11.5.2. The collection facility shall provide donors with written instructions on how to notify the collection facility with information relevant to the safety of the donation.

11.5.3. The facility shall have a process for managing post donation information about a donor's eligibility received from the donor or a third party.

11.6. Allogeneic Whole Blood Donor Qualification

11.6.1. The prospective blood donor is a healthy individual between the age of 18 to 65 years, UAE/GCC national or UAE resident as per UAE Blood Transfusion Policy. Holders of transit or visit visa are not eligible to donate blood in UAE.

11.6.2. The prospective blood donor shall meet the donor qualification requirements approved by DHA Blood Service and UAE Blood Transfusion Policy.

11.6.3. Donor eligibility criteria shall be unified in the Emirate of Dubai. (Refer to **Appendix 7**)

11.6.4. If the donor is deferred or if the donation is determined to be unsuitable, the donor's record will identify the donor as ineligible to donate and the donor will be notified of the reason for deferral.

11.6.5. Donors implicated in a transfusion-related acute lung injury (TRALI) event or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.

11.7. Apheresis donor qualification:

11.7.1. Selection of donors:

a. With the exception of the donation interval, the standards that apply to allogenic donor qualification shall apply to the selection of apheresis donors.

11.7.2. Automated plasmapheresis donation

a. Infrequent plasmapheresis donor: Donors shall undergo plasmapheresis no more frequently than once every four (4) weeks.

b. Frequent plasmapheresis donor: Plasma is donated more frequently than once every 4 weeks, the FDA requirements for donor testing and evaluation by a physical exam will be followed:

I. Collection shall occur a maximum of two times in a seven (7) day period and the interval between two collections shall be at least two (2) days.

c. Plasmapheresis donors shall be weighed at each donation.

11.7.3. Automated Cytapheresis donation

a. The interval between procedures for platelet, granulocyte, and leukocyte donors shall be at least two (2) days, and the total volume of plasma collected shall not exceed the volume of plasma cleared by the FDA for the instrument. A donor shall undergo the procedure a maximum of two times in a 7-day period. When greater than or equal to 6 × 1011 platelet collection is performed, the donor shall undergo the procedure a maximum of once in seven (7) days. Procedures shall not exceed twenty-four (24) times in a rolling 12-month period, except in unusual circumstances as determined by the Medical Director.

b. The interval between a Whole Blood donation and a subsequent Cytapheresis procedure shall be at least 8 weeks, unless the extracorporeal red cell volume of the apheresis machine is < 100 mL, in which case the interval shall be at least two (2) calendar days.

c. If it becomes impossible to return the donor's red cells during apheresis, at least 8 weeks shall elapse before a subsequent apheresis procedure, unless the red cell loss was < 200 ml.

11.7.4. Plateletpheresis donor's qualification: A blood sample shall be collected before each procedure for the determination of the donor's platelet count. The result shall be used as the platelet count to qualify the donor.

a. Plateletpheresis donors with a platelet count of < 200,000/ μ L shall be deferred from plateletpheresis donation until a subsequent platelet count is at least 200,000/ μ L.

b. If a donor has donated a single donor platelet (SDP) unit by aphaeresis and presents for whole blood donation allow a period of 15 days interval between them.

c. Validation and quality control of Apheresis Platelets shall demonstrate with 95% confidence that greater than 75% of units ≥ 3.0×10^{11} platelets and shall demonstrate with 95% confidence that > 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration. FDA criteria apply.

d. Plasma, apheresis platelets and whole blood for allogeneic transfusion shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.

e. 2-Unit Red Blood Cell Apheresis Donors qualification: The donor of a 2-unit Red Blood Cell apheresis collection shall meet specific haemoglobin/haematocrit and weight requirements for the device cleared by the FDA.

I. The donor shall be deferred from all donations for 16 weeks following a 2-unit Red Blood Cell apheresis collection.

II. The volume of red cells removed from apheresis donors shall not exceed a volume predicted to result in a donor haematocrit of < 30% or a haemoglobin < 10 g/dL after volume replacement.

III. Apheresis Red Blood Cells Leukocytes Reduced shall be prepared by a method known to ensure a final component containing a mean haemoglobin of ≥ 51g (or 153 mL cell volume). The sampling plan shall confirm with 95% confidence that more than 95% of units contain < 5×10^6 leukocytes. At least 95% of units sampled shall have > 42.5 g of haemoglobin (or 128 mL red cell volume). Validation and quality control shall demonstrate that these criteria or the criteria specified in the operator's manual are met. FDA criteria apply.

11.8. Protection of the recipient

11.8.1. On the day of donation and before collection, the prospective donor's history shall be evaluated and the donor examined to exclude donation by a person with evidence of disease transmissible by blood transfusion or other conditions thought to compromise the suitability of the blood or blood component.

11.8.2. If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained within 24 hours of collection.

11.9. Protection of the Donor

11.9.1. The collection facility shall have processes to minimize the adverse effects of donation.

11.9.2. On the day of donation and before collection, the prospective donor's history shall be evaluated and the donor examined to minimize the risk of harm to the donor.

11.9.3. The collection facility shall have a process to reduce the risk of adverse reactions in young donors.

11.9.4. The collection facility shall ensure that donor red cell losses for all donations and samples collected during any rolling 12-month period do not exceed the loss of red cells permitted for whole blood collections.

11.10. Autologous Donor Qualification

11.10.1. Due to the special circumstances related to autologous blood transfusion, rigid criteria for donor selection are not required.

11.10.2. In situations where requirements for allogeneic donor selection or collection are not applied, alternate requirements shall be defined and documented by the medical director.

11.10.3. A medical order from the patient's physician or other authorized health professional to collect blood for autologous use.

11.10.4. The hemoglobin concentration of the autologous donor's blood shall be > 11 g/dL, or the hematocrit shall be > 33%.

11.10.5. All blood collections from the autologous donor shall be completed > 72 hours before the time of anticipated surgery or transfusion.

11.10.6. Autologous donors shall be deferred when they have a clinical condition for which there is a risk of bacteremia.

11.10.7. The unit shall be reserved for autologous transfusion.

12. STANDARD EIGHT: DONORS REGISTRATION, DHQ, MEDICAL ASSESSMENT

12.1. Donors Registration

12.1.1. Licensed Blood Banks shall use the unified Blood Banks software system to have a single platform for donors and donations records at the level of Emirate of Dubai.

12.1.2. At registration, the donor is identified with a photo identity card using the emirates ID/GCC ID.

12.1.3. On the day of donation, the donor can fill the DHQ on site or also use the DHA app (Dammi Service) to read the educational material, fill the DHQ, and then approach for registration with the QR code.

12.1.4. Donors registration to be conducted by qualified and trained health care provider according to DHA Blood services standards.

12.2. Donor History Questionnaire and Selection.

12.2.1. It is an important step to ensure donors and patient safety.

12.2.2. The donor shall read all the educational materials before filling the “Donor History Questionnaire”. (Refer to **Appendix 6**)

12.2.3. The trained and qualified staff shall verify all the questions in the questionnaire including, travel history and carry out brief medical checkup and decide on final eligibility of the donor. (Refer to **Appendix 8**)

12.3. Blood Collection

12.3.1. Blood donation is a standardized medical procedure that ensures safety of donor, and phlebotomy is performed such that the sterility of the collected unit is preserved.

12.3.2. Phlebotomy must be performed only after proper donor identification and the donor has been found to be eligible for blood donation.

12.3.3. The following standard applies:

a. Blood shall be collected into a sterile closed system. Blood collection containers withdraw line (inlet) diversion pouches shall be used for any collection of platelets, including whole blood from which platelets are made.

b. The collection facility shall have a method to limit introduction of bacteraemia during collection, processing and sampling.

c. The venepuncture site shall be prepared to minimize risk of bacterial contamination.

12.3.4. Tubes for laboratory tests shall be properly labelled before the donation begins, shall accompany the blood container, and shall be re- identified with the blood container during or after filling and before the tubes and containers are separated.

12.3.5. Donor identification: Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.

12.3.6. Additional apheresis collection requirement: the process used in performing a phlebotomy and processing the blood shall be designed to ensure safe reinfusion of the non-retained component to the donor.

12.3.7. Leukapheresis collection: The Blood Banks shall have criteria for the administration and dose of any ancillary agents used.

12.4. Blood Units Storage and Transporting

12.4.1. If blood is to be transported from the collection site, it shall be placed in a qualified Container having sufficient refrigeration capacity to cool the blood continuously toward a temperature range of 1 to 10^0C until it arrives at the processing site.

12.4.2. Whole blood intended for room temperature processing and apheresis platelets shall be transported and stored in a manner intended to cool the blood and apheresis platelets toward a temperature range of 20 to 24^0C.

13. STANDARD NINE: PREPERATION AD PROCESSING OF COMPONENTS

13.1. Preparation and processing of components are the methods that ensure the quality and safety of components, including aliquots and pooled components, shall be employed.

13.2. Seal

13.2.1. If the seal is broken during processing, components shall be considered to have been prepared in an open system and expiration times specified for such components (open system within 24 hrs for packed cells).

13.3. Weld

13.3.1. If a sterile connection device is used to produce sterile welds between two pieces of compatible tubing, the following requirements shall apply:

a. The weld shall be inspected for completeness.

b. If the integrity of the weld is complete, the component shall have an expiration date/time assigned in accordance with the FDA.

c. If the integrity of the weld is incomplete, the container shall be considered an open system and may be sealed and used with a component expiration as indicated in current **Appendix 1**; requirement for storage, transportation and Expiration

d. Regardless of the integrity of the weld, if no storage time limit is specified in the package insert or the package insert is not available, the component shall have an expiration time of four (4) hours after transfer from original container.

e. Cross Match Segment at the time of collection or component preparation, the integral donor tubing shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent compatibility testing. The tubing must be segmented to at least six to eight crossmatch segments at the tubing attached to the final PC bag using the heat sealer.

13.4. Leukoreduction Method:

13.4.1. The Blood Banks shall entirely implement pre-storage Leukocyte-reduced blood and blood components. Leukocyte-reduced blood and blood components shall be prepared by a method known to reduce the leukocyte number to < 5 x 10^6 for red cells, apheresis or pooled platelets, and to < 8.3 x

10^5 for whole drive platelets. Validation and quality control shall demonstrate that > 95% of units sampled meet this criterion

13.5. Irradiation:

13.5.1. Irradiated blood and blood components shall be prepared by a method known to ensure that irradiation has occurred. A method shall be used to indicate that irradiation has occurred with each batch. The intended dose of irradiation shall be a minimum of 25 Gy (2500 cGy) delivered to the central portion of the container. The minimum dose at any point in the components shall be 15 Gy (1500 cGy). Alternate methods shall be demonstrated to be equivalent.

13.6. Pooled Components

13.6.1. The BB shall maintain records of the ABO/Rh, donation identification number, and collecting facility for each unit in the pool.

13.7. Red Blood Cells shall be prepared by separating the red cells from plasma portion of blood.

13.7.1. Red Blood Cells without additive solutions shall be prepared using method known to result in a final hematocrit of ≤ 80%.

13.7.2. Red Blood Cells Leucocyte Reduced: Red Blood Cells Leukocytes Reduced shall be prepared by a method known to retain at least 85% of the original red cells. The sampling plan shall confirm with 95% confidence that < 95% of units contain < 5×10^6 leukocytes.

13.7.3. Red Blood Cell, Low Volume: When 300 to 404 mL of whole blood is collected into an anticoagulant volume calculated for 450 ± 45 mL or when 333 to 449

mL of whole blood is collected into an anticoagulant volume calculated for 500 ± 50 mL, red cells prepared from the resulting unit shall be labeled Red Blood Cells Low Volume. No other components shall be made from a low volume collection.

13.7.4. Apheresis Red Blood Cells, Leukocyte reduced. Shall be prepared by a method known to ensure a final component containing a mean hemoglobin of ≥ 51g (or 153 mL cell volume). The sampling plan shall confirm with 95% confidence that more than 95% of units contain < 5×10^6 leukocytes. At least 95% of units sampled shall have > 42.5 g of hemoglobin (or 128 mL red cell volume). Validation and quality control shall demonstrate that these criteria or the criteria specified in the operator's manual are met.

13.7.5. Frozen Red Blood Cells shall be prepared by a method known to minimize post-thaw hemolysis. Red Blood Cells shall be frozen within 6 days of collection, except when rejuvenated Rare units may be frozen without rejuvenation up to the date of expiration.

13.8. Plasma Preparation:

13.8.1. Each unit of Plasma contains the equivalent plasma obtained by centrifugation and separation from one unit of whole blood. Plasma has the same risk of disease transmission as Red Blood Cells. Plasma contains ABO antibodies.

13.8.2. Fresh Frozen Plasma shall be prepared from a whole blood or apheresis collection and placed at −18°C or colder within the time frame required for the collection, processing, and storage system.

13.8.3. If a liquid freezing bath is used, the container shall be protected from chemical exposure.

13.9. Platelets

13.9.1. Validation and quality control of Platelets prepared from Whole Blood shall demonstrate that at least 90% of units sampled contain ≥ 5.5×10^{10} platelets and have a pH ≥ 6.2 at the end of allowable storage.

13.9.2. Apheresis Platelets

a. Validation and quality control of Apheresis Platelets shall demonstrate with 95% confidence that is > 75% of units contain ≥ to 3.0×10^{11} platelets and shall demonstrate with 95% confidence that > 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration.

b. Apheresis Platelets containing < 3.0×10^{11} platelets shall have the platelet content included on the label.

13.9.3. Platelets Leucocyte reduced validation and quality control of Platelets Leukocytes Reduced shall demonstrate that at least 75% of units sampled contain ≥ to 5.5×10^{10} platelets and at least 90% of units sampled have a pH ≥ 6.2 at the end of allowable storage. The sampling plan shall confirm with 95% confidence that more than 95% of units contain < 8.3×10^{5} leukocyte.

13.9.4. Pooled Platelets Leucocyte Reduced shall be prepared by a method known to result in a 95% confidence that more than 95% of units contain < 5 x 10^6 leukocyte and at least 90% of units sampled have a pH ≥ to 6.2 at the end of allowable storage.

13.9.5. Pathogen Reduced Platelets shall be collected and processed as per the manufacturer's written instructions.

13.10. Cryoprecipitate (Anti Haemophilic Factor) shall be prepared by a method known to separate the cold insoluble portion from Fresh Frozen Plasma and result in an average content of at least 150mg of fibrinogen and 80 IU of coagulation Factor VIII per container or unit.

13.11. General Labelling Requirement

13.11.1. The BDCS/BB shall have a labelling process. This process shall include all steps taken to: Identify the original unit, any components, and any component modifications. Complete the required reviews. Attach the appropriate labels.

13.11.2. Final Labelling. The BB shall have a process to ensure that all specified requirements have been met at final labelling following ISBT 128 labelling system.

13.12. Quarantine

13.12.1. The facility shall ensure that blood and blood components from ineligible donors are quarantined and are not issued for transfusion.

14. STANDARD TEN: ROUTINE BLOOD SCREENING TESTS

14.1. Determination of ABO Group for All Collections

14.1.1. Determination of ABO Group for All Collections: The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma for expected antibodies with A1 and B reagent red cells.

14.2. Determination of Rh Type for All Collections

14.2.1. The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, the blood shall be tested using a method designed to detect weak D. When either test is positive, the label shall read "Rh POSITIVE." When the tests for both D and weak D are negative, the label shall read "Rh NEGATIVE."

14.3. Detection of Unexpected Antibodies to Red Cell Antigens for Allogeneic Donors.

14.3.1. Serum or plasma from donors shall be tested for unexpected antibodies to red cell antigens. Methods for testing shall be those that demonstrate clinically significant red cell antibodies.

14.4. Tests Intended to Prevent Infectious Diseases Transmission (IDT) by Allogeneic Donations

14.4.1. Shall follow the UAE. National screening program for IDT. by a sample of blood from each allogeneic donation shall be screened using Individual Donor nucleic acid amplification test (ID NAT) to detect HBV DNA, HCV RNA and HIV-1 RNA & serological tests for HBsAg, anti-HBc, anti-HCV, anti-HIV-1/2, anti-HTLV-I/II, and syphilis by an FDA approved serologic test.

14.4.2. Blood and blood components shall not be distributed or issued for transfusion unless the results of these tests are negative

14.4.3. Autologous blood or components that shall be screened using Individual Donor nucleic acid amplification test (ID NAT) to detect HBV DNA, HCV RNA and HIV-1 RNA, & serological tests for HBsAg, anti-HBc, anti-HCV, anti-HIV-1/2, anti-HTLV-I/II, and syphilis by an FDA approved serologic test.

a. These tests shall be performed before shipping on at least the first unit collected during each 30-day period.

b. The patient's physician and the donor-patient shall be informed of any medically significant abnormalities discovered.

14.4.4. Quarantine and Disposition of Units from Prior Collections.

a. The Blood Banks shall have a process that is in accordance with standard requirements and recommendations for quarantine and disposition of prior collections when a repeat donor has a reactive screening test for anti-HBc, HBsAg, HBV DNA, anti-HCV, HCV RNA, anti-HIV1/2, HIV-1 RNA, anti-HTLV-I/II.

14.4.5. Look-Back: The collection facility shall have policies, processes, and procedures to notify consignees of blood or blood components from donors subsequently found to have, or be at risk for, relevant transmissible diseases. (Refer to **Appendix 9)**

15. STANDARD ELEVEN: INVENTORY MANAGEMENT

15.1. Inventory management encompasses all the activities associated with ordering, storing, handling, and issuing of blood products. The challenge is to keep enough stock to ensure a 100% supply of blood while keeping time expiry losses at a minimum.

15.2. The Blood Banks shall ensure the appropriate segregation of all stored products, including autologous units. The blood components inventory must be arranged on accordance to the collection and expiry dates.

15.3. The Blood Banks shall set an appropriate inventory level for the blood components based on storage devices capacity.

15.4. Blood Banks shall ensure the handling of packed red blood cell product shall not be exposed to temperatures outside refrigeration specifications for longer than 30 minutes, and for frozen blood product to be kept on dry ice or frozen ballast within a container to prevent temperature changes.

15.5. The blood and blood product unit and/or packaging integrity must be inspected before issuing and distribution.

15.6. The Blood Banks shall regularly provide the statistical data of blood and blood components utilization and wastage to the DHA Blood transfusion services.

15.7. Blood Banks inventory shall be viewed and accessed/connected to DHA Blood transfusion services to perform Blood Inter Hospital Transfer where necessary.

15.8. Blood Banks shall report all identified rare blood groups donors to the DHA Blood transfusion services.

15.9. Blood and Blood derivatives, and reagents shall be stored in accordance with the manufacturer's written instructions.

15.10. For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every 4 hours.

15.11. For open storage areas, the ambient temperature shall be monitored and recorded at least every four (4) hours.

15.12. Access to storage areas and authorization to remove contents shall be controlled.

16. STANDARD TWELVE: SAFETY AND INFECTION CONTROL PRACTICES

16.1. General Safety Considerations

16.1.1. Personnel working in Blood Collection, processing, storage and supply site may be exposed to risks from various chemicals, infectious materials, fire hazard, gas leak etc.

16.1.2. The environment is also at risk of being contaminated by hazardous materials used and wastes generated.

16.1.3. Safety therefore includes protection of both the staff and the environment from hazardous materials. General safety measures include:

a. Documentation of Safety Policies and Procedures.

b. All staff shall be aware about the laboratory safety policies and procedures and follow these at all times. Proper training from the beginning of employment is the key to a successful safety program. A

properly conducted training program will ensure comprehension and understanding.

c. A comprehensive warning labelling system should be implemented to identify contaminated objects or objects containing contaminated or hazardous materials. Labels exhibiting the universal biohazard sign should be placed on containers of regulated waste, refrigerators containing blood or other potentially infectious materials, sharps disposal containers, and any other spaces in which infectious materials are stored.

d. Eyewash stations shall be available and should be located within a 10-second walk (approximately 55 ft) from all locations in which hazardous chemicals are used or infectious materials are handled.

e. Emergency showers should be available in locations in which caustic and corrosive chemicals are used and in which the possibility of a large spill exists, and should be within a 10-second walk (approximately 55 ft).

f. Basic first aid kit needs to be available and restocked periodically. Unless otherwise specified, the minimally recommended contents of a first aid kit.

g. The Blood Collection site must be equipped with an Oxygen Cylinders, which must be maintained for emergency use.

h. Smoking should be prohibited in the technical work area by posting a no smoking sign.

i. Blood Collection site, blood processing, storage and supply site shall ensure proper preservation and security of blood units and samples.

j. Blood Collection, blood processing, storage and supply personnel shall be thoroughly trained in managing emergencies such as biohazard spillage etc. as applicable to the facility.

k. Periodic checking of all safety equipment and accessories shall be ensured.

l. Two-handed recapping of needles is strictly prohibited. Contaminated needles or other sharps must not be sheared, bent, recapped, or removed from syringes or other devices unless it can be accomplished using a mechanical device (such as a haemostat) or by a one-handed technique.

m. An updated list of hazardous materials used in the Blood Collection and Blood Supply site shall be maintained. All hazardous materials shall be accounted for on a continuous basis.

n. For reasons of both safety and security, personal belongings (coats, bags, pocketbooks, etc.) must not be kept in the work areas of the laboratories. Personal belongings must be secured in employees' lockers or staff designated areas.

16.2. Hand Hygiene

16.2.1. Any healthcare professional, nurses, laboratory technologist, phlebotomist, laboratory attendant involved in direct/indirect donor care needs to be concerned about hand hygiene and should be able to perform it correctly and at the right time.

16.2.2. Handwashing basins, paper towels should be provided in areas that conduct a medical procedure such as phlebotomy.

16.2.3. Antiseptic hand sanitizers should be in single use, non-refillable pouches inserted into dispensers.

16.3. Use of Personal Protective Equipment (PPE)

16.3.1. The mucous membranes of the mouth, nose and eyes are susceptible portals of entry for infectious agents, as well as skin if skin integrity is compromised. Therefore, use of PPE to protect these body sites is essential.

16.3.2. The selection of PPE should be based on the nature of the procedure/anticipated level of exposure and/or the mode(s) of transmission.

16.3.3. These types of PPE such as gloves, masks, disposable coats must be always available and discarded in the Infectious waste bin.

16.4. Environmental Cleaning & Disinfection

16.4.1. Ensure that a good standard of cleanliness and hygiene in procedure areas is observed and maintained following consistent and correct cleaning procedure, using appropriate disinfectants.

16.4.2. Monitoring the cleaning and external surfaces is essential to accurately assess/ gauge the level of compliance, improvement or deterioration of cleaning processes.

16.4.3. The sanitation of equipment must be in accordance to the Manufacturer's Instructions.

16.5. Waste Management

16.5.1. Blood, blood components, tissue and derivatives shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

16.5.2. Medical and/or Non-infectious wastes must be handled carefully and properly to prevent gross microbial contamination of the air, environment and all personnel handling and disposing the waste. Discard blood and sample tubes into a double-bagged yellow plastic bag.

16.5.3. Proper collection, containment and transportation of wastes from the source of generation to central waste collection compound for final disposal must be strictly adhered to in order to minimize significant amount of environmental contamination with microorganisms.

16.5.4. Pre-disposal treatment of laboratory wastes should be performed prior to disposing to a sanitary sewer line.

16.5.5. Sharps (i.e., needles, syringes with attached needles, scalpel blades) must be placed in a stable, rigid, puncture-resistant “sharps” container labelled with a biohazard warning label. Slides, coverslips, and capillary tubes may be placed in a rigid, puncture-resistant container or red-bagged biohazard waste container.

16.5.6. Sharps containers must not be overfilled. When a sharps container becomes two-thirds full, seal and discard it.

16.6. Spillage Management

16.6.1. All spillages of blood or body fluid, chemical spill must be considered as potentially infectious/hazardous and must be dealt with immediately, utilizing appropriate and available spill kits. These kits such as Biological Spill Kits, Vomit Spill Kits and Chemical Spill Kits must be readily available in procedure areas and must be inspected periodically.

16.6.2. Requirement of conducting proper training to all healthcare providers and housekeeping services on the usage of the appropriate spill kits is essential.

16.7. Occupational Exposures and Percutaneous Injury

16.7.1. Correct handling and disposal of sharps and proper use of Personnel Protective Equipment minimize the risks of percutaneous injuries and blood borne virus exposure to healthcare providers, donors, patients and visitors.

16.7.2. The Healthcare workers must adhere to the procedure of managing occupational exposures to percutaneous injuries (needle stick, and sharp injuries), splashes of blood and body fluids, secretions and excretions.

16.7.3. Accident/incident/injuries record of Healthcare workers should be maintained and reported to the designated authority.

16.7.4. The report should include description of the event, factors contributing to the event and information on first aid or other health care provided. This information can be analysed periodically towards effectively controlling and preventing future events. The Safety Officer should maintain the records.

17. STANDARD THIRTEEN: HEALTH RECORDS

17.1. Laboratory data management includes recording details of the donor medical check-up details, laboratory screening results and archiving the data for future reference.

17.2. The format of recording and reporting results should be described in the SOPs.

17.3. Equipment maintenance reports must be kept for future reference.

17.4. Donor Result Records and materials shall be retained aligned to the Guidelines for Managing Health Records and related AABB standards.

17.5. An internal policy must be available concerning the time keeping of the donors and laboratory reports as either hard copy or soft copy according to the Blood Bank.

17.6. Internal policies, which should be based on AABB standards. For further information regarding retention of patient result, records and materials refer to **appendix 10.**

17.7. Master list of documents including policies, processes, procedures, labels, equipment, and forms that relate to the collection until supply of blood must be maintained.

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APPENDICES

APPENDIX 1: REQUIREMENT FOR STORAGE, TRANSPORTATION AND EXPIRATION

Item No.	Component	Storage (°C)	Transport (°C)	Expiration	Additional criteria
Red blood cell component, whole blood derived or apheresis derived					
1	RBCs Leukocytes Reduced- whole blood derived or apheresis derived	(1 – 6 C)	(1 – 10 C)	CPDA-1: 35 days Additive solution; 42 days Open system: 24 hours	
2	Irradiated Leuko-Reduced Packed Cells	(1 – 6C)	(1– 10 C)	Original expiration or 28 days from date of irradiation, whichever is sooner.	
3	Frozen RBCs 40% glycerol	-65 C or colder if 40% glycerol	Maintained frozen state	Frozen within 6 days of collection. Expiration in 10 years of the day of freezing.	
4	Deglycerolized RBCs	(1 – 6C)	(1– 10 C)	Open system: 24 hours Closed system: 14 days	
Platelet components					
5	Leukocyte Reduced Pooled Platelets	(20 – 24 C) with continuous gentle agitation	(20 – 24 C) (as close as possible to)	4 hours after pooling or 5 days following collection of the oldest unit in the pool.	
6	Apheresis Platelets Leukocytes Reduced	(20 – 24 C) with continuou	(20 – 24C) (as close as possible to)	Open system; 4 hours Closed system; 5 days	

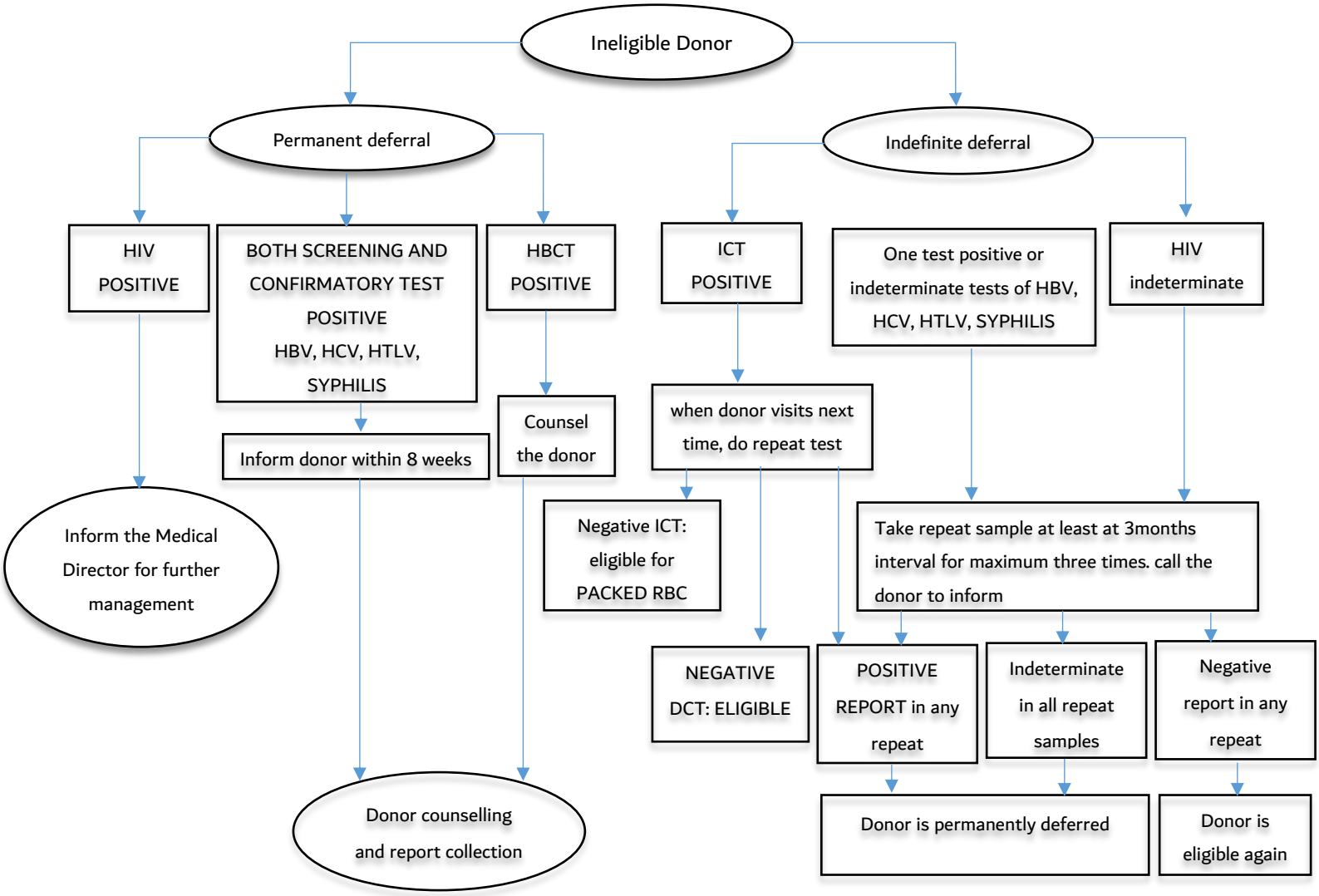
		s gentle agitation			
7	Apheresis Platelet Pathogen Reduced	20-24 C with continuous gentle agitation	(20 – 24C) (as close as possible to)	5 days	
8	Irradiated Platelets (SDP or Pool)	(20 – 24 C) with continuous gentle agitation	(20 – 24C) (as close as possible to)	No change from original expiration date	
Plasma components					
9	Cryoprecipitate AHF	(≤ -18C)	Maintain frozen state	12 months from original collection	Thaw at 1-6C. place the cryoprecipitate in the freezer within 1 hour after removal from refrigerated centrifuge.
10	Cryoprecipitate (AHF) after thawing	20-24C	(20 – 24C) (as close as possible to)	Single unit: 6 hours	Thaw at 30-37 C
11	Fresh Frozen Plasma (FFP)	(≤ -18 C)	Maintain frozen state	-18 C or colder: 12 months from collection	Placed in freezer within 8 hours of collection or as stated in FDA cleared operator manual/package inserts.
12	FFP (after thawing)	1-6C	1-10C	If issued as FFP: 24 hours	Thaw at 30-37C or by using an FDA cleared device.
13	Plasma Cryoprecipitate Reduced	-18 C or colder	Maintain frozen state	12 months from collection	Shall be frozen within 24 hours of thawing the FFP from which it was derived.

14	Plasma Cryoprecipitate Reduced (after thawing)	1-6 C	1-10C	If issued as plasma cryoprecipitate reduced: 24 hours If issued as thawed plasma cryoprecipitate reduced: 5 days from the date product was thawed or original expiration, whichever is sooner.	Shall have collected and processed in a closed system.
Granulocyte component					
15	Apheresis Granulocytes	20-24 C without agitation	As close as possible to 20-24 C without agitation	24 hours	Transfuse as soon as possible*
16	Apheresis Granulocytes (irradiator)	20-24 C without agitation	As close as possible to 20-24 C without agitation	No change from original expiration date	Transfuse as soon as possible*

Instructions:

- If the seal is broken during processing, components stored at 1 to 6 C shall have an expiration time of 24hours, and components stored at 20 to 24 C shall have an expiration time of 4 hours, unless otherwise indicated. This expiration shall not exceed the original expiration date or time.
- If a liquid freezing bath is used, the container shall be protected from chemical alteration.
- Leucocyte reduction filters or microaggregate filters shall not be used.

APPENDIX 2: FLOW CHART FOR DONOR NOTIFICATION OF ABNORMAL FINDINGS



APPENDIX 3: MANAGEMENT OF ADVERSE REACTION OF WHOLE BLOOD DONORS

Donor Reactions and Injury Prevention protocol:

Table 1: Arm Injuries:

	Small Hematoma/Bruise	**Large Hematoma/Bruise**	**Nerve Irritation**	**Arterial Puncture**
Signs & Symptoms	Pressure/swelling/ tenderness Redness/warmth	Small hematoma PLUS pain OR Large hematoma	Immediate intense pain at site. Numbness or tingling in fingers, hand or arm Shooting pain down arm Weakness of arm	Bright red blood Pulsing sensation in tubing Pulsing blood flow Rapid draw (< 4 minutes) Pressure/swelling/ tenderness
Routine Interventions	Continue collection with donor consent as long as hematoma does not worsen Upon needle removal, apply constant, firm pressure until bleeding stops Apply cold compress	Discontinue Procedure **Immediately** Apply constant, firm pressure until bleeding stops. Apply cold compress	Discontinue Procedure **Immediately** Apply constant, firm pressure until bleeding stops Apply cold compress	Discontinue Procedure **Immediately** Phlebotomist must apply constant firm pressure for at least 10 minutes. Check for radial pulses and good circulation after bleeding has stopped-If no pulses or circulation problems, call the ambulance.
Donor Instructions	Apply cold compresses intermittently for 12-24 hours, then use warm compresses thereafter. If bleeding resumes, apply firm, direct pressure and elevate arm directly above head. If condition worsens or there are any problems or concerns, contact donation center.	Apply cold compresses Intermittently for 12-24 hours, then use warm compresses thereafter. If bleeding resumes, apply firm, direct pressure and elevate arm directly above head. If condition worsens or there are any problems or concerns, contact donation center	Contact Donor Relations if condition worsens or there are any problems. A staff nurse will Contact the donor for follow-up.	Apply pressure should bleeding occur. Seek medical attention should bleeding, pain, numbness/tingling occur.

Table 2: Vasovagal /Hypovolemic reactions

	Mild vasovagal Reaction (VV) – no LOC	**Moderate VV Reaction – LOC, Uncomplicated**	**Severe VV reaction – LOC, complicated**	**Severe VV reaction With an injury**
Signs & Symptoms	Cold extremities/chills Feeling of warmth Hypotension Light-headedness/dizziness Nausea/vomiting Pallor (pale skin or lips) Slow or Rapid Pulse Sweating/ Twitching/Weakness	Mild signs and symptoms PLUS LOC < 60 seconds	Moderate signs and symptoms PLUS Convulsions LOC >60 seconds Loss of bowel/bladder control Tetany	Severe signs and symptoms PLUS Injury/Fall
Routine Interventions	Tilt donor bed back or lie donor down/Elevate feet Apply cold towels Offer fluids/Monitor V/S Observe and reassure donor If nauseous, discontinue procedure, turn towards side, and provide emesis bag	Discontinue procedure Tilt donor bed back or lie donor down, Elevate feet Apply cold towels Offer fluids/Monitor V/S Observe and reassure donor If nauseous turn towards side and provide emesis bag. Call physician.	Discontinue procedure Tilt donor bed back or lie donor down/Elevate feet Apply cold towels Offer fluids Monitor V/S Observe and reassure donor If nauseous turn towards side and provide emesis bag	Discontinue procedure Tilt donor bed back or lie donor down/Elevate feet Apply cold towels/Offer fluids Monitor V/S Observe and reassure donor If nauseous turn towards side and provide emesis bag Treat injury. Refer to emergency if needed.
Donor Instructions	If symptoms resume, sit down immediately, do not operate heavy machinery. Seek medical attention. Increase fluid intake. Contact DBDC for any questions or concerns.	If symptoms resume, sit down immediately, do not operate heavy machinery. Seek medical attention. Increase fluid intake. Contact DBDC for any questions or concerns	If symptoms resume, sit down immediately, do not operate heavy machinery. Seek medical attention. Increase fluid intake. A DBDC nurse will contact the donor to follow-up.	If symptoms resume, sit down immediately, do not operate heavy machinery. Seek medical attention. Increase fluid intake.

Table 3: Other types of Reactions

	Localized Allergic Reaction	Hyperventilation	Medical Emergency Stroke	Medical Emergency Cardiac	Medical Emergency Respiratory
Signs & Symptoms	Itching/Hives Skin irritation rashes	Rapid breathing with or without tingling of lips, fingers, and hands Perspiration Possible feelings of suffocation	Sudden numbness or weakness of the face, arm, or leg (especially on one side of the body) Sudden trouble seeing in one or both eyes Slurred Speech Sudden trouble walking, dizziness or loss of balance and/or coordination	Chest discomfort (may be described as squeezing, pressure) Discomfort in other areas of the upper body (arm, jaw, back, or stomach) Shortness of breath Profuse sweating Nausea Light-headedness	Feelings of suffocation, unable to breathe Talking/coughing is difficult Rapid laboured breathing Nasal flaring and breathing is laboured Audible wheezing upon Inspiration /expiration
Routine Interventions	Continue procedure with donor consent	Discontinue procedure Have donor breathe into paper bag for 1-3 minutes	Discontinue procedure Activate crash call Comfort Donor Monitor V/S	Discontinue procedure Activate crash call Comfort Donor Monitor V/S	Discontinue procedure Activate crash call Comfort Donor Monitor V/S
Donor Instructions	If symptoms worsen, seek medical attention. A cold towel may be applied to irritated area.	Provide routine post donation instructions. Educate and reassure donor.			

APPENDIX 4: MANAGEMENT OF ADVERSE REACTION. APHERESIS DONATION

Donor Reactions and Injury Prevention protocol:

Apheresis reactions

	Mild Citrate Reaction (Resolves with Oral Calcium)	**Severe Citrate Reaction**	**Allergic Reaction (other than localized)**	**Haemolysis**
Signs & Symptoms	Tingling around the mouth in the face and/or hands and feet/Lethargy/Feeling a sense of "vibration" Cramps in hands/feet	Confusion/disorientation Carpal –pedal spasms Tetany – muscle tightness Chills/Shivering Circumorally Paraesthesia Nausea/Vomiting/Pallor Rapid Pulse	Anaphylactic Shock Decreased BP/Itching in mouth/Wheezing Difficulty breathing Abdominal cramps Nausea/vomiting/Increased heart rate/Collapse/Pallor	Pinkish to cherry red fluid in collection line
Routine Interventions	Pause procedure Offer Calcium syrup/ Monitor donor and press "continue" when ready If s/s persist: Decrease ACD-A rate Monitor donor for 10 minutes Decrease ACD-A again if s/s Persist. Discontinue procedure if symptoms are intolerable – give rinse back if possible	Discontinue procedure **Do not give rinse back**. Contact physician on call. Monitor V/S periodically	Discontinue Procedure **Do not give rinse back** Contact physician on call Monitor V/S periodically	Discontinue Procedure **Do not give rinse back** Contact physician Monitor V/S periodically
Donor Instructions	Educate and reassure donor.	Educate and reassure donor	Educate and reassure donor	Educate and reassure donor.

Apheresis reactions (contd.)

	Infiltration	Reduced or no Anti-Coagulant flow	Anti-Coagulant and Saline Solutions were reversed
Signs & Symptoms	Swelling/Donor discomfort at phlebotomy site Apheresis machine producing "return" alerts IV fluid leaking into tissues or outside the vein.	Large egg-white appearing clump in platelet bag	Large egg-white appearing clump in platelet bag accompanied by s/s of a severe citrate reaction
Routine Interventions	Discontinue Procedure Do not give rinse back Apply constant, firm pressure to site until bleeding has stopped Apply cold compress to site.	Discontinue Procedure Do not give rinse back Contact Physician Monitor V/S periodically	Discontinue Procedure Do not give rinse back Contact Physician Consider calling ambulance Monitor V/S periodically
Donor Instructions	Apply cold compresses intermittently for 12- 24 hours, then use warm compresses thereafter. If bleeding resumes, apply firm, direct pressure and elevate arm directly above head. If condition worsens or there are any problems or concerns, contact donation center.	Educate and reassure donor. Provide any other instructions given by physician	Educate and reassure donor.

APPENDIX 5: POST DONATION INSTRUCTIONS

Dear Generous Donor, kindly follow the below instructions after Blood Donation for Your Own Safety

- Eat and drink something healthy before leaving your place of donation.
- Drink extra fluids on the day of and the day after your donation.
- Do not lift heavy objects and avoid strenuous exercise such as tennis, swimming, golf, jogging, etc. during the next 24 hours.
- Do not smoke for an hour after donation.
- Leave your bandage on 3-4 hours.
- If you see any new bleeding, raise your arm above your head and apply pressure until the bleeding stops.
- If you feel faint, dizzy, or lightheaded, sit or laydown until the feeling passes.
- If you experience any bruising of your arm at the donation site, apply ice in a cloth to the area for 15-20 minutes 3-4 times a day for the first day, second day apply warm cloth for 15-20 minutes 3-4 times a day, a rainbow of colors may see for about 10 days.
- It is advisable to take iron supplements to replenish the iron lost in your donations, as advised by our medical team.
- After donation, please take refreshment and rest for at least 15 minutes before you leave the donation area.
- You can donate whole blood every 2 months, platelet apheresis every 2 weeks double red cells every 4 months if you meet the eligibility criteria.

In the event that you test positive for COVID 19 or experience signs and symptoms suggestive of COVID 19 within 5 days of your donation, please call us

Please download the DHA app in your smart mobile phone and use "Dammi" service for future donation

Thank you for your generous donation

APPENDIX 6: DONOR HISTORY QUESTIONNAIRE

Name in Block Letters:		Gender:
Date of Birth:	Nationality:	ID No:
Address:	Occupation:	Mobile No:
Donor No:	Location:	Registration Time:
Donor Type Whole Blood Plateletpheresis Donor		

First time donor □ Regular donor □ Relative donor □

If relative, Pt's health card no_____ Hospital_____

Unit No.

Hb: _____gm/dl	**B.P:** _____ mmHg	**Pulse:** _____/min	**Temperature:** _____ °C	**Weight**: _____Kg

Please fill in the below questionnaire:	*Yes*	*No*
1. Are you feeling well today?		
2. Have you come for the purpose of being tested for HIV?		
3. Have you read and understood the educational materials today?		
4. Have you had alcohol in the last 12 hours?		
5. Have you ever been deferred or refused as a blood donor?		
6. Are you currently taking an antibiotic or medication for an infection?		
7. Have you taken any medications on the medication deferral List in the time frame indicated?		
8. Have you taken aspirin or aspirin containing medication in the last 48 hours?		
9. Have you been to the dentist in the past 72 hours?		
10. Had contact with someone who was vaccinated for smallpox in past 8 weeks?		
11. Have you donated whole blood, platelet or plasma in the past 8 weeks?		
12. In the past 12 months, been in juvenile detention, lockup, jail or prison for 72 hours or more consecutively		
13. In the past 16 weeks have you donated double unit of red cells in an apheresis machine?		
In the past 6 months, have you-		
14. Received vaccination or other injections?		
15. Had a blood transfusion or organ, tissue or bone marrow transplant, or bone or skin graft?		
16. Had a major surgery?		
17. Had a body piercing or tattoo?		
18. Had an accidental needle stick injury?		
19. Had or treated for syphilis or gonorrhea? If you need assistance, refer to the staff nurse.		
From 1980 through 1996,		
20. Did you spend time that adds up to three (3) months or more in the United Kingdom?		
From 1980 through 2001, did you		
21. Spend time that adds up to five (5) years or more in France or Ireland?		

From 1980 to the present, did you		
22. Receive a blood transfusion in the United Kingdom, France or Ireland?		
Travel questions-Have you been		
23. In the past 12 months out of the country (UAE)? If yes please name the country visited-		
24. To any country in the past 6 months known to have epidemic for West Nile Disease or Chagas's disease?		
General Health Questions: Have you ever had /Did you ever test positive for-		
25. Hepatitis, Malaria, West Nile Fever, Chagas Disease or Babesiosis? (See related educational Material).		
Please fill in the below questionnaire: Have you	Yes	No
26. Used clotting factor concentrate or Dura mater transplant?		
27. Had any type of cancer, bleeding disorder, G6PD or thalassemia?		
28. Had any of your relatives who had Creutzfeldt-Jacob disease (Mad Cow Disease)?		
29. Had hypertension, gout, stroke, T.B, epilepsy or any heart or lung disease?		
30. Female donors: In the past 6 months, have you been pregnant or are you pregnant now?		
Private questions-Have you:		
31. Ever had a positive test for the HIV/AIDS virus or taken medication to treat HIV infection?		
32. Ever taken any medication to prevent an HIV infection?		
In the past 6 months-		
33. Received money, drugs or other payment for sex?		
34. Used needles to take drugs, steroids or anything not prescribed by your doctor?		
35. Male donors: had sexual contact with another male?		
36. Female donors: had sexual contact with a male who had a sexual contact with another male in the past 6 months?		
37. ***In the past 6 months, have you had a sexual contact with anyone who has ever -***		
• HIV/AIDS or has ever had a positive test for the HIV/AIDS virus?		
• taken money, drugs or other payment for sex?		
• Used needles to take drugs, steroids or anything not prescribed by their doctor?		
In the past 12 months		
38. Have you had sexual contact or lived with a person who has hepatitis?		
39. Do you understand that if you have the AIDS virus, it can be transmitted to someone else though you may feel and have a negative AIDS test?		

Dear donor, your complete honesty in answering all questions is very important for the safety of the patients who receive your blood. All information you provide is confidential. If for any reason you feel that you are not prepared to be asked detailed questions about your private and personal life, you may say now and remove yourself from the donation process. If you realize after donation that your blood should not be used, notify DBDC immediately although your blood will still be tested.

Written Consent

I, the undersigned, am voluntarily donating my blood or blood component in Dubai Blood Donation Center, Dubai Health Authority. I hereby agree that my blood or blood component may be used in any way it seems advisable or for scientific purpose.

I understand that the tests and procedures used by the Dubai Blood Donation center in the collection of blood or blood components are standardized and safe

I have read and understood the educational materials on high-risk behavior. To the best of my knowledge, I am not at an increased risk for the transmission of AIDS or other infectious agents. I agree that there are some circumstances in which infectious disease tests are not performed. And that the results can be reported to other department in DHA according to current rules and regulations.

Donor signature..... ***Date***.....

Thank you for donating blood today!

Staff No. of Nurse_____ Date_____Time_____	Arm: R ☐ L ☐ Duration_____min Time _____ Staff No. of Phlebotomist_____	Reviewed by_____ Date_____

For further information please contact:

APPENDIX 7: CRITERIA FOR ELIGIBILITY OF INDIVIDUALS FOR DONATION

#	Factors	Criteria within Factors	Deferral Period
1.	Age	< 17 years	Till age is reached
		≥ 17 years < 18 years- request consent from parent.	Till age is reached
		> 65 years	Permanent(non-therapeutic)
2.	Volume to be collected (WB)	Calculate net volume (container and additives to be subtracted)	N/A
		Collect 450 ml±45 ml (10%). Alternatively, maximum of 10.5 ml/kg of donor weigh including samples	
3.	Donation Interval	**a.** 8 weeks after last whole blood donation	Till period is completed
		b. 16 weeks from last 2-unit red blood cell donation (by aphaeresis)	
		c. 4 weeks after infrequent plasmapheresis	
		d. 2 days or more after plasma, single platelet aphaeresis.	
4.	Blood Pressure	90 to≤ 180 mm Hg Systolic pressure	Till pressure is acceptable (see drug
		50 o≤ 100 mm. Hg Diastolic pressure	
5.	Pulse	**a.** 50-100/min	Till pulse becomes acceptable. Second check after some rest
		b. < 50/min for otherwise healthy athletes	
		c. Pulse not show pathologic irregularities.	
6.	Temperature	≤ 37.5^{o}C tympanic measurements	Till temp is back to normal
7.	Allergy	Mild, even on drugs other than oral or injected steroids.	None
		Moderate: hay fever, asthma, etc.	Accept if well on the day of donation and off steroid
		Severe symptoms due to allergy or the medication	Permanent defer
8.	Hemoglobin	≥ 12.5 g/dL, ≥38% for female and ≥ 13.0 g/dL,39% for male.	Till level is achieved
		Specimen is venous or free flowing from finger prick.	

9.	Body weight	Minimum 50 kg for whole blood and 55 kg for plateletpheresis donors		Below the specified weight
10.	Therapeutic Drug Intake	**Generic Name of drug**	**Trade Name of drug**	**Deferral period**
		Finasteride	**Proscar, Propecia**	**1 month after last dose**
		Isotretinoin	**Absorica, Accutane, Amnesteem, Claravis, Sotret, Myorisan, Zenatane**	**1 month after last dose**
		Dutasteride	**Avodart, Jaylyn**	**6 months after last dose**
		Acitretin	**Soriatane**	**3 years after last dose**
		Etretinate	**Tegison**	**Permanent**
		Platelet inhibitors: Aspirin **piroxicam Prasugrel, ticagrelor Ticlopidine, Clopidogrel, varopaxar**	**Aspirin, or aspirin-containing drugs** **Feldene** **Effient, Brilinta** **Ticlid, Plavix, zontivity**	**>48 hours after last dose if for SDP.** **7 days** **14 days after the last dose if for SDP**
		Warfarin	**Coumadin, Warfilone, Jantoven**	**7 days**
		Heparin	**Heparin, low molecular weight heparin**	**7 days**
		Rivaroxaban	**Xarelto**	**2 days**
		Dalteparin	**Fragmin**	**2 days**
		Enoxaparin	**Lovenox**	**2 days**
		Dabigatran	**Pradaxa**	**2 days**
		Apixaban	**Eliquis**	**2 days**
		Edoxaban	**Savaysa**	**2 days**
		Fondaparinux	**Arixtra**	**7 days**
		Thalidomide	**Thalidomid**	**One month**
		Upadacitinib	**Rinvoq**	**One month**

		Mycophenolate mofetil	**Cellcept**	**6 weeks**
		Tenofovir,	**Truvada,**	**Three months**
		Vismodegib	**Erivedge**	**24 months**
		Teriflunomide	**Aubagio**	**2 years**
		Hepatitis B immunoglobulin	**HBIG**	**12 months**
		Experimental medication or unlicensed vaccine		**12 months or as indicated by the Medical Director.**
		Other drug intake		**Special policy is attached.**
		HIV treatment also known as antiretroviral therapy (ART)		Ever
11	Medical	a. Donor is not in good general health		Till health is OK
	General health (Final decision is for BDC doctor)	b. Donor has a major organ disease (hear, liver, lungs)		Permanent
		c. History of cancer		Permanent
		d. Abnormal Bleeding tendency		Permanent
		e. Skin lesion at venipuncture site, possibly infected		Till lesion is cured
		f. Donors previously deferred for Family history of Creutzfeldt-Jakob disease (CJD)		Permanent
12	Pregnancy	a. Pregnant		Till 6 months after delivery; 6 weeks after incomplete pregnancy.
		b. Lactation		Defer if lactating
13	Received blood transfusion or tissue	a. Blood or components, human tissue graft or transplant, other than Dura		6 months
		b. Plasma-derived clotting factor concentrates		12 months
		c. Dura matter graft		Permanent
		d. Recipient of Dura Mater of Pituitary growth hormone of Human origin		Indefinite

	transplant	e. Recovered from SARS CoV-2 and received CCP product	6 months
14	Immunizations& Vaccinations	a. Toxoids, synthetic or killed vaccines- provided donor is symptomless [Examples: Anthrax, Cholera(vaxchora), Diphtheria, Hepatitis A, Hepatitis B, Influenza, Paratyphoid, Pertussis, Plague, Pneumococcal polysaccharide, Polio (injection), Rabies, Rocky mountain spotted fever, tetanus, meningitis and Typhoid (injection)].	None
		b. Recombinant Vaccine (e.g. HPV vaccine)	None
		c. Intranasal live attenuated flu vaccine	None
		d. Live attenuated vaccines [Examples: Measles, Mumps, Polio (oral), Typhoid (oral) and Yellow Fever]	2 weeks
		e. Live attenuated vaccines [German measles (rubella) and Chicken Pox/Shingles(Varicella-zoster)	4 weeks
		f. Small pox vaccinia vaccine (live virus vaccine comprised of vaccinia virus- "replication competent" vaccine.	Without complications:2 months. With complications: 14 days after resolution.
		g. Receipt of Jynneos vaccine for small pox and monkeypox (Attenuated, live, non-replicating vaccine)	None

		h. SARS CoV-2 vaccine	*No deferral for whole blood, DRBC and platelet donation. *Cannot donate CCP, unless: 1. Had symptoms of COVID 19 and a positive PCR result for COVID 19 2. Received the COVID 19 vaccine after the diagnosis of COVID 19 and 3. Are within 6 months after complete resolution of COVID 19 symptoms.
		i. Other vaccines, including unlicensed vaccines	12 months, or up to BDC physician
15	Infectious Diseases	a. History of viral hepatitis after 11th birthday	Permanent
		b. Confirmed Positive HBsAg test	Permanent
		c. Repeatedly reactive test for anti-HBc or at high risk of HIV infection	Permanent
		d. Repeatedly reactive test for anti-HTLV	Permanent
		e. Present or past clinical or laboratory evidence of HIV, HCV, HTLV or T. Cruzinfections	Permanent

		f. History of Babesiosis or Chaga's disease	Permanent
		g. Evidence and stigmata of parenteral drug use	Permanent
		h. Administration of non-prescription drug administered by a needle	Permanent
		i. mucous membrane exposure to blood.	6 months
		j. History of non-sterile skin penetration with instruments or equipment contaminated with blood or body fluids, other than donor's own. This includes tattoos with reusable ink.	6 months
		k. Sexual contact or lived with an individual with 1. Acute or chronic hepatitis B (proven by HBsAg testing) 2. Hepatitis C, symptomatic 3. Other viral hepatitis, symptomatic	6months
		l. Sexual contact with an individual having HIV infection or at high risk of HIV infection.	6 months
		m. Retention in a correctional institution, including juvenile detention, lockup jail and prison, for 72 or more than consecutive hours.	12 months

		n. Syphilis or gonorrhoea 1. Following the diagnosis of syphilis or gonorrhoea; a. Must have completed treatment. b. If donor was not treated for syphilis or gonorrhoea	6 months Indefinitely deferred

		o. West Nile virus infection- 1. The donor has been diagnosed of West Nile virus Infection 2. Had symptoms suggestive of WNV whilst he was in a WNV endemic area or after returning back. 3. In other case after a donor's return from a WNV endemic area.	Permanent deferral 6 months. 4 weeks.

		p. Malaria- irrespective of taking prophylaxis for malaria (excluding platelet Donors) 1. Donor had diagnosis of malaria. 2. Donor has lived for at least 5 years in a malaria-endemic part of the World and less than 3 years after departure from that area. 3. Donor has travelled to a malaria – endemic area in the past 6 months	1. Permanentdeferral. 2.Defer up to 3 years. 3. Defer up to 6 months from most recent date of departure from malaria endemic area(s).

		q. Chagas disease 1. H/O Chagas disease 2. H/O blood transfusion in any of the endemic countries for Chaga's disease. 3. Visit or lived in a country where epidemic has been reported but did not have signs and symptoms. r. Zika Virus 1. H/O zika virus. 2. Visit to any of the endemic countries for Zika Virus. 3. Sexual partner has visited any of the countries endemic for Zika Virus.	Permanent deferral. Permanent deferral. Deferred for 6 months. Defer for 6 months. Defer for 6 months. Defer for 6 months

		S. Ebola Virus. 1. H/O Ebola virus infection. 2. Visit to any of the endemic countries for Ebola Virus. 3. Contact with an affected individual.	Permanent deferral. Defer for 6 months Defer for 6 months

		t. SARS-CoV-2 • Had close contact with individuals diagnosed with or suspected of having COVID-19…" • Been diagnosed with COVID-19 or who are suspected to have COVID-19 and who had symptomatic disease, • Had a positive diagnostic test (e.g., nasopharyngeal swab) for SARS-CoV-2 but never developed symptoms. • Individuals who are tested and found positive for SARSCoV-2 antibodies, but who did not have prior diagnostic testing and never developed symptoms, u. Babesiosis: • If a donor gives a history of babesiosis or ever had a positive test result for Babesia v. Monkey pox: • Suspected case: A person of any age presenting in a monkeypox non-endemic country with an unexplained acute rash AND one or more of the following signs or symptoms: Headache, Acute onset of fever (>38.5oC), Myalgia, Back pain, Asthenia, Lymphadenopathy. • Probable case: A person meeting the case definition for a suspected case. AND • One or more of the following: a. Has an epidemiological link b. Reported travel history to a monkeypox endemic country in the 21 days before symptom onset c. Has had multiple sexual partners in the 21 days before symptom onset d. Is hospitalized due to the illness	Defer for 7 days after the last possible close contact exposure to a person. Defer for 14 days after complete resolution of symptoms or the date of the positive diagnostic test, whichever period is longer. Can donate without a waiting Period and without performing a diagnostic test (e.g. nasopharyngeal swab) Indefinitely deferred Defer donors, at least until signs and symptoms are gone or a minimum of 21 days after the onset of symptoms. Defer donors, at least until signs and symptoms are gone or a minimum of 21 days after the onset of

		• **Confirmed case:** A case meeting the definition of either a suspected or probable case and is laboratory confirmed for monkeypox virus by detection of unique sequences of viral DNA either by real-time polymerase chain reaction (PCR) and or sequencing.	Defer donors, at least until signs and symptoms are gone or a minimum of 21 days after the diagnosis.
16	Travel	Doctor will evaluate travel history for potential risk	Doctor'sdecision
		1. Those who travelled to UK and spent time that adds up to three months or more (1980 to 1996). 2. Those who have spent time that adds up to five or more years in Europe. (1980 to present). 3. Those who receive a blood transfusion in the United Kingdom or France. (1980 to present)	No deferral No deferral No deferral
17	Xenotransplantation	Receipt of any cells, tissues or organs from a non-human animal source. Note: Nonliving biological products or materials from non-human animals	Permanently

Criteria for eligibility of Individuals for Donation

Reasons for deferral because of some of the above drugs:

- **Anti-platelet agents affect platelet function,** so people taking these drugs should not donate platelets for the indicated time; however, you may still be able to donate whole blood.
- **Anticoagulants or "blood thinners"** are used to treat or prevent blood clots in the legs, lungs, or other parts of the body, and to prevent strokes. These medications affect the blood's ability to clot, which might cause excessive bruising or bleeding when you donate.
- **Isotretinoin, finasteride, dutasteride acitretin, etretinate, Proscar, Avodart, Jalyn, Propecia, Accutane, Absorica,**

Amnesteem, Claravis, Myorisan, Soriatane, Sotret, Zenatane, or Tegison can cause birth defects. The donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman. Once the medication has been cleared from the blood, the donor may donate again.

- **Thalidomid (thalidomide) Erivedge (Vismodegib), Odomzo (sonidegib), Aubagio (**teriflunomide) and Rinvoq (Upadacitinib)can cause birth defects or the death of an unborn baby if transfused to a pregnant woman. Once the medication has been cleared from the blood, the donor may donate again.
- **Growth hormone from human pituitary glands:** Donors previously deferred for receiving hGH are not eligible for re-entry as a precaution.
- **Insulin from cows (bovine, or beef, insulin):** Donors previously deferred for injecting bovine insulin can be assessed for requalification and may be eligible for re-entry (to be assessed by the physician). For any other IDDM donor, accepted for donation, it is recommended that the insulin is taken at least 6 hours prior to donation.
- **PrEP or pre-exposure prophylaxis** involves taking a specific combination of medicines as a prevention method for people who are HIV negative and at high risk of HIV infection.
- **PEP or post-exposure prophylaxis** is a short-term treatment started as soon as possible after a high-risk exposure to HIV to reduce the risk of infection.
- **ART or antiretroviral therapy** is the daily use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection.

- **Hepatitis B Immune Globulin (HBIG)** is an injected material used to prevent hepatitis B infection following a possible or known exposure to hepatitis B. HBIG does not prevent hepatitis B infection in every case, therefore, persons who have received HBIG must wait to donate blood.
- **Experimental Medication or Unlicensed (Experimental) Vaccine** is usually associated with a research study, and the effect on the safety of transfused blood is unknown.

Donors SHOULD NOT discontinue medications prescribed or recommended by their physician in order to donate blood.

APPENDIX 8: DONOR DEFERRAL "FOR DISEASES AND DRUGS"

1. PERMANENT DEFERRAL

A- INFECTIOUS DISEASES

- HIV positive- RNA and serology screening test.
- HBsAg positive with NAT positive.
- HBc Ab positive.
- Anti-HCV and HCV RNA positive.
- HTLV I/II positive with western blot.
- Syphilis antibody and TPHA positive
- Creutzfeldt Jacob Disease (CJD) - possibility is suggested by history of living in countries where disease had been reported at the period specified.
- History of Malaria.
- Babesiosis

B- BLOOD DISORDERS

- Haemophilia.
- Sickle cells trait.
- G-6-PD deficiency.
- Factor deficiency.
- Thalassemia Major
- Repeat DCT and ICT positive donors.

C- SYSTEMIC DISEASES

- Cardiovascular Disease.
- Chronic renal disease.
- Chronic liver disease- hepatitis or cirrhosis.
- Strokes.
- Cancer cases (except basal cell and localized squamous cell types).
- Established generalized allergic conditions.

- Vitiligo if extensive and needs treatment to suppress the condition.

D- MEDICINE INTAKE

- Tegison.
- Digitalis derivatives.
- Growth hormone if human derived (If previously deferred for receiving hGH).
- Anti-coagulant therapy (lifelong).
- Anti-convulsant drugs.
- Anti-retroviral Therapy

2. TEMPORARY DEFERRAL

A. 3 years deferral

- Soriatane.
- Epilepsy.

B. 2 years deferral

- TB.
- Brucellosis.
- Osteomyelitis.
- Rheumatic fever.

C. 12 months deferral

- Hepatitis B antiserum vaccination.
- Rabies vaccine.
- Inmate of prison.
- Close contact with hepatitis patient

D. 6 months deferral

- Accidental needle prick contaminated with body fluids.
- Anti-malarial drugs for prophylaxis.
- Pregnancy.
- Toxoplasmosis.

- Endoscopic examination with flexible instruments.
- Major surgery.
- Dengue
- Treatment with radioactive iodine
- Homosexuals.
- I.V. drug users.
- Paid for sex or drugs.
- Acupuncture, tattooing, ear-piercing, micro bleeding and hijama unless confirmed disposable tools has been used.
- Close contact with AIDS.
- Blood Transfusion.
- Allogenic hair transplant

E. 3 months deferral

- Antidepressant drugs (Individuals who are over anxious, depressed, manic or psychotic and cannot give valid consent).
- Minor surgery.
- Typhoid fever confirmed.
- HIV Prevention (PrEP and PEP) medication.

F. 6 weeks deferral

- Chicken pox.
- Diphtheria.
- Immunosuppressant (cellcept)

G. 4 weeks deferral

- German measles(rubella)and chicken pox (varicella zoster).
- Roacutain.
- Proscar.
- Measles.

- Saxenda injection

H. 3 weeks deferral

- Mumps.

I. 2 weeks deferral

- Live attenuated vaccines (measles, mumps, oral polio).
- Autologous PRP injection, autologous hair transplant, or Botox injection done in licensed clinic.

J. 1-week deferral

- Antibiotics.
- Common cold, sore throat.
- Systemic antifungal therapy.
- Root canal treatment, dental capping, dental implants or tooth extraction.

K. 3 days deferral

- Dental filling, scaling and superficial treatment.

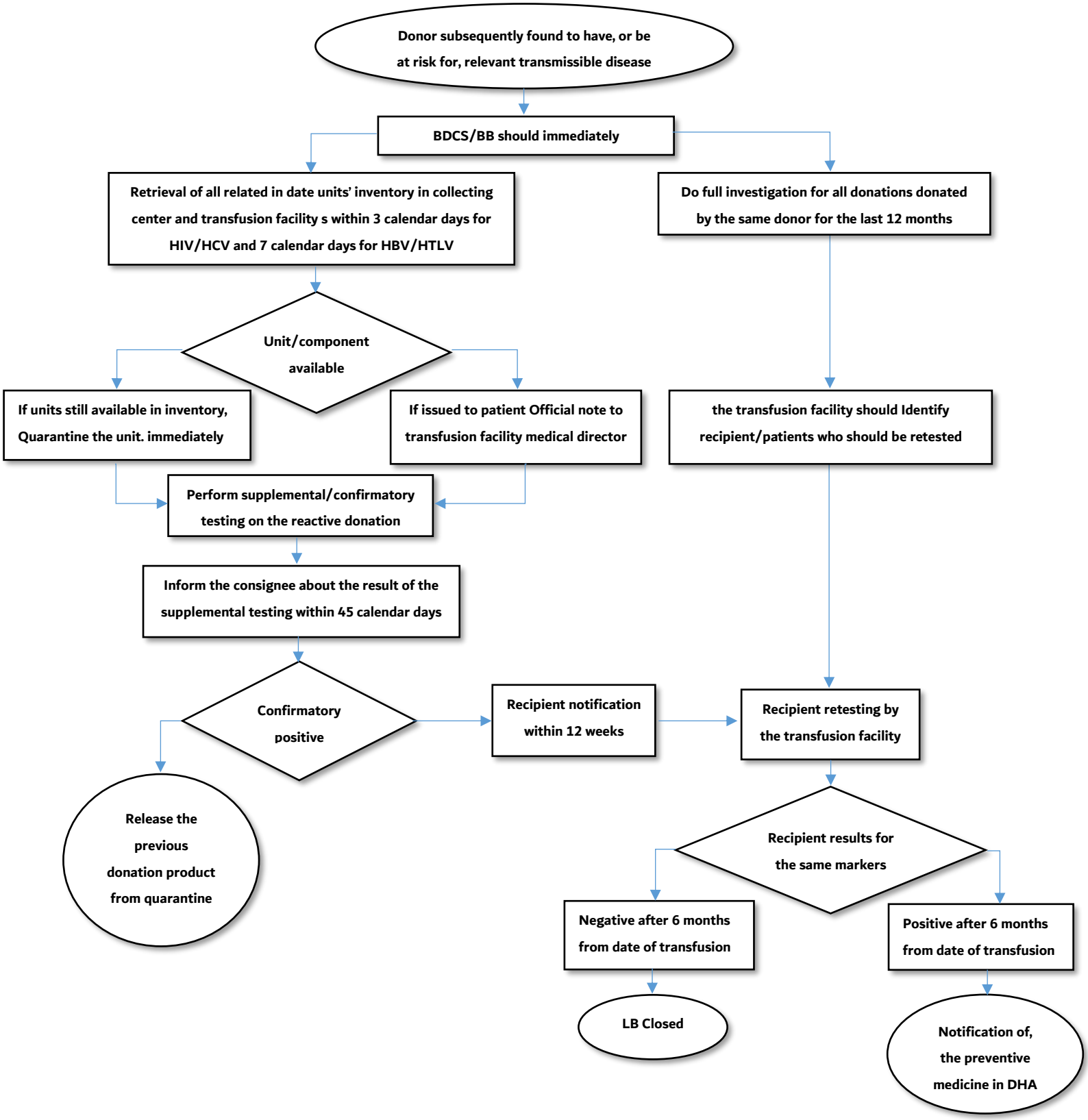
L. 48 hours deferral

- Pilots and Aircrew should not give blood 48 hours or less before flight.

M. Until donor is symptom-free

- Low Hb- other than inherited anaemias.
- Skin diseases- after full recovery.
- Renal colic- when symptom-free.
- Febrile illness, non-specific.

APPENDIX 9: LOOK BACK FLOW CHART



APPENDIX 10: RETENTION OF DONOR RECORDS

No.	Record to be Maintained	Minimum Retention Time (Years)
	UNIT RECORDS	
1.	Source to final disposition of each unit of blood or blood component.	10
2.	Unique identification of each unit	10
3.	Donor acknowledgement that educational materials have been read	10
4.	Consent of Donors	10
5.	Notification to donor of significant abnormal findings	10
6.	Donors placed on permanent deferral, indefinite and on surveillance for protection of recipient	Indefinite
7.	Donor information, including address, medical history, physical examination, health history, or other conditions thought to compromise suitability of blood or blood component (Donor History Questionnaire)	10
8.	A medical order from the patient's physician is required to collect blood for autologous use	10
9.	Platelet count for frequent plateletpheresis donors	10
10.	Identification of individuals performing each significant step in collection, processing and transportation of blood & components	10
11.	Inspection of Incoming blood and blood components	10
12.	Preparation of specific Components	10
13.	ABO group and RH type for all collections	10
14.	Interpretation of viral markers testing for allogenic donations	10
15.	Distribution or issue of units before completion of tests	10
16.	Quarantine of units from prior collections when a repeat donor has a reactive disease marker screening test	10
17.	Final Review of records relating to testing and acceptability criteria	10
18.	Review of donor records to ensure any units from an ineligible donor are quarantined	10
19.	Blood and components that are determined after release not to conform to specified requirements.	10
20.	Adverse events related to donation	10
21.	Look-Back investigation	10
22.	Requests for blood and components	5
23.	Traceability of blood, blood components and critical materials	10
24.	Allogeneic donor testing to detect unexpected antibodies to red cell antigens	10
25.	Control system results appropriate to the method of testing	10
26.	Serologic confirmation of donor blood ABO/Rh	10

27.	Reporting and resolution of ABO/Rh labelling discrepancies to collecting facility.	10
28.	Notification by consignee of a transfusion fatality or other serious adverse event.	10
29.	Collection facility's investigation of transmissible diseases	10
30.	A signed statement from the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood before completion of compatibility testing or infectious disease testing.	10
31.	Test Results and interpretation of patient's ABO Group and Rh type / Test Results and interpretation of serologic crossmatch	10
32.	Order for blood, blood components, tests and derivatives	5
33.	Control system results appropriate to the method of testing	10
34.	If a unit is returned for reissue, confirmation that the tubing identification number on reattached segments is identical and confirmation that the blood or blood components have been inspected and are acceptable.	10
35.	Detection of ABO incompatibility when no clinically significant antibodies are detected	10
36.	Computer detection of ABO incompatibility	10
37.	Final inspection of blood and blood components before issue, if the container is not intact or components are abnormal in appearance, maintain record of medical director approval	10
38.	Verification at issue of blood and blood components 1. The intended recipient's two independent identifiers, ABO group, and Rh type 2. The donation identification number, the donor ABO group and if required, the Rh type 3. The interpretation of crossmatch tests, if performed 4. Special transfusion requirements, if applicable 5. The expiration date and, if applicable, time 6. the date and time of issue 7. Personnel issuing and accepting blood components	10
39.	Notification of Abnormal Test Results	10
40.	Inspection of weld for completeness and identification numbers of blood or blood components and of lot numbers of disposables used during component preparation	10
41.	Verification of Irradiation Dose Delivery	10
42.	Donation Identification number and collecting facility for each Unit in pooled components	10
43.	Irradiation of Cellular components, if applicable	10
44.	A signed statement from the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood before completion of compatibility testing or infectious disease testing.	10
	Other Documents and Records	
45.	Management Review of effectiveness of the Quality System	5
46.	Exceptions to Policies, Processes and procedures	10
47.	Emergency Operation Plan tested at defined intervals	2
48.	Job Descriptions	5

49.	Qualification of personnel performing Critical tasks	5
50.	Training Records of Personnel	5
51.	Evaluations of competence of personnel	5
52.	Personnel Records of each employee	5
53.	Record of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
54.	Monitoring and maintenance of equipment	10
55.	Unique Identification of Equipment	5
56.	Temperature monitoring of refrigerators, freezers, and platelet incubators.	10
57.	Implementation and modification of software, hardware or database	2 after retirement of the system
58.	1.Validation of system software, hardware, databases, user defined tables, electronic data transfer, and/or electronic data receipt 2. Fulfilment of applicable life cycle requirements 3. Monitoring of data integrity for critical data elements 4. Numerical designation of system versions, if applicable with inclusive dates of use	2 after retirement of the system
59.	Evaluation and participation in selection of suppliers	5
60.	Inspection of incoming Critical Materials and containers	10
61.	Validation of new or changed processes and procedures	5
62.	Participation in Proficiency testing program	5
63.	Quality Control records and review of quality control results for reagents, equipment and methods	10
64.	Records of Storage temperatures for blood products/ Ambient temperature recorded every 4 hours when components are stored in open storage area	10
65.	Identification and Appropriate archival of Obsolete documents	5
66.	Corrective Action / Preventive Action	5
67.	Monitoring of biological, chemical and radiation safety	5
68.	Appropriate Discard of blood and blood components	10
69.	Agreements / Agreements review	5
70.	Agreements concerning activities involving more than one facility	5
71.	Inspection before shipping	10
72.	Participation in development of policies, processes and procedures regarding recipient consent for transfusion	5
73.	Biannual review of policies, processes and procedures	5
74.	Review and approval of new and revised documents before use	5
75.	Nature of nonconformance discovered after release and subsequent actions taken, including acceptance for use	10

76.	Review of assessment results	5
77.	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
78.	Alarm Investigation	5
79.	Description and evaluation of nonconforming blood, components, critical materials and services.	10
80.	Incoming containers, solutions and reagents meet or exceed applicable FDA criteria	10
81.	Disposition of nonconforming products	10
82.	Fatality reports	10
83.	Transfusion service evaluation and reporting of transmissible diseases	10
84.	Peer review assessment of blood utilization	5
85.	Container qualification and process validation records	10
86.	Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent haemolysis or other damage to blood or blood components	10
87.	Accreditation Documentation	5
88.	Lab results or other working record of test results for donors/patients	5
89.	QMS Records (Audit, Quality Manual, etc)	5
90.	Peer review assessment of blood utilization	5
91.	Equipment Operating Manual	5
92.	Equipment Qualification	5