Blood Bank Inspection Checklist- Final

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5	**STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES**				
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.				
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				
6.4.	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.				
6.6.5.	The Blood Banks shall be designed to easily accommodate People of Determination and aligned with the Dubai Universal Design Code.				
9	**STANDARD FIVE: MANAGEMENT OF EQUIPMENT**				
9.2.	Selection of Equipment				
9.2.1.	The Blood Banks shall have a process to define the selection criteria for equipment.				
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.				
9.15.	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.				
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.				
10.6.	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.				
10.9.	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				
10.11.2.	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)**				
11	**STANDARD SEVEN: DONOR EDUCATION, CONSENT, NOTIFICATION AND ELIGIBILITY**				
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.				
11.4.	Care of Donors				
11.4.1.	The collection facility shall have a policy to ensure that the donor qualification process is private and confidential.				
11.4.3.	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)**				
11.9.	Protection of the Donor				
11.9.1.	The collection facility shall have processes to minimize the adverse effects of donation.				
11.9.3.	The collection facility shall have a process to reduce the risk of adverse reactions in young donors.				
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.				
13	**STANDARD NINE: PREPERATION AND PROCESSING OF COMPONENTS**				
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.				
14	**STANDARD TEN: ROUTINE BLOOD SCREENING TESTS**				
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)**				
16	**STANDARD TWELVE: SAFETY AND INFECTION CONTROL PRACTICES**				
16.1.	General Safety Considerations				
16.1.3.	Safety therefore includes protection of both the staff and the environment from hazardous materials. General safety measures include:				
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.				
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				
16.2.2.	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.				
16.5.5.	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.				
17	**STANDARD THIRTEEN: HEALTH RECORDS**				
17.2.	The format of recording and reporting results should be described in the SOPs.				
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.				