Blood Donation Inspection Checklist- Random

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
6	**STANDARD TWO: HEALTH FACILITY REQUIREMENTS**				
6.3.	Special consideration should also be given to climate and ventilation control. The temperature and humidity within the Blood Collection site should be maintained within proper limits for effective performance of tests performed and maintained according to manufacturer's specifications. A comfortable working environment is considered 20 to 25o C with relative humidity of 35 to 50%.				
6.4.	The BDCS should install and operate equipment required for provision of the proposed services in accordance to the manufacturer's specifications.				
6.6.	The BDCS 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.				
7	**STANDARD THREE: HEALTHCARE PROFESSIONALS REQUIREMENTS**				
7.1.	All healthcare professionals in the BDCS must hold an active DHA professional license and work within their scope of practice.				
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.				
7.10.	The Blood Donation Collection Centre (BDCC) shall maintain charter of patients' rights and responsibilities, customer happiness charter, and donor journey posted at the premise in two languages (Arabic and English).				
7.11.	The BDCS should 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. (Related AABB standards applied).				
7.22.	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.	To guarantee the smooth operation and ensure safe and quality services are provided in the BDCS, the management lead by the Medical Director has certain responsibilities which include, but not limited to the following:				
c.	Apply current AABB standards in daily work and to be accredited from AABB or CAP as BDCS within a maximum period of 18 months from operation.				
j.	Maintain the recommended immunizations for health professionals working at the BDCS.				
l.	Designate a qualified person(s) or team for the following:				
i.	Quality Control Manager or competent authorized person to ensure quality assurance (for details regarding quality assurance refer to **Appendix 3)**.				
ii.	Fire Safety.				
t.	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 EQUIPMENTS**				
9.14.1.	The BDCS should use DBDC software for donor's management to have unified donor's data within the emirate of Dubai.				
9.14.2.	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.	The System shall be designed to prevent unauthorized access to computers and electronic records shall be established and followed.				
10	**STANDARD SIX: PROCESS CONTROL**				
10.3.1.	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.				
10.5.2.	Traceability; The BDCC 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.				
10.6.1.	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.				
10.6.2.	A unique identification shall be affixed by the collecting or pooling facility to each unit of blood, blood component, and attached container, or a tissue or lot. This identification shall not be obscured, altered, or removed by facilities that subsequently handle the unit.				
10.7.1.	Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.				
10.10.2.	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.				
11	**STANDARD SEVEN: DONOR INFORMATION, CONSENTS, AND NOTIFICATIONS**				
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.				
11.3.2.	BDCS qualified medical physician should notify the donor with any abnormal results found during pre donation testing or screening.				
11.3.3.	DHA. DBDC shall notify the donors with any abnormal results found post donation according to related AABB standards through a licensed and qualified physician.				
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 (refer to DBDC related SOPPHL002 Random Donor Whole Blood Donation).				
11.5.1.	The collection facility shall provide the donor with written instructions about Post phlebotomy care. (Refer to DBDC post donation instruction form).				
11.5.2.	The collection facility shall provide the donor with written instructions, including actions to take, about adverse events that may occur after donation.				
11.7.1.	The prospective blood donor is a healthy individual between the age of 18 to 65 years and meeting the donor qualification requirements contained in the "Donor Eligibility Criteria Requirements for Allogeneic Donor Qualification".(Refer to DBDC donor eligibility criteria form).				
11.7.2.	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.				
11.8.1.	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.				
11.9.2.	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.				
12	**STANDARD EIGHT: DONORS REGISTRATION & SELECTION**				

12.1.	Donors Registration				
12.1.5.	The system generates a unique donor number for all first-time donors. Repeat donors are linked to existing donor records by the donor number, which is unique for each donor.				
12.1.7.	As per UAE. Blood Transfusion standards (28/2008); only UAE. National, national of GCC and official UAE. Residents are allowed to donate blood. Holders of transit or visit visa are not eligible to donate blood in UAE.				
12.4.	Blood Collection (Refer to related DBDC SOP PHL002 and PHL019)				
12.4.3.	Donor will not be accepted if the pre-donation duration interval is less than 8 weeks unless an exceptional approval from the Medical Director.				
12.4.4.	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.				
12.4.5.	If a donor has donated double RBC units and presents for whole blood donation allow a period of 16 weeks interval between them.				
a.	Blood shall be collected into a sterile closed system. Blood collection containers with draw line (inlet) diversion pouches shall be used for any collection of platelets, including whole blood from which platelets are made.				
12.4.7.	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.				
12.4.8.	Donor identification: Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.				

12.5.	Blood Units Storage and Transporting (Refer to related DBDC SOP PHL027)				
12.5.1.	Whole blood after collection should be transported to Dubai Blood Donation Center within specified time and under controlled temperature condition.				
12.5.2.	Validated transport cool boxes are used along with frozen ice packs to maintain a cooler temperature and plastic shields to separate the ice packs from coming in direct contact with the blood to prevent haemolysis.				
12.5.3.	The temperature of the transport boxes are monitored regularly throughout the entire journey by validated and calibrated data loggers which is placed carefully between the blood bags.				
a.	Containers shall be qualified to transport blood to ensure that they maintain temperatures within the acceptable range for the expected duration of transport or shipping.				
b.	Handling, storage and transportation, the collection facility shall have a process to ensure that blood transported in a manner that meets the requirement of storage. Whole blood should be transported for cooling toward 20°C -28°C.				
12.6.	Ethical Consideration				
12.6.4.	Healthcare Professionals working in the blood collection site shall not use expired reagents/kits during blood collection. Evidence of documented validation must be readily available for any inspection.				
13	**STANDARD NINE: SAFETY & INFECTION CONTROL PRACTICES**				
13.1.3.	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.				
j.	Blood Collection site personnel shall be thoroughly trained in managing emergencies such as biohazard spillage/ etc. as applicable to the facility.				
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 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.				
13.2.	Hand Hygiene				
13.2.2.	Handwashing basins, paper towels should be provided in areas that conduct a medical procedure such as phlebotomy.				
13.2.3.	Antiseptic Hand Sanitizers should be in single use, non-refillable pouches inserted into dispensers.				
13.3.3.	These types of PPE such as Gloves, Masks, Disposable coats must be always available and discarded in the Infectious waste bin.				
13.5.	Waste Management				
13.5.1.	Blood, blood components, tissue and derivatives shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.				
13.5.2.	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 bags.				
13.5.4.	Pre-disposal treatment of Laboratory wastes should be performed prior to disposing to a sanitary sewer line.				
13.5.5.	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.				
13.5.6.	Sharps containers must not be overfilled. When a sharps				

	container becomes two-thirds full, seal and discard it.				
13.6.1.	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.				
13.7.	Occupational Exposures and Percutaneous Injury				
13.7.3.	Accident/incident/injuries record of Blood Collection site personnel should be maintained and reported to the designated authority.				
13.7.4.	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 Blood Collection site Safety Officer should maintain the records.				
14	**STANDARD TEN: HEALTH RECORDS**				
14.1.	Laboratory data management includes recording details of the donor medical check- up details, laboratory screening results and archiving the data for future reference.				
14.2.	The format of recording and reporting results should be described in the SOPs.				
14.3.	Equipment maintenance reports must be kept for future reference.				