Autologous Haematopoietic Stem Cell Transplantation Inspection Checklist- Random

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
4	**STANDARD ONE: HEALTH FACILITY REQUIREMENTS**				
c.	The lighting and utilities are adequate, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets, and communications.				
4.1.5.	The health facility design should provide assurance of patient and staff health and safety.				
4.4.	Accreditation				
4.4.1.	The hospital must be accredited as per DHA Policy for Hospital accreditation before the commencement of the service.				
4.4.2.	The hospital lab must be accredited as per DHA Policy for Clinical Lab before the commencement of service.				
4.4.4.	The service shall achieve and comply with FACT-JACIE International Standards for Cellular Therapy, Product Collection, Processing and Administration, Storage and Collection accreditation 24 months from licensure activation.				
4.5.	In house Lab Setup and Diagnostics				
4.5.1.	Equipment and supplies for a stem cell processing lab are set out in **Appendices 1 and 2.**				
b.	Backup equipment shall be identified where there is only one device is in use.				
c.	All essential equipment shall be connected with an uninterruptible emergency power supply.				
d.	All product contact reagents should be sterile and infusion-grade, and disposable.				

e.	Reagents should be dispensed into single-use containers before use to minimize waste.				
4.6.	There should be a mechanical freezer capable of storing a liquid nitrogen tank equipped with an audible alarm.				
4.6.4.	An oxygen sensor alarm to indicate when oxygen levels are dangerously low.				
4.6.5.	A temperature sensor should be fitted to track and temperature at least twice a day.				
4.6.6.	Adequate backup liquid (or vapour) nitrogen storage capacity should be in place.				
5	**STANDARD TWO: HEALTHCARE PROFESSIONAL REQUIREMENTS**				
5.2.	Only a DHA licensed consultant trained to provide AHSCT shall lead the AHSCT service as the Clinical Program Director.				
5.11.	AHSCT services shall have the minimum number of healthcare professionals for set up of the service detailed below:				
5.11.1.	A Clinical Program Director;				
5.11.2.	Facility Medical Director;				
5.11.3.	Attending Physician (Consultant and specialists in Hematology, Immunology, Oncology or Genetics);				
5.11.4.	Multidisciplinary support team;				
5.11.5.	A case manager;				
5.11.6.	An Administrator;				
5.11.7.	Two registered nurses;				
5.11.8.	Two lab technicians/technologists;				
5.11.9.	A Clinical Pharmacist;				
5.11.10.	A ward manager;				
5.11.11.	Nurse Patient Care Coordinator;				
5.11.12.	Health educator.				
5.11.13.	A Quality Assurance Manager; and				
5.11.14.	Infection control lead.				
6	**STANDARD THREE: PERMITTED INDICATIONS FOR AUTOLOGOUS HSCT**				
6.2.	Exclusions				

6.4.	Use of double or multiple umbilical cord cells that are not from the same individual.				
6.5.	Sale, storage or use of autologous stem cells for any other person(s) who is not the same patient/individual' is not permitted.				
6.6.	Transfer of Autologous Hematopoietic Stem Cell in or out of the health facility or Dubai is not permitted. Written approval shall be sought by the competent regulator (DHA or MoHaP).				
7	**STANDARD FOUR: AUTOLOGOUS HSCT SERVICE REQUIREMENTS**				
7.1.4.	Ensure there is a register for Autologous Hematopoietic Stem Cell Transplantation that is maintained.				
8	**STANDARD FIVE: STEM CELL COLLECTION, PROCESSING, STORAGE, TRANSPORTATION AND BANKING**				
8.2.	Processing of cells should be undertaken within 48 hours at a controlled temperature as per the latest evidence-based practice.				
8.2.2.	Cells shall be counted (CD34+ cell count), assessed for viability and sterility, and preliminary stored continuously in the recommended controlled temperature (initially -4°C).				
8.3.	The sample can be frozen in a controlled manner down to the target temperature of –156°C (vapour phase) to –196°C (liquid phase) for longer-term storage.				
8.3.2.	Assessment of the frozen cells should be performed after 72 hours.				
8.5.	Cells that require transportation shall:				
8.5.1.	Have an agreement and clear process between the sender and receiver.				
8.5.2.	Have in place a courier tracking mechanism to determine the status of the cells being transported.				
8.5.3.	Ensure cells are placed in a credo-box that is prepared to 4 °C.				
b.	There should be two temperature loggers, and temperature readings should be taken every 15mins.				

e.	The credo box shall include labels identifying the product being transported.				
9	**STANDARD SIX: SAFETY AND QUALITY REQUIREMENTS**				
9.5.	Written agreements with suppliers, blood banks and tertiary hospitals to ensure patient safety and quality of care are not compromised.				
9.5.1.	Twenty-four-hour availability of appropriate and irradiated blood products needed to care for cellular therapy recipients.				
9.15.	Cellular processing and storage/cryopreservation is controlled in the laboratory does not compromise the quality, quantity and efficacy of AHSCT.				
9.15.1.	Cryopreservation initial temperature –4°C.				
9.15.2.	–156°C when stored in the vapour phase.				
9.15.3.	–196°C when stored in the liquid phase, depending on where the specimen is stored in the container.				
9.16.	Cell typing is confirmed before infusion.				
12	**STANDARD NINE: POST-TRANSPLANT PERIOD**				
12.1.	The timeframes for anticipated engraftment and follow up are documented.				
APPENDIX 1	**Equipment Needed to Start A Cell-Processing Lab**				
A	**Required equipment:**				
1	Biosafety cabinet (or equivalent)				
2	Water bath				
3	Plasma extractor				
4	Cryo-transporter (-80 °C) or liquid nitrogen dry shipper				
5	Pipette aid				
6	Refrigerator				
7	Centrifuge (with carriers to hold 600 mL blood bags)				
8	Tubing sealer				
9	Micropipettes (100 µL and 1000 µL)				
10	Hemostats				

11	Balance (Scale)				
12	Freezer (<-70 °C)				
13	Tubing stripper				
14	Reference thermometer				
B	**Desired equipment:**				
1	Sterile connecting device				
2	Label printer				
3	Microscope				
4	Controlled rate freezer				
5	CO2 incubator				
6	Personal computer				
7	LN2 (Liquid nitrogen) storage freezer				
8	Hemocytometer				
C	**Shared equipment:**				
1	Flow cytometer				
2	Hematology analyzer				
3	Automated instrument for cell processing				
4	Microbiology lab for bacterial and fungal couture				
APPENDIX 2	**Essential requirements for setting up a stem cell processing laboratory**				
A.	**Miscellaneous laboratory supplies**				
1	Cryobags (for example: 50; 250; 500 mL)				
2	Transfer packs (300; 600 mL)				
3	Syringes (1, 3, 10, 30, 60 mL)				
4	Safety needles; couplers				
5	Spike to needle, spike to spike adapters; stopcocks				
6	Alcohol swabs, iodine swabs, syringe caps, sterile swabs				
7	Labels, laminating tags; zip ties				
8	15, 50, 175 mL conical tubes				
9	Pipettes (1-50 mL)				

10	Biohazard sample bags				
11	Tube racks				
12	Pipette tips				
13	Cryovials, microtubes				
14	Biohazard bags; sharp containers; garbage bags; trash can				
15	Dry ice				
16	Sterile overwrap bags				
B.	**Sample reagent list (will vary depending on products and services offered)**				
1	DMSO (dimethyl sulfoxide)				
2	Plasmalyte (or equivalent)				
3	ACD-A (acid citrate dextrose solution)				
4	Human serum albumin				
5	Hetastarch				
6	Heparin				
7	70% IPA (isopropyl alcohol); bleach; bactericidal and fungicidal detergent				
8	Flow cytometry reagents				
9	Trypan blue				