



Electronic copy is controlled under document control procedure. Hard copy is uncontrolled & under responsibility of beholder

It is allowed ONLY to access and keep this document with who issued, who is responsible and to whom it is applicable.

Information Security Classification: Open Shared -Confidential Shared-Sensitive Shared-Secret

Standards for Fertility Centers – Final

Name of the Facility: _____

Date of Inspection: ____/____/____

Ref.	Description	Yes	No	N/A	Remark
5.	Standard One: Registrations and Licensure Procedures				
5.3.	The fertility center is prohibited from providing any medical services until it obtains a license.				
5.6.	The fertility center shall have in place internal policies and procedures including but not limited to:				
5.6.1.	policy for sample collection, storage, and transportations.				
5.6.2.	Service Description and Scope of Services.				
5.6.3.	Laboratory and diagnostic services policy that includes turn-around timeframes for reporting noncritical and critical results.				
5.6.4.	Infection control policy to include management, prevention and surveillance in relation to patient, employees, infection control and frozen specimen safety.				
5.6.5.	Reprocessing of reusable equipment, safe use of chemicals used for cleaning and disinfecting.				
5.6.8.	Laundry and housekeeping services.				
5.6.9.	Medical and hazardous waste management policy as per the Dubai Municipality (DM) Requirements.				
5.6.10	There should be an allocated medical waste storage and collection area that is well ventilated, temperature controlled, monitored and secured from public and patient access.				
5.6.11	The medical waste storage and collection area shall be adequately labelled with a hazard sign to prevent unexpected entry from patients or the public.				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	1/8



5.6.12	Policy for sample collection, storage, sample transportations and the fate of non-mature collected samples.				
5.6.13	Contingency plan in the case of emergency as to where the gametes/ embryos will be transferred to in agreement with the receiving facility with a clear exit strategy.				
5.6.14	Patient assessment, acceptance, admission and referral criteria.				
5.6.15	Patient belongings.				
5.6.16	Patient education, communication and informed consent.				
5.6.17	Patient health record, confidentiality and privacy as per DHA Policy for Health Information Assets Management.				
5.6.18	Staffing plan, employee management and clinical privileging.				
5.6.19	Violence against Staff/Zero Tolerance.				
5.6.20	Clinical Audit including Quality, Performance Management and Learning System.				
5.6.21	Incident reporting.				
5.7.	All fertility centers shall have a business continuity plan to ensure the center's services are uninterrupted.				
6.	Standard Two: Fertility Center Requirements				
6.1.	The fertility center must be accredited by a globally recognized accreditation body that is approved by DHA within a period of three years.				
6.3.	The Fertility center shall ensure the treatment environment is accessible and supports patient needs, safety, privacy and confidentiality for all patient groups.				
6.4.	Fertility centers shall abide by offering their services to all clients including people of determination.				
6.8.	The ART lab should be accredited by recognized accreditation body that has specific ART lab standards as per DHA's clinical lab accreditation policy.				
6.12.1	Monitoring medical, electrical and mechanical equipment, visual inspections for apparent defects and maintenance by the competent entity with valid testing certificates as per DHA Standards for Medical Equipment Management.				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	2/8



6.12.2	Assure medical equipment and devices are in place for emergency scenarios.				
9.	Standard Five: Medical Equipment And Devices				
9.3.	Materials used in laboratory construction, painting, flooring and furniture should be appropriate for clean room standards, minimizing Volatile Organic Compounds (VOC) release and embryo toxicity.				
9.4.5.	UPS Generator.				
9.6.	Equipment must be adequate for optimal laboratory work, easy to disinfect and kept clean to avoid contamination.				
9.7.	All equipment must be validated as fit for its purpose and performance verified by calibrated instruments.				
9.9.	Gas cylinders should be located outside the laboratory, there should be an automatic change over system and sufficient cylinders stocked for immediate replacement. High purity gas and inline HEPA and VOC filters are highly recommended.				
9.10.	The fertility center shall maintain a copy of operator and safety manuals of all medical equipment and inventory list with equipment location. All Medical Equipment should be registered and documented properly in the inventory which will be updated every time a new equipment arrives prior to use. To follow the Standards for Medical Equipment Management.				
9.11.	Equipment validation, calibration, maintenance and repair must be documented and records retained.				
9.12.	Employ a biomedical engineer or maintain a service contract with a certified maintenance company to ensure safety, reliability, validity and efficiency of medical devices and mechanical equipment.				
9.14.	For every item of equipment, the instruction manual and the simplified instructions should be available.				
9.16.	Critical equipment such as incubators, fridges, freezers and liquid nitrogen cryo- storage units should be continuously monitored and equipped with alarm systems.				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	3/8



9.17.	An automatic emergency backup power system must be in place for all critical equipment. e.g.: includes incubator, fridge, and freezers.				
9.18.	Cryopreservation storage units should be continuously monitored and equipped with alarm systems, detecting any out of range temperature and/or levels of liquid nitrogen (LN2).				
11.	Standard Seven: Approved Medical Assisted Procedures				
11.5.1	A clear policy and procedure identifying the steps taken to preserve gametes and embryos.				
13.	Standard Nine: Infection Control				
13.2.	Policy for infectious diseases screening notification and protocols healthcare professionals should abide by for patients who test positive for specific diseases such as COVID, and HIV, Hepatitis B and C as per DHA Policy for Communicable Diseases Notification.				
13.3.	Policy and procedures to ensure employee safety and prevent cross-contamination should be established to prevent the transmission of pathogens across the fertility center:				
f.	Environmental cleaning, single use items and reprocessing of sterile instruments.				
h.	Sterilization may be outsourced and is subject to DHA approval.				
i.	In case sterilization is not outsourced then there should be a sterilizing area, which can be located near the procedure room with an adequate high-speed autoclave machine. Cleaning and sterilizing medical tools should be done in a sterilizing area next to the cleaning room for the tools to be cleaned, sterilized and then received from the cleaning room, preferably through a window passage.				
18.	Standard Fourteen: Laboratory Requirements and Safety Controls				
18.5.	The ART Laboratory should be adjacent to the operating room where clinical procedures are performed.				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	4/8



18.6.	Operating rooms must maintain positive pressure while keeping in consideration monitoring the air changes per hour based on ISO 100 instructions and standards.				
18.7.	Materials used in laboratory construction, painting, flooring and furniture should be appropriate for clean room standards, minimizing Volatile Organic Compounds (VOC) release and embryo toxicity.				
b.	Positive pressure is recommended to minimize air contamination- apart from cryopreservation room where negative pressure is required to protect from liquid nitrogen (LN2) leakage.				
18.8.	Laboratory access should be restricted to authorized personnel.				
18.9.	Laboratory design should ensure optimal workflow over small distanced while handling gametes/embryos during the whole treatment phase.				
18.10.	Rooms for changing clothes should be separate from the laboratory.				
18.11.	Hand washing facilities should be placed outside and within the laboratory.				
18.12.	Office spaces for administrative work should be available separately outside the laboratory while in close proximity of the ART laboratory.				
18.13.	Area for cleaning and sterilization of materials should be separate from the laboratory.				
18.15.	Mandatory Protective measures for laboratory employees to ensure aseptic conditions for tissue, gametes and embryos include:				
18.15.1.	Strict adherence to employees' hygiene regulations and aseptic techniques.				
18.15.2.	Use of protective laboratory clothing, preferably with low particle shedding.				
18.15.3.	Use of hairnets and nontoxic, non-powdered gloves and masks where appropriate.				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	5/8



18.15.4.	Use of appropriate Biological Class II flow hood cabinet in order to protect sample and operator.				
18.29.	All ART laboratory should have an emergency plan in place with specific procedures in case of failure of infrastructure and facilities.				
18.30.	The plan should describe actions related to the following:				
18.30.1.	Safety of personnel and patients.				
18.30.2.	Protection of all fresh and cryopreserved human material.				
18.30.3.	Limitation of damage to equipment and medical records.				
Appendix 1:	Minimum Equipment in Art Laboratory and Andrology Unit				
App1.1	2 TRI-GAS/CO2 incubator				
App1.2	BIOLOGICAL CLASS II HOOD Qt. 3 (2 in embryology Laboratory and 1 in Andrology Laboratory) - Backup 1				
App1.3	Stereomicroscope - Qt. 3 (the number should match the biological class II hood ratio 1:1) - Backup 1				
App1.4	1 Air filtration tower				
App1.5	1 Phase contrast microscope				
App1.6	1 Tube heater				
App1.7	1 Thermometer				
App1.8	1 ANTIVIBRATION TABLE				
App1.9	1 portable incubator				
App1.10	1 Continuous Monitoring System (24hrs)				
App1.11	2 O2 Sensor				
App1.12	2 Laboratory Oven				
App1.13	2 Gas Automatic Manifold				
App1.14	1 Laser System (if fertility center offers embryo genetic testing) and 1 back up				
Appendix 2:	Minimum Machinery Backup in Case of Emergency				
App 2.1	1 Inverted Microscope and 1 Backup				
App 2.2	1 Micromanipulator and 1 backup				
App 2.3	1 Centrifuge and 1 backup				
App 2.4	2 Freezing Tanks and 1 backup				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	6/8



App 2.5	2 Electrical pipettes and 1 backup				
App 2.6	2 Variable pipettes and 1 backup				
App 2.7	1 O2/CO2 GAS ANALYZER (the machine name must be the same name as stated) and 1 backup				
App 2.8	2Pharmaceutical fridge				
App 2.9	1 of each Camera and monitor				
App 2.10	1 Computer				
App 2.11	1 UPS BACKUP				
App 2.12	1 Backup warm plate and 1 backup				
App 2.13	1 Digital weighing media				
Appendix 3	Minimum Operating Room Equipment				
App3.1	1 IVF Vacuum pump and 1 backup				
App3.2	1 Suction Unit				
App3.3	1 Laparoscopy Unit (optional for hysteroscopy)				
App3.4	1 Tele-cam				
App3.5	1 Endoflater (optional for hysteroscopy)				
App3.6	1 Light source XEN (optional for hysteroscopy)				
App3.7	1 Monitor				
App3.8	1 Anesthesia machine				
App3.9	1 OR table				
App3.10	2 cardiac monitor O2 monitor				
App3.11	1 Crash cart & defibrillator along with Intubation Kit (laryngoscope with different sized blades, ETT Tubes different sizes, LMA different sizes) and AMBU Bag with different sizes Ambu masks.				
App3.12	1 ultrasound				
App3.13	1 OR lamp and 1 portable standby				
App3.14	1 Examination table				
App3.15	1 Hormone immunoassay (optional)				
Appendix 4	Minimum Additional Equipment In Ot Room				
App 4.1	1 Water bath or bottle holder heater for flush				
App 4.2	2 Block heater for tubes				
App 4.3	1 Surgical light				
App 4.4	1 Anesthesia pen tents				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	7/8



App 4.5	1 Anesthesia cart				
App 4.6	1 Patient shifting trolley				
App 4.7	1 nursing trolley				
App 4.8	1 Surgical chair				
App 4.9	1 Instrumental trolley				
App 4.10	1 IV pole				
App 4.11	1 Wormer				

Checklist	ID	Issue#	Issue Date	Revision Date	Page#
Standards for Fertility Centers -Final	CP_9.6.01_F53	01	09/12/2024	09/12/2027	8/8