Clinical Laboratory Inspection Checklist- Random

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5	**STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES**				
5.5.	The health facility shall provide documented evidence of the following:				
5.5.1.	Equipment maintenance services				
5.5.2.	Laundry services				
5.5.3.	Medical waste management as per Dubai Municipality (DM) requirements				
5.5.4.	Housekeeping services				
5.5.5.	Calibration of temperature dependent equipment (Refrigerator, freezer, incubator, water bath, room temperature monitoring device etc.)				
5.5.6.	Calibration of centrifuges, weighing balance, pipette, validation of biological safety cabinet.				
5.5.7.	Change of HEPA filter annually and fume hood validation.				
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.	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.				
5.11.	The Clinical Laboratory license shall be visibly posted at the reception of the health facility.				

6	**STANDARD TWO: HEALTH FACILITY REQUIREMENTS**				
6.4.	The health facility should install and operate equipment required for provision of the proposed services in accordance to the manufacturer's specifications and should be validated for it's intended use prior to using it in the service.				
6.7.	The health facility design shall provide assurance of patients and staff safety.				
7	**STANDARD THREE: HEALTHCARE PROFESSIONALS REQUIREMENTS**				
7.1.	All healthcare professionals in the DHA licensed health facility 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.				
7.6.1.	The Medical/Laboratory Director in an independent clinical laboratory or laboratory in hospital setup shall be a full time DHA licensed Pathologist (Clinical Pathologist or Anatomic Pathologist).				
7.6.2.	In case of a specialized laboratory, a licensed Clinical Laboratory Scientist (CLS) with doctoral degree in the specialized field and appropriate relevant training and experience may serve as the Laboratory Director.				
7.6.3.	Laboratory Director of a general Clinical Laboratory (not in hospital setting and without histopathology/cytopathology services) may be a full time CLS holding doctoral degree with appropriate relevant training and experience.				
7.6.4.	In an Outpatient Care Facility, a full time/part time pathologist may be the designated laboratory director.				

8	**STANDARD FOUR: MANAGEMENT RESPONSIBILITIES**				
8.1.5.	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.				
8.1.17.	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 THE CLINICAL LABORATORY OPERATIONS**				
9.1.1.	Requisition form				
b.	Should contain the patient's identity, age, sex, location, name of physician, last menstrual period, date of specimen collection, source of specimen when appropriate and the investigations requested. The referring physician should be encouraged to mention the provisional or working diagnosis and relevant clinical and treatment history in the space provided.				
9.1.3.	Specimen collection				
b.	It can be done at the patient's bedside or in the laboratory phlebotomy room/specimen collection facilities depending on the type of specimen required for the test.				
e.	Physicians, nurses or medical laboratory technologist can collect specimens who are regularly trained, to ensure their competency.				
g.	Clinical Laboratory may have a "Primary Specimen Collection Manual", containing information on patient preparation before specimen collection (if any), and exact methodology of specimen collection (type of collection container and amount of specimen to be collected, Phlebotomy order of draw and instructions for fill volume				

	and proper mixing) labelling, handling, transportation and storage of the specimens. This manual shall be available for reference and should be used for training of staff engaged in specimen collection. The laboratory shall provide adequate and appropriate information/instructions to patients wherever necessary.				
h.	Specimens shall be secured appropriately to prevent leakage, spillage or contamination. They must be transported in biohazard bags and sent to the laboratory along with the completed laboratory requisition form (in the absence of electronic data transfer).				
i.	A biohazard symbol shall be used on the specimen transportation containers during transportation.				
j.	Appropriate specimen transportation kit (such as use of dry ice, ice packs, etc.) shall be used wherever required.				
k.	Clinical laboratories shall have clear criteria for rejection of samples such as haemolysed or lipemic samples.				
9.1.4.	Accession List				
a.	Record of all the specimens received by the laboratory for analysis shall be prepared by the laboratory at the time of specimen receipt.				
b.	The accession list must record the patient's identity including name, age, sex, location in the hospital/health facility, name of referring physician, investigations requested, date and time of receipt of specimen and condition of the specimen at receipt.				
c.	Assigns a unique number to register each specimen received, which can be used to trace the specimen. The test results and remarks if any shall also be entered in the accession list.				
9.1.5.	Reporting test results				

a.	Test results approved and signed by the designated DHA licensed clinical laboratory staff shall be made available to authorized person(s).				
c.	For quantitative test, laboratory shall not report any numeric result outside the Analytical Measurement Range of the analyser, unless the sample is processed by dilution, a mixing procedure or concentration.				
9.1.6.	Ethical considerations				
d.	Healthcare Professionals working in the Clinical Laboratory shall not use expired reagents/kits/specimen collection supplies. The laboratory shall validate or verify assay performance of new tests, methods, or instruments prior to patient testing. Evidence of documented validation must be readily available for any inspection.				
9.1.7.	Outsourcing Clinical Laboratory Services				
a.	The outsourced laboratory shall:				
I.	Be accredited as per the DHA Clinical Laboratory Accreditation Policy.				
II.	Have a primary sample collection and handling manual, which may be electronic.				
V.	Clinical Laboratory test shall be performed only upon a request from a DHA licensed Physician and sent along with the specimen to the testing Clinical laboratory.				
VI.	Clinical laboratories shall refrain from promoting or marketing laboratory tests aiming to attract patients directly to visit the laboratory without consulting or referring from the DHA licensed treating Physician.				
9.1.8.	Outsourcing Clinical Laboratory Services outside the UAE				
a.	It is prohibited to send patient's samples outside UAE, unless the following conditions are met:				
I.	Unavailability of the requested medical test within the				

	laboratory services in the UAE.				
II.	Report from a consultant physician in case of rare tumor whose specialization does not exist in the UAE.				
III.	Sending samples should be through a laboratory or health facility licensed by the DHA.				
IV.	Clinical laboratories receiving the sample outside the country should be accredited; in accordance with the DHA Clinical Laboratory Accreditation Policy.				
9.2.1.	General Safety Considerations				
III.	Eyewash facility shall be available as "stand-alone" facility or attached to sink or portable. Sealed single use solution bottles may also be used. At locations where, hazardous chemicals are handled by employees, emergency eyewash and shower equipment shall be available no greater than ten (10) seconds travel distance from areas in the laboratory where hazardous chemicals are present with unobstructed pathway. The door must be open in the direction toward the eyewash/ shower station.				
IV.	Laboratories shall ensure proper preservation and security of specimens.				
VI.	Periodic checking of all safety equipment and accessories shall be ensured.				
IX.	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.				
X.	The laboratory shall restrict the access to testing area; for authorized personnel only.				
9.2.2.	Biohazard Materials				
a.	An updated list of hazardous materials used in the				

	laboratory shall be maintained. All hazardous materials shall be accounted for on a continuous basis.				
b.	Biohazard symbol shall be used on all containers containing biohazard materials while being transported to the laboratory or disposed of.				
f.	All anatomic pathology wastes are placed in a biohazard waste container for incineration.				
g.	Biohazard spill kits and chemical spill kits must be available in the Laboratory.				
9.2.3.	Chemical Safety				
b.	Chemical Safety Data Sheet (SDS) shall be available and accessible to all staff.				
c.	Containers of hazardous chemicals shall have precautionary labels indicating type of hazard.				
d.	The laboratory shall limit the storage of flammable and combustible chemicals as per the amount required and shall store these chemicals inside flammable storage cabinet.				
9.2.4.	Handling Sharps				
a.	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 using re-sheathing instruments or self-sheathing needles or retractable needles with locking system to prevent recapping of needles by hand. The laboratory shall have procedures to follow after a sharp injury; that includes needlestick injuries.				
b.	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.				
c.	Sharps containers must not be overfilled. When a sharps container becomes two-thirds full, seal and discard it into a red-bagged biohazard waste container or into a red bag for incineration.				
9.2.5.	Fire Safety				
g.	Train staff to respond to fire events on the premises.				
9.3.	Health Records				
9.3.3.	Laboratories sending reports electronically should include electronic signature of the authorized signatory. Laboratories should be able to provide critical information required by a physician on telephone.				
9.3.5.	Equipment maintenance reports must be kept for future reference.				
9.3.6.	Patient Result Records and materials shall be retained aligned to the DHA Guidelines for Managing Health Records.				
10	**STANDARD SIX: MOBILE LABORATORIES**				
10.2.1.	The mobile laboratory should be accredited as per the Clinical Laboratory Accreditation Policy.				
10.2.5.	The scope of services provided by the mobile laboratory should be elaborated and documented and the mobile laboratory should not provide any service that is out of its scope (e.g. a Mobile laboratory licensed to provide phlebotomy services, shall only provide that service).				
10.2.6.	There should be a dedicated space to park the vehicle to ensure the temperature requirement in the vehicle is maintained, as required.				

10.2.8.	Approved vendors shall maintain all the equipment and the maintenance performed shall be documented.				
10.2.9.	Equipment that is very sensitive to movement and fluctuation in temperature shall not be used in a mobile laboratory.				
10.2.11.	All healthcare professionals should be employed as per the service provided and should maintain a valid training/certification in basic CPR, or BLS or ACLS.				
11	**STANDARD SEVEN: BLOOD BANK AND TRANSFUSION SERVICES**				
11.1.	The Laboratory Director of the blood bank and/or transfusion services shall ensure storage of blood and blood components are at appropriate recommended temperatures, with continuous monitoring and recording of temperature-controlled spaces with an alarm system.				
12	**STANDARD EIGHT: CYTOGENETIC TESTING SERVICES**				
12.1.	Genetic testing shall only be requested by a DHA licensed Physician with enough clinical justification, after patient consultation, in a DHA licensed Health facility.				
12.3.	A Consultant/Specialist Physician shall be consulted before and after genetic testing.				
12.5.	Only the referring/treating Physician shall make recommendations or prescribe to the patient any medication or healthcare products, based on the laboratory results.				
12.9.	The Cytogenetic laboratory records and results shall accurately reflect all stages of the process and all results obtained.				
12.10.	The Cytogenetic laboratory records shall include the following:				
12.10.1.	Media used				
12.10.2.	Reactions observed				

12.10.3.	Number of cells counted				
12.10.4.	Number of cells karyotyped				
12.10.5.	Number of chromosomes counted for each metaphase spread				
12.10.6.	Quality of the banding.				
12.11.	The resolution should be appropriate for the type of tissue or specimen and the type of study required, based on the clinical information provided to the laboratory.				
12.12.	An adequate number of karyotypes should be prepared for each patient.				
12.13.	The Cytogenetic laboratory shall permanently retain slides, negatives, prints, or magnetic media for all abnormal cases.				
12.14.	The Cytogenetic laboratory report should include the following:				
12.14.1.	Use of appropriate nomenclature				
12.14.2.	Summary of the observations				
12.14.3.	Number of cells counted and analysed				
12.14.4.	Documentation of any preliminary report, such as a verbal or telephone report				
12.14.5.	All required clinical information.				
12.14.6.	For in situ hybridization (ISH) tests that provide independent predictive information, the patient report shall include information on specimen processing, the probe, and the scoring method used.				
12.17.	The Cytogenetic laboratory shall notify Physicians wishing to order a cytogenetic test that an informed consent is required and shall make available to the practitioner test-specific information for patient use in decision-making and the informed consent process shall be aligned with				

	the DHA Guidelines for Patient Consent.				
12.18.	Quality control data shall be reviewed and assessed once a month by the laboratory director or designee.				
13	**STANDARD NINE: MOLECULAR TESTING SERVICES**				
13.2.	Validation studies shall include representatives from each specimen type expected those that are to be tested in the assay and specimens representing the scope of reportable results.				
13.3.	Molecular testing reports shall include specific testing information including the following information:				
13.3.1.	Testing methodology				
13.3.2.	Limitations of the method				
13.3.3.	Interpretation of findings				
13.3.4.	Recommendations for additional testing.				
14	**STANDARD TEN: MOLECULAR GENETIC SERVICES**				
14.1.	Molecular Genetic testing shall only be carried out against a DHA licensed Physician's order.				
14.2.	All tests carried out should be FDA approved or equivalent.				
14.5.	Molecular genetic testing reports shall include the following information:				
14.5.1.	List of mutant genes for alleles tested.				
14.5.2.	Any recommendations for referral to a genetic counsellor.				
14.5.3.	Detection rate of the test.				
14.5.4.	Use of standard nomenclature for genes and mutations.				
14.5.5.	Clinical implications of mutations detected.				
14.6.	The laboratory should consider three categories of test performance in the evaluation process:				
14.6.1.	Analytic validity				

14.6.2.	Clinical validity				
14.6.3.	Clinical utility.				
15	**STANDARD ELEVEN: CYTOPATHOLOGY SERVICES**				
15.2.	Each individual evaluating cytology preparations by manual microscopic technique shall examine no more than hundred (100) slides (gynaecologic and non-gynaecological or both) in a day.				
15.3.	For the laboratory that perform immunochemical tests that provide predictive information that are independent of diagnosis or other cytopathologic findings, the patient report must include information on specimen fixation, specimen processing, antibody clone used and the scoring method used.				
15.7.	All cytopathologic reports shall be authorized by a DHA licensed pathologist.				
15.8.	The cytopathology reports shall include a concise descriptive diagnosis in a standard descriptive terminology that includes a general categorization and descriptive diagnosis.				
15.9.	The laboratory shall promptly notify the responsible clinician(s) when there are changes in the reports that significantly affect patient care.				
15.10.	Cytology slides and blocks are properly stored in a temperature controlled, pest-free, organized manner to prevent contamination from blood or other fluids or tissue and be readily accessible for retrieval.				
16	**STANDARD TWELVE: HISTOPATHOLOGY SERVICES**				
16.1.	All macroscopic tissue gross examinations are performed by a DHA licensed pathologist or by qualified competent laboratory DHA licensed healthcare professional under the supervision of a qualified pathologist.				

16.3.	All histopathology results shall be reviewed and authorized by a DHA licenced pathologist.				
16.5.	The laboratory shall promptly notify the responsible clinician(s) when there are changes to reports such as that significantly affect patient care.				
16.6.	The laboratory shall correlate the results of specialized studies with the morphologic diagnosis.				
16.7.	Slides and blocks shall be stored properly in a temperature-controlled, pest-free, organized manner to prevent contamination from blood or other fluids or tissues and be readily accessible for retrieval.				
16.10.	When frozen section and final diagnosis results are discrepant, there is a review of findings, and the discrepancy is resolved and shall record this in the final report.				
17	**STANDARD THIRTEEN: DRIVE THROUGH PHELBOTOMY**				
17.1.	The drive through Phlebotomy services shall be provided in an area within the premise of a DHA licensed Health facility.				
17.2.	The drive through Phlebotomy services shall be provided only by DHA licensed healthcare professionals (Registered Nurses or Phlebotomists)				
17.3.	Testing shall be initiated only upon physician's order and the result should be sent back to the treating physician. A copy of the results could be shared with the patient.				
17.4.	All staff shall maintain a current Basic Life Support (BLS) certification.				
17.5.	The drive through phlebotomy facility shall maintain accessibly available life support items and an Automated External Defibrillator (AED) for immediate and safe provision of care, if required. Mock drill should be				

	conducted accordingly.				
17.7.	Tests that requires special phlebotomy procedure such as blood culture tests and which requires a sterile technique, shall not be performed at these facilities.				
17.9.	The drive through phlebotomy facility shall also have a registration area before or at the entrance and a dedicated storage area for the proper storage of the specimens.				
17.10.	Curtains with 60% visibility could be positioned to divide the lane into 2 compartments at entry, in the middle and at the exit.				
17.11.	There shall be availability of an adjustable table to be inserted through the door of the car, in order for the patient to rest the arm.				
17.12.	Ensure provision of a blood collection chair for patients from who blood cannot be collected while sitting in the car.				
17.13.	Ensure availability of shaded parking spaces dedicated as resting areas after the blood collection.				
17.15.	Patients privacy should be ensured, especially for female patients.				
17.16.	Infants and children below the age of seven (7) years shall not tested at a drive through Phlebotomy.				