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**				
6.2.	All DHA licenced Clinical Laboratories shall obtain accreditation as per the DHA Clinical Laboratory Accreditation Policy.				
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 directly dealing with patient should maintain a valid training/certification of one (1) or more of the following:				
7.4.1	Basic Cardiopulmonary Resuscitation (CPR)				
7.4.2	Basic Life Support (BLS)				
7.4.3	Advanced Cardiac Life Support (ACLS)				
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) or a licensed holder of a doctoral degree in chemistry, physical, biological, or clinical laboratory science from accredited institution				
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.	In an Outpatient Care Facility, a full time/part time pathologist may be the designated laboratory director.				
7.6.4.	To ensure safe and high-quality care is upheld within DHA licensed facilities the Medical Director/laboratory director shall abide by the DHA Policy for Role and Responsibilities of Medical 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.				
8.1.6.	Maintain the recommended immunizations for health professionals working at the clinical laboratory, as per the DHA policy for Health Screening and Immunization of Healthcare Professionals.				
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.				
9.1.2.	Receiving specimens from outside the country will require the licensed health facilities/clinical laboratories to obtain approval from MOHAP				

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.				
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 most responsible physician/team and shall be made available to the ordering physician.				
b.	Results shall be reported clearly, without any errors, specifying measurement procedure where appropriate and units of measurement. Test results shall also contain the following:				
i.	Reference intervals as applicable				
ii.	Patient details with identification number				
iii.	Test details				
iv.	Date and time of specimen collection				
v.	Result reporting				
vi.	Specimen source				
vii.	Name				
IX.	Referral laboratory when applicable.				
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				
i.	The clinical laboratory shall validate or verify assay performance of new tests, methods, or instruments prior to patient testing.				
ii.	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.				
V.	Notify DHA with the entire laboratory tests sent outside the UAE. Permission shall be obtained once per specific laboratory test.				
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: WALK-IN LABORATORY TESTS**				
11.1.	Licensed Clinical Laboratories may accept walk-in patients for specific laboratory tests that do not require a physician's order. Refer to the list of services permitted elaborated in **Appendix 3.**				
11.1.1.	Critical laboratory results shall be reported clearly to the patient.				
12	**STANDARD EIGHT: BLOOD BANK AND TRANSFUSION SERVICES**				
12.1.	Blood bank and Transfusion Service shall have a medical director who is a licensed physician, qualified by training, experience.				
12.2.	Blood & components storage devices shall have the capacity and design to ensure that the proper temperature is maintained, monitored for storage of blood & component. Storage devices shall have an alarm system.				
12.2.1.	The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, reach unacceptable conditions				
13	**STANDARD NINE: CYTOGENETIC TESTING SERVICES**				
13.1.	Genetic testing shall only be requested by a DHA licensed Physician with enough clinical justification, after patient consultation, in a DHA licensed Health				

	facility.				
13.3.	A Consultant/Specialist Physician shall be consulted before and after genetic testing.				
13.5.	Only the referring/treating Physician shall make recommendations or prescribe to the patient any medication or healthcare products, based on the laboratory results.				
13.9.	The Cytogenetic laboratory records and results shall accurately reflect all stages of the process and all results obtained.				
13.10.	The Cytogenetic laboratory records shall include the following:				
13.10.1.	Media used				
13.10.2.	Reactions observed				
13.10.3.	Number of cells counted				
13.10.4.	Number of cells karyotyped				
13.10.5.	Number of chromosomes counted for each metaphase spread				
13.10.6.	Quality of the banding.				
14	**STANDARD TEN: MOLECULAR TESTING SERVICES**				
14.2.	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.				
14.3.	Molecular testing reports shall include specific testing information including the following information:				
14.3.1.	Testing methodology				
14.3.2.	Limitations of the method				
14.3.3.	Interpretation of findings				
14.3.4.	Recommendations for additional testing.				

15	STANDARD ELEVEN: MOLECULAR GENETIC SERVICES				
15.1.	Molecular Genetic testing shall only be carried out against a DHA licensed Physician's order.				
15.2.	The DHA licensed health facility shall refrain from requesting or performing paternity or genealogical tests; except in the following cases:				
15.2.1.	Obtain prior official written approval from DHA.				
15.2.2.	Upon a request from the competent judicial authorities in UAE and the concerned health authorities.				
15.3.	All tests carried out should be FDA approved or equivalent.				
15.6.	Molecular genetic testing reports shall include the following information:				
15.6.1.	List of mutant genes for alleles tested.				
15.6.2.	Any recommendations for referral to a genetic counsellor.				
15.6.3.	Detection rate of the test.				
15.6.4.	Use of standard nomenclature for genes and mutations.				
15.6.5.	Clinical implications of mutations detected.				
15.7.	The laboratory should consider three categories of test performance in the evaluation process:				
15.7.1.	Analytic validity				
15.7.2.	Clinical validity				
15.7.3.	Clinical utility.				
16	STANDARD TWELVE: CYTOPATHOLOGY SERVICES				
16.2.	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.				

16.3.	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.				
16.7.	All cytopathologic reports shall be authorized by a DHA licensed pathologist.				
16.8.	The cytopathology reports shall include a concise descriptive diagnosis in a standard descriptive terminology that includes a general categorization and descriptive diagnosis.				
16.9.	The laboratory shall promptly notify the responsible clinician(s) when there are changes in the reports that significantly affect patient care.				
16.10.	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.				
17	**STANDARD THIRTEEN: HISTOPATHOLOGY SERVICES**				
17.1.	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.				
17.3.	All histopathology results shall be reviewed and authorized by a DHA licenced pathologist.				
17.5.	The laboratory shall promptly notify the responsible clinician(s) when there are changes to reports such as that significantly affect patient care.				
17.6.	The laboratory shall correlate the results of specialized studies with the morphologic diagnosis.				

17.7.	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.				
17.10.	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.				
18	**STANDARD FOURTEEN: ALCOHOL AND DRUG TESTING SERVICES**				
18.1.	Clinical Laboratories should apply for alcohol, drug and substance abuse testing through Sheryan (under amend facility license request).				
18.2.	Alcohol and Drug Testing Laboratories should acquire the following accreditations within 2 years of application:				
18.2.1.	College of American Pathologists (CAP)				
18.2.2.	ISO accreditations ISO/IEC 17025				
18.4.	Each laboratory should have the capability to perform the screening and confirmatory tests at the same laboratory site.				
18.4.1.	If confirmatory test is not done in the same clinical laboratory, then there should be a contract in place with the outsourced laboratory that clearly includes the name of laboratory and their accreditation on each tested drug/substance.				
18.5.	The testing procedure of each laboratory shall be capable of detecting drugs, drugs metabolites, adulterants, and substituted specimens.				
18.6.	The specimen should be treated as evidence and all aspects of the procedure shall be documented and available for possible court testimony.				
18.8.	The availability of MOHAP approved Evidential				

	Breath analyser is mandatory to conduct alcohol testing.				
18.8.1.	The analyser should have a distinguishing level for alcohol from acetone at the 0.02% alcohol concentration.				
18.9.	The laboratory shall have the capability of conducting blood alcohol concentration, or urine alcohol level, these tests can be used as an extra evidential method in cases of positive breath analyser test.				
18.10.	An additional approval from General Civil Aviation Authority is required to conduct Alcohol and Drug Testing for all aviation industries.				
19	**STANDARD FIFTEEN: DRIVE THROUGH LABORATORY SERVICES**				
19.2.	The drive through laboratory services shall be provided in an area within the premise of a DHA licensed Health facility.				
19.5.	The drive through laboratory services shall be provided only by DHA licensed healthcare professionals (Registered Nurses or Phlebotomists)				
19.6.	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.				
19.7.	All staff shall maintain a current Basic Life Support (BLS) certification.				
19.8.	The drive through laboratory 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				
19.10.	Tests that requires special phlebotomy procedure such as blood culture tests and which requires a				

	sterile technique, shall not be performed at these facilities.				
19.11.	These facilities shall have a tunnel for entrance of the vehicle, where appropriate temperature is maintained, a registration area, and a dedicated storage area with maximum temperatures of 24 degrees centigrade.				
19.13.	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.				
19.14.	Ensure provision of a blood collection chair for patients from who blood cannot be collected while sitting in the car.				
19.17.	Patients privacy should be ensured, especially for female patients.				
19.18.	Infants and children below the age of seven (7) years shall not tested at a drive through laboratory services.				
20	**STANDARD SIXTEEN: SAMPLE COLLECTION SITE**				
20.1.	Sample collection site shall require a separate DHA license as a Medical laboratory.				
20.4.	The collection site shall be divided into minimum sections of waiting, collection, receiving, storage and medical waste.				
20.5.	Patient privacy shall be maintained at all times.				
20.6.	There shall be a minimum of two full-time healthcare professionals in the collection site who may be a DHA licensed physician, registered nurse or phlebotomists.				
20.7.	The collection site shall obtain accreditation within two (2) years from the date of obtaining the license and upon renewal.				
APPENDIX 2:	**GUIDELINES ON QUALITY ASSURANCE**				

4	Practice of IQC includes the following:				
4.4.	For quantitative tests, laboratories should perform IQC every day by using 2 levels of QC (high and low) on tests run daily or every time the tests are run in case of infrequently run tests.				
5	The level of QC per day for Quantitative Tests:				
5.1.	The following guidelines will be useful to the laboratories in the practice of IQC using either one level or two-level QC materials:				
5.1.1.	When one level QC is used: Reject test run if following errors occur:				
a.	Value is outside 3 SD (13s)				
b.	2 consecutive values are outside 2 SD on the same side, but within 3 SD (22s)				
c.	4 consecutive value are outside 1SD on the same side, but within 2SD (41s)				
5.1.2.	When two level QC are used: Reject test run if following errors occur:				
a.	Either QC value is outside 3 SD (13s)				
b.	Both QC values are outside 2 SD on the same side, but within 3SD (22s)				
c.	Difference between the two-level QC values is >4 SD i.e. one level QC is >2 SD and other level QC is < 2 SD (R4s)				
d.	10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)				
e.	5 consecutive values of one level QC and 5 consecutive values of the other level QC are above or below the mean, but within 2 SD (10x).				
APPENDIX 3:	**PERMITTED WALK IN LABORATORY TESTS**				
A3.1.	Anatomic Pathology: All tests under this category requires Prescription				

A3.2.	Clinical Biochemistry: General Clinical Biochemistry Testing Does not require Prescription // Special Clinical Biochemistry testing such as body fluids samples other than blood, especial enzymes and iso enzymes require Prescription				
A3.3.	Therapeutic Drug Monitoring: All tests under this category requires Prescription				
A3.4.	Drug Abuse Monitoring: All tests under this category requires Prescription				
A3.5.	Haematology: General haematology testing Does not require Prescription// Special haematology testing such as Malaria film, Bone marrow smear and biopsy require Prescription				
A3.6.	Coagulation: General Coagulation testing Does not require Prescription// Special Coagulation testing such as Factor testing, protein C, Protein S and Lupus Anticoagulant require Prescription				
A3.7.	Microbiology: General Microbiology and culture Do not require Prescription// Special Microbiology testing such as blood cultures, tissue sample cultures, CSF cultures and cultures which requires special sample to be collected require Prescription				
A3.8.	Immunology and endocrinology: General immunology and endocrinology Do not require Prescription// Special immunology and endocrinology testing such as hormonal suppression and challenging tests require Prescription				
A3.9.	Infectious disease: Permitted walk in laboratory tests: Infectious disease screening on condition that laboratory must comply with patients consent and notification of positive cases for authorities				
A3.10.	Blood bank and Transfusion: Permitted walk in				

	laboratory tests: Only blood grouping for screening purposes and not for blood transfusion// All other tests under this category requires Prescription				
A3.11.	Histocompatibility (HLA lab): All tests under this category requires Prescription				
A3.12.	Molecular biology: All screening molecular biology testing such as Respiratory, GIT, STDs panels, and HPV screening Do not require Prescription// All other tests under this category requires prescription				
A3.13.	Genetics: All tests under this category requires Prescription				
A3.14.	Forensic pathology: All tests under this category requires prescription				