Clinical Laboratory Inspection Checklist- Final

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5	**STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES**				
5.4.	The health facility should develop the following policies and procedure; but not limited to:				
5.4.1.	Patient education and Informed consent				
5.4.2.	Patient health record				
5.4.3.	Infection control measures and hazardous waste management				
5.4.4.	Incident reporting				
5.4.5.	Patient privacy				
5.4.6.	Emergency action plan				
5.4.7.	Patient discharge/transfer.				
5.4.8.	The laboratory shall have quality assurance policies for all services such as haematology, transfusion medicine, clinical chemistry, coagulation, immunology, microbiology and clinical microscopy etc.				
5.6.	The health facility shall develop and maintain easily accessible, detailed Standards Operating Procedures (SOPs) in an easy language, to be referred to as a laboratory benchmark work manual, to cover both analytical and operational procedures according to the scope of services described in the functional program of the Clinical Laboratory, which could include the following, but not limited to:				
5.6.1.	Professional expertise required to perform the tests				

5.6.2.	Staff appointment, training, evaluation.				
5.6.3.	List of tests performed in the clinical laboratory.				
5.6.4.	Maintenance of laboratory conditions including workspace, lighting, ventilation, temperature regulation, noise control, designated eating and smoking area.				
5.6.6.	Cleaning, sterilization and disinfecting procedures.				
5.6.7.	Equipment care, operation, calibration, validation and maintenance.				
5.6.8.	Data Management				
5.6.10.	Reference ranges and Turn Around Time (TAT)				
5.6.11.	Precautions & safety measures including treatment if required and appropriate vaccination of staff				
5.6.12.	Handling and disposal of waste, including bio-waste				
5.6.13.	Internal quality control procedures, including procedure for reporting abnormal test results and corrective action procedure for quality control outliers				
5.6.14.	Internal audit procedures.				
5.6.15.	Participation in external quality assessment programs.				
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.				
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.				
9	**STANDARD FIVE: MANAGEMENT OF THE CLINICAL LABORATORY OPERATIONS**				
9.1.3.	Specimen collection				
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.				
i.	This manual shall be available for reference and should be used for training of staff engaged in specimen collection.				
ii.	The laboratory shall provide adequate and appropriate information/instructions to patients wherever necessary.				
l.	The laboratory shall have procedures to care for patients who experience adverse reactions from phlebotomy such as hematomas, abrasions, nausea, fainting. Vomiting, nerve damage, seizures and injuries.				
9.1.5.	Reporting test results				
e.	The laboratory shall have a policy for identifying and reporting critical results.				
f.	The laboratory shall ensure that the expected Turn Around Time for each test is well defined in their internal policy.				
g.	The laboratory shall have a mechanism for correcting				

	erroneous result in a manner that identifies the corrected result as revised and the date and time of correction. Both the original and corrected reports must be maintained and retrievable by the laboratory.				
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.				
X.	The laboratory shall restrict the access to testing area; for authorized personnel only.				
9.2.2.	Biohazard Materials				
i.	Policies for Tb exposure control if the laboratory is processing the test for mycobacteriology.				
k.	As part of an institution-wide plan to prepare and respond to a bioterrorism event, the microbiology laboratory must have policies and procedures for the recognition of isolates that may be used as agents of bioterrorism.				
9.2.3.	Chemical Safety				
a.	The clinical laboratory shall have policies to ensure the safety of chemicals used in the laboratory that includes information concerning labelling, handling, hazard evaluation, safe storage and safe disposal of chemicals.				
e.	The laboratory shall have policy on formalin and xylene safety regarding frequency of monitoring, action limits,				

	and criteria for discontinuation of monitoring and documented records of monitoring shall be available.				
9.2.5.	Fire Safety				
b.	Establish a fire safety plan for early detection, confining, extinguishment, rescue and alerting the DCD.				
d.	Establish a No Smoking policy				
9.3.	Health Records				
9.3.7.	An internal policy must be available concerning the time keeping of the patient laboratory reports as either hard copy or soft copy according to the clinical laboratory's internal policies. For further information regarding retention of patient result, records and materials refer to DHA Policy for Health Information Assets Management.				
10	**STANDARD SIX: MOBILE LABORATORIES**				
10.1.	A mobile laboratory is a portable, enclosed structure on a vehicle, designed and equipped with the necessary and appropriate accommodations and environmental conditions for the transportation and use of laboratory equipment to carry out analyses in the field.				
10.2.4.	The mobile laboratory shall have effective and effective storage, testing and documentation solutions.				
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.				
12	**STANDARD EIGHT: BLOOD BANK AND TRANSFUSION SERVICES**				
12.3.	The Laboratory Director of the blood bank and/or transfusion services shall ensure updated policies and procedures are available to guide acceptable practices in the blood bank and/or health facility providing transfusion services, could include (if applicable), but not restricted to the following:				
12.3.1.	Accuracy of ABO and Rh Reagents				

12.3.2.	Selecting Blood and Components for Transfusion				
12.3.3.	Blood Issuance				
12.3.4.	Quarantine and discard of blood units				
12.3.5.	Transportation and storage of blood				
12.3.6.	Reporting, Investigating and Evaluation of suspected Transfusion Reaction.				
12.3.7.	Transportation and storage of blood				
12.3.8.	Handling of Life-threatening Situation to expedite testing or abbreviated testing such as in massive transfusion				
12.3.9.	All hospitals with blood transfusion services shall have a policy and procedure protocol for managing massive transfusion.				
14	**STANDARD TEN: MOLECULAR TESTING SERVICES**				
14.1.	The laboratory shall develop and maintain written policies and procedures for molecular testing as follows:				
14.1.1.	Appropriateness of testing (Note: For genetic testing, additional information might be required to select appropriate tests and to ensure accurate test interpretation and reporting of results).				
14.1.2.	Prevention of nucleic acid contamination (including in work areas, equipment, personal protective equipment, and reagents) during specimen preparation and testing and monitoring the presence of false positive results (e.g., due to nucleic acid contamination).				
14.1.3.	Documentation of all nucleic acid reagents, including probes and primers, used in a particular test.				
14.1.4.	Quality and quantity of nucleic acid needed for a particular test.				
14.1.5.	Investigation and corrective action taken for internal controls that fail to amplify.				
14.1.6.	Competition between target and internal controls (for				

	example, false negatives or presence of a target signal is strong, with a negative internal control signal).				
14.1.7.	Investigation of discrepant results between different methods.				
14.1.8.	Reuse of patient specimens for quality control purposes.				
15	**STANDARD ELEVEN: MOLECULAR GENETIC SERVICES**				
15.4.	The laboratory shall develop and maintain policies and procedures that address recommending referral for genetic counselling.				
15.5.	The laboratory shall have policies for molecular genetic testing that includes purification or isolation of nucleic acids, measuring the quantity and quality of nucleic acid, running of quality control, Nucleic Acid Amplification and interpretation of result.				
16	**STANDARD TWELVE: CYTOPATHOLOGY SERVICES**				
16.1.	The laboratory shall have procedures to prevent cross contamination of specimens between gynaecologic and non-gynaecologic specimens and non-gynaecologic cases that have high potential for cross-contamination from other nongynecological specimens during processing and staining.				
16.4.	The laboratory shall have a policy for correlation of the results of specialized studies (e.g., molecular studies, immunocytochemistry) with the cytologic diagnosis for non- gynaecologic cytopathology cases.				
16.5.	The laboratory shall have a policy on communication of significant and unexpected cytopathology findings and notification of significant amendments to patient reports. The laboratory shall have documented records of the same.				
17	**STANDARD THIRTEEN: HISTOPATHOLOGY SERVICES**				
17.2.	The laboratory shall have a policy that includes the				

	proper dissection, description and histologic sampling of various specimen types and to prevent cross-contamination of specimens during grossing.				
17.4.	The laboratory shall have a policy regarding the communication of significant and unexpected surgical pathology findings and notification of significant amendments to patient reports. The laboratory shall have documented records of the same.				
17.8.	The laboratory shall have a policy to prevent cross-contamination during the various phases of tissue handling such as processing, embedding, microtomy, staining and slide preparation.				
18	**STANDARD FOURTEEN: ALCOHOL AND DRUG TESTING SERVICES**				
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				
18.3.	Each lab should have procedure manual copies of all procedures and dates on which they are in effect should be maintained as part of the manual, which includes but not limited to:				
18.3.1.	Criteria of the collection site.				
18.3.2.	Chain of custody form.				
18.3.3.	Confidentiality of the Individual.				
18.3.4.	The principles of each test, preparation of reagents, standards and controls, calibration procedures, sensitivity of the method used for testing and cut-off values.				
18.3.5.	Mechanism of reporting results.				
18.3.6.	Criteria for unacceptable specimens and results.				
18.3.7.	Corrective actions to be taken when the test system is				

	outside of acceptable limits				
18.3.8.	Sampling method on direct observation.				
18.3.9.	Procedure of splitting sample and procedure of transportation of the samples.				
18.3.10.	Drug Screening Records (where, custodian, how long it is kept)				
19	**STANDARD FIFTEEN: DRIVE THROUGH LABORATORY SERVICES**				
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				
19.9.	The drive through laboratory facility shall maintain an Emergency Readiness Policy and Procedure to address any unforeseen emergencies.				
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.				
19.12.	Curtains with 60% visibility could be positioned to divide the lane into 2 compartments at entry, in the middle and at the exit.				
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.				
19.15.	Ensure availability of shaded parking spaces dedicated as resting areas after the blood collection.				
20	**STANDARD SIXTEEN: SAMPLE COLLECTION SITE**				

20.4.	The collection site shall be divided into minimum sections of waiting, collection, receiving, storage and medical waste.				
20.7.	The collection site shall obtain accreditation within two (2) years from the date of obtaining the license and upon renewal.				