Clinical Laboratory Inspection Checklist - Random

Name of the Clinical Laboratory: _____

Date of Inspection:____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
12	**Reception and Waiting Area**				
12.1	A reception/information counter or desk shall be available (optional in the outpatient facilities)				
12.3	Toilet(s) for public use and for giving samples shall be Conveniently accessible from the waiting area ensuring patient privacy. A hand-washing station shall be provided in the toilet room.				
12.4	Access to laboratory areas should be strictly limited to laboratory personnel.				
13	**Phlebotomy room/Specimen Collection Area**				
13.1	Phlebotomy room has the following: - work counter -hand-washing station				
13.3	Room shall be furnished with reclining chair				
13.2	Phlebotomy room location, design and door swings should be oriented to provide patient privacy				
15	**Laboratory Work/Testing area**				
15.2	Laboratory work area shall have appropriate facilities for storage and refrigeration of blood, urine, and other specimens				
15.6	Food items or cosmetics must not be stored in testing areas.				
15.8	Each laboratory must contain a sink for hand washing. Taps for hand washing should be elbow operated/foot operated/sensor operated				

15.9	Laboratory sinks shall have lips that protect sink drains from spills.				
16.2.4	Eye washing station shall be accessible within a maximum distance of 30.48 meters from the work area.				
17	**Chemical/Waste Storage**				
17.1	Sufficient space or facilities (e.g., storage cabinets with partitions) shall be provided so that chemicals and reagents can be physically separated and stored				
17.2	Chemical storage shelves shall not be placed above laboratory sinks.				
18	**Flooring**				
18.6	Slip-resistant flooring products shall be considered for flooring surfaces in wet areas such as the toilets and the work areas in the laboratory in addition to areas that include water for patient services				
18.7	Carpet cannot be used in phlebotomy rooms and Working areas. However, if used in patient waiting areas and corridors carpet shall be glued or stretched tight and free of loose edges or wrinkles				
20	**Lighting**				
20.1	Laboratory areas shall be provided adequate natural or artificial illumination to ensure sufficient visibility for operational safety				
20.2	Windows must be well sealed and provided with blinds.				
21	**Cleanability**				
21.1	Lab is easily cleaned. Bench tops must be a seamless One-piece design to prevent contamination. Laminate bench tops are not suitable				
21.3	Wooden and wood finish walls or floors and carpets are not appropriate because they can absorb hazardous and/or potentially infectious material				
21.4	Spaces between benches, cabinets, & equipment must be accessible for cleaning & allow for servicing of equipment				
22	**Autoclave and Sterilization Area**				
22.1	A method for decontaminating all laboratory wastes should be available in the facility.				
23	**Filing Cabinets and Storage**				
23.2	Filing cabinets and storage must be in safe location and must have restricted access.				
25	**Equipment and Supply Storage**				

25.1	Dedicated waste collection and storage area.				
25.2	General storage facilities for supplies and equipment shall be provided.				
25.3	Special storage for staff personal effects with locking drawers or cabinets shall be provided.				
25.4	Storage areas for Non-clinical records, documents, and office supplies shall be provided				
26	**Fume hoods**				
26.1	Laboratory must have fume hoods if they deal with toxic or noxious hazardous fumes vapors or dust.				
31	**Requisition Form**				
31.1	Requisition form is completed by a DHA licensed physician/licensed health professional				
31.2	It should contain the patient's identity, age, location, date of specimen collection & the investigations requested				
31.3	Licensed clinical laboratories may accept walk-in patients subject to internal policies and procedures of the laboratory.				
32	**Specimen Collection**				
32.3	Trained phlebotomist is employed by the clinical lab for specimen collection				
32.4	Specimen collection can be performed also by physicians, nurses or medical laboratory technologist who must be trained periodically to ensure their competency.				
32.9	Specimens should be secured properly to prevent leakage, spillage or contamination				
32.10	A Biohazard symbol should be used on the containers during transportation				
32.11	Appropriate specimen transportation kit (such as use of dry ice, ice packs, etc.) is used wherever required				
32.12	Clinical laboratories have clear criteria for rejection of samples such as hemolyzed, lipemic, leaked …etc, samples				
34	**Reporting Test Results**				
34.1	Test results approved & signed by the designated DHA licensed lab staff				
34.2	Results should be reported clearly, without any errors, specifying measurement procedure where appropriate & units of measurement & reference normal ranges				

36	**Outsourcing Clinical Laboratory Services**				
36.1	If Clinical Laboratory services are outsourced to another Clinical Laboratory facility (Reference Laboratory), it shall meet the outsourcing requirements				
36.2.1	The Reference laboratory must be accredited by a recognized agency				
36.2.3	Reference laboratory must have good facilities for the sample transport from the laboratory and fast turn-around time for the test.				
37	**General Safety Considerations**				
37.1	Documentation of Laboratory Safety Policies and Procedures				
37.2	All laboratory personnel should be aware about the laboratory safety policies				
20.6	Chemical safety provisions. These shall include emergency shower, eye-flushing devices, and appropriate storage for flammable liquids, etc				
37.3	Eye wash facility should be available as "stand-alone" facility or attached to sink or portable. Sealed single use solution bottles may also be used.				
37.6	Periodic checking of all safety equipment and accessories should be ensured.				
37.8	Laboratory personnel should follow safe hygienic practices which include hand washing, wearing protective clothing, gloves, eye protection… etc				
37.9	Mouth pipetting is strictly prohibited. A rubber bulb, automatic pipette or, or other safety device must be used for all pipetting.				
38	**Biohazard Materials**				
38.1	List of hazardous materials used in the laboratory should be prepared				
38.2	Biohazard symbol should be used on all containers containing biohazard materials				
38.3	Destruction/disposal of hazardous material should be Authorized, supervised and handled according to standard procedures.				
38.4	Solid biohazard waste disposal must be done through contracted DM approved companies.				

38.7	Biohazard spill kits and chemical spill kits must be available in the laboratory				
38.8	Accident/incident/injuries record of laboratory personnel should be maintained and reported to the designated authority.				
39	**Handling Sharps**				
39.2	-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				
39.3	Sharps containers must not be overfilled				
40	**Fire Safety**				
40.1	Establish a fire safety plan				
40.3	Establish a No Smoking policy				
40.5	Maintain and test fire protection and emergency communication systems.				
40.6	Train staff to respond to fire events on the premises ensuring documentation of all such activities including lessons learnt				
41	**Laboratory Reports & Data Management**				
41.2	Format of recording & reporting results should be described in the Standard Operating Procedures (SOPs)				
41.3	Laboratories sending reports electronically should include electronic signature of the authorized signatory				
41.4	Laboratories should have a policy outlining how to provide critical information required by a physician on telephone such as the reporting of panic values				
41.6	Laboratory Information System (LIS) alerts the technologist to all defined panic value results				
41.8	Provisions are made for securing Electronic lab reports				
41.9	Equipment maintenance reports must be kept for future reference				
42	**Retention of Patient Result Records and Specimens**				

42.2	An internal policy must be available concerning the retention of the patient laboratory reports and specimens either as hard copy or soft copy according to the clinical laboratory's internal policies.				
43	**Medical Director**				
43.1	The Medical director in an independent Clinical Laboratory or laboratory in hospital setup shall be a full time DHA licensed pathologist				
43.2	In case of a specialized laboratory a Clinical Laboratory Scientist (CLS) with Doctoral degree (in the specialized field) and appropriate training and experience may serve as the Laboratory Director for e.g. a genetics laboratory may be run by a CLS with Doctoral degree in genetics				
43.3	Medical director of a general clinical laboratory (not in hospital setting and without histopathology /cytopathology services) may be a full time Clinical Laboratory Scientist (general) holding Doctoral degree with appropriate training and experience				
43.4	In an Outpatient Care Facility the clinical laboratory may be run by a full time/part time pathologist.				
3.3.5	**Provide a documented policy and procedure for the following**				
3.3.5.1	Hazardous waste management				
3.3.5.2	Laboratory reports management.				
30	**Bio-safety in Microbiological and Biomedical Laboratories**				
30.1.1	**Bio-safety Level 1 (BSL-1)**				
30.1.2	**Bio-safety Level 2 (BSL-2)**, Primary containment barriers, include				
30.1.2.1	Biological safety cabinets, safety centrifuge cups, etc.,				
30.1.2.2	Hand washing sinks.				
30.1.2.3	Autoclaves or other waste decontamination equipment.				
30.1.3.1	Doors for access control (lockable door if housing restricted agents)				
30.1.3.3	Bench tops impervious to water and resistant to moderate heat and organic				
30.1.3.7	Eyewash station readily available				

30.1.3.8	Autoclave available in the facility				
30.1.3.9	No fabrics or carpeting; and new facilities with inward airflow (negative pressurization) without recirculation of air outside the laboratory (100% outside exhaust).				
30.1.4	**Bio-safety Level 3 (BSL-3)**				
30.1.4.1	Physical separation from access corridors				
30.1.4.2	Self-closing, double door access				
30.1.4.3	Exhausted air not re-circulated				
30.1.4.4	Entry through air lock or anteroom				
30.1.4.5	Hand washing sink near the laboratory exit				
30.1.5	**Bio-safety Level 4 (BSL-4)**				
30.1.5.1	Separate building or isolated zone				
30.1.5.2	Dedicated supply and exhaust, vacuum, and decontamination systems				

Inspectors: (Name & Signature)

1._____

2._____

3._____

4._____