



SAFETY AUDIT

DATE: 28 FEBRUARY 2021

SECTION 12: FACILITIES AND BIOSAFETY

Requirement	Y	P	N	Comments	Score
12.1 Is there documented evidence that the laboratory has evaluated the adequacy of the size and overall layout of the laboratory and organized the space so that workstations are positioned for optimal workflow?	Y yes	P	N		2
<i>ISO15189:2012 Clause 5.2.1</i>					
<i>Note: Documentation could be in the form of a floor plan, results from internal audits , etc.</i>					
12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another?	Y yes	P	N		2
<i>ISO15189:2012 Clause 5.2.1</i>					
<i>Note: Client service areas (i.e. waiting room, phlebotomy room) should be distinctly separate from the testing areas of the laboratory. Client access should not compromise "clean" areas of the laboratory. For biosafety reasons, microbiology and TB testing should be segregated in a separate room(s) from the general laboratory testing.</i>					
12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?	Y Yes	P	N		2
	Tick for each item as Yes (Y), Partial (P) or No (N)				
	Y	P	N		
a) Do the equipment placement / layout facilitate optimum workflow?	yes				
b) Are all needed supplies present and easily accessible?	Yes				
c) Are the chairs/stools at the workstations appropriate for bench height and the testing operations being performed?	yes				
<i>ISO15190 Clause 6.3.5</i>					
12.4 Is the physical work environment appropriate for testing?	Y N	P			2
	Tick for each item as Yes (Y), Partial (P) or No (N)				
	Y	P	N		
a) Free of clutter? <i>ISO 15190: 13.0</i>	Yes				
b) Adequately ventilated? <i>ISO 15190: 6.3.3</i>	Yes				
c) Adequately lit? <i>ISO 15190: 6.3.1</i>	Yes				
d) Climate-controlled for optimum equipment function? <i>ISO 15190: 6.3.2</i>	Yes				
e) Are filters checked, cleaned and/or replaced at regular intervals, where air-conditioning is installed?	Yes				
f) Are wires and cables properly located and protected from traffic?	Yes				
g) Is there a functioning back-up power supply (generator)?			No	We currently don't have a generator.	

h) Is critical equipment supported by uninterrupted power source (UPS) systems?	Yes			
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i) Is equipment placed appropriately (away from water hazards, out of traffic areas)?	Yes			
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j) Are appropriate provisions made for adequate water supply, including deionized water (DI) or distilled water, if needed?	Yes			
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k) Is clerical work completed outside the testing area?	Yes			
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l) Is major safety signage posted and enforced, including NO EATING, SMOKING, DRINKING?	Yes			
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ISO15189:2012 Clause 5.2
Note: The laboratory space should be sufficient to ensure the quality of work, safety of personnel and the ability of staff to carry out their tasks without compromising the quality of the examinations. The laboratory should be clean and well organized, free of clutter, well ventilated, adequately lit and within acceptable temperature ranges.

12.5 Laboratory Access Is the laboratory properly secured from unauthorized access with appropriate signage?	Y yes	P	N		2
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ISO15189:2012 Clause 5.2.2
Note: Access control should take into consideration safety, confidentiality, and quality.

12.6 Laboratory Storage Areas Is laboratory-dedicated cold and room temperature storage free of staff food items, and are patient samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?	Y Yes	P	N		2
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ISO15189:2012 Clause 5.2; 5.2.4
Note: there should be effective separation to prevent contamination.

12.7 Is the work area clean and free of leakage & spills, and are disinfection procedures conducted and documented?	Y yes	P	N		2
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ISO15189:2012 Clause 5.2.6
Note: The work area should be cleaned regularly. An appropriate disinfectant should be used. At a minimum, all bench tops and working surfaces should be disinfected at the beginning and end of every shift. All spills should be contained immediately and the work surfaces disinfected.

12.8 Biosafety Cabinet Where a Biosafety cabinet is required to perform work, is it certified and appropriate?	Y	P	N No	No biosafety cabinet in the laboratory.	2
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ISO 15189:2012 Clause 5.2.1; 5.2.2
Note: A biosafety cabinet should be used to prevent aerosol exposure to contagious specimens or organisms. For proper functioning and full protection, biosafety cabinets require periodic maintenance and should be serviced accordingly. Biosafety cabinet should be recertified according to national protocol or manufacturer requirements.

12.9 Laboratory Safety Manual Is a laboratory safety manual available, accessible, and up-to-date?	Y Yes	P	N		2
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Does the safety manual include guidelines on the following topics?	Yes			
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	Tick for each item as Yes(Y), Partial or No(N)		
	Y	P	N
a) Blood and body fluid precautions	Yes		
b) Hazardous waste disposal	Yes		
c) Hazardous chemicals/materials	Yes		
d) MSDS sheets	Yes		
e) Personal protective equipment	Yes		

f) Vaccination	Yes			
g) Post-exposure prophylaxis	Yes			
h) Fire safety	Yes			
i) Electrical safety	Yes			

ISO15190 Clause 7.4

Note: A safety manual should be readily available to all employees. The manual should be specific to the laboratory's needs; it must be document controlled.

12.10 Waste Disposal Is sufficient waste disposal available and adequate? Is waste separated into infectious and non-infectious waste, with infectious waste autoclaved/incinerate?	Y yes	P	N		2
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ISO15190 Clause 22

Note: Waste should be separated according to biohazard risk, with infectious and non-infectious waste disposed of in separate containers. Infectious waste should be discarded into containers that do not leak and are clearly marked with a biohazard symbol. Sharp instruments and needles should be discarded in puncture resistant containers. Both infectious waste and sharps containers should be autoclaved before being discarded to decontaminate potentially infectious material. To prevent injury from exposed waste, infectious waste should be incinerated, burnt in a pit or buried.

12.11 Hazardous Chemicals Are hazardous chemicals / materials properly handled?	Y Yes	P	N		2
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Tick for each item as Yes(Y), Partial or No(N)

Y P N

a) Are hazardous chemicals properly labelled?	Yes				
b) Are hazardous chemicals properly stored to ensure safety and prevent theft?		Partial			
c) Are hazardous chemicals properly utilized according to MSDS?	yes				
d) Are hazardous chemicals properly disposed according to national guidelines or MSDS?	yes				

ISO15190 Clause 17.1; 17.3

Note: All hazardous chemicals must be labelled with the chemical's name and with hazard markings. Flammable chemicals must be stored out of sunlight and below their flashpoint, preferably in a steel cabinet in a well-ventilated area. Flammable and corrosive agents should be separated from one another. Distinct care should always be taken when handling hazardous chemicals.

12.12 Handling of Sharps Are 'sharps' handled and disposed of properly in 'sharps' containers that are appropriately utilized?	Y Yes	P	N		2
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ISO15189:2012 Clause 5.2.3

Note: All syringes, needles, lancets or other bloodletting devices capable of transmitting infection must be used only once and discarded in puncture resistant containers that are not overfilled. Sharps containers should be clearly marked to warn handlers of the potential hazard and should be located in areas where sharps are commonly used.

12.13 Fire Safety Is fire safety included as part of the laboratory's overall safety program?	Y yes	P	n		2
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Tick for each item as Yes(Y), Partial (P) or No (N)

Y P N

a) Are all electrical cords, plugs, and receptacles used appropriately and in good repair?	Yes				
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b) Is an appropriate fire extinguisher available, properly placed, in working condition, and routinely inspected?	Yes			
c) Is an operational fire warning system in place?		Partial		
d) Are periodic fire drills conducted at defined period of time?		Partial		
ISO15190 Clause 9.3; 9.7				
<i>Note: Electrical cords and plugs, power-strips and receptacles should be maintained in good condition and utilized appropriately. Overloading should be avoided and cords should be kept out of walkway areas. An approved fire extinguisher should be easily accessible within the laboratory and be routinely inspected and documented for readiness. Fire extinguishers should be kept in their assigned place and not hidden or blocked; the pin and seal should be intact, nozzles should be free of blockage, pressure gauges should show adequate pressure, and there should be no visible signs of damage. A fire alarm should be installed in the laboratory and tested regularly for readiness; all staff should participate in periodic fire drills.</i>				

12.14 Safety Audits					
Are safety inspections or audits conducted regularly and documented?	Y	P partial	N		3
	Tick for each item as Yes (Y), Partial (P) or No (N)				
	Y	P	N		
a) Is there an audit plan/schedule that ensures all activities of the lab are checked for safety compliance?	Yes				
b) Are inspections/audits being carried out by authorized persons?	Yes				
c) Are the personnel conducting the internal audits trained in safety?	Yes			Our safety officer has been trained.	
d) Is cause analysis and action taken for nonconformities/noted deficiencies?	Yes				
e) Are safety findings documented and presented to the laboratory management and relevant staff for review?	Yes				

ISO15190 Clause 7.3.1 and 7.3.2

Note: The safety programme shall be audited and reviewed at least annually (by appropriately trained personnel).

12.15 Safety Equipment					
Is standard safety equipment available and in use in the laboratory?	Y Yes	P	N		2
	Tick for each item as Yes (Y), Partial (P) or No (N)				
	Y	P	N		
a) Biosafety cabinet(s) <i>ISO 15190: 16</i>			no	N/A	
b) Covers, safety caps, safety buckets on centrifuge(s)	YES				
c) Hand-washing station <i>ISO 15190: 12.7</i>	YES				
d) Eyewash station/bottle(s) and emergency showers where applicable <i>ISO 15190: 12.10</i>	YES				
e) Spill kit(s)	YES				

f) First aid kit(s) ISO 15190: 12.9	YES				
ISO15190 Clause 5.1 <i>Note: It is the responsibility of laboratory management to ensure that the laboratory is equipped with standard safety equipment. The list above is a partial list of necessary items. Biosafety cabinets should be in place and in use as required. All centrifuges should have covers. Hand-washing stations should be designated and equipped and eyewash stations (or an acceptable alternative method of eye cleansing) should be available and operable. Spill kits and first aid kits should be kept in a designated place and checked regularly for readiness.</i>					
12.16 Personnel Protective Equipment Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and consistently?	Y YES	P	N		2
ISO15190 Clause 12 <i>Note: Management is responsible for providing appropriate personal protective equipment (gloves, lab coats, eye protection, etc.) in useable condition. Laboratory staff must utilize PPE at all times while in the laboratory. Protective clothing should not be worn outside the laboratory. Gloves should be replaced immediately when torn or contaminated and not washed for reuse.</i>					
12.17 Staff Vaccinations Are laboratory personnel offered appropriate vaccination and employee medical surveillance?	Y YES	P	N		2
ISO15190 Clause 11.3 <i>Note: Laboratory staff should be offered appropriate vaccinations—particularly Hepatitis B. Staff may decline to receive the vaccination, but they must then sign a declination form to be held in the staff member's personnel file.</i>					
12.18 Post Exposure Prophylaxis Are post-exposure prophylaxis policies and procedures posted and implemented after possible and known	Y YES	P	N		2
exposures?					
ISO15190 Clause 9 <i>Note: The laboratory must have a procedure for follow-up of possible and known percutaneous, mucous membrane or abraded skin exposure to HIV, HBV or HCV. The procedure should include clinical and serological evaluation and appropriate prophylaxis.</i>					
12.19 Are adverse incidents or injuries from equipment, reagents, occupational injuries, medical screening or illnesses, documented and investigated?	Y YES	P	N		2
ISO15189:2012 Clause 5.3.1.6; 5.3.2.6; ISO15190 Clause 9 <i>Note: All occupational injuries or illnesses should be thoroughly investigated and documented in the safety log or occurrence log, depending on the laboratory. Corrective actions taken by the laboratory in response to an accident or injury must also be documented.</i>					
12.20 Biosafety Training Are drivers/couriers and cleaners working with the laboratory trained in Biosafety practices relevant to their job tasks?	Y YES	P	N		2
ISO15189:2012 Clause 5.1.5(d); ISO15190 Clause 5.10 <i>Note: all staff must be trained in prevention or control of the effects of adverse incidents.</i>					
12.21 Laboratory Safety Officer Is a trained safety officer designated to implement and monitor the safety program in the laboratory, including the training of other staff?	Y YES	P	N		2
ISO15190 Clause 7.10 <i>Note: A safety officer should be appointed, implement and monitor the safety program, coordinate safety training, and handle all safety issues. This officer should receive safety training.</i>					
Section 12: Facilities and Biosafety Subtotal					43

SUMMARY

Noted Commendations

Biosafety cabinet should be installed.
Generator is needed.
A JOJO tank should be installed.

Noted Challenges

RECOMMENDATIONS

See attached table of non-conformities

ACTION PLAN (if applicable)

Follow-up Actions	Responsible Person	Timeline	Signature
Installation of generator	Management	Within the 2022 financial year	
JoJo tank should be installed.	Management	30 TH of June 2021	


Health and Safety Officer