Appendix No. (44)

COVID – 19 Specimen Collection Guidelines

In addition to the general requirements of Laboratory Services that should be fulfilled in lab services provided at a medical facility or a free standing lab in Resolution No. 2 of 2019 issued by NHRA (Annex 7) please ensure the following requirements are available in any facility that is collecting Covid-19 samples.

First: General Standards

1- The facility must have an approval from the NHRA and the Ministry of Health to collect samples for Covid-19.

2- Materials needed for the sample collection: (Nasal & Throat swab):

No.	Item	Description/Details (if any)
1	Viral transport medium (VTM) #	Hi-Media
2	Polyester tipped plastic shaft swab *	Fisher Brand
		Hi-Media
3	Flocked Swab *	Hi-Media
		Copan
4	Tongue depressor	Disposable
5	Face mask	N95
6	Apron	Disposable apron
7	Gloves	Disposable Nitrile Gloves
8	Hand sanitizer	Alcohol based rub
9	Discard bag	Appropriate Biohazard Discard bag
10	Cool box	Thermocol box
11	Gel packs	To be frozen at -20oC prior use
12	Head cap	Disposable

13	Shoe Covers	Disposable
14	Safety Goggle	Reusable lab goggle
15	Brown tape	Sealing the sample box
16	Surgical spirit	Disinfect sample collection area
17	Cryo label	Sample Labelling

Ensure that health care workers who collect specimens adhere of using all above materials to infection prevention.

3 - Availability of clear policies that indicate methods of transferring samples and the established standards, whether the transport is within or outside the healthcare facility, and all employees must observe the standard infection control guidelines.

4 - Availability of clear policies for storing samples before sample transferring outside the healthcare facility and after completing the analysis in case the analysis is carried inside the healthcare facility.

5- Availability of patient consent form for sample collection.

6- Availability of a permission form including good communication with the laboratory and provide needed information Alerting the laboratory before sending specimens encourages proper and timely processing of samples and timely reporting. Specimens should be correctly labeled and accompanied by a diagnostic request.

7- existence of a system of reporting all cases in need of medical treatment, and availability of all related records, (Laboratories should follow national reporting requirements. In general, all test results, positive or negative, should be immediately reported to national).

8. Identifying all areas where samples collecting.

9 .The areas where samples collecting should be for a single purpose.

10. Area of sample collection should have adequate lighting.

11. Availability of a non-smoking sign in the sample collection areas.

12. If a laboratory is contracted to analyze the swabs, there should be a contract between the two institutions and it must be licensed by NHRA and have approval to conduct Covid – 19 testing.

13. Ensure that the screening checklist is filled completely, with the patient's' temperature measured.

14. Ensure sterilization of the room after each patient, with the availability of the availability of documented log.

15. A private toilet must be available for the patients and should be provided with the arm support rail.

16. Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or transportation is expected, store specimens at -70°C or below. If a delay occurs in extraction, store specimens at -70oC or lower. Store extracted nucleic acid at -70oC or lower. Personnel must be trained to pack and ship according to the MOH regulations.(see the table below).

17. For transport of samples for viral detection, use VTM (viral transport medium) .Avoid repeated freezing and thawing of specimens. Aside from specific collection materials indicated in the table also assure other materials and equipment are available: e.g. transport containers and specimen collection bags and packaging, coolers and cold packs or dry ice, sterile blood-drawing equipment (e.g. needles, syringes and tubes), labels and permanent markers, PPE, materials for decontamination of surfaces. (See the table below).

Specimen type	Collection materials	Transport to laboratory	Storage till testing	Comment
Nasopharyngeal and or pharyngeal swab	Dacron or polyester flocked swabs*	4 °C	≤5 days: 4 °C >5 days: -70 °C	The nasopharyngeal and or pharyngeal swabs should be placed in the same tube to increase the viral load.
Bronchoalveolar lavage	sterile container *	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	There may be some dilution of pathogen, but still a worthwhile specimen
(Endo)tracheal aspirate, nasopharyngeal aspirate or nasal wash	sterile container *	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	
Sputum	sterile container	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	Ensure the material is from the lower respiratory tract

Second: Engineering requirements:

1. The walls and floor of the room should be lined with a smooth layer that is easy to clean, and does not absorb liquids and the floor should be non-slip type.

2. All equipment in the room (a movable chair and a table for the placement of examination swabs and a set of PPE) should be arranged in a safe and spacious way without any crowding or obstructions. The room space should be sufficient to accommodate a patient with the employee- and area between (2.5*2.5) -(3*3) .

3. Provide a room for medical waste.

4. Ensure that there is a place designated for storage.

5. Sink and sanitizer is available, with the taps and sanitizers designed to be touch less or automatic without using the hands according to the standards of infection control.

6. Provide a fire extinguisher, the date of production and expiration must be displayed on the unit.

7. The doors should preferably be automatic.

Third: Professional staff

1. The Professionals (Physicians and nurses) should be trained to take the nasopharynx swab from the Ministry of Health, and be licensed by NHRA.
2. Physician: To identify the appropriate patient for COVID-19 testing ,To identify the appropriate specimen to be collected.
3. Nurses: Should have received appropriate training for sample collection from suspected COVID-19 cases, To collect appropriate samples as decided by the treating doctor, To wear proper PPE as prescribed by MOH, To strictly follow biosafety measures during collection and packing of samples and to follow the biomedical waste management guidelines for safe disposal of generated bio-waste.

COVID – 19 Specimen Analysis Guidelines

In the event that samples are analyzed by a laboratory in the health institution, in addition to the previous requirements, the following must also be followed:

First: general standards

1. Availability of refrigerators and safe places for storage according to need with a record.

2. The lab should set clear written instructions on: the correct way of collecting, handling, transferring, and preparing samples and should include the following:

- Patient identification.

- Samples collection and labeling.
- Storage and duration of storage of samples
- Sample transfer conditions.
- Method of receiving samples in the laboratory.
- Method of disposal of samples after completion of test

3. The Manager of a private lab should keep electronic or paper record to register the following data for each test that has been conducted in the lab:

- Serial number.
- Date of test.
- The patient's full name, nationality, age and personal ID number.
- Name of treating physician who has requested the test and his address.
- Type of test conducted
- Date of receiving the sample and date of sending its result to the treating physician
- Patient address
- Respiratory symptoms.

4. The laboratory provides a barcode system for the registration of samples, which includes the following:

- Name.
- Personal number.
- Date of birth.
- Nationality
- File number.
- Visit number.
- Type of test required.

5. Internal quality checks should be conducted periodically.

6. All solutions and laboratory reagents and materials used for sample testing should not have expired

7. The laboratory should pass the external quality inspection and the National quality Measurement program for the analysis of Covid 19 with NHRA and public health.

8. No eating and drinking in the laboratory.

9. Maintain passive pressure in the laboratory when dealing with Covid-19 samples .

10. Handle laboratory waste generated as a result of testing suspected or confirmed COVID-19 patient specimens by double packing into yellow bags labeled with the bio hazardous waste.

Collect sharps in puncture proof container labeled sharps and the start date. Dispose sharps after a month or if it is ¾ filled.

11. There should be clear policies and procedure for all methods of analysis and reporting that are derived from the MOH guideline.

12. Provide a safety program, and reliable guide safety for staff in the laboratory.

Second: Engineering requirements:

1. Electrical extensions are not used, and use only type G electrical plugs.

2. Have proper ventilation, temperature control and humidity monitoring, with a logbook.

3. The lab should keep all devices in a good functional condition through establishing a system of operating all the devices properly, cleaning them, and monitoring their quality and maintenance. Such system should include, but not limited to the following:

- A guideline of operation and maintenance.
- A maintenance schedule.
- Maintenance records.
- Maintenance label placed on the devices

4. The devices should be installed and distributed in accordance with the standards of the manufacturer .

5. The laboratory should automatically close and only authorized persons can enter.

6. Implement a fire safety program according to the plan followed by the facility.

7. Availability of areas for washing the eyes and body in case of emergency .

8. All doors leading to the laboratory should have clear signs that indicate caution .

In addition to Annex(7) , personnel working in laboratories should observe the following biosafety precautions

- All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.
- Initial processing (before inactivation) of all specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.
- Non-propagative diagnostic laboratory work (for example, sequencing, nucleic acid amplification test -NAAT]) should be conducted at a facility using procedures equivalent to Biosafety Level 2 (BSL-2)
- Propagative diagnostic laboratory work (for example, virus culture, isolation or neutralization assays) should be conducted at a containment laboratory with inward directional airflow (BSL-3).
- Appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, hydrogen peroxides, quaternary ammonium compounds and phenolic compounds).
- Following Standard Precautions when handling all clinical specimens
- Using automated instruments and analyzers

Third: Professional staff

The same requirements for Professional staff must be met with the laboratories services in the Resolution No. 2 of 2019 **(Annex 7)** issued by NHRA.