**GUIDANCE FOR MOLECULAR LABORATORY SET-UP FOR COVID-19 TESTING**

**Objective**

This guidance consists of important considerations for the set-up of a molecular laboratory for COVID-19 Polymerase Chain Reaction (PCR) testing in Nigeria. This guidance should be used alongside relevant laboratory training and essential day-to-day laboratory activities.

**Infrastructure**

The laboratory infrastructure consists of many important components which are essential to ensure effective functioning. These are:

1. The Laboratory Building – The building should be in an area of limited human traffic to ensure access to the laboratory is restricted. There sound be a minimum of four rooms for test processes and additional rooms for staff offices, a data room, store, donning and doffing areas and washrooms. According to the Medical Laboratory Science Council of Nigeria (MLSCN) standards, each laboratory room should be at least 5mx6m. The rooms of the test area should have a unidirectional flow that ensure room linkage without the need for zig-zag movements. Test processes should begin at one end and finish at the opposite end of the room.

MLSCN guidance documents on laboratory setup can be accessed via <http://web.mlscn.gov.ng/index.php/mlscn-approved-documents/> .

1. Power Supply – There MUST be a system in place for uninterrupted power supply. In addition to being connected to the national grid, the laboratory needs to have a power backup system of generators, solar or inverters that will ensure the laboratory is powered 24/7.
2. Water supply – There must be a 24/7 source of water supply to the laboratory, with sinks, wash areas and cleanup sections appropriately situated and positioned.
3. Laboratory Security – There should be appropriate security measures to ensure that ONLY approved personnel are able to access the rooms.
4. Biosafety - The laboratory must have essential facilities which would minimize the risk of any biological hazards. These include adequate water supply, sufficient ventilation and air filtration systems. Efficient systems for ensuring access control in and out of the laboratory MUST also be in place.
5. Waste Management – The laboratory MUST have a system of waste management for disposal of laboratory waste. An incinerator is recommended within the laboratory compound near the laboratory building. Where it is impossible to have an incinerator within the laboratory premises, arrangements should be made with appropriate medical waste disposal agencies or an incinerator in another facility nearby. It is important to note that all biological waste from the laboratory must first be incinerated before being sent to an external incinerator.

**Equipment**

**The minimum** equipment required for a laboratory include the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **S/N** | **EQUIPMENT**  | **MINIMUM UNITS REQUIRED** | **SPECIFICATION** |
| 1 | Biosafety Cabinet | 2 | 4 Feet NSF Certified SAFZONE Biosafety Cabinet, Class II Type A2 (230V/50-60Hz/7A) |
| 2 | High speed Centrifuge | 2 | Eppendorf Centrifuge 5427R (220-240V, 50-60Hz) |
| 3 | Mini Centrifuge | 2 | Eppendorf Minispin Plus (220-240V, 50-60Hz) |
| 4 | Vortex Mixer | 2 | Fisherbrand Digital Vortex Mixer (220-240V, 50-60Hz) |
| 5 | Dead Air Box | 2 | Airclean system dead air box (220-240V, 50-60Hz) |
| 6 | Heating Block | 1 | Digital high Precision heating block |
| 7 | Real time PCR Machine  | 1 | A PCR machine that is capable of amplifying at least 48 or 96 samples per run and has at least 6 dyes (CY5, HEX, JOE, FAM, TAM, JUN)  |
| 8 | Desktop | 1 | HP All in One, Windows 10, 1TB HDD, 8GB RAM, Core i7 |
| 9 | Laptop | 2 | Windows 10, 1TB HDD, 8GB RAM, Core i7 |
| 10 | Fridge-Freezer | 2 | 4 oC-18oC (220-240V, 50-60Hz) |
| 11 | Chest Freezer | 1 | (-40oC to -80oC) (220-240V, 50-60Hz) |
| 12 | Freezer (-80oC) | 1 | (-80oC) (220-240V, 50-60Hz) |
| 13 | UPS  | 3 | 5kV |
| 14 | Pipette (1-10ul) | 4 | ThermoFisher |
| 15 | Pipette (10-100ul) | 4 | ThermoFisher |
| 16 | Pipette (20-200ul) | 4 | ThermoFisher |
| 17 | Pipette (100-1000ul) | 4 | ThermoFisher |
| 18 | Autoclave | 2 | Tuttnauer , Vol 80L (220-240V, 50-60Hz) |
| 19 | Automated extraction machine***\*optional and based on laboratory’s choices and access to automated extraction kits suitable for use on the machine*** |  |  |

***Please note that this list is specifically for a BSL 2 Laboratory. For a BSL 3 Laboratory for work on infectious organisms such as Lassa Fever, a Level 3 Biosafety Cabinet (glove box) needs to be added.***

**Human Resources**

A critical requirement of a laboratory is adequately skilled staff. The table below should be used as a guide on the minimum number of laboratory staff.

|  |  |  |
| --- | --- | --- |
| S/N | **Staff Capacity** | **Minimum number required** |
| **Technical staff** |
|  | Virologists, Molecular Biologists, Medical Laboratory Scientists, Microbiologists | 4 |
|  | Laboratory Manager | 1 |
|  | Data Manager | 2 |
| **Support staff** |
|  | Health/Laboratory Technician | 2 |
|  | Laboratory Assistant | 2 |
|  | Waste Manager | 2 |
|  | Maintenance Manager | 1 |
|  | Administrative Officer and Accountant | 2 |

***Please note that the minimum number of staff above are ONLY a guide for what is minimally acceptable and depending on a typical 8-hour daily shift of work. This number should be increased if the laboratory intends to work longer shifts and with increased workload.***

**Quality Assurance**

The laboratory needs an instituted process for Quality Assurance and the most effective way to achieve this is to appoint a trained Quality Manager for the laboratory

**Laboratory Supply Chain Management**

**Efficient** and effective supply chain management needs to be available for the laboratory that takes into consideration the following:

* How will the laboratory ensure reagents and consumables are always available for the laboratory to function uninterruptedly?
* Who is responsible for financing the supplies for the laboratory?
* What access to the reagents and consumables market does the laboratory have?
* Who is responsible for coordinating this supply chain function?

For further inquiries regarding this guidance, please email ncdclabnetwork@ncdc.gov.ng and celestina.obiekea@ncdc.gov.ng