Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

April 18, 2020

DEPARTMENT CIRCULAR
No. 2020 - 0187

TO : **ALL REGIONAL DIRECTORS, HEADS OF HOSPITALS AND OTHER HEALTH FACILITIES, DIRECTOR OF RESEARSH INSTITUTE FOR TROPIAL MEDICINE, DIRECTOR OF DISEASE PREVENTION AND CONTROL PROGRAM, CHIEFS OF THE HEALTH FACILITIES AND SERVICES REGULATORY BUREAU AND THE CENTERS FOR HEALTH DEVELOPMENT – REGULATION, LICENSING AND ENFORCEMENT DIVISION, MINISTRY OF HEALTH OF THE BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (MOH-BARMM), REGULATORY OFFICERS AND OTHER STAKEHOLDERS CONCERNED**

SUBJECT : **Guidelines in the Interim Use of the Laboratories of the National TB Control Program as COVID-19 Testing Laboratories Performing Rapid PCR Testing for SARS-CoV-2**

Administrative Order No.2020-0014, titled Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines, was issued last April 7, 2020, to have more laboratories capable of detecting Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2), the causative agent of COVID-19. As of April 18, 2020, there are 17 licensed COVID-19 testing laboratories, using real time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR), with a combined daily output of 3,789 tests.

Latest data show that there are now 6,087 confirmed cases, with 516 recoveries and 397 deaths. However, 8,000 tests will have to be done daily to get a more accurate projection of infected individuals, making the current daily output 53% off from the target.

Different strategies, from having more licensed COVID-19 testing laboratories to extending the hours of operation of the licensed COVID-19 testing laboratories, have been considered to increase the daily test outputs. With the recent FDA approval of a Rapid PCR Tests for SARS-CoV-2, such as Xpert Xpress, which can be performed in a GeneXpert Instrument System, attention has turned to the culture laboratories of the National Tuberculosis (TB) Control

Program which has this functional system in place. The System, with its self-contained cartridges, is semi-automated, so that results can be obtained in 45 minutes to an hour.

Hence, the Laboratories of the National TB Control Program are being tapped to be COVID-19 testing laboratories.

GENERAL GUIDELINES:

1. COVID-19 testing shall also be done in the Laboratory of the National TB Control Program which shall be duly licensed by DOH as a COVID-19 testing laboratory performing Rapid PCR Testing for SARS-CoV-2.

2. A DOH licensed COVID-19 testing laboratory performing Rapid PCR Testing for SARS-CoV-2 shall cater exclusively to COVID-19 testing.

3. All the standards and requirements in A.O. 2020-0014 shall apply to a COVID-19 testing laboratory performing Rapid PCR Testing for SARS-CoV-2, except for the following:
    a. Personnel Complement and Required Trainings (details in Annex A – Assessment Tool for Licensing a COVID-19 Testing Laboratory Performing Rapid PCR Testing for SARS-CoV-2)
    b. Physical Plant (Annex B1 and B2 – Prototype / Reference Plan and Floor Plan Checklist of a TB Reference Laboratory performing Rapid PCR Testing for SARS-CoV-2)
    c. Equipment, reagents and supplies (Annex A – Assessment Tool for Licensing a COVID 19 testing laboratory Performing Rapid PCR Testing for SARS-CoV-2)
    d. The teams from HFSRB or CHD-RLED together with RITM or its designated 3rd party assessor shall conduct inspection of the said laboratory.

4. The DOH–LTO for a COVID-19 testing laboratory performing Rapid PCR Testing for SARS-CoV-2 shall only be issued upon full compliance to the standards and requirements set forth by HFSRB and RITM.

5. The DOH–LTO for a COVID-19 testing laboratory performing Rapid PCR Testing for SARS-CoV-2 shall be valid for 3 months.

6. An evaluation shall be done after 3 months to determine if an extension in the validity of the DOH-LTO is warranted.

For immediate implementation and strict compliance.

By Authority of the Secretary of Health:

MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV
OIC-Undersecretary of Health
Health Regulation Team

D.C. No. 2020 - _____
ANNEX A

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

ASSESSMENT TOOL FOR LICENSING A COVID-19 TESTING LABORATORY PERFORMING RAPID PCR TESTING FOR SARS-CoV-2 ASSAY

INSTRUCTIONS:

1. To properly fill-out this tool, the Licensing Officer shall make use of: INTERVIEWS, REVIEW OF DOCUMENTS, OBSERVATIONS and VALIDATION of findings.
2. If the corresponding items are present, available or adequate, place a (✔) on each of the appropriate spaces under the FINDINGS column or space provided alongside each corresponding item. If not, put an (**X**) instead.
3. The REMARKS column shall document relevant observations.
4. Make sure to fill-in the blanks with the needed information. Do not leave any items blank.
5. The Team Leader shall ensure that all team members write down their printed names, designation and affix their signatures and indicate the date of inspection/monitoring, all at the last page of the tool.
6. The Team Leader shall make sure that the Head of the facility or, when not available, the next most senior or responsible officer likewise affix his/her signature on the same aforementioned pages, to signify that the inspection/monitoring results were discussed during the exit conference and a duplicate copy also received.

I. GENERAL INFORMATION:

Name of Facility: _____

Address: _____
(Number & Street) (Barangay/District) (Municipality/City)

_____
(Province & Region)

Telephone/ Fax No._____ E-mail Address: _____

Initial:_____ Renewal: _____

Existing License No: _____Date Issued: _____ Expiry Date: _____

Name of Owner or Governing Body (if corporation):_____

Name of Head of Laboratory: _____

Classification According to:

Ownership: __ Government __ Private

Function: __ COVID-19 Testing Laboratory (Performing Rapid PCR Testing Sars-CoV-2 Assay)

Institutional-Character: __ Hospital-Based __Non-hospital-based

Service Capability: __ Add-on service to General Clinical Laboratory

__ Limited Service Capability to COVID-19 Testing

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
I. LEADERSHIP AND MANAGEMENT The provider organization's management team provides leadership, acts according to the organization's policies and has overall responsibility for the organization's operation, and the quality of its services and its resources			
Organizational Structure/Chart	**Observe** • Organizational Structure / Chart is posted in conspicuous area.		
Mission, vision and objectives shall be in accordance with RA 4688	**Document Review** • Written vision, mission, and goals **Observe** • Vision, mission, and goals displayed in a conspicuous area visible to clients		
License to operate and other documents	**Document Review** • Compilation of Clinical Laboratory AOs, Report of Inspection/Monitoring **Observe** • Valid DOH-LTO posted in a conspicuous area visible to clients		
Administrative and technical monitoring and Evaluation activities to assess management and organizational performance	**Document Review** • Supporting documents for evaluation and monitoring of activities such as records, logbooks, checklist of supplies, inspection report, purchasing or procurement and acceptance of supplies, etc.		
Policy on Management Review – Conduct of regular staff meetings held at least twice a year or as needed.	**Document Review** • Compilation of minutes of meeting (reflecting the date, time, attendance, agenda and action taken signed and approved by head of laboratory		
Procedures for handling complaints and client feedback	**Document Review** • Written protocol for handling complaints/ client feedback. • Forms for complaints/ client feedback • Suggestion box visible to clients • Records of complaints/ client feedback and actions taken		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
II. HUMAN RESOURCE MANAGEMENT **A. STAFF RECRUITMENT, SELECTION, APPOINTMENT AND RESPONSIBILITIES** There are relevant orientation, training and development programs to meet the educational needs of management and staff.			
Policy on continuing program for staff development and training	**Document Review** • Written policies and procedures for staff development and training • Proof of training through relevant certificates, memos, written reports, budgetary allocations **Interview** Human Resources Management Officer/Personnel Officer		
Policy for hiring, orientation and promotion for all levels of personnel	**Document Review** • Written policies and procedures on hiring, orientation and promotion of personnel at all levels		
Policy for discipline, suspension, demotion and termination of personnel at all levels	**Document Review** • Written policies and procedures on discipline, suspension, demotion and termination of personnel at all levels		
B. MANPOWER The COVID-17 testing laboratory shall have an adequate trained personnel to provide effective and efficient laboratory services.			
The organizational chart shall be clearly structured.	**Document Review** • Updated organizational chart indicating the names with latest pictures (at least passport size) and designation, reflecting lines of authority, accountability, communication, interrelationship, hierarchy of functions and flow of referrals.		
Duties and responsibilities shall be clearly spelled out.	**Document Review** • Written job description or duties and responsibilities of all laboratory personnel		
Adequate number of qualified personnel with documented training and experience to conduct the laboratory procedures performed.	**Document Review** • List of Personnel with designation • Area of assignments indicated in the posted work schedule signed and approved by head of laboratory • Proof of attendance		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
The head of the COVID-19 Testing Laboratory shall have the overall supervision on technical procedures as well as on the administrative laboratory management	**Document Review** • Proof of Supervisory visits at least **once a week** or as needed		
Each personnel shall have a record of updated 201 file Head of the Laboratory (1) RMT Analyst Per (2) machines (1) Laboratory Aide (1) Encoder Per (4) machines	**Document Review** • Proof of qualifications • Resume • PRC ID and Certificate • PSP Board Certificate • Training Certificate on Biosafety and Biosecurity • Training Certificate on rapid PCR system (e.g. GeneXpert System) • Notarized Employment Contract • Annual Health Status (Latest Medical Certificate) • Influenza Vaccination • Resume • PRC ID and Certificate • Training Certificate on Biosafety and Biosecurity • Training Certificate on rapid PCR system (e.g. GeneXpert System) • Notarized Employment Contract • Annual Health Status (Latest Medical Certificate) • Influenza Vaccination • Resume • Training Certificates on Biosafety and Biosecurity (maybe in-house) • Notarized Employment Contract • Annual Health Status (Latest Medical Certificate) • Influenza Vaccination		
NOTE: An increase in workload shall require a corresponding increase in the number of personnel.			

III. PHYSICAL PLANT, FACILITIES, AND WORK ENVIRONMENT There an adequate space with a unidirectional workflow for the safe & efficient operation of the COVID-19 testing laboratory			
CRITERIA	**INDICATOR / EVIDENCE**	**COMPLIED**	**REMARKS**
Program of proper maintenance and monitoring of physical plant and facilities	**Document Review** • Written policy and program for the proper maintenance and monitoring of physical plant and facilities • Proposed schedule for preventive maintenance **Observe** • Updated proof of actual implementation of maintenance as to structure, ventilation, lighting & water supply		
Policy guidelines on laboratory biosafety and biosecurity	**Document Review** • Written protocols on laboratory biosafety and biosecurity **Observe** • Provision of Personal Protective Equipment • Good Laboratory Practice that includes use of Personal Protective Equipment and other precautionary measures		
Procedures for the proper disposal of waste and hazardous/infectious substances that shall conform to the standards set by the DOH	**Document Review** • Policy on disposal of wastes that conform with Healthcare Waste Management Manual, and RA6969 • Notarized Memorandum of Agreement with infectious waste, toxic, and hazardous substances hauler **Observe** • Proof of proper management of wastes from point of generation, segregation (color-coded waste bins), disinfection, up to the final disposal		
IV. EQUIPMENT /INSTRUMENTS There shall be adequate equipment which are all in good working condition.			
Adequate number of operational equipment to provide the laboratory examinations that the laboratory is licensed for.	**Document Review** • Equipment listed available in the laboratory **Observe** • Equipment are operational		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
Program for calibration, preventive maintenance and repair for the equipment.	**Document Review** • Record of schedule and updated certificate of calibration and maintenance of equipment • Record of reports of preventive maintenance and repair		
Contingency plan in case of equipment breakdown	**Document Review** • Written policy on contingency plan in case of equipment breakdown.		
V. REAGENTS AND SUPPLIES There shall be adequate reagents and supplies which are in good condition and sufficient enough for the operations.			
Adequate supply of properly stored and inventoried reagents and supplies for the laboratory examinations to be provided.	**Document Review** • Quality records of supplies /reagents with **expiration date**, their **usage/ consumption** and disposal are available • Certificate of Product Registration from Food & Drug Administration (FDA) **Observe** • Availability and completeness of reagents and supplies • Validate the expiration dates of reagents		

Reagents and supplies are stored under the required conditions. Adequate storage facilities such as refrigerators for perishable reagents and supplies	**Document review**
	• Temperature monitoring records as follow:
	  ◦ Room temperature reading
	  ◦ Refrigerator and freezer temperature reading
	Observe
	• Temperature within the laboratory
	• Temperature of refrigerators and freezers		

Appropriate storage area/technique for flammable, combustible and hazardous chemical/reagents	**Document review** • Material Safety Data Sheet (MSDS) available for all reagents/supplies and accessible to all personnel at all times **Observe** • Organized per section with National Fire Protection Association (NFPA) Label		

VI. ADMINSTRATIVE POLICIES AND PROCEDURES

Policies and procedures for provision of laboratory services are formulated for the operation and maintenance of the laboratory.

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
Administrative policies & procedures for provision of laboratory services and for the operation and maintenance of the laboratory	**Document review** • Documented policies, protocols, procedures signed and approved by the head of laboratory • Guidelines in the operation and maintenance of the laboratory including policy on security of supplies, specimens and confidentiality of records		
Technical procedures of services provided in each section are available	**Document review** • Documented and updated policies and procedures for provision of laboratory services in the laboratory and in each of the sections • Documented policies, protocols, guidelines in the operation and maintenance of the laboratory		
A. Communication and Records			
Procedures for the receipt and performance of COVID-19 testing.	**Document review** • Documented procedures for receipt and performance of COVID-19 testing.		
Procedures for reporting of results of COVID-19 testing.	**Document review** • Documented procedures for reporting of results of COVID-19 testing. • Compilation of reports to DOH-EB, RESU, and RIM.		
All laboratory reports on shall bear the name of the pathologist who shall be the overall responsible for the reliability of the results.	**Document review** • Laboratory report forms bearing the name and original signature with PRC ID No. of the head. • Laboratory reports bearing the name of RMT and original signature with PRC ID No. who performed the examinations and shall bear the name and signature of senior RMT who validated the report. • Updated records of result (logbooks/ electronically stored data with back up) including entry, releasing & endorsement records.		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
Procedures for reporting of work load, quality control, inventory control, etc	**Document review** • Documented procedures for reporting of work load, quality control, inventory control, etc. • Updated reports, documents (Hard or soft copy with back up) • Worksheets/ machine print out per section as proof of actual performance		
Procedure for reporting and analysis of incidents, adverse events, etc.	**Document review** • Documented procedures for reporting and analysis of incidents, adverse events, etc • Compilation of written reports with resolutions		
The retention of records of the laboratory shall follow standards promulgated by the Department of Health **(DC# 70 s. 1996)** and/or competent professional Organizations	**Document review** • Documented procedure for the retention of records which follows standards promulgated by the Department of Health		
B. Quality Assurance Program			
Policy on Quality Assurance Program and Continuous Quality Improvement	**Document review** • Documented Internal Quality Assurance Program including Internal Quality Control and Continuous Quality Improvement • Updated QC reports conducted • Availability of reference materials and appropriate reagents & equipment used • Results/findings of Quality • Assurance audits/ assessments		
Participation in Proficiency Testing conducted by RITM prior to the operation of licensed COVID-19 testing laboratory	**Document review** • Documented procedure in the actual performance of proficiency testing • Certificate of Proficiency		
Participation in an National External Quality Assessment Scheme conducted by RITM	**Document review** • Documented procedure in the actual performance of NEQAS activities • Certificate of Performance in NEQAS with passing rate		

C. REFERRAL OF COVID-19 TESTING When COVID-19 testing are referred to and provided by another COVID-19 testing laboratory, the referring COVID-19 testing laboratory shall obtain assurance of the quality of services provided through an agreement or its equivalent with a licensed COVID-19 testing laboratory performing the laboratory services needed.			
Policy on referral and outsourcing of examinations	Documented Procedures on referral and outsourcing of examinations to other licensed COVID-19 testing laboratory Records of outsourced COVID-19 examinations (In the event of machine breakdown during actual process only) Notarized Memorandum of Agreement DOH license of referral COVID-19 testing laboratory		

LIST OF EQUIPMENT

I. Laboratory Equipment, Furniture and Supplies Required

1. The facility should make sure that the following equipment/supplies/furniture are available at all times.

a. Equipment and supplies

The following are minimum recommended equipment for this workstation:

NOTE: Quantity may be increased depending on purpose, manpower and workload of the laboratory

- ☐ Autoclave
- ☐ Biomedical freezer for specimens
- ☐ Biomedical refrigerator for reagents (cartridges) and specimens
- ☐ Biological Safety Cabinet Class II A2
- ☐ Rapid PCR Machine (e.g. GeneXpert)
- ☐ Gloves (different size: S, M, L)
- ☐ Micropipette tips
- ☐ Pass Box
- ☐ Vortex Mixer

b. Laboratory furniture

- ☐ Bench space with leg room and storage for consumables
- ☐ Computer
- ☐ Handwashing sink
- ☐ Laboratory chairs
- ☐ Laboratory deep sink
- ☐ Storage cabinets

c. Personal Protective Equipment

The following are minimum recommended Personal Protective Equipment:

- ☐ Respirator: N95
- ☐ Disposable laboratory gown
- ☐ Shoe cover
- ☐ Laboratory shoes
- ☐ Gloves
- ☐ Head cove
- ☐ Goggles
- ☐ Face shield

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Health Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process

[ ] For Issuance of License to Operate as

Validity from _____ **to** _____

[ ] Issuance depends upon compliance to the recommendations given and submission of the following within _____days from the date of inspection

_____

_____

_____

[ ] Non-issuance. Specify reason/s: _____

_____

_____

_____

Inspected by:

Printed name	Signature	Position/Designation

Received by:

Signature: _____

Printed Name: _____

Position/Designation: _____

Date: _____

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

A. For Monitoring Process

[ ] Issuance of Notice of Violation

_____

_____

_____

[ ] Non-issuance of Notice of Violation

_____

_____

_____

[ ] Others. Specify _____

_____

_____

_____

Monitored by:

Printed name	Signature	Position/Designation

Received by:

Signature: _____

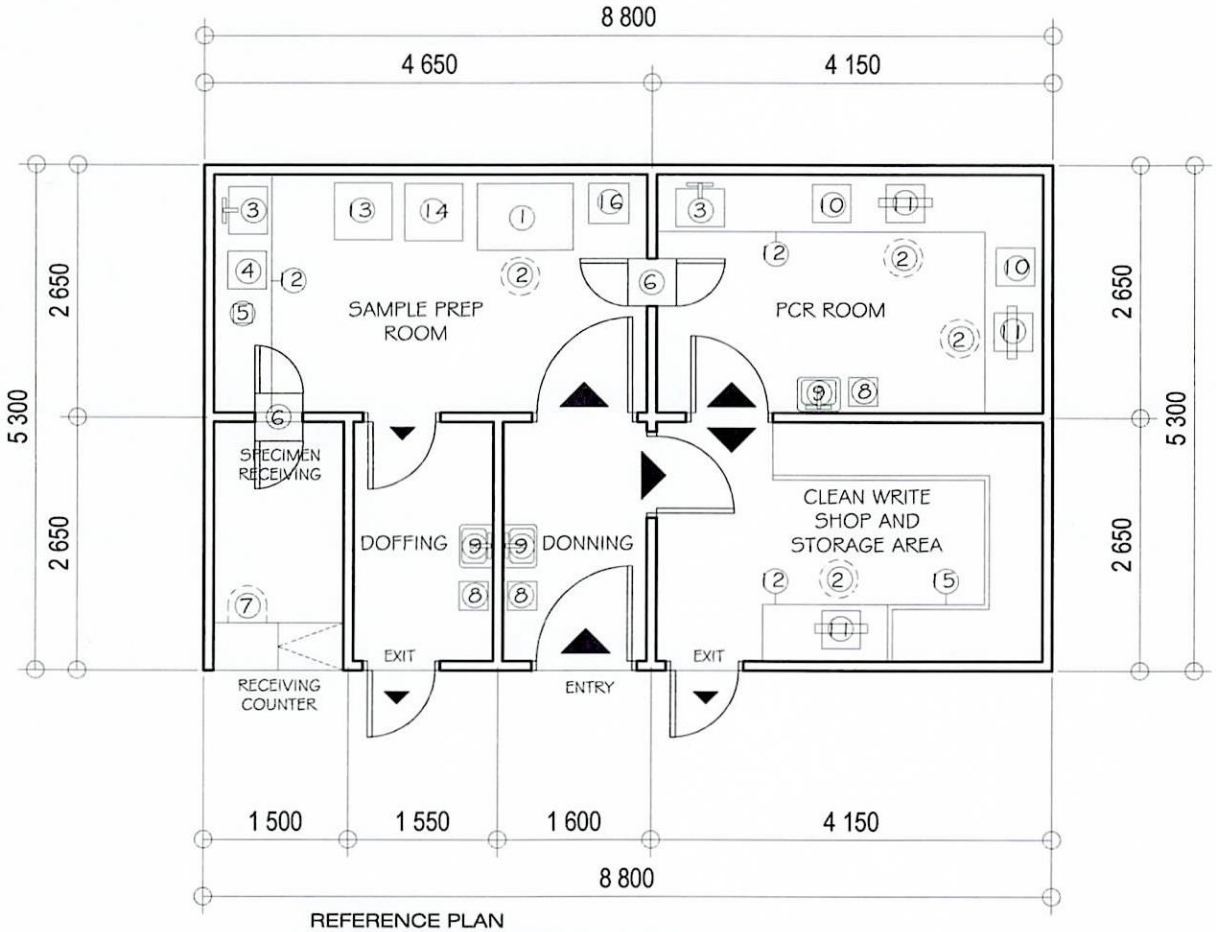
Printed Name: _____

Position/Designation: _____

Date: _____

ANNEX B1

D.C. NO. 2020-_____



REFERENCE PLAN

COVID-19 TESTING LABORATORY PERFORMING RAPID PCR TESTING FOR SARS-CoV-2 ASSAY

LEGEND

1. BIOSAFETY CABINET
2. LABORATORY CHAIR
3. LABORATORY DEEP SINK
4. MICRO CENTRIFUGE
5. VORTEX MIXER
6. PASS BOX
7. COMPUTER CHAIR
8. WASTE BIN
9. HAND WASHING SINK
10. PCR MACHINE (*e.g.* GENE XPERT)
11. COMPUTER
12. WORK COUNTER
13. REFRIGERATOR
14. FREEZER
15. STORAGE CABINET
16. AUTOCLAVE

GRAPHICAL SCALE:

0 0.50 1 2 3 5

Republic of the Philippines DEPARTMENT OF HEALTH CENTRAL OFFICE Rizal Avenue, Sta. Cruz, Manila City	TITLE REFERENCE PLAN/ SAMPLE PLAN COVID TESTING LABORATORY	NOTED BY: MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV OIC-USEC- HEALTH REGULATIONS TEAM	SHEET NO. 1 OF 2 VERSION 2 PRPD BY: HFSRB & RITM

ANNEX B1

D.C. NO. 2020-_____

GENERAL NOTES

DOORS

1. DOOR WIDTH MUST BE AT LEAST 1.00 METER IN ORDER TO ACCOMMODATE ENTRY AND EXIT OF EQUIPMENT. ALSO, PROVIDE VISION PANEL/S ON ALL DOORS AS APPLICABLE. THE DOORS MUST BE LOCKABLE AND SHALL HAVE A SELF CLOSING MECHANISM. ADOPT CHEMICAL RESISTANT AND EASY TO CLEAN DOOR FINISH.

WINDOWS

1. THE EXTERNAL/ INTERNAL WINDOWS SHALL EMPLOY FIXED TEMPERED/SAFETY GLASS WINDOW.

WALLS

1. ALL WALLS AND PARTITIONS SHALL BE STRUCTURALLY SOUND, SAFE AND MADE OF STURDY, IMPERVIOUS (WATER PROOF, IMPENETRABLE, IMPERMEABLE) MATERIALS AND EASY TO CLEAN, WITH ANTI-BACTERIAL/ANTI-FUNGICIDAL CHEMICAL RESISTANT FINISHES.

2. INTERIOR WALLS/ PARTITIONS MUST BE FLOOR TO FLOOR HEIGHT TO PREVENT CROSS CONTAMINATION AND FOR FIRE SAFETY COMPARTMENTALIZATION.

CEILING

1. THE CEILING HEIGHT SHALL BE AT LEAST 2.60M IN ORDER TO ACCOMMODATE BIOLOGICAL SAFETY CABINET.
2. THE CEILING SHALL BE STRUCTURALLY SOUND, SAFE AND MADE OF STURDY IMPERVIOUS (WATER PROOF, IMPENETRABLE, IMPERMEABLE) MATERIALS AND EASY TO CLEAN. ANTI-BACTERIAL/ANTI-FUNGICIDAL CHEMICAL RESISTANT FINISHES.

FLOOR

1. THE FLOOR MATERIAL AND FINISH MUST BE MONOLITHIC, STRUCTURALLY SOUND, SAFE AND MADE OF STURDY IMPERVIOUS (WATER PROOF, IMPENETRABLE, IMPERMEABLE) MATERIALS AND EASY TO CLEAN. ANTI-BACTERIAL/ANTI-FUNGICIDAL CHEMICAL RESISTANT FINISHES WITH COVED CORNERS.

EXHAUST

1. FOR THE SPECIMEN RECEIVING AND SPECIMEN HANDLING/ SAMPLE PREP ROOM , THE EXHAUST MUST PRODUCE AT LEAST 12 AIR CHANGES PER HOUR (ACH) AND MUST BE DIRECTED AWAY FROM PEOPLE AND ADJACENT STRUCTURES.
2. FOR THE PCR ROOM, THE EXHAUST MUST PRODUCE AT LEAST 6 AIR CHANGES PER HOUR (ACH) AND MUST BE DIRECTED AWAY FROM PEOPLE AND ADJACENT STRUCTURES.
3. THE REAGENT PREPARATION ROOM SHALL HAVE A POSITIVE PRESSURE ROOM CONDITIONED. ALSO, IT SHALL HAVE FILTERED AIR SUPPLY WITH A 90-95% EFFICIENCY.
4. ADDITIONAL EXHAUST REQUIREMENT TO BE CONSIDERED IF THE AREA HAS ADJACENT BUILDINGS, STACK SHOULD NOT HAVE GOOSENECK OR CAP AND SHOULD BE AT LEAST 3.00M HIGHER THAN THE HIGHEST POINT OF THE ROOF OR ADJACENT BUILDING.
5. INSTALLATION OF MAGNEHELIC GAUGE IS RECOMMENDED FOR MONITORING NEGATIVE PRESSURE FOR SPECIMEN RECEIVING AREA AND SPECIMEN HANDLING ROOM.

AIR CONDITIONING

1. ALL AIR CONDITIONING UNIT MUST BE SPLIT TYPE, AIR DIRECTION SHOULD BE AWAY FROM THE SAFETY CABINETS (BSC, PCR HOOD AND LAMINAR AIR FLOW)

PASS BOX

1. FOR INTERNAL PASS BOX, IT MUST HAVE A MINIMUM APPROXIMATE INTERNAL DIMENSION OF 0.30M X 0.30M X 0.30M (LXWXD), ELECTRICALLY AND MECHANICALLY INTERLOCKED.
2. FOR SPECIMEN RECEIVING PASS BOX, IT MUST HAVE A MINIMUM APPROXIMATE INTERNAL DIMENSION OF 0.40M X 0.40M X 0.40M (LXWXD), ELECTRICALLY AND MECHANICALLY INTERLOCKED.

CODES

1. ALL PLANS AND DRAWING REQUIREMENTS SUCH ARCHITECTURAL, CIVIL, ELECTRICAL, LIGHTING AND POWER, SANITARY AND PLUMBING AND MECHANICAL, AND OTHER RELATED TRADES SHALL BE IN ACCORDANCE WITH ALL RELEVANT AND EXISTING CODES OF THE PHILIPPINES AS APPLICABLE.

OTHERS

1. INSTALLATION OF INTERCOM FOR ALL ROOMS IS RECOMMENDED.
2. PROVISION FOR TOILET AND OTHER AMENITIES FOR THE LABORATORY STAFF SHALL BE LOCATED OUTSIDE BUT EASILY ACCESSIBLE TO PREVENT CONTAMINATION.

GRAPHICAL SCALE:

0 0.50 1 2 3 5

Republic of the Philippines DEPARTMENT OF HEALTH CENTRAL OFFICE Rizal Avenue, Sta. Cruz, Manila City	TITLE REFERENCE PLAN/ SAMPLE PLAN COVID TESTING LABORATORY	NOTED BY: MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV OIC-USEC- HEALTH REGULATIONS TEAM	SHEET NO. 2 OF 2 PRPD BY: HFSRB & RITM

Republic of the Philippines
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HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Annex B2
D.C. No. 2020-_____

CHECKLIST FOR REVIEW OF FLOOR PLANS
COVID-19 TESTING LABORATORY PERFORMING RAPID PCR TEST

Name of Health Facility: _____
Address: _____
Date: _____ Review: 1st_____ 2nd_____ 3rd _____

1. PHYSICAL PLANT

_____**1.1 Clinical Work Area**
- _____1.1.2 Receiving Counter
  - _____1.1.2.1 Pass Box going to **Sample Preparation Room**
- _____1.1.3 Sample Preparation Room
  - _____1.1.3.1 Work Counter with Laboratory Deep Sink
  - _____1.1.3.2 Pass Box going to **PCR Room**
  - _____1.1.3.3 Anteroom *for doffing* with handwashing Sink
- _____1.1.4 Anteroom for *donning* with hand washing sink, PPE Rack and Hamper
- _____1.1.5 Polymerase Chain Reaction (PCR) Room
  - _____1.1.5.1 Work Counter with Laboratory Deep Sink
- _____1.1.6 Clean Write Shop and Storage Area
  - _____1.1.6.1 Work Counter
  - _____1.1.6.2 Storage Cabinet

2. PLANNING AND DESIGN

_____2.1 Floor plans properly identified and completely labeled
_____2.2 Doors, windows, fixtures, furniture and equipment are properly laid out.
_____2.3 Meets prescribed functional programs:
- _____2.3.1 Zoning Requirement:
  - _____2.3.1.1 Laboratory location shall have less foot traffic yet accessible for receiving of specimen.
  - _____2.3.1.2 The flow of traffic of specimen going to specimen receiving counter shall not pass through general public areas.
- _____2.3.2 Floor plan suggests unidirectional workflow process from receiving of specimen to results data processing as applicable.
- _____2.3.5 Door access going to Sample Preparation Room shall have at least 1.00 meter clear width to accommodate entry and exit of equipment as applicable.
- _____2.3.6 Internal windows are laid out to promote visual observation between work rooms as applicable.
- _____2.3.5 Provision for toilet and other amenities for laboratory staff are located outside but easily accessible to prevent contamination.

_____2.4 Conforms to the applicable codes as part of professional service
- _____2.4.1. Exits restricted to the following types: door leading directly outside the building, interior stair, ramp, and exterior stair.
- _____2.4.2 Minimum of two (2) exits, remote from each other.
- _____2.4.3 Exits terminate directly at an open space to the outside of the building.

COMMENTS:

Name of Health Facility: _____
Address: _____
Date: _____

COMMENTS:

_____
_____
_____
_____
_____
_____
_____

HEALTH FACILITIES EVALUATION AND REVIEW COMMITTEE (HFERC)
[ ] Approved [ ] Disapproved

_____
Chairperson, HFERC

_____
Vice-Chairperson, HFERC

_____	_____	_____
Member	Member	Member
_____	_____	_____
Member	Member	Member