Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAY 20 2020

ADMINISTRATIVE ORDER
No. 2020 - 0014-A

SUBJECT : Amendment to the Administrative Order No. 2020-0014 "Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines"

The Department of Health Administrative Order (A.O.) No. 2020-0014 dated April 7, 2020, titled "Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines" was issued as a strategy to expand the testing capacity for SARS-CoV-2 in the country. It sets the standards that will ensure maintenance of quality and safety at all times.

Initially, only Real Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) is the acceptable diagnostic method to detect SARS-CoV-2, the causative agent of COVID-19. With the demand for more testing to be done and faster releasing of results, new diagnostic platforms with a shorter turnaround time have emerged, such as the cartridge-based technology or the automated platforms for nucleic acid based technology, and are now considered as a means to augment the current testing capacity. Moreover, innovative ways of setting up COVID-19 testing laboratories are being proposed by stakeholders to help the government address the demand for more testing.

To include the use of these new platforms as acceptable methods in detecting SARS-CoV-2 and the different models or designs of COVID-19 testing laboratories, such as but not limited to pop-up labs which may be the modular types laboratories or container vans converted into labs, etc., the following additional guidelines are hereby issued to supplement A.O. No. 2020-0014.

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V. IMPLEMENTING MECHANISMS

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Under Section V.A.7.

7. The COVID-19 testing laboratory shall be supervised by a Board Certified Clinical Pathologist, with training in Molecular Laboratory Diagnosis.

-XXX-

The aforementioned is hereby amended to read as follows:

-XXX-

7. The COVID-19 testing laboratory shall be supervised by a Board Certified Clinical Pathologist.

-XXX-

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MAY 26 2020
CORAZON S. DELA CRUZ
KMITS - RECORDS SECTION
Department of Health

Under Section V.A.13.

-XXX-

13. In reporting of results, COVID-19 testing laboratories shall follow DOH Department Memorandum No. 2020-0110 dated March 13, 2020, titled "Directive to All Public and Private hospitals and Healthcare Facilities on Reporting Coronavirus Disease (COVID-2019)"

-XXX-

The aforementioned is hereby amended to read as follows:

13. **The reporting of results in COVID-19 testing laboratories shall be in accordance with the following issuances:**

a) **Republic Act No. 11332, also known as the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act"**

b) **A.O. No. 2020-0013 dated April 9, 2020, titled Revised Administrative Order No. 2020-0012 "Guidelines for the Inclusion of the Coronavirus Disease 2019 (COVID-19) in the List of Notifiable Diseases for Mandatory Reporting to the Department of Health" dated March 17, 2020.**

c) **Department Memorandum No. 2020-0110 dated March 13, 2020, titled "Directive to All Public and Private hospitals and Healthcare Facilities on Reporting Coronavirus Disease (COVID-2019)"**

-XXX-

Under Section V.B.2.A.

A. PERSONNEL

There shall be an adequate number of personnel, depending on the workload.

1. The minimum number of personnel shall be SEVEN (7), but may be more depending on the workload, and shall be composed of the following:
    a) One (1) Board Certified Clinical Pathologist with knowledge in Infectious Diseases and training in Molecular Laboratory Diagnosis;
    b) Three (3) Full-time Analysts per eight (8) hour shift, which shall be composed of **EITHER** three (3) Registered Medical Technologists **OR** two (2) Registered Medical Technologists and any allied health professionals with a Bachelor's degree relevant to the job, and with knowledge, experience, and skills in molecular biology techniques, such as Molecular Biology and Biotechnology, Biology, Applied Biology, Biochemistry, and Microbiology;
    c) One (1) Full-time Laboratory Aide per eight (8) hour shift;
    d) One (1) Full-time Receptionist per eight (8) hour shift; **AND**
    e) One (1) Full-time Encoder per eight (8) hour shift.
2. The laboratory staff shall have the following trainings:
    a) Fundamentals of Biosafety and Biosecurity, which shall cover Biological Risk Assessment, Mitigation Controls (engineering, practices and procedures, administrative), Personal Protective

Equipment, specimen transport, waste management, decontamination and disposal, and Emergency Responses (biological spill drill), **AND**

b) Molecular Diagnostics.

-XXX-

The aforementioned is hereby amended to read as follows:

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A. PERSONNEL

There shall be an adequate number of personnel, depending on the workload.

1. The following are the minimum number of personnel, but may be more depending on the workload, and shall be composed of:

A. For COVID-19 laboratories performing rRT-PCR, the minimum number is SEVEN (7)

a) One (1) Board Certified Clinical Pathologist;

b) Three (3) Full-time Analysts per eight (8) hour shift, which shall be composed of **EITHER** three (3) Registered Medical Technologists **OR** two (2) Registered Medical Technologists and any allied health professionals with a Bachelor's degree relevant to the job, and with knowledge, experience, and skills in molecular biology techniques, such as Molecular Biology and Biotechnology, Biology, Applied Biology, Biochemistry, and
Microbiology;

c) One (1) Full-time Laboratory Aide per eight (8) hour shift;

d) One (1) Full-time Receptionist per eight (8) hour shift; **AND**

e) One (1) Full-time Encoder per eight (8) hour shift.

B. For COVID-19 laboratories using the cartridge-based technology to detect SARS-CoV-2, the minimum number shall be FOUR (4)

a) One (1) Board Certified Clinical Pathologist;

b) One (1) Full-time Registered Medical Technologist as Analysts per eight (8) hour shift for every (2) machines;

c) One (1) Full-time Laboratory Aide per eight (8) hour shift for every (4) machines; AND

d) One (1) Full-time Encoder per eight (8) hour shift for every (4) machines.

2. The laboratory staff shall have the following trainings:

a) Fundamentals of Biosafety and Biosecurity, which shall cover Biological Risk Assessment, Mitigation Controls (engineering, practices and procedures, administrative), Personal Protective Equipment, specimen transport, waste management, decontamination and disposal, and Emergency Responses (biological spill drill);

The abovementioned trainings, which can be provided in-house, shall be required for Laboratory Aide, Receptionist and Encoder.

b) **Molecular Laboratory Diagnosis or Molecular Laboratory Diagnostics for Clinical Pathologist and Analysts.**

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Under Section V.B.2.B.

B. PHYSICAL FACILITIES

COVID-19 testing laboratories shall have adequate and appropriate areas to safely, effectively and efficiently provide the services to clients.

1. There shall be a dedicated space for each of the following activities:
   a) Specimen reception;
   b) Virus inactivation and nucleic acid extraction (Pre-PCR);
   c) Reagent storage and handling;
   d) PCR; **AND**
   e) Clerical activities.

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3. The prototype floor plan and the floor plan checklist for constructing a COVID-19 testing laboratory shall be used as references in constructing the testing laboratory. (ANNEX D1 and ANNEX D2)

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The aforementioned is hereby amended to read as follows:

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B. PHYSICAL FACILITIES

COVID-19 testing laboratories shall have adequate and appropriate areas to safely, effectively and efficiently provide the services to clients.

1. There shall be a dedicated space for each of the following activities:
   A. For COVID-19 laboratories performing rRT-PCR
   a) Specimen reception;
   b) Virus inactivation and nucleic acid extraction (Pre-PCR);
   c) Reagent storage and handling;
   d) PCR; **AND**
   e) Clerical activities.

   B. For COVID-19 laboratories using the cartridge-based technology to detect SARS-CoV-2
   a) Specimen reception;
   b) Specimen Processing; AND
   c) Clerical Activities

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3. COVID-19 testing laboratories shall be in accordance with the prototype floor plan and floor plan checklist prior to construction of the laboratory.

The following are the references:

a. Prototype floor plan

1) **ANNEX D1 – for COVID-19 laboratories performing manual RNA extraction**
2) **ANNEX D3 – for COVID-19 laboratories using automated RNA extraction machines**
3) **ANNEX D4 – for COVID-19 laboratories using the cartridge-based technology to detect SARS-CoV-2**
4) **ANNEX D5 – for COVID-19 Pop-Up testing laboratories**

b. Floor plan checklist

1) **ANNEX D2 – for COVID-19 laboratories performing Real Time Reverse Transciptase Polymerase Chain Reaction (rRT-PCR)**
2) **ANNEX D6 – for COVID-19 laboratories using the cartridge-based technology to detect SARS-CoV-2**

c. General Notes – ANNEX D7

-XXX-

Under Section V.B.3.

3. EQUIPMENT AND INSTRUMENTS

COVID-19 testing laboratories shall have available and operational equipment and instruments appropriate and consistent to the designated areas. (Please refer to **Annex A** – Assessment Tool for Licensing a COVID-19 testing laboratory)

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The aforementioned is hereby amended to read as follows:

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3. EQUIPMENT AND INSTRUMENTS

COVID-19 testing laboratories shall have available and operational equipment and instruments appropriate and consistent to the designated areas.

For COVID-19 laboratories performing rRT-PCR – Please refer to Annex A1 (Assessment Tool for Licensing a COVID-19 testing laboratory)

For COVID-19 laboratories using the cartridge-based technology to detect SARS-CoV-2 – Please refer to Annex A2 (Assessment Tool for Licensing a COVID 19 testing laboratory using the cartridge-based technology to detect SARS-CoV-2).

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Under Section V.B.5.

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1. Pass the Proficiency Testing (PT) given by RITM prior to its operation.

-XXX-

The aforementioned is hereby amended to read as follows:

-XXX-

1. Pass the Proficiency Testing (PT) **or its equivalent** given by RITM prior to its operation.

-XXX-

Under Section V.B.9.4. and 6

-XXX-

4. The linelist of POSITIVE specimens shall be e-mailed to the following:
   a) Usec. Myrna Cabotaje – mcc6277@gmail.com
   b) DOH Epidemiology Bureau – 2019.ncov.central@gmail.com
   c) Director of the Hospital
   d) Appropriate Regional Epidemiology and Surveillance Unit (RESU)
   e) Dr. Celia Carlos – ccarlosphl@yahoo.com

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6. The linelist of NEGATIVE specimens shall be e-mailed to the following:
   a) DOH Epidemiology Bureau – 2019.ncov.central@gmail.com
   b) Director of the Hospital
   c) Appropriate Regional Epidemiology and Surveillance Unit (RESU)
   d) Dr. Celia Carlos – ccarlosphl@yahoo.com

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Submission of Linelist of POSITIVE and NEGATIVE specimens shall be at the Health Regulation Team instead of RITM, the aforementioned is hereby amended to read as follows:

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4. The linelist of POSITIVE specimens shall be e-mailed to the following:
   a) Usec. Maria Rosario Singh-Vergeire – hrtucovid19results@gmail.com
   b) Usec. Myrna Cabotaje – mcc6277@gmail.com
   c) DOH Epidemiology Bureau – 2019.ncov.central@gmail.com
   d) Director of the Hospital
   e) Appropriate Regional Epidemiology and Surveillance Unit (RESU)

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6. The linelist of NEGATIVE specimens shall be e-mailed to the following:
   a) Usec. Maria Rosario Singh-Vergeire – hrtucovid19results@gmail.com
   b) DOH Epidemiology Bureau – 2019.ncov.central@gmail.com
   c) Director of the Hospital
   d) Appropriate Regional Epidemiology and Surveillance Unit (RESU)

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Under Section VI.1.b.2.c

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c. Notarized list of personnel, including photocopies of valid PRC identification card, valid COVID-19 proficiency training certificate from RITM, and copy of certificates of all necessary trainings;

-XXX-

The aforementioned provisions are hereby amended to read as follows:

-XXX-

c. Notarized list of personnel, including photocopies of valid PRC identification card, valid COVID-19 proficiency training certificate **or its equivalent** from RITM, and copy of certificates of all necessary trainings;

-XXX-

Under Section VI.4

-XXX-

The following statement shall be inserted as items (3):

-XXX-

3. Proficiency Testing (PT) fees shall follow the Schedule of Fees currently prescribed by RITM.

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Under Section VII.3.b.

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b. To inspect and issue DOH-LTO CHD-RLEDs for non-hospital based COVID-19 testing laboratories and for COVID-19 testing laboratories based in level 1 general hospitals.

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To omit the term "CHD-RLEDs" in the abovementioned provision and this shall be read as follows:

-XXX-

b. To inspect and issue the DOH-LTO for non-hospital based COVID-19 testing laboratories and for COVID-19 testing laboratories based in level 1 general hospitals.

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VIII. TRANSITORY PROVISIONS

-XXX-

Under Section VIII.b.

b) All initial application shall be submitted to HFSRB whether hospital-based or nonhospital-based. However, renewal for COVID-19 testing laboratories in based in level 1 hospitals and non-hospital based shall be at their respective CHD-RLED.

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e) Team to conduct inspection or monitoring shall come from HFSRB and RITM or its duly recognized/authorized 3rd party assessors.

-XXX-

The aforementioned provisions are hereby amended to read as follows:

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b) All initial application shall be submitted to HFSRB whether hospital-based or nonhospital-based. **However, HFSRB may delegate the inspection of COVID-19 laboratories using the cartridge-based technology to detect SARS-CoV-2 to CHD-RLEDs.** Renewal for COVID-19 testing laboratories based in level 1 hospitals and nonhospital-based shall be at their respective CHD-RLED.

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e) Team to conduct inspection or monitoring shall come from HFSRB and RITM or its duly recognized/authorized 3rd party assessors. **However, inspection of COVID-19 laboratories using the cartridge-based technology to detect SARS-CoV-2 may be delegated to teams from CHD-RLEDs and RITM or its duly recognized/ authorized 3rd party assessors.**

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The following statements shall be inserted as items (f), (g), (h), and (i):

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f) The DOH-LTO of COVID-19 laboratories of the National Tuberculosis Control Program which performs SARS-CoV-2 testing shall be valid for three (3) months but may be extended, if warranted after evaluation.

g) The details as to the additional standards and requirements for new platforms deemed acceptable to detect SARS-CoV-2 shall be in the Assessment Tool for that particular platform, and shall be issued in the form of a Department Circular as an Annex of AO 2020-0014.

h) The DOH-LTO fee shall be waived.

i) RITM shall bear the cost of up to two (2) PT panels. However, if the applicant failed to pass the PT after two (2) attempts, the analyst shall undergo re-training and the laboratory shall pay the corresponding fees for the succeeding panels to RITM.

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XI. REPEALING CLAUSE

All other provisions of Administrative Order No. 2020-0014 shall remain in effect and provisions/issuances inconsistent or contrary to this Order are hereby rescinded or modified accordingly.

XII. SEPARABILITY CLAUSE

In the event that any provision or part of this issuance is declared unconstitutional or rendered invalid by any court of law or competent authority, the portions not affected thereby shall remain in full force and effect.

XIII. EFFECTIVITY

This Order shall take effect immediately.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

A.O. No. 2020 - 0014-A
ANNEX A1

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

ASSESSMENT TOOL FOR LICENSING A COVID-19 TESTING LABORATORY

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

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 pertinent 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-19 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 (3) Analysts (1) Laboratory Aide (1) Encoder (1) Receptionist	**Document Review** • Proof of qualifications • Resume • PRC ID and Certificate • PSP Board Certificate • Training Certificate on Molecular Laboratory Diagnosis • Notarized Employment Contract • Annual Health Status (Latest Medical Certificate) • Influenza Vaccination • Resume • PRC ID and Certificate • Training Certificates on Molecular Laboratory Diagnosis and Biosafety and Biosecurity • Notarized Employment Contract • Annual Health Status (Latest Medical Certificate) • Influenza Vaccination • Resume • Training Certificates on Biosafety and Biosecurity • 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
	• Monitoring of room temperature
	• Temperature of refrigerators (4^0C to 6^0C) and freezers, (-20^0C to -30^0C)		

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 of laboratory services in each of the areas. • 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 RITM.		
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 of the laboratory. • 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		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
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.

1.1. For Reagent Preparation

a. Equipment and supplies

The following are minimum recommended equipment for this workstation:

- ☐ PCR cabinet/laminar flow
- ☐ Biomedical refrigerator for reagents
- ☐ Biomedical freezer for reagents
- ☐ Cold rack for PCR tube
- ☐ Gloves (different size: S, M, L)
- ☐ Microcentrifuge
- ☐ Micropipette tips
- ☐ Minifuge
- ☐ Set of four adjustable-volume micropippettes with rack: 100-1000 l, 20-200 ul, 2-20 ul, and 0.5-10ul
- ☐ Vortex mixer

The quantity of the above-mentioned may be increased depending on purpose, manpower and workload of the laboratory.

b. Laboratory furniture

- ☐ Bench space with leg room and storage for consumables
- ☐ Storage cabinets
- ☐ Laboratory chairs

1.2. For Specimen Handling/ Sample Preparation

a. Equipment and supplies

The following are minimum recommended equipment for this workstation:

- ☐ Biological Safety Cabinet Class II A2
- ☐ Biomedical refrigerator with freezer for specimens
- ☐ Biomedical refrigerator with freezer for nucleic acid extracts
- ☐ Cold rack for PCR tube
- ☐ Computer and printer for accessioning
- ☐ Gloves (different size: S, M, L)
- ☐ Microcentrifuge
- ☐ Micropipette tips
- ☐ Minifuge
- ☐ Set of four adjustable-volume micropippettes with rack: 100-1000 l, 20-200 ul,
- ☐ 2-20 ul, and 0.5-10ul
- ☐ Vortex mixer

The quantity of the above-mentioned may be increased depending on purpose, manpower and workload of the laboratory.

b. Laboratory furniture

- ☐ Laboratory sink with drying rack
- ☐ Bench space with leg room and storage for consumables
- ☐ Storage cabinets
- ☐ Laboratory chairs

1.3. Amplification/PCR

a. Equipment

The following are minimum recommended equipment for this workstation:

- ☐ Biomedical refrigerator or freezer for storage of PCR products
- ☐ Computer and printer (associated with the Real-time PCR machine)
- ☐ Minifuge
- ☐ Real-time PCR machine

The quantity of the above-mentioned may be increased depending on purpose, manpower and workload of the laboratory.

b. Laboratory furniture

- ☐ Laboratory sink with drying rack
- ☐ Bench space with leg room and storage for consumables
- ☐ Storage cabinets
- ☐ Laboratory chairs

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: _____

A.O. No. 2020 - 0014-A
ANNEX A2

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

ASSESSMENT TOOL FOR LICENSING A COVID-19 TESTING LABORATORY USING THE CARTRIDGE-BASED TECHNOLOGY TO DETECT SARS-COV-2

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 using the cartridge-based technology to detect SARS-CoV-2

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 pertinent 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-19 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 cartridge-based technology (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 cartridge-based technology (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 (4^0C to 6^0C) and freezers, (-20^0C to - 30^0C)		

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 of laboratory services in each of the areas. • 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 RITM.		
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 of the laboratory. • Laboratory reports bearing the original signature, printed name of RMT and PRC ID No. who performed the examinations. • 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 with 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, Reagents 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 refrigerator for reagents (cartridges)
- ☐ Biomedical refrigerator for specimens
- ☐ Biological Safety Cabinet Class II A2
- ☐ Bond paper
- ☐ Ink / Toner
- ☐ Rapid PCR Machine with kits or cartridges (e.g. GeneXpert System)

b. Laboratory furniture

- ☐ Bench space with leg room
- ☐ Computer
- ☐ Handwashing sink
- ☐ Laboratory chairs
- ☐ Laboratory deep sink
- ☐ Storage cabinets

c. Personal Protective Equipment

The following are minimum recommended Personal Protective Equipment:

- ☐ Disposable laboratory gown
- ☐ Face shield / Goggles
- ☐ Head cover
- ☐ Laboratory shoes
- ☐ Powder-free nitrile gloves
- ☐ Respirator: N95 or higher
- ☐ Shoe cover

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

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:

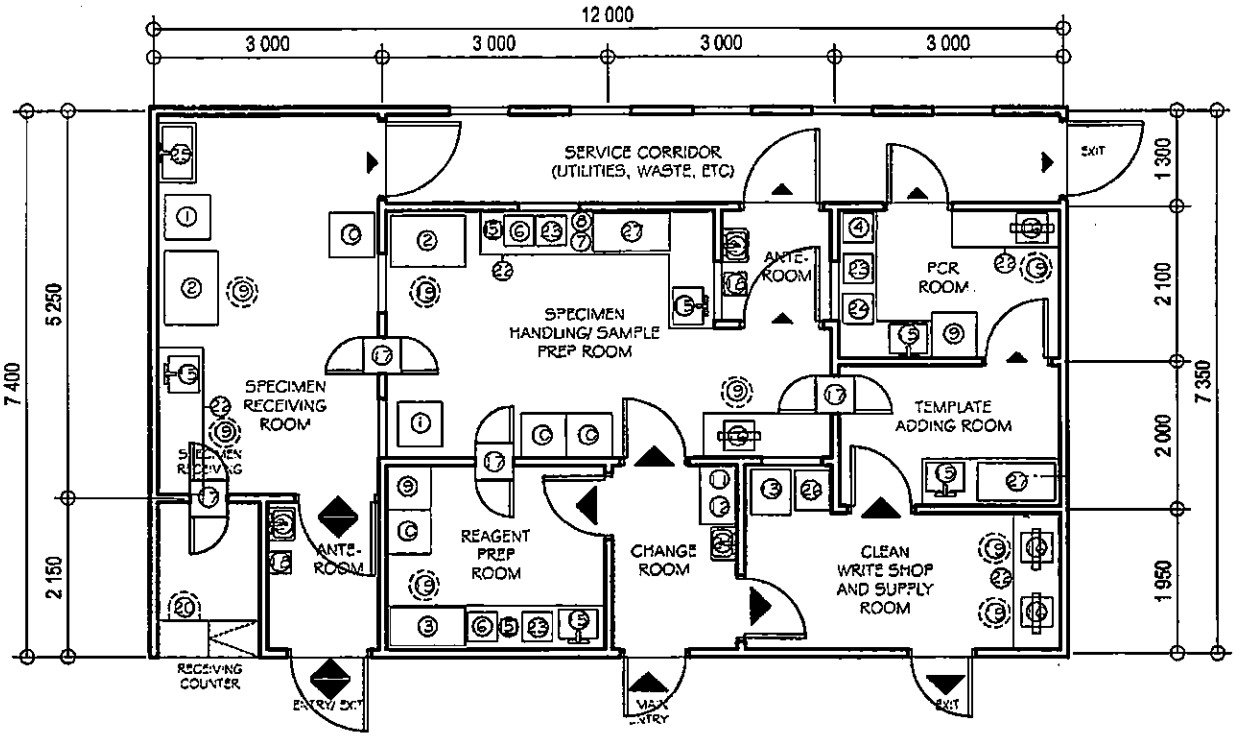
Signature: _____

Printed Name: _____

Position/Designation: _____

Date: _____

ANNEX D1
A.O. NO. 2020-0014-A



REFERENCE PLAN

COVID-19 TESTING LABORATORY PERFORMING MANUAL RNA EXTRACTION rRT-PCR

LEGEND

1. AUTOCLAVE
2. BIOLOGICAL SAFETY CABINET (BSC)
3. LAMINAR AIRFLOW (LAF) HOOD
4. REAL TIME POLYMERASE CHAIN REACTION (RT-PCR) MACHINE
5. VORTEX MIXER
6. MICRO CENTRIFUGE
7. PIPPETTORS
8. PIPPETTE FILTERED TIPS
9. FREEZER
10. REFRIGERATOR
11. PERSONAL PROTECTIVE EQUIPMENT (PPE) CABINET
12. PERSONAL PROTECTIVE EQUIPMENT (PPE)
13. FIRST AID KIT
14. COLD RACK
15. LABORATORY DEEP SINK WITH EYE WASH
16. COMPUTER
17. PASS BOX
18. WASTE BIN
19. LABORATORY STOOL
20. COMPUTER CHAIR
21. HAND WASHING SINK WITH EYE WASH
22. LABORATORY COUNTER
23. MINIFUGE
24. CONVENTIONAL PCR MACHINE
25. STAINLESS STEEL UTILITY SINK
26. SPILL KIT
27. PCR HOOD

NOTE:

THE PROPOSED COVID-19 TESTING LABORATORY SHOULD BE LOCATED IN A SEPARATE LOCATION/ OUTSIDE AN EXISTING INSTITUTION WHERE THERE IS LESS FOOT TRAFFIC FOR THE PROTECTION OF STAFF AND PUBLIC.

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	NOTED BY:	SHEET NO.
REFERENCE PLAN/ SAMPLE PLAN COVID-19 TESTING LABORATORY	MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV OIC-USEC- HEALTH REGULATIONS TEAM	version 3.0 PRPD BY: HFSRB & RITM

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

Annex D2
A.O. No. 2020- 0014-A

CHECKLIST FOR REVIEW OF FLOOR PLANS
COVID-19 TESTING LABORATORY USING rRT-PCR

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 **Specimen Receiving Room**
- _____1.1.3 Specimen Receiving Room
  - _____1.1.3.1 Anteroom with Handwashing Sink
  - _____1.1.3.2 Work Counter with Laboratory Deep Sink
  - _____1.1.3.3 Pass Box going to **Specimen Handling/ Sample Preparation Room/ Pre-PCR Room**
- _____1.1.4 Change Room with hand washing sink, PPE Rack and Hamper
- _____1.1.5 Specimen Handling/ Sample Preparation Room/ Pre-PCR Room
  - _____1.1.5.1 Work Counter with Laboratory Deep Sink
  - _____1.1.5.2 Pass Box going to **Reagent Preparation room**
  - _____1.1.5.3 Pass Box going to **Template Adding Room** (n/a if using automated RNA extraction)
  - _____1.1.5.2 Anteroom/ Doffing Room with Handwashing Sink
- _____1.1.6 Reagent Preparation Room
  - _____1.1.6.1 Work Counter with Laboratory Deep Sink
- _____1.1.7 Template Adding Room (n/a if using automated RNA extraction)
  - _____1.1.7.1 Work Counter with Laboratory Deep Sink
- _____1.1.8 Polymerase Chain Reaction (PCR) Room
  - _____1.1.8.1 Work Counter with Laboratory Deep Sink
- _____1.1.9 Clean Write Shop and Supply Room
  - _____1.1.9.1 Work Counter

_____**1.2 Support Area**
- _____1.2.1 Service Corridor (n/a for pop-up, modular or container van set-up laboratory)

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:
  - _____2.2.1.1 Laboratory location shall have less foot traffic yet accessible for receiving of specimen.
  - _____2.2.1.2 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.
- _____2.3.3 Specimen Receiving Room, Specimen Handling/ Sample Preparation Room/ Pre-PCR Room and PCR Room, have direct access to service corridor.

_____2.3.4 Service Corridor has a minimum clear and unobstructed width of 1.20 meters.

_____2.3.5 Door access from service corridor 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:

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

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

COMMENTS:

_____
_____
_____
_____
_____
_____
_____

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

_____
Chairperson, HFERC

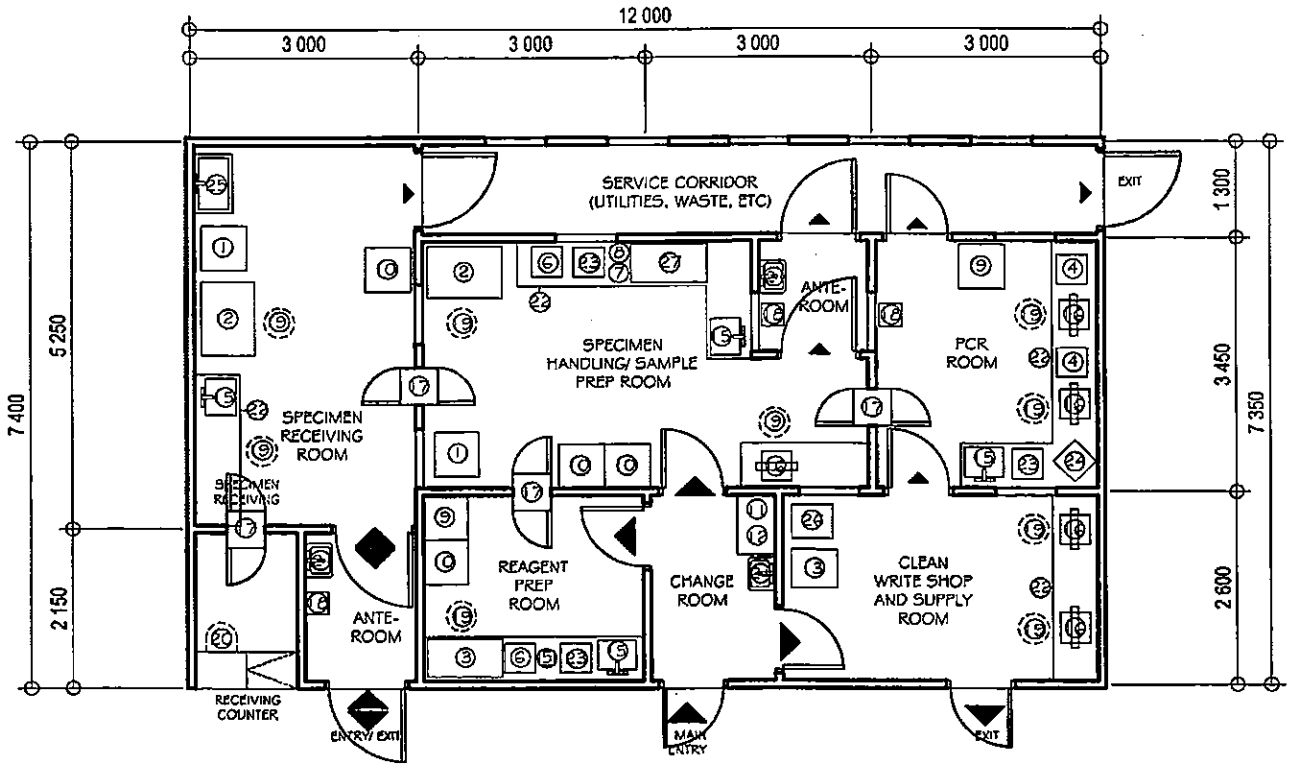
_____
Vice-Chairperson, HFERC

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

_____
_____
_____

ANNEX D3

A.O. NO. 2020-0014-A



REFERENCE PLAN

COVID-19 TESTING LABORATORY USING AUTOMATED RNA EXTRACTION rRT-PCR

LEGEND

1. AUTOCLAVE
2. BIOLOGICAL SAFETY CABINET (BSC)
3. LAMINAR AIRFLOW (LAF) HOOD
4. REAL TIME POLYMERASE CHAIN REACTION (RT-PCR) MACHINE
5. VORTEX MIXER
6. MICRO CENTRIFUGE
7. PIPPETTORS
8. PIPPETTE FILTERED TIPS
9. FREEZER
10. REFRIGERATOR
11. PERSONAL PROTRECTIVE EQUIPMENT (PPE) CABINET
12. PERSONAL PROTECTIVE EQUIPMENT (PPE)
13. FIRST AID KIT
14. COLD RACK
15. LABORATORY DEEP SINK WITH EYE WASH
16. COMPUTER
17. PASS BOX
18. WASTE BIN
19. LABORATORY STOOL
20. COMPUTER CHAIR
21. HAND WASHING SINK WITH EYE WASH
22. LABORATORY COUNTER
23. MINIFUGE
24. CONVENTIONAL PCR MACHINE
25. STAINLESS STEEL UTILITY SINK
26. SPILL KIT
27. AUTOMATED RNA EXTRACTION MACHINE

NOTE:

THE PROPOSED COVID-19 TESTING LABORATORY SHOULD BE LOCATED IN A SEPARATE LOCATION/ OUTSIDE AN EXISTING INSTITUTION WHERE THERE IS LESS FOOT TRAFFIC FOR THE PROTECTION OF STAFF AND PUBLIC.

GRAPHICAL SCALE:

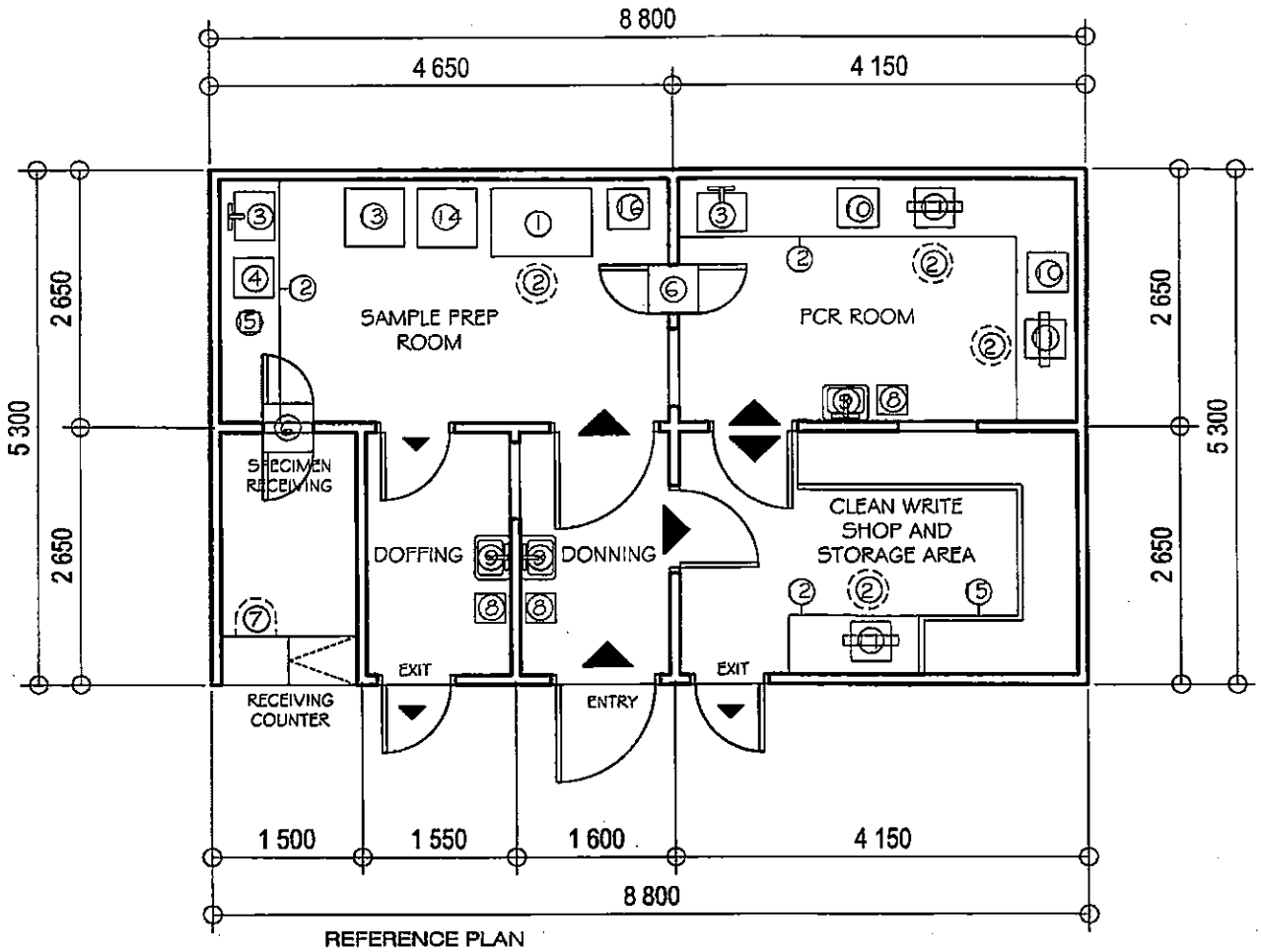
0 0.50 1 2 3 5

Republic of the Philippines
DEPARTMENT OF HEALTH
CENTRAL OFFICE
Rizal Avenue, Sta. Cruz, Manila City

TITLE	NOTED BY:	SHEET NO.
REFERENCE PLAN/ SAMPLE PLAN COVID-19 TESTING LABORATORY	MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV OIC-USEC- HEALTH REGULATIONS TEAM	version 2.0 PRPD BY: HFSRB & RITM

ANNEX D4

A.O. NO. 2020- 0014-A



REFERENCE PLAN

COVID-19 TESTING LABORATORY USING CARTRIDGE-BASED TECHNOLOGY 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

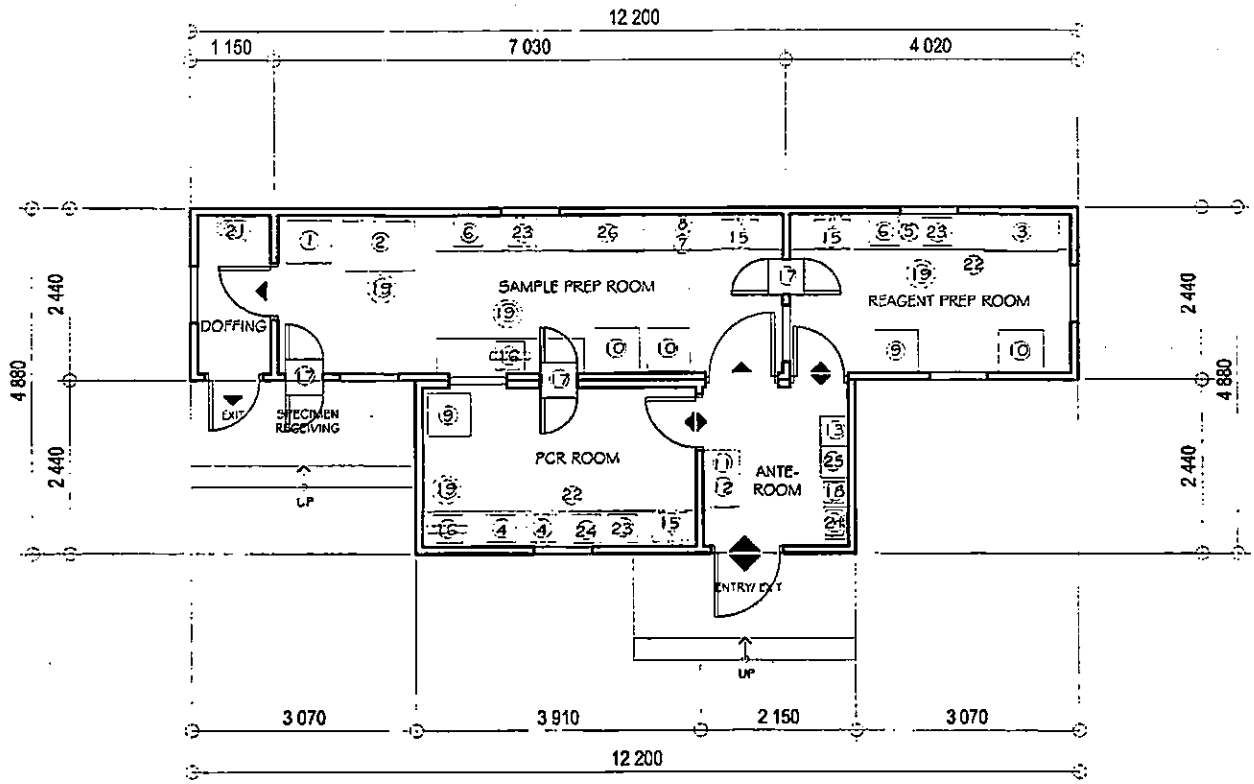
GRAPHICAL SCALE:

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-19 TESTING LABORATORY	NOTED BY: MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV OIC-USEC- HEALTH REGULATIONS TEAM	SHEET NO. VERSION 2 PRPD BY: HFSRB & RITM

ANNEX D5

A.O. NO. 2020- 0014-A



REFERENCE PLAN

COVID-19 POP-UP TESTING LABORATORY

LEGEND

1. AUTOCLAVE
2. BIOLOGICAL SAFETY CABINET (BSC)
3. LAMINAR AIRFLOW (LAF) HOOD
4. REAL TIME POLYMERASE CHAIN REACTION (RT-PCR) MACHINE
5. VORTEX MIXER
6. MICRO CENTRIFUGE
7. PIPPETTORS
8. PIPPETTE FILTERED TIPS
9. FREEZER
10. REFRIGERATOR
11. PERSONAL PROTECTIVE EQUIPMENT (PPE) CABINET
12. PERSONAL PROTECTIVE EQUIPMENT (PPE)
13. FIRST AID KIT
14. COLD RACK
15. LABORATORY DEEP SINK WITH EYE WASH
16. COMPUTER
17. PASS BOX
18. WASTE BIN
19. LABORATORY STOOL
20. COMPUTER CHAIR
21. HAND WASHING SINK WITH EYE WASH
22. LABORATORY COUNTER
23. MINIFUGE
24. CONVENTIONAL PCR MACHINE
25. SPILL KIT
26. AUTOMATED RNA EXTRACTION MACHINE

NOTES:

1. THE PROPOSED COVID-19 TESTING LABORATORY SHOULD BE LOCATED IN A SEPARATE LOCATION/ OUTSIDE AN EXISTING INSTITUTION WHERE THERE IS LESS FOOT TRAFFIC FOR THE PROTECTION OF STAFF AND PUBLIC.
2. THIS PROTOTYPE USES 40 FT AND 20 FT CONTAINER VANS.
3. DATA MANAGEMENT OFFICE, TOILET AND OTHER AMENITIES FOR STAFF CAN BE LOCATED IN A SEPARATE AND EXISTING ADJACENT STRUCTURE.

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-19 TESTING LABORATORY	NOTED BY: MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV OIC-USEC- HEALTH REGULATIONS TEAM	SHEET NO. version 2.0 PRPD BY: HFSRB & RITM

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

Annex D6
A.O. No. 2020- 0014-A

CHECKLIST FOR REVIEW OF FLOOR PLANS
COVID-19 TESTING LABORATORY USING CARTRIDGE BASED TECHNOLOGY

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:

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

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

_____
_____
_____

ANNEX D7

A.O. NO. 2020-0014-A

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-19 TESTING LABORATORY	NOTED BY: MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV OIC-USEC-HEALTH REGULATIONS TEAM	SHEET NO. PRPD BY: HFSRB & RITM