Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

APR 07 2020

ADMINISTRATIVE ORDER
No. 2020 - 0014

SUBJECT : Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines

I. RATIONALE/BACKGROUND

The current pandemic, Coronavirus Disease 2019 (COVID-19), has focused the attention on the scarcity of capable testing facilities. Local data, as of April 1, 2020, showed that there are 227 additional new confirmed cases with positive test results, bringing the number to 2,311 infected cases in the country, with 50 individuals recovering from the disease and 96 deaths reported.

The standard testing procedure for detecting Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19, is the Real Time Reverse Transcriptase – Polymerase Chain Reaction (rRT-PCR) as recommended by the World Health Organization (WHO). Its sensitivity to detect the presence of the virus early on will result in the immediate enforcement of precautionary measures, thus curbing the further transmission of the disease. It is a highly delicate process involving several steps to detect RNA viruses. As such, handling of specimens requires strict adherence to biosafety and biosecurity guidelines by WHO.

There are only few molecular laboratories in the country, and their services include genotyping, identifying mutation defects, deoxyribonucleic acid (DNA) sequencing and paternity testing. However, only the Research Institute for Tropical Medicine (RITM) has the laboratory recognized by the WHO as capable of doing COVID-19 testing.

These guidelines are being issued to set the standards in licensing COVID-19 testing laboratories as a strategy to expand testing capacity, to have more capable laboratories, and at the same time ensuring that quality and safety are maintained.

II. OBJECTIVE

This Order aims to ensure the safety of personnel and the general public, as well as the quality and accuracy of the generated reports of COVID-19 testing laboratories.

III. SCOPE

This Order shall apply to all private and government COVID-19 testing laboratories in the Philippines, whether hospital-based or non-hospital-based.

IV. DEFINITION OF TERMS

1. **Applicant** – an individual, partnership, corporation or association seeking a license to operate to maintain a COVID-19 testing laboratory.
2. **COVID-19 testing laboratory** – a health facility where COVID-19 testing (SARS-CoV-2 detection) is done on specimens from the human body to obtain information about the health status of a patient for the prevention, diagnosis and treatment of disease.
3. **Department of Health-License to Operate (DOH-LTO)** – a formal authorization issued by the DOH through the Health Facilities and Services Regulatory Bureau (HFSRB) to an individual, partnership, corporation or association seeking to perform SARS-CoV-2 detection in a COVID-19 testing laboratory in compliance with the requirements prescribed in this Order.
4. **DOH-Permit to Construct** – a permit issued by DOH through HFSRB to an applicant who will establish and operate a COVID-19 testing laboratory, upon compliance with required documents set forth in this Order prior to actual construction of the said facility. A DOH-PTC is also required for health facility with substantial alteration, expansion, renovation, etc. It is a prerequisite for License to Operate.
5. **Letter of Recommendation** – a formal endorsement issued by RITM or its duly recognized/authorized assessors upon full compliance of the applicant with their requirements, which includes proficiency testing of the laboratory.
6. **Real Time Reverse Transcriptase – Polymerase Chain Reaction (rRT-PCR)** – a PCR test designed to detect, measure and study RNA viruses. It allows a single strand of RNA to be translated into a complementary DNA which will then be amplified following the routine PCR method.

V. IMPLEMENTING MECHANISMS

A. GENERAL GUIDELINES

1. COVID-19 testing shall only be done in a DOH licensed COVID-19 testing laboratory.
2. The DOH-LTO for a COVID-19 testing laboratory shall only be issued upon full compliance to the standards and requirements of RITM and HFSRB/CHD-RLED.
3. The DOH-LTO of a hospital-based COVID-19 testing laboratory shall be subsumed in the LTO of the hospital.
4. For non-hospital-based COVID-19 testing laboratory:
    a. With existing licensed general clinical laboratory – the DOH-LTO of COVID-19 testing laboratory shall be subsumed in the current LTO of the general clinical laboratory.
    b. For facilities with Certificate of Registration by the DOH or without any DOH regulatory authorization – the DOH-LTO of COVID-19 testing laboratory shall be issued as clinical laboratory with limited service capability.
5. The COVID-19 testing laboratory shall be a separate unit, with its own designated working room.
6. Strict adherence to biosafety and biosecurity guidelines, as prescribed by the RITM based on WHO recommendations, shall be strictly enforced.

7. The COVID-19 testing laboratory shall be supervised by a Board Certified Clinical Pathologist, with training in Molecular Laboratory Diagnosis.
8. The staff shall have the appropriate trainings prescribed by RITM.
9. COVID-19 testing laboratories shall have a Manual of Operations, which shall include, but not limited to, the standard operating procedures being implemented in the facility; policies and procedures on biosafety and biosecurity, handling and transporting of specimens; disposal of infectious wastes; Infection Prevention and Control; records management; preventive maintenance of the facility and the equipment; and copies of relevant laws and DOH issuances.
10. COVID-19 testing laboratories shall only use FDA registered testing kits, reagents and devices.
11. COVID-19 testing laboratories shall adhere and ensure strict compliance with infection prevention and control guidelines.
12. COVID-19 testing laboratories shall be strictly prohibited from outsourcing of examinations.
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)"
14. COVID-19 testing laboratories shall follow the standards, criteria and requirements prescribed in the DOH Assessment Tool for Licensing a COVID-19 testing laboratory **(ANNEX A)**, RITM's Biosafety and Laboratory Assessment Tool **(ANNEX B1 and ANNEX B2)**, and accomplish the WHO risk assessment form **(ANNEX C)**.

B. SPECIFIC GUIDELINES

1. CLASSIFICATION OF COVID-19 TESTING LABORATORIES

A. According to Ownership

a) **Government** – created by law. A government facility may be under the national government, DOH, local government unit (LGU), Department of National Defense (DND), Philippine National Police (PNP), Department of Justice (DOJ), State Universities and Colleges (SUCs), Government Owned and Controlled Corporations (GOCCs) and others.

b) **Private** – owned, established and operated with funds through donation, principal, investment or other means by any individual corporation, association or organization. A private health facility may be a single proprietorship, partnership, corporation, cooperative, foundation, religious, non-government organization and others.

B. According to Institutional Character

a) Hospital Based – within the premises or the compound of the hospital. It may be a part of the general clinical laboratory, but with a specific designated room distinct from the main laboratory.

b) Non-hospital-based – located outside the premises or the compound of a hospital and independently functioning on its own.

2. STANDARDS

COVID-19 testing laboratories shall be organized to provide safe, quality and effective and efficient services.

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.
3. The staff shall be proficient on Molecular Diagnostic Techniques.
4. The staff shall undergo fit testing for respirator with at least 95% efficiency e.g. N95 mask.
5. The staff shall have an annual medical examination including influenza vaccination.
6. The staff shall have continuing updated trainings on biosafety and biosecurity, new techniques and technologies, among others.

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.

2. Unidirectional workflow following the abovementioned activities shall be maintained at all times.
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)**
4. Controlled and adequate ventilation with the prescribed air changes per hour shall be maintained for each specific area.
5. Adequate lighting shall be provided in all areas.

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) They shall comply with or have:

1. Required equipment, supplies and reagents are organized and appropriately located in their designated areas.
2. There shall be a documented inventory of equipment, supplies, reagents and control.
3. Periodic calibration and maintenance of equipment are carried out and duly documented.
4. The equipment shall undergo daily cleaning and maintenance.

4. SERVICE CAPABILITY

COVID-19 testing laboratories shall ensure that the services delivered to patients comply with the standards in the Assessment Tool for Licensing a COVID-19 testing laboratory **(ANNEX A)** and other relevant issuances. They must have:

1. Manual of Procedures and Work Instructions on the laboratory techniques.
2. Accomplished WHO Risk Assessment form.
3. Standard Operating Procedures of the facility, which shall include, but not limited to, Policies on Biosafety and Biosecurity; proper use of Personal Protective Equipment; Specimen Storage, Transport and Disposal; Waste Management; Emergency Response System (accidents, medical emergencies, spills, natural disasters, facility containment).
4. A copy (soft or hard copy) of RITM Biorisk Management Office Interim Biosafety Guidelines for Laboratories Handling and Testing SARS-COV-2 (COVID-19) Specimen Version 2 or its latest version.

5. QUALITY IMPROVEMENT ACTIVITIES

COVID-19 testing laboratories shall establish and maintain a system for continuous quality improvement activities, and be able to:

1. Pass the proficiency testing given by RITM prior to its operation.
2. Identify the many potential risks in the laboratory processes and document the recommendations to mitigate such risks.
3. Participate and pass in the National External Quality Assessment Scheme (NEQAS) given by RITM.

6. INFORMATION MANAGEMENT

Every COVID-19 testing laboratory shall maintain a system of communication, recording, reporting and releasing of the patient's results, in adherence to Republic Act (R.A.) No. 10173 also known as the "Data Privacy Act of 2012" **AND** R.A. No. 11332 also known as the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act".

There shall be logbook or record for:

1. Receiving of specimen with laboratory request from the health facility or attending physician.
2. Specimen storage, transport, and disposal.
3. Releasing of results to the DOH Epidemiology Bureau (EB) and DOH Regional Epidemiologic Surveillance Unit (RESU).
4. Sentinel/adverse events.
5. Preventive and corrective maintenance of equipment and instruments.
6. Maintenance and monitoring of health facility.

7. ENVIRONMENTAL MANAGEMENT

COVID-19 testing laboratories shall ensure that the environment is safe for its patients and staff, including the general public.

1. There shall be a written plan and program of proper disinfection and preventive maintenance of the facility.
2. There shall be appropriate signage, and that only authorized personnel shall be allowed entry.
3. The use of Personal Protective Equipment and adherence to Infection Control Policies shall be strictly observed.
4. There shall be procedures for the proper disposal of infectious wastes and toxic and hazardous substances in accordance with R.A. No. 6969 known as "Toxic and Hazardous Substances and Nuclear Wastes Act" and other related policy guidelines and/or issuance (e.g. DOH Healthcare Waste Management Manual).
5. There shall be a Memorandum of Agreement with infectious waste and toxic and hazardous substances hauler.

8. CONTINGENCY PLAN

Every COVID-19 testing laboratory shall have a contingency plan in case of equipment breakdown and shall have a Notarized Memorandum of Agreement (MOA) with another DOH licensed COVID-19 testing laboratory.

1. The COVID-19 testing laboratory shall inform in writing the DOH-HFSRB or CHD-RLED about the temporary suspension of their COVID-19 testing.
2. In case of equipment breakdown during the actual processing of specimens, the sample shall be immediately transported (in strict adherence to the guidelines for specimen handling and transport) to another COVID-19 testing laboratory, which they have a MOA with

3. In the event of machine breakdown, the COVID-19 testing laboratory shall not accept specimens from any patient or referral health facility.
4. The COVID-19 testing laboratory shall inform their clients and refer them to another DOH licensed COVID-19 testing laboratory.
5. Full operation shall be restored within three (3) months.

9. RELEASE OF RESULTS

1. Results shall be signed by the medical technologist who performed the test, verified by a senior technologist, and approved by the pathologist prior to release.
2. Releasing of results shall follow the DOH guidelines.
3. The Laboratory shall submit a linelist of POSITIVE specimens following the linelist format below:

Name of COVID-19 Testing Laboratory:

Date of Report:

LAB ID	PATIENT NAME	AGE	SEX	HEALTH FACILITY	SPECIMEN TYPE	PCR RESULT
COVIDID-XXXX	Dela Cruz, Juan	40	M	Hospital A	NPS/OPS	SARS-CoV-2 viral RNA detected
COVIDID-XXXX	Cruz, Gabriella	60	F	Hospital B	NPS/OPS	SARS-CoV-2 viral RNA detected

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
5. The Laboratory shall submit a linelist of NEGATIVE specimens following the linelist format below:

Name of COVID-19 Testing Laboratory:
Date of Report:

LAB ID	PATIENT NAME	AGE	SEX	HEALTH FACILITY	SPECIMEN TYPE	PCR RESULT
COVIDID-XXXX	Dela Cruz, Juan	40	M	Hospital A	NPS/OPS	SARS-CoV-2 viral RNA not detected
COVIDID-XXXX	Cruz, Gabriella	60	F	Hospital B	NPS/OPS	SARS-CoV-2 viral RNA not detected

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

VI. PROCEDURAL GUIDELINES

1. Licensing Process

a. DOH-Permit to Construct (DOH-PTC)
   1) A DOH –PTC shall be a prerequisite in the application of LTO.
   2) A completely filled out application form shall be submitted to:

a. HFSRB for COVID-19 testing laboratories based in levels 2 and 3 general hospitals, and specialty hospitals;

b. CHD-RLEDs for non-hospital based COVID-19 testing laboratories and for COVID-19 testing laboratories based in level 1 general hospitals.

3) Complete applications (based on A.O. No. 2016-0042, "Guidelines in Securing a DOH-PTC") shall be processed according to the Citizen's Charter timeline.

4) Once approved, the facility owners can commence with the construction of the laboratory.

b. DOH-License to Operate (DOH-LTO)

1) Filing of complete application requirements, whether manual or online, shall be at HFSRB or CHD-RLEDs.
   a. HFSRB for COVID-19 testing laboratories based in levels 2 and 3 general hospitals, and specialty hospitals;
   b. CHD-RLEDs for non-hospital based COVID-19 testing laboratories and for COVID-19 testing laboratories based in level 1 general hospitals.

2) Complete documentary requirements shall consist of the following:
   a. Notarized completely accomplished application form (ANNEX E);
   b. A copy of approved DOH-PTC and floor plan;
   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;
   d. List of equipment with specifications, reagents, and supplies;
   e. Copy of Certificate of Product Registration (CPR) from Food and Drug Administration for all equipment, reagents and supplies;
   f. Accomplished Self-Assessment Tool for Licensing a COVID-19 testing laboratory;
   g. For renewal, a copy of NEQAS, Certificate of Performance with PASSING results, conducted by RITM.

3) After evaluation of the submitted documents for technical completeness and correctness, the assigned team from HFSRB/CHD-RLED shall schedule an inspection date, in coordination with the team from RITM or its duly recognized/authorized 3rd party assessors.

4) Process for Inspection (initial or renewal) shall follow Section VI. E and F of A.O. No. 2012-0012, known as "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines" and the Quality Management System (QMS) guidelines of the Bureau.

5) RITM or its duly recognized/authorized 3rd party assessors shall transmit to HFSRB/CHD-RLED a Letter of Recommendation when the facility is fully compliant to the standards and requirements of RITM.

6) The DOH-LTO a COVID-19 testing laboratory shall be issued only after full compliance to the standards and requirements by HFSRB/CHD-RLED and the RITM.

7) The DOH-LTO shall be signed by the Director IV of HFSRB or CHD-RLED.

8) Processing from application to issuance of DOH-LTO shall be according to the Citizen's Charter Timeline.

2. Validity of DOH-LTO

The DOH-LTO, for both hospital-based and non-hospital-based COVID-19 testing laboratory, shall be valid for one (1) year. Annual renewal of DOH-LTO COVID-19 testing laboratory shall follow the annual cut-off dates as prescribed in A.O. no. 2019-0004 dated April 30, 2019, titled "Guidelines on the Annual Cut-off Dates for Receipt of Complete Applications for Regulatory Authorizations Issued by the Department of Health."

3. Monitoring

HFSRB/CHD-RLED together with RITM or its duly recognized/authorized 3rd party assessors may conduct unannounced visits to ensure continuous compliance to the standards.

4. Fees

1. The DOH-LTO fee shall follow the schedule of fees currently prescribed by the DOH.
2. The applicant, upon filing the application, shall pay the corresponding fee to the DOH Cashier/RO Cashier.

VII. ROLES AND RESPONSIBILITIES

1. Health Facilities and Services and Regulatory Bureau

a. To strictly enforce the provisions of this Order.

b. To set standards for the regulation of health facilities including COVID-19 testing laboratories.

c. To create/modify inspection and monitoring tools from time to time.

d. To disseminate regulatory policies, standards and forms for information and guidelines to the DOH-CHDs.

e. To provide consultation and technical assistance to stakeholder, including regulatory officers from the DOH-CHDs in regulation of COVID-19 testing laboratories.

f. To inspect and issue DOH-LTO for COVID-19 testing laboratories based in levels 2 and 3 general hospitals, and specialty hospitals.

g. To conduct unannounced monitoring visits to check for continuous compliance of DOH-LTO.

h. To promptly respond to complaints relative to the operation of COVID-19 testing laboratories.

2. Research Institute of Tropical Medicine (RITM) – the reference laboratory for COVID-19 testing recognized by the World Health Organization (WHO)

a. To provide laboratory reference / referral services for COVID-19.

b. To train laboratory personnel.

c. To maintain quality assurance program for COVID-19 testing laboratories through proficiency testing.

d. To perform technical evaluation of reagents and diagnostic kit.

e. To train & authorize 3rd party trainer and/or assessors.

3. **Center for Health Development – Regulation, Licensing, and Enforcement Division (CHD-RLED)**
   a. To strictly enforce the provisions of this Order.
   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.
   c. To conduct unannounced monitoring visits to check for continuous compliance of COVID-19 testing laboratories.
   d. To submit report on Suspension/Revocation/Cease and Desist Order issued on COVID-19 testing laboratories as soon as possible.
   e. To promptly respond to complaints relative to the operation of COVID-19 testing laboratories.
4. **Epidemiology Bureau and its Regional Epidemiology Surveillance Units**
   a. Collect and aggregate data from COVID-19 testing laboratories.
   b. Analyze and report data collected from COVID-19 testing laboratories.

VIII. TRANSITORY PROVISIONS

In view of the urgency of the need for more COVID 19 testing laboratories:

a) The DOH-PTC application shall be waived for existing facilities and shall submit an as built floor plan, in lieu of the DOH-PTC which reflects the workflow on the prototype reference plan.
b) All initial application shall be submitted to HFSRB whether hospital-based or non-hospital-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.
c) The technical assistance done by DOH, RITM or its duly recognized/authorized 3rd party assessors may serve as the initial inspection visit. As such, compliance to the recommendations done then and to the Assessment Tool for licensing a COVID-19 testing laboratory may preclude another visit prior to the issuance of DOH-LTO. A re-visit may be done by the team, if so warranted.
d) The laboratories already assessed by the team from HFSRB/CHD-RLEDs are advised to apply for a DOH-LTO, using these guidelines as reference.
e) Team to conduct inspection or monitoring shall come from HFSRB and RITM or its duly recognized/authorized 3rd party assessors.

IX. VIOLATION AND SANCTIONS

COVID-19 testing laboratories and/or the responsible personnel thereof, found to be violating any provision of these rules and regulations, related issuances, and other applicable policy guidelines, shall be penalized under the existing laws, which may include suspension or revocation of DOH-LTO.

X. APPEAL

Any hospital or health facility aggrieved by the decision of the Director IV of HFSRB, or in his/her absence or unavailability or when delegated, the Director III of HFSRB, may, within ten (10) days after receipt of the notice of decision, file a notice of appeal to the head of the Health Regulation Team (HRT). All pertinent documents and records of the applicant shall then be elevated by the HFSRB to the HRT. The

decision of the head of the HRT, if still contested, maybe brought on a final appeal to the Secretary of Health whose decision shall be absolute and executory.

XI. REPEALING CLAUSE

Previous issuances or any of their provisions which are inconsistent or contrary to the provisions of this issuance 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

CERTIFIED TRUE COPY
APR 15 2020
CORAZON S. DELA CRUZ
KMITS - RECORDS SECTION
Department of Health

A.O. No. 2020 - 0014
ANNEX A

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 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 (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		

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		

PART II
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
- ☐ 4^0C refrigerator for reagents
- ☐ -20^0C freezer for reagents
- ☐ Microcentrifuge
- ☐ Vortex mixer
- ☐ Minifuge
- ☐ Cold rack for PCR tube
- ☐ Set of four adjustable-volume micropippettes with rack:100-1000 l, 20-200 ul, 2-20 ul, and 0.5-10ul
- ☐ Micropipette tips
- ☐ Gloves (different size: S,M,L)

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
- ☐ 4^0C refrigerator with -20^0C for specimens
- ☐ 4^0C refrigerator with -20^0C for nucleic acid extracts
- ☐ Microcentrifuge
- ☐ Vortex mixer
- ☐ Minifuge
- ☐ Computer and printer for accessioning
- ☐ Cold rack for PCR tube
- ☐ Set of four adjustable-volume micropippettes with rack:100-1000 l, 20-200 ul,
- ☐ 2-20 ul, and 0.5-10ul
- ☐ Micropipette tips
- ☐ Gloves (different size: S, M, L)

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:

- ☐ Real-time PCR machine
- ☐ Conventional PCR machine
- ☐ Minifuge
- ☐ Computer and printer (associated with the Real-time PCR machine)
- ☐ -20^0C or -40^0C freezer for storage of PCR products

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: _____

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ANNEX B1

COVID-19 TESTING LABORATORY
LABORATORY ASSESSMENT TOOL

I. PARTICIPANT'S INFORMATION	
NAME OF PARTICIPANT First Name, MI, Surname	
SECTION	
DESIGNATION	
POSITION	

II. EVALUATOR'S INFORMATION	
NAME OF EVALUATOR First Name, MI, Surname	
SECTION	
DESIGNATION	
POSITION	

III. DETAILS OF ASSESSMENT	
START DATE (dd-mmm-yyyy)	
END DATE (dd-mmm-yyyy)	
NAME/S OF PROCEDURE/S (SM's and WI's	

IV. SCORING GUIDE PER KEY AREA			
1	Requirement met/Present/With complete evidence	0	Requirement not met/Absent
0.5	Requirement partially met/incomplete evidence of compliance (Use Remarks column	N/A	Not applicable

	ITEM	SCORE	REMARKS
1	FACILITIES AND WORKFLOW		
1.1			
1.1.1	Design and location of the facility appropriate to the laboratory needs		
1.1.2	Sufficient space is available to conduct testing activities (specimen reception and handling, PCR testing)		
1.1.3	Space is used efficiently with appropriate equipment		
1.1.4	Space is clean and well-organized		
1.1.5	Laboratory environment ensures safety to the work and the worker		
1.1.6	Laboratory has back up electrical power supply in the event of power failure		
1.2			
1.2.1	Dedicated space, equipment and consumables for specimen reception and handling		
1.2.2	Dedicated space, equipment and consumables for nucleic acid extraction		
1.2.3	Dedicated space, equipment and consumables for reagent storage and handling activities		
1.2.4	Dedicated space, equipment and consumables for clerical activities (data encoding, result generation, reporting)		
1.2.5	Work is carried out in a unidirectional workflow (from clean to dirty)		
1.3			
1.3.1	Mechanism for access restriction to authorized personnel is in place		
1.3.2	Minimum required signages are posted on the laboratory doors (i.e. nature of work being performed in the room, biohazard sign if applicable)		
	Raw Score		
	Average Score		
2	PERSONNEL REQUIREMENTS		
2.1			
2.1.1	Lines of supervision and accountability relevant to Molecular Detection of Respiratory viruses are clear to all staff		
2.1.2	Laboratory top management ensures that laboratory facilities are adequate to conduct Molecular Detection of Respiratory viruses		
2.1.3	Evidence available to show regular meetings with staff are held to discuss operational issues		
2.1.4	Evidence available to show laboratory supervisor critically reviews test worksheets and results for accuracy and completeness, and indicate need for follow-up actions		
2.1.5	Laboratory supervisor ensures that sufficient supplies, reagents and functional equipment are available to handle the laboratory's workload		
2.1.6	Laboratory supervisor ensures that raw data are recorded, results fully-documented and reported		
2.1.7	Arrangements are made for qualified back-up staff to sustain services during scheduled staff absences (eg. Vacation, study, maternity or paternity leave)		
2.2			
2.2.1	Staff with appropriate educational background for the position		
2.2.2	Documentation on staff of qualifications, training, experience and job descriptions filed accordingly		
2.2.3	Technical laboratory staff with valid license (if applicable)		
2.3			
2.3.1	Laboratory supervisor and staff with orientation on Molecular Detection of Respiratory viruses		
2.3.2	Laboratory supervisor and staff with training on Biosafety		
2.3.3	Laboratory staff with training on the Molecular Detection of Respiratory viruses		
2.3.4	Manual of Procedures and Laboratory Work Instructions are on file and accessible to all staff		
2.4			
2.4.1	Laboratory with proof of proficiency for PCR detection of respiratory viruses		
2.5			
2.5.1	Laboratory has identified a processing schedule (for specimen collection/handling, PCR testing, result reporting)		
2.5.2	Workload is commensurate to the number of staff		
	Raw Score		
	Average Score		
3	ASSAY REQUIREMENTS		
3.1			
3.1.1	System for inventory management is available (includes warning system for expiry and stock replenishment)		
3.1.2	Adequate time is allowed for replenishment of reagents and supplies		
3.1.3	Procurement planning system in place accounts for estimated delays, reagent expiry, etc. to ensure continuous supply of materials and reagents		
3.1.4	Reagents and supplies on stock are appropriate according to laboratory protocol requirements		
3.1.5	Reagents labelled appropriately with the identity, concentration, date of preparation, date of opening and expiry, storage conditions and name of person who prepared		
3.1.6	Reagents and supplies stored under appropriate conditions (eg. Temperature, humidity, light, containment)		
3.1.7	Storage area of reagents separate from that of specimens to avoid contamination		
3.2			
3.2.1	Controls are aliquoted to working volumes		
3.2.2	Controls are stored under proper storage conditions (separate from clinical specimens, -20°C)		
3.2.3	Non-conformances relevant to controls are documented and acted upon		
3.3			
3.3.1	Documentation system for acceptance and rejection of specimens is present		
3.3.2	Specimens are stored in dedicated compartments (e.g. unaliquoted specimens, aliquoted specimens for testing)		
3.3.3	A system for specimen tracking and archiving is present (traceability)		
3.3.4	Access to specimen storage area is restricted to authorized personnel		
3.3.5	Supporting documents (Request forms or tracking forms) accompany the specimen and are stored in a secure manner		
3.4			
3.4.1	Biosafety cabinet for specimen inactivation/aliquoting/inactivation/nucleic acid extraction		
3.4.2	Vortex mixer		
3.4.3	Microcentrifuge (2mL rotor capacity)		
3.4.4	Variable volume pipettors		
3.4.5	Real-time PCR machine		
3.4.6	An equipment inventory system/management is maintained		
3.4.7	All critical equipment are certified/calibrated periodically as appropriate, and record's are available		
3.4.8	Temperature of storage compartments (freezer, refrigerator) is being monitored		
3.4.9	All equipment appropriately located to ensure safety		
3.4.10	Equipment are cleaned and maintained well by the laboratory staff		
3.5			
3.5.1	Secure and safe place available for archiving raw data, documents and reports		
3.5.2	Access to laboratory data is restricted to authorized personnel only		
	Raw Score		
	Average Score		
4	QUALITY CONTROL		
4.1			
4.1.1	Reagents are pre-tested prior to routine use		
4.2			
4.2.2	Controls are pre-tested prior to routine use		
4.2.3	Performance of controls are monitored every run		
4.3			
4.3.1	Verification system for detection of errors in laboratory data encoding is in place		
4.3.2	Verification system for monitoring PCR run validity is in place		
4.3.3	Mechanism for ensuring invalid runs are investigated and repeated (according to analysis of probable cause of error) is in place		
4.3.4	Verification system for review of results prior to release is in place		
	Raw Score		
	Average Score		

FINAL RATING		
1	Facilities and Workflow	0
2	Personnel Requirements	0
3	Assay Requirements	0
4	Quality Control	0
	TOTAL	0

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ANNEX B2

COVID-19 TESTING LABORATORY
LABORATORY BIOSAFETY ASSESSMENT TOOL

I. PARTICIPANT'S INFORMATION	
NAME OF PARTICIPANT First Name, MI, Surname	
SECTION	
DESIGNATION	
POSITION	

II. EVALUATOR'S INFORMATION	
NAME OF EVALUATOR First Name, MI, Surname	
SECTION	
DESIGNATION	
POSITION	

III. DETAILS OF ASSESSMENT	
START DATE (dd-mmm-yyyy)	
END DATE (dd-mmm-yyyy)	
NAME/S OF PROCEDURE/S (PMs and WIs	

IV. SCORING GUIDE PER KEY AREA			
1	Requirement met/Present/With complete evidence	0	Requirement not met/Absent
0.5	Requirement partially met/Incomplete evidence of compliance (Use Remarks column to write down comments)	N/A	Not applicable

	ITEM	SCORE	REMARKS
1. Prior to conducting laboratory task			
1.1.	Laboratory personnel received appropriate immunization (e.g. Influenza)		
1.2.	Laboratory personnel has participated in biosafety courses (e.g. orientation/short training courses).		
1.3.	Laboratory personnel are proficient and trained to work with infectious agents.		
2. The following practices are prohibited in the laboratory:			
2.1.	Eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing food in lab areas		
2.2.	Use of open-toed shoes		
2.3.	Sniffing in vitro cultures or mouth pipetting		
2.4.	Use of plants or animals in the laboratory		
2.5.	Use of carpets, rugs, or fabric covered chairs in laboratory		
2.6.	Presence of children/minors within working areas		
3. Standard Practices			
3.1.	Personnel practices proper handwashing technique before and after working with potentially hazardous materials.		
3.2.	Use and unnecessary manipulation of sharps and glasswares are minimized		
3.3.	Use of puncture-resistant containers for sharps disposal		
3.4.	Use of appropriate disinfectant		
3.5.	Potentially infectious materials are decontaminated before disposal, using appropriate chemical disinfectant and/ or autoclave.		
3.6.	Laboratory traffic proceeds from areas of lower contamination (i.e., clean) to areas of higher contamination (i.e., dirty) should be established and followed		
3.7.	Gloves are changed when contaminated, integrity has been compromised, or when otherwise necessary.		
3.8.	Disposable gloves and other PPE are not washed or reused.		
3.9.	PPE are not worn outside the laboratory.		
4. Special Practices			
4.1.	Potentially infectious materials are placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.		
4.2.	All procedures involving the manipulation of infectious materials that may generate an aerosol are conducted within a BSC or other physical containment devices.These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, and harvesting infected tissues		
4.3.	Collecting samples, adding materials, or transferring culture fluids from one closed system to another are performed in a manner that prevents the release of aerosols or the contamination of exposed surfaces.		
4.4.	Centrifugation of infectious material where inhalation is the primary route of infection are carried out in sealed safety cups (or rotors) that are unloaded in a BSC.		
4.5.	Protective clothing appropriately disposed or laundered within the institution. Laboratory clothing are not taken home by employees for cleaning.		
4.6.	Gloves are not worn outside the laboratory except for some instances that require the use of gloves.		
5. Use of Personal Protective Equipment			
5.1.	Appropriate and dedicated PPE exclusively worn and stored specifically in each containment zone		
5.2.	Dedicated footwear are used and available		
5.3.	Gloves are worn when handling infectious material.		
5.4.	Protective laboratory coats, gowns, smocks, aprons or scrub suits designated for laboratory used inside the laboratory		
5.5.	Eye and face protection (goggles, mask, face shield or other splatter guard) are used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device		
5.6.	Availability of Respirator (N95, N100, P100 and PAPR)		
5.7.	All at risk personnel exposed to any potential aerosol in the laboratory passed Respirator Fit Test		
5.8.	Laboratory provides appropriate PPE size		
5.9.	PPEs available are durable and of good quality.		
6. Use of Laboratory Safety Equipment (Primary Barrier)			
6.1.	Certified BSCs are provided and used based on risk assessment.		
6.2.	BSCs are installed in correct location (away from high traffic areas, doors, openable windows, and air supply/exhaust diffusers) and should be free from obstruction.		
7. Laboratory Access			
7.1.	Access to containment zone is limited to authorized personnel.		
8. Laboratory Facility Design			
8.1.	Laboratory has a sink for hand washing.		
8.2.	Emergency eyewash and shower equipment provided inside the laboratory based on risk assessment		
8.3.	Ample space provided for the safe conduct of laboratory work and for cleaning and maintenance.		
8.4.	Dedicated facility for non laboratory activities (e.g.meeting, meal break)		
8.5.	Autoclave or other means of decontamination available preferably in close proximity to the laboratory.		
8.6.	First-aid kit and spill kit readily accessible		
9. Administrative Control and Oversight			
9.1.	Laboratory-Specific Biosafety Manual available and accessible for all		
9.2.	Laboratory has documented local (biological) risk assessment		
9.3.	Procedures / guidelines for safe and secure transport of waste from laboratory to designated storage / decontamination area		
9.4.	Restriction of work with infectious material and high risk laboratory procedures		
9.5.	A laboratory signage is posted and incorporates other information including the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and specific entry/exit requirements (vaccination, PPE).		
9.6.	Personnel health services program (medical surveillance, immunization)		
9.7.	There is a established Emergency Response System for:		
9.7.1.	Accidents/Incidents		
9.7.2.	Medical Emergencies		
9.7.3.	Spills		
9.7.4	Natural Disasters		
9.7.5	Facility/Containment Device		
10. Records and Documentation			
10.1.	Records of the following are kept on file:		
10.1.1.	Building and equipment maintenance, repair, inspection, testing, calibrations or certification, including performance verification and testing records		
10.1.2.	Validation and routine verification of decontamination technologies and processes		
10.1.3.	Training, proficiency, license, permits of laboratory staff		
10.1.4.	Incident reports, accidents, incidents and related investigations conducted		
10.1.5	Updated inventory and record of specimens, isolates, including biological materials transaction		

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ANNEX C

Annex 2 Risk assessment template

Although a qualitative approach to combining likelihood and severity parameters in a risk matrix is provided as a risk evaluation method here, it is important to note that quantitative (for example, simple numerical scoring schemes to complex mathematical models) and hybrid (semi-quantitative) methods can also be used for risk evaluation. Laboratories should use a risk evaluation/assessment method that best meets their unique needs, without excluding the possibility of developing customized evaluation approaches, scoring methods and definitions of the parameters.

While this template was primarily developed for biosafety risk assessment, it can also be used for general safety risk assessment of laboratory activities, especially when the biosafety and general safety risks are interlinked, for example, sample collection and transport, where appropriate and applicable.

Institution/Facility name	
Laboratory name	
Laboratory manager/Supervisor	
Project titles/Relevant standard operating procedures (SOPs)	
Date	

If using this template, complete all sections following the instructions in the grey boxes. The instructions and bullet points in the grey boxes can be copied into the text boxes beneath the instructions and used as prompts to gather and record the necessary site-specific information. The grey instruction boxes can then be deleted, and the text remaining will form a risk assessment draft. This draft must be carefully reviewed, edited as necessary and approved by the risk assessment team members.

STEP 1. Gather information (hazard identification)

Instructions: Provide a brief overview of the laboratory work and summarize the laboratory activities to be conducted that are included in the scope of this risk assessment.	
Describe the biological agents and other potential hazards (for example, transmission, infectious dose, treatment/preventive measures, pathogenicity).	
Describe the laboratory procedures to be used (for example, culturing, centrifugation, work with sharps, waste handling, frequency of performing the laboratory activity).	
Describe the types of equipment to be used (personal protective equipment (PPE), centrifuges, autoclaves, biological safety cabinets (BSCs)).	
Describe the type and condition of the facility where work is conducted.	
Describe relevant human factors (for example, competency, training, experience and attitude of personnel).	

Describe any other factors that may affect laboratory operations (for example, legal, cultural, socioeconomic).	

STEP 2. Evaluate the risks

Instructions: Describe how exposure and/or release could occur.	
What potential situations are there in which exposure or release could occur?	
What is the likelihood of an exposure/release occurring? x Unlikely: not very possible to occur in the near future x Possible: feasible to occur in the near future x Likely: very possible to occur in the near future	
What is the severity of the consequences of an exposure/release (negligible, moderate, severe)?	

Instructions: Evaluate the risk and prioritize the implementation of risk control measures. Circle the initial (inherent) risk of the laboratory activities before additional risk control measures have been put in place.
Note:

- x *When assigning priority, other factors may need to be considered, for example, urgency, feasibility/sustainability of risk control measures, delivery and installation time and training availability.*
- x *To estimate the overall risk, take into consideration the risk ratings for the individual laboratory activities/procedures, separately or collectively as appropriate for the laboratory.*

		Likelihood of exposure/release		
		Unlikely	Possible	Likely
Consequence of exposure/release	Severe	Medium	High	[redacted]
	Moderate	Low	Medium	High
	Negligible	[redacted]	Low	Medium

Laboratory activity/procedure	**Initial risk (very low, low, medium, high, very high)**	**Is the initial risk above the tolerance level? (yes/no)**	**Priority (high/medium/low)**

Select the overall **initial** risk.	[redacted]	☒ Low	☐ Medium	☐ High	[redacted]
Should work proceed without additional risk control measures?	☐Yes ☐No			

STEP 3. Develop a risk control strategy

Instructions: *List any requirements that have been prescribed by international and national regulations, legislation, guidelines, policies and strategies on biosafety and biosecurity.*	
Describe the measures required by national legislation or regulations (if any).	
Describe the measures advised by guidelines, policies and strategies (if any).	

Instructions: Describe the resources available for risk control and consider their applicability, availability and sustainability in the local context including management support.	
Are resources sufficient to secure and maintain potential risk control measures?	
What factors exist that may limit or restrict any of the risk control measures?	
Will work be able to proceed without any of the risk control measures; are there alternatives?	

STEP 4. Select and implement risk control measures

Instructions: Describe where and when risk control measures are needed, the level of ***residual*** *(remaining) risk when these risk control measures are in place, and an assessment of the availability, effectiveness and sustainability of the risk control measures.*

Laboratory activity/procedure	**Selected risk control measure(s)**	**Residual risk (very low, low, medium, high, very high)**	**Is the residual risk above the tolerance level? (yes/no)**	**Are risk control measures available, effective and sustainable? (yes/no)**

*Instructions: Evaluate the **residual** risk that remains after risk control measures have been selected to determine if that level of risk is now below the tolerance level and whether work should proceed. Circle the **residual** risk of the laboratory activities after risk control measures are in place.*

		Likelihood of exposure/release		
		Unlikely	Possible	Likely
Consequence of exposure/release	Severe	Medium	High	[redacted]
	Moderate	[redacted]	Medium	High
	Negligible	[redacted]	[redacted]	Medium

Overall **residual** risk:	[redacted]	☐ Low	☐ Medium	☐ High	[redacted]

If the residual risk is still above the risk tolerance level, further action is necessary such as additional risk control measures, based on the initial risk evaluated in STEP 2, redefining the scope of work such that it falls below the risk tolerance level with existing risk control measures in place or identifying an alternative laboratory with appropriate risk control strategies already in place that is capable of conducting the work as planned.

Should work proceed with selected risk control measures?	☐Yes ☐No
Approved by (Name and title)	
Approved by (Signature)	
Date	

Instructions: Describe how to communicate risks and risk mitigation strategies to personnel. Provide a mechanism of communication within the laboratory. Describe the process and timeline for ensuring that all identified risk control measures are purchased, have associated SOPs and training has been completed before starting the laboratory work.

Communication of the hazards, risks and risk control measures	
Purchase (and budgeting) of risk control measures	
Operational and maintenance procedures	
Training of personnel	

STEP 5. Review risks and risk control measures

Instructions: Establish a periodic review cycle to identify: changes in laboratory activities, biological agents, personnel, equipment or facilities; changes in knowledge of biological agents or processes; and lessons learnt from audits/inspections, personnel feedback, incidents and/or near misses.

Frequency of the review	
Person to conduct the review	
Describe updates/changes	

Personnel/procedures to implement the changes	
Reviewed by (Name and title)	
Reviewed by (Signature)	
Date	

5. Acknowledgements

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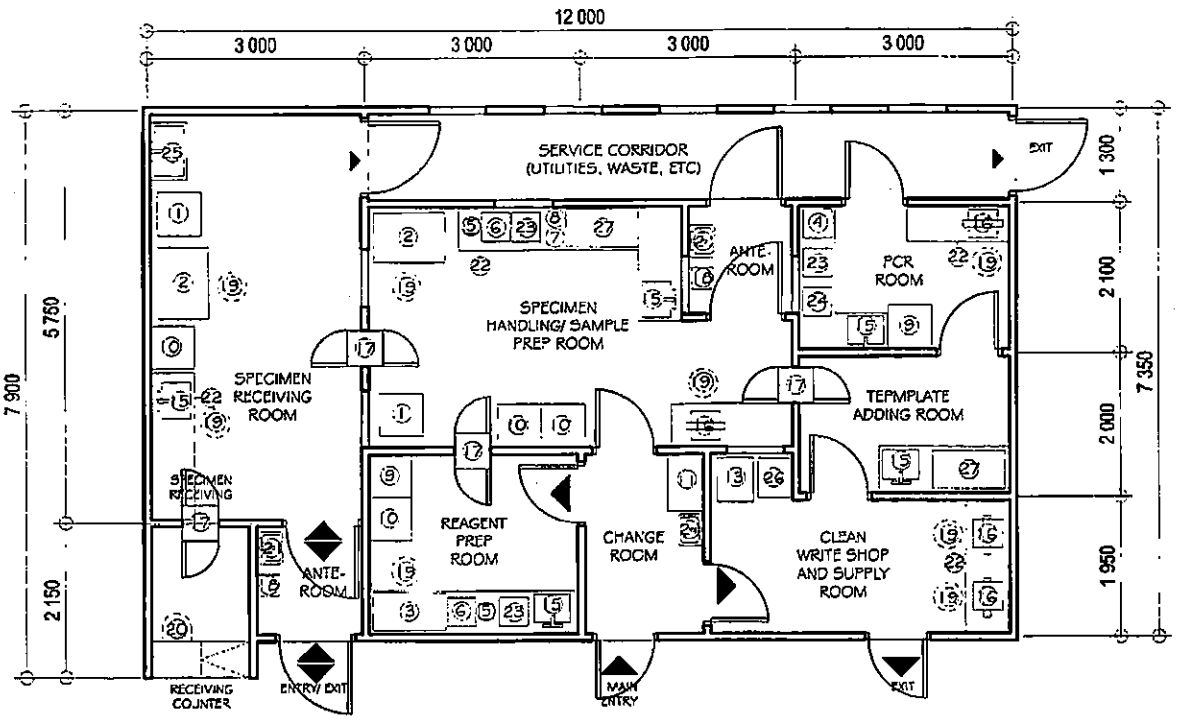
WHO reference number: WHO/WPE/GIH/2020.1

ANNEX D1

A.O. NO. 2020- 0014



REFERENCE PLAN

FREE-STANDING COVID-19 TESTING LABORATORY USING RT-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) CABINET
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 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 3.0 PRPD BY: HFSRB & RITM

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.

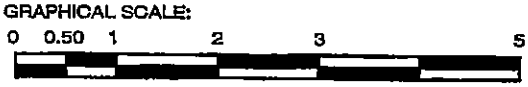
CODES

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:



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
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Annex D2
A.O. No. 2020-0014

CHECKLIST FOR REVIEW OF FLOOR PLANS
COVID-19 TESTING LABORATORY USING RT-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 **PCR Room**
  - _____ 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
  - _____ 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

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

_____
_____
_____

A.O. No. 2020-0014
ANNEX E

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

APPLICATION FOR LICENSE TO OPERATE COVID-19 TESTING LABORATORY

Name of Laboratory : _____

Address of Laboratory :

_____
No. & Street Barangay

_____
City/ Municipality Province Region

Telephone/ Fax No. : _____

Head of the Laboratory : _____

Name of Owner : _____

Contact Number : _____

License No. (if applicable) : _____

Date Issued : _____

Expiry Date : _____

[ ] Initial [ ] Renewal

Classification According to

Ownership : [ ] Government [ ] Private

Institutional Character : [ ] Hospital-based [ ] Non-hospital-based

Service Capability : [ ] Add-on service to General Clinical Laboratory
: [ ] Limited Service Capability to COVID-19 Testing

Checklist of Application Documents

A **Documents**	B **Please put (✔)**
1. DOH Approved PTC and floor plan	
2. Notarized list of personnel, including photocopies of valid PRC identification card. (ANNEX A)	
3. List of equipment with specifications, reagents, and supplies (ANNEX B)	
4. Copy of Certificate of Product Registration (CPR) from Food and Drug Administration of all equipment and reagents.	
5. Technical Procedure Manual or Manual of Operations for COVID-19 testing	
6. For renewal, a copy of NEQAS, Certificate of Performance with PASSING results, conducted by RITM.	

_____ _____
Name and Signature of Applicant **Date of Application**

Acknowledgement

REPUBLIC OF THE PHILIPPINES)
CITY/ MUNICIPALITY OF _____) S.S.

I, _____, _____, of legal age, _____, a resident of
Name *Civil Status* *Age*
_____, after having been sworn in accordance with law
Address
hereby depose and say that I am executing this affidavit to attest to the completeness and truth of the foregoing information and the attached documents required for the establishment/operation of health facility pursuant to existing rules and regulations. That the undersigned is aware and informed that any misrepresentation, falsification/deception herein can cause the denial of my application.

_____
Signature

Before me, this _____ day of _____ 20 in the City/Municipality of _____, Philippines, personally appeared the above affiant with Community Tax Certificate No. _____ issued on _____ at _____, Known to me to be the same person/s who executed the foregoing instrument and they acknowledge to me that the same is their free act and deed.

Owner *Community Tax Number* *Issued at/ on*

_____ _____ _____

known to me to be the same person/s who executed the foregoing instrument and they acknowledge to me that the same is their free act and deed.

IN WITNESS WHEREOF, I have hereunto set my hands this _____day of _____, 20___

Doc No. _____
Page No. _____
Book No. _____
Series of _____

NOTARY PUBLIC
My Commission Expires
Dec. 31, 20 ____

Annex A

List of Personnel

Name of Laboratory : _____

Address of Laboratory : _____

Name	Designation/ Position	Company I.D. No.	PRC Reg. No.	Valid		Date of Birth (mm/dd/yr)	Signature
				From	To		

Annex B

List of Equipment, Supplies, and Reagents

Name of Laboratory : _____

Address of Laboratory : _____

Type of Equipment Supplies, and Reagents	Manufacturer	Serial No. / Lot No.	Expiration Date