Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 0 8 2020

ADMINISTRATIVE ORDER
No. 2020 - 0014-B

SUBJECT : Amendment to the Administrative Order No. 2020-0014-A "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 (DOH) issued 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", and its Amendment last May 20, 2020, to ensure that the standards for the maintenance of safety for both personnel and the general public and for the quality of the generated test results are complied with at all times.

The regulation of COVID-19 testing laboratories continues to evolve with the introduction of innovative diagnostic platforms. As the number of licensed Covid-19 testing laboratories increases, the Assessment Team from the Health Facilities and Regulatory Bureau (HFSRB) and the Research Institute for Tropical Medicine (RITM) made several recommendations and improvements to the current requirements for the strict implementation of biosafety and biosecurity protocols. Likewise, modification in the reporting system was developed for a timely and accurate reporting.

Hence, the following provisions are being amended to incorporate the changes:

-XXX-

Under Section V.B.2.B.3.
B. PHYSICAL FACILITIES
-XXX-

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

-XXX-

The aforementioned provision is hereby amended as follows:

-XXX-

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

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KMITS - RECORDS SECTION
Department of Health

1) **ANNEX D1 Version 3 – Revised Prototype Floor Plan for COVID-19 laboratories performing manual RNA extraction**

-XXX-

The following statement shall be inserted as items (5):

5) **ANNEX D8 – alternate prototype for COVID-19 laboratories performing Cartridge-based technology**

-XXX-

Under Section V.B.3.

-XXX-

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).

-XXX-

The aforementioned is hereby amended to read as follows:

-XXX-

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 – **Revision 02** (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 – **Revision 02** (Assessment Tool for Licensing a COVID 19 testing laboratory using the cartridge-based technology to detect SARS-CoV-2)

-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. 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)

9

-XXX-

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)

-XXX-

The aforementioned provisions are hereby amended to read as follows:

-XXX-

4. **Completely accomplished Case Investigation Forms (CIF) and linelist of positive and negative results shall be immediately encoded to the digital platform recommended by the DOH, such as but not limited to, COVID KAYA, COVID Document Repository System (CDRS), etc.**

-XXX-

Item 6 shall be deleted.

-XXX-

XI. REPEALING CLAUSE

All other provisions of Administrative Order No. 2020-0014 and its amendment 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

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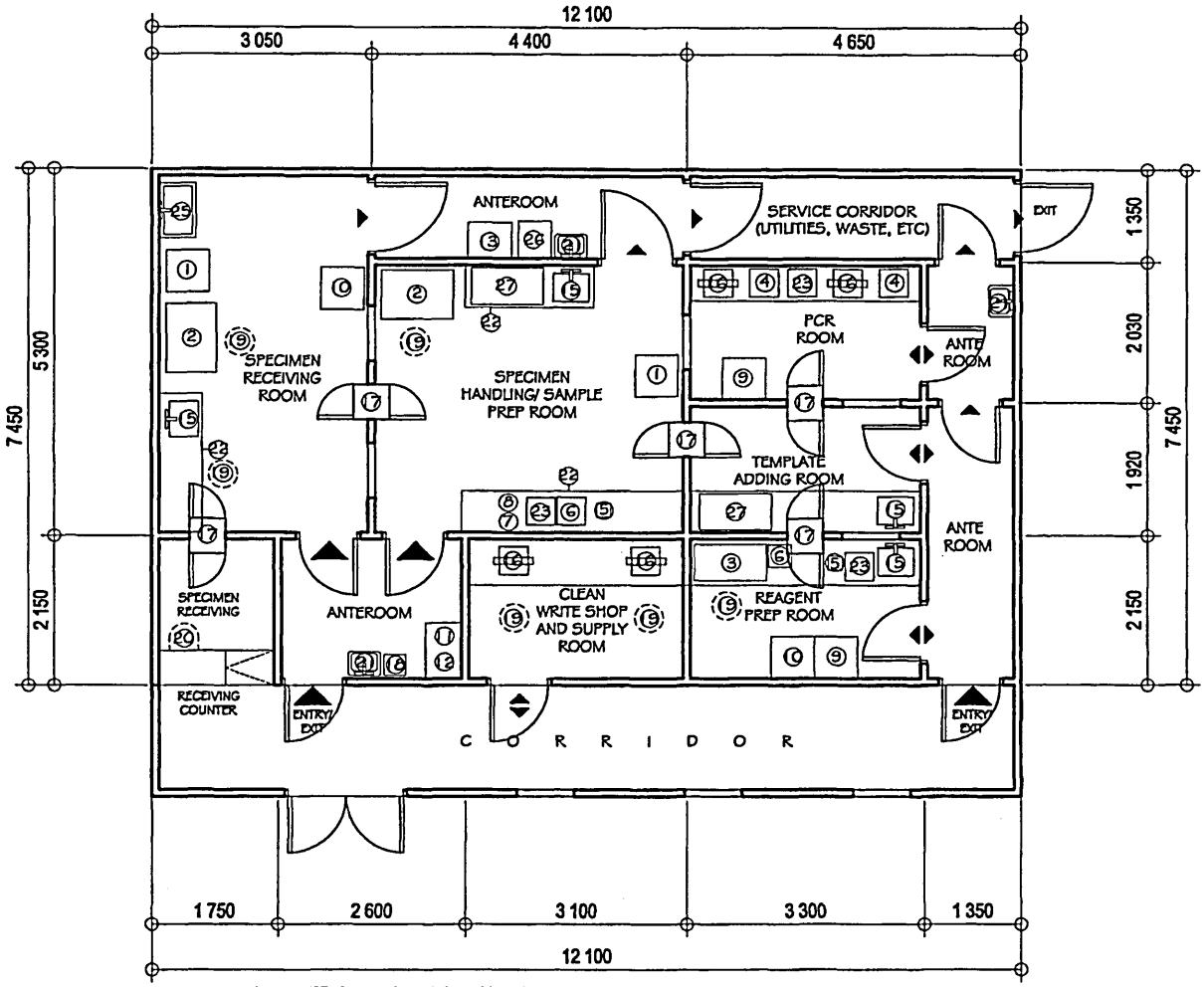
Department of Health

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



REVISED PROTOTYPE PLAN FOR

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 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. PCR HOOD

NOTE:

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 CAN BE ATTACHED TO AN EXISTING AND ADJACENT CORRIDOR OR CAN BE ENCLOSED AS APPLICABLE.

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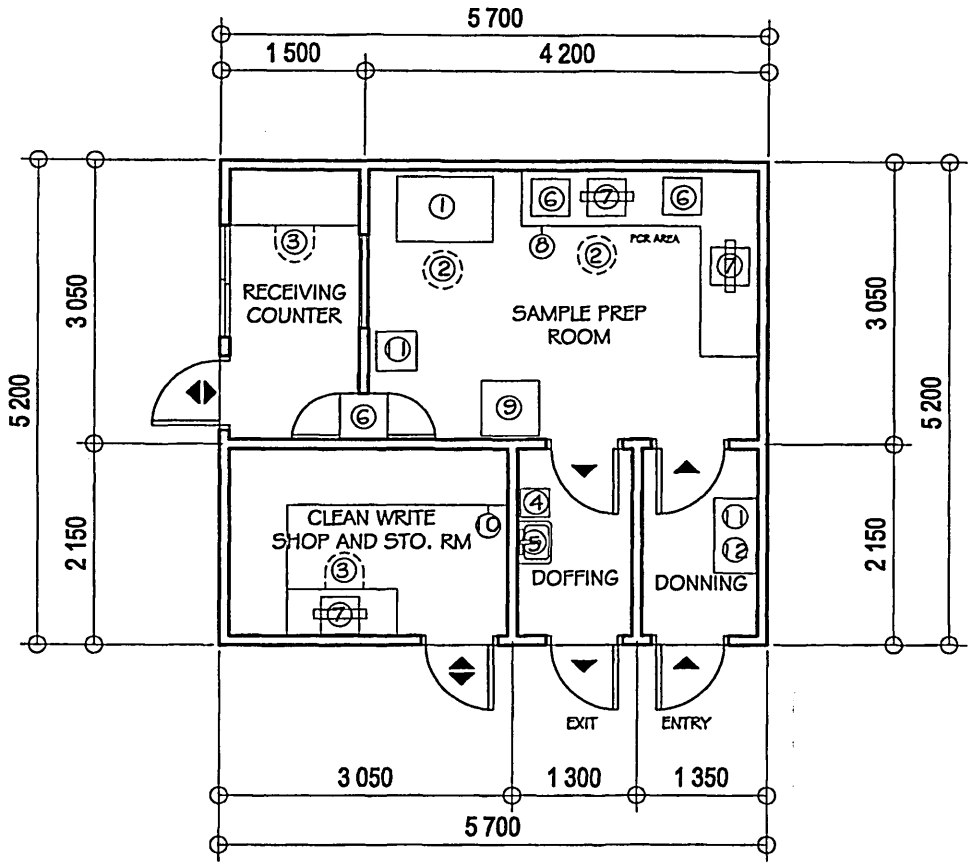
Department of Health

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

ANNEX D8

A.O. NO. 2020-0014-B



ALTERNATE PROTOTYPE PLAN FOR

COVID-19 TESTING LABORATORY PERFORMING CARTRIDGE-BASED TECHNOLOGY

LEGEND

① BIOSAFETY CABINET
② LABORATORY CHAIR
③ COMPUTER CHAIR
④ WASTE BIN
⑤ HAND WASHING SINK
⑥ PCR MACHINE (e.g. GENE XPERT)
⑦ COMPUTER
⑧ WORK COUNTER
⑨ REFRIGERATOR
⑩ STORAGE CABINET
⑪ AUTOCLAVE

NOTE:
1. THIS PROTOTYPE CAN PROCESS UP TO 128 SAMPLES PER 8 HOURS SHIFT

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KMITS - RECORDS SECTION
Department of Health

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

A.O. No. 2020 - 0014-B
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 COMPLIED 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** • List of available and functional equipment 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^{0}C to 6^{0}C) and freezers, (-20^{0}C to -30^{0}C)		

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 and original signature of RMT* 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	**Document review** • Documented procedures on referral and outsourcing of examinations to other DOH-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 • Copy of 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. Equipment and Supplies for Specimen Receiving Room

The following are minimum recommended equipment for this workstation:

- ☐ Autoclave (if the area is not adjacent to the sample handling/sample preparation room)
- ☐ Biological Safety Cabinet Class II A2
- ☐ Biomedical Refrigerator
- ☐ Gloves (different size: S, M, L)

1.2. Equipment and Supplies for Specimen Handling/ Sample Preparation Room

The following are minimum recommended equipment for this workstation:

- ☐ Autoclave
- ☐ 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)
- ☐ Heating block (for extraction kits that requires heating for elution buffer)
- ☐ Microcentrifuge
- ☐ Micropipette tips
- ☐ Minicentrifuge
- ☐ 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.

1.2. Equipment and Supplies for Template Adding Room

The following are minimum recommended equipment for this workstation:

- ☐ Gloves (different size: S, M, L)
- ☐ PCR hood/cabinet with "dead-air" box as the minimum specifications
- ☐ Minicentrifuge
- ☐ Vortex mixer

1.3. Equipment and Supplies for Reagent Preparation Room

The following are minimum recommended equipment for this workstation:

- ☐ Biomedical refrigerator for reagents
- ☐ Biomedical freezer for reagents
- ☐ Cold rack for PCR tube
- ☐ Gloves (different size: S, M, L)
- ☐ Microcentrifuge
- ☐ Micropipette tips
- ☐ Minifuge
- ☐ PCR cabinet/laminar flow

- ☐ 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.

1.3. Equipment for Amplification/PCR Room

The following are minimum recommended equipment for this workstation:

- ☐ Minicentrifuge or plate spinner
- ☐ Real-time PCR machine

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

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-B
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 COMPLIED 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	**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		
(1) RMT Analyst Per (2) machines	• 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		
(1) Laboratory Aide (1) Encoder Per (4) machines	• 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** • List of available and functional equipment 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 and original signature of RMT* with 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		

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	**Document review** • Documented procedures on referral and outsourcing of examinations to other DOH-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 • Copy of 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
- ☐ Rapid PCR Machine with kits or cartridges (e.g. GeneXpert System)

b. Personal Protective Equipment

The following are minimum recommended Personal Protective Equipment:

- ☐ Disposable laboratory gown
- ☐ Laboratory shoes
- ☐ Powder-free nitrile gloves
- ☐ Respirator: N95 or higher

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: _____