DRAFT as of January 17, 2022

**ADMINISTRATIVE ORDER**
**No. 2022 - _____**

**SUBJECT: Rules and Regulations Governing the Regulation of a COVID-19 Testing Laboratory Performing Nucleic Acid Amplification Test**

## I. RATIONALE/BACKGROUND

The Corona Disease 2019 (COVID-19) pandemic is still considered a threat over the world after approximate of two (2) years. According to the World Health Organization's (WHO) COVID-19 Weekly Epidemiological Update, over 346 million cases were reported globally from January 17 to 23, 2022. In the Philippines, there is a continuous rise in the number of cases, as of January 26, 2022, the Department of Health (DOH) – COVID-19 Bulletin number 683 recorded 230, 410 cases totaling to 3, 191, 219 documented cases in the country.

Prevention of person-to-person transmission is critical in the control and mitigation of COVID-19, and early detection through testing is vital in identifying the affected individuals. Currently, the gold standard for detecting Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19, is still the Real Time Reverse Transcriptase – Polymerase Chain Reaction (rRT-PCR), as recommended by the WHO. The DOH issued the standards and requirements in obtaining license to operate a COVID-19 testing laboratory, titled "Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines," and its amendments, to ensure accountability of COVID-19 testing laboratories on generation of accurate and precise results. From one (1) WHO-accredited laboratory capable of performing the test, the Research Institute for Tropical Medicine (RITM), there are now 318 licensed COVID-19 testing laboratories around the country (as of January 7, 2022), allowing the country's testing capacity to expand.

Feedback from key stakeholders was obtained and provided to DOH for the improvement on the current standards and requirements of COVID-19 testing laboratories as part of monitoring the implementation of DOH issuances and polices. As a result, the existing guidelines in securing a License-to-Operate for COVID-19 testing laboratory in the Philippines have been reviewed and updated. In addition, the term "Nucleic Acid Amplification Test" was adopted to encompass the other established and accepted COVID-19 molecular diagnostic platforms.

## II. OBJECTIVE

This Order shall serve as the new guidelines in the licensing of Nucleic Acid Amplification Test (NAAT) COVID-19 testing laboratories in the Philippines, to ensure its accountability to generate accurate and precise results while safeguarding the safety of the public as well as its personnel.

## III. SCOPE OF APPLICATION

This Order shall apply to all government and private-owned COVID-19 testing laboratories in the Philippines performing NAAT for SARS-CoV-2.

This Order shall also apply to Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) subject to the applicable provisions of RA 11054 or the "Bangsamoro Organic Act" and subsequent rules and policies issued by the Bangsamoro Government.

## IV. DEFINITION OF TERMS

A. **Applicant** — refers to an individual, partnership, corporation or association seeking a license to operate, establish and maintain a NAAT COVID-19 testing laboratory.

B. **COVID-19 testing laboratory (COVID-19 TL)** — refers to a COVID-19 testing facility involved in the (a) pre-analytical, (b) analytical, and (c) post-analytical procedures for the detection of SARS-CoV-2 genetic materials through NAAT on specimens from the human body to obtain information for the prevention, diagnosis and treatment, and surveillance protocols for COVID-19.

C. **Department of Health-License to Operate (DOH-LTO)** — refers to a formal authorization issued by the DOH through the Health Facilities and Services Regulatory Bureau (HFSRB) or Center to Health Development – Regulation, Licensing and Enforcement Division (CHD-RLED) to an individual, partnership, corporation or association seeking to perform SARS-CoV-2 detection in a NAAT COVID-19 TL in compliance with the requirements prescribed in this Order.

D. **DOH-Permit to Construct (DOH-PTC)** — refers to a permit issued by DOH through HFSRB or CHD-RLED to an applicant who will establish and operate a NAAT COVID-19 TL, 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, or for additional services beyond their service capability. It is a prerequisite for DOH-LTO.

E. **Certificate of Proficiency** – refers to a Certification from RITM signed by the Office of the Assistant Secretary Public Health Services Team (COVID-19 Laboratory Operations Team Lead) that the COVID-19 TL has completed and passed the proficiency testing.

F. **Nucleic Acid Amplification Test (NAAT)** — refers to a molecular test that amplifies or makes multiple copies of detected target genetic material from a given sample. The methods include, but are not limited to, polymerase chain reaction (PCR) such as rRT-PCR and Multiplex PCR, as well as isothermal amplification methods such as loop-mediated isothermal amplification (LAMP), and transcription mediated amplification (TMA).

1. **Real Time Reverse Transcriptase-Polymerase Chain Reaction (rRT-PCR)** — refers to a method of NAAT where RNA molecules are converted to their complementary DNA sequences through reverse transcriptase enzyme and followed by amplification of the synthesized complementary DNA. The most common principle of test for SARS-CoV-2 detection used in this Order.

G. **Referral** — refers to COVID-19 rRT-PCR tests sent-out to other DOH licensed COVID-19 TL in case of surges in number of specimens, machine breakdown or lack of supplies pursuant to the zoning guidelines of the COVID-19 Laboratory Network.

**H. Remote Collection** — refers to all collection activities for SARS-CoV-2 detection using NAAT, done outside and not within the hospital or DOH licensed COVID-19 TL, shall be considered as a remote collection activity.

1. **Freestanding/Standalone Collection Sites** — refers to facilities for the sole purpose of collecting specimens that are not owned by any COVID-19 TL. A valid Memorandum/Memoranda of Agreement (MOA) with DOH-licensed COVID-19 TL shall be required for independent swabbing facilities. Exemption for MOA if the swabbers/specimen collectors are from the Disease Reporting Units, Local Epidemiology and Surveillance Units (Provincial/City/Municipal ESUs) and Local Government Units
2. **Satellite Collection Site** — refers to collection facility owned by the DOH-licensed COVID-19 TL located outside the premises/compound of the COVID-19 TL.

## V. GENERAL GUIDELINES

**A.** COVID-19 testing shall only be performed in a DOH-licensed NAAT based COVID-19 TL.

**B.** The DOH-LTO for a NAAT based COVID-19 TL shall only be issued upon full compliance to the standards and requirements of HFSRB/DOH CHD-Regulation, Licensing and Enforcement Division (CHD-RLED) and RITM.

**C.** All the NAAT platforms, with the specific systems, being offered by the COVID-19 TL shall be reflected in the existing DOH-LTO:

1. NAAT using rRT-PCR offering both non-cartridge based and cartridge based.
2. Other NAAT platforms such as isothermal amplification.

**D.** The COVID-19 TL shall apply for the additional NAAT platform to be offered to the HFSRB or CHD-RLED for it to be subsumed in their DOH-LTO after full compliance to the requirements and standards of the particular platform.

**E.** For NAAT based COVID-19 TL using different rRT-PCR platforms, the proficiency testing of the higher complexity platform shall be accepted as valid for the other platforms (i.e., non-cartridge over cartridge based).

**F.** The DOH-LTO of a NAAT based COVID-19 TL in an institution shall be subsumed in the LTO of the health facility as an add-on service.

**G.** The NAAT based COVID-19 TL shall be a separate unit, with its own designated rooms or areas such as but not limited to receiving room, processing room/s, storage rooms and clerical/encoding room, appropriate for the number of staff employed by the laboratory and to the number of samples being processed.

**H.** The NAAT based COVID-19 TL performing different diagnostic NAAT platforms for COVID-19 aside from rRT-PCR, shall have its own set of personnel dedicated for the specific platform/s to perform such task, with adequate space and specific area for processing provided.

**I.** The staff of the NAAT based COVID-19 TL shall have the minimum appropriate trainings prescribed by RITM and HFSRB or CHD-RLED, when applicable.

**J.** The COVID-19 TL performing NAAT shall be headed by a board-certified clinical pathologist with training in Biosafety, Biosecurity, and Molecular Diagnostic Principles and Techniques.

**K.** NAAT based COVID-19 TL shall formulate its policies and procedures aligned with the current DOH guidelines, which shall be strictly enforced and implemented in the facility. Its Manual of Operations shall include, but not limited to the following: standard operating procedures; work instructions for each NAAT diagnostic platforms; 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.

**L.** The NAAT based COVID-19 TL shall only use Food and Drug Administration (FDA) authorized in-vitro medical devices (test kits, reagents and devices).

**M.** The NAAT based COVID-19 TL shall be strictly prohibited from outsourcing of examinations.

**N.** All remote collection facilities for NAAT based COVID-19 specimen shall register at the CHD-RLED and shall have a MOA with a NAAT based COVID-19 TL, if not owned by the COVID-19 TL.

**O.** All collection facilities for specimen for NAAT shall follow the currently DOH prescribed guidelines on swabbing facilities.

**P.** The NAAT based COVID-19 TL shall be part of the COVID-19 Laboratory Network and shall adhere to the current zoning guidelines promulgated by the DOH.

**Q.** All NAAT based COVID-19 TL shall adhere to the current DOH mandated price cap and shall make their prices accessible to the public as mandated by the UHC law and related DOH issuances.

**R.** The HFSRB or CHD-RLED shall be notified in writing of any change in management name, ownership, or headship or laboratory personnel, and the addition of new NAAT platforms. Failure to notify of any substantial change in the condition of the COVID-19 TL, i.e., changes in the physical plant, equipment, or personnel, in writing within fifteen (15) days, may be a basis for the suspension or revocation of the DOH-LTO.

**S.** The NAAT based COVID-19 TL shall report the required data elements to the DOH in accordance with the following issuances:

1. **Republic Act (RA) No. 11332**, also known as the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act."
2. **Administrative Order (AO) No. 2020-0013** issued on April 9, 2020, titled "Revised Administrative Order No. 2020-0012 "Guidelines for the Inclusion of the Coronavirus Disease 2019 (COVID-19) in the List of Notifiable Diseases for Mandatory Reporting to the Department of Health" dated March 17, 2020," and its amendments.
3. **Department Memorandum (DM) No. 2020-0542** issued on December 17, 2020, titled "Interim Guidelines on the Compliance of COVID-19 Testing Laboratories to Data Submission and Quality Standards."

T. **A standard information technology system shall be developed by the DOH Knowledge Management and Information Technology Service (DOH-KMITS) that will seamlessly synchronize in real-time all COVID-19 TL data reporting activities.**

U. COVID-19 TL shall follow the standards, criteria and requirements prescribed in the DOH Licensing Standards for NAAT specific for rRT-PCR COVID-19 TL (Annex A), Assessment Tool for Licensing a COVID-19 TL (ANNEX B), Guidelines in Securing for Remote Collection Permit for COVID-19 TL (Annex C), Planning and Design Guidelines (ANNEX D), and accomplish the WHO's risk assessment form (ANNEX __).

V. The details as to the additional standards and requirements for new platforms other than rRT-PCR shall be issued as a Department Circular as an Annex of this Order.

## VI. SPECIFIC GUIDELINES

### A. CLASSIFICATION OF COVID-19 TESTING LABORATORIES

1. **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.
2. **According to Institutional Character**
   a. Institution based — within the premises or the compound of a DOH regulated facility. It may be a part of the general clinical laboratory, but with a specific designated room distinct from the main clinical laboratory.
   b. Non-institution based
      i. located outside the premises or the compound of a DOH-regulated facility
      ii. located within the premises or compound of a DOH regulated facility but different owner and independently functioning on its own
3. **According to NAAT Service Capability**
   a. rRT-PCR
      i. Non-cartridge based — uses a loading plate or other material such as but not limited to tube strips, as its support for the samples with the corresponding mixture for testing.
      ii. Cartridge based — uses a cartridge as a container for the samples with the corresponding mixture for testing.
      iii. Other rRT-PCR
   b. Other NAAT as recommended by the Health Technology Assessment Council (HTAC)

### B. PROCEDURES AND PROCESSES

1. **LICENSING PROCESS**
   a. **DOH-PTC**
      i. A DOH -PTC shall be a prerequisite in the application of DOH-LTO.
      ii. A complete application shall be submitted to HFSRB or CHD-RLED and shall consist of the following:

1) Duly accomplished application form for COVID-19;
2) Proof of ownership;
3) Three sets of architectural floor plans signed and sealed by an architect and/or engineer;
4) Mechanical plan; and,
5) Computation of room air balance.

iii. Processing of the DOH-PTC application shall be in accordance with AO No. 2016-0042 titled "Guidelines in the Application for Department of Health Permit to Construct (DOH-PTC)" and shall be processed according to the Citizen's Charter.

iv. Once approved, the facility owners can commence with the construction of the NAAT based COVID-19 TL.

v. Existing NAAT based DOH-licensed COVID-19 TL shall submit updated floor plan to HFSRB or CHD-RLED, in lieu of an approved DOH-PTC. However, they shall be required to secure a DOH-PTC for major renovation or expansion, transfer of location, and change in ownership.

b. **DOH-LTO**

i. Filing of complete application requirements, whether manual or online, for initial and renewal, **(initial HFSRB, renewal CHD-RLED for non-institution based)** shall be at HFSRB or CHD-RLED, according to current DOH guidelines:

1) HFSRB – Medical Facility for Overseas Workers and Seafarers (MFOWS), Ambulatory Surgical Clinics (ASC) and Dialysis Clinics with ancillary services, level 2 and 3 general hospitals until the full implementation of AO No. 2021-0019 titled "Decentralization of Levels 2, 3 general hospitals and specialty hospitals to the DOH-CHD RLED and MOH-BARMM RLEC"
2) CHD-RLED – institution-based facilities, such as but not limited to level 1 hospitals, decentralized levels 2 and 3 general hospital, infirmary, general clinical laboratories, and non-institution based COVID-19 TL.

ii. **Initial application**

1) **Self-assessment and application**
   a) Notarized completely filled-out Application for License to Operate COVID-19 Testing Laboratory and other pertinent documents attached herewith:
      i) Copy of approved DOH-PTC and floor plan.
      ii) Pictures of the laboratory (complete setup) and a walkthrough video for initial assessment purposes before site inspection.
      iii) List of equipment with specifications, reagents, and supplies.
      iv) Notarized list of personnel, including photocopies of valid Professional Regulation Commission (PRC) identification card (ID), valid COVID-19 proficiency training certificate, or its equivalent, from RITM, and copy of certificates of all necessary trainings.
      v) RITM and WHO risk assessment.
      vi) Copy of Certificate of Product Registration (CPR) or its equivalent from FDA for all equipment, reagents and supplies.
      vii) Securities and Exchange Commission registration/Department of Trade and Industry/Sanggunian Resolution for the name and establishment of the COVID-19 TL, whichever is applicable.
   b) Accomplished Self-Assessment Tool for Licensing a COVID-19 TL.

c) Copy of Official Receipt of payment

2) **Onsite Assessment or virtual inspection**
   a) After evaluation of the submitted documents for technical completeness and correctness, an onsite visit/virtual inspection shall be arranged to check the NAAT based COVID-19 TL. The DOH Inspection Team shall provide the COVID-19 TL with assessment gaps, technical and safety recommendations, and a period to comply with the gaps and recommendations.

3) **Compliance**
   a) The NAAT based COVID-19 TL shall be given a period to comply with the requirements and submit evidence of compliance which shall be reviewed by HFSRB or CHD-RLED. Once complied, the NAAT based COVID-19 TL shall be recommended to the next stage by the DOH Inspection Team to RITM for proficiency testing or its equivalent.

4) **Proficiency Testing provided by RITM or its authorized representatives**
   a) Pre-licensing proficiency testing shall be done on a per laboratory basis.
   b) If the COVID-19 TL has two (2) rRT-PCR diagnostic platforms (non-cartridge based and cartridge-based), then the COVID-19 TL shall undergo proficiency testing for the higher complexity platform, with the certificate of proficiency applicable to both platforms.
   c) For already licensed NAAT based COVID-19 TL performing cartridge based rRT-PCR, but will add a non-cartridge based platform, the COVID-19 TL shall undergo another proficiency testing after complying with the standards and requirements for non-cartridge based rRT-PCR.
   d) RITM will issue a certificate of proficiency to the HFSRB or CHD-RLED that the COVID-19 TL can perform independent testing for SARS-CoV-2, if the COVID-19 TL has passed the proficiency testing.

5) **Issuance of DOH-LTO**
   a) Upon receipt of RITM certificate of proficiency and upon complete compliance to all requirements, the HFSRB or CHD-RLED issues the DOH-LTO.

**iii. Renewal Application**

1) Duly accomplished Form 1 application (downloadable at hfsrb.doh.gov.ph) together with the necessary attachments including the certificate of active participation in the COVID-19 Laboratory Network Quality Assurance Program.
2) The DOH-LTO of the COVID-19 TL shall be cancelled automatically without notice upon failure to submit a duly accomplished application form and failure to pay the proper fee based on the schedule in AO No. 2019-0004 titled "Guidelines on the Annual Cut-off Dates for Receipt of Complete Applications for Regulatory Authorizations Issued by the Department of Health."

**iv. Additional (add-on) Service Application**

1) Duly accomplished Form 2 application (downloadable at hfsrb.doh.gov.ph) for add-on services, such as additional NAAT platform or different system, use of saliva as specimen and pooled

testing, shall be submitted to HFSRB or CHD-RLED including the following additional requirements:

2) List of personnel for additional rRT-PCR and other NAAT platforms
3) Appropriate training based on DOH for the personnel such as specimen collection for saliva, training by the Philippine Society of Pathologists, Inc. (PSP) for sample pooling, and machine specific training by the distributor and/or manufacturer – include in the AT (machine specific training, if applicable)
4) Policies and procedures for the add-on platform
5) Work instructions for the add-on platform

v. The process for inspection, whether initial or renewal, shall follow Section VI. E and F of AO 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 HFSRB.

vi. RITM or its duly recognized/authorized third party assessors shall transmit to HFSRB or CHD-RLED a certificate of proficiency when the facility is fully compliant to the standards and requirements of RITM.

vii. The DOH-LTO a COVID-19 TL shall be issued only after full compliance to the standards and requirements by HFSRB or CHD-RLED and the RITM.

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

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

c. **Certificate of Registration**

i. Required for Freestanding/Standalone Collection Sites, to be updated yearly.

ii. Notarized completely filled-out Application for Certificate of Registration (Annex __) other pertinent documents.

d. **Remote Collection Permit**

i. A remote collection permit shall be secured by the COVID-19 TL for all remote collection activities. See Annex ___ for the guidelines in securing a RCP.

e. **Validity of DOH-LTO**

i. 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 AO 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."

f. **Monitoring**

i. The HFSRB or CHD-RLED may coordinate with RITM for the conduct of monitoring/unannounced visits to ensure continuous compliance to the standards.

g. **Fees**

i. The DOH-LTO fee shall follow the schedule of fees currently prescribed by the DOH.

ii. The applicant, upon filing the application, shall pay the corresponding fee to the DOH Cashier or Regional Office Cashier.

## VII. ROLES AND RESPONSIBILITIES

**A. Health Facilities and Services and Regulatory Bureau shall:**

1. Strictly enforce the provisions of this Order.
2. Set standards for the regulation of health facilities including COVID-19 TL.
3. Create/modify inspection and monitoring tools as need arises.
4. Disseminate regulatory policies, standards and forms for information and guidelines to the DOH-CHDs.
5. Provide consultation and technical assistance to stakeholder, including regulatory officers from the DOH-CHDs in regulation of COVID-19 TL.
6. Conduct unannounced monitoring visits to check for continuous compliance of COVID-19 TL.
7. Promptly respond to complaints relative to the operation of COVID-19 TL.

**B. Research Institute of Tropical Medicine – the reference laboratory for COVID-19 testing recognized, in the Philippines, by the WHO shall:**

1. Train COVID-19 TL staff/personnel.
2. Train and authorize third party trainer and/or assessors for external quality assessment program.
3. Provide assistance to the HFSRB for COVID-19 TL related technical concerns.
4. Submit reports to HFSRB the results of proficiency testing and quality issues that may be detected in the monitoring of quality indicators, laboratory visits, proficiency test events or over-all assessment.
5. Develop proficiency testing for other HTAC recommended NAAT platforms.

**C. Center for Health Development**

1. **Regulation, Licensing, and Enforcement Division shall:**
   a. Strictly enforce the provisions of this Order.
   b. Inspect and issue DOH-LTO for hospital based and non-hospital based COVID-19 TL except those located in ASC, MFOWS and Dialysis Clinics.
   c. Conduct unannounced monitoring visits to check for continuous compliance of COVID-19 TL.
   d. Submit **report to the HFSRB on** Suspension/Revocation/Cease and Desist Order (CDO) issued on COVID-19 TL not later than the 15th day of the following month after the covered quarter.
   e. Promptly respond to complaints relative to the operation of COVID-19 TL.
   f. Maintain the registry of freestanding/standalone collection facilities.
2. **CHD COVID-19 Laboratory Network Coordinator shall:**
   a. Organize and coordinate the referral of specimens within their region pursuant to the DOH zoning guidelines.

**D. Epidemiology Bureau (EB) and its Regional Epidemiology Surveillance Units (RESU) shall:**

1. Collect and aggregate data from COVID-19 testing laboratories.
2. Analyze and report data collected from COVID-19 testing laboratories.
3. Provide training for DOH-licensed COVID-19 TL for encoding and submission of results to the recognized DOH platform (i.e., COVID-19 Document Repository System (CDRS)).

**E. DOH-licensed COVID-19 TL shall:**

1. Continuously comply with the rules and regulations, licensing standards and requirements for COVID-19 TL, as provided in this Order and related issuances.

2. Participate in External QAP (EQAP) that may be administered by a designated NRL or other local and international EQAP approved by the DOH, surveys and other activities that will be required from them by the DOH.
3. In times of Pandemic of Public Health Event, be mandated to submit timely reports and data.
4. **Verify the correctness of all entries in the Case Investigation Forms for their walk-in patients/clients.**

## VIII. VIOLATIONS, SANCTIONS AND PENALTY

**A.** The NAAT based COVID-19 TL shall be sanctioned and penalized by the HFSRB/DOH-CHD Director upon violation of any of these guidelines and its related issuances and laws, or upon committal (commission/omission) of prohibited acts by the persons owning or operating the COVID-19 TL, and/or the persons under their authority, upon thorough investigation:

1. Change in the ownership, location, and head of the laboratory or laboratory personnel and addition of other NAAT platform without informing the HFSRB or CHD-RLED.
2. Refusal to allow HFSRB or CHD-RLED authorized personnel to conduct inspection or monitoring visits of the COVID-19 TL at any appropriate time.
3. Non-compliance to the price cap.
4. Non-reporting of remote collection activity.
5. Issuing false or fraudulent results, knowingly, willfully, or through gross negligence
6. Delayed releasing of result (more than 5 days).
7. Non-reporting to RESU and CDRS.
8. Non-compliance to NEQAS or failure in NEQAS for two (2) succeeding cycle.
9. Non-compliance to specimen collection guidelines.
10. Non-compliance with licensing or accreditation standards and requirements for manpower and physical plant
11. Continued operation even when it is non-compliant with regulatory standards and technical requirements.
12. Continued operation despite a cease-and-desist order with respect to the operation of the facility.
13. Continued operation of a regulated facility without a valid license

**B.** **Non-compliance with licensing or accreditation standards and requirements for equipment shall be considered a violation if deficiencies are not corrected within thirty (30) calendar days after receipt of official notice.**

**C.** Any person authorized or licensed to perform laboratory tests, who issues false or fraudulent laboratory test results knowingly, willfully or through gross negligence shall not be allowed to own, manage, operate, or be an analyst of any DOH-licensed NAAT based COVID-19 TL.

**D.** The following are the penalties and sanctions that shall be imposed on the NAAT based COVID-19 TL upon commission of any of the violations in this Order and other relevant issuances:

| Offense | | Sanctions and Penalty |
|---|---|---|
| 1. 1st Offense | — | Thirty Thousand Pesos (Php 30,000.00) |
| 2. 2nd Offense | — | Fifty thousand pesos (Php 50,000.00) |
| 3. 3rd Offense | — | Revocation of DOH-LTO |

**E.** Any person or entity who operates a NAAT based COVID-19 TL without securing the necessary DOH-PTC and corresponding DOH-LTO shall be issued a Cease-and-Desist

Order (CDO) and shall pay the administrative penalty of Fifty thousand pesos (Php50,000.00).

**F.** The HFSRB or CHD Director or his/her authorized representative shall investigate and verify if the NAAT based COVID-19 TL concerned, including its personnel, is liable for the alleged aforementioned violation or complaints. The HFSRB or CHD may preventively suspend the operations of the concerned facility for not more than sixty (60) days. Upon completion of the corrective actions on the findings noted during the investigation, or resolution of the case the preventive suspension can be lifted immediately and impose the appropriate penalty and/or sanction.

| Offense | | Sanctions and Penalty |
|---|---|---|
| 1. 1st Offense | — | Thirty Thousand Pesos (Php 30,000.00) |
| 2. 2nd Offense | — | Fifty thousand pesos (Php 50,000.00) |
| 3. 3rd Offense | — | Revocation of DOH-LTO |

**G.** The NAAT based COVID-19 TL shall discontinue the provision of its services until such time that all violations have been corrected and sanctions have been imposed and complied with.

**H.** A NAAT based COVID-19 TL with revoked licenses can only re-apply after one year from the date of DOH-LTO revocation.

## IX. APPEAL

Any COVID-19 TL or any of its personnel not amenable with the decision of the HFSRB/CHD-RLED may, within ten (10) days after the receipt of notice of decision, file a notice of appeal to the Head of the Health Regulation Team (HRT). All pertinent documents and records of the appellant shall then be elevated by HFSRB/CHD-RLED to the HRT. The decision of the Head of the HRT, if still contested may be brought on a final appeal to the Secretary of Health, whose decision shall be final and executory.

## X. REPEALING CLAUSE

These rules and regulations shall rescind AO No. 2020-0014 titled, "Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines," and its amendments, all AO and previous issuances inconsistent thereof.

## XI. SEPARABILITY CLAUSE

In the event that any provision or part of this Order be declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

## XII. EFFECTIVITY

This Order shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) copies to the University of the Philippines Law Center.

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