LICENSING STANDARDS FOR NUCLEIC ACID AMPLIFICATION TEST (NAAT) SPECIFIC FOR REAL TIME REVERSE TRANSCRIPTASE-POLYMERASE CHAIN REACTION (rRT-PCR) COVID-19 TESTING LABORATORIES (TL)

I. PHYSICAL FACILITIES

Every COVID-19 TL shall have an adequate and appropriate areas to safely, effectively and efficiently provide the services to clients.

A. The COVID-19 TL shall conform to all applicable local and national regulations for the construction, renovation, maintenance and repair of COVID-19 TL.

B. The COVID-19 TL shall have a dedicated space for each of the following:

1. For non-cartridge based rRT-PCR
   - a. Clean WriteShop (outside or main lab)
     - i. Specimen reception
     - ii. Receiving of document
     - iii. Encoding of Data
     - iv. Encoding of Results
   - b. Pre-Analysis
     - i. Specimen Receiving (unboxing)
     - ii. Specimen Handling
     - iii. Sample Preparation Virus inactivation
     - iv. Nucleic acid extraction (Pre-PCR)
     - v. Template Adding
   - c. Reagent Preparation
   - d. PCR
   - e. Support Area
     - i. Pathologist Area
     - ii. Supply Area
     - iii. Waste Holding Area
     - iv. Staff toilet and other amenities for staff
   - f. Specimen Collection for laboratories conducting swab collection
2. For cartridge-based rRT-PCR
   - a. Clean WriteShop (outside or main lab)
     - i. Specimen reception
     - ii. Receiving of document
     - iii. Encoding of data
     - iv. Encoding of results
   - b. Pre-Analysis/Analysis
     - i. Specimen Receiving (unboxing)
     - ii. Specimen Handling
     - iii. PCR
   - c. Support Area
     - i. Pathologist Area
     - ii. Supply Area

iii. Waste Holding Area
iv. Staff toilet and other amenities for staff

d. Specimen Collection (Swabbing)

C. Unidirectional workflow following the above-mentioned activities shall be monitored and maintained at all times for the following: staff, specimen, reagents and wastes.

D. The COVID-19 TL shall conform to the required space for the conduct of its activities. Personnel, fixtures, equipment, sink, etc. shall also be considered. Minimum area requirements for each are listed in Annex ____.

E. The COVID-19 TL shall have controlled and adequate ventilation with the prescribed air changes per hour maintained for each specific area.

F. The COVID-19 TL shall have periodic calibration, preventive maintenance, and certification shall be required for HVAC equipment and machine and shall be duly documented.

G. The COVID-19 TL shall have adequate lighting, clean, safe and functional areas based on the services provided.

H. The COVID-19 TL shall have program of proper maintenance and monitoring of physical plant and facilities.

I. The COVID-19 TL shall have policy guidelines on laboratory biosafety and biosecurity which includes risk assessment.

II. PERSONNEL

Every COVID-19 TL shall have an adequate number of qualified, trained and competent staff, depending on the workload, to ensure safe, efficient and effective delivery of quality services.

A. Head of the COVID-19 TL

1. The HOL shall be a competent and experienced ~~professional~~ clinical pathologist, with a specialized skill set related to molecular or related diagnostic platforms. The HOL is essentially responsible for the operation of the entire COVID-19 TL, its personnel, functions, and data, all of which shall meet the quality assurance criteria and regulatory requirements stipulated in ANNEX-Assessment Tool
2. The HOL shall oversee the operation and have administrative and technical supervision of the activities in the COVID-19 TL.
3. The HOL shall supervise the staff in accordance with the standards set by the Philippine Society of Pathologists.
4. The head of the laboratory shall visit once a month with at least twice a week of supervisory calls and/or videoconferencing OR at least once a week physical visit. For hospital-based DOH licensed COVID-19 TL, it shall be once a week physical visit by the HOL or his/her designated Associate Pathologist. The visits shall have to be well documented and recorded.

B. Registered Medical Technologist

1. The RMTs shall be adequate in number and required to be full-time to conduct the laboratory procedures. The number of staff shall depend on the workload of the COVID-19 TL.
2. There shall be a designated Biosafety and Biosecurity Officer in-charge primarily of the risk assessment of the COVID-19 TL.
3. There shall be a Supervisor or Officer in Charge, which may be designated.

C. Other Analysts

1. 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 shall be allowed to perform tests/activities in the COVID-19 TL as Analysts.

D. Support Staff

1. Support staff such as, but not limited to adequate number of laboratory aide, receptionists, and encoder shall be required from a COVID-19 TL.

E. Trainings

1. Fundamentals of Biosafety and Biosecurity, which shall cover Biological Risk Assessment, Mitigation Controls (engineering, practices and procedures, administrative), Personal Protective Equipment, specimen transport, waste management, decontamination and disposal, and Emergency Responses (biological spill drill). The abovementioned trainings, which can be provided in-house, shall be required for laboratory aide, receptionist and encoder.
2. Molecular Diagnosis or Molecular Laboratory Diagnostics for Clinical Pathologist and Analysts.
3. The staff of the COVID-19 TL shall be proficient on Molecular Diagnostic Techniques.
4. Staff (encoder) should undergo training on the COVID-19 Information System - COVID-19 Document Repository System (CDRS) as provided by the Epidemiology Bureau - COVID-19 Surveillance and Quick Action Unit and should possess the certification showing completion of training.

F. The staff shall undergo fit testing for respirator with at least 95% efficiency e.g. N95 mask. The COVID-19 TL may purchase Respirator Fit Testing kit, provided that a RITM trained staff of the COVID-19 TL will ~~provide~~ conduct the fit testing.

G. The staff shall have an annual medical examination including appropriate vaccination (i.e., COVID-19 and influenza).

H. All staff shall have daily medical monitoring for any sign or symptom.

I. The staff shall have continuing updated trainings on biosafety and biosecurity, new techniques and technologies, among others.

III. EQUIPMENT/INSTRUMENTS/REAGENTS/GLASSWARES/SUPPLIES

Every COVID-19 TL shall have an adequate equipment, instruments, reagents, glassware and supplies which are all in good working condition and sufficient for the operations.

B. The COVID-19 TL shall have available and operational equipment and instruments appropriate and consistent to the designated areas.

C. The COVID-19 TL shall have a calibration, preventive maintenance and repair program for every equipment/machines/instrument including the biosafety cabinet/s on a regular basis. These should be carried out and duly documented.

D. The COVID-19 TL shall have a contingency plan in case of equipment/machines/instrument breakdown and malfunction and shall not accept specimens from any patient or referral health facility. The COVID-19 TL shall have a notarized MOA with another DOH licensed COVID-19 TL.

1. The COVID-19 TL shall inform in writing the DOH HFSRB or CHD-RLED and the Epidemiology Bureau – COVID-19 Surveillance and Quick Action Unit about the temporary suspension of their COVID-19 TL.
2. The COVID-19 TL shall inform their clients and refer them to another DOH licensed COVID-19 TL.
3. Referral of samples shall be coordinated with the CHD-COVID-19 Laboratory network coordinator in accordance with Department Memorandum (DM) No. 2020-0188 "Interim Guidelines on the Zoning of COVID-19 Laboratories.
4. Full operation of the COVID-19 TL shall be restored within 30 days. However, if the laboratory still needs more time, they shall inform the HFSB or CHD-RLED in writing. Failure to do so, DOH-LTO may be revoked, and facility needs to re-apply.

E. The COVID-19 TL shall have an adequate available reagent, glassware and supplies for the conduct of test/s.

F. The COVID-19 TL shall have a documented inventory of equipment, supplies, glassware, reagents and control.

G. The COVID-19 TL shall have proper storage for reagents, glassware and supplies with required conditions.

H. For NAAT based COVID-19 TL rRT-PCR refer to Part III Annex B (Assessment Tool for Licensing a COVID-19 testing laboratory)

IV. SERVICE CAPABILITY

Every COVID-19 TL shall ensure quality and safe services to clients, to its personnel and to the general public.

A. The COVID-19 TL shall comply with the licensing standards in the Assessment Tool for Licensing a COVID-19 TL (ANNEX…) and other relevant issuances.

B. The COVID-19 TL shall be allowed to perform testing using ~~conduct~~ innovations in the diagnostic platform ~~in rRT-PCR tests, as add-on services, once~~ which are approved and recommended by the Health Technology Assessment Council (HTAC). It shall be an add-on service.

1. The relevant procedures for each of the innovations in the diagnostic platform shall be included in their Manual of Operations.

2. These RT-PCR COVID-19 TL shall first be certified by the Research Institute for Tropical Medicine (RITM) to perform the innovations in the plate based diagnostic platform prior to application for the add-on service.
3. All COVID-19 test kits to be used must be authorized by FDA for such specific use, such as use of saliva as specimen, and validated by RITM or other RITM-authorized institutions.
4. The personnel of the COVID-19 TL who will perform the innovations in the non-cartridge based diagnostic platform shall undergo the corresponding training for such procedures.
5. All COVID-19 laboratories offering these innovations in the diagnostic platform shall participate in the Quality Assurance Program provided by RITM. The RITM will furnish the HFSRB or CHD-RLED its findings and recommendations.
6. DOH licensed COVID-19 TL shall strictly follow the current and upcoming guidelines set by the DOH and RITM on the innovations in the RT-PCR plate based diagnostic platforms.
7. The verification protocol for pooled testing and the verification protocol for saliva as alternative specimen, which are both set by RITM for RT-PCR, shall be strictly followed.
8. For pooled testing, only FDA authorized RT-PCR kits already validated by RITM or its authorized institutions and have satisfied the 95% clinical sensitivity and 99% clinical specificity as recommended by the WHO shall be used.

V. QUALITY IMPROVEMENT ACTIVITIES

Every COVID-19 TL shall establish and maintain a system for continuous quality improvement activities.

A. There shall be a regular performance of Internal Quality Assurance Program which will includes:
   1. Internal Quality Control Program for technical procedures.
   2. Internal Quality Assurance Program for inputs, processes and outputs.
   3. Continuous Quality Improvement Program covering all aspects of laboratory performance which include identification of the many potential risks in the laboratory processes and document the recommendations to mitigate the risks, and monitor occurrences at least annually. This also includes analysis of the client feedback/customer satisfaction survey.
   4. Periodic Risk Management Plan.
   5. Monitoring of repeats and positivity rate.

B. The COVID-19 TL shall participate and pass in the National External Quality Assessment Scheme (NEQAS) given by RITM or other RITM recognized local and international providers:
   1. Proficiency testing will be made available for the different types of nucleic acid amplification testing platforms. If a laboratory offers more than one type of platform, proficiency testing shall be applied for each additional testing service.
   2. For renewal, a copy of NEQAS Certificate of Performance with passing result conducted by RITM
   3. Mandatory participation with RITM QAP

C. Evidence of Participation in the Laboratory Network QAP

1. EQA participation and records of ~~troubleshooting~~ root cause analysis done by laboratory management if the EQA results are less than 100%, including additional events from international bodies such as WHO, RCPA, CAP, as applicable.
2. Daily KPI-LQI data entry i.e., Lab dashboard for KPI/LQI showing daily submission of data or the acknowledgement email for KPI/LQI data submission
3. Results of Laboratory Assessment (if the lab is included in the priority list for assessment); copy of the report from RITM QA Team, records of actions done to address findings and/or recommendations for quality improvement (accomplished Root Cause Analysis - Corrective Action Plan form)
4. Other evidence/s of Quality Assurance activities, such as but not limited to:
   a. Records of Performance of quality control and validation
   b. Records of Competency assessments, training, learning and development interventions of staff
   c. Records of Internal quality assessments
   d. Monitoring of supplies, reagents as to optimal storage, expiration, and usage
   e. Records of preventive maintenance, repairs, calibration of equipment
   f. Records of continuous quality improvement activities based on customer feedback, IQA assessments, audit findings.

VI. INFORMATION MANAGEMENT

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

A. Administrative policies and procedures

1. The COVID-19 TL shall have written policies and procedures for the provision of laboratory services, the operation and maintenance of the laboratory and shall include accountabilities of every personnel working in the laboratory.
2. The COVID-19 TL shall have documented technical procedures for services provided which will ensure quality of laboratory results.
3. The COVID-19 TL shall have policy on biosafety and biosecurity plus risk assessment.
   a. Biosafety manual (institution specific/pathogen and procedure specific)
   b. Procedure for selection, use, PPE donning and doffing
   c. Specimen shipping and transport
   d. Specimen retention and disposal
   e. Decontamination of work surfaces
   f. Biological spill response
4. The COVID-19 TL shall have procedures for receipt and performance of requests.
5. The COVID-19 TL shall have procedures for the reporting of workload, quality control, inventory control, work schedule and assignments.
6. The COVID-19 TL shall have procedures for the reporting and analysis of incidents, adverse events, and in handling complaints.
7. The COVID-19 TL operating hours shall be known to its clients.
8. The COVID-19 TL shall post the price of its services in a conspicuous place.
9. Manual of Procedures and Work Instructions on the laboratory techniques.
10. 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).

11. Policies and procedures on specimen received from outside the facility (swab collectors) and remote collection sites (collection facilities/satellite facilities).
12. Accomplished World Health Organization (WHO) Risk Assessment form.
13. 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.
14. Policy on Management Review and Internal Quality Audit and findings which shall be presented to the management.
15. Policy on laboratory verification of registered/validated/authorized reagents and supplies.

B. Laboratory Report

1. The COVID-19 TL shall release results in accordance with DOH guidelines.
2. The COVID-19 TL shall release approved reports that bear the name, PRC registration number, and original signature of the registered medical technologist (s) who performed the laboratory examinations, and the pathologist who shall be accountable for the reliability of the results. The report shall also include the principle of the test performed (e.g. non-cartridge based or cartridge-based rRT-PCR).
3. The COVID-19 TL shall have a policy guideline on the use of digital signature, if applicable. The use of digital signature for laboratory results shall be permitted only if properly authenticated by the Department of Information and Communication-Philippine National Public Key Infrastructure. The use of digital signature shall also be in accordance with the provisions of the E-Commerce Law.
4. All Positive and Negative linelist must be uploaded to the CDRS following the prescribed format.
5. ~~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 FACILTY~~	~~SPECIMEN TYPE~~	~~PCR RESULT~~
~~COVIDID-XXXX~~	~~Dela Cruz, Juan~~	~~40~~	~~M~~	~~Hospital A~~	~~NPS/OPS~~	~~SARS-COVD-2 viral RNA detected~~
~~COVIDID-XXXX~~	~~Cruz, Gabriella~~	~~60~~	~~F~~	~~Hospital B~~	~~NPS/OPS~~	~~SARS-COVD-2 viral RNA detected~~

6. ~~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 FACILTY~~	~~SPECIMEN TYPE~~	~~PCR RESULT~~
~~COVIDID-XXXX~~	~~Dela Cruz, Juan~~	~~40~~	~~M~~	~~Hospital A~~	~~NPS/OPS~~	~~SARS-COVD-2 viral RNA not detected~~
~~COVIDID-XXXX~~	~~Cruz, Gabriella~~	~~60~~	~~F~~	~~Hospital B~~	~~NPS/OPS~~	~~SARS-COVD-2~~

						~~viral RNA not detected~~

7. 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, CDRS etc.
8. The COVID-19 TL shall include a quick response (QR) code and/or barcode for verification system.
9. A standard information technology system shall be adopted, once available, that will seamlessly synchronize all COVID-19 TL data reporting activities.
10. The COVID-19 TL shall have an information system capable of connecting with the COVID-19 Document Repository System through an API or, in the absence of said information system, should have adequate number of personnel to encode, scan, and upload documents to CDRS.
11. The COVID -19 TL shall adhere to the following reporting requirements:
    a. Mandatory zero reporting (reporting of no tests done if no tests were done, otherwise reporting of results) on a daily basis;
    b. Submission of results and data to the DOH-Epidemiology Bureau - COVID-19 Surveillance and Quick Action Unit (DOH-EB-CSQAU); and,
    c. Submission of results to the Regional and Local Epidemiology and Surveillance Units covering the address of the laboratory and the current address of the case.

C. Laboratory Records

1. The COVID-19 TL shall maintain and ensure the confidentiality of all records in accordance with the RA No. 10173 or Data Privacy Act of 2012. All records shall be kept in a secure area, protected from theft, tampering and damage.
2. The COVID-19 TL shall maintain complete records of all laboratory activities done from laboratory requests, sampling records, analytical reports, to quality control records.
3. The COVID-19 TL shall maintain personnel records, equipment maintenance records, computer programs and electronic data.
4. The COVID-19 TL records shall be kept and organized for easy retrieval
5. The COVID-19 TL shall have protocol on the retention of laboratory documents, records and specimens in accordance to the standards promulgated by the DOH and/or by competent authorities for such purposes.
6. The COVID-19 TL shall have logbook or digital record for:
    a. Receiving of specimen with laboratory request from the health facility or attending physician.
    b. Specimen storage, transport, and disposal.
    c. Reporting and submission of results to the DOH-EB-CSQAU and DOH Regional Epidemiologic and Surveillance Unit.
    d. Sentinel/adverse events.
    e. Preventive and corrective maintenance of equipment and instruments.
    f. Maintenance and monitoring of health facility.
7. The COVID-19 TL shall have a written plan on the maintenance and transfer of records in the event of change in ownership or termination of operation.

VII. ENVIRONMENTAL MANAGEMENT

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

A. The COVID-19 TL shall have a written plan and program of proper disinfection and preventive maintenance of the facility.

B. The COVID-19 TL shall have appropriate signage, and that only authorized personnel shall be allowed entry.

C. The COVID-19 TL shall strictly observe the use of Personal Protective Equipment and adherence to Infection Control Policies.

D. The COVID-19 TL shall have 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).

E. The COVID-19 TL shall have a Memorandum of Agreement (MOA)/Memorandum of Understanding (MUA) with infectious waste and toxic and hazardous substances hauler or EMB certificate, as applicable.