Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

May 26, 2020

DEPARTMENT CIRCULAR
No. 2020 – 0227

TO : **ALL HEADS OF HOSPITALS AND OTHER HEALTH FACILITIES, REGIONAL DIRECTORS, CHIEFS OF THE HEALTH FACILITIES AND SERVICES REGULATORY BUREAU AND THE CENTERS FOR HEALTH DEVELOPMENT – REGULATION, LICENSING AND ENFORCEMENT DIVISION AND OTHER STAKEHOLDERS CONCERNED**

SUBJECT : **Additional Requirement in the Licensing of a COVID-19 Testing Laboratory**

The current COVID-19 pandemic demanded an increase in the testing capability for SARS-CoV-2. To address such demand, the certification process by the Research Institute for Tropical Medicine and the licensing process of the Health Facilities and Regulatory Bureau were merged and streamlined. This measure resulted in a more efficient and faster licensing process (shorter than the prescribed Citizen's charter timeline). There are now 42 COVID-19 testing laboratories as of May 25, 2020, 38 of which perform real time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR), while 8 perform Cartridge Based Polymerase Chain Reaction (CB-PCR).

However, the discrepancy in the reporting of the number of confirmed cases and the number of unique individuals tested was noted. To address the issues on data reporting and harmonization, the COVID-KAYA application was developed. This shall now be the new format for the mandatory reporting of the licensed laboratory's daily output.

As such, all COVID-19 testing laboratories are hereby required to be oriented and trained on the use of the COVID-KAYA application prior to issuance of their License to Operate. This must be completed in Stage 3 of the certification and licensing process (Annex A). Moreover, the licensed COVID-19 testing laboratories shall submit their daily output to the COVID-KAYA

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COVID-19 testing laboratory **Encoders and their alternates** are enjoined to attend this free 2-hours online training for the COVID-KAYA being given by the Department of Health - Epidemiology Bureau (DOH-EB) or its deputized/recognized training provider, the Filinvest City Foundation. For particulars on the training schedules, you may contact Mr. Ray Justin Ventura or Ms. Mariz Blanco of DOH-EB at 2019ncov.central@gmail.com, or Mr. Marc Cristobal Baricaua for Filinvest at marcelo.baricaua@filinvestgroup.com.

For immediate implementation and strict compliance.

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

CERTIFIED TRUE COPY

JUN 23 2020

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

ANNEX A

RESEARCH INSTITUTE FOR TROPICAL MEDICINE'S (RITM) MULTISTAGE ASSESSMENT PROCESS AND HEALTH FACILITIES AND SERVICES REGULATORY BUREAU'S (HFSRB) LICENSING OF COVID-19 TESTING LABORATORY

STAGE 1: SELF ASSESSMENT AND APPLICATION FOR DOH-LICENSE TO OPERATE (DOH-LTO)

- The laboratory will conduct a self-assessment to check its readiness to perform the Polymerase Chain Reaction (PCR) method to detect SARS-CoV-2. This will include considerations for the design and layout of the facility, the direction of the workflow, the availability of equipment, trained personnel, logistics and supplies, management systems, and safety controls.

- The facility shall then submit a completely filled out Application Form (Annex E[1]) and the following self-assessment tools:
  - HFSRB's Assessment Tool for Licensing a COVID-19 testing laboratory (Annex A1[2])
  - RITM's Laboratory Assessment Tool (Annex B1[1])
  - RITM's Laboratory Biosafety Assessment Tool (Annex B2[1])
  - WHO risk assessment form (Annex C[1])

  [1]Administrative Order No.2020-0014: Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines.
  [2]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."

STAGE 2: ON-SITE ASSESSMENT (INSPECTION)

- The submitted filled out Application form and self-assessment tools shall be reviewed by the DOH Assessment Team, composed of personnel from HFSRB and RITM, to determine the facility's readiness which shall serve as a guide for prioritization in scheduling of inspection visits.
- An announced on-site visit shall be arranged to check/validate the requirements. The DOH Assessment Team shall then provide the results of the assessment done, specifically the gaps identified and offer technical and safety recommendations for correction.
- The laboratory shall be given a copy of the consolidated report of the findings of HFSRB and RITM.

STAGE 3: COMPLIANCE

- The Secretariat will send the laboratory a copy of the on-site report.
- The laboratory shall be given a period of time to comply with the requirements and recommendations, and shall submit evidences as proof of compliance.
- The DOH Assessment Team shall evaluate the submitted evidences for correctness and completeness

- Personnel training requirements must be complied with at this stage, such as but not limited to Fundamentals of Biosafety Training, COVID-KAYA orientation training for the encoders.
- If the requirement for RITM has been satisfactorily met, the laboratory can now proceed to the next stage (Proficiency Testing).
- The laboratory shall continue to comply with HFSRB's requirements and standards if not yet satisfactorily met.

STAGE 4: PROFICIENCY TESTING OR ITS EQUIVALENT

- The laboratory shall be provided a Proficiency Test (PT) panel consisting of a set of unknown samples to be tested by its staff. The answers to the PT panel shall be submitted to RITM for assessment of the laboratory's capability to correctly and accurately test for COVID -19. If a laboratory failed in the 1st PT panel, corrective measures should be undertaken before giving the 2nd panel. Failing the 2nd panel would require re-training of the analysts before another set of panel would be provided.
- If a laboratory successfully passes the PT, it can now proceed to the next stage.
- RITM may evaluate the Competency Assessment of the laboratory, in lieu of PT, for COVID-19 testing laboratory performing cartridge-based PCR.
- RITM shall then transmit to HFSRB a Certification that the laboratory has passed the Proficiency Testing or the Competency Assessment, whichever is applicable, as proof that the Molecular Laboratory can perform independent testing for COVID 19 (SARS-CoV-2)

STAGE 5: ISSUANCE OF DOH-LTO

- A License to Operate a General Clinical Laboratory for COVID-19 testing shall then be issued upon receipt of the Certification from RITM and upon satisfactory compliance to HFSRB's standards and requirements.
- Participation in the Proficiency Testing program of the RITM shall be enforced for performance monitoring.