Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

June 28, 2021

DEPARTMENT CIRCULAR
No. 2021 - 0275

FOR : **DIRECTORS OF CENTERS FOR HEALTH DEVELOPMENT (CHD); DIVISION CHIEFS OF CHD REGULATIONS, LICENSING AND ENFORCEMENT DIVISION (RLED) AND HEALTH FACILITIES AND SERVICES REGULATORY BUREAU; MINISTER OF HEALTH-BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (MOH-BARMM); REGULATORY OFFICERS; HEAD OF COVID-19 TESTING LABORATORIES; AND ALL OTHERS CONCERNED**

SUBJECT : **Advisory on the Regulation on Innovations in the RT-PCR Plate Based Diagnostic Platform for COVID-19**

Pursuant to Department Memorandum (DM) No. 2020-0512, "Revised Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, and Reintegration Strategies for COVID-19" issued on November 26, 2020, the Department of Health (DOH) continues to intensify the strategies for the screening and surveillance testing as part of COVID-19 response. Part of the innovative strategies identified and employed were pooled testing and use of saliva as a specimen for COVID-19 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) to efficiently identify cases and maximize the available resources.

In support of these innovations, DOH released DM No. 2020-0539 titled "Interim Guidelines on the Conduct of COVID-19 Pooled Testing" dated November 23, 2020, and its amendment issued on May 17, 2021, and DM No. 2021-0161 titled "Interim Guidelines for the Conduct of Saliva-Based RT-PCR Testing for the Detection of SARS-COV-2" dated March 31, 2021, to guide DOH licensed COVID-19 laboratories on the use of these innovations in the RT-PCR plate based diagnostic platform for COVID-19.

This Circular is being issued to reiterate the guidelines in the above-mentioned DMs and as a guide in the regulation of these innovative services:

1. The nasopharyngeal and/or oropharyngeal swabs (NPS/OPS) shall remain the specimen of choice for COVID-19 PCR testing.

2. Only DOH licensed plate-based RT-PCR COVID-19 testing laboratory shall be allowed to conduct these innovations in the diagnostic platform (i.e., pooled testing and use of saliva as specimen for RT-PCR testing) as add-on services, once recommended by the Health Technology Assessment Council (HTAC). The relevant procedures for each of the innovations in the diagnostic platform shall be included in their Manual of Operations.

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 local 1108, 1111, 1112, 1113
Direct Line: 711-9502; 711-9503 Fax: 743-1829 • URL: http://www.doh.gov.ph; e-mail: ftduque@doh.gov.ph

3. These RT-PCR COVID-19 testing laboratories 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.

4. 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.

5. 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.

6. 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 World Health Organization shall be used.

7. The personnel of the COVID-19 testing laboratory who will perform the innovations in the plate based diagnostic platform shall undergo the corresponding training for such procedures.

8. A full line list of negative and positive specimens shall be reported through the COVID-19 Repository Document System (CDRS).

9. Monitoring may be done by the Health Facilities and Service Regulatory Bureau (HFSRB)/Center for Health Development-Regulatory, Licensing and Enforcement Division (CHD-RLED).

10. 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/CHD-RLED its findings and recommendations.

11. All DOH licensed COVID-19 testing laboratories shall have policies and procedures for waste management in accordance with the DOH Healthcare Waste Manual.

12. All DOH licensed COVID-19 testing laboratories 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.

13. All DOH licensed COVID-19 testing laboratories shall strictly adhere to the standards and requirements set forth in AO No. 2020-0014 "Guidelines in Securing a License to Operate COVID-19 Testing Laboratory in the Philippines," its amendments and assessment tool at all times.

For dissemination.

By Authority of the Secretary of Health:

GERARDO V. BAYUGO, MD, MPH, CESO I
Undersecretary of Health
Health Regulation Team

Attachment

Additional Requirements for the Conduct of the Innovations in the RT-PCR Plate Based Diagnostic Platform for COVID-19

A. Pooled Testing

1. The indication for Pooled Testing shall follow eligibility criteria specified in Section III. Specific Guidelines of DM 2020-0539 and its amendment.

2. The personnel for pooled testing are required to attend documentation and sample pooling strategies provided by the Philippine Society of Pathologists through the Philippine Children's Medical Center for pooled testing.

3. The recommended maximum number of samples for pooled testing is up to five (5).

B. Saliva as Specimen for COVID-19 Testing

1. The indication for saliva as specimen shall follow the DOH guidelines and RITM's "Standard Method for Verification of Saliva as Alternative Specimen for SARS-COV-2 Real Time PCR Testing: Interim Guidance for Laboratories in the COVID-19 Laboratory Network" dated February 7, 2021.

2. There should be policies and procedures on saliva collection to ensure the quality of the sample. A laboratory staff shall oversee the saliva collection activity.