Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

October 26, 2020

DEPARTMENT MEMORANDUM
No. 2020 - 0468

TO: **ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS AND CENTERS FOR HEALTH DEVELOPMENT; MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO); EXECUTIVE DIRECTORS OF SPECIALTY HOSPITALS AND NATIONAL NUTRITION COUNCIL; CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA AND INSTITUTES; PRESIDENT OF THE PHILIPPINE HEALTH INSURANCE CORPORATION; DIRECTORS OF PHILIPPINE NATIONAL AIDS COUNCIL AND TREATMENT AND REHABILITATION CENTERS, AND OTHERS CONCERNED**

SUBJECT: **Supplemental Guidance on the Use of Rapid Antigen Test Kits**

I. BACKGROUND

This is to provide additional guidance on the use of rapid antigen test kits for COVID-19 and reiterate corresponding provisions on the Department Memorandum No. 2020-0439 entitled "Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, and Reintegration Strategies for COVID-19" and the Republic Act (RA) No. 11494 or the "Bayanihan to Health as One Act."

These guidelines are also made following the recommendations of the World Health Organization (WHO), Health Technology Assessment Council (HTAC), and results of the pilot studies on testing of close contacts of confirmed COVID-19 cases and travelers in Baguio City.

II. IMPLEMENTING GUIDELINES

1. Regardless of risk severity, minimum public health standards, including physical distancing, hand hygiene, cough etiquette, and wearing of masks, among others, shall be strictly implemented across all settings.

2. DM 2020-0439 entitled, "Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, and Reintegration Strategies for COVID-19" highlights the "quarantine or isolation first" approach, establishing exposure and identification of symptoms. Hence, close contacts shall be quarantined or isolated immediately and managed according to the severity of symptoms.

3. Rapid antigen tests shall be allowed for **diagnostic testing of close contacts** in communities and closed or semi-closed institutions with confirmed outbreaks and in

remote settings where RT-PCR is not immediately available.

a. For symptomatic close contacts, antigen testing can be used as a confirmatory test.
b. For asymptomatic close contacts, antigen test can be used provided that the negative results are confirmed with RT-PCR or be subjected to repeat antigen testing within 48 hours after the first negative test results.

4. The use of antigen tests is not recommended in settings with an expected low prevalence of disease or populations with no known exposure, such as among asymptomatic travelers or for border control.

5. Antigen tests are most useful during the acute phase of the disease when the viral load is high, which is within 5 days after onset of symptoms.

6. A positive antigen test among close contacts is interpreted as a confirmed COVID-19 case. For asymptomatic close contacts who test negative with rapid antigen test, the result of the confirmatory test (either through RT-PCR or repeat antigen test) shall be reflected in official DOH reports and tallies. Health care providers shall fill out the Case Investigation Form (CIF) prior to testing, and shall upload the results and CIF through COVID-19 Repository Document System.

7. For operational purposes, the following terminologies are defined:
   a. ***Closed or Semi-Closed Institutions*** - refers to settings where there are limited movement/access outside of the institution and who caters to people under the custody and supervision of certain institutions, such as prisons, psychiatric hospitals and other establishments for persons with physical, mental, or sensory disabilities; institutions for children and the elderly; centers for migrants, refugees, asylum or refugee status seekers, stateless and undocumented persons; and any other similar institutions.
   b. ***Limited RT-PCR Capacity***- adopting the criteria based on Section II.5 of Department Memorandum No. 2020-0446 entitled "Advisory on the Temporary Suspension for Select Regions on Securing License to Operate for COVID-19 Testing Laboratories using GeneXpert Technique"
      i. Regions with **three (3) or less** licensed COVID-19 testing rRT-PCR laboratories; and
      ii. Regions with **at least 30%** Geographically-Isolated and Disadvantaged Areas (GIDAs) barangays per province (*DM 2020-0277, Consolidated List of GIDAs based on Submission of Centers for Health Development (CHDs) and Ministry of Health-Bangsamoro Autonomous Region in Muslim Mindanao as of April 30, 2019).*
   c. ***Outbreak*** - refers to the occurrence of more cases of disease than normally expected within a specific place/area (e.g. community, workplace, public space, and others) or group of people over a given period of time. For novel diseases such as COVID-19, an outbreak is the occurrence of at least one confirmed case in a specific place or area. However, for the purpose of identifying areas who shall be allowed to use antigen testing, it is recommended in areas, or groups of people with an unusual increase in cases or whose number of confirmed cases exceeded the 75th percentile of the number of new cases based on the onset of illness. Outbreaks shall be declared by local government units, as recommended by local and regional epidemiology and

surveillance units, and affirmed by the Secretary of Health.

8. The collection and processing of the specimen should be done in a health facility setting (rural health units, hospitals, health facilities, and DOH licensed clinical laboratories) to ensure that appropriate conditions are in place to minimize risks in patients and health care workers. In GIDAs where access to health facilities is limited, collection may be done outside of a health facility provided that a trained health care worker conducts the specimen collection and appropriate conditions are observed to minimize risks. Use and interpretation of antigen tests should only be done by a qualified licensed healthcare professional in the health facility and should always be correlated with the overall clinical and epidemiological context (i.e. history of exposure).

9. Antigen kits to be procured by the National Government and Local Government Units **shall strictly be used within the bounds of HTAC and DOH recommendations only,** in accordance with Section 4.c.3 of RA 11494 or the Bayanihan to Recover as One Act.
    a. Antigen kits to be procured by the DOH shall be specifically used to support DOH facilities and national government closed or semi-closed institutions with outbreaks, such as but not limited to:
        i. DOH hospitals and health facilities;
        ii. National government-owned care homes; and
        iii. National government-owned correctional facilities
    b. LGUs that procure antigen kits shall strictly monitor its use and immediately report to the DOH all circumstances on indiscriminate use of antigen tests.

10. PhilHealth may opt to cover antigen kits in their benefit package, provided that the use will be strictly within the bounds of HTAC recommendations.

11. In any setting, only COVID-19 antigen test kits authorized by the Philippine Food and Drug Administration (FDA), validated by the Research Institute for Tropical Medicine (RITM), WHO-Foundation for Innovative New Diagnostics (FIND) and other DOH-designated institutions for test kit validation or those included in the World Health Organization Emergency Use Listing (WHO-EUL), and have met the minimum regulatory, technical and operational specifications set by the Health Technology Assessment Council (HTAC) can be used (Annex A).
    a. Only kits with a minimum of 80% sensitivity and 97% specificity are recommended for use.
    b. The DOH through RITM shall regularly publish the list of test kits that have been validated by the RITM and other DOH-designated institutions, as well as the validation results as published in the Foundation for Innovative New Diagnostics.

For strict compliance.

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

Annex A. Minimum Regulatory and Technical Requirements Set by Health Technology Assessment Council

Parameter	Requirement
Regulatory Requirement	Must have a certificate of product registration (CPR) or emergency authorization (EA) from the FDA Philippines
Test kit package content	It is desirable that rapid antigen test kits contain all materials and accessories necessary for the procedure.
Result output	Qualitative, result must be read visually or with a reader but must be operable using batteries
Human resource training	Less than half a day to no additional training needed for healthcare professionals to be able to optimize performance
Biosafety concerns	Can be done without the need for BSL 2 or 3 facilities, provided that there is evidence that the live virus was deactivated early in the process
Clinical Sensitivity	At least 80% sensitivity A useful assessment is the sensitivity of the test in patients with a rRT-PCR cycle threshold (Ct) below a specific value (e.g., 28 or 30)
Clinical Specificity	At least 97% specificity
Processing Time	Less than 2 hours from sample collection to result
Reference Standard	In-house laboratory RT-PCR test or if commercial RT-PCR test, must adhere to the specification stipulated in the HTAC Guidance Document on RT-PCR test kits
Sample Requirement in validation studies	Positive samples: minimum of 30 positive specimens Negative samples: 30 negative specimens Include details such as: • specimen type • specimen collection date • date of onset of symptoms (if present) • date of PCR testing • severity of symptoms (if known) • tests used to identify COVID19 patients, etc.
Requirement for Independent Validation	Must have been validated by an independent or a third-party reputable government or private research institution including but not limited to the following: • Research Institute for Tropical Medicine (RITM) • UP National Institutes of Health (NIH) • US Food and Drug Administration (US-FDA) • World Health Organization, Foundation for Innovative New Diagnostics (WHO-FIND) • Therapeutic Goods Administration (TGA, Australia) • Medicines and Healthcare products Regulatory Agency (MHRA, UK) • Japan Pharmaceuticals and Medical Devices Agency
Transport and Storage Requirements	The storage and working temperature can be 18 to 30 °C. It should be used in a controlled environment.
Shelf-Life	Shelf-life should not be shorter than 12 months at the time of delivery
Calibration Requirement	If calibration is required, it can be done onsite
Cost of test kit	The cost of the RAgT kit should be significantly less than the cost of the RT-PCR test kit