Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

March 31, 2020

DEPARTMENT CIRCULAR
No. 2020 - 0160

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 ALL OTHERS CONCERNED**

SUBJECT: **Guidance on Use of COVID-19 Rapid Antibody-based Test Kits**

In view of the ongoing threat of the spread of the Coronavirus Disease 2019 (COVID-19), the Department of Health (DOH) underscores the importance of having a **full and accurate picture** of COVID-19 in the country. Taking into consideration the recommendations of the Health Technology Assessment Council and the COVID-19 Technical Advisory Group, the following guidance is being issued to ensure that the use of COVID-19 rapid antibody-based test kits will not undermine current public health efforts:

1. Only FDA-approved rapid antibody test kits may be used to ensure that the tests fall within an acceptable range of quality. As a number of tests are currently being marketed, it remains the Department's responsibility to ensure that the public is protected against substandard rapid antibody-based test kits.

2. All rapid antibody-based test kits CANNOT be used as a stand-alone test to definitively diagnose COVID-19. RT-PCR test kits remain to be the gold standard in determining whether a person is infected and infectious.
    a. All rapid antibody-based test kits can only be used in people who had onset of symptoms for at least 5 days for IgM, and 21 days for IgG.
    b. Because a positive or negative IgM test DOES NOT confirm COVID-19:
        i. Individuals who tested positive for IgM shall be required to remain isolated and be swabbed for RT-PCR. Only after a positive RT-PCR test shall the individual count as a positive case.
        ii. Individuals who tested negative for IgM, especially those symptomatic, shall be required to remain isolated and be swabbed for RT-PCR test because they may be infectious.
    c. Individuals who tested positive for IgG-only shall be labeled as presumptive past COVID-19 patient and not be officially counted as confirmed UNLESS a further validation is conducted (e.g. validated with a PRNT by a third party).

3. The rapid antibody-based test kits (most of which test for both IgM/IgG) can be used as an **adjunct tool**. Results can serve as a basis for clearing patients who are asymptomatic and have completed their 14-day quarantine after they have been discharged from the health facility. In these cases, the presence of antibodies means viral clearance. Hence:
    a. If the individual tests positive for IgG, they may be cleared.
    b. If the individual tests negative for IgG, repeat swab and RT-PCR needs to be done.

4. In light of the above difficulties in interpretation and the high risk of misinterpretation:
    a. Rapid antibody-based test kits **cannot be used for mass testing or self-testing. over-the-counter, or self-testing**.
    b. Selling of COVID-19 rapid antibody test kits over-the-counter shall be strictly prohibited, unless with valid prescription.
    c. Only medical doctors can prescribe the use of the rapid antibody-based test kits, and interpret the results.

5. Since the Health Technology Assessment Council does not recommend the use of such technology, particularly for mass testing, no public funds shall be used to pay for any COVID-19 rapid antibody-based test kit.

6. The healthcare worker (medical technologist or physician) collecting serum for rapid antibody-based test kits must observe standard precautionary measures, including the use of full PPE.

7. Only results of RT-PCR tests shall be included in COVID-19 reports published by the Department of Health.

8. Failure to comply with these guidelines in contravention of R.A. No. 2382 or Medical Act of 1959, R.A. No. 9711 or Food and Drug Administration Act of 2009, and other pertinent laws, rules, and regulations, shall be dealt with accordingly.

For strict compliance.

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