Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

April 16, 2020

DEPARTMENT MEMORANDUM
No. 2020 - 0180

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: **Revised Interim Guidelines on Expanded Testing for COVID-19**

I. INTRODUCTION

Coronavirus disease 2019 (COVID-19) was first reported in December 2019 as a cluster of pneumonia cases of unknown etiology. With the increasing number of cases and deaths in various territories, the World Health Organization declared COVID-19 as a pandemic last March 11, 2020. With the increasing COVID-19 cases in the country, there is also a subsequent increase in the demand for RT-PCR testing all over the country. In order to maximize the limited testing capacity, the Department of Health issues these guidelines on risk-based testing for COVID-19.

II. GENERAL GUIDELINES

1. COVID-19 Expanded Testing is defined as testing all individuals who are at-risk of contracting COVID-19 infection. This includes the following groups: (1) suspect cases or (2) individuals with relevant history of travel and exposure (or contact), whether symptomatic or asymptomatic, and (3) health care workers with possible exposure, whether symptomatic or asymptomatic.

    a. The following exposures should have happened two (2) days before or within 14 days from onset of symptoms of a confirmed or probable case:
        1) Face-to-face contact with a confirmed case within 1 meter and for more than 15 minutes
        2) Direct physical contact with a confirmed case
        3) Direct care for a patient with probable or confirmed COVID-19 disease without using proper personal protective equipment

    b. Indiscriminate testing beyond close contacts of a confirmed COVID-19 case is not recommended.

2. The following reflects the sub-groups of at-risk individuals arranged in order of greatest to lowest need for testing:

    a. Subgroup A: Patients or healthcare workers with **severe/critical** symptoms, relevant history of travel/contact
    b. Subgroup B: Patients or healthcare workers with **mild** symptoms, relevant history of travel/contact, and considered **vulnerable**
    c. Subgroup C: Patients or healthcare workers with mild symptoms, relevant history of travel/contact
    d. Subgroup D: Patients or healthcare workers with no symptoms but relevant history of travel/contact

3. Due to global shortage of testing kits and limitation in local capacity for testing, there is a need to rationalize available tests and prioritize subgroups A and B.

4. However, in view of the expansion of testing capacity and to ensure healthcare workforce safety, subgroup C will be tested and health workers prioritized.

5. All subnational laboratories are directed to allocate between 20-30% of their daily testing capacity for health workers and the remaining 70%-80% for patients.

6. Based on current available evidence, real-time polymerase chain reaction (RT-PCR) testing is the confirmatory test. In the Philippines, this pertains to using RT-PCR test kits that are approved by the Food and Drug Administration (FDA), and validated by the Research Institute for Tropical Medicine (RITM).

7. Rapid antibody-based test kits shall not be used as standalone tests to definitively diagnose or rule out COVID-19. Because these must be used in conjunction with RT-PCR, care must be exercised to not unduly consume RT-PCR test kits for the sake of confirmation.

8. Reporting of confirmed and recovered cases shall continue to be based on RT-PCR testing, in accordance with Administrative Order 2020-0013.

9. Only rapid antibody-based test kits approved by the FDA and locally-validated by the RITM or the Department of Science and Technology may be used.

10. Disposal of test kits, including PPEs and other materials used in testing, shall adhere to existing guidelines on the management of healthcare wastes.

11. Expanded use of point-of-care rapid antibody-based test kits through validation and sero-epidemiological studies shall be explored for Subgroup D, as testing all asymptomatic contacts of confirmed cases using RT-PCR is not recommended until there is surplus testing capacity.

12. Results of such validation and sero-epidemiological studies shall be submitted to DOH, and to the Health Technology Assessment Council (HTAC) for their review and consideration. This should inform future prospects of financing of DOH and PhilHealth since both agencies may only finance or reimburse COVID-19 test kits that have been positively recommended by the HTAC as required by RA No. 11223.

III. SPECIFIC GUIDELINES

A. The following guidelines shall apply once the FDA-approved antibody-based test kits have been validated by RITM and other designated institutions.

B. Only licensed medical doctors may request and administer antibody-based tests.

1. The medical doctor shall be responsible for:
   a. wearing appropriate personal protective equipment provided by the health institution, prior to administering test;
   b. following DOH published guidelines on case management;
   c. filling online Case Investigation Form for each tested individual and coordinating with regional epidemiological surveillance unit;
   d. monitoring and reporting adherence to case management on a daily basis using the online form/app provided by the DOH to be submitted to covid19rdt@gmail.com (Annex A);
   e. referring antibody-based test positive cases which belong to Subgroup A and B for possible admission to hospital and confirmatory testing for RT-PCR; and referring antibody-based test positive cases which belong to Subgroup C and D for possible admission to Community Isolation Facilities; and
   f. Issuing official receipt to the patient for the services rendered.

2. Failure to comply with the above mentioned responsibilities may be considered violation of RA 11332, which penalizes "non-cooperation of persons and entities that should report and/or respond to notifiable diseases or health events of public concern", penalty of which is fine not less than Php 20,000 but not more than Php 50,000 or imprisonment of not less than one month but not more than 6 months, or both such fine and imprisonment, and other applicable laws, rules and regulations

C. For Health Care Workers

1. All **symptomatic healthcare workers** should be isolated and tested using RT-PCR test.

   a. All symptomatic healthcare workers who test positive using RT-PCR must be isolated or hospitalized depending on the severity of symptoms.

   b. After 14 straight days without symptoms, the healthcare worker can be subjected to antibody testing.
      i. If IgG is positive, regardless of IgM result, the health worker can return to work and does not need repeat testing unless s/he develops symptoms.
      ii. If IgG remains negative, an RT-PCR can be done:
         1. If RT-PCR is negative, the healthcare worker can return to work.
         2. If RT-PCR is positive, the healthcare worker should undergo repeat RT-PCR testing after 7 days and can be cleared once the test returns negative.
      iii. If there is no available RT-PCR, the healthcare worker can be tested using antibody-based tests every 7 days and cleared for work once IgG turns positive, regardless of IgM result.

c. All symptomatic healthcare workers who test negative using RT-PCR may return to work upon resolution of symptoms, then be subject to guidelines for asymptomatic healthcare workers

2. All **asymptomatic healthcare workers** with unprotected exposure should be isolated and tested with RT-PCR. If there is no available RT-PCR, they can be tested using antibody-based tests every 14 days and cleared for work if IgM and IgG is negative, if IgG is positive, or if RT-PCR is negative.

    a. Exposure is defined as working in a healthcare facility with confirmed COVID-19 patients within the last 14 days without appropriate PPE.

    b. All IgM positive but IgG negative healthcare workers who are asymptomatic can be tested with RT-PCR, if and when the testing capacity becomes available.

        i. If cleared using a negative RT-PCR, they are allowed to return to duty granted that they have remained asymptomatic. They may be retested with an antibody test after 14 days for development of IgG. If IgG remains negative, continue testing with antibody test or RT-PCR every 14 days as long as exposure is occuring.
        ii. If they develop symptoms, they shall be prioritized for RT-PCR testing and shall follow protocol indicated in Section III.C.1.

    c. All IgG positive healthcare workers, whether IgM positive or negative, can return to work, provided they be retested with an RT-PCR if they develop symptoms.

D. For Symptomatic Non-Health Care Workers

1. Testing of all symptomatic patients who are close contacts of a known or probable case must be conducted by health workers equipped with proper Personal Protective Equipment. Patients must be isolated at all times.

2. Testing of symptomatic patients who are close contacts of a known or probable case with rapid antibody-based test kits *alone* is not recommended. If there is no available RT-PCR, validated rapid antibody-based testing that detects both IgM and IgG may be used. **However, regardless of results, patients should remain isolated for 14 days or until asymptomatic, whichever is longer** (Annex B).

    a. If **IgM negative**, collect samples for RT-PCR testing
        i. If RT-PCR negative, the patient is not a COVID-19 case but has to complete the 14-day quarantine.
        ii. If RT-PCR positive, the patient is a confirmed COVID-19 case and shall be treated and undergo isolation accordingly.
        iii. If RT-PCR testing is not available, isolate the patient for 14 days or until asymptomatic, whichever is longer.
            1. If the initial IgG is positive, the patient can be released from quarantine once 14 days is completed or asymptomatic, whichever is longer. If the initial IgG is negative, repeat rapid antibody-based testing once asymptomatic or after 14 days, whichever is longer.

2. If results on repeat testing are IgG positive, regardless of IgM result, patients can be released from quarantine.
3. If results on repeat testing are IgM and IgG negative, patients can be released from quarantine.
4. If results on repeat testing are IgM positive and IgG negative, extend quarantine by seven-day increments and repeat testing. If persistently IgM positive but IgG negative for two consecutive retestings after the 1st 14 day period, consider potential false positives and confer with infectious diseases specialists.

b. If IgM positive, the patient is a probable COVID-19 case. Collect swab for RT-PCR testing.
   i. If RT-PCR positive, the patient is a confirmed COVID-19 case and shall be treated and undergo isolation accordingly.
   ii. If RT-PCR negative, the patient has to complete the 14-day quarantine or until asymptomatic whichever is longer and repeat rapid antibody-based test once asymptomatic.
      1. If results on repeat testing are IgG positive, regardless of IgM result, patients can be released from quarantine.
      2. If results on repeat testing are still IgM positive and IgG negative, extend quarantine by seven-day increments and repeat testing. If persistently IgM positive but IgG negative for two consecutive retestings after the 1st 14 day period, consider potential false positives and confer with infectious diseases specialists.
   iii. If RT-PCR testing is not available, isolate for 14 days or once asymptomatic whichever is longer. Repeat rapid antibody-based testing once asymptomatic or at 14 days of quarantine whichever is longer;
      1. If results on repeat testing are IgG positive, regardless of IgM result, patients can be released from quarantine.
      2. If results on repeat testing are still IgM positive and IgG negative, extend quarantine by seven-day increments and repeat testing. If persistently IgM positive but IgG negative for two consecutive retestings after the 1st 14 day period, consider potential false positive and confer with infectious diseases specialists.

E. For Asymptomatic Non-Health Care Workers

1. All asymptomatic non-health care workers who are close contacts of confirmed cases need to complete 14 days of quarantine from the date of last contact with the confirmed case either at a temporary treatment and monitoring facility or home quarantine if with a solo room and toilet, ***regardless of rapid antibody-based test result***. If symptoms develop at any time, collect samples for RT-PCR testing.

2. Rapid antibody-based testing may be used for asymptomatic non-health care workers who are close contacts of confirmed COVID-19 cases, provided rapid antibody-based kits are validated, PPEs are available for the healthcare worker performing the test.

3. For settings where resources permit and there is sufficient availability of rapid antibody-based testing kits and PPEs, testing may be done twice. First must be done

at the time of isolation, but preferably at least 5 days from exposure, and another on the last day of quarantine (Annex C).

a. If the patient tests negative for both IgM and IgG, repeat testing on the 14th day. if still negative, they may be released from quarantine.

b. If the patient tests positive for IgG, regardless of the result of IgM, the patient is considered a presumed recovered case, and there is no need to repeat the test at the end of the quarantine period. The contacts of the patient, as defined in Section II.1.a. of this policy, shall be subjected to COVID-19 testing as well.

c. Patients who test IgM positive but IgG negative on the 1st test shall repeat testing on the 14th day of quarantine. If results are still IgM positive and IgG negative, extend quarantine by seven-day increments and repeat testing. If persistently IgM positive but IgG negative for two consecutive retestings after the 1st 14 day period, consider potential false positives and confer with infectious diseases specialists.

4. For settings with limited availability of rapid antibody-based testing kits and PPE, testing may be done once only, during the 14th day from contact with a confirmed case.

   a. If IgM-positive but IgG-negative, extend quarantine by seven-day increments and repeat testing. If persistently IgM-positive but IgG-negative for two consecutive retestings after the 1st 14 day period, consider potential false positives and confer with infectious diseases specialists.
   b. If IgM-negative and IgG-negative, or IgG-positive regardless of IgM, they can be released from quarantine.

5. If there are no available rapid test kits and/or PPE, patients can be released from quarantine after 14 days as long as the patient remains asymptomatic.

F. For Returning Overseas Filipinos (OFs)

1. All OFs returning to the Philippines from countries with community-based COVID-19 transmission shall undergo mandatory 14-day quarantine.

2. The OF may be tested with an antibody test at time of admission to the quarantine facility for baseline and at the end of the 14-day quarantine period for appropriate action regarding discharge.

3. The results at the end of 14-day quarantine are to be interpreted as follows:
   a. If both IgM/IgG remain negative, release from quarantine
   b. If IgG-positive and asymptomatic, release from quarantine
   c. IgM-positive but IgG-negative, extend quarantine by seven-day increments and repeat testing. If persistently IgM-positive but IgG-negative for two consecutive retestings after the 1st 14 day period, consider potential false positives and confer with infectious diseases specialists.
   d. If the patient becomes symptomatic anytime during the quarantine, perform a nasal swab for RT-PCR.

G. For Surveillance of Areas with Suspected COVID-19 Community-Based Transmission

1. Expanded testing in areas with suspected COVID-19 community-based transmission can be performed at the household, purok, and barangay level with a proper sampling methodology in collaboration with the Epidemiology Bureau and local health officials.

2. A properly validated antibody testing kit should be used for this purpose.
   a. Pending availability of PRNT validation by RITM, all who intend to conduct their own validation studies are requested to:
      i. register their studies through covid19rdt@gmail.com (including update on status of ethics approval)
      ii. use the protocol for local validation study for asymptomatic contacts provided (Annex C)
      iii. report testing results

3. Testing of asymptomatic people should be performed with proper safety precautions, including hand hygiene, use of appropriate PPEs for conducting the test, respiratory hygiene, waste disposal, and patient care equipment.

4. All symptomatic patients should be referred for RT-PCR testing and isolated accordingly.

IV. REPEALING CLAUSE

Department Memorandum 2020-0151 entitled "Guidelines on Expanded Testing for COVID-19" and other related issuances inconsistent or contrary to the provisions of this Memorandum are hereby repealed.

For strict compliance.

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

Annex A. CASE TABULATION FORM

Brand of Test Kit	PhilHealth ID Number	Date of exposure to known case	IgM/IgG result (+/-)		Date IgM/ IgG done	RT-PCR result (only if IgM+/IgG- OR if developed symptoms)	Outcome at the end of 14 days from exposure (asymptomatic, symptomatic non-COVID, COVID confirmed asymptomatic, COVID confirmed symptomatic)
			IgM	IgG			
1.							
2.							
3.							
4.							
5.							

Data analysis

Positive and negative results will be tabulated and analyzed. Since there is no gold standard for asymptomatic patients, serology results will not be used to confirm presence of absence of disease. Only positive RT-PCR patients will be labeled as confirmed cases. Patients with isolated IgM but are PCR negative and remain asymptomatic for 14 days will be considered false positives.

ANNEX B. USE OF RAPID ANTIBODY TESTS AS ADJUNCT TEST FOR TESTING COVID-19 AMONG SYMPTOMATIC PATIENTS WITH RELEVANT HISTORY OF TRAVEL/EXPOSURE

<table>
<tr><th colspan="2">Initial Result</th><th rowspan="2">Action</th><th rowspan="2">Action after 14-day quarantine or until asymptomatic, whichever is longer</th></tr>
<tr><th>IgM</th><th>IgG</th></tr>
<tr><td rowspan="2">(-)</td><td rowspan="2">(-)</td><td rowspan="3">Swab for RT-PCR
• If RT-PCR (+), COVID-19 CASE. Treat and isolate accordingly.
• If RT-PCR (-), not a COVID-19 case, but has to complete 14-day isolation. No need to repeat antibody tests.
• If RT-PCR not available, isolate for 14 days or until asymptomatic, whichever is longer</td><td>Repeat antibody test if RT-PCR is not available.

If IgM(-) & IgG(+), or IgM(+) & IgG(+), or IgM(-) & IgG(-),
• release from quarantine

If IgM(+)&IgG(-),
• extend quarantine by seven-day increments and repeat testing
• If persistently IgM positive but IgG negative for two consecutive retestings after the 1st 14 day period, consider potential false positives and confer with infectious diseases specialists.</td></tr>
<tr><td>(-)</td><td>(+)</td><td>No need to repeat antibody test. Release from quarantine.</td></tr>
<tr><td rowspan="2">(+)</td><td rowspan="2">(-)</td><td rowspan="2">Probable COVID-19 Case:
Swab for RT-PCR
• If RT-PCR (+), COVID-19 CASE. Treat and isolate accordingly.
• If RT-PCR (-), not a COVID-19 case, but has to complete 14-day isolation. Repeat antibody test.
• If RT-PCR not available, isolate for 14 days or until asymptomatic, whichever is longer</td><td>Repeat antibody test RT-PCR (-) or RT-PCR not available.

If IgM(-) & IgG(+), or IgM(+) & IgG(+), or IgM(-) & IgG(-),
• release from quarantine

If IgM(+)&IgG(-),
• extend quarantine by seven-day increments and repeat testing
• If persistently IgM positive but IgG negative for two consecutive retestings after the 1st 14 day period, consider potential false positives and confer with infectious diseases specialists.</td></tr>
<tr><td>(+)</td><td>(+)</td></tr>
</table>

** Rapid antibody-based test is an adjunct test and shall **not be used as a standalone test** to definitively diagnose or rule out COVID-19*

The medical practitioner shall wear **full personal protective equipment provided by the health institution, when collecting specimens both for RT-PCR and rapid antibody test.*

ANNEX C. USE OF RAPID ANTIBODY-BASED TESTS FOR TESTING COVID-19 AMONG ASYMPTOMATIC PATIENTS WITH RELEVANT HISTORY OF TRAVEL OR EXPOSURE

<table>
<tr><th colspan="2">Results on Day 1 Quarantine</th><th rowspan="2">Action</th></tr>
<tr><th>IgM</th><th>IgG</th></tr>
<tr><td>(-)</td><td>(-)</td><td>Repeat testing on Day 14
• If still negative, release from quarantine</td></tr>
<tr><td>(+)</td><td>(+)</td><td rowspan="2">Presumed recovered case
• Release from quarantine
• No need to repeat the test at the end of the quarantine period</td></tr>
<tr><td>(-)</td><td>(+)</td></tr>
<tr><td>(+)</td><td>(-)</td><td>Probable COVID-19 Case:
Repeat testing on Day 14
• If still IgM (+) and IgG (-), extend quarantine by 7 day increments
○ If persistently IgM (+) and IgG (-) for two consecutive retestings after the 1st 14 day period, refer to infectious diseases specialist
• If IgG (+), regardless of IgM result, release from quarantine</td></tr>
</table>

This tool is applicable only when there is sufficient supply of rapid antibody test kits and assurance that health workers administering the tests are equipped with full personal protective equipment.

ANNEX D. CLINICAL DIAGNOSTIC UTILITY OF AN IgM/IgG LATERAL FLOW ASSAY IN COVID-19 FOR ASYMPTOMATIC CONTACTS

Introduction

COVID-19 is a respiratory disease caused by the SARS-CoV-2 virus. As cases continue to increase in the Philippines, scaling up testing has been challenging. The test of choice for COVID-19 is an RT-PCR which requires a BSL2 facility, expensive equipment and materials, and highly trained personnel. The turnaround time is typically 6 to 8 hours. Due to the current high demand for testing and limited capacity, tests have been significantly delayed and cause major issues in hospital management of suspected COVID-19 patients. In the meantime, lateral flow assays have appeared on the market purportedly to test IgM and IgG antibodies for quick diagnosis. Lateral flow assays can offer results in as little as 15 minutes from a small sample of blood. However, lateral flow assays can be notoriously inaccurate compared to ELISAs and other immunoglobulin-based tests. In addition, due to the short incubation period of COVID-19, the production of IgM is only starting at symptoms onset and will have a significant risk of being falsely negative even in symptomatic individuals. This project will look at the clinical utility of an approved COVID-19 IgG/IgM (Whole Blood/Serum/Plasma) Rapid Test as an adjunct diagnostic to RT-PCR in the diagnosis of COVID-19.

There is very little peer reviewed data on the utility of lateral flow assays for COVID-19. A study by Li and colleagues (2020) reported a sensitivity was 88.66% and specificity was 90.63% with a caveat that the gold standard used was PCR. A study by Guo et al. (2020) profiling early humoral response in COVID-19 using ELISA showed that combining IgM and RT-PCR results resulted in an increased positive detection from 51.9% for PCR alone to 98.6% by combining both tests. An ELISA developed by Duke/NUS has been validated using viral neutralization assays but results have not yet been published in peer-reviewed literature

(https://www.gov.sg/article/how-a-breakthrough-lab-test-expert-contact-tracing-solved-mystery-behind-largest-covid-19-cluster).

Objectives

1. Determine the distribution of results of an IgM/IgG lateral flow assay in asymptomatic patients who are in close contact with known COVID-19 patients.
2. Determine whether IgM positivity correlates to a positive RT-PCR in asymptomatic patients.
3. Determine whether IgM positive asymptomatic patients eventually develop symptoms consistent with COVID-19 within a 14-day period.

Methodology

- Study design : cross-sectional
- Study population : asymptomatic but with known close contact with a confirmed case in the last 5 days or more
- Inclusion criteria: asymptomatic close contact
- Exclusion criteria: symptomatic patients
- Sample size computation: using the population of ____ and an estimated 20% prevalence of IgG, confidence level of 95% and a margin of error of 5%, the computed total sample size is at least ___

Site of the study : ____

Study methodology :

- Asymptomatic patients with a history of close contact with a known COVID-19 case will be enrolled. Either a finger stick or venous whole blood from a laboratory draw will be used to

inoculate the IgM/IgG test kits for the cross-sectional study. If the patient develops any COVID-19 type symptoms for the duration of the study, he/she should be tested with an RT-PCR regardless of IgM/IgG results.

- The results of the IgM/IgG test will be reported according to the manufacturer's recommendations.
- The results of the IgM/IgG test will be interpreted according to the following algorithm: