



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

May 29, 2020

DEPARTMENT MEMORANDUM

No. 2020 - 0258

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: Updated Interim Guidelines on Expanded Testing for COVID-19

I. INTRODUCTION

With the increasing number of cases and deaths in various territories, the World Health Organization declared Coronavirus disease 2019 (COVID-19) as a pandemic last March 11, 2020.

In response to this pandemic, the Inter-Agency Task Force on Emerging Infectious Diseases (IATF-EID) National Action Plan set forth the “Detect, Isolate, and Treat” strategies to mitigate, identify, contain, and manage the disease. However, the increasing number of suspect, probable, and confirmed cases COVID-19 cases and close contacts in the country also entails the subsequent increase in the demand for RT-PCR testing.

Cognizant of the increasing capacity of COVID-19 testing in the country, the Department of Health issues these updated guidelines on the expanded risk-based testing for COVID-19 to cover all individuals who are at-risk of contracting the disease.

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 RT-PCR 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**. Vulnerable populations include those elderly and with preexisting medical conditions that predispose them to severe presentation and complications of COVID-19.
 - 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
 - e. Subgroup E. Frontliners indirectly involved in health care provision in the response against COVID-19 which includes, but not limited to the following:
 - i. Personnel manning the Temporary Treatment and Quarantine Facilities (LGU- and Nationally-managed);
 - ii. Personnel manning Quarantine Control Points, including those from Armed Forces of the Philippines, Bureau of Fire Protection, and others;
 - iii. National/Regional/Local Risk Reduction and Management Teams;
 - iv. Barangay Health Emergency Response Teams and barangay officials providing barangay border control and performing COVID-19-related tasks;
 - v. Personnel of Bureau of Corrections and Bureau of Jail Penology and Management;
 - vi. Personnel manning the One-Stop-Shop in the Management of the Returning Overseas Filipinos;
 - vii. Personnel serving at the COVID-19 swabbing center; and
 - viii. Social workers providing amelioration and relief assistance to communities and performing COVID-19-related tasks.
 - f. Subgroup F. Other vulnerable patients such as those with comorbidities, those who will undergo high-risk, elective surgical procedures, those living in confined spaces such as persons deprived of liberty or institutionalized persons, and others. These also include:
 - i. Pregnant patients who shall be tested during the peripartum period;
 - ii. Dialysis patients and patients who are immunocompromised, such as those who have HIV/AIDS, inherited diseases that affect the immune system, those in chemotherapy or radiotherapy, who shall be tested at the discretion

of the attending physician, following the existing guidelines of Philippine Society for Microbiology and Infectious Diseases.

3. Due to global shortage of testing kits and other supplies, 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 for diagnosis. 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 cases shall continue to be based on RT-PCR testing, in accordance with Administrative Order 2020-0013, entitled "Revised AO2020-0012 Guidelines for the Inclusion of COVID-19 in the List of Notifiable Diseases for Mandatory Reporting to the Department of Health dated 17 March 2020". Reporting of the full line list of positive and negative specimens from the start of the operations shall adhere to Administrative Order 2020-0014-A entitled, "Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines."
9. Discharge and recovery criteria for suspect, probable, and confirmed COVID-19 cases shall no longer entail repeat testing. Symptomatic patients who have clinically recovered and are no longer symptomatic for at least 3 days and have completed at least 14 days of isolation either at home, temporary treatment and monitoring facility, or hospital, can be tagged as a recovered confirmed case and reintegrated to the community without the need for further testing, provided that a licensed medical doctor clears the patient. Patients who test RT-PCR positive and remain asymptomatic for at least 14 days can discontinue quarantine and tagged as a recovered confirmed case without need for further testing, provided a licensed medical doctor clears the patient.
10. Only antibody-based test kits approved by the FDA and locally-validated by the RITM or the Department of Science and Technology or those with acceptable performance of >90% sensitivity and >95% specificity validated by World Health Organization-Foundation for Innovative New Diagnostics (WHO-FIND) may be used.
11. Disposal of test kits, including PPEs and other materials used in testing, shall adhere to the 4th Edition of Health Care Waste Management Manual.

12. Expanded use of 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. Antibody tests, particularly validated ELISA tests, can be used for community seroprevalence surveys to gauge the status of infection in a community using appropriate sampling methodologies.
13. 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 or the Universal Health Care Act.

III. SPECIFIC GUIDELINES

- A. The following guidelines shall apply once the FDA-approved antibody-based test kits have been locally-validated by the RITM or the Department of Science and Technology or those with acceptable performance of >90% sensitivity and >95% specificity validated by WHO-FIND:
 1. Only licensed medical doctors may request, administer, and interpret results of rapid antibody-based tests. Other licensed health professionals may administer the rapid antibody tests, provided that they wear appropriate PPEs and they are supervised by licensed medical doctor. 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 provided by the DOH to be submitted to hrtucovid19results@gmail.com (Annex A) or through COVID CART (detectcovid.doh.gov.ph);
 - 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 other subgroups for possible admission to temporary treatment and monitoring 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.

B. For Symptomatic Patients

1. Testing of all symptomatic patients who are close contacts of a confirmed 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 confirmed 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.
3. Suspect, probable and confirmed COVID-19 patients who have clinically recovered and are no longer symptomatic and have completed at least 14 days of isolation can be discharged and tagged as recovered without RT-PCR or antibody testing, provided that a licensed medical doctor clears the patient.

C. For Asymptomatic Patients

1. All asymptomatic non-health care workers who are close contacts of confirmed or probable COVID-19 cases need to complete 14 days of quarantine from the date of last contact with the confirmed or probable COVID-19 case either at a temporary treatment and monitoring facility or home quarantine if with a solo room with toilet.
2. Asymptomatic close contacts of confirmed or probable COVID-19 symptoms may be tested using RT-PCR at the discretion of the contact tracing team and subject to the availability of testing capacity. If symptoms develop at any time, prioritize collecting samples for RT-PCR testing.
3. Patients can be released from quarantine after 14 days as long as the patient remains asymptomatic for the entire duration of the quarantine, even without testing or test results. There is no need to repeat RT-PCR testing prior to discharge and tagging as recovered.

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


1. Expanded testing in areas with suspected COVID-19 community transmission can be performed at the household, purok, and barangay level with a proper sampling methodology in collaboration with the Epidemiology Bureau, Centers for Health Development and local health officials.
2. Properly validated antibody tests by RITM, DOST or FIND, can 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 (Annex A) through hrtucovid19results@gmail.com or through COVID CART (detectcovid.doh.gov.ph).
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 2020-0180 entitled "Guidelines on Expanded Testing for COVID-19," Department Memorandum 2020-0229 entitled "Revised Criteria for Discharge and Recovered for COVID-19 Cases," 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, confirmed COVID asymptomatic, confirmed COVID 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

Initial Result		Action	Action after 14-day quarantine or until asymptomatic, whichever is longer
IgM	IgG		
(-)	(-)	Swab for RT-PCR <ul style="list-style-type: none"> • 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 	Repeat antibody test if RT-PCR is not available. If IgM(-) & IgG(+), or IgM(+) & IgG(+), or IgM(-) & IgG(-), <ul style="list-style-type: none"> • release from quarantine If IgM(+)&IgG(-), <ul style="list-style-type: none"> • 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.
	(+)		No need to repeat antibody test. Release from quarantine.
(+) (+)	(-)	Probable COVID-19 Case: Swab for RT-PCR <ul style="list-style-type: none"> • 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 	Repeat antibody test RT-PCR (-) or RT-PCR not available. If IgM(-) & IgG(+), or IgM(+) & IgG(+), or IgM(-) & IgG(-), <ul style="list-style-type: none"> • release from quarantine If IgM(+)&IgG(-), <ul style="list-style-type: none"> • 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.
	(+)		

** 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. 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:

