Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

April 9, 2020

DEPARTMENT CIRCULAR
No. 2020 - 0184

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

SUBJECT: **Clarification on the Financing and Reimbursement of COVID-19 Antibody Test Kits by the Department of Health (DOH) and Philippine Health Insurance Corporation (PhilHealth), respectively**

This is to clarify the financing and reimbursement of COVID-19 antibody test kits by the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth), respectively.

Pursuant to Republic Act No. 11223 or the Universal Health Care Act which established the the process of Health Technology Assessment, only technologies, which have the **positive recommendation** of the **Health Technology Assessment Council** (HTAC) may be financed by the DOH and reimbursed by Philhealth, to wit:

> Section 34. Health Technology Assessment (HTA). -
>
> (a) The HTA process shall be institutionalized as a fair and transparent priority setting mechanism that shall be recommendatory to the DOH and PhilHealth for the development of policies and programs, regulation, and the determination of a range of entitlements such as drugs, medicines, pharmaceutical products, and other devices, procedures and services as provided for under this Act: Provided, ***That investments on any health technology or development of any benefit package by the DOH and PhilHealth shall be based on the positive recommendations of the HTA***: Provided, farther, That despite having undergone the HTA process, all health technology, intervention or benefit package shall still be subjected to periodic review: Provided, furthermore, That a health technology

PhilHealth: Provided, finally, That the HTA process shall adhere to the principles of ethical soundness, inclusiveness and preferential regard for the underserved, evidence-based and scientific defensibility, transparency and accountability, efficiency, enforceability and availability of remedies, and due process.

COVID-19 antibody test kits are among those technologies covered by this requirement. At present, the HTAC does not recommend the use of COVID-19 antibody test kits as a screening and diagnostic tool for COVID-19 when there is limited scientific evidence of its accuracy, and does not show clear benefit nor preclude harm. Thus, DOH and PhilHealth remain precluded from financing and reimbursing the same, unless in the context of conducting validation studies to be done by the Research Institute for Tropical Medicine (RITM) and DOH designated research facilities as positively recommended by the HTAC (See ***Annex A***). The results of these shall be made publicly available. Rest assured that the HTAC is continuously on the watch for future evidence on its utility.

However, public or private institutions, are not prohibited from purchasing and using FDA-approved COVID-19 antibody test kits, provided that FDA and DOH guidelines on the use of these test kits (See ***Annexes B, C and D***) are followed.

The DOH reiterates that RT-PCR testing remains the standard for diagnosing COVID-19 and that COVID-19 antibody-based test kits cannot be used as standalone tests to diagnose COVID-19. Because deployment of antibody-based tests to populations outside of those indicated in the above policy can undermine public health response, public and private institutions who opt to deploy such technologies shall be responsible for ensuring measures are in place to mitigate such risks. Coordination with local public health authority must be undertaken.

For dissemination to all concerned.

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

Annex "A"

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

06 April 2020

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

ATTENTION: COVID-19 Emergency Operations Center

Dear **Secretary Duque:**

In relation to our letter dated 25 March 2020 regarding the assessment of **IgG and IgM Rapid Diagnostic Test (RDT) Kits,** the HTA Council would like to reiterate that it **does not recommend the use of the said health technology as a sole screening and diagnostic tool for COVID-19, at this time** when there is still a need for scientific evidence of its accuracy. Rest assured that the Council is continuously on the watch for future evidence on its utility including the exploration of its use for serologic studies for public health purposes. A **parallel multi-site clinical trial** by the Research Institute for Tropical Medicine (RITM) and other designated health research facilities **is highly recommended**. These facilities and the participants should have access to the rapid antibody-based test kits procured with government funds. In addition, the test kits to be funded by the government should be those that can differentiate between IgG and IgM.

For non-health professionals (e.g., local government units) who may be responding to a public clamor for mass testing, they will have to be advised that **the antibody-based testing itself is not recommended as a diagnostic test for COVID-19**. When used in tandem with Reverse transcription polymerase chain reaction (RT-PCR), the antibody testing needs a **health expert for interpretation of results**. The Food and Drug Administration (FDA) certification is **not a permit for unrestricted public use**. In case the COVID-19 RDT kits will be utilized by government and private institutions, there should be capable health teams at the local government unit (LGU) level, possibly at provincial/chartered city level to perform the test, in close coordination with RITM or other subnational hospitals also performing the RT-PCR test.

Further, the HTA Council supports the **Philippine Society for Microbiology and Infectious Diseases (PSMID) guidelines**, as quoted below:

1. Only Food and Drug Administration (FDA) approved kits should be used.
2. A COVID-19 antibody test CANNOT be used as a stand-alone test to definitively diagnose COVID-19 and CANNOT be used for mass testing, but only for monitoring patient status.

3. This should only be used in people who had onset of symptoms for at least 5 days (i.e., for IgM) and 21 days (i.e., for IgG).
4. Anyone who tests positive for IgM should be tested with an RT-PCR to confirm the positive test.
5. A negative IgM test DOES NOT rule out COVID-19 and the symptomatic patient should REMAIN ISOLATED and swabbed using RT-PCR for confirmation.
6. IgG-only positive individuals without RT-PCR should be labeled as presumptive past COVID-19 and not be officially counted as confirmed unless there is a further validation test in the future, or if validated with a PRNT (Plaque reduction neutralization test) or viral culture by a third party. If a patient is symptomatic, an RT-PCR should be done, and the patient should be quarantined. If a patient is asymptomatic, there is no need to test using an RT-PCR.
7. The IgG antibody can be used as an adjunct test to clear quarantined patients who remain asymptomatic at 14 days post discharge. The presence of antibodies typically indicates viral clearance. If IgG is positive, the patient can be released from self-quarantine. If IgG is negative, a repeat RT-PCR should be performed.
8. ONLY medical doctors can prescribe and interpret the use of the antibody-based test kits. These kits will not be available over the counter. In accordance with the FDA Advisory 2020-498 "Purchase and Administration of FDA Approved COVID-19 Rapid Antibody Test Kits" released on 01 April 2020, this product must be acquired through a prescription from a licensed physician from licensed hospitals or drugstores/pharmacies/botica.

Attached herewith is the evidence summary for your reference.

For your information and guidance. Thank you very much.

Respectfully yours,

For the Health Technology Assessment Council

Marita V.T-Reyes

MARITA V. TOLENTINO- REYES, MD
Chair, HTAC

Department of Health
HEALTH TECHNOLOGY ASSESSMENT (HTA)

SUMMARY OF EVIDENCE
IgG/IgM Rapid Diagnostic Test Kits

Section 1.
Detailed description of the proposed health technology

General information

Product name	IgG/IgM Rapid Diagnostic Test Kits
Product description	An immunographic test kit which can detect IgM and IgG simultaneously in the human blood within 15 minutes.
Technical specification	It has a gold nanoparticle-based immunographic test kit with a plastic backing, sample pad, conjugate pad, an absorbent pad and NC membrane.
Indication	Used in the rapid detection of COVID-19
Global Medical Devices Nomenclature (GMDN)	not provided
Universal Medical Device Nomenclature System (UMDNS)/ ASEAN medical device nomenclature	not provided
Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?	**Description of registered trademark:** not provided **Origin of IP Office Application:** not provided

Section 2.

Context of the health technology

Background

The World Health Organization (WHO) declared the novel coronavirus disease (COVID-19) caused by severe acute coronavirus 2 (SARS-COV-2) a global pandemic. The most common symptoms are fever, sore throat, malaise and dry cough. The symptoms are usually mild and begin gradually. It can spread from person-to-person through small droplets when coughing or sneezing. As of 06 April 2020, it has affected more than 209 countries and regions with at least 1,136,851 cases and 62,955 deaths worldwide. Locally, there are over 3,246 cases and 152 deaths.

Currently, there are no known treatments for COVID-19. As a response to this pandemic, the Department of Health has implemented a triage algorithm in conducting diagnostic testing for patients with suspected cases of COVID-19. Patients presenting with acute respiratory illness may be classified as (1) person under investigation or (2) person under monitoring, depending on the patient's history of exposure, pre-existing conditions and travel history. The algorithm does not recommend diagnostic testing for patients presenting with mild symptoms (with or without travel history to any area with local transmission of COVID-19 or close contact to a confirmed COVID-19 case but no symptoms within 14 days) and those considered asymptomatic high-risk patients, thus creating public clamor for mass testing.

Section 3.

Details of supporting evidence on the use of the proposed HT

3.1. Clinical evidence

The use of rapid disposable tests for IgG/IgM detection has not been recommended for COVID-19. There is still a need to test the performance and operational utility of these kits. Testing guidelines of other countries (e.g., Canada, United States of America, United Kingdom and China) generally recommend the use of Reverse Trasncriptase Polymerase Chain Reaction (RT-PCR) in symptomatic patients while self-quarantine is advised for asymptomatic patients. On the other hand, Korea offers testing for mild and asymptomatic at-risk cases using RT-PCR; Singapore offers free testing to asymptomatic healthcare workers while Thailand only offers free testing to those who have traveled in crowded places. The reports do not specify the tests used. As of now, IgG and IgM Rapid Diagnostic Test (RDT) kits are already registered in the Philippine Food and Drug Administration while Provisional/Emergency Use Authorization has been given by other counterpart regulatory agencies for these test kits. Some of these tests have also been registered with the CE-IVD in the European Union but no country has included it yet in their national testing program.

There was only one accuracy study found in this review (Li et al, 2020), which shows that COVID-19 IgG and IgM RDT has a specificity of 90.63% and sensitivity of 88.66%. However, based on the appraisal, there were considerable flaws observed in the study design. The positive predictive value of the test appears to be very high because the prevalence of COVID-19 in the study is greater than 75%. The likelihood of a false-negative result from immunoassays, in general, must be considered given that strong evidence on the real accuracy of immunoassay for COVID-19 is yet to be established. Further, the analytical specificity and sensitivity have not yet been determined as stated by the authors. In addition, the cross-reactivity with other coronaviruses and flu viruses as well as the detection limit have not yet been ascertained. It was noted that while the study authors suggest a potential application of the test kit in testing asymptomatic patients, study results do not provide any evidence on the clinical characteristics of the sampled patients, thus being unable to identify its accuracy with regards to screening of asymptomatic and mild cases.

3.2. Economic Evaluation

The cost of the immunoassay per test was not included in the submission, and no economic evaluation was found in our search.

Section 4.
Ethical, Legal, Social, and Health System Impact

4.1 Ethical, Legal and Social Impact

From a social point of view, the higher likelihood of false negative results from this may undermine the social distancing policy that is being advocated nationally and ethically put the tested individuals, their families and contacts at unjustified risks. No relevant evidence was found regarding the ethical and legal implications of IgG/IgM RDT kits.

4.2 Health system impact

In general, mass testing is considered to be costly and can be challenging for a variety of reasons including accessibility, adherence, awareness, and training requirements.

Section 5.
Recommendation

The HTA Council **does not recommend at this time the use of IgM/IgG Rapid Diagnostic Test (RDT) Kits as a sole screening and diagnostic tool for COVID-19**, pending further scientific evidence on its accuracy. The Council is continuously on the watch for future evidence on its utility. However, **a parallel multi-site clinical trial is highly recommended** to be spearheaded by the Research Institute for Tropical Medicine (RITM). Only those who will enroll in the RITM-led clinical trial research should have access to the rapid antibody-based test kits procured with government funds. In addition, the test kits to be funded by the government should be those that can differentiate between IgG and IgM.

For non-health professionals (e.g., local government units) who are responding to a public clamor for mass testing, please be advised that **the antibody-based testing itself is not recommended as a diagnostic test for COVID-19.** When used in tandem with Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), the antibody testing needs a **health expert for interpretation of results**. The Food and Drug Administration (FDA) certification is **not a permit for unrestricted public use.** In case the COVID-19 IgG and IgM RDT kits will be utilized by government and private institutions, there should be capable health teams at the local government unit (LGU) level, possibly at provincial/chartered city level to perform the test, in close coordination with RITM or other subnational hospitals also performing the RT-PCR test.

Further, the HTA Council supports the **Philippine Society for Microbiology and Infectious Diseases (PSMID) guidelines**, as quoted below:

1. Only Food and Drug Administration (FDA) approved kits should be used.
2. A COVID-19 antibody test CANNOT be used as a stand-alone test to definitively diagnose COVID-19 and CANNOT be used for mass testing, but only for monitoring patient status.
3. This should only be used in people who had onset of symptoms for at least 5 days (i.e. for IgM) and 21 days (i.e. for IgG).
4. Anyone who tests positive for IgM should be tested with an RT-PCR to confirm the positive test.
5. A negative IgM test DOES NOT rule out COVID-19 and the symptomatic patient should REMAIN ISOLATED and swabbed using RT-PCR for confirmation.
6. IgG-only positive individuals without RT-PCR should be labeled as presumptive past COVID-19 and not be officially counted as confirmed unless there is a further validation test in the future, or if validated with a PRNT (Plaque reduction neutralization test) or viral culture by a third party. If a patient is symptomatic, an RT-PCR should be done, and the patient should be quarantined. If a patient is asymptomatic, there is no need to test using an RT-PCR.
7. The IgG antibody can be used as an adjunct test to clear quarantined patients who remain asymptomatic at 14 days post discharge. The presence of antibodies typically indicates viral clearance. If IgG is positive, the patient can be released from self-quarantine. If IgG is negative, a repeat RT-PCR should be performed.
8. ONLY medical doctors can prescribe and interpret the use of the antibody-based test kits. These kits will not be available over the counter. In accordance with the FDA Advisory 2020-498 "Purchase and Administration of FDA Approved COVID-19 Rapid Antibody Test Kits" released on 01 April 2020, this product must be acquired through a prescription from a licensed physician from licensed hospitals or drugstores/pharmacies/botica.

For inquiries, you may contact the HTA Unit:

4th Floor Pharmaceutical Division, Philippine Blood Disease and Transfusion Center, Diliman, Quezon City | Health Regulation Team, Department of Health, San Lazaro Compound, Sta. Cruz Manila | hta.philippines@gmail.com | doh.gov.ph | 8-875-7734 loc. 260 or 258

Annex "B"

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

01 APR 2020

FDA Advisory
No. 2020-497

TO : **All Licensed Importer/Distributors of COVID-19 Test Kits**

SUBJECT : **DISTRIBUTION OF FDA APPROVED COVID-19 RAPID ANTIBODY TEST KITS**

The Food and Drug Administration (FDA) reiterates to all licensed importer/ distributors that COVID-19 test kits are strictly for medical professional use and not intended for personal use.

The product should be strictly distributed to appropriate establishments or institutions. Subsequently, this should be acquired by the general public through a prescription from a licensed physician. The administration of the test must be performed by a doctor or a trained health professional Furthermore, the interpretation of results must be done by a doctor.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Annex "C"

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

01 APR 2020

FDA Advisory No. 2020-498

TO: **THE GENERAL PUBLIC**

SUBJECT: **PURCHASE AND ADMINISTRATION OF FDA APPROVED COVID-19 RAPID ANTIBODY TEST KITS**

The Food and Drug Administration (FDA) informs the public on the purchase of Rapid Antibody Test Kits for COVID-19.

This product must be acquired through a prescription from a licensed physician from licensed hospitals or drugstores/pharmacies/botica. Online sale is prohibited. Subsequently, administration of the test must be performed by a doctor or a trained health professional. Interpretation of the result must be guided by a physician.

The public is urged to report incidents regarding the improper dispensing and use of COVID-19 Rapid Antibody Test Kits. You may submit as much detail and information as possible about the source, name of product, importer/distributor and other necessary details to our email covidresponse@fda.gov.ph.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

Annex "D"

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

March 31, 2020

DEPARTMENT MEMORANDUM
No. 2020 - 0151

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

I. INTRODUCTION

Coronavirus disease 2019 (COVID-19) was first reported in Wuhan City, China 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 during the two (2) days before or 14 days after the 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% 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 (RTIM).
7. Pending results of local studies, use of point-of-care 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. Expanded use of point-of-care rapid antibody-based test kits shall be explored through validation and sero-epidemiological studies particularly for use in Subgroup D, as testing all asymptomatic contacts of confirmed COVID-19 cases using RT-PCR is not recommended until there is surplus testing capacity.
9. Results of such studies shall be submitted to the Health Technology Assessment Council (HTAC) for their review and consideration. DOH and PhilHealth may only finance or reimburse COVID-19 test kits that have been positively recommended by the HTAC as required by RA No. 11223.
10. Only one RT-PCR test with negative results is enough to clear a COVID-19 positive patient.

III. SPECIFIC GUIDELINES

A. The following guidelines shall apply once the FDA-approved antibody-based test kits have been validated through local studies.

B. Only licensed medical practitioners may prescribe and administer antibody-based tests.
   1. The medical practitioner 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 all and coordinating with regional epidemiological surveillance unit;
      d. monitoring and reporting adherence to case management on a daily basis
      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
      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 with RT-PCR.
    a. All symptomatic healthcare workers who test positive using RT-PCR must be home-quarantined or hospitalized depending on the severity of symptoms.
        i. After 14 straight days without symptoms, the healthcare worker can be subjected to antibody testing.
            1. If IgG is positive, the health worker can return to work and do not need repeat testing unless they develop symptoms.
            2. If IgG remains negative, an RT-PCR can be done:
                a. If negative, the healthcare worker can return to work.
    b. 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 due to limited availability, they can be tested using antibody-based tests every 14 days until IgG develops, but the **healthcare worker should remain isolated for 14 days unless RT-PCR tests are available.**
    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 recovered from all symptoms. They can be retested with an antibody test after 14 days for development of IgG. If IgG remains negative, continue antibody testing 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.

3. Test all healthcare workers with unprotected exposure every 14 days. If symptomatic, follow the protocol in Section III.C.1. If asymptomatic, test with an antibody-based test every 14 days until IgG develops. All IgM positive but IgG negative healthcare workers who are asymptomatic shall follow the protocol indicated in Section III.C.2.b.

D. For Symptomatic Non-Health Care Workers

1. Testing of <u>symptomatic</u> patients who are close contacts of a known or probable case with rapid antibody-based test kits alone is <u>not recommended</u>, and can be dangerous if not done with proper Personal Protective Equipment. Isolate the patient and conduct RT-PCR testing as recommended.

2. If there is no available RT-PCR due to limited availability, rapid antibody-based testing can be used, but the **patient should remain isolated for 14 days regardless of result** (See Annex A).
    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. Repeat rapid antibody-based testing once asymptomatic, and follow protocols indicated in Section E for asymptomatic patients.
    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 home quarantine and repeat rapid antibody-based test.
        iii. If RT-PCR testing is not available, isolate for 14 days. Repeat rapid antibody-based testing once asymptomatic, and follow protocols indicated in Section E for asymptomatic patients.

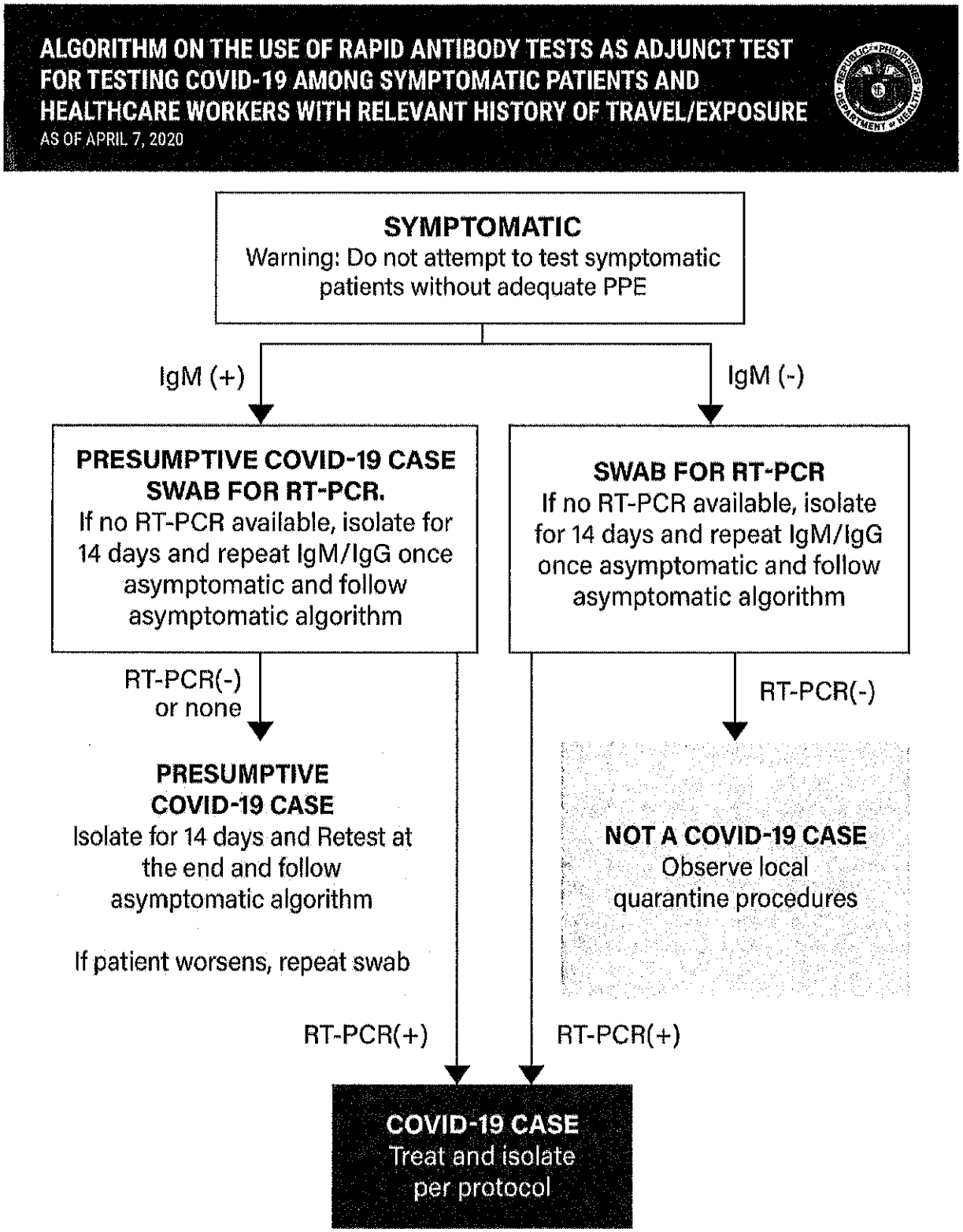
E. For Asymptomatic Non-Health Care Workers : Rapid antibody testing may be used for asymptomatic non-health care workers, particularly for close contacts of confirmed COVID-19 cases (See Annex B).

1. If the patient tests negative for both IgM and IgG, there is no need to isolate, unless the patient becomes symptomatic. However, they shall strictly observe the quarantine procedures in their locality.
2. If the patient tests positive IgG only, the patient is considered a presumed recovered case, and there is no need to isolate. However, they shall strictly observe the quarantine procedures in their locality.
3. Patients who test IgM positive shall be **isolated at home or at a community quarantine facility for 14 days**. If they become symptomatic, they will be treated as probable COVID-19 cases and shall follow the protocol indicated in Section D.

For strict compliance.

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

ANNEX A. Algorithm on the Use of Rapid Antibody Tests as Adjunct Test for Testing COVID-19 among Symptomatic Patients and Healthcare Workers with Relevant History of Travel/Exposure



ANNEX B. Algorithm on the Use of Rapid Antibody Tests for Testing COVID-19 among Asymptomatic Patients and Healthcare Workers with Relevant History of Travel/Exposure