Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

27 September 2021

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

Dear **Secretary Duque:**

In fulfilment of its mandate of promoting evidence-informed health policymaking, the Health Technology Assessment Council (HTAC) continues to update its assessments of health technologies, especially in addressing COVID-19.

In light of the recently published World Health Organization (WHO)-updated interim guidance entitled "Recommendations for National SARS-CoV-2 Testing Strategies and Diagnostic Capacities" dated June 25, 2021, DOH Epidemiology Bureau advice on risk level categories, and the recently issued government price cap for rapid antigen test kits, HTAC updated its recommendation for rapid antigen testing.

Relative thereto, we are respectfully submitting our updated HTAC recommendation as of September 2021. Enclosed herewith is a matrix (Annex A) highlighting the specific changes to the April 2021 version of the HTAC recommendation which will not change the overall interim recommendation previously released, as there are no changes in the evidence used.

The HTAC shall continue to update its recommendation in light of rapidly evolving information becoming available.

We thank you for the opportunity to be of assistance to the Department of Health.

Respectfully yours,

For the Health Technology Assessment Council (HTAC):

Marita V. T- Reyes
MARITA V. TOLENTINO-REYES, MD
Chair
Health Technology Assessment Council

Approval of the HTAC Recommendation:

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

CC: Undersecretary Atty. Charade B. Mercado-Grande
Undersecretary Maria Rosario S. Vergeire, MD, MPH, CESO IV

Annex A. Matrix for the comparison of changes (in blue text) following the review of the issuances shared by the Office of Secretary of Health and the updating of Evidence Summary

April 2021 HTAC Recommendation	September 2021 HTAC Recommendation
Main recommendation	
The HTAC **maintains that RT-PCR remains the standard diagnostic test for COVID-19**, and would like to emphasize that the following interim recommendations on rapid antigen testing are subject to change pending new evidence. The HTAC **does not recommend the use of rapid antigen tests** for indiscriminate use in mass screening, for return-to-work clearance and for COVID-19 diagnosis in individuals with low index of suspicion (i.e., asymptomatic and no history of exposure). We reiterate the previous HTAC recommendation that rapid antigen tests when positive are most useful in immediately identifying COVID-19 cases and therefore can be used to initiate contact tracing, epidemiological surveillance and clinical management.	
Recommended Use Cases	
Rapid antigen tests are currently recommended **by HTAC only for very specific purposes:** For targeted screening and diagnosis of suspected and probable cases of COVID-19 (i.e., with a high index of suspicion), meeting the clinical and/or epidemiologic criteria in the hospital or community settings **as defined below**: ● Suspected cases of COVID-19 are individuals: ○ with acute onset of the following signs and symptoms adopted on the WHO clinical criteria, (Fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnea, anorexia/nausea/vomiting, diarrhea, altered mental status, anosmia (loss of smell) or ageusia (loss of taste)) OR ○ satisfying the following epidemiology criteria): residence or work in an area with high risk of transmission of virus (e.g.	Rapid antigen tests are currently recommended **by HTAC only for very specific purposes:** For targeted screening and diagnosis of suspected and probable cases of COVID-19 (i.e., with a high index of suspicion), meeting the clinical and/or epidemiologic criteria in the hospital or community settings **as defined below**: ● Suspected cases of COVID-19 are individuals: ○ with acute onset of the following signs and symptoms adopted on the WHO clinical criteria, (Fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnea, anorexia/nausea/vomiting, diarrhea, altered mental status, anosmia (loss of smell) or ageusia (loss of taste)) OR ○ satisfying the following epidemiology criteria): residence or work in an area with high risk of transmission of virus (e.g.

congregate settings), residence or travel to an area with community transmission, or work in any healthcare setting ● Probable cases of COVID-19 are: ○ Individuals meeting the above clinical criteria AND is a contact of a probable or confirmed case or linked to a cluster of COVID-19 cases ○ Suspect cases with chest imaging suggestive of COVID-19 ○ Individuals with sudden onset of anosmia (loss of smell) or ageusia (loss of taste) in the absence of any other identified cause.	congregate settings), residence or travel to an area with community transmission, or work in any healthcare setting ● Probable cases of COVID-19 are: ○ Individuals meeting the above clinical criteria AND is a contact of a probable or confirmed case or linked to a cluster of COVID-19 cases ○ Suspect cases with chest imaging suggestive of COVID-19 ○ Individuals with sudden onset of anosmia (loss of smell) or ageusia (loss of taste) in the absence of any other identified cause. ○ Death, (1) not otherwise explained; **AND** (2) in an adult with respiratory distress preceding death; **AND** (3) was: (a) contact of a probable or confirmed case; **OR** (b) linked to a COVID-19 cluster. *(Note: Added fourth criterion was also included in the WHO definition of probable COVID-19 case dated 07 August 2020)*
For local border screening at points of entry **for individuals travelling from areas with a high daily positivity rate averaged over a seven-day period (i.e., >10%) or as reported by the DOH-Epidemiology Bureau** based on its periodic updates of prevalence rate/positivity rate; and,	For local border screening at points of entry: ● **For individuals travelling from areas:** ○ **with a confirmed outbreak (DC 2020-0397);** ○ **with a suspected outbreak** (Interim Guidance Document on Cholera Surveillance, 2017)**;** ○ **with a presumptive outbreak** (where the result of the RT-PCR test of one suspect case has not yet been released, and in settings where RT-PCR is not immediately available, where delayed release of the result, or a prolonged turnaround time is expected based on HTAC Recommendation on the used of Rapid Antigen Test published April 2021)**;** ○ classified as **moderate or high-risk** based on average daily attack rate /Two Week Growth Rate (ADAR/2WGR), or as reported by the DOH-Epidemiology Bureau **for** areas under Alert Level 1 to 4; and,

	○ with unknown ADAR/2WGR even if fully vaccinated (wherein high prevalence/incidence can be assumed due to some localized reported and/or unreported outbreaks). For working individuals who cross borders at least 2-3 times per week, results of RAgT should be valid within 48 hours after the conduct of the test.
Intended Population	
People **coming from an area with a high positivity rate averaged over a seven-day period** (i.e., >10%) or as reported by the DOH-Epidemiology Bureau based on its periodic updates of prevalence rate/positivity rat	People coming from the following areas**:** ● **with a confirmed outbreak (DC 2020-0397);** ● **with a suspected outbreak** (Interim Guidance Document on Cholera Surveillance, 2017)**;** ● **with a presumptive outbreak** (where the result of the RT-PCR test of one suspect case has not yet been released, and in settings where RT-PCR is not immediately available, where delayed release of the result, or a prolonged turnaround time is expected)**;** ● classified as **moderate or high-risk** based on average daily attack rate /Two Week Growth Rate (ADAR/2WGR), or as reported by the DOH-Epidemiology Bureau **for** areas under Alert Level 1 to 4; and, ● with unknown ADAR/2WGR even if fully vaccinated (wherein high prevalence/incidence can be assumed due to some localized reported and/or unreported outbreaks)
People residing in **closed or semi-closed institutions** (as defined in DM 2020-0468), **crowded area**s (i.e., more than one person per three square meter circular area or those sharing common facilities) **with suspected outbreak** (as defined above**) or confirmed outbreaks** (per DM 2020-0397)	People residing in the following areas: ● **closed or semi-closed institutions** (as defined in DM 2020-0468), ● **crowded areas** (i.e., more than one person per three square meter circular area or those sharing common facilities) **with presumptive outbreak** (as defined above**) or confirmed outbreaks** (per DC 2020-0397) ● **areas with a high positivity rate (***i.e., ≥5%, in accordance with WHO standards***) averaged over a seven-day period**

Recommended specifications for RAgT kits using nasal, nasopharyngeal and/or oropharyngeal swabs	
The total cost of the initial and possible repeat testing using the RAgT kit should be significantly less than the cost of the ***government price cap for RT-PCR test kit.***	The total cost of the initial and possible repeat testing using the RAgT kit should not exceed the *government price cap for Rapid Antigen Testing based on DOH Department Circular 2021-0323 (i.e., Php 960.00).*