Evidence Summary on the Use of Self-Administered Antigen Testing for COVID-19

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Acronyms Used in the Evidence Summary	
Acronym	**Definition**
Australia TGA	Australian Therapeutic Goods Administration
Australia DOH	Australia Department of Health
Cambodia MOH	Cambodia Ministry of Health
China CDC	China Center for Disease Prevention and Control
Ct	Cycle threshold
DOH	Department of Health (Philippines)
ECDC	European Center for Disease Prevention and Control
Germany MOH	Germany Ministry of Health
Indonesia MOH	Indonesia Ministry of Health
Malaysia MOH	Malaysian Ministry of Health
NPS	Nasopharyngeal Swab
OPS	Oropharyngeal Swab
PHAC	Public Health Agency of Canada
PhilHealth	Philippine Health Insurance Corporation
SAAgT	Self-administered Antigen Test
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
Singapore MOH	Singapore Ministry of Health
South Korea MHW	South Korean Ministry of Health and Welfare
Thailand MOH	Thailand Ministry of Health
Uganda MOH	Uganda Ministry of Health
UK DOHSC	United Kingdom Department of Health and Social Care
UK MHRA	United Kingdom Medicines and Health Products Regulatory Agency

UK NHS	United Kingdom National Health Service
US CDC	United States of America Center for Disease Control and Prevention
US FDA	United States of America Food and Drug Administration
Vietnam MOH	Vietnam Ministry of Health
WHO	World Health Organization
China NHC	National Health Commission

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I. Background

Burden of COVID-19 and the Omicron Variant

As of 16 March 2022, the COVID-19 pandemic has affected more than 222 countries and regions with at least 460,280,168 cases and 6,050,018 deaths worldwide (WHO, 2022). The Omicron variant was introduced as a variant of concern on 26 November 2021 due to its numerous mutations compared to previous variants and high transmissibility, as manifested by its growth advantage over the Delta variant.

Last January, the Omicron variant surged across more than 149 countries, causing rapid record high outbreaks in these countries. On 31 December 2021, the Philippines officially declared its first seven cases of the Omicron variant. Since then, the DOH Philippines has declared the likelihood of Omicron to become the dominant variant, and the surge which occurred in January 2022 may be due to Omicron.

Epidemiological trend

The WHO emphasized in their technical report (21 January 2022) that the growth advantage of Omicron over Delta is significantly higher, as evidenced by rapid spread and community transmission. The protective effects of pre-existing immunity complicates the comparisons of population-level infection-fatality rate (IFR) for the Omicron wave compared to other waves with different dominant strains (Bhattacharyya & Hanage, 2021). A surge of COVID-19 cases is occurring worldwide, with Omicron taking over as the dominant variant. The surge also hit the Philippines in January 2022, with the number of active cases tripling from early to mid-January, then subsiding by the end of this month. A record-high of 39,004 new cases was counted on January 15. The positivity rate on January 15 reached 47.1% nationwide and increased by 5133% from the 0.9% positivity rate last December 12 (DOH, 2022; Mateo, 2021). Case tallies in the Philippines do not include COVID-positives tested via antigen test, whether done in the laboratory or self-administered. Other suspected cases might not be counted due to the current limitations in the testing capacity or hesitance to get tested. The OCTA Research group stated that cases in Metro Manila alone may be six to fifteen times higher than what is being recorded in the DOH case tracker (Doudy & D'Souza, 2020;).

In the National Capital Region, the positivity rate drastically increased by 8287%, from a constant 0.62% during mid-December into 52% by mid-January. The positivity rate for this region dropped to 4.64% by late February. Genome sequencing done in early January revealed that 60.42% of samples were Omicron-infected, with trends in NCR showing predominance of the omicron strain. The most recent genome sequencing run done in early February revealed a dominance in Omicron (94.35%) over Delta strains(1.21%). Sequencing done late January revealed BA.2 to be the most dominant sub-lineage. (Cabico, 2022; DOH, 2022; DOH, 2022) . The DOH reported that while cases are rapidly increasing, more than 90% of the currently-active cases are mild in nature and hospital utilization rate remains low. Mortality rate remains at 1.55% (as of 06 March 2022).

The positivity rate during early to mid-January went way above the recommended benchmark set by the WHO (3-12%), which according to the Harvard Global health Institute (2020) may indicate inadequacy in testing. Moreover, only 4.2 tests per confirmed case were being done in the country, as opposed to the benchmark of 10-30 tests per confirmed case set by WHO for adequate testing (Our World in Data, 2022). Currently, the positivity rate is at 3.9% (as of 06 March 2022), and 24.9 tests per new confirmed case were being conducted in the country (as of 04 March 2022), both of which are within the WHO-recommended benchmarks.

Pathophysiology compared to older variants of concern

Molecular Structure **-** The Omicron variant is known to have more than 50 mutations in total compared to the original DG14G strain (Zhao et al, 2021). Cryo-electron microscopy structural analysis revealed that the variant exhibits 37 mutations in spike protein as compared to the D614G strain, which can explain the variant's higher transmissibility and ability to breach antibodies obtained from immunization (Mannar et al (2021). The analysis also showed that Omicron has a stronger binding capacity to ACE2. Their analysis on the genomic pattern further reveals that Omicron may not have been derived from any of the currently-circulating variants of concern. In addition, Omicron was found to have three sublineages, which include BA.1 (B.1.1.529.1), BA.2 (B.1.1.529.2), and BA.3 (B.1.1.529.3). Omicron BA.2 is the most transmissible sublineage and most capable vaccine breakthrough (Chen & Wei, 2022)

Virulence - There is evidence for a **higher rate of reinfection** with Omicron in contrast to other variants. It has been found to be 3-5 times more infectious than the Delta variant (Magsambol, 2022). US CDC (2021) suggests **shorter incubation period** (median 3 days as opposed to ≥4 days in other variants) and milder symptoms among individuals who have been previously vaccinated or infected. Sharma (2022) further reported that COVID-19 symptoms appeared between 2 to 14 days after exposure. The spike mutations in Omicron have contributed to reduced effectiveness of immunization. Preliminary studies suggest a reduction in neutralizing titers against Omicron in individuals who have received a primary dose series vaccination or those who have had prior infection. On the other hand, homologous or heterologous booster doses increase neutralizing antibody response especially against hospitalization, but this efficacy is significantly less with Omicron compared to Delta (WHO, 2021). Garcia-Beltran et al. (2021) suggests that an mRNA booster after mRNA primary series increases the breadth and cross-reactivity of neutralizing antibody response.

Clinical manifestations - According to Sharma, 2022, symptoms from the Omicron strain generally last from 3 to 5 days. Preliminary research data indicated that the first signs of Omicron infection often manifested as headache, body pain, sore throat, cough, fatigue, and nasal congestion. Zafra et al. (2022) found in a Norwegian survey that these signs and symptoms appeared 3 to 4 days after exposure (Bean, 2022; Zafra, Linde, & Llaneras, 2022). These flu-like symptoms are in line with evidence that Omicron has a host preference for the upper respiratory tract (URT), in contrast to the previous variants' host

tropism in the lower respiratory tract. Zhao et al. (2021) revealed that the Omicron variant replicated more poorly in the transmembrane serine protease 2 (TMPRSS2)-overexpressing VeroE6 cells within the lungs unlike Delta, indicating that Omicron relies more on the endocytic pathway for replication. This study strengthens the evidence that Omicron predominantly affects the URT, which manifests in URTI-associated symptoms. The US CDC (2021) received reports that individuals previously infected exhibited milder clinical manifestations during Omicron infection. A preprint study from Lewnard et al. (2022) found a reduced propensity for the Omicron variant to cause severe clinical illness. The average duration of hospital stay was 70.7% (64.4-76.0%) shorter among patients infected with Omicron compared to patients affected by Delta infection. The US CDC emphasized that it is difficult to distinguish if mild clinical symptoms are due to pre-existing immunity or if these are true clinical manifestations for Omicron. Despite exhibiting milder clinical manifestations, the Omicron variant still has the capability to overwhelm the healthcare system due to higher rates of morbidity.

Transmissibility - The current global epidemiology of SARS-CoV-2 is characterized by the emergence of Omicron variant, declining prevalence of Delta variant, and very low levels of Alpha, Beta, and Gamma variant circulation. The WHO noted that the Omicron variant has a much higher growth advantage, rapidly replacing other variants. It is more capable of infecting individuals with prior immunity because mutations in its spike proteins lower the effectiveness of antibodies acquired from vaccination or previous infection (Wilhelm et al, 2021). The US CDC emphasized that surgical masks may not work well to mitigate viral transmission from Omicron and has recommended the use of N95 and KN95 masks for more effective filtration (Davis, 2022). These masks ensure proper fit and adequate filtration. Surgical masks are loosely fit and may not properly filter out pathogens. Saseedharan and Patil (2022) recommend 'double-masking' if using surgical masks. Cloth masks are unable to filter out pathogens, so if only this is available, this must be paired with a surgical mask to be effective. If only cloth masks are available, Jha (2022) recommends doubling the layer of cloth to at least provide a better fit (Uniyal, 2022).

Performance of diagnostic tests

Omicron does not significantly affect the diagnostic accuracy of routine RT-PCR and RAgT assays (WHO, 2021). Comparative sensitivity analyses are shown in excerpts below.

Reverse transcription polymerase chain reaction (RT-PCR) - SARS-CoV-2 is generally detected in RT-PCR by the presence of the following viral gene targets: open reading frame lab (ORF1ab), nucleocapsid (N), envelope (E), and spike (S). Omicron is often differentiated in RT-PCR by the lack of S-gene, known as S-gene target failure (SGTF). However, gene sequencing is required to confirm the Omicron strain because the deletion of the S gene can also be found in Alpha and subsets of Gamma and Delta variants (Kidd et al, 2021; WHO, 2021). The US FDA (2021) noted that some RT-PCR tests are designed to detect multiple genetic targets, while others detect only a single target. The mutation heavily impacts the sensitivity of tests which rely on only single targets.

Tests which rely on the detection of only the S-gene are most affected in terms of sensitivity and thus most prone to false negative results (Bengaluru, 2021). The US FDA further emphasized that most but not all omicron-infected samples exhibit gene target failure, and not all gene target failures automatically translate to the omicron variant.

Rapid antigen tests (RAgTs) **-** Rapid antigen tests (RAgTs) have shown adequate sensitivity in testing individuals with a high viral load (Zafra, Linde, & Llaneras, 2022). A preprint study from Bekilz et al (2021) indicated that based on analytical sensitivity testing, RAgTs had lower sensitivity values for Omicron compared to other variants. This lower sensitivity may be a result of mutations in the nucleocapsid of the virus, which serves as a target site for most RAgTs. The findings in this study suggest that while RAgTs can still be used for screening symptomatics, the detection of Omicron among asymptomatic patients or in the early symptomatic phase may not be reliable. On the other hand, Deerain et al (2021) reported that the ten antigen kits they used in their study had similar analytical sensitivity for both Omicron and Delta variants. They reported that all ten kits were able to detect delta at Ct 25.4 and omicron at Ct 25.8. Both studies emphasized that RAgTs enable reliable detection of high viral loads.

COVID-19 testing in the Philippines

Policies, programs, and financial allocation for COVID-19 testing

Since the onset of the pandemic, there have been numerous evidence-based public health programs to detect and control SARS-CoV-2 spread. This includes multiple guidelines on testing released by the DOH. Initial guidelines for laboratory testing of COVID-19 were first laid out in DM 2020-0034 which patterned after testing guidelines for community-acquired pneumonia. The guidance for use of rapid antigen test kits as an adjunct tool to RT-PCR testing was detailed in DC 2020-0160, which was released on 31 March 2020. Additional guidance for the use of RAgT is written in DM 2020-0468. Laboratories allotted for COVID-testing initially included only the RITM and 5 subnational hospitals in 2020 but have since expanded to 331 testing laboratories nationwide as of April 2022. AO 2020-0014 set the guidelines for securing a license to operate covid-19 testing laboratories in order to expand testing capacity (DOH, 2022). The DM 2020-0191 was released to allow real-time, in-vitro detection of the SARS-CoV-2 virus through the use of GeneXpert machines normally used in detecting tuberculosis strains.The Office of the Vice President also launched the 'Swab Cab' since March 2021 which provides free mobile RAgT services across the country (OVP, 2021).

In 2021, the National Government announced that the Research Institute for Tropical Medicine's (RITM) proposed budget for 2022 would be reduced by PHP 170 million because there are already numerous laboratories performing diagnostic tests. They further justified this cut by claiming that much of the testing is already being done by the private sector (Magsambol, 2021; Romero, 2021). The Committee on Finance further stated that funding is

sufficient for COVID-19 testing with the following proposed allocations: PHP 17.85 billion for COVID-19 Laboratory Network Commodities which can be tapped for the provision of free tests, in which PHP 7.92 billion of this budget is allocated for DOH programs; PHP 250 million under DILG for the hiring of contact tracers; and an additional PHP 1 billion allowance which can be used for testing programs (Ismael, 2022). On the other hand, there are only 331 licensed COVID-19 testing laboratories in the country, more than half of which are catered to the private sector. Almost 40% of these testing centers are located in NCR. Resource-limited regions still have difficulty scaling up their testing capacity (DOH, 2021; Lau, Hung, & Wilson, 2020).

The DOH released DC 2022-0002 on 06 January 2022 which stipulated the priority groups for testing in instances of supply scarcity as follows:

1. *Close contacts belonging to Priority Group A2 or senior citizens, and A3 or persons with comorbidities who cannot facilitate testing by themselves or their employers*
2. *Close contacts other than Priority Group A2 and A3 who cannot facilitate testing by themselves or their employers*
3. *Close contacts belonging to Priority Group A2 and A3 who can facilitate testing by themselves or their employers*
4. *Close contacts other than Priority Group A2 and A3 who can facilitate testing by themselves*

Within these 4 groups, the unvaccinated comes as the first priority, followed by the partially vaccinated, then the vaccinated group.

Meanwhile, from DM 2022-0013 released last 14 January 2022, the following protocols for testing are currently recommended for the priority groups:

[Table taken from DOH DM 2022-0013, Annex B: Updated Testing Protocols.]

Who is being tested?	***Why is testing being done?***	***Should you test?***	***Remarks***
A1 or Health Care Workers	Surveillance to plan for adequate health system capacity	**YES** *Hospital Infection Prevention and Control Committee (HIPCC), Provincial Health Office coordinated with provincial HIPCC, and other sectors authorized by the IATF with strict industry standards on Infection Prevention Control can determine need for testing upon careful assessment of benefits and risks*	Use **antigen test** only when symptomatic, and when RT-PCR is not available

A2 Senior Citizens or A3 Persons with Co-morbidities *(Including those at high risk for severe disease)*	Confirming COVID-19 to know if investigational drugs can be given	YES	
All except A1, A2 and A3 - no symptoms	Confirming COVID-19 after exposure to positive case	**OPTIONAL**, quarantine ASAP, and monitor symptoms	
All except A1, A2 and A3 - mild symptoms	Confirming COVID-19 after onset of symptoms	**OPTIONAL**, isolate ASAP, teleconsult, home care if with capacity to be managed at home	

Regulatory considerations for COVID-19 testing

Since 2020, the FDA Philippines has been warning the public about the unregulated market of unregistered antigen test kits, stating that the safety and accuracy of these kits cannot be ensured if they have not yet undergone regulatory certification. However, multiple test kits are still being sold by unlicensed distributors. In response to this predicament, the FDA issued a series of advisories related to non-certified antigen test kits. The FDA also issued FDA Advisory No. 2021-1239, which reiterates the importance of Republic Act No. 9711 in the distribution, purchase, and administration of FDA-certified test kits. (CNN Philippines, 2020; FDA, 2021; FDA, 2021).

Current challenges in COVID-19 testing in the Philippines

Currently, RT-PCR remains the reference standard for confirmatory testing to diagnose COVID-19 in the Philippines. However, the RT-PCR-based assay poses several challenges such as long turnaround time particularly during surges, need for specialized equipment, skilled operators, more personal protective equipment, laboratory facilities, and high cost. The nationwide limited capacity to perform laboratory-based tests has led to the exploration of other diagnostic or screening methods since 2020, such as the use of rapid antigen tests. Rapid antigen tests (RAgTs) are immunoassays which detect the presence of a specific viral antigen to indicate current viral infection. These are generally cheaper and have faster turnaround times (approximately 15-30 minutes). Globally, the currently available antigen tests include point-of-care, laboratory-based, and self-tests.

HTAC recommendations on RAgTs

In October 2020, after the evaluation of the use of RAgTs in the Philippines, the Health Technology Assessment Council (HTAC) recommended the use and financing of RAgTs only for very specific purposes, while the RT-PCR remained the standard diagnostic test for COVID-19. The recommended use cases for RAgT were as follows:

- *For targeted screening and diagnosis of suspect and probable cases of COVID-19 meeting the clinical and/or epidemiologic criteria as defined by the WHO (i.e., with high index of suspicion) meeting the clinical and/or epidemiologic criteria as currently defined by WHO in the hospital or community settings;*
- *For testing of patients in the hospital setting, where the turnaround time is critical, to guide patient cohort management*
- *For targeted screening and diagnosis of suspect and probable cases of COVID-19 in suspected outbreaks (as currently defined by the DOH – Epidemiology Bureau) of COVID- 19 in remote settings, (e.g., geographically isolated areas), where RT-PCR is not immediately available;*

In line with the WHO recommendation, the HTAC specified at least 80% and 97% specifications for clinical sensitivity and clinical specificity of rapid antigen tests, respectively. The HTAC also emphasized that the RAgT should be used only by trained healthcare professionals to optimize performance. Additional training is further required for test kits which utilize a reader or detection system.

In September 2021, the HTAC updated its evidence review on RAgTs. The table below reflects the changes in recommendation in this version.

Table 1: Summary of changes in HTAC Recommendations for Rapid Antigen Testing, September 2021

Parameters	*Changes in the September 2021 version compared to the October 2020 version*
Recommended use cases	Added definition of **suspected cases of COVID-19** and **probable cases of COVID-19** Added use case for **local border screening** points of entry for individuals travelling from areas confirmed, suspected, or presumptive outbreak (with updated definitions of outbreak); or from moderate or high-risk areas based on average daily attack rate Updated the recommendation to no longer limit the use of rapid antigen testing to remote settings
Intended population	Expanded intended population to include the following individuals: ● People in close contact with a suspected, probable, or confirmed case ● People coming from areas with a confirmed, suspected, or presumptive outbreak (with updated definitions of outbreak); or from moderate or high-risk areas based on average daily attack rate ● People residing in closed/semi-closed institutions, crowded areas, and areas with a high positivity rate

	• People working in areas with presumptive or confirmed outbreaks Updated recommendation to include **serial rapid antigen testing**, i.e, If sufficient testing capacity is available, *at least weekly* in congregate settings (e.g., workplaces, prisons, nursing homes) with *moderate transmission* and *at least twice weekly* for areas with substantial or *high community transmission*
Timing of collection	Revised the timing of collection from "*5 days after onset of symptoms*" to *"5-7 days after onset of symptoms*".
Sample specimen	Specified nasal, nasopharyngeal and/or oropharyngeal swabs as specimens to be collected
Interpretation of results	Changed time interval for taking a confirmatory RT-PCR test after rapid antigen test from *"2 days*" to "*48-72 hours*". Updated recommendation to include repeat antigen testing as confirmatory test for negative rapid antigen after 48-72 hours since confirmatory RT-PCR test may not be practical in community settings where RT-PCR laboratories may not be accessible
Other recommendations	Added the following overarching recommendations • Testing (using RAgTs or NAATS) should be used in addition to other health measures such as minimum public health standards (including the use of face masks/face shields), physical distancing, ventilation, quarantining/isolation, symptom-based screening and contact tracing
Human resource training	Revised "*Less than half a day to no additional training needed for healthcare professionals*" to "***Minimum of 4-hour long training needed*** *for healthcare professionals*" for optimal performance
Requirement for independent validation	Added that RAgTs "***must be authorized by the Philippine Food and Drug Administration***" in addition to being validated by a reputable government or private research institution. Added in the list of reputable government and private research institutions "***Other DOH-designated institutions for test kit validation recognized by RITM in its letter to the Secretary of Health dated 01 April 2021 (Annex A) unless these laboratories are developing their own test kits***".
Cost of test kits	Revised recommended cost of testkit to "*RAgT kit should be significantly less than the cost of the RT-PCR test kit*" with "***RAgTs must not exceed the government-set price cap of PhP 960***", based on DOH Department Circular 2021-0323.

This evaluation led to the integration of RAgT kits in the Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, and Reintegration Strategies for COVID-19 (DM 2020-0439) and other succeeding issuances. However, to date, the Philippine Health Insurance Corporation (PHIC) has yet to develop its benefit package to cover RAgT.

Self-administered antigen tests

Late 2021, several countries started using self-administered antigen test (SAAgT) (also known as self-testing, self-collecting, at-home testing, home test, take at home test, self-sampling, self-swabbing, over-the-counter test, rapid lateral flow test, self-performance of testing, or self-reading of results). The US FDA defines self-testing as "a test that can be fully administered entirely outside of a lab or healthcare setting" (US FDA, 2020). In collaboration with the Philippine FDA, the Research Institute of Tropical Medicine (RITM) defined COVID-19 self-administered rapid antigen test as a "test which can be performed by non-healthcare professionals or lay users in home, non-hospital, or non-laboratory settings."

It has become a popular method for testing because it is cheaper, readily-accessible, easy-to-use, and has a faster turnaround time for those who need immediate test results. However, false positive results can arise from reusing the test cassette or buffer solution and contamination of testing materials (Patriquin et al, 2021; Roche, 2021; Gans et al, 2022)], False negative results can arise from shallow swabbing, adding too little drops of buffer to the test cassette, diluting buffer solution, and testing too early or too late (Patriquin et al, 2021; Roche, 2021)] result if done by untrained individuals. The sensitivity of SAAgTs can increase by training the users or providing them with detailed but easy-to-understand instructional materials.

The WHO recognizes SAAgT as a complement to health system-based testing done by trained providers. The WHO has issued interim guidelines dated 9 March 2022 on the use cases of SAAgT.

II. Rationale and objectives of this evidence review

Cognizant of the current surge in the country brought about by variants of concern which further aggravates the limitation of our testing capacity, there is value in using a testing technology with shorter turnaround time, and can be made readily accessible to the public such as the self-administered antigen tests. According to the WHO, there is consistent evidence that Omicron spreads substantially faster than the Delta variant with a doubling time of 2 to 3 days. Thus, the demand for more efficient testing is needed so that treatment of the most vulnerable populations may be instituted within the first 5 days of infection.

In light of the request of the Disease Prevention and Control Bureau (DPCB) to assess the value of self-administered rapid antigen test as part of COVID-19 testing guidelines, this evidence summary looked into the following:

- Validation requirements and performance specifications on SAAgTs from selected regulatory agencies
- Performance characteristics of SAAgT based on the findings of the systematic review of Adajar et al., 2021 from the Philippine Living Clinical Practice Guidelines (LCPG) on the

accuracy of SAAgTs alone compared to RT-PCR in diagnosing COVID-19 among patients suspected to have COVID-19.
- Existing recommendatory testing guidelines on the use of SAAgTs
- Estimated cost of covering SAAgTs in the Philippines
- Perception, acceptability, and self-reporting capacity of SAAgT

III. Policy Question

Should the DOH or PhilHealth consider financing or covering self-administered antigen tests (SAAgT) in the Philippines?

IV. Research Questions

A. Responsiveness to Disease Magnitude, Severity, and Equity

- Can SAAgT significantly reduce the impact and severity of COVID-19 in the general population?
- Does it reduce or not further add to existing inequities in the health system?

B. Validation Requirements and Performance Specifications

What are the current validation requirements and performance specifications for Emergency Use Authorization of SAAgTs among stringent regulatory agencies?

C. Diagnostic Performance

Among patients suspected to have COVID-19, how accurate are SAAgTs alone compared to RT-PCR for the diagnosis of COVID-19?

D. Review of Guidelines

- Which countries are currently implementing SAAgTs and for which use case/s?
- Which countries are mandating reporting of SAAgT results?

E. Estimated Cost of Self-administered Rapid Antigen Testing

What is the estimated cost of covering SAAgTs in the Philippines?

F. Acceptability of Self-administered Rapid Antigen Testing

- What are the knowledge and perceptions of using self-administered antigen tests (SAAgT) among Filipinos?
- What is the level of acceptability in using SAAgT among Filipinos?

- What is the capability and willingness for self-reporting of SAAgT results among Filipinos?

V. Evidence Considered

A. Responsiveness to Disease Magnitude, Severity, and Equity

Burden of the disease

Burden of COVID-19

As of 16 March 2022, the COVID-19 pandemic has affected more than 222 countries and regions with at least 460,280,168 cases and 6,050,018 deaths worldwide (WHO, 2022). Locally, there are at least 3,672,069 confirmed cases and 57,735 deaths (as of 16 March 2022) (DOH, 2022). Of the 46,537 active cases in the Philippines (as of 13 March 2022), 1,006 (14.3%) are severe and critical admission cases. The most recent tally on case count per severity was done on 06 March 2022. Of 48,793 active cases, 401 (0.82%) were asymptomatic, 44,131 (90.45%) were mild, 2,693 (5.52%) were moderate, 1,279 were (2.62%) severe, and 289 (0.59%) were critical cases. (DOH, 2022). The early clinical manifestations among symptomatic individuals infected with the SARS-CoV-2 virus include fever, dry cough, fatigue, loss of taste and smell, diarrhea, headache, sore throat, body pain, and conjunctivitis. The virus may also be transmitted by asymptomatic individuals (WHO, 2021). Individuals who exhibit pneumonia, an oxygen saturation of ≤92%, respiratory rate of >30 breaths per minute, systolic blood pressure <90mmHg, or altered mental status are considered moderate to severe cases and must be referred to a designated tertiary facility. Individuals are considered critical if they exhibit impending respiratory failure and shock, prompting the need for mechanical ventilation and ICU admission. (DOH, 2020).

COVID-19 has impacted various economic and social sectors all over the globe. The table below presents the socioeconomic consequences of COVID-19 to developing countries (Fallesen, 2021; France-Presse, 2020; Loayza & Pennings, 2020):

Table 2. Economic and social impacts in developing countries by the COVID-19 pandemic

Economic	• Decreased economic activity due to imposition of lockdowns and curfews • Fiscal stress as a result of rise in expenditures • Business closures and drop in investments • Worker layoff and unemployment

	• Incapacity to work due to lack of needed equipment (for work from home) or transportation • Heavy impact on trade and tourism industries • Massive poverty, especially in vulnerable communities • Currency devaluation which result in more poverty • Higher school dropout rate as a result of poverty • Higher school dropout rate due to lack of needed equipment
Social	• Social immobility of individuals who rely on public transportation • Increased lack of transparency and accountability in governance • Loss of compliance or salience due to prolonged mitigation measures • Incapacity to observe cultural practices due to need for physical distancing • Stigma against the COVID-infected • Spread of misinformation regarding COVID-19-related topics • Increased social deviance • Hesitance to seek healthcare due to fear of catching the infection • Psychological consequences brought about by negative news and fear of getting infected

The higher transmissibility of the Omicron variant has significantly contributed to the surge experienced worldwide in early 2022. As such, there is value in considering the use of self-administered antigen tests in bringing efficiency in our testing by declogging the current demand for laboratory testing across the country.

Current Challenges in COVID-19 Testing in the Philippines

There are two main factors which make the administration of adequate RT-PCR tests challenging. First, diagnostic tests for COVID-19 are not widely available for free. Although RT-PCR price in the country is relatively similar to those in other countries, it is still perceived to be costly by most Filipinos, even with the price cap set by the DOH as indicated in DC 2021-0374. In fact, the price cap is still not followed by some service providers. The average RT-PCR test price in the Philippines is equivalent to two days' worth of minimum wage. Unlike in other countries, it is not as easy to avail of cheaper antigen tests in the Philippines (Connor et al, 2021; Tan, 2022; Villanueva, 2022). Another factor which affects testing is the long turnaround time for RT-PCR (3-5 days), and this might take longer depending on demand, especially during surges. Lengthened logistics are attributed to the referral of institutions or LGU to respective Hospital Epidemiological Surveillance Units (HESU) (LCP, 2021).

Laboratory-based test results take too long to release, causing overall delays in case surveillance. Delayed acquisition of the test and slow release of RT-PCR results can lead to complacency and unintentionally exposing others during the asymptomatic period (Cerullo, 2021). When results of the testing are hobbled by delays, the authorities would have difficulties in determining the extent of infection thus, the attempt to immediately contain and avoid the spread of the virus is hampered (Angara, 2022). Furthermore,

perceived high cost and slow release of RT-PCR results lead to unregulated selling of test kits in the market. As noted in the Background, FDA released various issuances on the unregulated illegal selling of test kits since 2020. Inaccessibility to testing and delays in testing fuel transmissibility because infectious spread is not immediately detected and controlled, which if not addressed may lead to a surge of infections.

These challenges in the current COVID-19 testing strategies call for a need to introduce a testing strategy that is cheaper, readily-accessible, easy-to-use, and has a faster turnaround time for those who need immediate test results.

The WHO recognizes SAAgT as a complement to health system-based testing done by trained providers. The WHO has issued interim guidelines dated 9 March 2022 on the use cases of SAAgT, which are as follows:

- COVID-19 self-testing, using SARS-CoV-2 Ag-RDTs, should be offered in addition to professionally administered testing services (Strong recommendation, low to moderate certainty evidence).
- SAAgT can be considered for diagnostic purposes if there is ongoing community transmission, in testing individuals with symptoms ≤ 7 days, in testing individuals with recent exposures (such as close contacts and health and care workers) who are asymptomatic, and in testing to detect and respond to suspected outbreaks. Individuals who test positive can be considered as probable cases of SARS-CoV-2 infection (depending on national policy) and should take infection control measures according to the current national guidelines. A negative self-test result in someone who has had a recent confirmed or probable exposure or is experiencing symptoms should be advised to continue standard infection prevention and control practices and to consider re-testing, e.g. 24 to 48 hours later
- SAAgT can be considered for screening among asymptomatic individuals without known exposure irrespective of intensity of community transmission who want increased confidence that they do not have a SARS-CoV-2 infection. A positive self-test result requires further confirmatory testing and precautionary measures on infection control while a negative result may be considered as the absence of infections especially when there is low to no community transmission, but the possibility of false negative results should be noted.

One of the defining advantages of the SAAgT is that it can be used anywhere without requiring the supervision of a healthcare professional. Since these devices are targeted for the general public, these are generally easier to use, requiring nasal, mid-turbinate, saliva or a combination of these samples rather than nasopharyngeal or oropharyngeal samples.

On 26 January 2022, the DOH issued DM 2022-0033, also known as "Guidelines on the Use of Self-Administered Antigen Testing for COVID-19." This memorandum is in accordance with the following previously-issued memoranda:

- AO 2021-0043, Omnibus Guidelines on the Minimum Public Health Standards for the Safe Reopening of Institutions
- DM 2020-0468, Supplemental Guidelines on the Use of Rapid Antigen Test Kits
- DM 2021-0496, Authority for Centers for Health Development (CHDs) and the BARMM-Ministry of Health to procure SARS-COV-2 Antigen Rapid Diagnostic Test Kits
- DC 2022-0002, Advisory on COVID-19 Protocols for Quarantine and Isolation
- DM 2022-012, Updated Guidelines on Quarantine, Isolation, Testing for COVID-19 Response and Case Management for the Omicron Variant

Only SAAgTs approved by the Philippine Food and Drug Administration (FDA) and validated by the Research Institute for Tropical Medicine (RITM) may be used. Approved self-test kits can be found in the FDA database of approved test kits (See Annex A.2). SAAgTs are **recommended for symptomatic individuals only within 7 days from onset of symptoms**. While RT-PCR still remains as the preferred standard for COVID-19 testing, SAAgTs are recommended only if capacity for timely RT-PCR results is limited or not available. SAAgTs are not recommended for asymptomatic close contacts and screening of asymptomatic individuals.

In addition, the Department Memorandum noted the **mandatory reporting of positive results** from symptomatic, suspect, or probable cases to the nearest Local Health Office or Epidemiology and Surveillance Unit. Positive results among symptomatic, suspect, or probable individuals will be managed as a confirmed COVID-19 case.

Responsiveness to equity

The COVID-19 pandemic has introduced immense inequity in the access to health care services. Globally, the higher-income countries have access to most of the prophylaxes and equipment dedicated to COVID-19 response efforts. Locally, vaccines, medications, and screening devices are not equally-accessible across populations. Having a decentralized health system, most of the health services and skilled health personnel are concentrated within the metropolized regions (Bayani & Tan, 2021). Such services include testing, wherein most testing centers are within commercialized areas, and some provinces lack laboratories which provide RT-PCR. The geographically isolated and disadvantaged areas (GIDAs) especially lack the necessary laboratory, equipment, and staff to provide adequate COVID-19 screening and diagnosis. Moreover, RT-PCR kits are costly for those who cannot avail of PhilHealth coverage package. As self-administered test kits are catered for non-supervised use, SAAgTs are more user-friendly for the general public, as well as easy to store at room temperature. These have faster

turnaround time compared to RT-PCR, which is beneficial considering the 'golden period' for the administration of oral antivirals (i.e., within 5 days from onset of symptoms). They are also easier to procure individually as over-the-counter devices. Furthermore, the benefit of self-administration reduces issues related to the lack of adequate skilled personnel and equipment for conducting a test. To ensure that the SAAgTs' value is optimized, the government shall ascertain the provision of adequate, intensive information dissemination and training on the proper use of the technology for the public. The government shall further secure adequate distribution within the market to ensure availability for all, especially the GIDAs. Since SAAgT is a straightforward one-time test which can be done at home, accessibility may improve for the users if the technology is well-distributed.

B. Safety and Effectiveness

1. Validation Requirements and Performance Specifications

What are the current validation requirements and performance specifications for Emergency Use Authorization of SAAgT among stringent regulatory agencies?

Details of this section are tabulated in Annex A.1.

Authorized Use case

Four countries (Australia, US, UK, Philippines) reviewed with Emergency Use Authorization of SAAgT have varying authorized use cases. In the Philippines, 13 importers have been authorized to distribute six brands for use as of March 22 according to the public portal of Philippine FDA. The guideline specifications developed by the Research Institute for Tropical Medicine (RITM) Philippines were reviewed as they are the agency which assists the FDA Philippines in the performance of validation and technical review of applicant products for COVID Testing including SAAgTs. For detailed procedures on waste disposal of SAAgTs and mechanism of reporting, guidelines in DM 2022-0033 stipulated by the DOH were used.

TGA Australia and US FDA have indicated diagnosis as the authorized use of SAAgT in their jurisdictions.

- TGA Australia has authorized the use of SAAgTs as diagnosis for symptomatic individuals and close contacts (whether symptomatic or asymptomatic)
- US FDA has authorized the use of SAAgTs for diagnosing the presence of COVID-19 infection among asymptomatic and symptomatic individuals aged two and above

Meanwhile, UK MHRA has authorized the use of SAAgTs for screening the presence of COVID-19 infection for asymptomatic individuals.

Validation requirements

- *Sample size* - The sample size requirements for validation tests of the regulatory agencies were widely varied. For symptomatic individuals, the US FDA requires a minimum of 30 positive and 30 negative specimens that were consecutively enrolled. On the other hand, the US FDA requires at least 10 positive individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection. The RITM Philippines indicated that clinical validation studies must have a minimum of at least 30 PCR negative samples and 30 PCR positive samples. The UK MHRA has set a minimum of 150 SARS-COV-2 positive cases without prior knowledge of their disease status. Meanwhile, TGA Australia noted the statistically appropriate specimen numbers and sample selection for the evaluation of a COVID-19 rapid antigen self-test which are as follows:
    - 100 NAT positive samples from early infection within the first 7 days after symptom onset; samples should represent naturally occurring viral loads
    - 300 negative samples from non-infected individuals
    - 100 from hospitalised patients
    - 50 potentially interfering and cross-reactive samples
- *Other tests needed* - All regulatory agencies require some form of usability study since the kits will be used without the supervision of a healthcare professional. TGA Australia emphasized the conduct of usability study for SAAgTs in a non-supervised setting which should include at least 30 lay users that are known antigen positive for diagnostic sensitivity or at least 60 lay users that do not know their status for diagnostic specificity. The US FDA requires flex, usability and user comprehension tests while UK MHRA has set an acceptable level of usability where over 95% of participants must be able to complete the test procedure, read the result, interpret it correctly and understand the consequence. The RITM Philippines requires validation studies (e.g. flex studies, usability studies, and user comprehension studies) covering different types of end-user populations from sample collection to results interpretation.
- *Reference test* - Variation in reference tests was observed among the three regulatory agencies. The US FDA recommends comparator sample types to be a nasal mid-turbinate sample for home-collected nasal swabs. TGA Australia stated that sampling should be matched for antigen and NAAT testing for symptomatic individuals. Reference RT-PCR tests must also be used for specimens from asymptomatic individuals. Meanwhile, the UK MHRA uses RT-PCR tests with the UK Conformity Assessed (UKCA), UK Northern Ireland (UKNI), or the Conformitè Europëenne (CE) marking as the standard reference test to SAAgTs provided that these RT-PCR tests performs within desirable analytical and clinical performance specifications. The RITM Philippines implied that the RT-PCR test is the reference standard given the clinical validation requirements.
- *Special requirements in relation to emerging variants of concern* - Both US FDA and UK MHRA requires the manufacturer to confirm the performance in detection of both current and emerging strain variants of SARS-CoV-2. TGA Australia also

requires a supplemental clinical study within 6 months of approval showing the outcome of testing at least 30 clinical samples collected from individuals that are SARS-CoV-2 positive by RT-PCR for the delta variant. The RITM Philippines did not specify any requirement related to emerging variants of concern.

Performance specifications

- *Clinical sensitivity* - Two regulatory agencies (US FDA and TGA Australia,) have set a minimum of 80% positive percent agreement. TGA Australia qualified this for specimens collected within 7 days of symptom onset. Meanwhile, UK MHRA noted a minimum of 80% diagnostic sensitivity where the two-sided confidence interval must be entirely above 70%. The RITM Philippines also requires a minimum clinical sensitivity of at least 80% for specimens collected within 7 days of symptom onset.
- *Clinical specificity* - The US FDA and TGA Australia have indicated a minimum of 98% specificity, while the UK MHRA set at least 99.5% specificity with the two-sided confidence interval entirely above 97%. Meanwhile, the RITM Philippines requires a clinical specificity of at least 97%.

Other specifications

- *Turnaround time* - All three regulatory agencies indicated a turnaround time of 30 minutes or less for obtaining results from SAAgTs. In agreement with the US FDA, the US CDC has set a turnaround time of 15 to 30 minutes. The Australian Government, in accordance with TGA Australia, indicated that the test results may be obtained within 20 minutes. The UK MHRA specified that the desirable turnaround time for results should be no more than 10 minutes, while acceptable turnaround time shall not be more than 30 minutes. The RITM Philippines did not indicate the turnaround time for obtaining test results. However, they indicated the turnaround time for product evaluation through the Technical Document Review, which shall take at least 10 working days.
- *Sample specimen* - The US FDA recommends use of either saliva or nasal specimens obtained from the anterior nasal or nasal mid-turbinate. TGA Australia also recommends the use of nasal swab or saliva specimen. The UK MHRA recommends the use of saliva, sputum, stool, or breath samples for the test. Specimens collected from nasal and throat swabs are deemed acceptable. Meanwhile, the RITM Philippines did not specify a recommended sample specimen.
- *Number of antigens to be detected* - UK MHRA indicated that dual or more SARS-CoV-2 targets are desired for testing, while a single target is acceptable. The rest (US FDA,TGA Australia, and RITM Philippines) did not identify the number of antigens to be detected for testing.
- *Storage requirements* - Both US FDA and TGA Australia indicated that storage requirements for test kits are specified in the manufacturer's instructions. All

SAAgTs which have received an EUA from the US FDA require a storage temperature within the range of 2°C to 30°C. The NSW Government, in accordance with TGA Australia, stated that test kits must be stored in a safe, dry, cool space. Meanwhile, UK MHRA specified that desirable storage conditions for test kits must be at 0-40°C, while acceptable storage conditions are at 15 to 30 °C. The RITM Philippines indicated a storage condition temperature within 18°C to 30°C.

- *Operating conditions* - The US FDA indicated that operating conditions for test kits are specified in the manufacturer's instructions. These test kits specified being unable to withstand extreme moisture, humidity, and temperature, because such conditions may yield inaccurate results. The NSW Government, in accordance with TGA Australia, did not specify optimal operating conditions. The UK MHRA specified a desirable relative humidity of ≤80% and acceptable relative humidity of ≤70%. The RITM Philippines specified that the working condition temperature should be within 18°C to 30°C.
- *Waste disposal* - Three out of four regulatory agencies emphasized the need for proper waste disposal for the observance of biosafety. Waste disposal measures for each agency are as follows:
    - *US CDC, in accordance with US FDA:* After testing, the specimen collection swab or tube must be discarded in the trash, and surfaces that the specimen may have touched must be disinfected.
    - *NSW, in accordance with TGA Australia:* Some tests come with a plastic bag for test kit disposal after use. If no bags are provided within the test kit, the user must obtain a small plastic bag that can be sealed. The plastic bag used for disposing of the test kit is then placed in the household trash. Test kit materials are not recyclable. Hands must be washed carefully after disposal.
    - *UK MHRA*: Design should mitigate the need for special requirements to dispose tests and the accessories needed to perform the test. No special biosafety measures should be required for self-testing.
    - *DOH Philippines* - For the Philippines, the DOH has issued DM 2022-0033 which details the guidelines on disposal and management of waste from SAAgTs on Annex A. Used SAAgT kits and relevant protective equipment are considered infectious waste and thus should be segregated from normal waste upon disposal. Infectious wastes should be sealed in bags or containers that are leak-resistant, durable, and impervious to moisture. The bag/container shall then be labelled properly with the warning, *"Caution: Infectious wastes"*. In case of spills or leaks, immediate decontamination should be done using appropriate disinfectants, preferably 1,000ppm or 0.1% sodium hypochlorite for a minimum contact time of 5 minutes. These wastes should not be stored longer than 48 hours during cool season and 24 hours during hot season.
- *Mechanism of reporting* - All the reviewed guidelines except the Philippines, have provided guidelines on how to report the results from SAAgTs.
    - The US FDA stipulated that all test results should be reported to healthcare providers and relevant public health authorities in accordance with local, state,

and federal requirements, using appropriate codes defined by the Laboratory In Vitro Diagnostics Test Code Mapping for SARS-CoV-2 Tests provided by CDC.
    - TGA Australia noted that positive test results must be reported to the state or territory health department or via website.
    - The UK MHRA emphasized that lateral flow test results must be reported to their website or via call whether positive, negative or invalid. Any problems encountered with the test kit may also be reported via the UK MHRA website. Close contacts may be contacted by the NHS Test and Trace, which utilizes text messages, email, or phone. Moreover, instructions on how to use test kits and what must be done after knowing one's result are detailed online.
    - The RITM, in accordance with DM 2022-0033 written by DOH, stated that all individuals with a positive self-antigen test shall report to their respective Barangay Health Emergency Response Team (BHERT) or healthcare provider. Healthcare providers must report cases by filling out a COVID-19 Case Investigation Form (CIF) within 24 hours of detection. Healthcare providers shall submit the accomplished CIF to their Local Epidemiology and Surveillance Unit, who shall submit it to the appropriate reporting platform. The COVID-19 CIF and guidelines in filling out the form are provided in a website and DM 2020-0436, respectively. LGUs and telemedicine providers accredited by DOH shall use their own reporting system. The memorandum further notes that PHST shall develop an online self-reporting system for the general public to report their respective test-results.
- *IT infrastructure for reporting* - All the reviewed guidelines except the Philippines, have provided specifications for the IT infrastructure for reporting.
    - The US FDA noted several options to allow for reporting of test results, including automatic reporting through a mobile application, instructions directing users to a website where reporting is easily facilitated, among others and that they are open to alternative approaches that ensure appropriate reporting. Moreover, they specified that any smartphone application should be simple and that error messages should be readily understandable, and troubleshooting should be included in the device instruction. The display should also promote understanding of results and what individuals should do next, including how to care for themselves and when to seek follow up care. Finally, the application should automatically report all test results when appropriate in accordance with local, state, and federal requirements.
    - According to TGA Australia, there are general requirements that the technical file of software for SAAgTs should include evidence for. This applies whether the software development methodology is agile (or a variant of agile) or other methodology. These include:
        - Overall description of functions
        - Software architecture and design, physical and logical;
        - Validation artefacts
        - Defect management process
        - Human factors/usability
        - Cybersecurity risks and how they have been addressed
        - Data privacy
        - Clear instructions for lay people on how to use the software, as part of the Instructions For Use (IFU).

- Minimum specifications for the device for the software to operate on
- The minimum resolution for images used by an app for recording images of results should be 1920x 1080 (horizontal) resolution. The test itself should occupy at least 80% of the vertical height of the image.

- The UK MHRA noted that devices that simplify remote data captured electronically into a central data reporting system may be advantageous.
- The RITM Philippines does not currently require the companies to have an existing IT infrastructure for reporting of results of their test kits.

The detailed data extraction of these regulatory guidelines are provided in Annex A.1.

2. Diagnostic Performance

Among patients suspected to have COVID-19, how accurate are SAAgT alone compared to RT-PCR for the diagnosis of COVID-19?

Description of the review

The LCPG group conducted a systematic review (Adajar et al, 2021) on the accuracy of self-administered rapid antigen tests compared to RT-PCR for the diagnosis of COVID-19. RQ of the review: *Among patients suspected to have COVID-19, how accurate are SAAgT alone compared to RT-PCR for the diagnosis of COVID-19?*

Both published and preprint studies were included in the literature search through several databases and study registry. Their last search was performed on January 6, 2022. Methodological qualities of the diagnostic studies were assessed by independent reviewers using the QUADAS-2 instrument. From the 475 titles and abstracts found, the final included studies were seven observational studies that are specific to the diagnostic accuracy of self-administered RAgTs. From the updated search, five new studies were added increasing the total number of included studies to 12 involving 10,185 samples.

Other details of this subsection will refer to the report of the LCPG group review.

Summary of findings of the review:

Characteristics of included studies

Twelve observational studies including a total sample of 10,185 participants were found to assess the diagnostic performance of SAAgTs compared to RT-PCR. The studies used nine different brands and five types of specimen. Eight studies included symptomatic patients, five included asymptomatic patients, while two included both symptomatic and asymptomatic patients (mixed) with no disclosed subgroup data. Only one study included children as participants.

Methodological quality of included studies

The overall methodological quality of included studies was rated to be moderate by the review authors. Four studies were found to have a high quality while eight studies

were found to have moderate quality due to issues of unclear patient selection, index test, and reference standard.

Diagnostic accuracy of SAAgTs

The overall pooled sensitivity of SAAgTs was 82% (95% CI: 71-89; I^2: 89.6%), based on 12 studies; while the overall pooled specificity of SAAgTs was 100.0% (95% CI: 99-100; I^2: 97.2%), based on 12 studies.

Given the substantial heterogeneity for pooled estimate of sensitivity, subgroup analysis was pre-determined according to test brand, presence of symptoms, timing of testing, type of specimen used, and CT value of RT-PCR used.

- Among the included brands, the COVID-VIRO Antigen Rapid Test (AAZ) showed the highest pooled sensitivity at 97% (95% CI: 85 to 100, n=234, 1 study). Other test brands that had 80% sensitivity or higher were the following: *Inflammacheck* at 92% (95% CI: 64 to 100, n=105, 1 study), *BIOSYNEX COVID-19 Ag BSS (Biosynex SA)* at 91% (95% CI: 71 to 99, n=106, 1 study), *Dräger Antigen Test SARS-CoV-2* at 89% (95% CI: 79 to 95, n=379, 1 study), *Abbott Panbio* at 84% (95% CI: 71 to 94; n=290, 1 study), and *STANDARD Q COVID-19 Ag Test* at 82% (95% CI: 73-89, n=569, 4 studies) Meanwhile, *E25Bio Rapid Diagnostic Test (E25Bio)*was slightly below 80% sensitivity at 79% (95% CI 68-87; n=257, 1 study). Brands with the lowest sensitivity were the following: *BinaxNOW SARS-CoV-2* at 57% (95% CI: 37-76, n=44, 1 study), and Innova LFT at 40% (95% CI: 28-52, n=5,504, 1 study).
- In terms of the presence of symptoms, the pooled sensitivity of SAAgTs was higher among symptomatic patients (87%; 95% CI: 77-93; n=1,246, 8 studies) than in asymptomatic patients (41%; 95% CI: 33-73, n=5,881, 5 studies).
- When the test was used for testing patients in the early phase (0-7 days) of the disease, the pooled sensitivity estimate was found to be 87% (95% CI: 77-93; n=3,883, 7 studies). The reviewers noted that none of the studies used SAAgTs exclusively during the late phase.
- In terms of the specimen used, those taken from exhaled breath showed the highest pooled sensitivity of 92% (95% CI: 64-100; n=105, 1 study) followed by those taken from nasal mid-turbinate with sensitivity of 81% (95% CI: 73-87; n=723, 3 studies and nasopharyngeal samples (sensitivity range of 79-97; n=3,188, 2 studies).)
- In terms of the cycle threshold value of RT-PCR used, SAAgTs had higher sensitivity against RT-PCR assays that used a lower Ct values of < 25 (sensitivity range of 69-96%) compared to those who used Ct values > 25 (sensitivity range of 9-67%)
- In terms of methodological quality, studies with risk of bias decrease the sensitivity of SAAgT to 79% (95% CI 68-87; n=974, 5 studies).

Table 3. Summary of Subgroup Analysis from Adajar et al. (2021)

Subgroup analyses			
Subgroup	Pooled Sensitivity	Number of pooled studies	Number of positive samples

By brands			
COVID-VIRO Antigen Rapid Test (AAZ)	97% (95% CI: 85-100)	1 study (n=234)	35
Inflammacheck® device (Exhalation technology LTD, Cambridge, UK) : highest pooled sensitivity	92% (95% CI: 64-100)	1 study (n=105)	13
BIOSYNEX COVID-19 Ag BSS (Biosynex SA)	91% (95% CI: 71-99)	1 study (n=106)	22
Dräger Antigen Test SARS-CoV-2 (Dräger Safety AG and Co. KGaA, Lübeck, Germany)	89% (95% CI: 79-95)	1 study (n=379)	70
PanbioTM Ag-RDT (Abbott)	84% (95% CI: 71-94)	1 study (n=290)	45
STANDARD Q COVID-19 Ag Test (SD Biosensor, Korea)	82% (95% CI: 73-89)	4 studies (n=569)	125
E25Bio Rapid Diagnostic Test (E25Bio)	79% (95% CI: 68-87)	1 study (n=257)	76
BinaxNOW SARS-CoV-2 (Abbott)	57% (95% CI: 37-76)	1 study (n=44)	28
Innova LFT (Innova Medical Group Inc)	40% (95% CI: 28-52)	1 study (n=5,504)	70
By presence of symptoms			
Mixed	Cannot be pooled (Range: 79 - 92)	2 studies (n=3,056)	89
Symptomatic	87% (95% CI: 77-93)	8 studies (n=1,246)	298
Asymptomatic	53% (95% CI: 33-73)	5 studies (n=5,881)	88
By timing of testing in relation to symptoms			
Early (0-7 days)	87% (95% CI: 77-93)	7 studies (n=3,883)	84
Mixed (early and late)	Cannot be pooled (Range: 74 - 84)	2 studies (n=577)	299
By type of specimen			

Exhaled breath condensate	92% (95% CI: 64-100)	1 study (n=105)	13
Nasopharyngeal	Cannot be pooled (Range: 79 - 97)	2 studies (n=3,188)	111
Nasal mid-turbinate	81% (95% CI: 73-87)	3 studies (n=723)	180
Anterior nares	Cannot be pooled (Range: 57 - 89)	2 studies (n=423)	98
Nasal + oropharyngeal	Cannot be pooled (Range: 40 - 67)	2 studies (n=5,544)	73
By cycle threshold (Ct) value			
Low (< 25)	Cannot be pooled (Range: 69 - 96)	2 studies (n=63)	63
Mixed	80% (95% CI: 68-88)	5 studies (n=961)	190
High (>25)	Cannot be pooled (Range: 9 - 67)	2 studies (n=52)	52
By methodological quality			
Low Risk of bias	82% (95% CI: 73-89)	4 studies (n=644)	114
High risk of bias	79% (95% CI: 67-87)	5 studies (n=974)	222
Unclear risk of bias	Cannot be pooled (Range: 40 - 97)	3 studies (n=5,837)	139

3. Review of Country Guidelines

What are the current use cases of self-administered rapid antigen tests based on country guidelines?

For this review, we applied the following operational definitions set by the DOH DM 2020-0439, for the different use cases, as applied in the previous reviews of the HTA Unit and the HTAC:

Table 4. Operational Definition of Use Cases per DOH DM 2020-0439

Use Case	Definition
Diagnosis	*Diagnostic testing/ testing for diagnosis looks for presence of COVID-19 at the individual level and is performed when there is a particular reason to suspect that an individual may be infected (i.e. manifestation of symptoms or known*

	history of exposure). Diagnostic testing intends to diagnose an infection in patients suspected for COVID-19 by their healthcare provider, such as in symptomatic individuals, individuals who have had recent exposure, and individuals who are in high-risk group such as healthcare providers with known exposure. In these guidelines, this shall be applied to close contacts and suspect cases identified after symptoms-based screening.
Screening	*Screening testing/ testing for screening intends to identify infected individuals prior to development of symptoms or those infected individuals without signs of symptoms who may be contagious, so measures can be taken to prevent them from infecting others. This includes broad screening of asymptomatic individuals without known exposure and then deciding on the next courses of action based on individual test results. In these guidelines, this shall be applied to travelers from high prevalence areas.*
Surveillance	*Testing for surveillance is primarily used to obtain information at a population level, rather than an individual level. Surveillance testing may be random sampling of a certain percentage of a specific population, to (1) monitor for increasing or decreasing prevalence, and (2) determine the effects of community interventions such as physical distancing at the population level. In these guidelines, these shall be applied to front liners and essential workers.*

Of 34 countries/ agencies reviewed, the reviewers found a total of 36 recommendations (*Note: Some countries have several guidelines and different use case recommendations depending on the target populations)*. Of the reviewed guidelines:

24 Recommending		**5 Not Recommended**	**7 With guidelines for RAGT but no explicit mention of SAAgT**
Mandatory	**Optional**		
Singapore MOH	US, UK, Australia, Netherlands, Malaysia, Cambodia, Canada with 9 recommendations for specific provinces, Singapore with 3 different use case for specific subpopulations, Germany, Philippines, China, Brazil, and the WHO with 2 different use case recommendations for specific populations	Singapore Health Sciences Authority, Kenya MOH, South Africa DOH, Namibia Medicines Regulatory Council, Vietnam	EU CDC, Nigeria CDC, Government of Pakistan, Uganda MOH, Indonesia MOH, Vietnam and Seychelles DOH

- **Positive recommendations on SAAgT:** Twenty-four (24) recommendations from 13 countries/agencies *(US CDC, UK NHS, Australia DOH, Government of the Netherlands, Malaysia MOH, Cambodia MOH, Government of Canada with 9 recommendations for specific*

provinces, Singapore MOH with different use case recommendation for 4 specific subpopulations, Germany MOH, DOH Philippines, China NHC, Government of Brazil, and the WHO with 2 different use case recommendations for specific populations) currently recommend the of use of SAAgT and their specific use cases in the testing strategies for COVID-19;

  - Of these 24 positive recommendations, one (1) (Singapore) is mandatorily recommending SAAgT for screening of close contacts of symptomatic COVID-19 positive case and vaccinated travellers; while the rest (including certain sub-populations in Singapore) are optionally recommending its use for specific use cases.

- **Negative recommendations on SAAgT:** Five (5) recommendations *(Singapore Health Sciences Authority, Kenya MOH, South Africa DOH, Namibia Medicines Regulatory Council and Vietnam [specifically for travellers])* currently do not recommend the use of SAAgT for the detection of COVID-19.
- **General antigen test guidelines:** Seven (7) recommendations *(EU CDC, Nigeria CDC, Government of Pakistan, Uganda MOH, Indonesia MOH, Vietnam and Seychelles DOH)* countries have available guidelines which are for rapid antigen test (RAgT) but there is no explicit mention of SAAgT; and,

Meanwhile, thirteen (13) countries (*Korea, Thailand, India, Solomon Islands, Afghanistan, Malawi, Somalia, Yemen, Ethiopia, Angola, Tunisia, Mauritius, Bangladesh*) have no guidelines that could be accessed. See Annex B for the detailed extracted guidelines.

Of the 24 positive recommendations, we classified the use cases for the use of SAAgT in their settings, how they interpret the results of the test, their method of collection, and their timing of sample collection.

Thirteen of twenty-four positive recommendations recommend the use of SAAgTs for screening purposes. Many of these screening guidelines (Government of Netherlands, Malaysia MOH, Government of Canada, China NHC, Brazil MOH) apply to symptomatic individuals, close contacts whether symptomatic or asymptomatic, or both. Meanwhile, some (Government of Canada, Singapore MOH) allow its use for asymptomatic individuals who are not necessarily close contacts of a COVID-19 case but with a high risk of exposure *(e.g., for travellers entering the country/territory, for the pediatric population going to schools and for unvaccinated individuals).* There are also recommendations, specifically from the WHO, which allows its use for individuals without symptoms or known exposure to a positive case.

Meanwhile, less than half (ten of twenty-four) of all positive recommendations allow its use for diagnosis purposes. This applies to suspected cases, in situations where people may meet without a mask (i.e. private visit or at a celebration) or in the event where the individual has no symptoms or was not exposed but will be in a gathering with other

people. In Alberta (Canada), it is also recommended to be used for the general population.

Lastly, one of the positive recommendations (i.e. Singapore MOH which recommends its use for routine testing of employees) recommended its use for surveillance purposes.

In terms of incorporating SAAgT-positive results in the case count:

- Among the country guidelines recommending the use of SAAgT, three (US CDC, Australia DOH, and UK NHS) include the reporting of a positive antigen test result as an official case count. Australia DOH advises those who had a positive SAAgT result to follow local health advice and register as a COVID-19 positive case. Although the US CDC recommends to include positive antigen results in the official case count, there is no specific provision for SAAgTs. Meanwhile, the UK NHS includes the results of SAAgTs in the weekly report of cases and positivity rate. The government of the UK provides free SAAgT kits through free-standing booths and can also be ordered online through providers. Each test kit has a unique QR code enabling for easier tracking of the dispensed test kits.
- Among countries who do not recommend SAAgT or have no SAAgT guidelines yet, three (Kenya MOH, Cyprus MOH, and South Africa DOH) include the reporting of a positive antigen test result as an official case count.

Regarding the guidelines for reporting positive results from SAAgT, 19 of the 24 positive recommendations provided guideline provisions requiring the reporting of their results mainly via local health authorities offices. Malaysia specifically uses a phone application for their reporting mechanism, while the US, UK, Australia, Canada and Singapore require result reporting via website.

Below are more details on their reporting procedures:

- *US CDC:* Report the result if positive via a local health provider or the local health department through call, email, or website/applications (if available). May report negative or invalid results if a person is a close contact or is experiencing symptoms.
    - Washington Portal: (https://hipaa.jotform.com/220053184973051)
    - Montgomery County Portal: (https://www.co.montgomery.ny.us/systems/publicwebforms/covid-isolation.asp).
- *Australia DOH:* Report positive result online via this website: https://dhvicgovau.powerappsportals.com/rapid-antigen-test/
- *UK:* Report whether positive, negative, or invalid via:
    - UK government website (https://www.gov.uk/report-covid19-result) or hotline for the general population,

    - Self-isolation service hub website (https://www.gov.uk/guidance/nhs-test-and-trace-workplace-guidance) for employers with employees who tested positive and
    - on NHS portal (https://www.nhsinform.scot/campaigns/coronavirus-covid-19-report-your-test-result) for health worker, social worker and those working in the NHS
- *Netherlands:* Report if positive or negative to the municipal health service; for worsening symptoms, set an appointment with municipal health service for further assessment.
- *Malaysia MOH:* Report whether positive or negative to *MySejahtera* application
- *Cambodia MOH:* Report if positive via reporting to health officials or the nearest authorities, or contact 1222 for Phnom Penh
- *Canada:* Report via local health authority or website
    - New Brunswick: If positive, confirm with the local assessment center.
    - British Columbia: If positive, complete the COVID Positive Test Result Reporting Form via website (https://reportcovidresults.bccdc.ca/)
    - Alberta: If positive, complete the Alberta Self-report of COVID-19 Rapid Antigen Test Result. Reporting is not required but encouraged.
    - Manitoba: If positive, individuals are advised to isolate but reporting is not required
    - Saskatchewan: If positive or negative but symptomatic, contact 811 or the nearest Saskatchewan Health Authority (SHA)
    - Quebec: If positive, report via screening appointment platform (https://cv19quebec.ca/s/?language=en_CA). If negative but with worsening symptoms, report by informing a healthcare professional.
    - Ontario: If positive, report to any laboratory testing center to receive confirmatory RT-PCR
- *Singapore:* Report whether positive or negative via government agency website (*https://form.gov.sg/#!/61515cd8855f49001279b2ef*).
- *Germany:* If positive, report to the local public health office or call the coronavirus hotline.
- *Brazil*: The result of the self-testing must be reported through an online electronic form whether positive or negative. (https://servicos.min-saude.pt/covid19/Login?ReturnUrl=%2fcovid19%3fctx%3d3&ctx=10) If no report was submitted, the individual will be notified through SMS.
- *China*: People who have positive antigen test results should immediately report to local authorities regardless of having respiratory symptoms or fever. They will be transferred to designated medical facilities for nucleic acid tests.
- *Philippines:* If positive, report to Barangay Health Emergency Response Team (BHERT) or healthcare provider
- *WHO:* Countries that use self-tests should consider how to best integrate reporting on self-testing into existing monitoring and surveillance efforts.

Table 5. Summary of Reporting Mechanism per Country

VIA local health authorities	VIA website	VIA phone application	Reporting not required
US Netherlands Cambodia Germany New Brunswick Philippines Saskatchewan Quebec Ontario China Canada (General)	US Australia UK Singapore Canada (Quebec) British Columbia Brazil	Malaysia	Alberta Manitoba

The detailed data extraction of these country guidelines are provided in Annex B. The next subsections shall discuss the summary of these country guidelines on the use of SAAgT.

Guidelines recommending the use of SAAgT for Diagnosis

Summary

Ten *(US CDC, Australia DOH, Cambodia MOH, UK NHS, Canada-State of Alberta and Manotiba, Singapore MOH, Germany MOH, DOH Philippines and WHO)* of the 24 recommendations recommend the use of SAAgT for the diagnosis of COVID-19 infection for individuals who are symptomatic or exposed to a COVID-19 case, and in the event where the individual has no symptoms or was not exposed but will be in a gathering with other people.

Specific guidelines per country:

- The US CDC currently recommends self-administered antigen tests (via nasal swab) in the following target population:
    - *Among patients with or without symptoms, those who have been exposed or potentially exposed to an individual with COVID-19, or those who are to contact other people* - The recommended timing on when the test is to be performed immediately if with COVID-19 symptoms or at least 5 days after exposure to others with COVID-19. Meanwhile, the test is also recommended to be used immediately before gathering with other people .
        - The guideline stated that if the result of the self antigen test is positive, it is already treated as a positive case as the guideline

mentioned that individuals with positive results shall be isolated for at least 5 days to avoid spreading the infection.
        - Meanwhile, a negative result indicates that the test did not detect the virus though it does not rule out an infection. However, it is noted that some self-tests are designed to be used in a series; hence, repeating the test within a few days (at least 24 hours between tests) may increase the confidence of not being infected.
    - *For inbound travellers* - SAAgt may be administered 24 hours before the flight given that the testing procedure is supervised by a telehealth care provider affiliated with the manufacturer of the test kit via video and audio connection.
        - The guidelines state that if the result is positive, self-isolation is required; therefore, delaying the travel is delayed until isolation is completed.
        - If the result is negative, the individual may board the flight.
- The Australia DOH recommends the use of SAAgTs (via nasal swab or saliva sample) for adults who are symptomatic or have had close contact with someone who has tested positive and for those who have been advised to do so by a health professional. The test should be taken within the first 7 days from when symptoms first appear. SAAgTs are used as a direct alternative to RT-PCR.
    - In cases of positive results, the individual should report to health authorities and isolate at home for 7 days. They may leave isolation after 7 days once symptoms clear up.
    - If negative, no isolation and confirmatory test needed.
- The Cambodia MOH recommends the use of self-test rapid antigen (via nasal swab) for persons who are suspected (i.e., symptomatic or a patient with severe acute respiratory infection and requiring hospitalization and with no other etiology that fully explains the clinical presentation) to have COVID-19. The guideline did not specify when to take the test. Their guidelines for antigen testing in general do not specify it either.
    - For positive results, they are obliged to notify health authorities so that they may be further evaluated and advised about the standard protocol for home treatment or referral to a health center or COVID-19 hospital.
    - For negative results, there was no further information provided.
- The UK NHS recommends self-testing for use case diagnosis (via throat and nose swab or nose swab only) specifically for people who do not have symptoms. The test may also be done with the supervision of a trained operator who processes and reads the result of the test (assisted test). The timing of collection was not specified.
    - If the result of the test is positive, no PCR confirmatory test is needed. Instead, a 10-day self-isolation period is required. The counting starts on the day the symptoms started or if asymptomatic, on the day the result was released. If there are no more symptoms after the 10-day isolation, or

if all that was left was cough or anosmia, the person may return to normal living. Meanwhile, it is possible to end the 10-day isolation early if: a lateral flow diagnostic (LFD) test is taken at day 5 after the day the symptoms started (or the day your test was taken if you did not have symptoms), and another LFD test is taken on the following day. If both tests are negative and the individual has no high temperature, he/she can end the isolation.
    - For a negative result, and the patient feels unwell, stay at home until you feel better. If feeling sick, having diarrhea and high temperature, stay at home for 48 hours or if symptoms have stopped.
- Canada - State of Alberta - All residents can get free SAAgTs to help detect infections early and stop the spread with a limit of one kit per person/health care number within a 14-day period. Sample specimen is taken via nasal swab There is no need to take confirmatory PCR as only the high risk population are required.
    - If the test is positive, fully vaccinated residents are required to self-isolate for five (5) days or until the symptoms are gone. Meanwhile, for those not fully vaccinated, isolation must be up to ten (10) days or until symptoms are gone.
    - If the test is negative and the individual is asymptomatic, there is no need to isolate but continue monitoring for symptoms and follow standard health protocols. Meanwhile, if negative and symptomatic, the individual must isolate for 24 hours and take a repeat antigen test. Continue isolating until symptoms are resolved.
- Canada - State of Manitoba recommends the use of SAAgT for symptomatic individuals (via nasal swab). The timing of collection was not specified.
    - If the result is positive, a 5-day isolation is required without the need for confirmatory testing.
    - If negative, take a second test 24 hours after your first and if available a third test 24 hours after the second.
- The Singapore MOH recommends SAAgT as diagnosis for fully vaccinated travellers and for travellers with low risk of infection (via nasal midturbinate or nasal swab). The self-test must be taken within 24 hours of arrival.
    - Positive test result: For individuals who are not under vulnerable category and feeling well, isolate for 72 hours. If unwell, no confirmatory test required but the individual must follow the advice of a medical professional for the recovery.
    - If the test result is negative, continue to adhere to public health measures.
- Germany MOH recommends SAAgT for private individuals who meet in situations without a mask such as a private visit or at a celebration (via nasal swab, throat swab or saliva sample). The timing of collection was not specified but they noted that the viral load is at its peak during onset of symptoms and at the beginning of infection.

    - If the result is positive, a confirmatory test is not necessary especially in the case of high incidences but isolation and conforming to the general safety protocol is encouraged.
    - If the result is negative and the individual has mild symptoms, go to voluntary quarantine and you may have yourself tested; otherwise, conform with the general safety protocol.
- The DOH Philippines recommends the use of SAAgT for symptomatic individuals with or without exposure (method of collection depends on the brand to be used). The test must be administered within seven (7) days of symptom onset.
    - If the test result is positive, no confirmatory test is needed but isolation is strictly mandated. The result must also be reported to the Barangay Health Emergency Response Team (BHERT) or healthcare provider.
    - For asymptomatic close contacts or individuals with a high index of suspicion for COVID-19, if the test is negative, immediately quarantine, conduct symptom monitoring, and consult with a healthcare provider
- The WHO recommends the diagnostic use of SAAgT for individuals with symptoms and/or recent exposures (such as contacts or health and care workers),. The type of specimen to be collected is not specified. It is recommended to use within the first 5-7 days of the infection.
    - If the result is positive, it can be considered to be a probable or confirmed test thus, no confirmatory test is needed but compliance to safety protocol is encouraged. If the person manifests symptoms, consider clinical consult and confirmatory testing.
    - For someone who had a recent confirmed or probable exposure or is experiencing symptoms, if the result is negative, consider retesting (e.g. 24 to 48) hours later.

Guidelines recommending the use of SAAgT for Screening

Summary

Thirteen *(Singapore MOH, Government of Netherlands, Malaysia MOH, Government of Canada with 7 unique recommendations, WHO, Government of Brazil and China)* of the 24 recommendations currently recommend the use of SAAgTs for screening of possible COVID-19 cases. Similar to the users of rapid antigen tests, the most common application of SAAgT for screening is for symptomatic or close contacts of COVID-19 positive cases (regardless of symptoms). Note that several guidelines also allow SAAgTs as screening for asymptomatic individuals without exposure to a COVID-19 case but with high risk/ potential of exposure, such as:

- travellers/ individuals who frequently cross borders (Singapore, Malaysia,, Netherlands, Canada)
- personnel/workers (Netherlands)
- for those people expecting visitors or will be visiting others (Netherlands)
- students and pediatric population going to schools (Netherlands)

- people employed in the commercial transportation industry (Canada)
- unvaccinated individuals (Canada)

In addition, some guidelines also allow the use of SAAgT as screening for the general population - individuals without exposure and are not necessarily with high risk of exposure, such as:

- for those who want to know their status (Malaysia)
- free testing kits for residents of Alberta (Canada)

Timing of Tests

In terms of timing of test, specifically for symptomatic individuals, the guidelines recommend varying timing of tests (e.g. within 24 hours after getting in contact with a positive patient; anytime, especially for those with mild symptoms; for repeat testing before the end of isolation period). Meanwhile, for testing of asymptomatic individuals, the timing of the test generally depends on the specific population using the SAAgT.

Sample Specimen for SAAgT

Majority of the guidelines recommend nasal swab as a sample specimen for the test, while some guidelines also allow other samples such as nasal mid-turbinate, saliva, nasopharyngeal swabs, and throat swabs.

Supervised SAAgT

British Columbia and Ontario (Canada) guidelines stated that self swabbing can only be performed when observed by a health care professional or a trained individual to ensure that important quality and reporting standards are met.

Table 6. Operational definition of supervised and unsupervised self-testing

Fully self-testing	Administration of antigen test is done by users without the need for expert supervision
Supervised self-testing	Administration of antigen test is done by the users themselves but requires expert supervision

Specific guidelines per country:

- In Singapore, SAAgTs are used to screen COVID-19 cases in the following target populations:
    - *Close contacts of a COVID-19 positive case with health risk notice:* SAAgTs (via nasal mid-turbinate or nasal swab) are legally required to be taken within 24 hours, the result of which shall be submitted online.
        - Positive result:

- If feeling well or with mild symptoms, individuals with positive results shall isolate for 72 hours and repeat the SAAgT. Continued self-test shall be continued if the repeat test is positive.
- If with severe symptoms, the doctor will order both a healthcare-administered antigen rapid test and a PCR test.

■ Negative result: An individual with a negative result can leave the house and resume normal activities but must still complete the 5-day monitoring period while following safety protocols (i.e. wearing a mask when leaving their homes).

○ *For close contacts without health warning:*

■ If results are positive but feeling well or with mild symptoms, wait for 72 hours for a repeat ART self-test. Repeat until the test becomes negative.

■ If negative results, the individual may proceed to regular activities but the 5-day monitoring period must be completed.

- The Government of the Netherlands recommends the *immediate* use of SAAgT (via nasal swab) for general adult populations, pediatric individuals going to schools, asymptomatic and mildly symptomatic population, close contacts of confirmed COVID-19 cases, and travellers. The test is recommended to be done any time especially for those with mild symptoms.
  - For positive results of the SAAgT, the individual is advised to perform self-isolation immediately and book an appointment with the municipal health service for a confirmatory test to ensure that the "*self-test did not produce a false positive*". If the confirmatory test is negative, the individual is advised to stop isolation.
  - If negative results, the status of the individual is classified as negative for COVID-19, but they may have another infection caused by a "contagious virus or bacteria". The person is required to continue and follow the minimum public health standards to prevent the spread of the virus.
- The Malaysia MOH recommends SAAgT (via nasal swab or saliva sample) to be administered to any individual who wants to know his/her status; to those who have contact with a positive case; and as an appropriate screening test for border control such as cross-state and international entrance. It is also recommended for pre-employment screening and the like. The test is recommended to be done any time. All results of the test are reported to *MySejahtera* application.
  - In case of a positive result, individuals are required to go to either a private health facility, COVID-19 Assessment Center or a health clinic for further health assessment.
  - The procedure is the same if the results are negative and the patient manifests symptoms.
- In Canada, a positive SAAgT result should seek a confirmatory PCR test as soon as possible. Meanwhile, individuals with negative results shall continue to follow

all local public health measures. In terms of target users, different provinces have their specific guidelines which are detailed below:

- *Brunswick:* SAAgTs are indicated for individuals who frequently cross borders for the purpose of childcare, education, work or to fulfill child custody arrangements, and employed in the commercial transportation industry.
- *British Columbia:* SAAgTs are indicated for people without COVID-19 symptoms. However, it should only be supervised by a health professional or a trained individual to ensure that important quality and reporting standards are met. If the individual tested positive, an online form must be completed to report the test result. For a negative result, self-isolate until your symptoms improve and you feel well enough to return to regular activities.
- *Alberta:* All residents can get free SAAgTs to help detect infections early and stop the spread with a limit of one kit per person/health care number within a 14-day period. The high risk population, in particular, are required to take a PCR confirmatory test once SAAgT result is positive. These tests can be performed to individuals 14 years and older or by an adult to children aged 2-13 years old. The guidelines did not specify that training is required for those who will administer self-test thus any adults can use and administer this test.
- *Saskatchewan:* SAAgTs shall only be used by asymptomatic individuals. Symptomatic individuals shall book a PCR test at the Saskatchewan Health Authority.
- *Manitoba:* SAAgTs are used for the screening among the following individuals: healthcare workers who provide direct patient care and first responders; staff who have direct contact with patients, residents, and clients in hospitals and congregate living settings/residential care facilities (including personal care homes, assisted living, group homes, shelters, and correctional institutions); symptomatic residents in congregate living settings/residential care facilities if there has been no known case in the facility or specific unit in the last 14 days; and people who may be eligible for COVID-19 treatment and determined by a prescribing clinician to require PCR test.
- *Ontario:* Indicated as screening for individuals without COVID-19 symptoms It can only be performed under supervision of a health professional or trained individual. The self-swabbing training resource developed by Ontario Health and Public Health Ontario shall be consulted when performing self-swabbing.
- *Quebec:* Symptomatic individuals should use SAAgT as soon as possible.

- Another guideline from the government of Canada recommended the use of SAAgt (via nasal swab) for the unvaccinated, asymptomatic and symptomatic individuals. The timing of collection was not specified in the guidelines.

    - In case of a positive test result, a confirmatory PCR test is required and further safety measures must be observed.
    - In case of a negative test result, the individual is encouraged to continue to follow public health guidelines such as staying at home when ill, following regional/local health guidelines regarding the need for PCR test, improving indoor ventilation, practicing hand hygiene and respiratory etiquette, cleaning/disinfecting surfaces and objects, avoiding closed spaces and crowded places, minimizing in-person interactions and practicing physical distancing, wearing a mask, and avoiding non-essential travel outside of Canada.
- The China NHC recommends the use of self-tests (via nasal swab, oropharyngeal swab, nasopharyngeal swab) for symptomatic individuals visiting medical facilities, and those undergoing isolation. The timing of collection is not specified.
    - If the result is positive, a confirmatory test – nucleic acid tests (PCR) is required and the individual must undergo a centralized quarantine.
    - Meanwhile, there is no recommendation if the result is negative.
- The WHO recommends the use of self-testing as screening test for individuals without symptoms or known exposure to COVID-19, regardless of the intensity of community transmission. The route of administration was unspecified. There was no specific information for the timing of the test but the WHO mentions that the test is self-directed for those who want to know if they do not have the infection.
    - For individuals who tested **positive**, confirmatory testing is advised, and compliance to minimum public health standards is encouraged.
    - For individuals who tested **negative**, no confirmatory testing is required, but compliance to minimum public health standards is still encouraged.
- The Brazil MOH recommends the use of self-testing for individuals who are symptomatic and close contacts of COVID-19 cases (via nasal swab and saliva sample). Individuals who are symptomatic must perform self-testing between the 1st and 7th day of the onset of symptoms. For individuals who had close contact with someone who tested positive, wait five days before using the self-test.
    - Individuals with **positive test results** must seek medical attention and confirm results with RT-PCR.
    - Individuals with **negative test results and are asymptomatic** must self-isolate for five days and repeat the test after one to two days.
    - Individuals with **negative test results and are symptomatic** must repeat the self-test after one to two days and monitor their symptoms. If symptoms worsen, they must seek medical attention and confirm test results with RT-PCR.

Guidelines recommending the use of SAAgT for Surveillance

- The Singapore MOH recommends the use of routinary self-testing for working individuals who are more vulnerable or have higher risk exposure to COVID-19 (via nasal swab). Unvaccinated personnels must undergo mandatory testing twice per week while vaccinated individuals must undergo mandatory testing once a week.
    - Once positive, the employee should continue to self-isolate and self-test daily until they obtain a negative result or until 12pm on Day 7 if vaccinated or Day 14 if not fully vaccinated.
    - If negative results, the personnel is allowed to work and continue prescribed routine self-testing/surveillance.

C. Household Financial Impact

Currently, the Philippine Insurance Corporation (PhilHealth), per Philhealth Circular 2022-0003, covers the following COVID-19 testing:

- ***RT-PCR testing***
    - As a confirmatory test
    - Plate-based and cartridge RT-PCR done in DOH-licensed laboratory using saliva (for plate-based RT-PCR), and nasopharyngeal and/or oropharyngeal specimen
    - The validity period of confirmatory testing for the purpose of claims filing is 14 days or less prior to admission.
- ***Rapid Antigen Testing***
    - As a confirmatory test for symptomatic patients
    - Facility-based Rapid Antigen Testing using nasal, nasopharyngeal and/or oropharyngeal specimens
    - The validity period of confirmatory testing for the purpose of claims filing is 14 days or less prior to admission.
- ***Antibody Testing***
    - As an adjunct test for symptomatic patients with 2 negative RT-PCR, antibody test done 15 days after in a DOH licensed laboratory may be accepted

As such, if SAAgTs will be eventually available in the Philippine market, households will incur out-of-pocket costs for the purchase of the kits in addition to medical consultation and transportation costs, until PhilHealth or DOH or other government entities issue for its policy coverage.

In addition to these financing policy policies to facilitate the access to COVID-testing, in January 2022, the DOH has updated the price cap for rapid antigen tests to Php 660.00 and has set a price cap of SAAgT kit at Php 350.00, per DOH DC 2021-0323.

D. Cost-effectiveness

The evidence was not reviewed. A full-blown cost-effectiveness analysis is currently not done for rapid reviews under a pandemic situation due to its emergency nature. A full blown cost-effectiveness analysis that takes on a societal perspective (i.e., including the economic and social impacts) will be performed once sufficient evidence is available and when full market authorization has been granted.

E. Affordability and Viability

What is the estimated cost of covering self-administered rapid antigen test kits in the Philippines?

This section presents the estimated budget impact of covering SAAgTs for the target population of DOH based on the Updated Testing Protocol this January 2022.

Inputs to the costing analysis

Cost items

The intervention in our costing analysis is the cost of implementing the self-administered rapid antigen test. This costing considered the cost of SAAgT kits, as well as the overall cost of information instructure needed for the self-reporting mechanism. The cost of the reporting mechanism was based on the cost of developing the system which includes web cloud server, database, storage, and chatbot & SMS services for 6 months, as provided by the DOH Knowledge Management and Information Technology Service. For the instructional materials, there is no additional cost of developing and implementing IEC materials for SAAgT as this is already included in the overhead cost of the Communication Management Unit, according to the Health Promotion Bureau.

On the other hand, the comparators consist of the other existing COVID-19 tests:

- facility-based rapid antigen test,
- RT-PCR test (cartridge-based test), and
- RT-PCR test (plate-based test)

These costs included the kits and the corresponding operational costs such as other laboratory expenses, professional and other personnel fees.

Estimation of the target population to be covered

The estimates of the target population for this costing analysis was based on the target individuals for A1, A2, and A3 from the 2022 estimates of Philippine Statistics Authority as cited by the priority group targets of the National Vaccination Operations Center (NVOC). As we have noted some inconsistent values between the target individuals for vaccination versus the number partially vaccinated individuals, we used the number of partially vaccinated individuals of the priority group whenever it exceeds the respective estimated target number of individuals for the priority group.

To estimate the target number of individuals for testing in this costing analysis:

- A1: We assumed 100% coverage for all healthcare workers
- A2 and A3: Since the updated testing protocol indicated that vulnerable populations (e.g. senior citizens, and people with comorbidities) who are symptomatic and close contacts are prioritized for testing, the coverage of their testing is assumed at 50% which was based on the positivity rate in January 2022. The final number of target population are as follows:

Priority Group	Target individuals for vaccination Estimated Number of Individuals	Coverage scenario simulated in the costing analysis	Target Number of Individuals for Testing used in the costing analysis
A1 - Frontline health workers	2,128,867	100%	2,128,867
A2 - Senior Citizens	9,234,308	50%	4,617,154
A3 - Individuals with Comorbidities	9,253,423	50%	4,626,712

Resource Utilization

Following the Updated Testing Protocol as stipulated in DOH DC 2022-0002, the target population in this costing analysis included the healthcare workers (A1), the senior citizens (A2), and people with comorbidities (A3), The testing of healthcare workers (A1) for COVID-19 surveillance is being done to plan for adequate health system capacity. In the costing analysis, we assumed that healthcare workers are being tested twice a week given the current positivity rate of approximately 50%. We also assumed that they will be tested for 4-16 weeks.

As regards the testing of symptomatic individuals belonging to vulnerable populations such as the senior citizens (A2) and people with comorbidities (A3), one test will be covered per individual. We also consider the case of providing them two tests in case of mishandling or a false negative result from the first test.

Cost values

The unit cost of SAAgT is Php 350.00 which was based on the price cap set by DOH per issuance DC 2021-0323BThe total cost of the reporting system is Php 3,941,925.00 for all users. Details on the breakdown of cost of the reporting system can be found in Annex C.

The unit cost of RAgT is Php 660.00 which was based on the price cap set by DOH per issuance DC 2021-0323B.

Meanwhile, the costs of cartridge-based RT-PCR and plate-based RT-PCR are Php 2,450 and Php 2,800 respectively, based on the PhilHealth package indicated in Circular No. 2021-0021.

Costing scenarios

Scenario	Covered population	Number of tests to be covered		
		A1	A2	A3
1	A1a only	8 kits/tests per person *Twice a week testing for 4 weeks, per person*	-	-
2	A1b only	32 kits/tests per person *Twice a week testing for 16 weeks, per person*	-	-
3	A2 only	-	1-2 kits/ tests per person	-
4	A3 only	-	-	1-2 kits/ tests per person
5	A1a + A2 + A3	8 kits/tests per person *Twice a week testing for 4 weeks, per person*	1-2 kits/ tests per person	1-2 kits/ tests per person
6	A1b + A2 + A3	32 kits/tests per person	1-2 kits/ tests per person	1-2 kits/ tests per person

		Twice a week testing for 16 weeks, per person		
7	A1a + A2	8 kits/tests per person *Twice a week testing for 4 weeks, per person*	1-2 kits/ tests per person	-
8	A1b + A2	32 kits/tests per person *Twice a week testing for 16 weeks, per person*	1-2 kits/ tests per person	-
9	A1a + A3	8 kits/tests per person *Twice a week testing for 4 weeks, per person*	-	1-2 kits/ tests per person
10	A1b + A3	32 kits/tests per person *Twice a week testing for 16 weeks, per person*	-	1-2 kits/ tests per person
11	A2 + A3	-	1-2 kits/ tests per person	1-2 kits/ tests per person

Results of the costing analysis

Cost per user

Surveillance for HCW (A1)

As expected, the cost of using RT-PCR gives the highest cost per user, followed by RAgT, while SAAgT, having the lowest unit cost per test kit gives the lowest cost per user.

The cost of SAAgT per user of covering the surveillance of a healthcare worker is Php 600.00 in one week. As such, the cost covering SAAgT per user from one month to four months ranges from Php 2,400.00 to Php 9,600.00. Considering the cost of the self-reporting system, there will be an additional Php 1.85 per user given the number of HCWs that will use this.

There is a slight increase in cost if RAgT will be used for their surveillance. The cost of RAgT per user is Php 660.00 in one week. Hence, the cost covering SAAgT per user from one month to four months ranges from Php 3,200.00 to Php 12,800.00.

Meanwhile, the weekly cost of cartridge-based RT-PCR use in surveillance per user is Php 4,900.00 while plate-based RT-PCR costs Php 5,600.00. The cost of RT-PCR for one month ranges from Php 19,600.00 to 22,400.00 while the cost for four months ranges from Php 78,400.00 to Php 89,600.00.

Diagnosis for vulnerable population (A2, A3)

Similar findings are observed in this scenario where in the cost per user was highest if RT-PCR testing was used, and lowest if SAAgT was used. The cost per user of covering one to two kits of SAAgT for the vulnerable population ranges from Php 300.00 to Php 600.00. Including the cost of the self-reporting system, there will be an added cost of Php 0.85 per user given the number of A2 or A3 population that will use this. Meanwhile, covering one to two RAgT kits costs from Php 660.00 to Php 1,320.00. Since RT-PCR is presumed not to be repeated, the cost per user ranges from Php 2,450.00 to Php 2,800.00 depending on the type of RT-PCR.

Budget Impact - Cost for the estimated number of target population

If the DOH will decide to cover the estimated number of target A1, A2, and A3 populations, the total costs for the following tests will be as follows: Php 9.2 B to Php 30.32 B for SAAgTs; Php 17.34 B to Php 57.16 B for RAgTs; and, Php 64.37 B to PHP 216.62 B for RT-PCR.

Meanwhile, if the DOH will cover the surveillance testing of A1 group only, the total costs for the following tests will be as follows: Php 5.96 B to Php 23.85 B for SAAgTs; 11.24 B to Php 44.96 B for RAgTs; and, Php 41.73 B to Php 190.75 B for RT-PCR.

Lastly, if the DOH will cover the testing of vulnerable groups only (A2+A3), the total costs for the following tests will be as follows: Php 3.24 B to Php 6.47 B for SAAgTs; 6.10 B to Php 12.2 B for RAgTs; and, Php 22.65 B to PHP 25.88 B for RT-PCR.

The estimated cost for the other scenarios and other costing details are provided in **Table X.**

Table X. Costing Analysis of Testing Kits by Priority Group Included (in Pesos)

Scenarios	Total Cost of SAAgT (Php)		Total Cost of RAgT (Php)		Total Cost of RT-PCR (Php)	
Priority Group Included	1 kit per person for A2&A3	2 kits per person for A2&A3	1 kit per person for A2&A3	2 kits per person for A2&A3	Plate-based	Cartridge-based
A1a+A2+A3	9.2 B	12.44 B	17.34 B	23.44 B	73.57B	64.37B
A1b+A2+A3	27.08 B	30.32 B	51.06 B	57.16 B	216.63B	189.55B
A1a		5.96 B		11.24 B	47.69B	41.73B

A1b		23.85 B		44.96 B	190.75B	166.9B
A2	1.62 B	3.24 B	3.05 B	6.09 B	12.93B	11.31B
A3	1.62 B	3.24 B	3.05 B	6.11 B	12.95B	11.34B
A2+A3	3.24 B	6.47 B	6.1 B	12.2 B	25.88B	22.65B
A1a+A2	7.58 B	9.2 B	14.29 B	17.34 B	60.61B	53.04B
A1b+A2	25.46 B	27.08 B	48.01 B	51.06 B	203.67B	178.22B
A1a+A3	7.58B	9.2 B	14.29 B	17.35 B	60.64B	53.06B
A1b+A3	25.47B	27.09 B	48.02 B	51.07 B	203.7B	178.24B

Legend:

A1a - Twice a week testing for 4 weeks of frontline health care workers, per person
A1b - Twice a week testing for 16 weeks of frontline health care workers, per person
A2 - Senior Citizens
A3 - Individuals with Comorbidities

F. Acceptability of SAAgT

Literature scoping was conducted on February 2, 2022 to detect existing studies on the acceptability aspects related to the use of SAAgT. The search included peer-reviewed articles, published within the last two (2) years, regardless of country setting and population. Editorials, news briefs, communication briefs, and studies not written in English or Filipino were excluded from the search. These studies were subjected to thematic analysis, and the results of which were used as preset codes for the focus group discussions (FGDs) to be conducted.

Four (4) FGDs were conducted from 15-24 February 2022 by the HTAC Joint Subcommittee (JSC) on Self-Administered Antigen Test (i.e. Subcommittee on Clinical Equipment and Devices, and Subcommittee on Other Health Technologies) and the HTAD via an online platform to reduce the risk of COVID-19 transmission. The following were the objectives of the FGDs:

- To assess the perception about SAAgT
- To assess how acceptable using SAAgT is among Filipinos
- To assess self-reporting capability and willingness in using SAAgT

Below were the participants of the four FGDs:

- FGD 1: Health Workers
- FGD 2: At-risk Patient Groups
- FGD 3: Economic Frontliners
- FGD 4: Micro, small and medium enterprises (MSMEs) and Academic Institutions

Each FGD was facilitated by two to three representatives from the HTA Core and/or JSC on SAAgT. FGDs were used to have in-depth discussions and exchange of ideas and to observe the patterns of interaction among the participants (Neuman, 2014). The FGD questions, available in English and Filipino, were developed by the JSC and HTAD covering questions on: the perceptions of Filipinos regarding self-antigen tests. First-level codes with at least three hits were included in the thematic analysis.

Results from the Literature Review

Four databases (Pubmed, Cochrane, GoogleScholar and ScienceDirect) were searched for ethical-social, legal, and health systems implications of self-administered antigen test (SAAgT).

The search yielded 2,657 search results. None of which were duplicates of each other. Of these, 21 articles were included based on the initial title and abstract screening. Further, full-text screening excluded 4 studies due to having limited data on acceptability or not specific to SAAgT. In total, 17 articles were included as the basis for pre-coding.

Among the results of the content analysis, we discuss the five (5) codes that emerged as unique to the literature review but not in the FGDs.

Conformity in Self-Testing

Individuals are more likely to perform self-testing if the people around them accept and perform self-testing. In a study in a tertiary academic institution in the UK (Wanat et al, 2021), students reported that peers have an influence on their decision to do university testing.

Educational Attainment as predictor of compliance

Compliance with the ideal use of SAAgT and/or reporting of results increases as the person's educational background increases. (e.g., compliance is more likely for people who had post-graduate studies as compared to people who finished basic education only). Level of literacy is reported to be related to the understanding of the necessity to do COVID-19 surveillance. It is also noted to be connected to the ability to perform and interpret self-testing with confidence (Undelikwo et al, 2022; Tonen-Wolyec et al, 2020).

Gender-Based Preferences in Self-testing

Differences in the health-seeking behavior between males and females (e.g. likelihood to utilize a self-test) were found in a survey in Indonesia where women were more likely to choose conventional facility-based testing and have assistance from healthcare workers. Indonesian men were found to value privacy and confidentiality leading them to choose self-testing (Thomas et al, 2022).

Self-testing for Workload Reduction in Health Facilities

SAAgT is being used to reduce the number of individuals being tested in health facilities, thus reducing the workload of healthcare workers as well as the reallocation of resources. Self-testing is overall considered to be an effective society-grounded strategy to reduce the burden on the healthcare system in Indonesia, Nigeria, and the US (Thomas et al, 2022; Frediani et al, 2021; Undelikwo et al, 2022).

Sociocultural differences in testing

Race, social class, and cultural differences were shown to have a significant impact on an individual's perception in self-testing. One such example was the willingness of Caucasians to have more frequent testing than African-Americans and other minorities (Love et al, 2021).

Results from the FGD Series

We divide the discussion of the results of content analysis according to the three main objectives of the FGD series. The comparison of the first-level codes across the FGDs and literature review is in Annex D.

Perception of using SAAgT

Hiya as a barrier to COVID-Testing

- *Hiya*, in Sikolohiyang Pilipino (Indigenous Filipino Psychology), elicits many different meanings depending on the affixes attached to the root word. The theme *Hiya* is seen as a disadvantage because this can make individuals complacent about isolation and quarantine protocols. Some participants from the at-risk groups highlighted unique experiences of *hiya* in the context of testing.
- **Thematic implication:** Hiya may be a culture-related challenge that can discourage reporting of test results due to the possibility of being stigmatized or becoming the "talk of town".

Padrino System

- The Padrino System, otherwise known as the *palakasan* system, is a value system in the government in which a person gains favor, promotion, or appointment for COVID-19 testing because of close ties or relationships with a supervisor / official, familial affiliations, or "*utang na loob*" of the one giving the favor to the one gaining the favor (Encarnacion-Tadem and Morada, 2006). Participants expressed fears that access can be a problem for COVID testing because some public officials may distribute the kits to their allies, and not to those who actually need it.
- **Thematic Implication:** This system decreases the perceived utility of potential COVID tests among target individuals, and may consequently reduce COVID test utilization.

Perceived financial barriers in testing

- The low cost of testing is perceived only as a preferred quality of test — that it is more of a "want", rather than an actual need. For economic frontliners, however, the cost of testing can take a significant portion of their earnings / revenue that would otherwise be used for more valid and more important expenses (e.g., food, tuition, rent, etc.). Some participants in this group emphasized that the cost of testing makes them hesitant to get tested. If the government is unable to provide it for free, cost burden may potentially be alleviated through subsidization programs, or as part of private health insurance policies.
- **Thematic implication:** Out-of-pocket costs of testing becomes a barrier to testing especially for individuals who are unemployed or earn minimum to below-minimum wage.

Acceptability in using SAAgT

Personal Convenience as a Motivator to Testing

- Healthcare workers and at-risk groups explained that self-testing at home can be more convenient for individuals who will be needing testing because it lessens

the "grueling" time that can be experienced when lining up or waiting for RT-PCR or RAgT and the long turnaround time for the results to be released. Individuals at high risk for severe COVID-19 especially cannot go to testing facilities during times of surge because they want to avoid crowded areas as much as possible.

- They also lean towards the option which delivers faster test results especially when it will be used as a requirement in the workplace, for travel, or before undergoing certain hospital-based treatments or procedures (i.e., dialysis or surgery). They also have more confidence towards forms of testing handled by the public healthcare system. Target users also seek forms of self-testing which involves the least amount of discomfort.
- The decreased costs associated with self-testing is another important characteristic commonly raised by all FGD groups. This includes transportation costs, logistical costs (storage), and the cost of the kits themselves compared with other forms of testing. Individuals with unstable income desire testing that will limit or even eliminate loss of income and productivity time.
- Compliance and utilization of self-testing were also reported to have improved following support from employers and managers. Participants verbalized that receiving support following a positive COVID-19 test result encourages more employees to undergo self-testing. This support comes in the form of setting up/allowing a work-from-home setup for the employee, providing paid leaves, providing spaces for quarantine, and shouldering the cost of the testing itself (including subsequent tests).
- **Thematic implication:** Factors affecting personal convenience for potential users of SAAgT can be a significant effect, but are not necessary, for the acceptability of SAAgT.

Community Mobilization and Capacity Building in Self-Testing

- Common concerns of the participants stemmed from the idea that potential users of SAAgT may have different perceptions about their vulnerability to COVID-19, which, in turn, affect their motivation to undergo testing, and SAAgT in particular. This, coupled with misconceptions about testing, SAAgT, and COVID-19, can potentially decrease the utilization of SAAgT kits. As such, participants from all FGDs agreed that communities, and not just individuals, must be mobilized to take an active role in testing implementation. Suggested steps include alternative routes to information, education, and communication platforms and positive forms of reinforcement to increase the confidence of individuals towards SAAgT.
- **Thematic Implication:** Implementation of a community-centered, grassroots-based approach can improve the salience of the people for an increased utilization of SAAgT.

Self-testing access for Rural Areas and GIDAs

- This includes concerns about population characteristics and logistical concerns (e.g. storage, infrastructure, etc.). They explained their sentiment that their staff residing in areas in Visayas and Mindanao might not have the same level of access to self-test and its adjunct services compared to those living in Metro Manila. These adjunct services include the system of reporting results, the distribution points, and the education and guidance, which are all more accessible in urban areas. In particular, it also affects access to treatment (e.g. dialysis, tuberculosis) of individuals with existing illnesses since negative COVID-19 test results are required by HCPs before they can proceed with their treatment.
- **Thematic Implication:** Access to self-testing among GIDAs and rural areas can potentially become a problem. Concerns regarding provision of self-testing to rural areas and GIDAs involve population characteristics and logistical concerns (storage, infrastructure, etc.).

Streamlining Self-Testing

- Using health facilities within the national service delivery network as a centralized hub for distribution will allow for better reach of self-test kits, especially among rural areas and geographically isolated and disadvantaged areas (GIDAs). In this centralized system, participants believe that priority in the distribution should be (1) those exposed to potential / current COVID-19 case, (2) vulnerable sectors (e.g., older adults, people with disabilities, people with acute comorbidities), and (3) indigent individuals.
- Participants from the HCW sector emphasized that test kits should be controlled by regulatory agencies in order to ensure their quality and avoid unregulated distribution.
- **Thematic Implication:** Considerations in streamlining (inclusion of its implementing guidelines into the existing testing guidelines) self-testing include: need for enhanced service delivery network for equitable and accessible distribution of kits, regulatory control in distribution of kits, and fair prioritization of populations upon distribution.

Capability and Willingness for Self-reporting of SAAgT

Streamlining Self-Reporting

- The participants expressed the need for centralized reporting and systematic patient information systems (i.e., telemedicine). The national government can use this centralized reporting and patient information system for surveillance and screening of COVID-19. One participant in the economic frontliner group also suggested using applications or websites for case reporting.
- **Thematic Implication:** Developing a centralized reporting system for SAAgT can empower users and encourage self-reporting.

Hiya as a barrier to COVID-Testing

- Other members of the community might end up avoiding COVID-positive individuals (*'mahihiya ako*, *iiwasan ka' [I'll feel shame being avoided by others]*) or being disgusted towards them ('*pinandidirian ka ng kapitbahay mo' [your neighbors will be disgusted towards you*). Two market vendors repeatedly emphasized their fear of being gossiped about as COVID-positive. This image of being "contagious" may become an individual's persona even if the actual infection has since been resolved, that it has already become a '*badge of carriage na nagka-COVID ka na.' [badge of carriage of having been infected by COVID]*).
- **Thematic Implication:** This image of being "contagious" may become an individual's persona even if the actual infection has since been resolved. This, in turn, can potentially discourage people from reporting their self-test result

V. Recommendations *(as of 06 Apr 2022)*

A. 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 government financing of self-administered rapid antigen testing are subject to change* pending availability of new evidence.

B. The HTAC recommends the financing of SAAgTs for the following use cases in areas with high and/or increasing case counts and increasing healthcare capacity (total bed and intensive care unit) utilization (i.e., identified as at least alert level 3 based on *Inter Agency Task Force Guidelines on the Nationwide Implementation of Alert Level System for COVID-19 Response as of 14 December 2021*):
   1. Diagnosis of suspect and probable cases among people with high risk of developing severe COVID-19 needing immediate provision of antiviral drugs (refer to list from **CDC*** or subject to the discretion of a physician)
   2. Screening and diagnosis for A1 Population (i.e., Healthcare workers)

C. HTAC also recommends regulated distribution through Barangay Health Stations (directly reporting and coordinating with the City/Municipal Health Office) as points of access for the abovementioned target population

Table 4. HTAC Recommendations for Self-Administered Rapid Antigen Testing (SAAgT)

Recommendation	**Self Administered Rapid Antigen Testing**
Recommended Use Cases	Self-administered 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) among individuals with high risk of developing severe COVID-19 and needing immediate provision of antiviral drugs (refer to list from **CDC*** or subject to discretion of a physician), and 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 ■ 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. At the time of this review, there was no sufficient data to support any HTAC recommendation on the use of the self-administered antigen test for border screening of local and international travellers.
Intended Population	● In general, the SAAgT **can** be used for individuals with a high index of suspicion: ○ Symptomatic individuals with or without known exposure [considering high pretest probability for symptomatic individuals, and in areas identified as at least Alert Level 3 by IATF Guidelines as of Dec 2021 (i.e., areas with high and/or increasing case counts and increasing healthcare capacity utilization including total bed and intensive care unit utilization)] ■ Following the CDC (2022) recommendations for RAgT, the HTAC recommends that for symptomatic individuals with or without unknown exposure, perform SAAgT immediately after onset of symptoms (US CDC, 2022). ○ Asymptomatic individuals with exposure ■ For asymptomatic individuals with exposure, the SAAgT is recommended to be performed on day 5 after exposure, even before symptoms develop. Test immediately if symptoms develop before the 5th day. (CDC, 2021; Harvard Health Publishing, 2022). ● The intended population for SAAgT are: 1. Individuals with high risk of developing severe COVID-19 needing immediate provision of antivirals (refer to list from **CDC*** or subject to the discretion of a physician) 2. Healthcare workers 3. **Close contacts of suspected, probable or confirmed cases** (e.g., household members, workmates) consistent with the following definitions adopted from WHO: - Face-to face contact with a suspected, probable or confirmed case within 1 meter and for at least 15 minutes; - Direct physical contact with a suspected, probable or confirmed case; - Direct care for a patient with probable or confirmed COVID-19 disease without using recommended personal protective equipment; - Other situations as indicated by local risk assessments - Note: Window of exposure to suspected, probable or confirmed cases is anywhere between 2 days before or within 14 days of onset of symptoms.

Sample Specimen	In SAAgT, the specimens to be collected are preferably *nasal swabs which are easier and safer to self-perform*. Oral and nasopharyngeal samples also can be collected for SAAgT. The use of SAAgT must be in accordance with the manufacturer's instruction-for-use (IFU).
Interpretation of Results and Management	● It is recommended that **individuals with positive SAAgT results (positive for COVID-19)** be isolated and managed as COVID-19 cases. ● It is important to always correlate the test results with the overall clinical and epidemiological context (e.g., history of exposure). Individuals with a high index of suspicion and who tested negative using SAAgT should be isolated until they can be confirmed through a repeat SAAgT after 24-48 hours (WHO, 2022; CDC, 2021; TGA Australia, 2021). ○ If the repeat test is positive, isolate and manage as COVID-19 case; ○ If the repeat test is still negative and the patient is: ■ Symptomatic, perform confirmatory RT-PCR testing immediately; ■ Asymptomatic, release from quarantine and follow minimum public health standards
Reporting	● Both positive and negative results should be reported to the Barangay Health Emergency Response Team (BHERT) or healthcare providers**.** ● Reports should be compliant with the following minimum data elements (MDE) consistent with the required MDE for RT-PCR tests submitted daily by the Disease Reporting Units (DRUs) to CDRS ● Minimum data to be reported include the following: ○ Name ○ Age ○ Address ○ Result ○ Date of testing ○ Brand ● The DOH shall use a platform for reporting that is simple, convenient to use, and secures data privacy. ● If this will be procured by the government, mandatory reporting of both positive and negative results shall be done. ● DOH should develop a system to track individuals who do not report results. ● Failure to report SAAgT will be considered a violation of the relevant provision of Republic Act 11332 or the Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act.
Other comments/ recommendations	Other overarching recommendations of the HTAC are as follows: ● Publicize standards on diagnostic performance to address the observed wide variability of performance in all COVID-19 testing kits in the market, and update on a regular basis (e.g., once a month). Updates should include consideration of

	recent validation testing made by RITM, RITM-recognized DOH-designated institutions and other stringent and reputable international institutions. ● **Require BHERT and healthcare providers to report both positive and negative results to the DOH.** ● Strengthen the system for monitoring and evaluation of compliance of manufacturers to regulatory standards and post-marketing requirements. Departmental constraints must be addressed to enable strict compliance and to strengthen enforcement ● Testing (using RAgTs or NAATS) should be used in addition to other health measures such as minimum public health standards (including the use of face masks/face shields), physical distancing, ventilation, quarantining/isolation, symptom-based screening and contact tracing. ● Used self-administered antigen test kits shall be disposed of as household waste and shall be properly sealed in a plastic bag. The HTAC is actively on the watch for evidence as it is rapidly evolving, and shall update its recommendation when new information becomes available.

Table 5. Recommended specifications for SAAgTs

Parameter	Self Administered Rapid Antigen Testing (as of 19 January 2022)
Regulatory Requirement	Must be issued a special certification by the Philippine Food and Drug Administration (FDA) which includes validation by the Research Institute of Tropical Medicine (RITM)
Test kit package content	It is desirable that self-administered rapid antigen test kits contain all materials and accessories necessary for the procedure.
Result output	Qualitative, result must be read visually or with a reader but must be operable using batteries
Users Instructions	Based on DOH DM 2022-0033, *manufacturers, suppliers, and distributors shall develop references for appropriate use for the general public that shall include:* *i. Instructions for Use that are readable, user-friendly, and simplified to provide adequate guidance to the lay public on the test kit's proper administration, interpretation of results, and disposal* *ii. A step-by-step video guide specific to the antigen kit for easy reference of the public, and references and links submitted to the DOH for public posting.* *iii. Filipino-language translation of the reference materials in plain language format, and preferably with other additional regional dialect translations if available*
Clinical Sensitivity	At least 80% sensitivity

Clinical Specificity	At least 97% specificity
Processing Time	Within 30 minutes from sample collection to result
Reference Standard	In-house laboratory RT-PCR test or if commercial RT-PCR test, must adhere to the specification stipulated in the HTAC Guidance Document on RT-PCR test kits
Sample Requirement in Validation Studies	Symptomatic samples: ● Positive samples: minimum of 30 positive specimens ● Negative samples: 30 negative specimens Asymptomatic samples: additional 10 positive specimens (US FDA) Include details such as: ● specimen type ● specimen collection date ● date of onset of symptoms (if present) ● date of RT-PCR testing ● severity of symptoms (if known) ● tests used to identify COVID19 patients, etc.
Requirement for Independent Validation	SAAgTs must be authorized by the Philippine Food and Drug Administration, and validated by any of the following: ● Research Institute for Tropical Medicine (RITM) and RITM-recognized DOH-designated institutions indicated in its letter to the Secretary of Health dated 01 April 2021 (Annex A) unless these laboratories are developing their own test kits ● US Food and Drug Administration (US-FDA) ● World Health Organization, Foundation for Innovative New Diagnostics (WHO-FIND) ● Therapeutic Goods Administration (TGA, Australia) ● Medicines and Healthcare products Regulatory Agency (MHRA, UK) ● Japan Pharmaceuticals and Medical Devices Agency
Transport and Storage Requirements	The storage and working conditions shall follow the manufacturer's specifications. In general, store in a cool, dry place and not exposed to direct sunlight prior to use. Do not freeze.
Shelf-Life	Shelf-life should not be shorter than twelve (12) months at the time of delivery.

Cost of test kit	The total cost of the initial and possible repeat testing using the SAAgT kit should not exceed the *government price cap for Self Administered Rapid Antigen Testing indicated in Department Circular 2021-0323-B*.

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VII. Annexes

Annex A

Table A.1. Regulatory Specifications on the Self-administered Antigen Test Kits

Specifications	US FDA	TGA Australia	UK MHRA	RITM Philippines
Intended Use	Used in the screening of SARS-CoV-2. The US FDA has granted EUA for these antigen tests.	Screening for symptomatic individuals and close contacts "Protocol 1: COVID-19 confirmed by a positive RAT or PCR test If confirmed by a positive rapid antigen test (RAT), isolate for at least 7 days from the day the test was taken. If symptoms started at Day 6, you must stay at home until symptoms are gone. If you have no symptoms at Day 7, you can return to normal living and leave your home. **You do not need a further test.** Protocol 2: Close contact and have symptoms Close contacts that have symptoms must stay home for 7 days since last contact with	Self-test used to: - help identify current SARS-CoV-2 infection (rule in) AND/OR - help determine the absence of current SARSCoV-2 infection (rule out).	No intended use case (no approved SAAgT yet by FDA Philippines)

		the person who contracted COVID-19. Take a RAT self-test or PCR test “		
Target Population	Intended for asymptomatic and symptomatic individuals. Used for 2 years and older in a non-laboratory setting.	Intended for symptomatic individuals; Can be for asymptomatic individuals provided that the manufacturer satisfies the validation standards “You should only perform a rapid antigen self-test if you have symptoms of COVID-19. Rapid antigen self-tests can be used to test adults and children.”	**Desired:** Adults and all school age children (≥3 years) without symptoms. Adults and children without appropriate physical and mental capacity should have their test conducted or supervised by an appropriate individual **Acceptable:** Adults and secondary school age children (≥11 years) without symptoms. Adults and children without appropriate physical and mental capacity should have their test conducted or supervised by an appropriate individual	No target population specified
Turnaround time	15-30 minutes	You can easily perform the test at home and should get your results within 20 minutes.	**Desirable:** No more than 10 minutes **Acceptable:** No more than 30 minutes	Not indicated
Number of antigens to be detected	No specific guideline found	No specific guideline found	**Desired:** Dual (or more) SARS-CoV-2 targets (e.g. nucleic acid(s), antigen(s) or other targets) **Acceptable:** Single SARS-CoV-2 target (e.g. nucleic acid, antigen	No specific guideline found

			or other target)	
Specimen	Anterior nasal, nasal mid-turbinate, saliva specimen Source: CDC	Nasal swab or saliva specimen (Reference)	**Desirable:** saliva, sputum, stool, breath sample **Acceptable:** nasal and.or throat swab	No specific guideline found
Storage temperature	*"Store all test components according to the manufacturer's instructions until ready for use."* Source: CDC All EUA-registered at-home kits in the US indicate a storage temperature of a range within 2°C to 30°C. Source: Package inserts hyperlinked in US FDA	Store the test kit in a safe, dry, cool space. Refer to the test kit instructions.	**Desirable:** No cold storage ≤80% relative humidity **Acceptable:** 4 – 30 0C ≤70% relative humidity	Storage condition temperature within 18°C to 30°C.
Operating conditions (temperature, humidity, etc.)	*"Store all test components according to the manufacturer's instructions until ready for use."* Source: CDC At-home test kits are unable to withstand moisture, extreme humidity, and extreme temperatures. Use under these conditions may cause false positive or false negative results. Source: Package inserts hyperlinked in US FDA	No temperature or humidity requirement mentioned in the guidelines. May depend on the instructions for use of specific brands:	**Desirable:** 0 - 40 0C ≤80% relative humidity **Acceptable:** 15 - 30 0C ≤70% relative humidity	Working condition temperature should be within 18°C to 30°C.

Biosafety	Countertop where the test will be performed must be clean. Test devices and their other components cannot be reused. After testing, the specimen collection swab or tube must be discarded in the trash, and surfaces that the specimen may have touched must be disinfected. Source: CDC	Disposal will vary according to information provided with the test instructions. Some tests come with a plastic bag to place the contents of the test into (including the swab). This bag is then placed into another bag for disposal with the household rubbish. Test kit materials are not recyclable. If no bags are provided you can place the used items from the test into a small plastic bag that can be sealed. This bag should be put into another bag that can be sealed and disposed of in the household rubbish. Wash your hands carefully after completing the test and disposing of the test kit contents.	Design should mitigate need for special requirements to dispose test and the accessories needed to perform test No special biosafety measures should be required for self-testing	No specified biosafety measures

Sample Size	•Individuals should be consecutively enrolled (i.e., in an "all comers" style) until 30 positives and 30 negatives are obtained. •Asymptomatic: If your test is intended for use in asymptomatic individuals not suspected of COVID-19, you should enroll at least 10 positive individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection. Additional post-authorization studies in individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection may be recommended.	*Clinical performance* **Symptomatic:** The TGA expects *statistically appropriate specimen numbers* and sample selection for the evaluation of a COVID-19 rapid antigen self-test. For example, the European Commission's Medical Device Coordination Group (MDCG 2021-21): ● 100 NAT positive samples from early infection within the first 7 days after symptom onset; samples should represent naturally occurring viral loads ● 300 negative samples from non-infected individuals ● 100 from hospitalised patients ● 50 potentially interfering and cross-reactive samples **Asymptomatic:** For studies to demonstrate performance in asymptomatic individuals, it is recommended that testing should be performed on a minimum of 20 consecutively collected asymptomatic positive specimens and at least 100 consecutively collected	At least 150 SARS-CoV-2 positive cases (per sample type). The population and user group should be representative of the claimed target population and user groups (i.e people without symptoms) without prior knowledge of their disease status (e.g. single-gate design)	The RITM Philippines indicated that clinical validation studies must have a minimum of at least 30 PCR negative samples and 30 PCR positive samples.

		negative specimens. *Usability study* Diagnostic sensitivity, non-supervised – at least 30 lay users that are known antigen positive Diagnostic specificity, non-supervised – at least 60 lay users that do not know their status		
Reference Test	•FDA recommends the comparator sample type be either a health care provider-collected NP or mid-turbinate swab sample (collected from each patient in the study within a reasonable time frame from when the test sample was obtained/tested, preferably during the same visit) or a home-collected nasal swab	*Clinical performance* **Symptomatic:** Sampling should be matched for antigen and NAT testing, e.g., two simultaneous samples from each individual or optimally NAT- and antigen testing from the same sample (e.g. from the eluate of one swab) **Asymptomatic:** All specimens should also be tested with the reference RT-PCR tests. *Usability study* The diagnostic sensitivity and specificity in the hands of the lay person should be estimated in comparison with the results of the professional test i.e. by RT-PCR testing.	A validated CE, CE UKNI or UKCA marked RNA extracted RT-PCR laboratory method in current clinical use that itself performs within the desirable analytical and clinical performance specifications of this TPP, against which the Negative/Positive Percent Agreement is calculated.	The RITM Philippines implied that the RT-PCR test is the reference standard given the clinical validation requirements.

Analytical Sensitivity	FDA recommends that preliminary LoD be determined by testing a 2-3-fold dilution series of 3 replicates per concentration, and then confirmed with 20 replicates of the concentration determined to be the preliminary LoD	analytical sensitivity (limit of detection) of at least 102 – 103 TCID50/mL accompanied with a Ct value which states the number of copies of virus per mL.	[Definition] quotient of the change in an indication and the corresponding change in the value of a quantity being measured [Limit of Detection, LoD] **Desired:** An appropriate unit of measurement for the target analyte (e.g. International Units) equivalent to a viral load of less than 1000 SARS-CoV-2 RNA copies/mL of sample **Acceptable:** An appropriate unit of measurement for the target analyte (e.g. International Units) equivalent to a viral load of less than 1,000,000 SARS-CoV-2 RNA copies/mL of sample.	Limit of Detection study

Analytical Specificity	Concentrations of 105 pfu/ml, or TCID50/mL (tissue culture infective dose) or higher for viruses.	Studies to demonstrate the test detects all SARS-CoV-2 strains and will not produce a false positive result due to cross-reactivity with other human coronavirus (except SARS-CoV-1) or interference by an unrelated pathogen or substance. Studies should include non-infected individuals, potentially interfering and cross-reactive samples, and other respiratory pathogens, including bacteria.	No clinically relevant cross reactivity to common seasonal respiratory pathogens. Minimal interference caused by common interferents at clinically relevant concentrations (dependant on sample type and analyte). Demonstration of SARS-CoV-2 variant detection in silico and in vitro, where suitable reference materials are available.	Cross reactivity study

Minimum Acceptable Clinical Sensitivity/PPA	Minimum sensitivity of ≥ 80% for all sample types submitted For OTC single-use testing in all patient populations, including individuals with or without symptoms or other epidemiological reasons to suspect COVID-19: ≥ 80% PPA demonstrated in a clinical evaluation including both symptomatic and asymptomatic individuals; For OTC testing in all patient populations, including individuals with or without symptoms or other epidemiological reasons to suspect COVID-19, with additional mitigations such as serial screening, as discussed in the "Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing" : ≥ 80% PPA with a lower bound (LB) of the two sided 95% confidence interval (CI) ≥70%, demonstrated in a clinical evaluation including symptomatic individuals only or both symptomatic and	**Symptomatic:** minimum clinical sensitivity of at least 80% (for specimens collected within 7 days of symptom onset) **Asymptomatic:** *No minimum acceptable requirement indicated* *Acceptable sensitivity* - clinical sensitivity greater than 80% PPA *High sensitivity* - clinical sensitivity greater than 90% PPA *Very high sensitivity* - clinical sensitivity greater than 95% PPA	**For tests to help rule in:** ≥80% (95% two sided CI entirely above 70%) **For tests to help rule out:** ≥97% (95% two sided CI entirely above 95%)	At least 80% for specimens collected within 7 days of symptom onset

	asymptomatic individuals; For prescription home use single-use testing in individuals suspected of COVID-19 by their healthcare provider: ≥ 80% PPA demonstrated in a clinical evaluation including symptomatic individuals only (note that, for antigen tests, the indication may be limited to symptomatic individuals within a certain number of days of symptom onset, depending on the data); or For OTC single-use testing in symptomatic individuals: ≥80% PPA demonstrated in a clinical evaluation including symptomatic individuals only (note that, for antigen tests, the indication may be limited to symptomatic individuals within a certain number of days of symptom onset, depending on the data). The indications for use for tests with PPA <95% should be limited to providing presumptive negative results.			

Minimum Acceptable Clinical Specificity/ NPA	Minimum specificity of ≥98%	**Symptomatic:** a minimum clinical specificity of at least 98% **Asymptomatic:** *No minimum acceptable requirement indicated*	≥99.5% (95% two sided CI entirely above 97%)	At least 97%
Any other special requirement of performance standards required for detection of Variants of Concerns?	The EUA revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance	Within 6 months of inclusion in the ARTG, the sponsor must provide a supplemental clinical study to the TGA, which shows the outcome of testing at least 30 clinical samples collected from individuals that are SARS-CoV-2 positive by RT-PCR for the delta variant.	There is a requirement on suppliers to confirm performance in detection of both current and emerging strain variants of SARS-CoV-2 as they arise and confirm this to MHRA where VOC (variants of concern) or VUI (variants under investigation) are reported in line with MHRA requirements If the performance of the assay is directly impacted by new virus variant(s), a Field Safety Notice should be issued immediately to alert customers.	No other special requirement
Mechanism of reporting	The US FDA stipulated that all test results should be reported to healthcare providers and relevant public health authorities in accordance with local, state, and federal requirements, using appropriate codes defined by the Laboratory In Vitro Diagnostics	TGA Australia noted that positive test results must be reported to the state or territory health department or via website.	The UK MHRA emphasized that lateral flow test results must be reported to their website or via call whether positive, negative or invalid. Any problems encountered with the test kit may also be reported via the UK MHRA website. Close contacts may be contacted by the NHS	The RITM Philippines does not yet have a mechanism for reporting test results because self-administered antigen tests are not yet implemented in the country.

	Test Code Mapping for SARS-CoV-2 Tests provided by CDC.		Test and Trace, which utilizes text messages, email, or phone. Moreover, instructions on how to use test kits and what must be done after knowing one's result are detailed online.	
IT Infrastructure	The US FDA noted several options to allow for reporting of test results, including automatic reporting through a mobile application, instructions directing users to a website where reporting is easily facilitated, among others and that they are open to alternative approaches that ensure appropriate reporting. Moreover, they specified that any smartphone application should be simple and that error messages should be readily understandable, and troubleshooting should be included in the device instruction. The display should also promote understanding of results and what individuals should do next, including how to care for themselves and when to seek follow up care. Finally, the application should automatically report all test results when appropriate in	According to TGA Australia, there are general requirements that the technical file of software for SAAgTs should include evidence for. This applies whether the software development methodology is agile (or a variant of agile) or other methodology. These include: ● Overall description of functions ● Software architecture and design, physical and logical; ● Validation artefacts ● Defect management process ● Human factors/usability ● Cybersecurity risks and how they have been addressed ● Data privacy ● Clear instructions for lay people on how to use the software, as part of the	The UK MHRA noted that devices that simplify remote data captured electronically into a central data reporting system may be advantageous.	The RITM Philippines does not currently require the companies to have an existing IT infrastructure for reporting of results of their test kits.

	accordance with local, state, and federal requirements.	Instructions For Use (IFU). ● Minimum specifications for the device for the software to operate on ● The minimum resolution for images used by an app for recording images of results should be 1920x 1080 (horizontal) resolution. The test itself should occupy at least 80% of the vertical height of the image.		
References	US FDA (2021). Template for Developers of Antigen Tests. Retrieved from https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F137907%2Fdownload&wdOrigin=BROWSELINK US FDA (2021). Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Home Use. Retrieved from https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F140615%2Fdownload&wdOrigin=BROWSELINK	Australian Government Department of Health. (2021). Rapid antigen self-testing for COVID-19 | Australian Government Department of Health. Retrieved from: https://www.health.gov.au/health-alerts/covid-19/testing/rapid-antigen-self-testing Therapeutic Goods Administration (01 Jan 2022) COVID-19 rapid antigen self-tests that are approved in Australia. Retrieved Jan 6, 2022 from: https://www.tga.gov.au/covid-19-rapid-antigen-self-tests-are-approved-australia Therapeutic Goods Administration (06 Jan 2022)	UK MHRA (2021) Target Product Profile: In Vitro Diagnostic (IVD) self-tests for the detection of SARS-CoV-2 in people without symptoms. Retrieved 06 January 2021 from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/994793/Self-Test_Virus_Version_1_0_19June2021.pdf	RITM Philippines (06 January 2022). Interim Guidelines For Product Evaluation Of Covid-19 Self-Administered Rapid Antigen Test Kit.

		COVID-19 rapid antigen self-tests for home use. Retrieved Jan 6, 2022 from: https://www.tga.gov.au/covid-19-rapid-antigen-self-tests-home-use#ms Therapeutic Goods Administration (2021) COVID-19 rapid antigen self-tests Performance requirements and risk mitigation strategies. Retrieved Jan 6, 2022 from: https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-performance-requirements-and-risk-mitigation-strategies.pdf New South Wales Government (2021). Rapid antigen tests for community (COVID-19) | NSW Government. Retrieved Jan 6, 2022 from: https://www.nsw.gov.au/covid-19/stay-safe/testing/how-testing-works/rapid-antigen-self-tests-for-community		

Table A.2 COVID-19 Test Kits and Distributors Approved by RITM (as of 25 March 2022)

	Importer and Distributor's Name	Product Name	Manufacturer's Name	Specimen	Sensitivity	Specificity
1	Clearbridge Medical	SARS-CoV-2 Antigen Rapid	Labnovation	Nasal swab	97.45%	100.00%

	Philippines Inc.	Test	Technologies, Inc. - 101 and 5th Floor, Building 1, No. 68, 18th Road, Guangming Hi-Tech Park, Tangjia Community, Fenghuang Street, Guangming District, Shenzhen 518107, China			
2	Sunfu Solutions Inc.	Panbio COVID-19 Antigen Self-test	Abbott Rapid Diagnostics Jena GmbH-Orlaweg 1, D-07743 Jena, Germany	Nasal swab	83.30%	100.00%
3	Mohs Analytics Inc.	One step test for SARD-CoV-2 Antigen	Getein Biotech Inc-No. 9 Bofu Road, Luhe District, Nanjing China	Nasal swab	96.43%	100.00%
4	Allied Hospital Supply International Corporation	Panbio COVID-19 Antigen Self-test	Abbott Rapid Diagnostics Jena GmbH-Orlaweg 1, D-07743 Jena, Germany	Nasal swab	83.30%	100.00%
5	AJ Research & Pharma Inc.	JusChek COVID-19 Antigen Rapid Test Cassette (oral fluid) (self-test)	Hangzhou Alltest Biotech Co., Ltd - #550, Yinhai Street, Hangzhou Economic & Technological Development	Oral Fluid	90.00%	100.00%

			Area, hangzhou, 310018, P.R. China			
6	UC Bioscience Inc.	JusChek COVID-19 Antigen Rapid Test Cassette (oral fluid) (self-test)	Hangzhou Alltest Biotech Co., Ltd - #550, Yinhai Street, Hangzhou Economic & Technological Development Area, hangzhou, 310018, P.R. China	Oral Fluid	90.00%	100.00%
7	Macrohealth, Inc.	Panbio COVID-19 Antigen Self-test	Abbott Rapid Diagnostics Jena GmbH-Orlaweg 1, D-07743 Jena, Germany	Nasal swab	83.30%	100.00%
8	Roche (Philippines), Inc.	SARS-CoV-2 Antigen self-Test Nasal	SD Biosensor, Inc - C-4&5 Floor, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si Gyeonggi-so, 16690, Republic of Korea	Nasal swab	87.50%	99.30%
9	Murex Diagnostic Products Specialists	SARS-CoV-2 Antigen self-Test	Labnovation Technologies, Inc. - 101 and 5th Floor, Building 1, No. 68, 18th Road, Guangming, Fenghuang Street,	Nasal swab	a) 97.45% b) 95.45%	100.00%

			Guangming District, Shenzen 518107, China			
10	Sparti Logistics Corporation	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	Nanjing Vazyme Medical Technology Co., Ltd. - Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China	Nasal swab	96.25%	100.00%
11	Gregan 101 Corporation	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	Nanjing Vazyme Medical Technology Co., Ltd. - Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China	Nasal swab	96.25%	100.00%
12	Pinnacle Supplies & Services Unlimited Inc.	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal	Nanjing Vazyme Medical Technology Co., Ltd. - Floor 1-3,	Nasal swab	96.25%	100.00%

		Gold-Based)	Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China			
13	Grand Premiere International Trading Incorporated	Grand Premier International Trading Incorporated	Nanjing Vazyme Medical Technology Co., Ltd. - Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China	Nasal swab	96.25%	100.00%

Annex B

Table B.1. Country and International Guidelines on the Self-administered Antigen Test Kits

Recommended, Mandatory						
Country (Agency)	**Recommendation Statements (Date of Recommendation)**	**Use Case**	**Target users**	**Interpretation of Results**	**Method of Collection**	**Timing of Collection**

Singapore (Ministry of Health)	*"Protocol 3 - For close contacts of a COVID positive case "* ● **Individuals with Health Risk Notice** (specifically those who have been identified to be close contacts of a COVID positive case, based on TraceTogether / SafeEntry records and a household member of a COVID positive case): *"You should take an Antigen Rapid Test (ART) self-test within 24 hours. You can continue with normal activities for the day if the test result is negative."* *(March 9, 2022)*	Screening	Close contacts of a confirmed case (Individuals with health risk warnings)	**Positive test result:** ● If positive but feeling well or with mild symptoms, isolate for 72 hours and repeat ART self-test. - If the repeat test is positive, continue to self test. Whenever your ART self-test is negative, continue regular activities. - If the repeat test is negative, continue regular activities. ● If with severe symptoms, the doctor will order both a healthcare-administered ART and PCR swab. **Negative Test Result:** If you test ART negative, you can leave your house for normal activities. Do minimise unnecessary social interactions. You must still complete the 5-day monitoring period.	Nasal Midturbinate or Nasal Swab	Within 24 hours from receipt of a "health risk warning". If positive but feeling well, repeat testing: 72 hours after
Singapore (Singapore Government Agency) MOH	*For fully vaccinated travellers and Category I travellers (Low Infection Category)* *"Vaccinated Travel Lane (VTL) and Category I travellers (low infection travellers) would only be required to take an unsupervised self-swab*	Diagnosis On top of pre-departure Antigen-Rapid Test (ART) or Polymerase	Vaccinated travelers and Category I (Low infection travellers)	**Positive test results**: ● If feeling unwell: No confirmatory test required. Follow the protocols for the recovery procedure as advised by the medical provider. ● If feeling well but falls on	Nasal Midturbinate or Nasal Swab	Within 24 hours of entry

Singapore: COVID Recovery for Travellers	*Antigen Rapid Test (ART) within 24 hours of entry into Singapore. This replaces the previous requirement for a supervised self-swab ART. Travellers are required to report their unsupervised self-swab ART test result via sync.gov.sg1 before proceeding with their activities in Singapore."* (March 11, 2022))	Chain Reaction (PCR) Test within 2 days before departure for Singapore		the criteria below, follow medical advice: ○ Children aged less than 3 years old; ○ Persons aged 70 years and older; ○ Persons who are/have: pregnant, on dialysis, diagnosed with HIV or AIDS, had organ transplant surgery, diagnosed with cancer before, any disease or taking medications that weaken the immune system, any disease affecting their heart, lungs, kidneys, liver or brain that required hospital admission in the last 6 months Otherwise, isolate at your hotel or residential accommodation for 72 hours. Following exit from 72 hour isolation, you do not need to adhere to further testing as part of the travel health control measures you were originally subjected to **Negative test result:** If feeling unwell: Continue to adhere to the travel health control measures		

Singapore (Health Promotion Board) Advisory on work and leave arrangements for employees who test positive for COVID-19 but are mildly symptomatic or physically well (February 24, 2022)	[General] *For personnel/workers* *"Rostered Routine Test is a surveillance testing program for identified groups who are more vulnerable or have higher risk of exposure to COVID-19. Regular Routine Testing (another term for rostered routine test) is key to our ability to re-open and allow more economic/social activities to continue even as we detect cases/clusters. Under the fast and easy test (FET) regime, enterprises are required to ensure that their employees and persons who work under their directions (e.g. contractors and subcontractors) undergo regular fast and easy test (FET) using the COVID-19 Antigen Rapid Test ("ART"), regardless of their vaccination status. Self-employed persons working in these settings should also ensure that they adhere to the FET regime."* (November 30, 2021)	Surveillance	All personnel working in the food and beverage industry, personal care services, gym and fitness studios. In settings where there is frequent community interaction: retail mall workers, supermarket staff, last-mile delivery personnel (including parcel and food delivery personnel), as well as public and private transport workers (taxi drivers, private hire car drivers and all public transport frontline staff).	**Positive test result:** ● If positive but mildly symptomatic or physically well, isolate for 72 hours and repeat ART self-test. ○ If the repeat test is positive, continue to self test. Whenever your ART self-test is negative, employees may return to work and resume daily activities. ○ If the repeat test is negative, employees may return to work and resume daily activities. ● **Negative test result:** Allowed to work but routine testing is still required.	Nasal Midturbinate Nasal Swab	● Vaccinated: Every 7 days ● Unvaccinated ○ Twice a week

Recommended, Optional						
Country (Agency)	**Recommendation (Date of Recommendation)**	**Use Case**	**Target users**	**Interpretation of Results**	**Method of Collection**	**Timing of Collection**
US (Center for Disease Control and Prevention)	*For patients with COVID-19 symptoms or have been exposed or potentially exposed to an individual with COVID-19* *For people who have no symptoms or were not exposed but will be in a gathering with other people* *"COVID-19 self-tests (also referred to as home tests or over-the-counter (OTC) tests) are one of many risk-reduction measures, along with vaccination, masking, and physical distancing, that protect you and others by reducing the chances of spreading SARS-CoV-2, the virus that causes COVID-19.* *Self-tests can be taken at home or anywhere, are easy to use, and produce rapid results.* *You can use self-tests, regardless of vaccination status, or whether or not you have symptoms. Follow all of the manufacturer's instructions for performing the test."*	Diagnosis	For patients with COVID-19 symptoms or have been exposed or potentially exposed to an individual with COVID-19 For people who have no symptoms or were not exposed but will be in a gathering with other people	**Positive test result:** Indicates that you likely have a current infection, and you should stay home or isolate for at least 5 days and wear a well-fitted mask if others could have contact with you. Tell a healthcare provider about the positive test result and stay in contact with them. If illness becomes severe, seek medical attention. If you think your positive test result may be incorrect, contact the test manufacturer for assistance, consider taking another at-home test, or contact a healthcare provider for help. **Negative test result**: Indicates that the test did not detect the virus though it does not rule out an infection. However, some self-tests are designed to be used in a series, hence, individuals are advised to consider	Nasal Swab	Used immediately if with COVID-19 symptoms or at least 5 days after exposure to others with COVID-19. Use immediately before the gathering, or as close to the time of the event as possible

	(March 9, 2022)			repeating the test 24 to 48 hours later. US CDCP notes that multiple negative results increase the confidence that one is not infected with the COVID-19 virus.		
US CDC Travel Guidelines	*For inbound travellers* *"The test must be a SARS-CoV-2 viral test (nucleic acid amplification test [NAAT] or antigen test) with Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) OR the relevant national authority where the test is administered.* *The testing procedure must include a telehealth service affiliated with the manufacturer of the test that provides real-time supervision remotely through an audio and video connection. Some FDA-authorized self-tests that include a telehealth service may require a prescription."* (January 27, 2022)	Diagnosis	For all air passengers arriving in the United States	**Positive Test Result:** The guidelines state that if the result is positive, self-isolation is required; therefore, delaying the travel is delayed until isolation is completed. **Negative Test Result:** If the result is negative, the individual may board the flight.	Nasal swab	At most 24 hours before entry
UK (NHS)	*For people who do not have symptoms* *"These are usually for people who*	Diagnosis	For people who do not have symptoms	**Positive test result:** If the result of the test is positive, no PCR	Throat and Nose swab	Not Specified

MHRA	*do not have symptoms, they give a quick result using a device similar to a pregnancy test.”* *(March 18, 2022)* “A lay person is supervised by a professional user whilst the lay person performs the sample collection and operation of the COVID-19 professional use rapid lateral flow test” (February 14, 2022)			confirmatory test is needed. Instead, a 10-day self-isolation period is required. The counting starts on the day the symptoms started or if asymptomatic, on the day the result was released. If there are no more symptoms after the 10-day isolation, or if all that was left was cough or anosmia, you may return to normal living. Meanwhile, it is possible to end the 10-day isolation early if: a lateral flow diagnostic (LFD) test is taken at day 5 after the day the symptoms started (or the day your test was taken if you did not have symptoms), and another LFD test is taken on the following day. If both tests are negative and the individual has no high temperature, he/she can end the isolation. **Negative test result:** If the patient feels unwell, stay at home until you feel better. If feeling sick, having diarrhea and high temperature, stay at home for 48 hours or if symptoms have stopped.	Or Nose swab only	

Australia (Department of Health)	*For symptomatic adults, close contacts of someone who has tested positive and for those have been advised to do so by a health professional* *"If you are a close contact of someone who has COVID-19 you must isolate for 7 days (10 days in South Australia) from the last time you were in contact with that person.* *You should get tested as soon as possible if you have even the mildest cold or flu symptoms. Early diagnosis means you can avoid spreading the virus to someone else."* *(March 8, 2022)* *."*	Diagnosis	Symptomatic individuals, close contacts of someone who has tested positive and for those have been advised to do so by a health professional	**Positive Test Result:** Let the health authorities know of your result and isolate at home for 7 days. You may leave isolation after 7 days if your symptoms cleared up. **Negative Test Result:** No confirmatory test and isolation needed.	Nasal swab or saliva sample	Within the first 7 days from when symptoms first appear
Netherlands (Government of the Netherlands)	*For general and pediatric population going to schools, asymptomatic and mildly symptomatic population, close contacts of confirmed COVID-19 cases, travellers* May be bought on-the-counter in a shop, chemist, or pharmacy. These are intended for people who have mild symptoms that	Screening	General and pediatric population going to schools, asymptomatic and mildly symptomatic population, close contacts of confirmed COVID-19 cases,	**Positive test result:** It is very likely that you have coronavirus. You must stay at home and notify the people you have been in contact with. Anyone you live with, whether vaccinated or unvaccinated, must also stay at home. You need to make an appointment to get tested	Nasal swab	May be done anytime, especially for those with mild symptoms

	could indicate COVID-19. Coronavirus self-test may be used for: ● Individuals with mild COVID-19 symptoms (immediate) ● Individuals who have contacted someone with COVID-19 ● Individuals returning from a country with yellow or green travel advisory (immediate or may consult GGD) ● Individuals expecting visitors or visiting others (immediately before visiting) ● Individuals going to work, especially those who cannot work from home (twice a week) ● Students (twice a week), even if they don't have any symptoms, are vaccinated and/or have previously already had coronavirus. ● Pupils (twice a week) in primary or secondary schools even if they don't have any symptoms, are vaccinated and/or have previously already had coronavirus. Coronavirus self-test may not be used for:		travellers	by the municipal health service (GGD). This ensures: ● that you know for certain whether you have coronavirus, and that the self-test did not produce a false positive; and ● that you are entitled to proof of recovery, which happens only after the municipal health service (GGD) registers your case. If the municipal health service (GGD) test comes back negative, you can stop self-isolating and anyone you live with can stop self-quarantining. **Negative test result:** you probably don't have coronavirus. Your symptoms may be caused by another contagious virus or bacteria. Continue to exercise caution and follow the basic rules to prevent the spread of coronavirus, like staying 1.5 metres away from others, washing your hands often and staying home if you have COVID-19 symptoms. You should also take extra care around people with a medical condition.		

	• Individuals who lose their sense of taste or smell • Individuals considered at-risk, severely ill, or come into contact with people at-risk • Individuals in self-quarantine • Individuals whose work brings them in contact with people considered at risk ** These individuals must be tested by the municipal health service (GGD) (February 2022)					
Malaysia Ministry of Health Malaysia - Medical Device Authority	*For any individual who wants to know their status; Individuals who have has contact with COVID-19 cases and other appropriate screenings (international entrance, cross-state, pre-employment screening, pre-admission to higher institutions, etc.)* [Translated] *The COVID-19 Self-Test Kit that can be used is the one that has got recommendations from the Medical Devices Authority (MDA). List of types of these test kits will be updated on the MDA website from time to time.* *The COVID-19 Self-Test Kit can be*	Screening **The COVID-19 rapid test kit (self-test)) is used as a self-administered* ***screening test****. It does not replace the reverse-transcription polymerase chain reaction (RT-PCR) for COVID-19*	• Any individual who wishes to know their COVID- 19 status • Individuals who have had contact with COVID-19 cases • Other appropriate screenings (such as International Entrance, cross-state, pre-employment screening, pre-admission	**Positive test result:** A positive result must be reported to *MySejahtera* application. If conditions worsen while self-quarantining, individuals **are required** to go to a private health facility, COVID-19 Assessment Center, or a nearby health clinic for health assessment and further action. **Negative test result:** A negative result must be reported to *MySejahtera* application. Symptomatic individuals who test negative for COVID-19	Nasal or saliva	May be done anytime

	used for ● *Self-screening by any individual who wishes to know the status of COVID-19* ● *Individuals who have has contact with COVID-19 cases* ● *Other appropriate screenings (international entrance, cross-state, pre-employment screening, pre-admission to higher institutions, etc.)* (July 2021)	*real-time diagnostic function, but it does have the advantage of determining patient status immediately and conveniently"*	to higher institutions and others) ● B*efore and after participating in activities involving individuals from different households.*	should go to a private health facility or clinic for a health assessment. if the individual concerned is a contact to a COVID-19 case, the individual must continue to undergo compulsory quarantine until the end of the quarantine period. Invalid test results should be reported to the application and **repeated**.		
Cambodia (Ministry of Health)	*For persons suspected to have COVID-19* Person suspicious to have Covid-19 positive can use Covid-19 rapid antigen test by themselves by properly following the method of use and the Covid-19 antigen rapid test waste management (detail guideline is attached with each rapid test kit) and must implement health safety guidelines to avoid the spread of Covid-19 eventually (July 7, 2021)	Diagnosis	Persons "Suspicious" to have COVID-19	**Positive test result:** Persons who have tested positive in the self-test are obliged to notify health authorities so that they may be further evaluated and advised about the standard protocol for home treatment or referral to a health center or COVID-19 hospital. For individuals who tested positive of Covid-19 and in case quarantine is required, must implement in accordance with instructions, and health measures in force. **Negative test result:** No	Nasal swab	Not specified

				statements provided		
Canada (Government of Canada) **References linked per province**	*[General]* *For individuals with or without symptoms* The following provinces have specific guidances on rapid testing (Government of Canada, 2021) Brunswick: The frequency of these tests may vary by the type of program being implemented, but minimum 2x/weekly and often 3x/weekly is most appropriate. Self-test rapid antigen is recommended for the following populations: Individuals who frequently cross New Brunswick borders for the purpose of childcare, education, work, or to fulfill child custody arrangements Individuals employed in the commercial transportation industry who may be required to make trips outside of New Brunswick on a regular basis. Points of entry to New Brunswick, such as land borders, airports, or marine ports where testing would be opportune. British Columbia Indicated for individuals without COVID-19 symptoms. At this time, nasal swab collection can be done	Screening	Individuals with or without symptoms Those living in rural and remote areas that lack access to a standard Assessment Center for RT-PCR testing for COVID-19. Times when many new cases of COVID-19 are being diagnosed in a community; or an outbreak has been diagnosed in a workplace or facility. Long term Care homes, Nursing homes and Adult Residential facilities- staff visitors and residents	**Positive test result:** Those receiving a positive rapid test result should seek a PCR test as soon as possible for a confirmatory diagnosis. This also allows local public health authorities to identify the nature of the virus and track variants of concern. Follow all isolation and quarantine advice given by public health officials while you wait for test results. **Negative test result:** Continue to follow all local public health measures	Nasal swab	Serial asymptomatic testing for populations who may be at increased risk for exposure to COVID-19; or during times when there is a higher level of viral activity in the community. May be done routinely if institution / company resources permit.

	by a health care professional or a trained individual. Self-collected nasal swabs are now permitted when observed by a health care professional or a trained individual. Training is required for anyone collecting or observing self-collected nasal swabs and for all individuals performing these tests, to ensure that important quality and reporting standards are met. All training requirements are outlined in the B.C. COVID-19 Rapid Antigen Screening Program, Guidelines and Requirements Standard Operating Procedures. Please refer to the content below for more about these documents. <u>Alberta</u> Only the high risk population are required to take a PCR confirmatory test once SAAgT result is positive To ensure as many people have access as possible, there is a limit of one kit per person/health care number within a 14-day period. Rapid tests can be used by people aged 14 and older, and children aged 2-13 if performed by an adult. <u>Saskatchewan</u> Must only be used by asymptomatic individuals. Individuals with symptoms must					

	book for a lab PCR test at the Saskatchewan Health Authority. <u>Manitoba</u> Only symptomatic individuals who fall into one of the following groups are required to take confirmatory PCR test: healthcare workers who provide direct patient care and first responders; staff who have direct contact with patients, residents, and clients in hospitals and congregate living settings/residential care facilities (including personal care homes, assisted living, group homes, shelters, and correctional institutions); symptomatic residents in congregate living settings/residential care facilities if there has been no known case in the facility or specific unit in the last 14 days; and people who may be eligible for COVID-19 treatment and determined by a prescribing clinician to require PCR test. <u>Ontario</u> Indicated for individuals without COVID-19 symptoms. Specimen collection for antigen POCT may be done by health professionals, or other trained individuals (including self swabbing), in accordance with the manufacturer's label. Any individual supervising self-swabbing or doing					

	self-swabbing must consult the self-swabbing training resource developed by Ontario Health in collaboration with Public Health Ontario and ensure they have appropriate knowledge, skills and judgement to collect a specimen. Antigen POCT is used for screening purposes only and NOT for diagnostic purposes. Antigen POCT should NOT be used to test for COVID-19 infection in symptomatic individuals or individuals with known close contact with a positive COVID-19 case. Quebec Persons with symptoms similar to those of COVID-19 should use a [self-administered] rapid test as soon as possible. If positive, the patient must make an appointment at a screening center. An invalid result warrants a redo of the rapid test. (December 8, 2021)					
Canada (Government of Alberta	Alberta Albertans can get free COVID-19 rapid antigen testing kits for at-home use to help detect infections early and stop the spread. Non-high risk populations need not to take PCR test.	Diagnosis	For all residents of Alberta	**Positive test result:** If fully vaccinated, isolate for 5 days or until symptoms resolve, whichever is longer, plus 5 days of wearing a mask at all times when around others outside of home.	Nasal swab	One kit per person/health care number within a 14-day period as part of early detection of infection.

	(2021)			If not fully vaccinated, isolate for 10 days or until symptoms resolve, whichever is longer. **Negative test result:** If asymptomatic, no need to isolate but continue monitoring symptoms and follow health standards. If symptomatic, isolate for 24 hours and take a repeat antigen test. Continue isolating until symptoms resolve before cautiously resuming normal activities.		
Canada (Government of Manitoba)	*For all individuals who are symptomatic*	Diagnosis	Individuals who are symptomatic	**Positive test result:** For most situations, you do not need a confirmatory PCR test. You should isolate for 5 days after your symptoms start and until you have no fever and your other symptoms have improved over the past 24 hours. **Negative test result:** If you have a negative result do not assume you are negative for COVID-19, it is recommended you take a second test 24 hours after your first and if available a third test 24 hours after the second.	Nasal Swab	Not specified

Government of Canada	For unvaccinated and asymptomatic individuals, symptomatic individuals *"In the event of a COVID-19 resurgence, self-testing may be an effective tool for screening people who are asymptomatic and unvaccinated. It could also quickly identify potential infections in people with symptoms."* (August 2021)	Screening	For unvaccinated and asymptomatic individuals	**Positive test result:** Encouraged to follow public health guidance. Should be confirmed with laboratory-based PCR. **Negative test result:** Encouraged to follow public health guidance	Nasal swab	Not specified
Singapore (Ministry of Health)	*For people close contactswithout health risk warnings* *"If you think you have been in contact with a COVID positive case, but have not received a Health Risk Notice, monitor your health over the next few days.* ● *If you are feeling unwell, including having a fever, cough, sore throat, etc., visit a doctor. The doctor will assess and advise you on your next steps.* ● *If you are well, but are still worried, you can take an Antigen Rapid Test (ART)."* (February 16, 2022)	Screening	People unsure of exposure (without health risk warnings)	**Positive test result:** If positive but feeling well or with mild symptoms, isolate for 72 hours and repeat ART self-test. - If the repeat test is positive, continue to self test. Whenever your ART self-test is negative, continue regular activities. - If the repeat test is negative, continue regular activities. **Negative test result:** If you test ART negative, you can leave your house for normal activities. Do minimise unnecessary social interactions. You must still complete the 5-day monitoring period.	Nasal Midturbinate Nasal Swab	Not specified

Germany MOH Self-test	*For private individuals specifically on situations where people may meet without a mask such (i.e. private visit or at a celebration)* *"Self-tests get their name because everyone can do these tests themselves, for example at home. Self-tests are intended for use by private individuals. For this purpose, the instructions for use must be easy and understandable, and taking and evaluating samples must be correspondingly simple. Self-tests can provide additional security in specific situations in everyday life - especially where people may meet without a mask, for example on a private visit or at a celebration. They can also be used as part of the test concepts of the federal states in schools and day-care centers."* (February 2022)	Diagnosis	Private individuals specifically on situations where people may meet without a mask such (i.e. private visit or at a celebration)	**Positive test result:** A confirmatory test is usually not necessary especially in the case of currently high incidences, and should be weighed up on the basis of clinical criteria; however, you may book an appointment to get a PCR confirmatory test. Isolate immediately, avoid contact with others, keep your distance, observe hygiene rules and wear a mask in everyday life. **Negative test result:** If feeling well, keep your distance, observe hygiene rules and wear a mask in everyday life. If with mild cold symptoms: Go to voluntary quarantine and avoid contact with other people. You may also have yourself tested with a correctly performed and evaluated rapid antigen test.	Nasal swab, throat swab or saliva sample	*"The amount of virus is highest just before the onset of the symptoms and at the beginning of the infection."*
China (National Health Commission)	*For symptomatic individuals visiting medical facilities, and those undergoing isolation* (March 14, 2022)	Screening	For symptomatic individuals	**Positive test result:** Individuals positive for self-testing will be managed as COVID-19 cases. They will undergo centralized quarantine and take multiple nucleic acid tests.	Nasal swab, oropharyngeal swab, nasopharyngeal swab	Not Specified

				Nucleic acid tests (PCR) will still be considered as basis for confirming the infection. **Negative test result:** Not Specified		
DOH Philippines	*For symptomatic individuals with or without exposure* *"Self-administered antigen testing shall be recommended only for symptomatic individuals within 7 days from onset of symptoms, especially if capacity for timely RT-PCR results is limited or not available."* (January 26, 2022)	Diagnosis	For symptomatic individuals with or without exposure	**Positive test result:** Isolate and inform their respective close contacts. Report to their Barangay Health Emergency Response Team (BHERT) or healthcare provider. **Negative test result:** "Asymptomatic close contacts or individuals with a high index of suspicion for COVID-19 who test negative with a self-administered antigen test are recommended to immediately quarantine, conduct symptom monitoring, and consult with a healthcare provider."	*Unspecified.* Depends on the brand of test kit to be used.	Within 7 days upon symptom onset
WHO	*For diagnosis of symptomatic individuals or those who have been recently exposed to SARS-CoV-2* *"Where there is ongoing community transmission , and testing is targeted towards individuals with symptoms*	Diagnosis	Diagnosis of symptomatic individuals or those who have been recently exposed to SARS-CoV-2	**AS DIAGNOSIS** **Positive test result:** Can be considered to be a probable (or confirmed) case of COVID. Post-test actions should then be taken according to current national guidelines,	*Not specified*	If used as diagnosis, perform within the first 5-7 days of the disease course.

	and/or recent exposures (such as contacts or health and care workers), COVID-19 self-testing can be considered for diagnostic purposes, without a requirement for further confirmatory testing." (March 9, 2022)			such as self-isolation, notification of contacts, masking and physical distancing. For symptomatic, consider seeking clinical care services, which may include therapeutic options for COVID-19. In some settings, confirmatory testing may be desired before prescribing therapeutics. **Negative test result:** For those with probable exposure or is experiencing symptoms, standard infection prevention and control practices and to consider retesting, e.g. 24 to 48 hours later.		
WHO	*For screening of individuals without symptoms or known exposure to SARS-CoV-2* "Self-testing for screening purposes can be considered among individuals without symptoms or known exposure to SARS-CoV-2 irrespective of intensity of community transmission. For this application, a negative self-result could enable participation in an activity and, depending on the epidemiological situation, a positive self-test result may	Screening	Screening of individuals without symptoms or known exposure to SARS-CoV-2	**AS SCREENING** **Positive test result:** May consider seeking confirmatory testing and exercise infection prevention and control practices **Negative test result:** Exercise infection prevention and control practices	*Not specified*	*"*(Self-directed) *For individuals with unknown or no known exposure who want increased confidence that they do not have a SARS-CoV-2 infection"*

	be followed by confirmatory testing" (March 9, 2022)					
Government of Brazil The Brazilian Report Brazil National Health Surveillance Agency	*For symptomatic and close contacts* *'Self-test for the detection of the SARS-CoV-2 antigen is understood to be the medical device for in vitro diagnosis whose intended use is to provide an orientation result, but not conclusive for the diagnosis, performed by a lay user."* (January 28, 2022)	Screening	Symptomatic and close contacts	**Positive test result:** Seek medical attention and confirm results with RT-PCR test. **Negative test result:** If there are no symptoms, must self-isolate for five days and repeat the test after one to two days. If with symptoms, must repeat the self-test after one to two days and monitor their symptoms. If symptoms worsen, they must seek medical attention and confirm test results with RT-PCR	Nasal and saliva	Symptomatic: To be performed within 1st day to 7th day of the onset of symptoms Close contacts: If you have no symptoms but have had contact with someone who tested positive, wait 5 days before using the self-test.

Not recommended	
Country (Agency)	**Latest Recommendation (Date of Recommendation)**
Singapore (Health Sciences Authority)	For the general population who are not feeling well (i.e., having fever, cough, sore throat, etc.,); had nasal surgery in the last 4 weeks; had facial surgery in the last 8 weeks. Use RT-PCR instead of self-administered Antigen Rapid Test (ART).

	(February 16, 2021)
Kenya **(Ministry of Health)**	Self-testing using the Antigen rapid test is NOT PERMITTED. (December 2020)
South Africa **(Department of Health)**	According to the Regulatory Requirements for COVID-19 Rapid Test Kits (last update March 2020), Covid-19 Rapid Test Kits may not be advertised to the public, are intended for use by professionals only, and are not intended for self-testing and may not be sold to the public. According to the Department of Health guidelines (released July 2021), all rapid antigen tests should be conducted by health professionals and reported to the National Health Laboratory Services surveillance portal. (July 21, 2021)
Namibia **(Medicines Regulatory Council)**	Rapid Diagnostic Tests are available as laboratory-based tests and for near-patient use. The rapid test kits should ONLY be supplied and used in health facilities (as defined in the Health Facility Act No. 36 of 1994) or institutions where medical personnel certified is/are present to perform the test. It is the responsibility of the supplier to ensure that the medical personnel to be performing the tests have received training on specimen collection… Therefore, only certified users are permitted to perform the tests. Negative results for the Antigen Rapid Diagnostic Tests (Ag-RDTs) are considered presumptive negative and in most cases requires confirmation with a RT-PCR test. For this reason, they are not recommended for use in home or office settings except for clinic or casualty settings where their use is controlled. (August 24, 2021)
Vietnam	*"Foreign arrivals are required to:* ● *Take a COVID-19 negative test using the RT-PCR method 72 hours before entering Vietnam OR a rapid Antigen test (no self-test) 24 hours before entering Vietnam. This does not apply to children under 2 years of age;"* (March 16, 2022)

Available guidelines are for RAGT but no explicit mention of SAAgT	
Country (Agency)	**Latest Recommendation (Date of Recommendation)**
EU (ECDC)	While self-sampling under supervision and subsequent rapid antigen detection tests (RADT)performed at the laboratory can be an acceptable solution for a certified test, RADTs performed by untrained individuals should not be used for issuing of any formal certificate. Self-test RADTs should not be used for the purpose of issuing a formal certificate such as testing, or recovery certificates. (October 26, 2021)
Nigeria (Center for Disease Control)	Only rapid diagnostic tests (RDTs) that have been granted World Health Organization (WHO) Emergency Use Authorisation (EUA), and have been validated by the relevant national authorities, can be used in Nigeria. Antigen (Ag) based rapid diagnostic test RDT is a Point of Care (POC) test that detects the presence or absence of an antigen directly. This method is commonly used for the detection of a number of pathogens including SARS-CoV-2. (January 2021)
Pakistan (Government of Pakistan)	Only those labs which are already integrated into the national database will be allowed to use Antigen Rapid Diagnostic Test (Ag-RDT). Pakistan's Ministry of National Health Services Regulations and Coordination will issue explicit instructions for use of Antigen Rapid Diagnostic Test (Ag -RDT) by the private sector. Pakistan (after a thorough consultative process) has decided to adopt Rapid Antigen Testing for enhanced disease mapping and to complement PCR based-testing but under strict control/monitoring. (December 2020)
Uganda (Ministry of Health)	[Citing WHO guideline] WHO Interim guidance of 11th September 2020 recommend that SARS-CoV-2 antigen detection rapid diagnostic test

	(Ag) RDTs that meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity compared to a Nucleic Acid Amplification Test (NAAT) reference assay can be used to diagnose SARS-CoV-2 infection in a range of settings where NAAT is unavailable or where prolonged turnaround times preclude clinical utility. However, antigen tests have limitations of sensitivity, especially in the presence of low viral loads. (June 2021)
Indonesia **(Minister of Health)**	Central Government and Local Government is responsible for availability Rapid Diagnostic Antigen (RDT-Ag) for contact tracing, diagnosis in facility service health owned by government, and screening under certain circumstances (events that can result in the speed of COVID-19) (2021)
Seychelles (A & B) **(Department of Health)**	All suspect cases must be tested by RT-PCR. All high-risk contacts of known COVID-19 cases should be tested by RT-PCR at baseline. (May 13, 2020) For seafarers, the use of Rapid Antigen Test aboard vessels is encouraged. (January 6, 2022)
Vietnam	The Ministry of Health has received proposals from many Departments of Health of the provinces and centrally-run cities for comments on the use of antigen rapid test results to identify people infected with SARS-CoV-2 and SARS-CoV-2. October 6, 2021

Annex C

Breakdown of Cost for the Development of Online Reporting System of Self-administered Antigen Test Kits

Cost Item	*Cost*	Unit	Months	*Total*	Details
Web cloud server	*₱106,250.00*	1	6	*₱637,500.00*	Compute Container: (2) Private space - CPU: 8 cores, 52x compute - 14GB RAM - SSL, Always On - Unlimited Process types - Horizontal Scaling Queue workers: (2) Performance M (2.5GB RAM, CPU 12x dedicated server) Dev environments (staging and demo): (4) Standard 2x (1GB RAM, CPU 4x-8x)
Database and storage	*₱127,250.00*	1	6	*₱763,500.00*	Amazon Aurora PostgreSQL 13 (2) r6g.4xlarge - 16 vCPU - 128GB memory - Up to 10Gpbs Network Bandwidth - 4750 Mbps Block Storage Bandwidth Amazon S3 - S3 Standard 1TB provision per month, 2M requests/month

Chatbot cloud server and services*	*₱130,800.00*	1	6	*₱784,800.00*	Isolated Service (SEA): 4vCPU with 14GB RAM, 1TB SSD storage; Azure SQL API management chatbot 1GB cache SLA 99.95% 2,500 requests/sec. Amazon Lambda 500 Million requests / month 10 ms duration per request 1GB memory allocation Amazon API Gateway 500 Million requests / month 10 KB per request
API services and subscriptions	*₱67,687.50*	1	6	*₱406,125.00*	Third party subscriptions: (maps service, DDoS protection, email services, unit testing, web and logs monitoring, querying tool) Amazon SES - Email 400k emails / month Librato, Simple analytics, Papertrail, Redis caching (memcache or redis) PHPunit, Cypress, Jira, Github (15 users, includes DOH)
Google cloud platform	*₱150,000.00*	1	6	*₱900,000.00*	Big Query Cloud SQL Compute Engine
SMS service	*₱75,000.00*	1	6	*₱450,000.00*	Semaphore backup for service downtime
TOTAL				**₱3,941,925.00**	

Annex D

Codes	Literature Review	Health workers	At-risk groups *(e.g., Older Adults, Vulnerable Individuals)*	Economic frontliners	MSMEs and Academic Institutions
GENERAL EXPERIENCES/PERSPECTIVES ON COVID-19 TESTING					
Autonomy on Testing	✓	✓	✓		
Confidence in the Accuracy of Results	✓	✓	✓	✓	✓
Confidence in the Healthcare System	✓	✓	✓		✓
Confidence in Regulation of Test Kits		✓			
Out-of-Pocket Costs as Barrier to Testing	✓	✓	✓	✓	✓
Perceived Vulnerability to COVID-19	✓	✓	✓	✓	✓
Prevention of Cross-Infection	✓	✓	✓	✓	✓
Proximity of Testing	✓	✓	✓		
Rapid Release of Results	✓	✓	✓	✓	
Risk-Based Testing	✓	✓	✓	✓	✓
BARRIERS ON COVID-19 TESTING (GENERAL)					
Alternative routes for specimen collection	✓	✓			✓
Fear of being discriminated	✓	✓	✓	✓	✓
Gender-Based Preferences in Testing	✓				

Codes	Literature Review	Health workers	At-risk groups *(e.g., Older Adults, Vulnerable Individuals)*	Economic frontliners	MSMEs and Academic Institutions
Grapevine communication as a barrier to testing				✓	
Hiya as a barrier to COVID-Testing		✓	✓	✓	✓
Incurred Cost by Institutions as Perceived Barrier	✓	✓			✓
Ineffective Health Education for COVID-19	✓	✓	✓	✓	✓
Padrino System			✓		
Sociocultural Differences in Testing Acceptability	✓				
DESIRED CHARACTERISTICS OF SELF-TESTING					
Employer-Supported Testing					✓
Out-of-Pocket Costs as Barrier to Testing	✓	✓	✓	✓	✓
Rapid Release of Results	✓	✓	✓	✓	
Discomfort in Self-administration of Test	✓	✓	✓		✓
Time Convenience of Testing	✓		✓		✓
EXPERIENCES / PERSPECTIVES ON SELF-TESTING					
PROS					
Autonomy on Testing	✓	✓	✓		
Conformity and Self-testing	✓				

Codes	Literature Review	Health workers	At-risk groups *(e.g., Older Adults, Vulnerable Individuals)*	Economic frontliners	MSMEs and Academic Institutions
Discomfort in Self-administration of Test	✓	✓	✓		✓
Prevention of Cross-Infection	✓	✓	✓	✓	✓
Time Convenience of Testing	✓		✓		✓
CONS					
Conformity and Self-testing	✓				
Disability and self-testing	✓		✓		
Educational Attainment as Predictor of Compliance	✓				
Fear of being discriminated	✓	✓	✓	✓	✓
Grapevine communication as a barrier to testing				✓	✓
Hiya as a barrier to COVID-Testing		✓	✓	✓	✓
Isolation as a consequence of testing	✓		✓	✓	✓
Out-of-Pocket Costs as Barrier to Testing	✓	✓	✓	✓	✓
Self-efficacy and self-testing	✓	✓		✓	✓
PROGRAMMATIC CONSIDERATIONS FOR SAAGT					
PERSPECTIVES ON DOH APPROACH TO SELF-TESTING					
Autonomy on Testing	✓	✓	✓		

Codes	Literature Review	Health workers	At-risk groups *(e.g., Older Adults, Vulnerable Individuals)*	Economic frontliners	MSMEs and Academic Institutions
Centralized Distribution of Kits			✓		✓
Community Mobilization in Self-Testing	✓	✓	✓	✓	✓
HRH Capacity building in SAAgT		✓			
Increased Access to Rural Areas and GIDAs for Self-Testing					✓
Testing and Case Management	✓	✓	✓	✓	✓
Self-Testing for Workload Reduction in Health Facilities	✓				
Streamlining Self-Testing	✓		✓	✓	✓
ACTIONS FOLLOWING TEST RESULTS					
Alternative Routes for IEC	✓	✓	✓	✓	✓
Positive Reinforcement for Testing	✓		✓		
Streamlining Self-Testing	✓		✓	✓	✓
PERSPECTIVES ON REPORTING TEST RESULTS					
Alternative Routes for IEC	✓	✓	✓	✓	✓
Centralized Reporting and Patient Information System		✓	✓	✓	✓
Community Mobilization in Self-Testing	✓	✓	✓	✓	✓

Codes	Literature Review	Health workers	At-risk groups *(e.g., Older Adults, Vulnerable Individuals)*	Economic frontliners	MSMEs and Academic Institutions
Increased Access to Rural Areas and GIDAs for Self-Testing			✓		✓
Positive Reinforcement for Testing	✓		✓		
Streamlining Self-Testing	✓		✓	✓	✓

General experiences or perspectives on COVID-19 testing

- Literature review and all 4 FGD groups expressed the following:
    - confidence or lack of confidence in the accuracy of results
    - concern over out-of-pocket costs related to COVID-19 testing. (i.e., out-of-pocket costs as a barrier to testing).
    - willingness to get tested due to feeling vulnerable of contracting COVID-19 (i.e., perceived vulnerability to COVID-19)
    - use of testing in preventing cross-infection among the immediate social circles and significant others (i.e., prevention of cross infection).
    - feeling the need to get tested because of being at risk to COVID-19 infection (i.e., risk-based testing).
- Literature review and 3 FGD groups (health workers, at-risk groups, economic frontliners) emphasized that antigen testing yielded faster results than RT-PCR. (i.e., rapid release of results)
- Literature review and 3 FGD groups (health workers, at-risk groups, MSMEs) expressed their confidence in the healthcare system.
- Literature review and 2 FGD groups (health workers and at-risk groups) discussed about:
    - being able to choose their preferred method of testing (i.e., autonomy on testing)
    - proximity as a factor for motivation to get tested (i.e., proximity of testing)
- Only the health worker group expressed the need for regulation of test kits

Barriers on COVID-19 testing

- Literature review and all four FGD groups emphasized the following:
    - fear of being discriminated due to positive COVID-19 test results
    - the challenges of ineffective health education (i.e. misconceptions on SAAgT, testing, isolation and COVID-19)
- Literature review and two FGD groups (health workers, and MSME and academic institutions) mentioned the following:
    - importance of diversifying specimen collection methods to address concerns such as preference, aversion to invasive procedures, and convenience (i.e. alternative routes for specimen collection)
    - cost burden or the incurred cost by institutions and test implementers as a perceived barrier
- Only the literature review discussed about the following:
    - gender-based preferences in testing
    - sociocultural differences in testing acceptability
- All the FGD groups explained about *hiya* (i.e. a Filipino's sense of propriety) as a barrier to COVID-19 testing
- Only the at-risk group identified the *padrino system* in COVID-19 testing which involves the personal favor, promotion, or appointment due to having close ties or relationships with an official, familial affiliations, or *utang na loob* of the one giving the favor to the one gaining the favor

- Only the economic frontliner group discussed about the hesitancy to test or report test results due to fear of being gossiped (i.e. grapevine communication) as a barrier to testing

Desired characteristics of self-testing

- Literature review and all 4 FGD groups expressed low cost of testing as a preferred characteristic in self-testing. (i.e., out-of-pocket costs as a barrier to testing).
- Literature review and 3 FGD groups (health workers, at-risk groups, economic frontliners) expressed their preference for a self-test that yields faster turnaround time (i.e., rapid release of results).
- Literature review and 3 FGD groups expressed their preference for a self-test that does not elicit too much discomfort (i.e., discomfort in self-administration of test).
- Literature review and 2 FGD groups (at-risk groups, MSME and academic institutions) highlighted their preference for a self-test which does not hamper their routine or time for other activities (i.e., time convenience of testing).
- Only the MSME and academic institutions group discussed the provision of institutional financial support and incentives for self-testing to employees. This did not emerge in the literature review.

Experiences or perspectives on self-testing

- Literature review and all four FGD groups emphasized that:
    - conforming to self-testing reduce the risk of transmitting SARS-CoV-2 infection, including practices of isolation and preventive measures as result of self-testing (i.e. prevention of cross-infection)
    - out-of-pocket expenses associated with testing hinder individuals from getting testing services, and consequently affect the financial status of families and other groups in communities (i.e., out-of-pocket costs as barrier to testing
    - potential test users are discouraged to get tested because of the fear of being stigmatized, publicly humiliated, or viewed negatively after everyone discovers that one will undergo testing, procure test kits, or report positive for COVID-19.
- All FGDs emphasized that the indigenous concept of *hiya* [rough trans. sense of propriety] can be a potential significant barrier in testing (i.e., *Hiya* as a barrier to testing). In letting others know that they have tested positive for COVID-19, there is a high possibility of being stigmatized or becoming the “talk of town”.
- Literature review and three FGDs (at-risk groups, economic frontliners, and MSMEs and academic institutions) expressed concerns on:
    - various social, economic, and cultural implications involved in isolation/quarantine as a result of a positive test (i.e., isolation as a consequence of testing).
    - hesitancy to get tested because this may result in forced isolation which may hamper their daily activities. The economic frontliner group especially highlighted that being forced to isolate greatly affected their livelihood due to being unable to go out and work (i.e., isolation as a consequence of testing).

- Literature review and three FGD groups (health workers, at-risk, MSMEs and academic institutions) discussed the perceived uncomfortable, unpleasant, or painful experience upon self-swabbing (ie. burden in self-administration of test) of an individual
- Literature review and three FGD groups (health workers, economic frontliners, and MSMEs and academic institutions) mentioned that:
    - the individual's concerns about their own capability to follow instructional manual for test kits and correctly perform self-testing (i.e. self-efficacy and self-testing)
    - being unable to properly perform self-testing is due to their lack of confidence and knowledge to accurately perform the test (i.e., self-efficacy and self-testing).
- Literature review and two FGD groups (health workers and at-risk groups) highlighted the use of SAAgT as a personal choice (i.e. autonomy on testing) of each individual
- Literature review and two FGD groups (at-risk groups and MSMEs and academic institutions) identified the importance of the flexible nature of self-administered testing that allows individuals and their families to perform the test at their most convenient schedule as it can be done outside a health facility (i.e. time convenience of testing)
- Literature review and the at-risk groups expressed concerns that self-testing may not be conducive for use among people with disabilities, thus emphasizing on the need for disability-responsive kits, policies, and guidelines for SAAgT
- Only the literature review discussed that:
    - Individuals, families, and communities are more likely to perform self-testing if the people around them accept and perform self-testing (conformity and self-testing
    - low educational attainment is a potential barrier to testing because of its association with lower health literacy (i.e., educational attainment as predictor of compliance).
- Two FGDs (economic frontliners, and MSMEs and academic institutions) expressed their fear that, after testing positive, people will be gossiped about (i.e., grapevine communication as a barrier to testing). This image of being "contagious" may become an individual's persona even if the actual infection has since been resolved, that it has already become a '*badge of carriage na nagka-COVID ka na.*' [badge of carriage of having been infected by COVID]).

Programmatic considerations for SAAgT

- Literature review and all 4 FGD groups expressed the following:
    - Program implementation of SAAgT requires the need to mobilize individuals in the community for COVID-19 test, maximizing social resources and utilizing society-grounded strategies (i.e., community mobilization on self-testing).
    - Other methods can improve IEC campaign reach in the community (i.e., alternative routes to IEC). These include (1) instructions in the vernacular language of the target audience, (2) return demonstrations, and (3) video presentations. Some participants complained about the instructions on currently used test kits because these are written in non-native languages (e.g. Chinese) and may not be readily understandable to an average Filipino. IECs should not only be printed; instead, video guides catered to communities can be created

    - SAAgT testing is preferred to be used for surveillance, initial identification, and prerequisite for referral to conduct confirmatory testing (i.e., testing and case management).
- All FGD groups expressed that
    - COVID-19 test results must be managed and reported through a unified health information system across the country (i.e., Centralized Reporting and Patient Information System).
- Literature review and three FGDs (at-risk groups, economic frontliners, academic institutions and MSMEs) emphasized that SAAgT-related policies and guidelines be streamlined to fit in the currently existing national testing strategies for COVID-19 (i.e., streamlining self-testing).
- Literature review and two FGD groups (health workers and at-risk groups) emphasized that in the implementation of self-testing, the use of SAAgT should be viewed as a personal choice (i.e., autonomy on testing).
- Literature review and two FGD groups (at-risk groups, and academic institutions and MSMEs) agreed that increasing the access to SAAgT to include populations with limited access to healthcare facilities, such as, but are not limited to, those in rural areas and GIDAs (i.e., increased access to GIDAs for self-testing). Population characteristics and logistical concerns (storage, infrastructure, etc.) need to be considered in the implementation of testing in general, of which includes SAAgT.
- Literature review and the health workers explained that cost burden among institutions is perceived as a barrier to testing, and should therefore be considered when SAAgT is implemented (i.e., incurred cost by the institution as a perceived barrier).
- Literature review and the at-risk groups recognized that, when incentives are given for individuals in the community, positive attitudes towards the use of SAAgT are more likely to be reinforced, and SAAgT can have higher utilization (i.e., positive reinforcement for testing).
- Two FGDs (at-risk group and MSMEs and academic institutions) emphasized that COVID-19 testing kits should be distributed only through health facilities within the service delivery network (i.e., centralized distribution of kits).
- Only in the literature review was implementation of SAAgT viewed as a way to reduce the number of individuals being tested in health facilities, thus reducing the workload of health care workers and resources are reallocated (i.e., testing for workload reduction in health facilities).
- Only the health workers advocated for the provision of capacity building among human resources for health, especially those involved in the grassroots implementation of SAAgT and its adjunct services (e.g., barangay health workers). They also emphasized the need to perform cascading of training for effective roll out of SAAgT.
- Only the MSMEs emphasized that assistance given by employers is crucial in minimizing their employees' out-of-pocket costs for COVID testing and motivating them to perform testing (i.e., employer-supported testing).

Annex E

GRADE Assessment of Adamson et al., 2022

No.	DOMAIN	RATING	EXPLANATION
1	Study design	N/A	Retrospective cohort
2	Risk of Bias	**VERY SERIOUS**	More than 1 high rating in QUADAS-2 RoB (See Below)
3	Indirectness	**SERIOUS**	Population in the recomm: symptomatic; Population in the evidence: workers Use of Saliva PCR as a reference standard for nasal rapid antigen may yield uneven sample comparisons due to different collection route
4	Inconsistency	N/A	Cannot assess consistency of studies because this study is not a systematic review
5	Imprecision	**SERIOUS**	NA in the upper confidence interval in the median time suggests that there is lack of positive PCR samples that had a positive antigen to estimate the upper confidence limits of the survival curve
6	Publication bias	N/A	Cannot be assessed Based on definition, "systematic under or over estimation of the underlying beneficial or harmful effect of the intervention, due to the selective publication of studies or availability of their data."
7	Upgrading for dose effect, large effects residual plausible bias and confounding	N/A	Cannot be assessed
8	Other considerations	N/A	Two authors reported being unpaid board member of SalivaDirect

		VERY LOW QUALITY OF EVIDENCE	

QUADAS-2	RISK OF BIAS	RATING	EXPLANATION
1	**PATIENT SELECTION Could the selection of patients have introduced bias?**	**HIGH**	**"The data reported here represent a convenience sample of employees at a selection of workplaces that partner with Infectious Economics LLC for Covid-19 prevention, including corporate offices, entertainment, retail trade, and manufacturing."**
1.1	Was a consecutive or random sample of patients enrolled?	NO	convenience sample
1.2	Was a case–control design avoided?	UNCLEAR	Not mentioned
1.3	Did the study avoid inappropriate exclusions?	YES	"Among hundreds of workplace-detected Covid-19 cases in December 2021, we identified 30 individuals with 62 matched pairs of rapid antigen and positive PCR results from specimens collected at the same time. This retrospective cohort study identified individuals in occupational safety programs who were diagnosed with Covid-19 between December 1-31, 2021 during Omicron outbreaks at five workplaces in New York, NY, Los Angeles, CA, and San Francisco, CA. The populations were fully vaccinated by employer mandate and highly boosted by choice. To isolate the window of acute infection, cases were included if they were receiving daily testing at the time of diagnosis, had paired SARS-CoV-2 quantitative reverse-transcriptase polymerase chain reaction (RT-qPCR) test results and rapid antigen test results on Day 0 or 1 relative to first positive specimen

			collection date and were excluded if missing a recent negative test" Results included 30 individuals
2	**INDEX TEST** **Could the conduct or interpretation of the index test have introduced bias?**	**UNCLEAR**	**"The results of the index test were interpreted with knowledge of the results for the reference standard.** **"The rapid antigen tests kits used were Quidel QuickVue At-Home OTC COVID-19 Test and Abbott BinaxNOW COVID-19 Antigen Self-Test. PCR to detect SARS-CoV-2 RNA was the ThermoFisher Combo Kit, allowing for the ability to detect an S-gene dropout."**
2.1	Were the index test results interpreted without know- ledge of the results of the reference standard?	UNCLEAR	Not mentioned
2.2	If a threshold was used, was it pre-specified?	UNCLEAR	Not mentioned
3	**REFERENCE STANDARD** **Could the reference standard, its conduct, or its interpretation have introduced bias?**	**LOW**	**We defined the index as the specimen collection date for the first PCR test with detectable SARS-CoV-2 with Ct <35, the event being the first positive** **rapid antigen test result, and censoring at the most recent antigen test date.** **Based on observed transmission events in these workplaces that were confirmed by contact tracing and genomic epidemiology investigation, we defined infectious viral load as corresponding to Ct values <29 in this analysis**
3.1	Is the reference standard likely to correctly classify the target condition?	UNCLEAR	Use of Saliva PCR as a reference standard for nasal rapid antigen may yield uneven sample comparisons due to different collection route

3.2	Were the reference standard results interpreted without knowledge of the results of the index test?	YES	Ct value as basis (independent of RAgT)
4	**FLOW AND TIMING** **Could the patient flow have introduced bias?**	**HIGH**	**We evaluated concordance of PCR and rapid antigen test results in matched samples over time.** **Based on supplemented data, not all were tested using both RT-PCR and RAgT every time**
4.1	Was there an appropriate interval between index tests and reference standard?	NO	"Day 0 or 1 relative to first positive specimen collection date" The "or" in the term may mean that the first RT-PCR was not taken at the same time with the first RAgT
4.2	Did all patients receive a reference standard?	NO	While all patients receive the reference standard at one point in time; not all time points had a reference standard
4.3	Did all patients receive the same reference standard?	YES	RT-PCR was used for all
4.4	Were all patients included in the analysis?		"Among hundreds of workplace-detected Covid-19 cases in December 2021, we identified 30 individuals with 62 matched pairs of rapid antigen and positive PCR results from specimens collected at the same time. This retrospective cohort study identified individuals in occupational safety programs who were diagnosed with Covid-19 between December 1-31, 2021 during Omicron outbreaks at five workplaces in New York, NY, Los Angeles, CA, and San Francisco, CA. The populations were fully vaccinated by employer mandate and highly boosted by choice. To isolate the window of acute infection, cases were included if they were receiving daily testing at the time of diagnosis, had paired SARS-CoV-2 quantitative reverse-transcriptase polymerase chain reaction (RT-qPCR) test results and rapid antigen test results on Day 0 or 1 relative to first positive specimen

			collection date and were excluded if missing a recent negative test" Results included 30 individuals
	Overall RoB	**VERY SERIOUS**	