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*.