Section 4.

Household financial impact

No evidence available

Section 5.

Cost-effectiveness

No evidence available

Section 6.

Affordability and viability

No evidence available

Section 7.

Recommendation

HTAC DOES NOT RECOMMEND the use of RATs in:

- use case 1a. i.e. as a standalone test, irrespective of RT-PCR result.
- seroprevalence surveys, return-to-work decisions, or entry-to-country/ province policies

due to the lack of evidence regarding the link of presence of antibodies and the immunity to subsequent infection AND on the persistence of protection from COVID-19.

- disease surveillance activities (i.e. contact tracing or as part of acute outbreak investigations) to guide public health decisions.

A **validated** rapid antibody test kit **may** be used as an adjunct to diagnosis of patients who satisfy ALL of the following criteria:

- *symptomatic patients (greater than or equal to 15 days from symptom onset, AND*
- *tested at least twice negative with RT-PCR, AND*
- with clinical and diagnostic manifestations of COVID-19

Furthermore, the HTAC advises that only licensed medical doctors may request, administer, and interpret results of rapid antibody-based test.

Please be reminded that the result of the testing is only applicable to the health status of the patient at the time of the test and does not prevent future risk of infection. Following minimum public health standards is still recommended.

What do the recommendations mean?

The rapid antibody tests are unreliable in determining whether or not one has the COVID virus. Timing of the conduct of the test is important. If the test is done too early, i.e., within 14 days from exposure, there is a high probability that the finding will be negative even if the person tested is truly positive for COVID-19 because it takes time for the body to develop antibodies. Moreover, independent tests of these rapid antibody tests show wide variability in performance, and that the accuracy of these tests can depend not only on the test itself, but also on factors such as when the test is conducted and how a user interprets the result. Thus, the HTAC specifically states that rapid antibody tests are not suitable for determining if personnel may return to work, nor for establishing whether people can return to the province. The HTAC only recommends the use of the rapid antibody tests on patients who have symptoms that are highly suggestive of COVID-19 but whose RT-PCR (swab) examinations have turned out to be negative.

What does a positive RAT result mean?

A positive result means that a person was infected with SARS-CoV-2 and the body's immune system has responded by creating antibodies. Due to the way the body responds to the virus, it often takes about 2 to 3 weeks for an infected person to test positive after being infected with SARS-CoV-2. It means that RATs should not be used to diagnose COVID-19 in the acute phase of the disease. Additionally, there is no evidence that having antibodies for COVID-19 will have a protective effect in the long-term.

What does a negative RAT result mean?

A negative result may mean any of these four things:

- that there was not enough time yet for the body to have an immune response to an ongoing infection
- that the circulating level of antibodies for SARS-CoV-2 is too low to be detected by the particular test
- that the brand of RAT used is not sensitive enough to detect the circulating antibodies
- that the antibodies for SARS-CoV-2 are absent, and the person was not infected

In addition, there has not been enough evidence to prove that either a positive/ negative RAT result can protect a person from future SARS-CoV-2 infection.

Furthermore, the Council has set the minimum regulatory, technical, and operational requirements for RATs as an adjunct test for COVID-19 to guide purchasing decisions of the Department of Health and its accredited COVID-19 testing laboratories:

Requirement Domains	Recommendation
Regulatory requirement	Must have a **certificate of product registration (CPR)** or **emergency authorization (EA)** from the FDA Philippines.
Validation	Must have been validated by an independent or a third-party reputable government or private research institution including but not limited to the following: • Research Institute for Tropical Medicine (RITM) • Department of Science and Technology (DOST) • UP National Institutes of Health (NIH) • 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)
Test Format	A test kit that contains the necessary materials for the procedure, such as: the RAT cartridge, the reagent, droppers/ applicators, and the lancet.
Target Analyte	**Immunoglobulin G, and M, with separate indicators** for each immunoglobulin
Sample Type	**Capillary whole blood** from fingerstick sample
Results Output	**Qualitative,** result must be read visually, without need for a reader/ additional equipment.
Storage, expiration, and stability	The expiration date must not be less than **six (6) months** from date of manufacture. The storage and working temperature must be **18 to 30 °C**. It should be used in a controlled environment. Must **pass the acceptance testing** by RITM at the cost of the winning supplier.
Human resource	Must not require more than the **basic competency** of personnel equipped with skills on **sample collection and proper infection prevention and control (IPC)** procedures.
Viral Antigen Targets	Either **N and S protein**, preferably both, plus other protein targets

Analytical Sensitivity (Gene Targets)	Not specified
Clinical Sensitivity	Must have at least 98% sensitivity at least 2 weeks from symptom onset.
Clinical Specificity	Must have at least 98% specificity
Processing Time	Not more than twenty (20) minutes from sample application.
Reference Standard	Either ELISA or RT-PCR.
Sample Size Requirement in Validation Studies	Positive samples: 70 to 100 Negative samples: 70 to 100 Include details such as: • the specimen type, • the specimen collection date, • date of onset of symptoms (if present), • date of PCR testing, • severity of symptoms (if known), tests used to identify COVID19 patients, etc.

Note: *The sensitivity and specificity thresholds using field validation results must be added to the technical requirements once clinical studies are available.*

Section 8.

References

1 World Health Organization (WHO). (2020). *WHO Coronavirus Diseases (COVID-19) Dashboard*. https://covid19.who.int/ (accessed 13 July 2020)

2 Health Technology Assessment Unit - Policy, Planning, and Evaluation (PPE) Team. (2020). *Rapid Review on Use of Rapid Antibody-Based Test Kits for Various Cases for COVID-19*. Department of Health (Philippines), Sta. Cruz, Manila.

3 Health Technology Assessment Unit - Policy, Planning, and Evaluation (PPE) Team. (2020). *Guidance Document on Technical Requirements for SARS-CoV-2 Rapid Antibody Test Kits as an Adjunct Test for COVID-19*. Department of Health (Philippines), Sta. Cruz, Manila.

4. Cascella M, Rajnik M, Cuomo A, et al. Features, Evaluation and Treatment Coronavirus (COVID-19) [Updated 2020 Jul 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK554776/