

# Performance of Rapid Antigen Test for Coronavirus Disease 2019 (COVID-19)

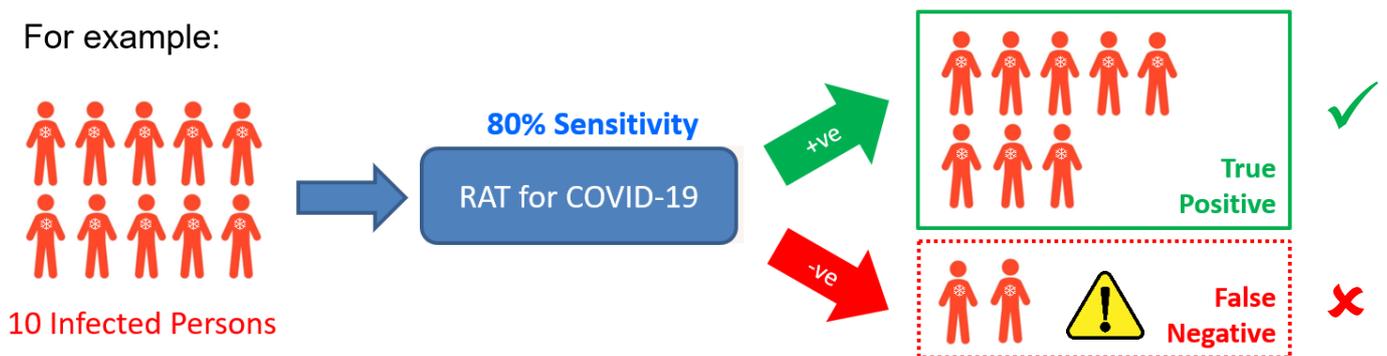
## 1. Introduction

Rapid antigen test (RAT) is one of the screening methods for COVID-19. Most RATs are administered by trained healthcare professionals, but some may be used by laypersons. At present, RATs are less sensitive than nucleic acid test. Therefore, it can only serve as a reference and cannot replace the nucleic acid test which is used for COVID-19 diagnosis. This pamphlet introduces two major performance characteristics (i.e. Sensitivity and Specificity) and the corresponding limitations of RAT.

## 2. Sensitivity

**Sensitivity** of RAT for COVID-19 is the ability to identify positive results from individuals with infection.

For example:



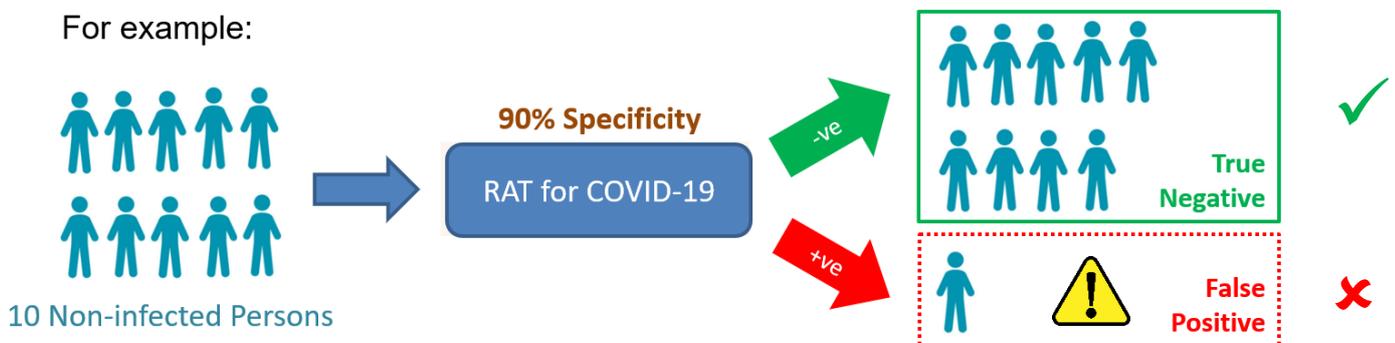
**True Positive** – Infected persons correctly identified by the RAT as positive

**False Negative** – Infected persons incorrectly identified by the RAT as negative

## 3. Specificity

**Specificity** of RAT for COVID-19 is the ability to identify negative results from individuals without infection.

For example:



**True Negative** – Non-infected persons correctly identified by the RAT as negative

**False Positive** – Non-infected persons incorrectly identified by the RAT as positive

## 4. Limitations of RAT for COVID-19

Inaccurate test results		
Potential harms	As the test result indicates the user is not infected, it may lead to the following: - <ol style="list-style-type: none"> <li>1. Spread of the virus to the user's family and the community</li> <li>2. Delay in seeking medical advice</li> </ol>	As the test result indicates the user is infected, it may lead to the following: - <ol style="list-style-type: none"> <li>1. Unnecessary quarantine for the user and his/her close contacts</li> <li>2. Unnecessary anxiety and panic</li> <li>3. Consuming time and resources for further testing</li> </ol>
Possible reasons	<ol style="list-style-type: none"> <li>1. Improper collection, extraction or transportation of specimens</li> <li>2. Improper usage, storage or handling of RATs</li> <li>3. Level of antigen in the sample below the detection limit of RATs (i.e. during window period or in late stage of infection)</li> <li>4. Incapable of screening emerging virus variants using RATs</li> </ol>	<ol style="list-style-type: none"> <li>1. Other similar viruses co-exist in the sample</li> <li>2. Cross-contamination among samples</li> <li>3. Environmental contamination to the sample</li> </ol>

Users with negative result should not rule out the possibility of COVID-19 infection and they should continue to carry out prevention and control measures. Users with symptoms of infection should seek medical attention immediately and follow the instructions of healthcare professionals on further testing.

## 5. Other Important Points:



➤ Users should follow the instructions for use provided by the manufacturer of RAT, including sample collection, reading of result and management of testing sample.

➤ Sample collection is one of the critical factors affecting the performance of any diagnostic test on respiratory fluids, including RAT. Demo video of RAT for COVID-19 can be found in the following website: <https://youtu.be/yzFAUzTtmKk>

➤ The performance of the RAT was affected by various factors, including viral load of the user and the prevalence of the disease.

➤ RAT cannot replace the results of clinical interpretation and other laboratory tests, such as nucleic acid test.

➤ Diagnosis of COVID-19 should be made by healthcare professionals only.

➤ When the test kit indicates positive result, the user should further undergo nucleic acid testing for confirmation and follow-up. More information can be found in the following website: <https://www.coronavirus.gov.hk/eng/early-testing.html#rat>

More information on the Rapid Antigen Test for COVID-19 listed under the Medical Device Administrative Control System can be found in the following website:

<https://www.mdd.gov.hk/en/whats-new/rapid-antigen-tests-covid-19/index.html>

更多資訊 For more information:



醫療儀器科  
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[www.mdd.gov.hk](http://www.mdd.gov.hk)



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