

Rapid Antigen Test (RAT) for COVID-19

1. What is RAT for COVID-19 (RAT)?

RATs are designed to directly detect SARS-CoV-2 virus proteins (antigens) in respiratory specimens. The RAT is intended for qualitative detection of antigens in specimens from individuals with suspected infection in conjunction with the results of clinical interpretation and other laboratory tests. There are different manufactured tests currently available on the market. Most of them require nasal or nasopharyngeal swab samples or deep throat saliva samples. The test is easy to perform and the testing results are usually available within 30 minutes. At present, most RATs are intended for being administered by trained professionals, but some can be done in home setting.

For information on selecting and using RAT kits, public may visit <https://www.coronavirus.gov.hk/eng/rat.html>.

2. What is RAT used for?

Nucleic acid test is at present the gold standard for diagnosis of COVID-19.

Notwithstanding its limitations, RATs may play a role in facilitating access to testing and earlier detection in some people.

If you have COVID-19 symptoms, please seek medical advice and perform testing according to advice of medical professionals.

3. How to choose a suitable test?

The World Health Organization recommends the tests to have a minimum sensitivity of 80% and specificity of 97%.

Purchase from reputable suppliers. Read the product information carefully and understand the type of sample and method of collection required for the test before purchase. Most of the products have the expiry date displayed and members of the public should pay attention before purchasing. If in doubt, please seek advice from healthcare professionals.

The Government accepts RAT kits that have been recognised by the relevant authorities of major markets (including Hong Kong, Mainland, Europe and the United States) as set out below:

- Department of Health, Hong Kong: Listed Rapid Antigen Tests for COVID-19 under the Medical Device Administrative Control System;

- National Medical Products Administration: List of approved medical devices for COVID-19 preventive and control uses;
- European Union: Common list of COVID-19 rapid antigen tests; and
- U.S. Food and Drug Administration: List of SARS-CoV-2 antigen diagnostic tests with Emergency Use Authorization.

For details, please refer to the website: <https://www.coronavirus.gov.hk/eng/rat.html>.

4. How to perform and read the test?

Pay attention to and follow the instructions from the manufacturer to perform the test and read the test result properly. If you need to record the test result, take a photo of the test result immediately after reading the test. If you need assistance on how to conduct and read the test, please seek advice from healthcare professionals.

Observe personal hygiene and environmental hygiene while taking the respiratory specimen. Before starting, gently blow your nose into a tissue paper, dispose the tissue paper properly and then wash your hands. You also need to wash your hands after performing the test. Minimize non-essential items in the specimen collection area. Collect the sample in a well-ventilated place, and keep a distance of at least 2 metres from other people if collecting the specimen at a place in the absence of other persons is not possible. If the environment is contaminated during the process, clean the environment with 1 in 49 diluted bleach solution. For metallic surfaces, use 70% alcohol to disinfect the area.

5. What to do if test result is positive?

Members of the public tested positive by RAT (including vaguely positive with a faint band showing on the test kit), whether distributed by the Government or on their own purchase, should be considered positive cases. Individual product may recommend repeating the test if a vaguely positive result is obtained. Please refer to the instructions for use.

Persons tested positive (including those tested positive by RAT) may visit the website <http://www.coronavirus.gov.hk/eng/tested-positive.html> for relevant information.

6. What to do if test result is negative?

RAT has its limitations in terms of sensitivity, a negative result of RAT should not be fully trusted as it may lead to a false sense of security. A single negative RAT result cannot preclude the possibility that the testee has been infected but during the period of incubation, or at an early stage of infection. Members of the public should remain vigilant and maintain personal protection measures, including wearing masks properly and maintaining personal hygiene. Persons with symptoms or high exposure risk should continue to be tested repeatedly within a short period of time and closely monitor their health conditions. The Government will not accept negative RAT result as a negative result required under compulsory testing.

7. What to do if test result is invalid?

If there is no band appearing in the control region, the test result is invalid. One should check whether the sample type, sample collection method and testing method are correct according to the instructions provided by the manufacturer. If not, repeat the test with correct methods with a new device. If no problem is identified, one may also repeat the test with a new test device. If in doubt, please seek medical assistance.

8. How to dispose of the materials after the test?

Respiratory specimen is a kind of body fluid and is potentially infectious. Therefore, they should be handled with care and disposed of carefully.

After conducting the test, wrap and seal all the product components of the testing kit carefully and dispose properly according to manufacturers' instructions. Wash hands properly afterwards.

9. What is the limitation of the test?

Rapid antigen tests are known to have limitations on their limit of detection and have lower sensitivity as compared with nucleic acid tests. In addition, a positive result can actually be false positive and the positive predictive value is especially low in a low prevalence setting.

Inappropriate self-collection of specimen and self-performance of the rapid antigen test may also affect the sensitivity and reliability of the results, e.g. false negative results. A negative test result cannot completely exclude COVID-19 infection. A false negative result may be obtained when the level of antigen in the sample is below the detection limit of the test, when sample type / collection is improper, or when the test is performed incorrectly.

This test performs better in patients with high viral loads during the pre-symptomatic (1-3 days before symptom onset) and early symptomatic phases of the illness (within the first 5-7 days of illness). The chance of having false negative result will be higher 5-7 days after the onset of symptoms.

More information on Performance of Rapid Antigen Test for COVID-19 can be found in the website of MDD:

<https://www.mdd.gov.hk/filemanager/common/mdacs/RAT-pamphlet-EN.pdf>

10. Is it safe to use and handle RAT?

RATs are safe if handled and used according to the instruction from manufacturer. However, chemicals contained in the solutions used in the test kits may be harmful if swallowed or absorbed inadvertently. Users should follow the instructions for use, including methods of use and disposal. Do not swallow the solutions and avoid contact with eyes and skin. For accidental spillage, rinse with water. Wash hands thoroughly after using the RATs. Tests on children should be performed with adult assistance. Test kits should be kept away from children and pets.