



2nd May 2022

Standards for the importation, sale and use of devices for self-testing for Covid-19 by the public

Preamble

Vaccination, early diagnosis with testing and isolation, quarantine of close contacts, wearing a well-fitted mask, and physical distancing, help in the management of the pandemic by reducing the chances of spreading Covid-19. The availability of self-administered COVID-19 tests can be used as an adjunct to professionally-administered Rapid Antigen Test (RAT) tests and Nucleic Acid Amplification tests (NAAT) such as RT-PCR¹. Latest guidance by WHO considers self-testing to be acceptable, feasible and helps to reduce inequalities in access to testing according to its latest March 2022 guidance². Whilst in Malta, there is no limitation in access to free testing with the various free swabbing facilities available, at this phase of the pandemic, regulated self-testing for COVID-19 can enhance the national testing strategy. The availability of free testing services by the Health Authorities will remain available and will remain the preferred testing modality for diagnostic purposes. Testing using Covid-19 self-test is an individual choice and nobody should be obliged to test oneself. The WHO Guideline Group who reviewed the evidence for self-testing as compared to professionally administered RATs have concluded that the accuracy achieved using self-tests enabled individual risk-based decision making and allowed detection of cases which would otherwise have been missed. This expert group concluded that there was no potential of societal harm however there may be the potential of a false sense of security upon receipt of a negative test which would need to be mitigated using the appropriate information provided by professionals and with

¹ RT-PCR- Reverse Transcriptase Polymerase Chain Reaction test for SARS-CoV-2 which is considered the gold standard

² World Health Organisation. (2022). *Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing*.



informing the general public of the opportunity of re-testing apart from support on the interpretation of results.²

This standard lays out the procedure for importation, distribution and sale of self-testing test with the appropriate characteristics, guidance on when to use a device for self-testing for Covid-19 and how to interpret the outcomes of the test with the assistance of one's GP.

Terminology

'*Rapid antigen test*' (RAT) is a rapid diagnostic test suitable as a COVID-19 Test Kit that directly detects the presence or absence of SARS-CoV-2 antigen. A RAT test is intended for 'professional use only' as a Point-of-Care Test for Covid-19

'*Devices for Self-Testing for Covid-19*' means a testing device for the identification of the presence of Covid-19 which is intended by the manufacturer to be used by persons, not acting within the capacity of health care professionals or health care workers. This Standard is not applicable for devices identifying the presence of antibodies. A kit intended for 'professional use only' must not be sold as a self-test.

'*Reactive result (positive)*' means that the Covid-19 rapid antigen test or Covid-19 self-test has detected the virus in the collected sample.

'*Non-reactive result (negative)*' means that the Covid-19 rapid antigen test or Covid-19 self-test has not detected the virus in the collected sample at the time of testing. This does not rule out an infection.

Use of Devices for Self-Testing for Covid-19

A Covid-19 self-test is for personal use only. This means that the result, whether it's Reactive or Non-reactive cannot be used in any legally binding manner. Therefore, the result of Covid-19 self-test is **not valid** for:

- The generation of a document to be used for travel purposes
- The application for quarantine leave



- To apply for early release from isolation
- For issuing a Recovery certificate

Standards for types of devices for self-testing for Covid-19 which are allowed to be imported and distributed

Only tests with a high specificity and sensitivity in accordance with the recommendations made by the EU Health Security Committee, of $\geq 90\%$ sensitivity and $\geq 98\%$ specificity, are allowed for use in Malta. These criteria would maximise the correct detection of positive cases to include those persons who truly are infected with SARS-CoV-2, minimise false positive cases whilst also providing reassurance that an acceptable proportion of negative tests are truly negative.

Criteria for Validation of Devices for Self-Testing for Covid-19

- Self-test has to be CE marked and certified by a Notified Body intended as a self-test;
- Self-test conforms to the In-Vitro Diagnostic Directive or In-Vitro Diagnostic Regulation's essential requirements for self-testing devices;
- External and internal labelling and instructions for use should be in Maltese or English;
- Only anterior nasal or saliva sampling methods are allowed;
- Self-test kit must contain everything necessary to collect and analyse the specimen, as well as to interpret the result;
- Self-test needs to have minimal sensitivity of 90% or greater for subjects with a Ct < 25 and specificity of 98%;
- Have Two (2) independent evaluations
- Proof of the self-test being authorised by at least one (1) other EU Member States



A national list of Covid-19 self-tests approved by the Malta Medicines Authority (MMA) can be found <https://medicinesauthority.gov.mt/medicaldevices>.

When purchasing a self-testing test ensure that:

1. the test is one of those listed on the MMA website
2. the expiry date is in line with the date of intended use of the test
3. the tests are stored according to the recommended instructions and out of direct sunlight
4. there are clear instructions on how to perform the testing including details on the interpretation of the result.

Do not open the package of the individual test kit until immediately prior to use

Sale of devices for Self-Testing for Covid-19

The sale of self-tests for Covid-19 is **limited to pharmacies across Malta and Gozo**. This is to allow pharmacists to clearly explain how these tests should be used, providing the necessary information to minimise the degree of error when patients carry out the self-test.

Self-Tests for Covid-19 need to be approved by the Malta Medicines Authority. Therefore, pharmacies offering such self-tests need to ensure that their supplier has undergone the proper validation process. This can be confirmed by requesting the Authority issued Self-Test Notification Letter from the supplier.

Covid-19 self-tests cannot be sold in any other setting or location under current legislation.

Criteria for Use of Covid-19 Self-Test

A self-test can be used in the following instances for **diagnostic purposes** (1 & 2) and for **screening purposes** (3)

1. If you were a close contact of a positive Covid-19 case
2. If you have symptoms of Covid-19 – up to 5 days from symptom³ onset
3. If you wish to test before a gathering or meeting persons who may be clinically vulnerable

When to test

1. If one has symptoms, testing should take place immediately but certainly within the first 5-7 days of onset of symptoms.
2. If one has no symptoms but has had a known close contact exposure to a positive case one can also self-test. The ideal timing for this would be around 2-4 days after the last exposure. If one self-tests negative immediately upon learning of close contact, it is advised that the self-test or a professional test is repeated after 2 days or immediately if one becomes symptomatic.
3. When testing for screening purposes (no symptoms and no known exposure to a positive case) prior to attending an event or meeting clinically vulnerable persons, the test should take place as close as possible to the event in question.

Symptomatic person

A person with symptoms who receives a non-reactive (negative) result should remain home in isolation until symptoms resolve. A negative test does not provide certainty that the individual does not have Covid-19 - this could be a false negative test. If symptoms do not

³ Symptoms of Covid-19 include cough, fever, shortness of breath and sudden onset of anosmia, ageusia or dysgeusia. Additional less specific symptoms may include sore throat, runny nose, nasal obstruction, headache, chills, muscle pain, fatigue, vomiting and/or diarrhoea and confusion, but may also include other symptoms

resolve the Covid-19 test should be repeated within 24-48 hours, more so if one had a known close contact exposure to a positive case.

In the case the self-test result is reactive (positive), the patient should call his GP to obtain guidance on clinical management and on Isolation/Quarantine of household members in line with the [Standards for Isolation and Quarantine](#).

Please note that an official isolation mandate will be received only if an official test is performed at a registered swabbing centre (public or private) through the positive result. When testing positive with a self-test, absence certification for work/school (for the case) would need to be requested from one's caring GP.

If one has been exposed to Covid-19

If one has had a high-risk encounter with a person with Covid-19 and one would like to check whether he/she got infected, a Covid-19 self-test can be performed.

This should be performed immediately if symptomatic otherwise one could test 2-4 days after the last contact. If one decides to test immediately upon learning of the exposure and the result is non-reactive, one should consider repeating this test after a couple of days or immediately upon appearance of symptoms.

Screening

One may decide to screen prior to attendance at a mass event or prior to attending a social event where there may be vulnerable persons. Considering the current sustained community spread a reactive result (positive) would be considered a probable covid-19 case.

Interpretation of Results of a Device for Self-Testing for Covid-19

The following protocols need to be followed depending on the self-test result obtained.

In the case of a Reactive (Positive) self-test result:

- Contact your GP for further clinical assistance and guidance



- It is recommended to have a NAAT or Rapid Antigen Test (RAT) by a health professional. One can apply at <https://covidtest.gov.mt/> or by calling the Helpline 111 or book through a private licensed designated centre
- A reactive test requires the patient to self-isolate until symptoms resolve or NAAT or Rapid Antigen Test (RAT) has been performed

In the case of Non-Reactive (Negative) self-test result:

- A negative test does not provide certainty that the individual does not have Covid-19
- A person with symptoms should still self-isolate until 24 hours after symptoms resolve
- If symptoms do not resolve the Covid-19 test should be repeated within 24-48 hours

Current Isolation / Quarantine Measures for positive cases and household contacts

Details on current isolation/ quarantine measures in place can be found on [Standards for Isolation of cases and quarantine of close contacts](#)