

12th February 2021

COVID-19 – Standards on the use of Point-of-Care Rapid Antigen Tests for SARS-CoV-2

The following standards are issued under the Public Health Act Chapter 465 of the Laws of Malta and the Prevention of Disease Ordinance Chapter 36¹, and Legal Notice 49/2021 titled ‘Delivery and Testing of COVID-19 using Point-of-Care Rapid Testing, Regulations 2021’².

THESE STANDARDS MUST BE METICULOUSLY ADHERED TO BY EVERYONE INVOLVED

Preamble

Testing to detect persons infected with the SARS-CoV-2 virus is the cornerstone of Malta's COVID-19 strategy. The availability of **point-of-care rapid antigen tests (RAT)** using antigen detection technology will help to further consolidate this approach. Wider testing and the application of emerging approaches can lead to better management and containment of the pandemic. These standards provide the procedural and regulatory requirements to carry out RAT testing for the SARS-CoV-2 virus. These standards apply to all persons designating their premises for RAT testing, healthcare professionals who administer and manage the results of RATs and to patients who present to and undertake these tests.

A RAT is at its highest sensitivity potential to detect cases when the viral load is high and in pre-symptomatic and early symptomatic cases (up to 5 days from symptom onset). These cases account for a significant proportion of transmission.

¹ Prevention of Disease Ordinance (Chapter 36)

Restriction of movement of person suspected of disease.

13. (1) Where the Superintendent (of Public Health) has reason to suspect that a person may spread disease he may, by order, restrict the movements of such person or suspend him from attending to his work for a period not exceeding four weeks, which period may be extended up to ten weeks for the purpose of finalising such microbiological tests as may be necessary.

(2) Any person who acts in contravention of the provisions of this section shall be guilty of an offence against this Ordinance.

² LN. 49 of 2021 MEDICINES ACT (CAP. 458) Delivery and Testing of COVID-19 using Point-of-Care Rapid Testing, Regulations 2021

WHO recommends testing kits that meet the minimum performance requirements of $\geq 90\%$ sensitivity and $\geq 97\%$ specificity. These standards refer to the rapid tests which are approved for use locally, which list will be published in the Government Gazette and available to view on <https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Pages/covid-19-infographics.aspx>.

RATs are rapidly developing technologies for the detection of SARS-CoV-2. These standards are aligned with the interim guidance published by World Health Organisation which is constantly being updated. However, it is very important to note that while RATs offer helpful solutions for the diagnosis of SARS-CoV-2 infection in a range of settings and scenarios, their clinical performance is not yet optimal and **great caution should be exercised especially in the interpretation of and the consequences following a positive or negative test result.**

These standards are applicable for use by any healthcare professional who performs such tests according to the Regulations for the Delivery and Testing of COVID-19 using Point-of-Care Rapid Testing in both public and private settings.

Criteria for Testing with RATs

Testing with RATs is indicated in the following situations:

1. Symptomatic close contacts of 'notified'³ positive cases (immediate booking of swab).
2. Asymptomatic close contacts of 'notified' positive cases, if indicated (pre-booking of contacts within 5-7 days of contact with positive case).
3. Persons with early symptoms (up to 5 days from symptom onset)
4. Persons from specific settings for outbreak investigation and rapid isolation of persons when 'presumed positive' by a rapid test, e.g. long-term care facilities, correctional and detention facilities, outbreaks in schools. This will be carried out at the discretion of the Public Health Authorities following risk assessments of specific situations.

³ The term 'notified' is being used to imply ALL persons who have been informed that they are positive from a RT-PCR test whether or not they have been already contacted by the Public Health COVID-19 Response Team

5. Persons from specific settings for rapid detection of new cases and for repeated or periodic testing purposes, e.g. airport. This will be carried out at the discretion and authorisation of the Public Health Authorities following risk assessments of specific situations.

Administration of test

The processes described below are illustrated in the flow-chart in Annex A.

- RAT may then be requested through the COVID-19 Helpline (111 or +356 21324086) in the public setting, or else in the private sector in designated premises by licenced healthcare professionals as per Regulations for the Delivery and Testing of COVID-19 using Point-of-Care Rapid Testing
- The RAT requires the extraction of a mucus sample extracted from the upper respiratory passages, most typically from the nasopharynx. This must be administered ONLY by a trained health care professional (medical practitioner, dental surgeon, nurse, midwife, pharmacy technician, pharmacist) or by a healthcare worker under the direct supervision of a licensed healthcare professional. The test is analyzed at the same venue where the sample is collected. The test result can be read after 20-25 minutes. Manufacturer instructions for sample collection, safe handling, waste management and use need to be followed precisely.
- The person administering the test must wear the correct personal protective equipment (PPEs), including FFP2/N95 mask, haircap, long-sleeve water-proof gown, disposable non-sterile gloves, protective eyewear such as a face shield or safety goggles. The double gloving technique should be applied, and the outer set of gloves are changed between clients that are tested after each other. The test administrator must use the correct technique and procedure for the proper donning and doffing of PPEs (see Annex B). The appropriate designated spaces for donning and doffing of PPEs and for the swabbing of the clients need to be identified, clearly demarcated and observed.
- Ideally consecutive appointments are given for RATs to patients so that they can be conducted in one session on the same swabbing site with the intention that donning

and doffing procedures are kept to a minimum. Proper hand hygiene should be performed, in between patients, as per MFH protocols⁴.

- The RAT must be administered in a controlled environment that has adequate ventilation. After administering the test, the surfaces used in the testing process need to be cleaned using appropriate disinfecting chemicals and techniques before another client is admitted. An application is to be submitted to the Medicines Authority on application available at <http://www.medicinesauthority.gov.mt/mdforms> in order to obtain approval for the designation of a premises for the carrying out of point of care tests.
- The test administrator must provide the test result to the client in a pre-agreed format. Ideally the client is contacted soon after the result is available, and the test result is sent via mobile phone or email. The procedures described below will need to be followed according to whether the RAT result is positive or negative.

⁴ <https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Pages/mitigation-conditions-and-guidances.aspx>

Results of the test

The following procedures need to be pursued according to whether the test result is Reactive (positive) or Not Reactive (negative).

A. In the case of a Reactive (positive) RAT result and the patient FITS Criteria 1, 2, 3 and 4 of the 'Criteria for Testing with RATs':

1. The test result must be reported to the PH COVID-19 Response Team using the web application available through this link: <https://covidrapidtest.gov.mt/>, within 24-36 hours
2. These patients are considered COVID-19 positive and COVID-19 RT-PCR test is not required in such instances. The patient must be instructed to remain in self-isolation until contacted by Public Health Authorities (as per the Prevention of Disease Ordinance)¹. Once Public Health Authorities take over the management of the public health aspects of this patient including contact tracing, they will be placed into mandatory quarantine for at least 14 days.

B. In the case of a Reactive (positive) RAT result and the patient DOES NOT fit Criteria 1, 2, 3 or 4 of the 'Criteria for testing with RATs':

1. The test result must be reported to the PH COVID-19 Response Team using the web application available through this link: <https://covidrapidtest.gov.mt/>, within 24-36 hours.
2. A confirmatory COVID-19 RT-PCR test is required in such instances. The test administrator must advise the patient to order a RT-PCR test. The patient can undergo a PCR test either by completing and submitting an application to <https://covidtest.gov.mt/> or by calling the Helpline 111 or through a private licenced medical diagnostic laboratory. The patient will be allotted a priority appointment

for a confirmatory RT-PCR test. The confirmatory RT-PCR test needs to be performed soon after the issue of the positive RAT result (max. 36 hours).

3. Patients must be instructed to remain in self-isolation until the confirmatory RT-PCR result is issued (as per the Prevention of Disease Ordinance)¹.
4. Public Health Authorities will take over the management of the public health aspects of the patient in the event of a confirmatory positive RT-PCR test. Public Health Authorities also retain the right to start contact tracing procedures based on a reactive RAT.

C. In the case of Not Reactive (negative) RAT results:

1. The test result must be reported to the PH COVID-19 Response Team using the web application available through this link: <https://covidrapidtest.gov.mt/>.
2. Patients with symptoms who get a Not Reactive (negative) test result must be instructed to remain in self-isolation for at least 24 hours following the complete resolution of the symptoms. Patients are to call Helpline 111 if symptoms persist or recur, to book another swab test.

Notes on the interpretation of RAT results:

- i. Interpreting a Not Reactive (negative) result must consider the clinical context of the test (asymptomatic vs symptomatic) and the pre-test probability of infection in the person tested.
- ii. Not Reactive (negative) results for persons that have a low pre-test probability, do not need to go into self-isolation if asymptomatic.

The table below illustrates the relationships between pre-test probability and the likelihood of positive and negative predictive values⁵.

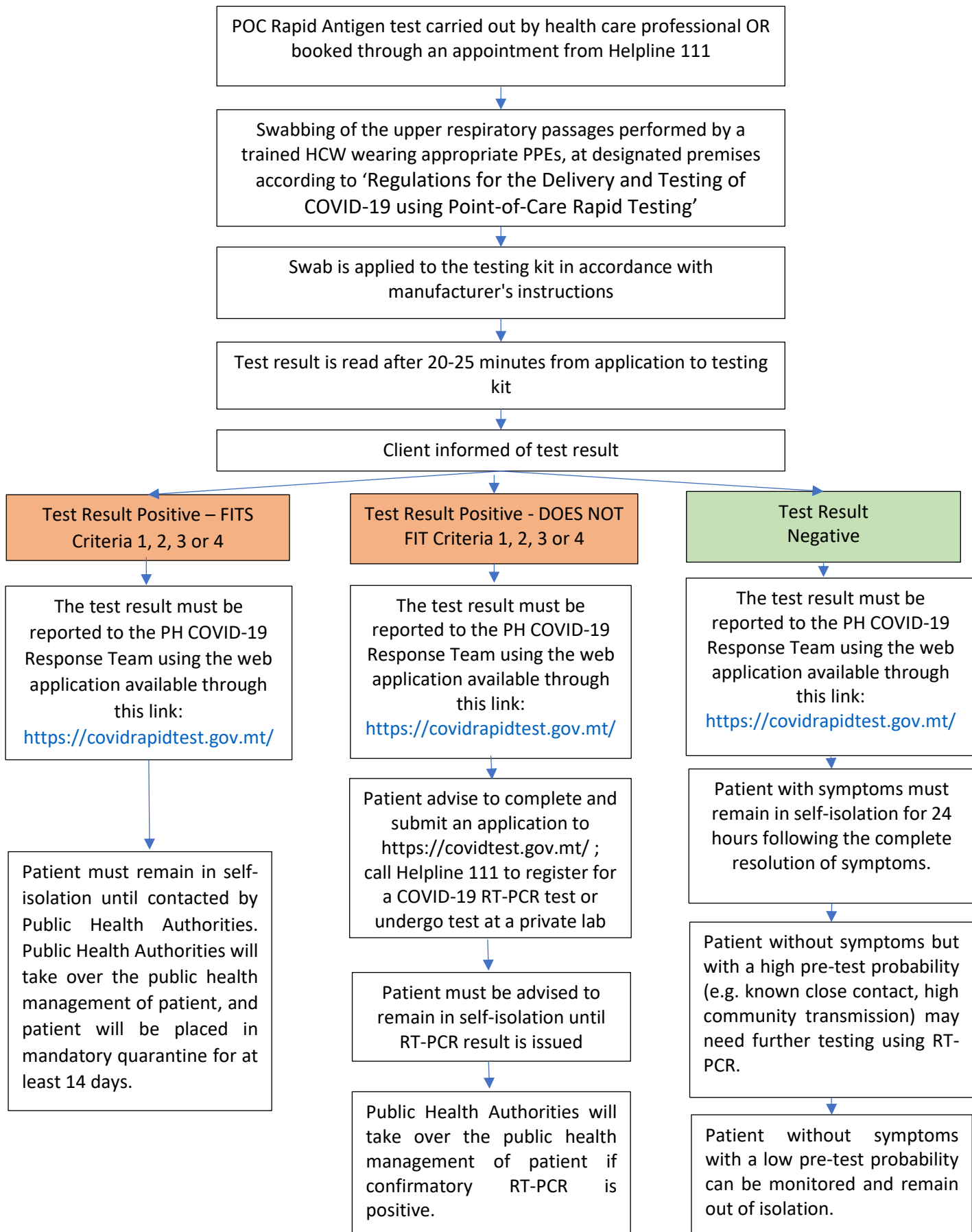
Pretest Probability*	Negative Predictive Value**	Positive Predictive Value**	Impact on Test Results
Low	High	Low	Increased likelihood of False Positives Increased likelihood of True Negatives
High	Low	High	Increased likelihood of True Positives Increased likelihood of False Negatives

*Sensitivity and specificity of tests are generally stable and not affected by pre-test probability.

**Predictive values are affected by pre-test probability.

⁵ Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, Centres for Disease Control and Prevention (September 2020). Accessible from: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#table3>

Annex A: Flowchart illustrating all the procedures described in the Standards



Annex B - Use of Personal Protective Equipment (PPE) by healthcare professionals administering a RAT

- Staff should wear a FFP2 or N95 mask and a visor when providing a service to a client. The face mask should completely cover the face from the bridge of the nose down to the chin. Clean hands with soap and water or alcohol-based hand sanitiser before putting on and taking off the face mask. When taking off the face mask, remove it from behind, avoiding touching the front side. Dispose of the face mask safely by placing it in a plastic bag and put it in the trash if it is disposable. Wash your hands or apply 70% alcohol hand-rub immediately after removing the face mask.
- Face masks are not intended to be used more than once. If your mask is damaged or soiled, or if breathing through the mask becomes difficult, you should remove the face mask, discard it safely, and replace it with a new one.
- Visors should ideally be the reusable type, should reach below one's chin and should be disinfected appropriately when doffing.
- The double gloving technique should be applied, and the outer set of gloves are changed between clients that are tested after each other.
- Proper hand hygiene should be performed in between patients.
- A disposable gown should be worn and changed when doffing.

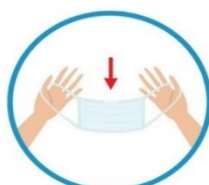
Used PPEs, swabs and kits should be disposed of safely in a yellow biohazard bags.



Wash your hands
with soap and water or
sanitizer before touching
the mask



Inspect the mask
for tears or holes



Find the top side
where the metal piece
or stiff edge is



Hold the mask from the
elastic loops and place it
on your face. Ensure the
coloured-side faces
outwards



Avoid touching the
front side of the mask
while putting it on
your face



Place the metal piece
or stiff edge over
your nose



Cover your mouth,
nose and chin. Do not
leave gaps on the side



Remove the mask from
behind the ears or from
the elastic loops



Keep the used mask
away from you and
surfaces once it is
removed



Dispose of the mask
immediately after use
in a safe way



Wash your hands
either with soap and
water or sanitizer after
discarding the mask