

Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 20,698, 10 ta' Settembru, 2021

Taqsimha B

L.N. 357 of 2021

**MEDICINES ACT
(CAP. 458)**

Testing of COVID-19 Regulations, 2021

IN EXERCISE of the powers conferred by article 106 of the Medicines Act, the Minister responsible for public health, after consultation with the Licensing Authority, has made the following regulations:-

1. The title of these regulations are the Testing of COVID-19 Regulations, 2021. Citation.

2. In these regulations, unless the context otherwise requires: Interpretation.

"Act" means the Medicines Act; Cap. 458.

"Authority" means the Medicines Authority established under article 4 of the Act;

"COVID-19" means a disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus;

"COVID Result Submission Malta" means the COVID-19 Result Submission Web Application;

"COVID-19 Test Kit" means an in-vitro diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test for the identification of the presence of SARS-CoV-2 or any other marking agent related to it;

"COVID-19 Testing" means testing for the SARS-CoV-2 virus by means of a nucleic acid amplification test, a rapid antigen test, or an antibody test;

"designated premises" means any premises designated pursuant to regulation 5;

"device for self-testing" means any testing device for the identification of the presence of COVID-19 or any other marking agent related to it and which is intended by the manufacturer to be used by persons not acting within the capacity of health care professionals or health care workers or not carrying out COVID-19 Testing within designated premises;

Cap. 464. "health care professional" shall have the same meaning as assigned to it by article 2 of the Health Care Professions Act;

"health care worker" means a person who is trained to deliver care and services to the sick and ailing but who is not a health care professional;

"nucleic acid amplification test" or "NAAT" means a type of viral diagnostic test for COVID-19 which specifically identifies the RNA (ribonucleic acid) sequences that comprise the genetic material of the virus, including but not limited to a reverse transcription polymerase chain reaction (RT-PCR) test;

"Point-of-Care Test for COVID-19" means any test that does not require the submission of the test specimen to a laboratory and that is intended to be used to detect and identify the presence of SARS-CoV-2 or any other marking agent related to it;

"rapid antigen test" or "RAT" means a rapid diagnostic test suitable as a Point-of-Care Test for COVID-19 that directly detects the presence or absence of SARS-CoV-2 antigen;

"Regulation (EU) 2016/679" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);

Cap. 465. "Superintendent" shall have the same meaning as assigned to it by the Public Health Act.

General principles. **3.** (1) COVID-19 Testing is to be carried out in line with these regulations and any other applicable regulations. For the avoidance of any doubt these regulations shall apply to all health care professionals, health care workers and designated premises whether operating within the public health system or otherwise:

Provided that regulation 9 shall not apply to antibody tests.

Cap. 465. (2) Any health care professional who performs a Point-of-Care Test for COVID-19 shall follow the Standards - Point-of-Care Rapid Antigen for SARS-CoV-2 issued by the Superintendent under article 4(c) of the Public Health Act.

Obligations when you carry a Point-of-Care Test for COVID-19. **4.** Any person intending to carry out a Point-of-Care Test for COVID-19 shall:

(a) do so on designated premises;

(b) use a Point-of-Care Test for COVID-19 that is approved by the Authority;

(c) be a health care professional or a health care worker working under the direct supervision of a health care professional; and

(d) comply with the reporting obligations laid down in regulation 9.

5. (1) Any person who wishes to designate their premises for the carrying out of Point-of-Care Tests for COVID-19 shall submit an application to the Authority indicating: Designated premises.

(a) the name and address of the premises;

(b) the name, surname and contact details of the responsible health care professional; and

(c) a declaration that the premises meet the general safety and performance requirements set out by the Authority.

(2) Where a person to be tested is house bound or quarantined, a Point-of-Care Test for COVID-19 may, in exceptional circumstances, be carried out at the person's residence by a health care professional. In these cases, reporting of the test result shall still be required and must be submitted through COVID Result Submission Malta.

(3) The Authority shall issue a certificate of approval for each designated premises pursuant to these regulations, and no premises shall be permitted to commence such testing unless so approved.

6. (1) The Authority shall monitor and review any operations conducted within designated premises to ensure that they are carried out in accordance with the provisions of these regulations and in compliance with any decision taken by the Authority. Monitoring and review of operations.

(2) For the purposes of this regulation, the Authority or any person so authorised, shall have the right at all reasonable times and, where necessary, with the assistance of the Executive Police, to enter and inspect any designated premises.

7. (1) Any person who wishes to place a COVID-19 Test Kit on the Maltese market shall submit an application to the Authority for approval. List of approved COVID-19 Test Kits.

(2) A list of approved COVID-19 Test Kits shall be published in the Gazette by the Superintendent which list shall also be made

available on the official COVID-19 website.

Issuance of approval.

8. The Authority shall issue its approval or rejection for designated premises and COVID-19 Test Kits following the consideration of all relevant documents, and any other information as may be deemed necessary in order to ensure fulfilment of the authorisation requirements submitted by the applicant:

Provided that the Authority may, in its own discretion, request additional information it deems necessary for the evaluation of the application.

Reporting obligations for all tests.

9. Any health care professional who performs COVID-19 Testing shall, without prejudice to any regulation herein, be required to report the results of all tests carried out and related personal data to the Superintendent for each test and shall also report all details pursuant to the Schedule using the COVID Result Submission Malta:

Provided that health care professionals forming part of Malta's public health system and health care workers working in Malta's public health system under the direct supervision of a health care professional shall not be required to submit test results through COVID Result Submission Malta if they have already been submitted through another public health information system.

Public health interest.

S.L. 427. 16.

10. (1) The Authority may, where it so deems necessary, restrict market access to COVID-19 Test Kits in the interest of public health and in accordance with the In Vitro Diagnostic Medical Devices Regulations.

(2) Devices for self-testing shall not be made available, put into service, distributed or used in Malta.

(3) The sale of COVID-19 Test Kits by distributors directly to the public shall be prohibited.

Advertising.

11. In the advertising of COVID-19 Test Kits, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the person to be tested with regard to the device's intended purpose, safety and performance:

Provided that any advertisements which are in violation of these regulations shall be amended, replaced or removed as necessary.

Data protection. Cap. 586.

12. (1) Nothing in these regulations shall prejudice the applicability of the Regulation (EU) 2016/679 and the Data Protection Act and the fundamental rights and freedoms of data subjects.

(2) Where the Superintendent in his capacity of a controller

processes the personal data listed in the Schedule through the COVID Result Submission Malta for reasons of public interest in the area of public health pursuant to Articles 6(1)(e) and 9(2)(i) of Regulation (EU) 2016/679, he shall:

(a) comply with all the principles relating to the processing of personal data pursuant to Article 5(1) of Regulation (UE) 2016/679; and

(b) apply appropriate technical and organisational measures to ensure a level of security appropriate to the risk posed, and prevent abuse or unlawful access to or transfer of, personal data pertaining to the data subjects.

(3) The controller shall only process personal data which is strictly necessary for the purposes of these regulations:

Provided that the controller shall retain the personal data of the data subjects, including the information in relation to the test performed on the data subjects for the purposes of these regulations, for a period of two (2) years from the date of the performance of the test.

(4) Data subjects shall have the right to exercise their data protection rights pursuant to Chapter III of Regulation (EU) 2016/679 in relation to any personal data processed by the controller.

13. Whenever, after assessing the circumstances surrounding COVID-19, the Superintendent deems that the use of COVID Result Submission Malta is no longer necessary, the Superintendent shall:

Decommission
of the
application.

(a) decommission COVID Result Submission Malta; and

(b) cease to process any personal data under these regulations.

14. Any person who fails to abide by the provisions of these regulations shall be guilty of an offence and shall, on conviction, be liable to the payment of a penalty of not less than one hundred euro (€100) and not more than five hundred euro (€500) for each and every instance in which these regulations are breached.

Offences and
penalties.

15. The Delivery and Testing of COVID-19 using Point-of-Care Rapid Testing Regulations are hereby repealed and this without prejudice to the validity of anything done or omitted to be done on the basis thereof.

Repeal and
saving.
S.L.458. 60.

SCHEDULE

Data to be submitted to the Superintendent with each notified test result:

- (a) tested person's identification document number (in order of preference: Malta identity card number or passport number or Malta hospital identity number);
 - (b) tested person's first name and surname;
 - (c) tested person's date of birth;
 - (d) tested person's sex according to official documentation;
 - (e) tested person's nationality;
 - (f) tested person's contact number in Malta (a mobile number is preferred);
 - (g) tested person's email address (when available);
 - (h) tested person's postal address in Malta;
 - (i) test type;
 - (j) test name (only in case of rapid antigen test);
 - (k) test manufacturer (only in case of rapid antigen test);
 - (l) testing facility name;
 - (m) test result;
 - (n) test reason (only in case of rapid antigen test);
 - (o) test specimen collection date and time; and
 - (p) test result date and time (only in case of nucleic acid amplification test).
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