TURKS AND CAICOS ISLANDS

PUBLIC AND ENVIRONMENTAL HEALTH (TESTING OF COVID-19) REGULATIONS 2020

(Legal Notice 35 of 2020)

ARRANGEMENT OF REGULATIONS

REGULATION

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PUBLIC AND ENVIRONMENTAL HEALTH (TESTING OF COVID-19) REGULATIONS 2020

(Legal Notice 35 of 2020)

MADE by the Governor under section 62(1) of the Public and Environmental Health Ordinance for giving effect to any recommendations made by the Public and Environmental Health Board.

Citation, commencement and expiry

1. (1) These Regulations may be cited as the Public and Environmental Health (Testing of COVID-19) Regulations 2020 and comes into operation on publication in the *Gazette*.

(2) These Regulations, if not earlier revoked, shall expire at the end of two years from the date it was made unless extended by the Governor for a specified further period.

Interpretation

2. In these Regulations—

"Covid-19" means the disease known as Coronavirus;

"Director" means the Director of the National Public Health Laboratory;

"health care facility" means premises at which health services are provided by a registered and licensed health practitioner;

"health services" means services where the collection and testing of specimens can be conducted under these Regulations;

"Ministry" means the Ministry responsible for health;

"PAHO" means the Pan American Health Organization;

"PCR testing" means a Polymerase Chain Reaction (PCR) testing procedure used for purposes of identifying the virus;

"suspect case definition" means the WHO's suspect case definition for Covid-19 as defined by the World Health Organization from time to time and as may be published by the Chief Medical Officer for purposes of the Islands;

"virus" means the virus known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is the virus responsible for the disease Covid-19;

"WHO" means the World Health Organization;

"WHO guidelines" means the WHO Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV).

Clinical Management of testing COVID-19

3. The Chief Medical Officer shall be responsible for the clinical management and outbreak control for the rapid collection and testing of specimens from patients meeting the suspect case definition for the virus and in doing so, shall work in collaboration with the public health officials and the Director.

Testing

4. (1) The National Public Health Laboratory is the approved laboratory responsible for testing for the virus in the Islands, except as otherwise provided in these Regulations.

(2) Every patient who meets the suspect case definition shall be tested for the virus regardless of whether another respiratory pathogen is found.

(3) No health care facility shall provide testing for the virus but shall only collect a specimen from a patient meeting the suspect case definition and submit it to the National Public Health Laboratory.

(4) Notwithstanding subregulation (3), the Chief Medical Officer may, where a need arises to supplement the testing capacity available for the Islands and of the National Public Health Laboratory, approve an application by a health care facility to test patients for the virus if the health care facility satisfies the following—

(a) if the health care facility has the approved testing equipment and protocols;

(b) if the health care facility has registered and licenced personnel who have been appropriately trained to deal with testing for the virus;

(c) if the health care facility satisfies the standards for laboratory services issued by the Ministry;

(d) if the health care facility has Standard Operating Procedures (SOPs) and protective equipment for staff to ensure safe and proper specimen collection, transportation of the specimen, clinical specimen storage and the destruction of the

specimen safely and confidentially, (i.e., the protocols for collecting, identifying, processing, transportation and disposing of specimens tested or that may be tested periodically); and

(e) if the health care facility can deliver the specimen or results in a timely manner and provide a report which indicates who delivered and received the specimen or results and that it was delivered and reported only to the persons authorized to receive such specimen or results and report.

(5) In order for the testing equipment and protocols to be approved in terms of subregulation (4)(*a)*, the equipment has to satisfy the WHO and PAHO equipment requirements and certifications.

(6) An application made under subregulation (4) shall be made in the Form set out in the Schedule and shall be accompanied by—

(a) a list of all existing, relevant or approved testing equipment and safety Standard Operating Procedures (SOPs) and testing protocols;

(b) a list of registered and licenced personnel who will manage the testing at the health care facility;

(c) proof that the registered and licensed personnel have undergone the requisite training for the conduct and management of the testing of the virus;

(d) a copy of a valid business licence; and

(d) a completed checklist indicating that the health care facility satisfies the requirements.

(7) An approval made by the Chief Medical Officer under this Regulation shall be made in writing and shall specify the conditions of approval.

Testing by rapid lateral flow test

5. (1) A health care facility may conduct a test by use of a rapid lateral flow test kit.

(2) A test conducted by using a rapid lateral flow test kit does not diagnose the virus and shall not be used for diagnostic purposes, but can only determine whether a person has been exposed to Covid-19.

(3) A health care facility which wishes to conduct a test on a patient by using a rapid lateral flow test kit shall—

(a) ensure the test is conducted by a registered and licensed health practitioner;

(b) submit the test kit for vetting and approval by the Ministry;

(c) not use the test kit to diagnose the virus;

(d) ensure that a health practitioner fully discloses to the patient orally and in writing, that the test kit is not used to diagnose the virus and that the results of the test shall not be interpreted to determine whether the patient is positive or negative of the virus, but that it is used to determine whether the patient has been exposed to Covid-19; and

(e) put in place Standard Operating Procedures (SOPs) and testing protocols for use of the test kit.

(4) A health practitioner who conducts a test in the manner specified in subregulation (3) shall, where he believes that a patient meets the suspect case definition—

(a) collect specimen for testing in terms of regulation 6 and transport it to the National Public Health Laboratory in terms of regulation 7; or

(b) if the health care facility is approved to conduct tests for the virus under regulation 4(4), conduct the test.

(5) Regulations 8, 9 and 10 shall apply to specimens collected and tests conducted by a health care facility under subregulation (4).

Collection of specimen

6. (1) A health care facility which seeks to collect specimens of the virus—

(a) shall put in place adequate safety Standard Operating Procedures (SOPs) in accordance with the WHO's guidelines; and

(b) shall have staff who are trained for collection of the specimen of the virus, storage, packaging and transportation of the specimen to the National Public Health Laboratory for testing.

(2) A health care facility shall ensure that health professionals who collect specimens comply with the WHO's guidelines.

(3) All specimens collected and submitted to the National Public Health Laboratory shall be accompanied by the relevant

forms which must be completed in order for testing to be carried out.

(4) The relevant forms referred to under subregulation (3) shall be issued by the National Public Health Laboratory or published by the Ministry on the government website or by any means, from time to time.

Transportation of specimen

7. (1) Every specimen collected from a health care facility shall be transported to the National Public Health Laboratory for testing or investigation, except for specimen collected and tested at an approved health care facility.

(2) Any specimen collected and transported to the National Public Health Laboratory or to any regional reference laboratory testing shall be regarded as potentially infectious.

(3) All specimens shall be transported according to the standards set in the WHO guidelines.

Types of testing

8. (1) The National Public Health Laboratory shall adopt PCR testing of collected specimens or any new WHO or PAHO approved serological testing technologies for patients who meet the suspect case definition.

(2) The National Public Health Laboratory screening protocols for suspected cases shall include screening for the virus with nucleic acid amplification tests (NAAT), such as RT-PCR.

Referral of testing

9. Whenever testing for the virus is not available at the National Public Health Laboratory, the Chief Medical Officer shall refer testing and receive test results from regional reference and international laboratories designated by the Ministry.

Testing and results

10. (1) Where a health care facility is approved for testing of the virus, the health care facility shall submit the results to the National Public Health Laboratory in a timely manner, along with the specimen; and the results shall be in such form as may be issued by the National Public Health Laboratory or published by the Ministry on the government website or by any means, from time to time.

(2) All test results received by the National Public Health Laboratory from the approved health care facilities within the

Islands and from the regional or international reference laboratories designated by the Ministry shall be forwarded as official and verified by the Director to the Chief Medical Officer.

(3) On receipt of the official and verified results, the Chief Medical Officer shall cause and enhance national reporting and the public health function to quarantine and conduct contact tracing in accordance with the Public and Environmental Health (Control Measures)(COVID-19) Regulations 2020.

Duty to provide information

11. The Chief Medical Officer may request any person to provide to the Chief Medical Officer with information relevant to the testing of the virus in the Islands and such other information the Chief Medical Officer considers necessary to assess whether adequate and safe measures are in place to conduct testing of the virus and to assess what precautions should be taken to prevent the spread of the virus in the Islands.

Offences

12. A person who—

(a) conducts testing for the virus for suspected cases without the written approval of the Chief Medical Officer;

(b) contravenes the specified conditions for the testing of suspected cases as approved by the Chief Medical Officer;

(c) in executing the approved testing for the virus, wilfully or by culpable negligence fails to ensure personnel access and adherence to the Standard Operating Procedures (SOPs) for safe specimen collection, identification, processing, transportation, storage, confidential result delivery, and disposing of specimens tested;

(d) fails to report results in sufficient details as required in a timely manner;

(e) does or permits or suffers any act likely to lead to the infection of any other person,

commits an offence and is liable to a fine or to a term of imprisonment, or to both.

SCHEDULE

(Regulation 4(6))

APPLICATION FOR APPROVAL TO TEST FOR COVID-19

Name of Applicant : _____

Name of Healthcare Facility : _____

Address of Healthcare Facility : _____

_____

Telephone: _____

Email: _____

Head/Medical Laboratory: _____

Chief Medical Technologist of the Healthcare Facility Laboratory:

_____

Type of Facility: : [ ] Hospital Based [ ] Free standing

_____

Checklist of Application Documents

✓ Please tick to confirm the requisite document is provided in column B

✓

A Documents	B
1. Declaration of Employment and Standard Operating Procedure (SOP) Letter denoting: 1.1 Verification of Laboratory Personnel Employment i.e., - • Employee Name • Period of Employment • Declaration that employee's training covers testing for the COVID-19 virus with the equipment approved by the Ministry of Health. 1.2 Declaration that the Laboratory has: • Established written SOPs to which the staff adheres (for safe and proper specimen collection, transportation of the specimen, clinical	[ ]

specimen storage and the destruction of the specimen safely and confidentially, (i.e., the protocols for collecting, identifying, processing, transportation and disposing of specimens tested or that may be tested periodically). • Made the SOPs available for examination by the Ministry of Health along with the authorized person, in the employment of the healthcare facility, to give all reasonable assistance with and to answer all questions relating to the examination.	
2. Proof of Licensure of the laboratory staff including (per attached form): • Registration Number: • Licence Number • Licence Period	[ ]
3. List of Ministry of Health approved COVID-19 Testing Equipment at the healthcare facility (per attached form) and, also, make available the packaged, manufacturer Equipment Specification Data Sheets and other aligned information for examination by the Ministry of Health along with the authorized person, in the employment of the healthcare facility, to give all reasonable assistance with and to answer all questions relating to the examination.	[ ]

Please note that there is a verification process to ensure that the information given is correct.

I _____(declarant), certify that the information contained in the application is complete and true and accurate and all required documents have been submitted.

List of Personnel

Personnel Particulars (*provide the following information for the registered and licenced personnel who will manage testing for the COVID-19 virus at the healthcare facility*):
Name of Healthcare Facility : _____
Address of Healthcare Facility:_____
_____

Name	Position/Designation	Council Issued Registration No	Council Issued Licence No.	Period Valid	
				From	To

List of Equipment

Equipment Particulars: (*provide the following information for the type and quantity of* Ministry of Health *approved PCR equipment/WHO/PAHO approved serological testing technologies that will be utilized in testing for the COVID-19 virus at the healthcare facility):*

Name of Healthcare Facility: _____

Address of Healthcare Facility: _____

Brand Name	Model	Serial Number	Quantity

MADE this 30th day of April 2020.

NIGEL DAKIN
GOVERNOR

EXPLANATORY NOTE

(This Note is not part of the Regulations)

These Regulations seeks to put in place appropriate and safe measures for the testing of the virus known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is the virus responsible for the disease COVID-19 (Coronavirus).