



Ministry of Health

Title: **SUPERVISED ANTIGEN TESTING/FIT-TO-FLY TEST CERTIFICATE PROTOCOL**

Effective: March 1, 2022

Version: 1.2

**1. RECENT DOCUMENT CHANGES**

Date of Change	Version	Nature and location of change
17 Jan 2022	1.0	First Version
19 Jan 2022	1.1	Clarification of Terms
1 Mar 2022	1.2	Inclusion to Waiver

**2. REFERENCES**

- [Allied Health Professions Act 2018](#)
- [Bermuda Health Council Act 2004](#)
- [CDC's Amended Global Testing Order; "Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States."](#)
- [ISO 13131:2021 Health informatics - Telehealth Services](#)
- [ISO 15189:2012 Medical laboratories - Requirements for quality and competence](#)
- [Medical Practitioners Act 1950](#)
- [Public Health \(Clinical Laboratories\) Regulations 2002](#)

**3. DEFINITIONS**

- **Clinical Laboratory:** means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings
- **Fit-to-Fly Certificate:** A medical certificate/letter certifying that the holder has recently tested negative for COVID-19.
- **Health Professional (Bermuda):** means a person who is registered to practise his or her health profession by the relevant regulatory authority
- **Health Service Provider (Bermuda):** means a person, group of persons or organization that operates a business offering health services to the public, but does not include a person who is an employee under a contract of service.
- **Healthcare Provider (USA):** Under US federal regulations, is a licensed or registered: doctor of medicine or osteopathy, podiatrist, dentist, chiropractor, clinical psychologist, optometrist, nurse practitioner, nurse-midwife, clinical social worker, (or other allied health professional) who is authorized to practice by the State and is performing within the scope of their practice as defined by State law.
- **Registered Person:** means an exempted medical practitioner, a medical officer of the armed forces, a registered medical practitioner, a specialist, a Government medical officer, an authorized visiting practitioner, a locum tenens, a house officer, or any other person declared by the Minister by notice published in the Gazette to be a registered person

#### 4. PURPOSE

Per policy direction, this document serves to outline the eligibility requirements, approval process, and procedures governing supervised antigen test certification in general and specifically the fit-to-fly certificate process for international travel. *This protocol is only in respect of testing for SARS-CoV-2.*

#### 5. BACKGROUND

SARS-CoV-2 has prompted changes in travel requirements across the globe. For example, the CDC has determined a SARS-CoV-2 test, no more than 1 calendar day before a flight from an international country, is necessary for all passenger, regardless of vaccination status, to protect the public health of the United States. Such changes in testing requirements for travel have added requirements to Bermuda's COVID-19 testing infrastructure and the clinical laboratories that have traditionally provided these services. In response, registered health service providers and their associated registered health professionals are being granted the ability to conduct supervised SARS-CoV-2 antigen testing and issue fit-to-fly certificates in an effort to meet testing capacity needs. This service of providing supervised antigen test is in respect of [Bermuda Market Authorized test kits](#) that meet criteria of being "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result".

#### 6. ELIGIBLE ENTITIES

A health service provider (business) or health professional (person) may provide supervised antigen testing and issue a fit-to-fly certificates if the following conditions are met:

- Have received regulatory approval to provide such services in Bermuda (See section 7).
- The health professional must be registered, and in good standing with, one of the following Statutory Bodies in Bermuda that govern the professions:
  - *Bermuda Dental Board*
  - *Bermuda Medical Council*
  - *Bermuda Nursing Council*
  - *Bermuda Psychologists Council*
  - *Council for Allied Health Professions*
  - *Optometrists and Opticians Council*
  - *Pharmacy Council*
- The health professional must be associated with a health service provider that is registered with the Bermuda Health Council.
- Testing must take place at a facility or location that is registered with or approved by the Bermuda Health Council.
- There must be protocols in place to manage safety of both the persons performing the test and the persons being tested.
- The designated health professional must be clearly identifiable and accessible and have the competence to ensure and take responsibility for all testing being performed (including staff training) and be available to provide clinical advice when required.
- The health service provider must ensure that staff performing or supervising the performance of the test are trained in the correct performance and interpretation of the test including specimen collection. Note: inadequate or incorrect sample collection can affect the accuracy of the test.
- The privacy and confidentiality of individuals must be maintained at all times. Consent should be obtained

from the individual to allow the collection and testing to be carried out.

- Collection of specimens must be performed with accurate identification of the person being tested to ensure traceability of specimen collection to final result.
- If self-collection of a swab is necessary, this must be conducted under the supervision of a person who has been trained in sample collection in order to verify patient identification and ensure an appropriate sample is collected. Poor sample collection can result in false negative results.
- The health professional must agree to follow Bermuda Health Council guidance as issued (inclusive of [fit-to-fly certificate format – Annex 3](#)), reimbursement, and health safety directives).
- If the method of service delivery is telehealth, the telehealth-related health service provider must, be locally registered, and use an interactive audio and video telecommunications system that permits and documents/records real-time communication between the patient and the observer, from sample collection to result.

## 7. APPROVAL PROCESS (HOW TO RECEIVE REGULATORY APPROVAL)

Each jurisdiction has may have unique requirements for reviewing SARS-CoV-2 test results for travel. This may include that results come from a registered laboratory. [As criteria for all jurisdictions may not be the same](#), the approval process for providing supervised antigen testing for SARS-CoV-2 and for issuing fit-to-fly certificates include different options. As such, to receive approval to conduct Supervised Antigen Testing for SARS-CoV-2 and issue fit to fly certificates, health service providers and health professionals must:

**Option 1:** Be a registered clinical laboratory ([See Annex 4](#))

**Option 2:** Have a documented partnership/affiliation agreement with a registered clinical laboratory, naming the health professional as an external specimen collection site. In such agreements, clinical laboratories must inform the Bermuda Health Council of all partnership/affiliation agreements, which will be listed on the Council’s website, [here](#). In addition, clinical laboratories must inform their accrediting agencies of each external partner/affiliation. Clinical laboratories will be responsible for all testing conducted by their partners/affiliations, with possible implications to their continued registration with the Bermuda Health Council. ([See Annex 5](#))

**Option 3:** Health service providers and health professionals who meet all criteria **under section 6** may seek a waiver from laboratory affiliation from the Council, [here](#). ([See Annex 6](#))

[Click Here to Submit Application](#)

## 8. PUBLICATION OF APPROVALS

All approved health services providing COVID-19 antigen testing, and fit-to-fly certificates are listed on the Council’s website [here](#).

## 9. ELIGIBLE TESTS

The test selected must be a viral test able to determine current COVID-19 infection. Eligible tests are limited to Bermuda Market Authorized Antigen testing kits, as approved by the Bermuda Health Council, [can be found here](#).

Please note that test eligibility is also limited to those accepted by the destination of travel. For example, in the US “viral

antigen test cleared, approved or issued an emergency use authorization (EUA) by the U.S. Food and Drug Administration, or granted marketing authorization by the relevant national authority for the detection of SARS-CoV-2, performed in accordance with the approval/clearance/EUA/marketing authorization.”

The Customs and Health Department has created the “[COVID-19 Test Kit Pre-approval Process](#)” to ensure importers of COVID-19 related products receive speedy pre-approval.

## Annex 1: International Travel Requirements (Direct routes from Bermuda)

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### UNITED STATES OF AMERICA

Prohibits the boarding of any passenger, 2 years of age or older, without:

- A negative pre-departure viral test result for SARS-CoV-2 conducted within 1 calendar day
- Letter (Fit-to-Fly Certificate) from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel, or
- Documentation of having recovered from COVID-19 in the past 90 days

*Note: State requirements may vary by airline, governing health authority, or entry agency.*

### CANADA

Fully vaccinated foreign nationals are allowed to enter Canada for discretionary travel. Travelers over 5 must present proof of a Negative pre-arrival test of the following type:

- PCR - Polymerase chain reaction
- Nucleic acid test (NAT) or Nucleic acid amplification test (NAATs)
- Reverse transcription loop-mediated isothermal amplification (RT-LAMP)
- RAPID ANTIGEN TESTS AREN'T ACCEPTED.

### UNITED KINGDOM

Fully vaccinated travelers before traveling to England must:

- Book and pay for a COVID-19 test to be taken after arrival
  - Complete a passenger locator form 48 hours before arrival
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## Annex 2: Fit-To-Fly Certificate Format

A Fit-to-Fly Certificate may be issued in paper or digital form, and must include the following information:

<b>Traveler Information/Identifiers</b>	<ul style="list-style-type: none"><li>• Name</li><li>• Date of Birth</li><li>• Passport Number</li><li>• Travel Date</li><li>• Traceable Certificate Number</li></ul>
<b>Sample/Testing Information</b>	<ul style="list-style-type: none"><li>• Sample Collection Date</li><li>• Test Type or Methodology</li><li>• Test Kit Name/Manufacturer</li><li>• Test Kit Lot Number</li><li>• Start &amp; End Time of Video Call (telehealth only)</li></ul>
<b>Testing Facility Information</b>	<ul style="list-style-type: none"><li>• Collection Location</li><li>• Affiliated Clinical Laboratory</li><li>• Laboratory Registration Number</li><li>• Testing Location (if different from collection site)</li><li>• Test Reviewer Signature (Registered health professional)</li></ul>
<b>Test Results</b>	<ul style="list-style-type: none"><li>• Must explicitly state the following: negative, RNA not detected, SAR-CoV-2 Antigen Not Detected, COVID-19 Not Detected</li><li>• Test marked “Positive” or “Invalid” are NOT acceptable</li><li>• Note: all positive results must be reported to the appropriate authority and are subject to the guidance issued by the Ministry of Health’s regarding reflex RT-PCR testing, and quarantine requirements.</li></ul>



# COVID-19 TEST RESULT CERTIFICATE

Certificate Use (e.g., Travel)

Order No.

XXXXXXXX

Certificate No.

XXXXXXXX

**PATIENT NAME**

Test Result: **XXXXXXXXXXXX**

Sex:	M/F/Other	Test Type	Antigen
Date of Birth:	dd/mm/yyyy	Sample Taken:	dd/mm/yyyy at xx:xx xm
Passport Number:	xxxxxxxxxx	Result At	dd/mm/yyyy at xx:xx xm
Facility	xxxxxxxxxx	Certificate Issued	dd/mm/yyyy
National Provider Identifier:	xxxxxxxxxx	Certificate Expiration	dd/mm/yyyy
Registration Number:	xxxxxxxxxx	Accrediting Agency	xxxxxxxxxxxxxxxxxxxxxxxxxx

### Symptom Verification

- **No** recent symptoms associated with COVID-19, including but not limited to: high fever, cough, shortness of breath, muscle pain, headache, sore throat or disturbance in sense of smell/taste.
- **No** evidence of an active COVID-19 infection on the test date.
- **No** reported recent contact with a case of COVID-19.

I can confirm that based on the above information, this patient did not have any evidence of an active COVID-19 infection and is FIT TO FLY.

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Reviewing Health Professional Name  
Registration Number: xxxx

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Reviewing Health Professional Signature

Annex 4: Registered Clinical Laboratories

<b>Reg. #</b>	<b>Facility</b>
CL-001	BHB DEPARTMENT OF PATHOLOGY
CL-002	ISLAND HEALTH SERVICES
CL-004	HOPE HEALTHCARE
CL-008	C & S WEST MEDICAL SERVICES
CL-010	FAMILY MEDICAL SERVICES
CL-011	MEDILAB
CL-012	POINT FINGER ROAD MEDICAL CENTER
CL-015	WOODBOURNE MEDICAL LABORATORY
CL-016	NORTHSHORE MEDICAL & AESTHETICS CENTER
CL-017	PREMIER HEALTH & WELLNESS
CL-018	HELIX GENETIC AND SCIENTIFIC SOLUTIONS
CL-019	HMC URGENT CARE & MEDICAL IMAGING
CL-020	BERMUDA MOLECULAR DIAGNOSTICS LABORATORY
CL-021	HAMILTON HEALTH CENTER

## Annex 5: Partnership Agreement

- Partnership agreements may only be held between a registered clinical laboratory and a registered health service provider, operated by a health professional, who is operating within his or her scope of practice, as outlined by the appropriate statutory board.
- This agreement states that the health service provider facility is an external specimen collection site, and subject to all regulations governing the conduct of clinical laboratories. As such, a clinical laboratory may accept or deny an affiliation request at their discretion.
- The Health Council will hold the clinical laboratory responsible for testing related activities conducted at partner/affiliation facilities, and may require the termination of a partnership agreement if deemed necessary.
- The clinical laboratory is to be responsible for documenting the following items below with its external site(s). External sites are subject to operating within the parameters of this information, to which they must have access to at all times:
  - List of Testing Personnel
  - Records of Training and Competency
  - Collaboration with Environmental Surveillance Unit and Ministry of Health
  - Quality Assurance Program
    - Internal and External Quality Control
    - Testing Validation
    - Proficiency Testing (evidence of enrollment and submission within 30 days)
  - Documented Policies and Procedures
    - Infection control
    - Pre-analytical processes (i.e. social distancing, patient registration, etc.)
  - Sample Management/Standard Operating Procedure Manual (site specific)
    - Sample Collection
      - acceptability criteria
      - rejection criteria
    - Sample Transport
    - Testing Procedure
    - Results Release
    - Sample Storage
    - Sample Destruction
    - Reflex and Positive Results Procedure
    - Trouble shooting, corrective, and preventive actions

## Annex 6: Waiver from Laboratory Affiliation

The Bermuda Health Council strongly recommends that testing health facilities be partnered with a registered clinical laboratory to ensure the highest version of quality results. However, a health service provider may seek a waiver to provide COVID-19 testing, and issue fit-to-fly certificates without such partnership.

- Waivered facilities must agree to follow Bermuda Health Council guidance as issued (inclusive of fit-to-fly certificate format, reimbursement, and health safety directives).
- Waivered facilities must follow all manufacturer's instructions in the performance of each testing procedure. Additionally, all kits, reagents, and controls must be stored and handled in accordance to manufacturer recommendations. No modifications may be made by the facility to the manufacturer's procedure.
- Quality controls (QC) must be performed and recorded per manufacturer's instructions, and QC results must be reviewed, and found to be acceptable prior to patient result reporting. If QC is not acceptable, patient results may not be reported, and the cause of the QC failure must be investigated. All QC results must be reviewed monthly and stored for 2 years.
- Each facility is expected to maintain a current, accurate list of testing personnel. Each testing staff member must have documented training, and a competency assessment in the testing procedure. These waived facilities and their associated health professionals must agree to be included on a publishable list of registered persons for the purpose of providing supervised antigen testing and issuing fit-to-fly certificates.
- The Council may conduct ad-hoc site visits to ensure all requirements are met. The Council may also remove a facility's or professional's testing approval for non-compliance or upon change to policy at its discretion.