



National Policy on the Use of Antigen-Detecting Rapid Diagnostic Tests (“Lateral Flow Tests”)

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Cayman Islands
Government

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The information contained within the document will be reviewed regularly and republished when new information becomes available and/or procedures change.

Background

SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to severe strain on healthcare systems and causing societal disruption. To respond effectively to the outbreaks of this disease, rapid detection of cases and contacts is critical, in conjunction with appropriate population based mitigating interventions, supplemented by timely, evidenced clinical care.

Beginning in September, 2021, the surge in people with COVID-19 in the Cayman Islands community has stretched our Public Health Department’s (PH) resources. Laboratory based molecular or polymerase chain reaction (PCR) testing in the Cayman Islands is free and widely accessible, with results generally available with 24 hours. However, when the PH team is faced with large numbers of contacts from multiple positive cases who need to be tested rapidly for SARS-CoV-2, the use of a more scalable, accessible and rapid testing method is highly desirable.

The Government of the Cayman Islands has sought to respond to these concerns by expanding the approved testing methods to be included in our national testing protocols for screening and surveillance of SARS-CoV-2. Regulations enacted under the Public Health Act on 15 October, 2021, “Control of COVID-19 (Testing) Regulations, 2021” provide for the introduction and supply of approved antigen-detecting rapid diagnostic or lateral flow tests (“LFTs”) in addition to describing the approval process for molecular testing.

These LFTs are intended to be used alongside PCR testing which is still the “gold-standard” for clinical diagnostic detection of SARS-CoV-2. Given the recent significant improvements in the sensitivity and specificity of LFTs, they have the potential to successfully assist in quickly identifying persons who have tested positive.

While PCR tests remain the highest standard for accuracy and confidence, LFTs which meet the specifications for approval for use in the Cayman Islands can allow for a different approach which will reduce the impact of isolation of close contacts. In many circumstances, close contacts can be permitted to continue to operate in the community subject to undertaking daily LFT surveillance.

General Guidance on Antigen-Detecting Rapid Diagnostic or Lateral Flow Tests

What are Antigen-Detecting Rapid Diagnostic or Lateral Flow Tests?

Antigen-Detecting Rapid Diagnostic Tests use lateral flow immunoassays to detect SARS-CoV-2 viral proteins (antigens) in swabs from the nose, or both throat and nose, to offer a faster and less expensive method to detect SAR-CoV-2 than PCR tests. The tests give a quick result, often between 15-30 minutes, using a disposable test cassette that is similar to some pregnancy tests.

The World Health Organization's performance standards require that such tests correctly identify at least 80% of infected people (test sensitivity) and correctly identify the infection cause to be SARS-CoV-2 in 97% of cases (test specificity). In the Cayman Islands, by Regulations, only LFTs that meet these standards can be imported or supplied.

What are some Key Benefits of Lateral Flow Tests?

Some of the key benefits that the Government expects to receive are as follows:

1. They are affordable relative to a PCR test;
2. They can be used and interpreted by a non-medical person, and many are designed for home use;
3. People can conduct the tests at home or at the workplace, so travel to and mixing with people in a healthcare setting is not required;
4. They are self-empowering which many members of the public will be grateful for (e.g. in the protection of the elderly and vulnerable);
5. They can assist in identifying people who are infected but asymptomatic in a matter of minutes;

6. Their use can decrease the workload on laboratory services;
7. They greatly increase access to a reliable diagnostic technique; and,
8. Their use can decrease disruptions within educational, caregiving and employment settings.

What are some Key Limitations of Lateral Flow Tests?

Although LFTs do not tend to perform as well as the more sensitive PCR tests when viral loads are low, they do perform well with higher viral loads (when someone is most infectious) or when used repeatedly.

It should also be noted that all testing for SAR-CoV-2, including lateral flow testing, depends on the integrity of the sample. Care must be taken to avoid an improper or insufficient collection of the sample (e.g. swabbing the nostril too quickly). The manufacturer's instructions must be followed carefully and exactly in order to ensure the accurate results.

Policy Purpose

The purpose of this policy is to provide a framework and guidance for the strategic use of lateral flow tests, both for home and supervised use, in order to:

- ensure the tests used by the Government, private sector and home use are accurate and reliable;
- reduce the threat of SARS-CoV-2 infections with the early detection and isolation of any positive person which will have an immediate impact on the numbers who might present to clinics and hospitals;
- achieve more rapid and widespread testing capacity in the Cayman Islands;
- enhance our ability to protect some of our most vulnerable populations, including our children in our early childhood care and education centres and schools, who are not yet eligible for an approved COVID-19 vaccination;
- provide additional information to guide the Government's policies, from the collection and reporting of testing results; and
- build confidence that places of work and recreation can be safe environments even in the face of community transmission, and that attending or patronising such places does not create unreasonable risks to a person's health or the health of family members with whom they live.

Additionally, this national policy also serves as the overarching framework for various sectors (e.g. education, tourism, social care services, etc) to create guidance documents that will assist with the deployment of LFTs in their respective organisation or setting. Private sector employers may also use this policy to assist in developing their own lateral flow testing policies as this document outlines the reporting requirements and other recommendations such as testing intervals.

Policy Scope

This policy provides guidance for:

- The selection of lateral flow tests for use in the Cayman Islands;
- The safe and appropriate use of lateral flow tests, and
- When and how and to whom the results of lateral flow tests should be reported.

This policy is expected to remain in effect for the duration of the public health emergency related to COVID-19 which was declared a pandemic in March 2020 and includes any renewals made by approval of the Cabinet of the Cayman Islands in accordance with regulations made under the **Public Health Act (2021 Revision)** and associated legislation.

This policy is subject to periodic review to assess whether it remains an appropriate and proportionate public health and safety measure, in relation to developments of the pandemic internationally and any changes in the transmission levels in the Cayman Islands.

Key Definitions

Below are the definitions for some key terms that are used in this policy:

- Diagnostic test - generally used to refer to molecular or antigen tests, both of which can be used to diagnose the presence of viral proteins that are part of the SARS-CoV-2 virus.
- The Three Main Testing Regimes:
 - » Diagnostic testing - a testing regime that can be applied for SARS-CoV-2 testing to identify persons actively infected with SARS-CoV-2 virus (based on symptoms or exposure) to help guide clinical and infection control decisions.
 - » Screening testing - a testing regime that can be applied to identify people with a SARS-CoV-2 infection who have not displayed signs or symptoms of COVID-19 disease. The purpose of screening testing is to identify persons with pre-symptomatic or asymptomatic SARS-CoV-2 infection in order to prevent additional spread of the virus within specific settings (e.g. education, residential care homes, workplaces, etc).
 - » Surveillance testing - a testing regime that can be applied to indicate the incidence and prevalence of the virus; the data collected is anonymised and, thus, results are not linked to individual people.

Policy Statements

Criteria for the Selection of Lateral Flow Tests

Only LFTs that meet the criteria set out in the Control of COVID-19 (Testing) Regulations, 2021, should be supplied for the purpose of SARS-CoV-2 rapid testing in the Cayman Islands (including tests used in workplaces or homes for personal use).

The UK Health Security Agency (formerly known as Public Health England) has undertaken rigorous testing for a large number of lateral flow devices and this is set out in the following link:

<https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices>

Three LFTs brands have been initially identified for use by the Health Services Authority and were selected based on recommendations and proven outcomes as noted by the regulatory bodies at World Health Organization (WHO) and the UK Health Security Agency (formerly known as Public Health England). These three are:

- ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test
- Bioperfectus Technologies Novel Corona Virus Ag Rapid Test kit, and
- Hughes Veritas Rapid Antigen Test for SARS-CoV-2.

Any other LFT brand selected for use by the Cayman Islands Government will undergo confirmatory testing by the accredited laboratory of the Cayman Islands Health Services Authority (HSA).

Who can be Screened Using Lateral Flow Tests?

In order to prevent additional spread of the virus, screening is intended to identify persons with SARS-CoV-2 infection who have either no symptoms or mild symptoms (sometimes termed 'paucisymptomatic') and who might otherwise go undetected. Unless otherwise guided by Public Health, the recommended age for persons to be screened with LFTs is 2 years and older.

Screening is not intended for persons who are symptomatic. In line with Public Health advice, persons with symptoms should stay home when sick. Any person with symptoms suggestive of COVID-19 disease should contact their local healthcare provider or the **Flu Hotline** to seek advice on the best next steps. The Flu Hotline can be reached on **1-800-534-8600** or **947-3077** (Digicel), or email flu@hsa.ky.

Screening is not intended for persons who have recovered from a laboratory confirmed (PCR) COVID-19 test within the past 90 days and are asymptomatic. To avoid false positives, they should follow the advice of the Public Health Department on how to conduct future testing (including screening tests).

The Cayman Islands Government recommends the use of approved LFTs for a wide range of purposes and contexts, including the following:

- For testing at home, as part of a personal routine to safeguard the health and safety of individuals and their families.
- Under the direction of PH for diagnostic purposes, as part of an outbreak investigation and response, in order to:
 - » provide a more rapid response for identifying persons actively infected with SARS-CoV-2 virus to help guide clinical and infection control decisions; and
 - » reduce the number of children and families required to isolate as a result of a positive case.
- For routine testing for some healthcare workers and other frontline workers.
- For high risk congregate settings that house some of our most vulnerable populations (e.g. schools, institutional homes, prisons and detention centres).

- Organisations providing high touch and personal services to the public (e.g. *barbershops, hairdressing salons, and spas*), social venues (e.g. *restaurants, bars, nightclubs, and cinemas*), and fitness facilities (e.g. *gyms, fitness centres, or other indoor fitness areas*).
- As part of a voluntary or mandatory testing programme by employers, especially within organisations with high volumes of customer traffic, in order to ensure that workplaces operate as safely as possible and can maintain business continuity.
- With sports athletes and staff engaging in moderate and high risk sports organised by sports leagues, including youth sports teams and activities.
- Visitors, prior to entry into certain settings, including but not limited to healthcare facilities and institutional care homes; prisons and places of detention; and as may be required by certain businesses and venues.

Screening Testing Using Lateral Flow Tests in the Workplace

Where routine screening of employees using LFTs is conducted, it is recommended that it be administered regardless of whether or not persons are fully vaccinated, and as a minimum recommended standard, tests should be conducted **twice weekly**, with each test taken **within a minimum of three days of each other**.

Employers may choose to set up their own workplace testing, or they may choose to hire a third-party provider to administer the tests.

Employers may also provide employees with test kits and ask employees to carry out tests at home before attending the office and may choose to implement appropriate protocols for confirming that the tests have been administered as requested and to confirm the results.

Where testing is implemented in the workplace by employers, the employers may choose to implement the testing as a voluntary regime to which the employee is invited to participate, in order to encourage the health and safety of the entire workplace. Where a testing regime is mandatory, it is recommended that employers conduct a comprehensive assessment of any legal issues before introducing such a policy.

Where testing is introduced into the workplace by employers, the plans in respect of workplace testing should be set out in a formal workplace testing policy document. This policy should help to provide employees with sufficient information and assist in enabling testing to be carried out privately, fairly, and consistently. Employers should engage with employees prior to introducing employee testing.

The testing regime must be carried out in a manner that is compliant with the **Data Protection Act (2021 Revision)** and its requirements for the storing and processing of sensitive personal data relating to the health of the employees. *(For related guidance, please see guidance note on "[Employee Vaccination Status Checks](#)" published by the Office of the Ombudsman.)* Where LFTs are used for screening testing within an organisation, they must be implemented as part of a layered approach that includes other prevention measures, as the tests alone cannot be relied on as a means of completely eradicating SARS-CoV-2 infections within the organisation, even if employees are entirely compliant.

Other prevention and control strategies that should be implemented alongside screening testing include:

- promoting vaccination uptake;
- consistent and correct use of masks;
- physical distancing;
- handwashing and respiratory etiquette;
- improved ventilation;
- routine cleaning with disinfection;

- remote working;
- flexible working arrangements;
- split shifts or separating teams; and
- staying home when sick and getting tested.

How will the costs of implementing a screening testing programme be met?

The Government will initially cover the costs associated with procuring LFTs to be used for screening testing employees within the Civil Service and the wider public service. Statutory authorities and government companies that wish to obtain test kits which have been procured by Government, should liaise with their respective Ministries.

All test kits for screening and surveillance testing using LFTs for staff, teachers and children/students in educational institutions, both Government and private, will be provided by the Government and are free of charge to staff, teachers, and children/students. For avoidance of doubt, educational institutions means early childhood care and education (ECCE) centres, schools, and post compulsory educational organisations such as colleges or universities. Supplies of test kits will initially be provided to staff, teachers, and children/students for routine screening and, in the event of an outbreak or a positive case, additional supplies will be provided for those individuals only.

In any other scenario, the full cost of implementing a screening regime using LFTs, including the purchase of LFT kits, must be borne by the employer, organisation, or individual.

When Lateral Flow Tests May be Administered by Public Health

LFTs may be used by PH for diagnostic purposes, as part of an outbreak investigation and response. Where LFTs are used by PH for this purpose:

- The tests will be administered to affected children and adults, regardless of vaccination status.
- These LFTs will form part of a PH strategy to:
 - » Provide a more rapid response for identifying persons actively infected with SARS-CoV-2 virus, to help guide clinical and infection control decisions.
 - » Reduce the number of children and families required to isolate as a result of a positive case.

Evaluating the Results of Lateral Flow Tests

This section provides general guidance as it relates to the evaluation of LFT results. Further guidance may be provided in lateral flow test deployment guidance documents that are developed for various sectors (e.g. *education, tourism, healthcare, social care, etc.*).

If a member of a household tests **positive** on an LFT, the individual must isolate immediately and follow PH protocols for reporting the positive result. PH will advise when it is safe for the individual to be released from isolation.

Where the other members of the household are vaccinated, each individual, including children, should conduct daily LFT testing for 10 days. Daily testing must continue until all positive cases in the household are cleared by PH.

If an individual receives a **negative** LFT result, that individual can attend school/work if daily test results continue to be negative.

If an individual receives a **positive** LFT result, that individual must:

- stay at home and
- contact Public Health immediately.

If an individual refuses to test, they are required to isolate for 10 days.

Where the other members of the household are **NOT vaccinated**, and they are 18 years of age or older, they are to isolate for 14 days. PH should be notified. PH will advise the date of the PCR test and will confirm final approval for release. Unvaccinated children under 18 years old residing in the household can continue to go to school if daily LFT result is negative. Daily testing must continue until all positive cases in the household are cleared by PH.

Follow-up testing, using a PCR test may be conducted by the Public Health Department, but a positive or equivocal/inconclusive lateral flow test should be treated as indicating someone has a SARS-CoV-2 infection.

It should be noted that if any individual is contacted by Public Health and they are instructed to isolate, a negative lateral flow test cannot be used to override the Public Health instruction in accordance with the **Public Health Act (2021 Revision)** and any relevant regulations. Public Health may also instruct members of the individual’s household with other directions that must be followed.

Reporting Requirements for the Results of Lateral Flow Tests

At a national level, the Ministry of Health will provide guidance on the reporting test results. A webform has been developed for reporting purposes with details as specified by Public Health and may be accessed [here](#). However, if a person who does not have access to the webform, a person should contact their local healthcare provider or the **Flu Hotline** to report a positive and seek advice on the best next steps. The Flu Hotline can be reached on **1-800-534-8600** or **947-3077** (Digicel), or email flu@hsa.ky.

The results of any positive tests must be reported to Public Health in accordance with the Public Health Act (2021 Revision) because SARS-CoV-2 is a notifiable disease which is required to be reported to the Medical Officer of Health as soon as someone is aware of a positive result or a potential case.

Where employers introduce the reporting of results as part of their company policy, it is recommended that employers conduct a comprehensive assessment of any legal issues and ensure that the policy is carried out in a manner that is compliant with the **Data Protection Act** (2021) and its requirements for the storing and processing of sensitive personal data relating to the health of the employees.

Guidance Documents for the Deployment of LFTs in Specific Sectors and Settings

The following are available guidance documents for specific sectors or settings:

- Guidance for Deployment of Lateral Flow Tests in Early Childhood Care and Education (ECCE) Centres and Schools in the Cayman Islands
- Guidance for Tourism
- Guidance for Care Homes
- Guidance for Prisons and Detention Centres
- Guidance for Large Events
- Guidance for Gyms and Indoor Exercise Facilities



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