



Lateral Flow Tests Introduced for Next Steps in COVID-19 Strategy

Grand Cayman, 6 October 2021 – As the Cayman Islands continues to adapt and respond to living with COVID-19 in the community, Chief Medical Officer, Dr. John Lee OBE, has endorsed lateral flow tests for fast identification of positive cases. These specific tests play an integral role in the Government’s overall management strategy by empowering people to proactively stay aware of their COVID-19 status via these testing kits and reducing the need for persons to attend a health care facility for initial testing.

“The SARS CoV-2 rapid test kits, also known as lateral flow tests or antigen tests, are a positive step for the country”, shared Dr. Lee. “There have been significant improvements in the sensitivity and specificity of lateral flow tests, and we have seen that they can successfully assist in quickly identifying potential positives in the community. While PCR tests remain the highest standard for accuracy and confidence, lateral flow tests provide the confidence to allow us to safely and successfully resume many activities that are impacted by the current Regulations. I am therefore happy to recommend to the Government that we formally introduce lateral flow tests as part of our control and management of COVID-19 strategy.”

Guidance for purchasing lateral flow tests has been issued by the CMO and sets out the criteria for tests to be used in the Cayman Islands. The Government intends to introduce Regulations under the Public Health Act (2021 Revision) to the same end.

Three lateral flow tests have been initially identified for use by the HSA 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 kits are:

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

Dr. Delroy Jefferson, Medical Director of the Cayman Islands Health Services Authority (HSA) notes that the HSA will incorporate lateral flow testing as part of the testing regime and will also provide validation for tests beyond the three kits identified.

Vendors who are interested in having other kits considered for use by the HSA must liaise with the HSA to have the test kits reviewed by HSA's accredited laboratory for validation.

“Our strategy for the Cayman Islands remains the same—putting the health and safety of all people in our country as the highest priority. The rapid test kits will help to provide a level of reassurance for individuals as they go about their daily lives but also provides additional information to guide the policies this government is putting in place to protect us all. I encourage all persons to familiarize yourselves with the personal safety steps and ensure that you have a preparedness plan in the event the virus reaches your household,” said Premier Hon. Wayne Panton.

“Throughout the pandemic, personal responsibility has been a key factor in the suppression of COVID in our community. As we slowly resume travel and further open our borders, it is even more important for us to recommit to our individual responsibility to ensure the safety of ourselves and those we interact with through our daily lives.”

For more information on safety guidelines and what you can do to be prepared, please visit the official Cayman Islands COVID-19 information pages at:

www.explore.gov.ky/coronavirus.

Guidance for purchasing Lateral Flow Tests

According to the WHO, care must be taken when selecting rapid testing products while keeping in mind the national testing strategy and resources. It must be noted that the marketplace is replete with various brands of rapid testing kits but there are variations in testing accuracy, quality and intended use claims.

The CMO, in recognising the need for local medical facilities, pharmacies, medical suppliers and businesses to acquire lateral flow tests is issuing guidance to assist those seeking to import them for distribution. The Government intends to introduce Regulations under the Public Health Act (2021 Revision) to the same end.

Criteria for selection of test kits

For SARS-CoV-2 rapid testing kits to be considered for local testing the following criteria should be met:

- Test kits should ideally have **proof of certification**;

- Test kits must be **approved or authorised** by at least one of the following bodies:
 - UK Health Security Agency (formerly known as Public Health England)
 - World Health Organisation
 - MHRA - Medicines and Healthcare Products Regulatory Agency
 - Food and Drug Administration (USA)

- Test kits must have a **sensitivity of greater than or equal to 80%** and a **specificity of greater than or equal to 97%**;

- Care must be taken to ensure that Lateral Flow tests designed for **clinical use only** are distributed to medical professionals and/or facilities. This is because these are designed to be handled by a trained professional;

- Lateral Flow tests which are to be sold to the general public should clearly indicate that they have the ability to be **self-administered**. These self-administered or home-kits would be appropriate for personal usage, schools, gyms, entertainment venues, and employers wishing to regularly screen their employees; and
- Full details of the validation process conducted by UK Health Security Agency (formerly known as Public Health England) 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>

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