This fact sheet informs you of the significant known and potential risks and benefits of the emergency use of the Pelican COVID-19 Ultra-Rapid Mobile Test.

The Pelican COVID-19 Ultra-Rapid Mobile Test is a reliable, rapid digital immunoassay for the qualitative detection of specific proteins of SARS-CoV-2 present in the human saliva that are collected by a healthcare professional for individuals aged 2 years or older. This test is intended for use in individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection. The Pelican COVID-19 Ultra-Rapid Mobile Test is authorized for point-of-care use.

**What are the symptoms of COVID-19?**

Many patients with COVID-19 develop fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhoea.

Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days.

This test is to be performed only using saliva specimens collected by a healthcare professional for an individual aged 2 years or older. This test is authorized for use in these individuals regardless of whether they have symptoms or other epidemiological reasons to suspect a COVID-19 infection.
What do I need to know about Pelican COVID-19 Ultra-Rapid Mobile Test?

• The Canary Global Inc’s Pelican COVID-19 Ultra-Rapid Mobile Test can be used to test directly collected saliva specimens using a saliva collection device provided by the manufacturer.

• COVID-19 is an acute respiratory infectious disease caused by infection of the SARS-CoV-2 virus, a novel coronavirus belonging to the beta genus of the coronaviruses. After infection, there is an incubation period of 1 to 14 days.

Canary Global Inc’s Pelican COVID-19 Ultra-Rapid Mobile Test helps in selective detection of analytes which in turn serve the purpose for fast and precise detection of COVID-19.

• Canary Global Inc’s Pelican COVID-19 Ultra-Rapid Mobile Test is authorized for point-of-care use.

Specimens should be collected with appropriate infection control precautions. When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used.

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that protein from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicentre locations) in making a final diagnosis and patient management decisions. The Pelican COVID-19 Ultra-Rapid Mobile Test has been designed to minimize the likelihood of false positive test results.

However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All healthcare providers using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen test negative for the virus that causes COVID-19?

A negative test result for this test means that SARS-CoV-2 antigens were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The amount of antigen in a sample may decrease as the duration of illness increases.

As days post-symptom onset increase, antigen test results may be more likely to be negative compared to a molecular SARS-CoV-2 assay. Therefore, negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. It is possible for a person to test too early or too late during COVID-19 infection to make an accurate diagnosis using the Pelican COVID-19 Ultra-Rapid Mobile Test. When diagnostic testing is negative, the possibility of a false negative result should be considered in the
The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g. other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare professionals in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions.