

## GLCM's Covid-19 Rapid Test

### About the test kit

Graphene Leaders Canada (GLC) Inc. and its subsidiary GLC Medical (GLCM) Inc. are pleased to announce the development of a graphene-based screening test that will be able to determine whether a person is infected with COVID-19 in less than one minute.

Upon final regulatory approval, this technology will undergo a [screening trial in the late fall](#) of 2020 at the [Edmonton International Airport](#) in partnership with Edmonton Airports. Further information on this trial and the process will be made available in the coming weeks.

The Edmonton based company developing this device is working closely with EIA for this screening trial. Airports have a critical need to implement a rapid testing system with the ability to screen passengers before boarding a plane, with accurate and real time results, which will ensure the safety of passengers and help bring peace of mind back to the public as people begin to travel again.

### Type of Testing Device

**GLCM's Covid-19 Rapid Test** is an *Antigen-Based IVD* type test which identifies the presence of **SARS-CoV-2** proteins in saliva.

### Health Canada Certification Process

GLC Medical will work with all appropriate regulators, including Health Canada, to obtain market authorization for the test in advance of starting the trials with the EIA. This includes a plan to submit an application to Health Canada under the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*. This means that once the trial commences with EIA, the device will have already undergone laboratory validation to determine selectivity and sensitivity and will have passed through human (clinical) trials. Once GLC Medical has market authorization, GLC Medical will work with EIA along with Health Canada to oversee trials for a joint Rapid-Test Protocol. The results of this trial will help **GLCM's Covid-19 Rapid Test** obtain broader market acceptance across Canada and into international markets. More information on regulation will be shared as it is determined.

### How the device works

This end-user friendly sensor eliminates the need for a nasopharyngeal swab as it detects the presence of SARS-CoV-2 in saliva as the sample medium. It is practical and very safe for all ages to use.

- The individual being tested will provide their saliva sample directly into a disposable saliva collection vessel which will then be plugged into a reusable electronics device.
- Dual graphene biosensors are housed inside the disposable saliva collection vessel. One of which sets the baseline and the other is specifically designed to bond directly to the SARS-CoV-2 spike protein in the virus.



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- The binding event of the spike protein that occurs in conjunction with the baseline reading will generate a measurable change that will send a direct electrical signal to the microelectronics receiver.
- Built-in firmware will analyze the signal to detect the presence of SARS-CoV-2 and within 30-60 seconds, a red or green LED light will indicate whether a person is infected or not.

### Overview

**GLCM's Covid-19 Rapid Test** is incomparable to any other product currently on the market or being tested, as it uses scalable production processes to generate a functionalized, tailorable graphene surface as the active sensing surface. This exclusive and cost-effective testing platform presents unique benefits and provides accurate results in just seconds, rather than minutes, hours or days.

The risk of cross contamination is reduced significantly as the saliva sample is provided directly into a one-time-use, disposable saliva collection vessel which then attaches to a reusable external electrical reader which can be used multiple times. This affordable approach will give people peace of mind with "*at-the-door*" screening when they are entering any type of venue where social distancing is required, while limiting excessive waste.

This *point-of-care* test kit can be administered by any employee of a venue who has gone through training and has been certified, to ensure that the test is carried out safely, following all health guidelines and protocols.

As there are no preparation or specialist requirements for the transfer of specimens, it's ease-of-use makes this device the perfect screening solution for travel, large sporting and music events, social events, as well as for businesses and public entities.

### Technical specifications

- Graphene Biosensor allows for binding of a spike protein and generates a change in electrical signal
- Saliva based test (no nasal swab)
- Point-of-care test that can be administered at the door of any type of venue
- No transfer or cross contamination of saliva samples
- Fast & easy to use
- No medical specialist or equipment requirements
- Battery operated (removeable for recycling)
- LED light indication for operation and for positive/negative results
- Dual sensor for enhanced accuracy
- Sensors safely enclosed within a disposable saliva cup
- Built in electronics and firmware
- Tailorable to detect other viruses and pathogens



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### Frequently Asked Questions & Answers

**GLCM's Covid-19 Rapid Test** is unique to any other product on the market or currently being tested as it uses scalable production processes to generate a functionalized, tailorable graphene surface as the active sensing surface.

#### What type of testing device is this?

This device is an *antigen-based in vitro diagnostic (IVD)* device meaning that the process is non-invasive, and the sample is collected and then analyzed outside of the body.

#### Does it pick up COVID-19 virus detection at day 1, 2 or 3 or early on if someone gets COVID-19?

Our development target for the **GLCM's Covid-19 Rapid Test** is to have comparable limits of detection to molecular diagnostic test methods. While the link between concentration of virus in the saliva and time following infection is not well documented at this time, we are focused on developing a test that is as sensitive as possible to ensure the diagnosis is achieved as soon as possible after infection.

#### What types of infection rates will this device pick up of the COVID-19 virus? Is there a range?

The rate of infection of a disease is the probability within a population that a person will become infected. While this parameter is not quantified by **GLCM's Covid-19 Rapid Test** for SARS-COV-2, this qualitative test is useful as a screening tool which will help to reduce reproduction numbers which means that the disease will spread less rapidly.

#### Where will this test be available?

**GLCM's Covid-19 Rapid Test** is still currently under the developmental phase and does not yet have market authorization in Canadian or US jurisdiction. After market authorization the device will be available for passenger screening at Edmonton International Airport and through other distribution channels to supply venues, clinics and pharmacies, and other businesses with the test kit. More information will be provided on availability upon final regulatory approval and updates to our website will be provided when distributors and sellers have been identified.

#### Who will be administering the test?

This is a *point-of-care* test that can be administered at the door of any type of venue or facility. Although the test kit does not need to be administered by a healthcare professional, anyone administering the test as point-of-care, will need to go through user training and be certified, in order to follow health and safety guidelines and protocol.



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### **What happens if you test positive?**

**GLCM's Covid-19 Rapid Test** is designed to detect viral material present in the saliva and is an indication that active infection is suspected. The test kit is being designed to be a rapid screening device that will detect potentially infected individuals to be excluded from travel and entering venues to minimize the further spread of infection to other people. Any positive result obtained from the test kit should be confirmed with a lab based diagnostic test and all local government recommendations on what to do if you show Covid-19 symptoms should be followed.

### **How much does the unit cost?**

Final wholesale pricing for packages including the **GLCM Covid-19 Rapid Test** along with saliva collection/sensor vessels is still being determined.

### **When will the unit be available?**

Our target is to achieve market authorization in January 2021.

