# FACT SHEET FOR PARTICIPANTS

## Molecular screening test for asymptomatic population surveillance

*(not FDA approved, cleared or authorized)*

You are being given this Fact Sheet because your saliva sample(s) will be tested for the presence of the SARS-CoV-2 viral genome using a molecular screening test for asymptomatic population surveillance called **Darwin's CovLaB**. This test is not intended to be used as a diagnostic test for COVID-19 disease, but rather as a screening tool for general surveillance of viral presence in a population. This test is not FDA approved or authorized.

This Fact Sheet contains information to help you understand the risks and benefits of using this test as a screening tool. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please speak with your sponsor.

***Do not eat, drink, smoke, or chew gum 30 minutes prior to providing your sample.***

**What is COVID-19?**

COVID-19 is a contagious respiratory illness caused by the SARS-CoV-2 virus. COVID-19 can cause a mild to severe illness and has spread worldwide, including in the United States. Older adults and people of any age who have underlying medical conditions might have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 can results in hospitalization or death. The virus that causes COVID-19 can be spread to others before and after a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

**What is a screening test for asymptomatic population surveillance?**

This molecular-based screening tool is designed, for use by trained personnel, to detect the virus (SARS-CoV-2) that causes COVID-19 in saliva specimens. It is not intended to be used as a diagnostic test for COVID-19 disease.

**Why will my sample be tested?**

You may elect to be tested because your educational institution, employer, or healthcare provider is carrying out surveillance screening in order to provide a safe environment to carry out education, business and essential activities. Depending on the scenario, you may be asked to provide a saliva sample for screening on a regular basis, such as once per week or several times per week.

Testing of the samples will help find out if you may have been exposed to the SARS-CoV-2 virus, the causative agent of COVID-19.

**What are the known and potential risks and benefits of the test?**

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection
- Possible incorrect test results (see below for more information).

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**What does it mean if I have a positive test result?**
If you have a positive test result, it is likely that your saliva contains the SARS-CoV-2 virus. *It does not mean that you have been diagnosed with COVID-19.* Your institution may request that you take an FDA approved or authorized test to confirm the screening test result. If a confirmatory test is carried out with an FDA approved or authorized test, your healthcare provider will work with you to determine how best to care for you based on the test results along with your medical history and your symptoms.

**What does it mean if I have a negative test result?**
A negative test result means that the SARS-CoV-2 virus that causes COVID-19 was not found in your saliva sample.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people that may have the SARS-CoV-2 virus in their saliva. This means that you could still have the SARS-CoV-2 virus in your saliva even though the test result is negative. If your test is negative, the institute that administered the test will provide recommendations for how to best proceed.

It is important that you work with the institute that administered your test to help you understand the next steps you should take.

**Is this test FDA-approved or cleared?**
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). This test is currently submitted to the FDA as an EUA application. Additionally, this test is being validated for use by various State public health laboratories. The United States Health and Human services department is currently allowing screening tests for asymptomatic population surveillance, such as this one, to be used at the discretion of an administering institution with the consent of those individuals being tested.

More information regarding issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov