

FACT SHEET FOR INDIVIDUALS

SalivaDirect, Inc.

SalivaDirect for use with DTC Kits

Updated – July 1, 2024

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because you are collecting an individual saliva specimen at home (which includes in a community-based setting) using the SalivaDirect DTC Saliva Collection Kit and sending your sample for the Coronavirus Disease 2019 (COVID-19) testing with an FDA authorized molecular test at a CLIA laboratory.

This Fact Sheet contains information to help you understand the risks and benefits of using this Direct to Consumer (DTC) product for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:

<https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before 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 the SalivaDirect for use with DTC Kits?

The product is designed to detect the virus that causes COVID-19 in saliva specimens collected at home (which includes in a community-based setting) using the

SalivaDirect DTC Saliva Collection Kit which you then send to a CLIA laboratory, identified by SalivaDirect, Inc., for COVID-19 testing with the FDA authorized test called the SalivaDirect for use with DTC Kits.

Why should my sample be tested?

You may want to have your sample tested because you or your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because you:

- Live in or have recently traveled to a place where transmission of COVID-19 is known to occur; or
- Have been in close contact with an individual suspected of or confirmed to have COVID-19; or
- Believe there is another reason to investigate your COVID-19 status.

Testing of your sample will help find out if you may have COVID-19.

Laboratories may use pooling when testing your specimen, which means they combine your sample with other individuals samples prior to testing and test them as a “pool”. The laboratory may return a result for the entire pool together or may return individual results.

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 result (see below for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19. If you have a positive result you should follow up with your healthcare provider who will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. You should follow the latest CDC guidance to avoid spreading the virus to others, such as self-isolation, to reduce the potential transmission of disease.

If you were tested as part of a pool that returned a positive or invalid test result, you may have COVID-19 and should consider yourself to have a positive test result unless or until you receive a negative test result when re-tested individually. However, as most individuals in a positive pool will likely receive a negative result when re-tested individually, you should isolate until receiving a negative result when re-tested individually and should not be grouped with other individuals who have received a positive or presumptive positive result.

There is a small possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19.

What does it mean if I have a negative test result?

A negative test result means that the virus that causes COVID-19 was not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected. In particular, people infected with COVID-19 but who have no symptoms may not shed enough virus to trigger a positive test. This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, but you either develop symptoms or continue to have symptoms and/or they get worse, you should reach out to your healthcare provider who will work with you to determine the next steps you should take. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing

If you develop symptoms or your symptoms get worse you should seek medical care. If you have the following symptoms you should seek immediate medical care at the closest emergency room:

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake up or stay awake
- Bluish lips or face

COVID-19. If you have no symptoms but have been tested because you thought you may have been exposed to COVID-19, you should continue to monitor your health and let your healthcare provider know if you develop any symptoms of COVID-19.

If your test result indicates your specimen was pooled and you have a negative test result there a small chance that your result is incorrect. You should talk with your healthcare provider if you are concerned.

You should talk with your healthcare provider if you are concerned. It is important that you work with your healthcare provider 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, but it has been issued an Emergency Use Authorization (EUA). FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of

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the COVID-19 declaration justifying the emergency use of in vitro diagnostics, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has 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>.

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