You are provided this Fact Sheet because you obtained the Detect™ Covid-19 Test for testing yourself or dependants for genetic material (nucleic acid) from the virus that causes COVID-19. If you are suspected of Covid-19 (symptomatic or exposed), you can use a single Detect Covid-19 Test. If you have no reason to suspect Covid-19 (for example you do not have symptoms and you were not exposed to someone who had Covid-19), testing must be performed twice over 3 days with at least 24 hours (and no more than 48 hours) between tests.

This Fact Sheet contains information to help you understand the risks and benefits of using this over the counter (OTC)/non-prescription use 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 Detect™ Covid-19 Test?
The product is a molecular nucleic acid amplification test (NAAT) that detects the genetic material of the SARS-CoV-2 virus using a molecular amplification reaction that is a similar, alternative amplification method to polymerase chain reaction (PCR). When you have COVID-19 the SARS-CoV-2 virus can be present in your nostrils. This test can detect genetic material from the SARS-CoV-2 virus in your nostrils.

There are different kinds of tests for diagnosing COVID-19. This test is a molecular test, which detects genetic material from the virus. Antigen tests detect proteins, small parts of the virus. Another type of test is the antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection. This molecular test and antigen tests cannot detect a previous COVID-19 infection. Antibody tests are not suitable to diagnose an active COVID-19 infection.

The Detect™ Covid-19 Test is intended for the qualitative detection of nucleic acid from the virus that causes COVID-19 in anterior nasal swab samples collected from either individuals with symptoms of COVID-19 OR individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Clinical performance of the Detect™ Covid-19 Test
In a clinical study conducted in the USA, individuals self-tested or tested their children using the Detect™ Covid-19 Test in a home or a simulated home environment. The Detect™ Covid-19 Test was compared to a FDA authorized molecular laboratory PCR test for COVID-19. In comparison to the laboratory test, Detect™ Covid-19 Test correctly identified 90.9.9% (30/33) of positive samples and 97.5% (77/79) of negative samples. The 2 missed negative samples had a correct negative result with the Detect™ Covid-19 Test, but were incorrectly interpreted by the user.

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.
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, and/or
- have been in close contact with an individual suspected of or confirmed to have COVID-19.
- believe there is another reason to investigate your COVID-19 infection status.

Testing of your sample will help find out if you may have 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 result (see below for more information).

Potential benefits include:
- The results, along with other information, can help 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 others in your community.

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 for a minimum of 10 days, to reduce the potential transmission of disease. 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 infection.


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, this may be more common in individuals with no symptoms. 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 you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

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

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](https://www.cdc.gov/COVID19). In addition, please also contact your healthcare provider with any questions/concerns.
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.