You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Revogene SARS-CoV-2 assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test 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 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 Revogene SARS-CoV-2 assay? The test is designed to detect the virus that causes COVID-19 in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swab specimens.

Why was my sample tested? You were tested because 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;
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples 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 those you come in contact with.

What does it mean if I have a positive test result for SARS-CoV-2? If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a smaller possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many

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.
cases of COVID-19. Your healthcare provider will work
with you to determine how best to care for you based on
the test results along with medical history, and your
symptoms.

**What does it mean if I have a negative test result for
SARS-CoV-2?**
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.

This means that you could possibly still have COVID-19
even though the test result is negative. If your test is
negative, your healthcare provider will consider the test
result together with all other aspects of your medical
history (such as symptoms, possible exposures, and
geographical location of places you have recently
traveled) in deciding how to care for you.

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
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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