You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the CentoSure SARS-CoV-2 RT-PCR 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 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 CentoSure SARS-CoV-2 RT-PCR Assay?
The test is designed to detect the virus that causes COVID-19 in dry oropharyngeal 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, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.
- You and your healthcare provider believe there is another reason to investigate your COVID-19 infection status.

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.

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.
FACT SHEET FOR PATIENTS
CENTOGENE US, LLC.
CentoSure SARS-CoV-2 RT-PCR Assay
September 29, 2020

- 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?
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
cases of COVID-19 infection. 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?
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, 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.

If you have no symptoms but have been tested because
your doctor 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 you develop symptoms you
may need another test to determine if you have
contracted the virus causing COVID-19.

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

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. 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). The EUA for this test is supported by the
Secretary of Health and Human Service’s (HHS’s)

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