FACT SHEET FOR PATIENTS

You are being given this Fact Sheet because your sample(s) was
tested for the Coronavirus Disease 2019 (COVID-19) using the
BioGX SARS-CoV-2 Reagents for BD MAX™ System.

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.

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which
can cause mild to severe respiratory illness, was first identified in
Wuhan, China, and has now spread globally, including the
United States. There is limited information available to
characterize the spectrum of clinical illness associated with
COVID-19 but it likely spreads to others when a person shows
signs or symptoms of being sick (e.g., fever, coughing, difficulty
breathing, etc.).

What is the BioGX SARS-CoV-2 Reagents for
BD MAX™ System?
The test is designed to detect the virus that causes COVID-19 in
respiratory specimens, for example nasal or oral swabs.

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.

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 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. Therefore, it is also likely that you may be placed in
isolation to avoid spreading the virus to others. There is a very
small chance that this test can give a positive result that is
wrong (a false positive result). Your healthcare provider will
work with you to determine how best to care for you based on
the test results along with other factors of your medical history,
and your symptoms, possible exposures, and geographic
location of places you have recently traveled.

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. For COVID-19, a negative test
result for a sample collected while a person has symptoms
usually means that COVID-19 did not cause your recent illness.
However, it is possible for this test to give a negative result that
is incorrect (false negative) in some people with COVID-19. This
means that you could possibly still have COVID-19 even though
the test is negative. If this is the case, your healthcare provider

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.
will consider the test results 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.

**Is this test FDA-approved or cleared?**

No. This test is not yet approved or cleared by the United States FDA. However when a manufacturer meets a specific set of criteria established by the United States FDA, the manufacturer is allowed to make the test available while the manufacturer pursue Emergency Use Authorization (EUA).

**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.