FACT SHEET FOR PATIENTS
ID NOW COVID-19 – Abbott Diagnostics Scarborough, Inc. March 27, 2020
Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the ID NOW COVID-19 test.

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. 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 ID NOW COVID-19 test?
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

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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 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. 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 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. 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)
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

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