You are being given this Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using the Access SARS-CoV-2 IgG II.

You should not interpret the results of this test as an indication or degree of immunity or protection from infection.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV-2, the virus that causes 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. You have the option to refuse use of this test. However, your doctor may be recommending this test because they believe it could help with your care.

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.

How are people tested for COVID-19?
Two kinds of tests are currently available for COVID-19: diagnostic tests and adaptive immune response tests (such as antibody tests).

- A diagnostic test tells you if you have a current infection.
- An adaptive immune response test, such as an antibody test, tells you if you may have had a previous infection.

What is the Access SARS-CoV-2 IgG II?
This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

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.

What does it mean if I have a positive test result?
If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. A positive test result may also occur after receipt of a COVID-19 vaccine. However, the meaning of a positive antibody

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.
result in individuals who received a COVID-19 vaccine is unknown. 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,
your symptoms, possible exposures, and geographical
location of places you have recently traveled.

There is also a chance that this test can give a positive
result that is wrong (a false positive result). Even a high-
performing antibody test when used in a population
without many cases of COVID-19 infection may produce
as many or more false results as true results because
the likelihood of finding someone who has been infected
is very small.

Your healthcare provider will work with you to determine
the likelihood of false result.

This test may give you a numerical result, but you
should not interpret the number to mean that having
any measurement of antibodies to SARS-CoV-2 will
protect you from getting infected again or help
reduce the severity or duration of a future COVID-19
infection. This topic is being studied, but the
information is unknown. It is also not known how
long antibodies to SARS-CoV-2 will remain present
in the body after infection.

Regardless of your test result, you should continue
to follow CDC guidelines to reduce the risk of
infection, including social distancing and wearing
masks.

What does it mean if I have a negative test result?
A negative test result means that antibodies to the virus
that causes COVID-19 were 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 antibodies. Additionally, a negative result
may occur if you are tested early in your illness and your
body hasn’t had time to produce antibodies to infection.
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.

The meaning of a negative antibody result for individuals
that have received a COVID-19 vaccine is unknown.

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. FDA may issue an Emergency Use
Authorization (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 emergency of IVDs, 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-
advise-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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