FACT SHEET FOR PATIENTS
Qorvo Biotechnologies, LLC.
Omnia™ SARS-CoV-2 Antigen Test

Updated: July 29, 2022

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Omnia™ SARS-CoV-2 Antigen 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 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 Omnia™ SARS-CoV-2 Antigen Test?
The Omnia™ SARS-CoV-2 Antigen Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in respiratory specimens, for example anterior nasal swab (NS) 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 other risk factors and you are within the first six days of the onset of symptoms, or you are undergoing serial testing even though you do not have symptoms or other risk factors for 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). Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as if you have no known exposures to SARS-CoV-2 or are residing in a community with low prevalence of infection. Your healthcare provider will work with you to determine how

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.
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The most up-to-date information on COVID-19 are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you will not have an additional test to determine if you are contagious, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers)
- Other symptoms have improved (for example, when your cough or shortness of breath has improved) **Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation
- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf.

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 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?**
There are no approved available alternative antigen tests. Any tests that have received full marketing status (i.e., 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](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](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).

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