FACT SHEET FOR PATIENTS
Princeton BioMeditech Corp.  Updated: October 27, 2021

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.
The results of this test may help limit the spread of COVID-19 and/or influenza to your family and others in your community.

**What does it mean if I have a positive test result for SARS-CoV-2?**

If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. 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 very small chance 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 positive test result for influenza A and/or B viruses?**

If you have a positive test result for the presence of influenza A and/or influenza B viruses, it is very likely that you have the flu. If you have a positive result for an influenza virus, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. 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, medical history, and your symptoms.

**What does it mean if I have a positive test result for SARS-CoV and influenza (A and/or B) viruses?**

It is possible for an individual to be infected with SARS-CoV-2 virus, influenza A virus, and/or influenza B virus, at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

**What does it mean if I have a negative test result for SARS-CoV-2, influenza A, or influenza B viruses?**

A negative test result means that proteins from the virus that causes COVID-19 or influenza 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 or influenza. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 or influenza after your sample was collected and then have become infected.

This means that you could possibly still have COVID-19 or influenza 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. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens may be more likely to be negative compared to a molecular assay for SARS-CoV-2 or influenza.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

**What are the differences between antigen tests and other COVID-19 tests?**

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but 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.

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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 do not have an additional test to determine if you are infected and may spread the infection to others, 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 days 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)
- At least 10 days have passed since your symptoms first appeared.


**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?**
There are approved/cleared influenza antigen tests, but there is not yet an approved available alternative antigen test for influenza combined with COVID-19 in one test. 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/deviceadvice-comprehensive-regulatory-assistance/medicaldevice-databases](https://www.fda.gov/medical-devices/deviceadvice-comprehensive-regulatory-assistance/medicaldevice-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-andresponse/mcm-legal-regulatory-and-policyframework/emergency-use-authorization](https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policyframework/emergency-use-authorization).

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