FREQUENTLY ASKED QUESTIONS FOR PATIENTS

INDICAID®
COVID-19 RAPID ANTIGEN TEST
PHASE SCIENTIFIC

ABOUT COVID-19	
What is COVID-19?	COVID-19 is a respiratory illness caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a virus from the coronavirus subfamily. COVID-19 is a highly infectious disease and can spread through human-to-human transmissions, such as close contact with infected individuals or by being in enclosed spaces where contaminated droplets or airborne particles circulate. For more and updated information on COVID-19 transmission, visit https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html
What are the symptoms of COVID-19?	Symptoms may begin 1-14 days after exposure to the virus, and can include fever, cough, breathing difficulties, fatigue, and loss of smell and taste. Most people with COVID-19 exhibit mild to moderate symptoms, while some exhibit no noticeable symptoms at all. However, there are people who will develop severe symptoms from COVID-19, with outcomes that can include hospitalization, intensive care, post-sickness conditions, and even death. Individuals infected with COVID-19 can remain contagious for up to 20 days, and can spread the virus even if they themselves do not develop symptoms. For more and updated information on COVID-19 symptoms, visit https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Who is most at risk of severe illness due to COVID-19?	People most at risk are older people aged 60 years and over, as well as individuals of any age with underlying medical conditions such as high blood pressure, heart or lung disease, diabetes, or cancer. However, anyone can get sick with COVID-19 and become seriously ill, even people considered healthy and low risk. For more and updated information on groups at increased risk of severe illness due to COVID-19, visit https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html
Why is it important to test for COVID-19?	Testing individuals, groups, or populations for SARS-CoV-2 can be an important part of the strategies to stop or slow the spread of COVID-19. Robust and responsive testing can help reduce transmission by diagnosing infections, screening for isolation, or monitoring trends, not just for healthcare providers but also for organizations in non-healthcare settings, such as schools, workplaces, or congregate housing.
ABOUT INDICAID® COVID-19 RAPID ANTIGEN TEST	
What is the INDICAID® COVID-19 Rapid Antigen Test?	The **INDICAID®** COVID-19 Rapid Antigen Test is a lateral flow immunoassay designed for the qualitative detection of SARS-CoV-2 antigens. Antigen tests are designed to detect proteins from the virus that causes COVID-19 through swab specimens taken from the patient's nose.
What are the advantages of the I INDICAID® COVID-19 Rapid Antigen Test?	This test can be administered with no equipment or training needed. The test has high sensitivity and can detect lower viral load samples against competitive products. This test has been granted Emergency Use Authorization (EUA) by the United States Food and Drug Administration.
What is swab testing?	The swab test method is utilized by the biomedical community for the collection of upper-respiratory specimens for molecular and rapid antigen testing. The CDC supports and promotes this testing method in light of the current COVID-19 pandemic climate for its practicality, simplicity, and efficiency of gathering much-needed data in bulk.

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How is this test performed and who can perform it?	The test is performed by a CLIA Certified Health Care Provider (HCP) using direct anterior nasal swab specimens from suspected COVID-19 individuals within the first five (5) days of symptom onset. Anterior nasal swab specimens may be collected by an HCP or self-collected by individuals 18 years of age or older, under the supervision of an HCP.
What do batch-collection and bulk-testing mean?	**INDICAID**'s intuitive design allows the collection of multiple samples within a very short timeframe, followed by bulk-testing of samples within only two hours.
What are the known and potential risks and benefits of the test?	The **INDICAID®** COVID-19 Rapid Antigen Test is for diagnosis only and is safe to use, with no long-term impact on human health. ***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 those you come in contact with.
What does a positive test result mean?	A positive test result means that proteins from the virus that causes COVID-19 were found in your sample. This means that it is likely that you have COVID-19, even if you do not have any symptoms. There is also a very small chance that this test can give a positive result that is incorrect (a false-positive), particularly when used in a population without many cases of COVID-19. Your healthcare provider will discuss the next steps with you and how to best care for you based on your medical history and symptoms.
What does a negative test result mean?	A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. This means that you are not infected with the virus. However, it is possible for this test to give a negative result that is incorrect (false-negative) in some people with COVID-19. 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.
What factors can influence an incorrect test result?	• This test does not differentiate between SARS-CoV and SARS-CoV-2 viruses, so you may receive a positive result but have a different coronavirus that does not cause COVID-19. • It is possible to test a person too early or too late during COVID-19 to make an accurate diagnosis. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results from patients with symptom onset beyond 5 days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. • Improper handling of the test kit not according to guidelines may yield imprecise test results. • When an incorrect result is suspected, it is important that you engage with your healthcare provider to help you understand the situation and evaluate your next steps.
Should antigen test results be considered definitive of COVID-19 status?	Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.
What are the differences between antigen tests and other COVID-19 tests?	There are different kinds of tests for 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

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	out infection. If your antigen test result is negative, you should discuss with your healthcare provider whether a molecular test would help with your care, and when you should discontinue home isolation if necessary. If a molecular test is not available, the CDC recommends that you should stay home until three things have happened: 1. You have had no fever for at least 24 hours (one full day of no fever without the use of medicine that reduces fevers). 2. Acuteness of other symptoms has lessened (for example, when your cough or shortness of breath has improved). 3. At least 10 days have passed since your symptoms first appeared.
How effective is this test with different variants of SARS-COV-2?	Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
Does INDICAID® detect the Omicron variant?	Data from our US multi-center clinical study demonstrates similar performance for detection of the COVID-19 Omicron variant compared to the original COVID-19 strain.
What is the shelf-life of INDICAID®?	The shelf-life of the INDICAID® test is one (1) year from the date of manufacture. The one (1) year expiration date is provided on the label of the outer box.
Are there other approved alternative antigen tests?	There are no other approved (available) alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), contrary to an EUA by the FDA can be found by searching the medical device databases here: FDA Medical Device Database
Does insurance, Medicare, or Medicaid cover rapid antigen tests? If so, what are the codes for them?	The Insurance Code: **U003** The Medicaid CPT Code: **87426* | 87811QW** The Medicare CPT Codes: **87635 | 86769 | 86328** **Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19])* Source: AMA, 2020
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Has the efficacy of the INDICAID® COVID-19 Rapid Antigen Test been validated in clinical trials?	The **INDICAID®** COVID-19 Rapid Antigen Test has been validated clinically. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2021 and March 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation.
Is the INDICAID® COVID-19 Rapid Antigen Test available in the United States?	The **INDICAID®** COVID-19 Rapid Antigen Test is available in the United States under an emergency access mechanism called an Emergency Use Authorization (EUA) by the US Food and Drug Administration. The EUA for this test is supported by the Secretary of Health and Human Services 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.
Where is PHASE Scientific located?	**PHASE SCIENTIFIC US** is a biotech company that empowers people by building innovative tools that provide better information about people's health. Founded by bioengineers from the University of California, Los Angeles (UCLA), the company has three locations:

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	• **PHASE Scientific USA:** US Corporate Headquarters 10527 Garden Grove Boulevard, Garden Grove, CA 92843, U.S.A. • **PHASE Scientific USA:** Sales and Marketing 8000 Avalon Boulevard, Ste 100, Alpharetta, GA 30009, USA • **PHASE Scientific International:** International Corporate Headquarters 32 & 33/F, Gravity 29, Hing Yip St., Kwun Tong, Kowloon, Hong Kong You may also reach the company email at **ussales@phasesci.com** or visit our website at phasescientificusa.com