FREQUENTLY ASKED QUESTIONS FOR HEALTHCARE PROVIDERS

INDICAID™ COVID-19 Rapid Antigen Test

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What is the INDICAID™ COVID-19 Rapid Antigen Test?	The INDICAID™ COVID-19 Rapid Antigen Test (CE-IVD) is a lateral flow immunoassay designed for the qualitative detection of SARS-CoV-2 antigen in direct nasal swab samples.
What are the advantages of a rapid antigen test?	This test can be administered with no equipment or training needed, and results can be developed in as fast as 20 minutes. 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.
How does a rapid antigen test work?	Antigens are present in the SARS-CoV-2 virus, and can bind with specific antibodies. When a virus enters a human body and begins to multiply, the body begins to react to the viral antigen, possibly resulting in symptoms. The INDICAID™ COVID-19 Rapid Antigen Test detects antigen from SARS-CoV-2 virus and can be used for COVID-19 screening during active infection.
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.
How many collection methods do the CDC support?	The CDC recognizes three methods: the *nasopharyngeal* (NP), the *anterior nares* (nasal), and *oropharyngeal* (throat) swabs. However, the CDC advocates for and uses ONLY two methods to collect COVID-19 samples, namely the *nasopharyngeal* (NP) and the *anterior nares* (nasal) *swab test* for bulk collection.
What kind of swab does INDICAID™ use?	INDICAID™ utilizes the anterior nasal swab test method. It is less invasive and safe to use.
How is this test performed and who can perform it?	The test is performed by any CLIA Certified Health Care Provider (HCP) using direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their HCP within the first five (5) days of symptom onset. Anterior nasal swab specimens may be collected by a HCP or self-collected by individuals 18 years of age or older, under the supervision of an HCP.
What laboratories are authorized to use this test and under what conditions can it be used?	This test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., inpatient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
What precautions should be taken in administering this test?	Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available on the CDC website. When collecting and handling specimens from

	individuals suspected of being infected with COVID-19, appropriate personal protective equipment (PPE) should be used as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).
What does it mean if the specimen tests positive for the virus that causes COVID-19?	A positive test result for COVID-19 indicates that nucleocapsid antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions.
What about if the specimen tests come back negative for the virus that causes COVID-19?	A negative test result for this test means that nucleocapsid antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.
What are the risks of false-positive results using this test?	This test has been designed to minimize the likelihood of false-positive test results. However, positive results can be due to present infection with non-SARS-CoV-2 coronavirus strains that do not cause COVID-19, such as SARS-CoV.
What are the risks of false-negative results using this test?	When diagnostic testing is negative, the possibility of a false-negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false-negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.
What factors can cause an incorrect result in this type of test?	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. Specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, 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.
Should this test be used as a sole basis to determine COVID-19 infection?	Results from antigen testing should not be used as the sole basis to diagnose or exclude COVID-19 infection. A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings (Interim Guidance).
How was the performance of this test evaluated?	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.
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.
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), as opposed to an EUA by the 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
What is the process for reporting adverse effects from this test?	Report adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.

Does insurance, Medicare, or Medicaid cover rapid antigen tests?	Yes. Insurance, Medicaid, and Medicare cover rapid antigen tests.
What are the codes for insurance, Medicare, and Medicaid for rapid antigen testing?	The Insurance Code: **U003** The Medicaid CPT Code: **87426** The Medicare CPT Codes: **87635 | 86769 | 86328**
What is batch collection and bulk-testing?	**INDICAID's** intuitive design allows the collection of multiple samples within a very short timeframe, followed by bulk-testing of samples up to two hours after sample collection.
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 in effect for the duration of the COVID-19 declaration justifying emergency unless terminated or revoked (after which the test may no longer be used).
What is the company that makes the INDICAID™ COVID-19 Rapid Antigen Test?	**PHASE SCIENTIFIC US** is a biotech company that empowers people by building innovative tools that provide better information about health. Founded by bioengineers from the University of California, Los Angeles (UCLA), the company's office is located at 10527 Garden Grove Boulevard, Garden Grove, CA 92843, U.S.A. You may also reach the company email at **ussales@phasesci.com** or visit our website at phasescientificusa.com