FREQUENTLY ASKED QUESTIONS FOR HEALTHCARE PROVIDERS

INDICAID®
COVID-19 RAPID ANTIGEN TEST
PHASE SCIENTIFIC

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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 the SARS-CoV-2 virus and can be used for COVID-19 screening during active infection.
What is swab testing?	The biomedical community utilizes the swab test method to collect 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 suspected of COVID-19 by their HCP 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 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, which meets requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at 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 is 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).

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ABOUT INDICAID® COVID-19 RAPID ANTIGEN TEST	
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 detection limit. However, a negative result does not rule out COVID-19 and should not be used solely for treatment or patient management decisions, including infection control decisions. Antigen tests are 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 an 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 for determining 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.

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Does INDICAID® detect the Omicron variant?	Data from our US multi-center clinical study demonstrates similar performance for detecting 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), as opposed to a 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.

ABOUT WHO CAN PERFORM THE TEST	
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. It can also be performed from suspected individuals without COVID-19 symptoms, or other epidemiological reasons, when tested twice over two or three days with at least 24 hours (and no more than 28 hours between tests). 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 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, which meets requirements to perform moderate complexity, high complexity, or waived tests. This test is also authorized for use at the Point of Care (POC) locations, i.e., inpatient care settings operating under the CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
What is the CLIA	According to the CDC the CLIA is also known as: *"The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. Exceptions to the CLIA regulations exist for certain testing, including employment-related drug testing by SAMSHA certified laboratories, testing performed for forensic purposes (criminal investigations), and research or surveillance testing performed on human specimens in which patient-specific results are not reported (if the results are not used for diagnosis or treatment decisions). For more information, please refer to CLIA at 42 CFR 493.3."*

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Who regulates and supports the CLIA?	Along with the ***CMS*** and the ***FDA***, the ***CDC*** oversees the CLIA program. Each entity maintains specific clinical and laboratory responsibilities in the program, namely: ➢ CMS (Centers for Medicaid and Medicare Services) ○ Issues laboratory certificates ○ Collects user fees ○ Conducts inspections and enforces regulatory compliance ○ Approves private accreditation organizations for performing inspections, and approves state exemptions ○ Monitors laboratory performance on Proficiency Testing (PT) and approves PT programs ○ Publishes CLIA rules and regulations ➢ US (Food & Drug Administration) ○ Categories tests based on complexity ○ Reviews requests for Waiver by Application ○ Develops rules/guidance for CLIA complexity categorization ➢ CDC (Centers for Disease Control) ○ Providing analysis, research, and technical assistance ○ Developing technical standards and laboratory practice guidelines, including standards and guidelines for cytology ○ Conducting laboratory quality improvement studies ○ Monitoring proficiency testing practices ○ Developing and distributing professional information and educational resources ○ Managing the Clinical Laboratory Improvement Advisory Committee (CLIAC)
What are the two kinds of CLIA Tests that a Health Care Provider can apply for?	**The two kinds of CLIA Tests are:** **I. CLIA Waiver by Application or Waived Testing:** ■ **As of 04/09/202,** the FDA Clarified CLIA-waived Status for ***Point-of-Care SARS-CoV-2 Tests under EUA*** *"The U.S. Food and Drug Administration (FDA) recently clarified that, when it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived. For the duration of the national emergency declaration for COVID-19,* ***such tests can be performed in any patient care setting that operates under a CLIA Certificate of Waiver or Certificate of Compliance/Certificate of Accreditation****. In addition, FDA clarified that tests for SARS-CoV-2 that are offered prior to or without an EUA have not been reviewed by FDA, are not FDA authorized, and have not received a CLIA categorization external icon. Thus, those tests are considered high complexity by default until they receive an EUA or other FDA approval that indicates they may be performed as moderate complexity or waived tests."* ■ CLIA's definition of Waived Tests: *"**[These are] simple tests with a low risk for an incorrect result**."* These include: ● Certain tests listed in the CLIA regulations ● Tests cleared by the FDA for home use ● Tests that the manufacturer applies to the FDA for waived status by providing scientific data that verifies that the CLIA waiver criteria have been met Sites performing only Waived Testing must have a CLIA certificate and follow the manufacturer's instructions; other CLIA requirements do not apply to these sites. Here is the FDA's webpage on CLIA Waivers: "*Under CLIA, FDA categorizes in vitro diagnostic (IVD) tests by their degree of complexity: waived, moderate complexity, and high complexity. Tests that are waived by regulation under 42 CFR 493.15(c), or cleared or approved for home use, are automatically categorized as waived following clearance or approval. Otherwise, following clearance or approval, tests may be categorized either as moderate or high complexity according to the CLIA categorization criteria listed in 42 CFR 493.17."*

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	II. Nonwaived Testing: *"Nonwaived testing is the term used to refer collectively to moderate and high complexity testing. Laboratories or sites that perform these tests need to have a CLIA certificate, be inspected, and must meet the CLIA quality standards described in 42 CFR Subparts H, J, K, and M."*

ABOUT CPT CODES, MEDICAL COVERAGE, & PHASE SCIENTIFIC	
Does insurance, Medicare, or Medicaid cover rapid antigen tests?	Yes. Insurance, Medicaid, and Medicare cover rapid antigen tests.
What are the CPT Codes for insurance, Medicare, and Medicaid for rapid antigen testing?	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
What does batch-collection and bulk-testing mean?	**INDICAID's** functional design allows the collection of multiple samples within a 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 protocol 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).
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: • **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