INDICAID™ COVID-19 Rapid Antigen Test

The **INDICAID™ COVID-19 Rapid Antigen Test** is a point-of-care kit designed for the detection of SARS-CoV-2 antigens in direct nasal swab samples.

The test is intended for use by healthcare professionals in symptomatic individuals within 5 days after onset of symptoms.

This product has received **FDA Emergency Use Authorization**.

Product Advantages

- **Fast:** Results in 20 minutes
- **Convenient:** No equipment or training needed
- **Simple Sampling:** Self-collected shallow nasal samples
- **Batch Testing:** Easily collect and test multiple samples

Intuitive Workflow

01 Collect Nasal Swab

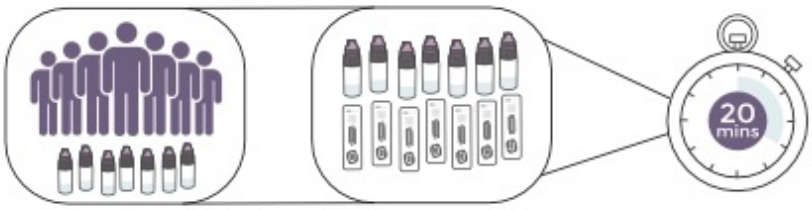
02 Insert and Stir

03 Apply Sample

04 Read Visually
After 20 Minutes

Batch Testing

Intuitive design allows for the concurrent collection of a large number of samples followed by batch testing of individual samples within 2 hours.



Collection Testing Results

Clinical Performance

In a prospective US clinical study, INDICAID™ accurately identified 84% of those who were positive (PPA) and 97% of those who were negative (NPA) for SARS-CoV-2.

Product performance against variants of concern are evaluated on an ongoing basis.

Technical Bulletin available upon request.

About Us

PHASE Scientific is a high-growth biotech company founded by bioengineers from UCLA. We build tools that empower people by giving them better information about their health.

indicaid@phasesci.com
us.phasescientific.com

PHASESCIENTIFIC

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INDICAID® COVID-19 Rapid Antigen Test

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Product Advantage

Fast: Results in 20 minutes

Convenient: No equipment or training needed

High Sensitivity: Detect lower viral load samples against competitive products

Emergency Use Authorization issued by the Food and Drug Administration

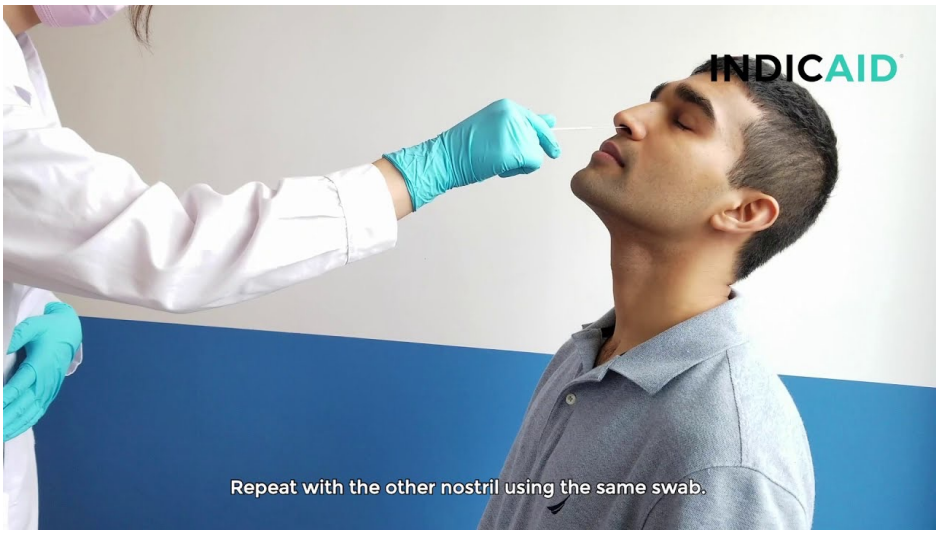
BLVD MEDICAL

Specifications

Features	Specifications
Product code	2110200
Items per box	25x
Specimen type	Nasal and nasopharyngeal swab
Limit of detection	140 $TCID_{50}$ / swab
Intended use	For deteremining the presence of SARS-CoV-2 antigens in direct nasal swab sampless
Shelf life	12 months
Storage condition	2-30°C. Do not freeze. Avoid direct sunlight

Only shallow nasal depth required

Great for kids and sensitive patients



Data / Performance

The performance of INDICAID® COVID-19 Rapid Antigen Test has been validated clinically. Below are the results of in-house and independent clinical validation.

In-house Validation

INDICAID® COVID-19 Rapid Antigen Test limit of detection (LoD) was determined by testing limiting dilutions of inactivated SARS-CoV-2 virus in pooled human nasal matrix from presumed negative donors. Each test concentration was inoculated onto kit-provided swabs and processed according to the test procedure. The LoD was determined by confirming the lowest detectable concentration of SARS-CoV-2 at which 95% of the 20 replicates analyzed resulted in a positive test. The INDICAID® COVID-19 Rapid Antigen Test LoD in nasal matrix was confirmed to be 140 $TCID_{50}$ per swab.

Concentration ($TCID_{50}$/swab)	Number of Positives/Total	% Detected
140	20/20	100

Figure 1 - The results show that 100% detection of positive nasal samples can be achieved at the LoD of 140 $TCID_{50}$ per swab.

Clinical Validation

The clinical performance of the INDICAID® COVID-19 Rapid Antigen Test was evaluated by testing 50 positive and 50 negative SARS-CoV-2 retrospective clinical specimens from unique donors that were previously confirmed by a molecular test. The 100 clinical specimens were nasopharyngeal swab samples eluted in saline. Testing was performed at one investigational site by two untrained operators who were blinded to the RT-PCR results of the samples. The samples were first randomized, then each sample eluate was inoculated onto kit-provided swabs and processed as instructed in test procedure. The INDICAID®COVID-19 Rapid Antigen Test correctly detected 48 / 50 positive samples and demonstrated no false positives for the negative samples.

INDICAID® COVID-19 Rapid Antigen Test	Comparator Method		
	Positive	Negative	Total
Positive	48	0	48
Negative	2	50	52
Total	50	50	100
Positive Percent Agreement (PPA)	96% (95% CI: 86.3% - 99.5%)		
Negative Percent Agreement (NPA)	100% (95% CI: 92.9% - 100%)		

Figure 2 – The results show that INDICAID® COVID-19 Rapid Antigen Test reaches a positive percent agreement of 96% and a negative percent agreement of 100% with regard to the results of RT-PCR.
Recombinant N protein from UK (B.1.1.7), South Africa (B.1.351), US (B.1.2), and Brazil (B.1.1.28) variants were tested and found to be detectable by INDICAID® COVID-19 Rapid Antigen Test, suggesting that it may be able to detect the presence of these COVID-19 variants in patients.

INDICAID
Rapid Antigen Test

Purchase Process SOP

1: Purchase order made out to Adaptiv Biomed
Also include:
- Order Number that we will assign.
- Any Sales Tax Exemption Form or Resale Certificate
- CLIA Number or CLIA Waiver (assistance can be provided in obtaining CLIA Waiver.
- NPI if doctor or medical practice

2: Authorized Distributor will email confirmation of receiving PO, provide a Sales Order and propose delivery schedule.

3: Customer wires funds order to Authorized Distributor.
If financing, financing or terms are finalized.

4: Authorized Distributor drop ships direct from US facility to Customer's desired US delivery destination. International orders may ship from origin outside US.

Shipment confirmation and tracking provided.

FACT SHEET FOR HEALTHCARE PROVIDERS

PHASE Scientific International, Ltd.

INDICAID™ COVID-19 Rapid Antigen Test

July 28, 2021

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the INDICAID™ COVID-19 Rapid Antigen Test.

The INDICAID™ COVID-19 Rapid Antigen Test is authorized for use using direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: PHASE Scientific International, Ltd. - INDICAID™ COVID-19 Rapid Antigen Test.

What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

This test is to be performed only using direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset.

- The INDICAID™ COVID-19 Rapid Antigen Test can be used to test direct anterior nasal swab specimens. Anterior nasal swab specimens may be collected by a healthcare provider (HCP) or self-collected (by individuals 18 years of age or older, under the supervision of an HCP).
- The INDICAID™ COVID-19 Rapid Antigen Test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset.
- The INDICAID™ COVID-19 Rapid Antigen Test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity, high complexity, or waived tests.
- The INDICAID™ COVID-19 Rapid Antigen Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Please refer to the INDICAID™ COVID-19 Rapid Antigen Test Instructions for Use for additional information.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019*

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**

(COVID-19). For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "*Where can I go for updates and more information?*" section).

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. Patient management should follow current CDC guidelines.

The INDICAID™ COVID-19 Rapid Antigen Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests 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.

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. It is possible to test a person too early or too late during COVID-19 to make an accurate diagnosis via the INDICAID™ COVID-19 Rapid Antigen 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. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient from a false negative result include: delay or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

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)* (see links provided in "*Where can I go for updates and more information*?" section).

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. 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.

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA 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 (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative antigen tests. 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/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.

Where can I go for updates and more information?

CDC webpages:
General: https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs:(includes links to fact sheet for individuals and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

PHASE Scientific International Limited:
32 & 33F Gravity, 29 Hing Yip St.,
Kwun Tong, Kowloon, Hong Kong

Technical Support in the U.S.:
Website: www.phasescientific.com
Email: indicaid@phasesci.com
Telephone: +1 (657) 296 6106

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**