Medek
Health Systems

COVID-19 Antigen

Rapid Diagnostic At-Home Test

The INDICAID COVID-19 Rapid Antigen Test is an anterior nasal swab collection for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2.

- **Identify acute infection with 95% sensitivity and 99.5% specificity**
- **Rapid 20 Minute Results**
- **Anterior Nasal Swab Collection**
- **FDA EUA authorized**

EACH KIT CONTAINS

Test Device	Nasal Swab
Extraction Vial	Control Swab

MEDEKTESTKITS.COM

131 Waterman Ave
Mount Dora - FL 32757
888-996-3335

The MEDEK supplied test kit is FDA EUA for use without a separate reading machine at the Point of Care.

Product Information and Limitations of Sale:

- Results in 20 minutes w/ rapid testing
- Each set (box) has 25 individual tests
- For use as an aid in identifying, nucleocapsid protein
- Verification of use case prior to shipping is mandatory

Governance

A. Qualitative detection of nucleocapsid protein antigen from SARSCoV-2 in 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. 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). Emergency use of this test is limited to authorized laboratories.

   Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This 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.

B. Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency issued on the web on March 16, 2020, by U.S. Food and Drug Administration (FDA") which may be found here: https://www.fda.gov/media/135659/download

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

Compliance

A. All sales of Products are subject to the purchaser's compliance with the Policy and that the Products shall only be used by health professionals as defined in subsection (g) at:

   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=810.2

B. The Products shall not be made available, offered, distributed, or marketed, directly or indirectly, to the general public, or made available, sold, distributed, or marketed to anyone who the Representative or the Approved Account knows or has any reason to

know will make available, offer, distribute or market, directly or indirectly, the Products to the general public.

C. The Products are only for preliminary screening purposes and shall only be used to determine if additional testing is required.

Buyer Requirements

A. Qualified parties who agree to follow the guidance in the Policy including, but not limited to, validation, FDA notification, reporting of results, Emergency Use Authorization, clinical testing and distribution.

B. Payment must be made prior to shipment.

C. Payments accepted: Wire transfer or Credit Card (AMEX Preferred).

D. Order questions: Medek Health Systems, LLC - (352) 516-3072.

E. Wire transfer questions: (352) 383-2111

F.

BANK:	First National Bank of Mount Dora
ABA:	063104312
BENEFICIARY:	Medek Health Systems, LLC 131 Waterman Avenue Mount Dora, FL 32757
ACCOUNT NO:	30112085

Misc.

A. FDA guidelines for the product are attached below.

B. COVID-19 Antigen Rapid Diagnostic package insert is attached below.

C. Fact sheet for healthcare providers is attached below.

D. Fact sheet for patients is attached below.

July 28, 2021

Erika B. Ammirati RAC, MT(ASCP)
Ammirati Regulatory Consulting
Representing - PHASE Scientific International, Ltd.
10527 Garden Grove Blvd
Garden Grove, CA, 92843

Device:	INDICAID COVID-19 Rapid Antigen Test
EUA Number:	EUA210259
Company:	PHASE Scientific International, Ltd.
Indication:	Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in 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. 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). Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This 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.

Dear Erika B. Ammirati:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

[1] For ease of reference, this letter will use the term "you" and related terms to refer to PHASE Scientific International, Ltd.
[2] For ease of reference, this letter will use the term "your product" to refer to the INDICAID COVID-19 Rapid Antigen Test, used for the indication identified above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "INDICAID COVID-19 Rapid Antigen Test Instructions for Use" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a lateral flow immunoassay intended for the qualitative detection of

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

nucleocapsid protein antigen from SARS-CoV-2 in 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. 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). Your product does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of the viral antigen, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative 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.

Testing of direct anterior nasal swab specimens using your product, as outlined in the "INDICAID COVID-19 Rapid Antigen Test Instructions for Use" is limited to laboratories certified under CLIA that meet the requirements to perform moderate complexity, high complexity, or waived tests. This 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.

To use your product, the direct anterior nasal swab specimen is first placed and mixed in a Buffer Solution Vial to elute the specimen from the swab before removing the swab and capping the tube with the Buffer Solution Vial cap before three (3) drops of the Buffer Solution into the sample well (S) of the Test Device. The Test Device is composed of SARS-CoV-2 specific antibodies and a control antibody that are immobilized onto a nitrocellulose membrane support as two distinct lines. The test line (T) region contains monoclonal anti-SARS-CoV-2 antibodies and the control line (C) region contains polyclonal control antibodies. Polyclonal and monoclonal anti-SARS-CoV-2 antibodies conjugated with red-colored colloidal gold particles are used to detect the SARS-CoV-2 antigen. Formation of the Control line "C" serves as the internal control. The test result is read at 20 mins after application of the specimen to the Test Device.

The INDICAID COVID-19 Rapid Antigen Test includes the following materials or other authorized materials: Test Devices, Buffer Solution Vials, and Nasal Swabs.

Your product requires various types of quality control, including the procedural internal control that is built in the "control line" of the test device and the External Positive and Negative Controls, or other authorized control materials (as may be requested under Condition O. below), which are not included with your product but are available from you with the "INDICAID COVID-19 Antigen Quality Controls" instructions for use to be run as outlined in the "INDICAID COVID-19 Rapid Antigen Test Instructions for Use":

- COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives)
- COVID-19 Antigen Negative Control Vials (buffered solution with preservatives)

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The labeling entitled "INDICAID COVID-19 Rapid Antigen Test Instructions for Use," "INDICAID COVID-19 Rapid Antigen Test Quick Reference Guide," and "INDICAID COVID-19 Antigen Quality Controls" instructions for use (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: PHASE Scientific International, Ltd. - INDICAID COVID-19 Rapid Antigen Test
- Fact Sheet for Patients: PHASE Scientific International, Ltd. - INDICAID COVID-19 Rapid Antigen Test

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section

564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

PHASE Scientific International, Ltd. (You) and Authorized Distributor(s)[5]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) will include a physical copy of the "INDICAID COVID-19 Rapid Antigen Test Instructions for Use" and the "INDICAID COVID-19 Rapid Antigen Test Quick Reference Guide" with each shipped kit of your product to authorized laboratories.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

[5] "Authorized Distributor(s)" are identified by you, PHASE Scientific International, Ltd., in your EUA submission as an entity allowed to distribute your product.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number distributed.

G. You and authorized distributor(s) must collect information on the performance of your product. You will report to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

I. You and authorized distributor(s) must make available the control material "INDICAID COVID-19 Antigen Quality Controls" with the "INDICAID COVID-19 Antigen Quality Controls" instructions for use, or other authorized control materials (as may be requested under Condition O. below), at the same time as your product.

PHASE Scientific International, Ltd. (You)

J. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

K. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

L. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to

make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

P. You must evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

R. You must complete the agreed upon in-use/opened reagent stability study for use with your product in an FDA agreed upon post authorization study within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. You must complete the agreed upon real-time stability study for your "INDICAID COVID-19 Antigen Quality Controls" and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately.

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

Authorized Laboratories

V. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

W. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

X. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Y. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Z. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov), and you (via email: indicaid@phasesci.com, or via phone at Technical Service: +1-657-296-6106) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

AA. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

PHASE Scientific International, Ltd. (You), Authorized Distributor(s) and Authorized Laboratories

BB. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

CC. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

DD. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

EE. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure
Technical Correction: July 29, 2021 – Update contact address.

FACT SHEET FOR HEALTHCARE PROVIDERS

PHASE Scientific International, Ltd. **July 28, 2021**

INDICAID™ COVID-19 Rapid Antigen Test

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**

FACT SHEET FOR PATIENTS

PHASE Scientific International, Ltd.
INDICAID™ COVID-19 Rapid Antigen Test

July 28, 2021

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the INDICAID™ COVID-19 Rapid Antigen Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the INDICAID™ COVID-19 Rapid Antigen Test?
The INDICAID™ COVID-19 Rapid Antigen Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19, in direct anterior nasal swabs. The presence of viral proteins indicate you may have been infected with the virus and are likely to be contagious.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and you are within the first five (5) days of symptom onset.

What are the known and potential risks and benefits of the test?
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 it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. 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. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

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.

What does it mean if I have a negative test result?
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If your test result 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 collected after you have had symptoms for more than 5 days may be more likely to be negative compared to a molecular assay. 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 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. 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 will not have an additional test to determine if you are contagious, 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 day of no fever without the use of medicine that reduces fevers).

AND

- Other symptoms have improved (for example, when your cough or shortness of breath has improved)

**Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation.

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf

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?
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? 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.

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For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use only

For prescription use only

INDICAID™

COVID-19 Rapid Antigen Test

For Rapid Detection of SARS-CoV-2 Antigen

INSTRUCTIONS FOR USE

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Intended Use

The INDICAID™ COVID-19 Rapid Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in 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. 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). Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate

complexity, high complexity, or waived tests. This 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.

The INDICAID™ COVID-19 Rapid Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative 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.

The INDICAID™ COVID-19 Rapid Antigen Test is intended for use by trained clinical laboratory personnel and medical and healthcare personnel in Point of Care (POC) settings. The INDICAID™ COVID-19 Rapid Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation of the Test

Coronaviruses are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as MERS and SARS-CoV. A novel coronavirus (SARS-CoV-2) was discovered in December 2019 and has resulted in millions of confirmed human infections worldwide. COVID-19, the disease brought on by the virus, produces symptoms in infected patients that are similar to the other viral respiratory diseases including fever, cough, and shortness of breath. The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection.

The INDICAID™ COVID-19 Rapid Antigen Test is a non-invasive rapid point-of-care diagnostic test for the qualitative detection of SARS-CoV-2 antigen in respiratory specimens. Each INDICAID™ COVID-19 Rapid Antigen Test is single-use and can analyze one anterior nasal swab sample. The total time required to perform one test is approximately 20 minutes from clinical specimen collection to result.

Principles of the Procedure

The INDICAID™ COVID-19 Rapid Antigen Test is an immunochromatographic lateral flow assay that uses highly sensitive antibodies to detect antigen from SARS-CoV-2 in direct anterior nasal swab

samples from patients who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a nitrocellulose membrane support as two distinct lines. The test line (T) region contains monoclonal anti-SARS-CoV-2 antibodies and the control line (C) region contains polyclonal control antibodies. Polyclonal and monoclonal anti-SARS-CoV-2 antibodies conjugated with red-colored colloidal gold particles are used to detect the SARS-CoV-2 antigen.

During the test, the swab containing patient sample is placed and mixed in a Buffer Solution Vial. That Buffer Solution is then applied to the sample well of the test device. If SARS-CoV-2 antigen is present, it will bind to the antibody-gold conjugate forming an immunocomplex. The immunocomplex will then travel across the strip via capillary action towards the test line. The immunocomplex will then bind to the anti-SARS-CoV-2 antibodies at the test line (T), forming a visible red-colored line to indicate detection of antigens. If SARS-CoV-2 antigens are not detected in the sample, no color will appear at the test line (T).

The control (C) line is used for procedural control and should appear regardless of the test result. The appearance of the control line (C) serves to ensure the test is performing properly and the test result is valid.

The INDICAID™ COVID-19 Rapid Antigen Test is validated for use from direct specimens testing without transport media.

Reagents and Materials Provided

Kit Component	Quantity	Description
Test Devices	25	Individually foil pouched test device containing one test strip in a plastic device cassette. Each strip has one control line and one test line.
Buffer Solution Vials	25	Vial with cap and integrated dispensing tip, containing 400 µL of buffer solution.
Nasal Swabs	25	Individually wrapped, sterile specimen collector.
Package Insert	1 Instructions for Use 1 Quick Reference Guide	Instructions for use and Quick Reference Guide

Chemical and Safety Information

The extraction buffer in the INDICAID™ COVID-19 Rapid Antigen Test Buffer Solution vials contain the following hazardous ingredients:

Reagents	Hazards	Link to MSDS
Triton™ X-100	• Harmful if swallowed. • Causes skin irritation. • Causes serious eye damage. • Very toxic to aquatic life with long lasting effects.	https://www.sigmaaldrich.com/US/en/sds/sial/x100
ProClin™ 300	• Harmful if swallowed or inhaled. • Causes severe skin burns and eye damage. • May cause an allergic skin reaction. • Very toxic to aquatic life with long lasting effects.	https://www.sigmaaldrich.com/US/en/sds/sial/48914-u

The extraction buffer in the INDICAID™ COVID-19 Rapid Antigen Test Buffer Solution vials contain hazardous ingredients as shown in the table above. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. In case the irritation persists, please seek medical advice at: https://www.poison.org/contact-us or 1-800-222-1222.

Materials Required but not Provided

- Timer
- External Positive and Negative Controls (sold separately) – P/N: 2110410/2110420
  - 250 µL single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives)
  - 250 µL single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives)
- Any necessary personal protective equipment (PPE)

Precautions

- For *in vitro* diagnostic use only.
- For prescription use only.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the requirements to perform moderate complexity, high complexity or waived tests. This 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.
- This product is only authorized for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

- In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
- Do not use this kit beyond the use by date printed on the product label.
- Do not use if the Test Device package is damaged.
- All components in this test kit should remain sealed until ready for use. Immediately use after opening and removing the Test Device from the pouch.
- To obtain accurate results, the test must be performed as indicated in this Instructions for Use.
- Do not interpret the test result before 20 minutes or after 25 minutes, following application of the sample to the Test Device.
- All kit components are single use only. Do not re-use any kit components or mix components from different kit lots or different products.
- Do not store specimens in viral transport media for specimen storage.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Use appropriate precautions when collecting, handling, storing, and disposing of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Nitrile or latex gloves should be worn when performing this test.
- If Buffer Solution comes into contact with eyes and/or skin, flush abundantly with water.
- Handle all specimens as though they contain infectious agents. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- Test Devices used in a laminar flow hood or in areas with high air flow should be covered during test development to ensure proper sample flow.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at phasescientific.com.

Storage and Stability

- Store the test kit in a cool, dry place between 2-30°C (36-86°F). Do not freeze. Avoid direct sunlight.
- Kit contents are stable until the use by date printed on the product label and outer packaging. Do not use after the date indicated.
- All components in this test kit should remain sealed until ready for use.

Quality Control

Internal Quality Control:

The INDICAID™ COVID-19 Rapid Antigen Test Device contains an internal procedural control to ensure that the test is functioning properly. The control line (C) on the Test Device will appear as a red-colored line and should appear regardless of the test result. If the control line does not develop within 20 minutes, the test result is considered invalid and retesting should be performed with a newly collected sample, new Buffer Solution Vial, and a new Test Device.

External Quality Control:

The use of INDICAID™ COVID-19 Antigen Quality Control external positive and negative controls is recommended to ensure that the reagents and materials are working and that the test procedure is correctly performed. Positive and negative controls should be run once with every new lot, shipment, and each new user, using the test procedure provided in this Instructions for Use. Contact PHASE Scientific Technical Support for External positive and negative controls that are available separately.

If either or both external control results are unexpected or invalid, repeat the external controls with a new Swab, Buffer Solution Vial and Test Device and if results continue to be unexpected or invalid, contact PHASE Scientific Technical Support at +1 (657) 296 6106 or indicaid@phasesci.com before testing patient specimens.

Specimen Collection, Handling, and Transport

The INDICAID™ COVID-19 Rapid Antigen Test should only be used with the swabs provided in the kit to collect direct nasal samples according to the procedures in these Instructions for Use. Specimens should be tested **immediately** after collection for best performance. Do not transport or store specimens for later testing. Inadequate specimen collection or improper handling, storage, and transport may lead to incorrect results. Do not test specimens 2 hours after collection.

Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Note:

- If stored refrigerated, allow test components (Test Device and Buffer Solution Vial) to equilibrate to room temperature (15–30°C or 59-86°C) before starting the Test Procedure.
- Nasal swab specimens may be self-collected by the patient if the collection procedure is instructed and observed by a healthcare professional.
- Process the collected specimen immediately after collection.
- Use only the swab provided in the INDICAID™ COVID-19 Rapid Antigen Test Kit.
- Wear appropriate personal protective equipment and gloves when collecting and handling patient samples and when running the test.

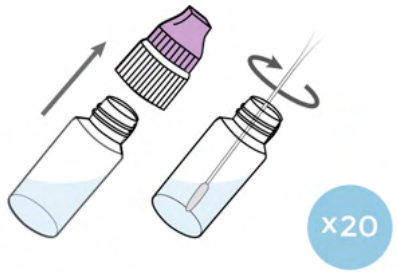
- Inspect all test reagents and materials for damage prior to use. Do not use any test components that show evidence of damage.

01 Remove the Swab and Test Device from their packaging. Place the Test Device on a horizontal (flat) surface for running the test.

02 Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab. Repeat in the other nostril using the same swab.

03 The Buffer Solution Vial cap is composed of two parts (purple and white). **Remove the entire cap.** Stir the swab into the Buffer Solution, **ensuring that the swab head is fully submerged by tilting the vial.**

Twist the swab back and forth 20 times in the Buffer Solution. Roll the swab head against the inner wall of the vial to release the liquid from the swab, then discard the swab.



04 Close the entire vial cap tightly. **Immediately** proceed to the Test Procedures to process the sample.

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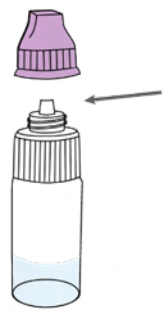
Test Procedure for Patient Swabs

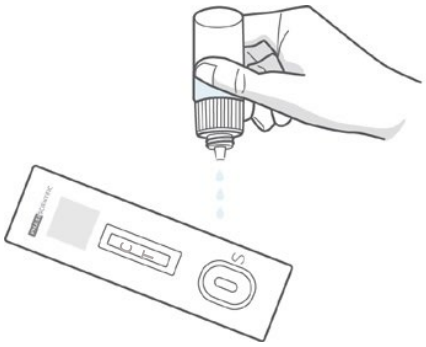
Note:

- Perform the following Test Procedures immediately after the specimen has been collected in the Buffer Solution Vial.
- The Test Device should be placed on a horizontal (flat) surface when running the test. Do not perform testing with the Test Device in any other orientation.

01 **Remove the purple top half of the cap** to expose the dropper tip.



02 Hold the vial vertically above the sample well (S). **Slowly squeeze and apply 3 drops** of the Buffer Solution into the sample well (S) of the Test Device.



03 **Read the test line (T) and control line (C) results promptly at 20 minutes**, and not earlier to ensure proper test performance.

Results after 25 minutes should not be used.

Result Interpretation

- Test results are interpreted visually, without the aid of instruments.

Positive Result

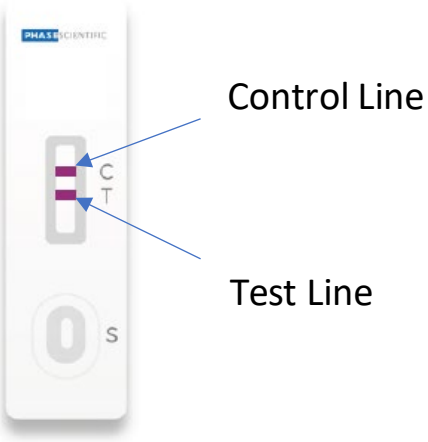
The presence of both the red-colored control line (C) **and** red-colored test line (T) indicates the presence of SARS-CoV-2 antigen. The result suggests current SARS-CoV-2 infection. Samples with low levels of antigen may produce a faint test line. Any visible test line is considered positive.

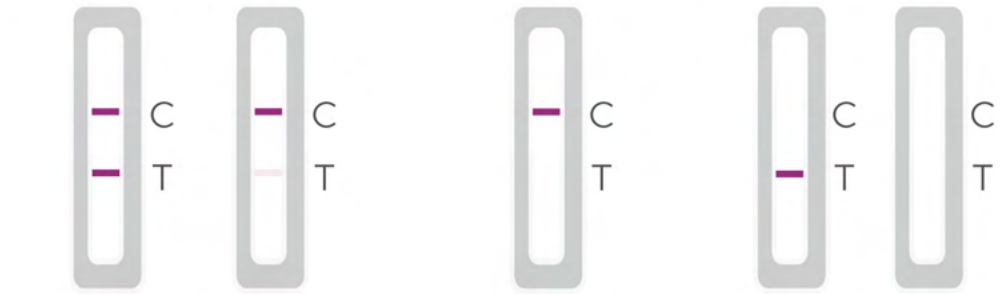
Negative Result

The presence of the red-colored control line (C) **and** no visible test line (T) indicates a negative result. No SARS-CoV-2 antigen was detected.

Invalid Result

If the red-colored control line (C) is not visible, DO NOT interpret the test result. **The result is invalid regardless of the appearance of the test line.** Collect a new nasal swab sample and repeat the assay with a new INDICAID™ COVID-19 Rapid Antigen Test.





Positive Negative Invalid

External Quality Control Test Procedure

Please refer to the complete INDICAID™ COVID-19 Antigen Quality Controls Instructions For Use.

01 Remove a new Swab and Test Device from their packaging. Place the Test Device on a horizontal (flat) surface for running the test.

02 Hold a new INDICAID™ COVID-19 Antigen Positive Control Vial

vertically and open the cap.

03 Dip the new Swab into the Positive Control Vial, making sure that the Swab head is fully submerged in the solution. Roll the Swab head around in the solution to ensure the swab is wetted. Remove the Swab from the Vial.

04 Test the Swab immediately performing the same steps as described in section "Test Procedure for Patient Swabs" above.

05 Repeat all the above steps to test the INDICAID™ COVID-19 Antigen Negative Control Vial.

Limitations

- The test is designed for use with nasal swab samples only. Performance has not been established for use with other specimen types. Other specimen types have not been evaluated and should not be used with this assay.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- A negative test result may occur if the level of SARS-CoV-2 antigen in a sample is below the detection limit of the test.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and presence of clinical signs and symptoms consistent with COVID-19.
- Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.
- Positive results do not rule out co-infections with other pathogens. Test results are not intended to rule out or diagnose other non-SARS viral or bacterial infections.
- The Test Device, Buffer Solution Vial, and Swab should not be re-used (single use only).
- This test detects both viable (live) and non-viable SARS-CoV-2 virus. Test performance depends on the amount of SARS-CoV-2 antigen in the sample and may or may not correlate with viral culture results performed on the same sample.
- Test performance is dependent upon proper specimen collection, handling, storage, and preparation. Failure to follow proper procedures may produce inaccurate results.
- Failure to follow these Instructions for Use may adversely affect test performance and/or invalidate the test result.

- Specimens should be tested immediately after specimen collection. Do not test specimens after 2 hours of collection.
- False negative results may occur if insufficient Buffer Solution is applied to the Test Device (e.g. less than 3 drops).
- False negative results may occur if the Swab is not twisted 20 times in the Buffer Solution Vial. False negative results may occur if the Swab head is not rolled against the inner wall of the Buffer Solution Vial to release as much liquid from the Swab as possible.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g. PCR testing) should be considered.
- The clinical performance of this test has not been evaluated in patients without signs and symptoms of respiratory infection or other reasons to suspect COVID-19 infection.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 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.

Conditions of Authorization for Laboratory and Patient Care Settings

The INDICAID™ COVID-19 Rapid Antigen Test Letter of Authorization along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

However, to assist with clinical laboratories using the INDICAID™ COVID-19 Rapid Antigen Test, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to

- Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and PHASE Scientific International, LTD (via email: indicaid@phasesci.com, or via phone at Technical Service: +1-657-296-6106) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- PHASE Scientific International, LTD, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Performance Characteristics

Clinical Performance and Point-of-Care Use

The clinical performance of the INDICAID™ COVID-19 Rapid Antigen Test was evaluated in a prospective study performed at a COVID-19 Community Testing Center in San Fernando, CA, U.S. Testing was performed by a total of five healthcare professionals (HCP) with no laboratory experience, representing the intended users at the point-of care. The operators had no prior training with the INDICAID™ COVID-19 Rapid Antigen Test and only had the Quick Reference Guide for instruction on how to perform the test.

A total of 270 patients presenting with one or more symptoms typical of COVID-19 infection within five days of symptom onset were sequentially enrolled. Each patient provided one self-collected nasal swab to perform the INDICAID™ COVID-19 Rapid Antigen Test, one HCP-collected nasal swab to perform the INDICAID™ COVID-19 Rapid Antigen Test and one HCP-collected nasal swab to perform the comparator molecular test. For the self-collected sample, the HCP provided specimen collection

perform moderate complexity, high complexity, or waived tests. This 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." as "authorized laboratories."

instructions according to the Quick Reference Guide and observed the specimen collection by the patient. The order of the second and third HCP-collected samples was randomized for testing with the investigational antigen test and an FDA EUA molecular comparator method to ensure that bias was not introduced due to unequal distribution of viral material. The self-collected and HCP-collected nasal swab samples for the INDICAID™ antigen test were immediately tested after collection while the nasal swab sample for comparator analysis was eluted in viral transport media and shipped to the comparator testing laboratory.

The INDICAID™ COVID-19 Rapid Antigen Test results for the self-collected and HCP-collected samples were compared against the results of the FDA EUA molecular comparator assay to calculate the positive percent agreement (PPA), negative percent agreement (NPA), and overall percent agreement (OPA). One specimen that was lost during handling and one specimen that was deemed quantity not sufficient for comparator testing were excluded from the analysis, bringing the total number patient samples analyzed to 268.

Table 1: INDICAID™ COVID-19 Rapid Antigen Test Performance Against Comparator Method (HCP-Collected Sample)

INDICAID™ COVID-19 Rapid Antigen Test	Comparator Method		
	Positive	Negative	Total
Positive	27	7	34
Negative	5	183	188
Total	32	190	222
PPA	84.4% (95% CI: 68.2% - 93.1%)		
NPA	96.3% (95% CI: 92.6% - 98.2%)		

Table 2: INDICAID™ COVID-19 Rapid Antigen Test Performance Against Comparator Method (Self-Collected Sample)

INDICAID™ COVID-19 Rapid Antigen Test	Comparator Method		
	Positive	Negative	Total
Positive	27	6	33
Negative	5	184	189
Total	32	190	222
PPA	84.4% (95% CI: 68.2% - 93.1%)		
NPA	96.8% (95% CI: 93.3% - 98.5%)		

Table 3: Positive results by age (years) of patient

Age (years)	Total*	Comparator Positive	Prevalence	INDICAID™ Positive

5 to 20	39	10	25.6%	10
21 to 40	88	7	8.0%	5
41 to 60	77	13	16.9%	10
60+	17	2	11.8%	2

*Age information not provided for 1 patient out of 222

Table 4: Positive results by days since symptom onset

Days Since Symptom Onset	Cumulative Comparator Positive	Cumulative INDICAID™ Positive	PPA
1	6	6	100.0%
2	13	12	92.3%
3	26	22	84.6%
4	30	25	83.3%
5	32	27	84.4%

Contrived samples near the test's limit of detection (2xLoD) and simulated negative matrix were also performed by the same HCP operators who performed the clinical POC evaluation study at the same site. The contrived samples were blinded to the HCP operators.

Table 5: INDICAID™ COVID-19 Rapid Antigen Test (near cut-off) Performance

Contrived Sample	Number of Tests Interpreted Correctly/Total	% Concordance w/ Expected Result
2xLoD (near cut-off)	11/12	91.7%
Negative matrix	12/12	100%

Limit of Detection (Analytical Sensitivity)

The INDICAID™ COVID-19 Rapid Antigen Test limit of detection (LoD) was determined by testing limiting dilutions of gamma-irradiated SARS-CoV-2 virus (Isolate USA-WA1/2020, NR-52287) 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.

INDICAID™ COVID-19 Rapid Antigen Test Limit of Detection

SARS-CoV-2 Concentration			Number of Positives/Total	% Detected
$TCID_{50}$/mL	cp/mL	$TCID_{50}$/swab		
2.8×10^3	1.75×10^6	1.4×10^2	20/20	100%

Cross-reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity and microbial interference of common respiratory pathogens with the INDICAID™ COVID-19 Rapid Antigen Test was evaluated by testing the panel of microorganisms at the concentration presented in the table below. For cross-reactivity testing, each microorganism was prepared in pooled human nasal matrix from healthy donors in absence of SARS-CoV-2 and tested in triplicate. For microbial interference testing, microorganisms were tested individually or in a pool of 2 to 4 organisms per pool in the presence of irradiated SARS-CoV-2 (3x LoD, 4.2 x 10^2 $TCID_{50}$/swab) and tested in triplicate. No cross-reactivity or microbial interference was observed for the following organisms when tested at the concentration listed.

Type	Potential Cross-reactant	Test Concentration
Bacteria	*Bordetella pertussis A639*	1.0 x 10^6 CFU/mL
	Chlamydia Pneumoniae	1.0 x 10^6 IFU/mL
	Haemophilus influenzae	1.0 x 10^6 CFU/mL
	Legionella pneumophila	1.0 x 10^6 CFU/mL
	Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL
	Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
	Streptococcus pyrogenes	1.0 x 10^6 CFU/mL
	Staphylococcus aureus	1.0 x 10^6 CFU/mL
	Staphylococcus epidermidis	1.0 x 10^6 CFU/mL
Virus	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL
	Adenovirus	1.0 x 10^5 $TCID_{50}$/mL
	Human Metapneumovirus (hMPV)	1.0 x 10^5 $TCID_{50}$/mL
	Influenza A	1.0 x 10^5 $TCID_{50}$/mL
	Influenza B	1.0 x 10^5 $TCID_{50}$/mL
	Rhinovirus	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 1	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 2	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 3	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 4	1.0 x 10^5 $TCID_{50}$/mL
	Enterovirus Type 68	1.0 x 10^5 $TCID_{50}$/mL
	Respiratory Syncytial Virus Type A	1.0 x 10^5 $TCID_{50}$/mL
	Respiratory Syncytial Virus Type B	1.0 x 10^5 $TCID_{50}$/mL
	MERS-Coronavirus	1.0 x 10^5 $TCID_{50}$/mL
Yeast	Candida albicans	1.0 x 10^6 CFU/mL
Other	Pooled human nasal wash	100%

In silico analysis was performed using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) to estimate the likelihood of cross-reactivity with microorganisms not available for wet-testing. The degree of protein sequence homology was determined between the SARS-CoV-2 nucleocapsid protein antigen and the following microorganisms:

- Human Coronavirus HKU1: Sequence homology between SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1 nucleocapsid protein is relatively low at 36.7% across 82.0% of sequences, but cross-reactivity cannot be ruled out.
- *Mycobacterium tuberculosis:* No protein sequence homology was found between the SARS-CoV-2 nucleocapsid protein and *Mycobacterium tuberculosis* total protein (5925 sequences). Homology-based cross-reactivity cannot be ruled out.
- *Pneumocystis jirovecii* (PJP): No protein sequence homology was found between the SARS-CoV-2 nucleocapsid protein and *PJP* total protein (3762 sequences). Homology-based cross-reactivity cannot be ruled out.
- SARS Coronavirus: Sequence homology between SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus nucleocapsid protein was found to be 90.5% with 100% query sequence coverage. Cross-reactivity with SARS Coronavirus cannot be ruled out.

High Dose Hook Effect

A high-dose Hook Effect Study was performed to evaluate whether a false negative test result occurs when very high levels of target is present in a sample. The INDICAID™ COVID-19 Rapid Antigen Test was evaluated using increasing concentration of inactivated SARS-CoV-2 virus in negative clinical matrix (pooled human nasal fluid in PBS). A total of 5 concentrations starting from 2.8×10^1 $TCID_{50}$/mL (1.4 $TCID_{50}$/swab) up to a concentration of 2.8×10^5 $TCID_{50}$/mL (1.4×10^4 $TCID_{50}$/swab) and a blank (negative) sample were tested. Each concentration was tested in triplicate. No high-dose Hook Effect was observed up to 2.8×10^5 $TCID_{50}$/mL (1.4×10^4 $TCID_{50}$/swab) of gamma-irradiated SARS-CoV-2 virus with the INDICAID™ COVID-19 Rapid Antigen Test.

Endogenous Interfering Substances

Fourteen (14) substances including over-the-counter medications that may be found in respiratory specimens of patients who are symptomatic for respiratory illness were evaluated for potential interference with the INDICAID™ COVID-19 Rapid Antigen Test. Test samples containing the endogenous substances at the listed concentrations all produced the expected positive and negative test line results in the presence and absence of 3x LoD inactivated SARS-CoV-2 virus, respectively.

		Test Result	
Potential Interferent	**Test Concentration**	**(+) SARS-CoV-2 (3x LoD)**	**(-) SARS-CoV-2**
Whole Blood	4%	Positive	Negative

Mucin	0.5%	Positive	Negative
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Positive	Negative
Naso GEL (NeilMed)	5% v/v	Positive	Negative
CVS Nasal Drops (Phenylephrine)	15% v/v	Positive	Negative
Afrin (Oxymetazoline)	15% v/v	Positive	Negative
CVS Nasal Spray (Cromolyn)	15% v/v	Positive	Negative
Zicam	5% v/v	Positive	Negative
Homeopathic (Alkalol)	1:10 dilution	Positive	Negative
Sore Throat Phenol Spray	15% v/v	Positive	Negative
Tobramycin	4 µg/mL	Positive	Negative
Mupirocin	10 mg/mL	Positive	Negative
Fluticasone Propionate (Flonase)	5% v/v	Positive	Negative
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	Positive	Negative

Technical Support

For more information, questions, or support, please visit www.phasescientific.com, or contact us at:

Telephone: +1 (657) 296 6106 email: indicaid@phasesci.com

Symbols

Rx Only	For prescription use only		Keep away from moisture
IVD	*In vitro* diagnostic medical device		Do not reuse
	Consult Instructions for Use	REF	Catalog number
	Caution—consult accompanying documents	LOT	Batch code
30°C 2°C	Temperature limitation		Use by
	Keep away from sunlight		Manufacturer
Σ	Sufficient for use		

INDICAID™

QUICK REFERENCE GUIDE

INDICAID™ COVID-19 Rapid Antigen Test

For Emergency Use Authorization (EUA) Only

Intended Use

The INDICAID™ COVID-19 Rapid Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in 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. 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). Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This 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.

The INDICAID™ COVID-19 Rapid Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative 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.

The INDICAID™ COVID-19 Rapid Antigen Test is intended for use by trained clinical laboratory personnel and medical and healthcare personnel in Point of Care (POC) settings. The INDICAID™ COVID-19 Rapid Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Materials required but not provided

1. Timer
2. Personal protective equipment
3. INDICAID™ COVID-19 Antigen Quality Control (Sold Separately)

Materials provided in kit

1. 25 individually wrapped Test Devices
2. 25 Buffer Solution Vials
3. 25 individually wrapped Swabs
4. 1 IFU and Quick Reference Guide

IMPORTANT:

- See Package Insert for complete instruction, warnings, precautions, limitations, storage & handling conditions, and Quality Control recommendations.
- For in vitro diagnostic use only.
- Specimens should be tested immediately after specimen collection. Do not test specimens after 2 hours of collection.
- All components in this test kit should remain sealed until ready for use.
- All components in this test kit are for one-time use only. Do not reuse.
- Store at 2-30°C. Do not freeze. Avoid direct sunlight.
- If Buffer Solution comes into contact with eyes and/or skin, flush abundantly with water.
- Do not use the test kit after the expiration date.

Test Procedure

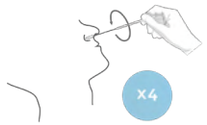
Wear appropriate personal protective equipment and gloves when handling patient samples and running the test. Nasal swab spec- imens may be self-collected by the patient if collection procedure is observed by a healthcare professional.

01 Remove the Swab & Test Device from their packaging.

Place the Test Device on a horizontal (flat) surface for running the test.

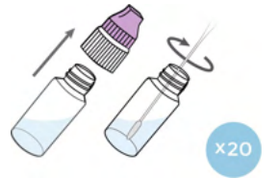
02 Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall **at least 4 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.

Repeat in the other nostril using the same swab.



03 The Buffer Solution Vial cap is composed of two parts (purple and white).

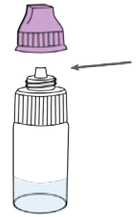
Remove the entire cap. Stir the swab into the Buffer Solution, **ensuring that the swab head is fully submerged by tilting the vial.**



Twist the swab back and forth 20 times in the Buffer Solution. Roll the swab head against the inner wall of the vial to release the liquid from the swab, then discard the swab.

04 Close the entire cap tightly. **Immediately** perform steps 5 - 7.

05 **Remove the purple top half of the cap** to expose the dropper tip.



06 Hold the vial vertically above the sample well (S). Slowly **squeeze and apply 3 drops** of the Buffer Solution into the sample well (S) of the Test Device.

07 **Read the test line (T) and control line (C) results promptly at 20 minutes,** and not earlier to ensure proper test performance.

Results after 25 minutes should not be used.

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Interpretation of the test results

Positive result:

The presence of both the red-coloredcontrol line (C) and colored test line (T) indicates the presence of SARS-CoV-2 antigen. The result suggests current SARS-CoV-2 infection. Samples with low levels of antigen may produce a faint test line. Any visible test is considered positive.

Negative result:

The presence of red-colored control line (C) and no visible test line (T) indicates anegative result. No SARS-CoV-2 antigenwas detected.

Invalid result:

If the red-colored control line (C) is not visible, DO NOT interpret the test result.The result is invalid regardless of the appearance of the test line. Collect a newnasal swab sample and repeat the assaywith a new INDICAID™ COVID-19 Rapid Antigen Test.

INDICAID™ COVID-19 Rapid Antigen Quality Control Kit is available separately from PHASE Scientific International, Ltd.We recommend that these external positive and negative controls are run once with every new kit lot, new shipment, and each new user.

External Control Test Procedure:

1. Remove a new Swab & Test Device from their packaging. Place the Test Device on a horizontal (flat) surface for running the test.
2. Hold the external positive control vial vertically and removethe entire cap.
3. Dip the Swab into the vial, making sure that the Swab head is fully submerged in solution. Remove the Swabfrom the vial.
4. Test the Swab by performing Steps 3 through 7 of the Test Procedure in this Quick Reference Guide.
5. Repeat to test the external negative control.

Disclaimers:

In the USA, this product has not been FDA clearedor approved, but has been authorized by FDA under an EUA for useby authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. § 263a, that meet requirements to perform moderate complexity, high complexity, or waived tests. Thisproduct 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. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, theemergency use ofthis product is only authorizedfor the duration of the declaration that circumstancesexist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus thatcauses COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Manufactured By

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

Caution, Consult accompanying documents

Temperature Limitation

Sufficient for Use

Keep away from sunlight

Keep away from moisture

Do not reuse

Consult Instructions for Use

IVD In-Vitro Diagnostic Medical Device

REF Catalog number

LOT Batch code

Use by

Manufacturer

For more information, please visit

www.phasescientific.com

If you have questions, please contact Customer Service:

Indicaid@phasesci.comUS

+1 (657) 296-6106

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INDICAID™ COVID-19 Antigen Quality Controls

For use with the INDICAID™ COVID-19 Rapid Antigen Test

Intended use

The INDICAID™ COVID-19 Antigen Quality Controls are intended for quality control testing performed on the INDICAID™ COVID-19 Rapid Antigen Test. The Quality Controls provide users with assurance that the device is performing within specification.

Summary and explanation of the test

The INDICAID™ COVID-19 Antigen Quality Controls are external liquid quality controls. The controls are specifically formulated and manufactured to ensure that the test's reagents and materials are working and that the test procedure is correctly performed. The Quality Controls consist of positive and negative control samples that should be run once with every new lot, shipment, and each new user, using the test procedure provided.

It is the responsibility of each laboratory or healthcare setting using the INDICAID™ COVID-19 Rapid Antigen Test to establish an adequate quality assurance program to ensure the performance of the test kit under its specific locations and conditions of use. Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

Warnings and precautions

- For *in vitro* diagnostic use only.
- Quality Control Vials are for one-time use only. Do not reuse vials.
- Exercise the normal precautions required for handling all laboratory reagents.
- Do not swallow or inhale.
- Avoid contact with your eyes. If contact occurs, flush with copious amounts of water immediately.

Storage and Stability

- Store controls between 2°C and 8°C (36 – 46°F).
- Unopened controls that are stored between 2°C and 8°C (36 – 46°F) can be used until the expiration date. Do not use Quality Controls beyond the expiration date given on the label.
- Quality Control Vials should remain sealed until ready for use. Open a Quality Control Vial only when you are planning to perform a quality control test.

Materials provided in kit

REF 2110410	• 50 x 250 µL single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives) • 50 x 250 µL single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives)
REF2110420	• 5 x 250 µL single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives) • 5 x 250 µL single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives)

Materials required but not provided

1. INDICAID™ COVID-19 Rapid Antigen Test Device
2. INDICAID™ COVID-19 Rapid Antigen Test Buffer Solution Vial
3. INDICAID™ COVID-19 Rapid Antigen Test Individually Wrapped Swab
4. Timer

Preparing the quality controls

The liquid controls are supplied ready to use. Each Quality Control Vial is single-use only.

Test Procedure

Wear appropriate personal protective equipment and gloves when handling patient samples and running the test.

1. Remove a new Swab and Test Device from their packaging. Place the Test Device on a horizontal (flat) surface for running the test.
2. Hold a new INDICAID™ COVID-19 Antigen Positive Control Vial vertically and open the cap.
3. Dip the new Swab into the Positive Control Vial, making sure that the Swab head is fully wetted by the solution. Remove the Swab from the Vial.
4. Test the Swab immediately performing the same steps as described in section "Test Procedure for Patient Swabs" of the INDICAID™ COVID-19 Rapid Antigen Test Instructions For Use (Package Insert).
5. Repeat all the above steps to test the external negative control in the INDICAID™ COVID-19 Antigen Negative Control Vial.

Expected Results

Consult the INDICAID™ COVID-19 Rapid Antigen Test Instructions for Use or Quick Reference Guide for instructions on how to interpret a test result using the Quality Control.

The Test Devices are working properly and all handling has been done correctly when the following expected test results are obtained:

- The INDICAID™ COVID-19 Antigen Positive Control should provide a **positive result**.
- The INDICAID™ COVID-19 Antigen Negative Control should provide a **negative result**.

If the external controls do not produce the expected results, do not use the test for patient testing or report patient results. Please contact PHASE Scientific Technical Support during normal business hours before using the tests with patient specimens.

Manufactured By

PHASE Diagnostics, Inc.
10527 Garden Grove Boulevard.
Garden Grove, CA 92843, USA

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug

and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

For more information, questions, or support, please visit www.phasescientific.com, or contact us at:

Telephone: +1 (657) 296 6106 email: indicaid@phasesci.com

Symbols

IVD	*In vitro* diagnostic medical device		Do not reuse
	Consult Instructions for Use	REF	Catalog number
	Caution—consult accompanying documents	LOT	Batch code
2°C 8°C	Temperature limitation		Use by
	Keep away from sunlight		Manufacturer
Σ	Sufficient for use		Keep away from moisture