PHASE SCIENTIFIC

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

PI-2110400ENG | Rev E | Dec 2022

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PHASE SCIENTIFIC

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 collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptoms onset when tested at least twice over three days with at least 48 hours between tests or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. 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, high or waived complexity tests. This product 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 or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in direct anterior nasal swab specimens 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 fully determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are 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 medical professionals or operators who are proficient in performing tests in point of care settings. The INDICAID™ COVID-19 Rapid Antigen Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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 latex microspheres 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-latex microsphere 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 specimen 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

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)

Warnings, Precautions, and Safety Information

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If the individual has had symptoms longer than 5 days you should consider**

testing them at least three times over five days with at least 48 hours between tests.

- This product is only authorized for use by laboratories certified under the CLIA that meet the requirements to perform moderate complexity, high complexity or waived tests. This product 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.
- 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 test kit beyond the expiration date printed on the outside of the box.
- Do not use if any of the test kit contents or packaging 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.
- Do not read the test result before 20 minutes or after 25 minutes. **Results read before 20 minutes or after 25 minutes may lead to a false positive, false negative, or invalid result.**
- 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 use the test on children under 2 years of age.
- An anterior nasal swab sample can be self-collected by an individual age 18 years and older. Children age 2 to 18 years should be tested by an adult.
- 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.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- 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.
- Do not touch the swab tip.

- 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.
- 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.
- Once opened, the test device should be used within 2 hours.
- 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.
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [e.g., skin, eyes, nose, or mouth]. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table above). If the solution contacts your [e.g., skin, eyes, nose, or mouth], flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.

Chemical Name	GHS Code for each Ingredient	Concentration
Triton™ X-100	H302, Harmful if swallowed H315, Skin irritation H318, Serious eye damage H410, Toxic to aquatic life	0.1% v/v[1]
ProClin™ 300	H302 + H332, Harmful if swallowed or if inhaled H314, Skin burns and eye damage H317, May cause an allergic skin reaction H410, Toxic to aquatic life	0.3% v/v[1]

[1] Chemical agent is not considered hazardous at this concentration.

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 (using a new swab), 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 care@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:

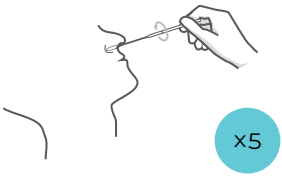
- If stored refrigerated, allow test components (test device and buffer solution Vial) to equilibrate to room temperature (15–30°C or 59-86°F) before starting the test procedure.
- Nasal swab specimens may be self-collected by the patient (age 18 years or older) if the collection procedure is instructed 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.

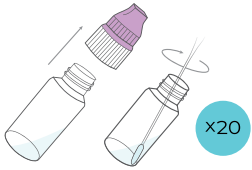
Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall **at least 4 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.

Repeat in the other nostril using the same swab.



03 **Check the buffer solution volume in the vial. If the vial is empty, DO NOT use and obtain a new buffer solution vial.**
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.

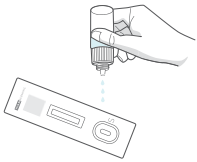
Test Procedure for Patient Swabs

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 d evice.



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

- Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.
- Test results are interpreted visually, without the aid of instruments.
- Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

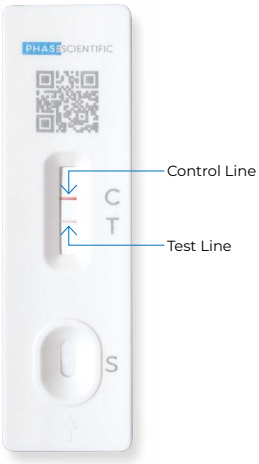
Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

Repeat testing does not need to be performed if patients have a positive result at any time. A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the INDICAID™ COVID-19 Rapid Antigen Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.



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.

To increase the chance that the negative result for COVID-19 is accurate, you should:

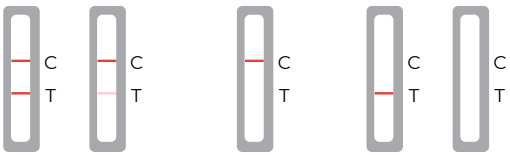
- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

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.



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 performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2021 and September 2021. The clinical performance has not been established for 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient’s first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.

- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

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.
- 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: care@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.

[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 perform moderate complexity, high complexity, or waived tests. This product 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."

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 297 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 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 295.

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	40	8	48
Negative	5	242	247
Total	45	250	295
PPA	88.9% (95% CI: 76.5% - 95.2%)		
NPA	96.8% (95% CI: 93.8% - 98.4%)		

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	39	7	46
Negative	6	243	249
Total	45	250	295
PPA	86.7% (95% CI: 73.8% - 93.7%)		
NPA	97.2% (95% CI: 94.3% - 98.6%)		

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

Age (years)	Total*	Comparator Positive	Prevalence	INDICAID™ Positive
5 to 20	57	13	22.8%	13
21 to 40	130	14	10.8%	12
41 to 60	88	16	18.2%	13
60+	19	2	10.5%	2

*Age information not provided for 1 patient out of 295

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	15	14	93.3%
3	35	31	88.6%
4	39	34	87.2%
5	45	40	88.9%

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

SARS-CoV-2 Concentration $TCID_{50}$/mL	Number of Tests Interpreted Correctly/Total	% Concordance w/ Expected Result
2x LoD	21/22	95.5%
Negative matrix	22/22	100%

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications and performance may differ in these populations.

DATA ESTABLISHING PPA OF COVID-19 ANTIGEN SERIAL TESTING

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARSCoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a

composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table 5.

Table 5: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen in study combined.

Days after first PCR positive test result	Asymptomatic on first day of testing			Symptomatic on first day of testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test =one(1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection SARS-CoV-2.

2 Test =two(2) tests performed and average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Test =three(3) tests performed and average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later, and a final test performed 48 hours after the second test.

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. Fifty (50) uL of 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%

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess performance with the omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the INDICAID™ COVID-19 Rapid Antigen At-Home Test detected 100% of live virus Omicron samples at a Ct-value of 24.0 (n=5) and 40% of samples at a Ct-value of 24.8 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 24.8) were not detected by the INDICAID™ COVID-19 Rapid Antigen At-Home Test in this study.

Omicron Pool 2 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	INDICAID™ COVID-19 Rapid Antigen At-Home Test Percent Positive (n=5)
Omicron-Dilution 1	19.8	100	100	100
Omicron-Dilution 2	20.8	100	100	100
Omicron-Dilution 3	21.5	100	100	100
Omicron-Dilution 4	22.7	100	100	100
Omicron-Dilution 5	23.6	100	0	100
Omicron-Dilution 6	24.0	60	0	100
Omicron-Dilution 7	24.8	0	0	40
Omicron-Dilution 8	25.8	0	0	0
Omicron-Dilution 9	27.4	0	0	0
Omicron-Dilution 10	28.1	0	0	0
Omicron-Dilution 11	29.1	0	0	0

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.indicaidusa.com or contact us at:

Telephone: +1 (877) 934 9344
Email: care@indicaidusa.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
2°C 30°C	Temperature limitation		Use by
	Keep away from sunlight		Manufacturer
Σ	Sufficient for use		

PHASESCIENTIFIC

INDICAID™ COVID-19 RAPID ANTIGEN TEST

For Rapid Detection of SARS-CoV-2 Antigen

INSTRUCTIONS FOR USE

PI-2110400ENG | Rev E | Dec 2022

INDICAID™ **QUICK REFERENCE GUIDE**

INDICAID™ COVID-19 Rapid Antigen Test

For Emergency Use Authorization (EUA) Only

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by 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. This product 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. 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 the virus that causes 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**

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 collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptoms onset when tested at least twice over three days with at least 48 hours between tests or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. 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, high or waived complexity tests. This product 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 or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in direct anterior nasal swab specimens 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 fully determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are 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 medical professionals or operators who are proficient in performing tests in point of care settings. The INDICAID™ COVID-19 Rapid Antigen Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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

- **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

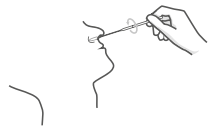
Wear appropriate personal protective equipment and gloves when handling patient samples and running the test. Nasal swab specimens may be self-collected by the patient if collection procedure is observed by a healthcare professional.

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.

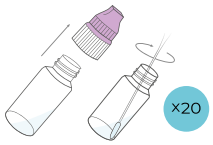
Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall **at least 4 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.

Repeat in the other nostril using the same swab.

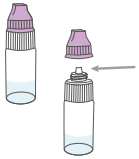


03 **Check the buffer solution volume in the vial. If the vial is empty, DO NOT use and obtain a new buffer solution vial.**
The buffer solution vial cap is composed of two parts (purple and white).

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.

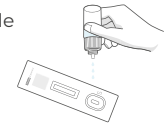


04 Close the entire cap tightly. **Immediately** perform steps 5 - 7.



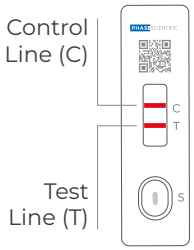
05 **Remove the purple top half of the cap** to expose the dropper tip.

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.**

INTERPRETATION OF THE TEST RESULTS



RESULT INTERPRETATION

- Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.
- Test results are interpreted visually, without the aid of instruments.
- Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Positive result:
The presence of both the red-colored control 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. **Repeat testing does not need to be performed if patients have a positive result at any time.**

Note: Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

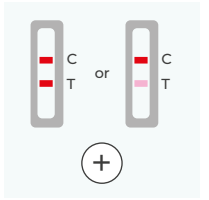
Negative result:
The presence of red-colored control line(C) and no visible test line (T) indicates a negative result. No SARS-CoV-2 antigen was detected.

Note: To increase the chance that the negative result for COVID-19 is accurate, you should:

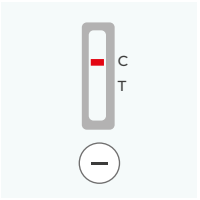
- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

Note: A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.
All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

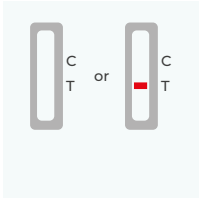
Invalid result:
If the red-colored control line (C) is not visible, DO NOT interpret the test result. The result is invalid regardless of the appearance of the test line. Collect a new nasal swab sample and repeat the assay with a new INDICAID™ COVID-19 Rapid Antigen Test.



Positive Result



Negative Result



Invalid Result

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 remove the entire cap.
3. Dip the swab into the vial, making sure that the swab head is fully submerged in solution. Remove the swab from 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.

PHASE Scientific International Limited
1/F, Building 22E, Phase 3, Hong Kong Science Park,
Shatin, New Territories, Hong Kong

IVD	In-vitro diagnostic medical device		Keep away from moisture
	Consult Instructions for use		Do not reuse
	Caution—consult accompanying documents	REF	Catalog number
30°C 2°C	Temperature limit	LOT	Batch code
	Keep away from sunlight		Use-by date
Σ	Sufficient for use		Manufacturer

For more information,
please visit www.indicaidusa.com

If you have questions, please contact customer service:
care@indicaidusa.com (US) +1 (877) 934-9344

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PI-2110400QS (C) | Dec 2022 Edition
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PI-2110400QS (D)