PHASE SCIENTIFIC

For *in vitro* diagnostic use only

For use with anterior nasal (nares) specimens

INDICAID™

COVID-19 Rapid Antigen At-Home Test

For Rapid Detection of SARS-CoV-2 Antigen

HEALTHCARE PROVIDER INSTRUCTIONS FOR USE

PHASE SCIENTIFIC

Contents

Intended Use

The INDICAID ™ COVID-19 Rapid Antigen At-Home Test is a rapid lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is intended for home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older, or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older.

This test is intended for individuals with symptoms of COVID-19 within the first 6 days of symptom onset when tested at least twice over three days with at least 48 hours between tests (for a total of at least two tests), and for 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 (for a total of at least three tests).

The INDICAID™ COVID-19 Rapid Antigen At-Home 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 (nares) swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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 and the agent detected may not be the definite cause of disease. Individuals who test positive with the INDICAID™ COVID-19 Rapid Antigen At-Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

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.

Additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as an individual with close contact with COVID-19 or with suspected exposure to COVID- 19, or in communities with high prevalence of infection. 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.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their healthcare provider.

The INDICAID™ COVID-19 Rapid Antigen At-Home Test is intended for self-use and/or as applicable an adult lay user testing another person 2 years of age or older.

Explanation of the Test

COVID-19 (short for "Coronavirus disease 2019") is a disease first recognized in 2019 that is caused by type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The INDICAID™ COVID-19 Rapid Antigen At-Home Test is a rapid qualitative immunochromatographic assay for the determination of the presence of SARS-CoV-2 antigens in anterior nasal swab specimens. Each INDICAID™ COVID-19 Rapid Antigen At-Home Test is single-use and can analyze one anterior nasal (nares) swab sample. The total time required to perform one test is approximately 20 minutes from clinical specimen collection to result.

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). Test results are interpreted visually at 20 minutes after the sample has been properly applied to the test according to the instructions. Results should not be read after 25 minutes.

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 At-Home Test is validated for use with direct specimens testing without transport media.

Materials Provided

Kit Component	Quantity	Description
Test Devices	2, 4, 12, or 24	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	2, 4, 12, or 24	Vial with cap and integrated dispensing tip, containing 400 µL of buffer solution.
Nasal Swabs	2, 4, 12, or 24	Individually wrapped, sterile specimen collector.
Package Insert	1 User Instructions/Quick Reference Guide	Documentation for user instructions.

The INDICAID™ COVID-19 Rapid Antigen At-Home Test kits are available in packs of 2, 4, 12 or 24. The components will remain the same and only the quantity of each component will be varied.

Kit Size	Identifier
INDICAID™ COVID-19 Rapid Antigen At-Home Test (2-test kit)	UPC 860008407801 Catalog #P0092
INDICAID™ COVID-19 Rapid Antigen At-Home Test (4-test kit)	UPC 860008407825 Catalog #P0093
INDICAID™ COVID-19 Rapid Antigen At-Home Test (12-test kit)	UPC 860008407818 Catalog #P0094

INDICAID™ COVID-19 Rapid Antigen At-Home Test (24-test kit)	UPC 860008407832 Catalog #P0095

Materials Required but not Provided

- Timer

Warnings and Precautions

- For *in vitro* diagnostic use only.
- This product is only intended for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Read the Instructions for Use carefully before performing test. Failure to follow directions may produce inaccurate test results.
- Wear a facemask when collecting specimen from another individual.
- 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.
- Do not use the test on children under 2 years of age.
- Use only the contents provided in the test kit.
- All test components are single use. Do not re-use.
- Wash hands thoroughly for at least 20 seconds before and after using the test.
- Do not open the kit contents until ready for use. Use within 2 hours of opening the test device pouch.
- Leave the swab inside its packaging until instructed to swab the nose. Keep the swab clean. Do not allow anything to touch the soft tip of the swab until instructed to swab the nose.
- When collecting a sample, use only the nasal swab provided in the kit.
- Perform the test as soon as possible after swabbing both nostrils, and within 30 minutes after adding the swab to the vial.
- This test is read visually. Users with impaired vision or color impaired vision may not be able to read the test.
- Do not interpret the test result before 20 minutes or after 25 minutes, following application of the sample to the test device.
- 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 and rolled against the inner wall of the buffer solution vial to release as much liquid from the swab as possible.

- 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 www.indicaidusa.com.
- Dispose of used specimens and test components in accordance with Federal, State, and Local requirements.
- Keep testing kit and all test components out of the reach of children and pets before and after use.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products (e.g., 1% bleach) may result in an incorrect test result.
- Do not mix components from different kit lots.
- Test devices that contain patient samples should be handled as though they could transmit disease. Follow universal precautions when handling samples, this kit, and its contents. Wear appropriate personal protection equipment (PPE) and gloves when running the test and handling a patient's test device. Change gloves between tests.
- In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- Do not ingest.
- Keep out of reach of children.
- Inserting the swab deeper than the recommended ½ to ¾ inches may cause harm.
- The chemicals in the reagent solution may be hazardous to the skin and eye. Please see the links in the table below for safety recommendations regarding skin and eye irritation. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, please contact your Local Poison Control Centre in Canada.

Chemical Name	Concentration	Link to the MSDS
Triton™ X-100	0.1 % v/v[1]	www.sigmaaldrich.com/US/en/sds/sial/x100
ProClin™ 300	0.3% v/v[1]	www.sigmaaldrich.com/US/en/sds/ sial/48914-u

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

Limitations

- Do not use the test on anyone under 2 years of age.
- Children aged 2-13 years of age should be tested by an adult.
- The device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- False negative results may occur if specimen is improperly collected or handled.
- 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.
- The control line (C) only indicates that the reagents have properly migrated through the test device. The control line does not indicate that an adequate human sample was added to the test device.
- Negative results do not rule out COVID-19, should be treated as presumptive, and confirmed with a molecular assay, if necessary for clinical management.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Positive test results do not rule out co-infection with other pathogens.
- This test detects both viable (live) and non-viable 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.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give a negative result in an individual with COVID-19 as compared to a molecular test.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between December 2021 and January 2022. 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.

- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
- Symptomatic individuals that test negative should repeat test at least twice over three days with at least 48 hours between tests and at least three times over five days with at least 48 hours between tests if they are asymptomatic.
- The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

Storage and Stability

- The INDICAID™ COVID-19 Rapid Antigen At-Home Test should be stored in a cool, dry place between 2-30°C (35.6-86°F). Do not freeze. Avoid direct sunlight.
- Kit components in the INDICAID™ COVID-19 Rapid Antigen At-Home Test are stable until the expiration date printed on the label.
- The test device must remain in the sealed foil pouch until use. Once the pouch has been opened, the test device should be used within 60 minutes.
- Test samples immediately after collection, but no more than 5 minutes after specimen collection before placement into extraction buffer or up to 2 hours after placement into extraction buffer, if kept at room temperature.

Disposal

Dispose of all used test kit components and patient samples in a trash receptacle. Do not flush or pour test liquids down the drain.

Quality Control

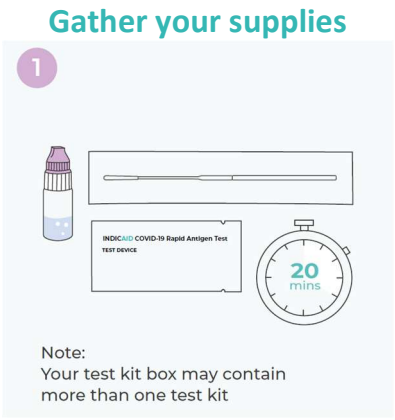
Each INDICAID™ COVID-19 Rapid Antigen At-Home Test device has a built-in internal procedural control. The red line appearing at the “C” position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct, red-colored line should always appear if the test has been performed correctly. If the control line does not appear, the test result is invalid, and a new test should be performed using a new sample and new test kit. If the

internal procedural control line (C) is still absent after the retest, contact PHASE Scientific Technical Support at +1 (877) 934 9344 or care@indicaidusa.com.

Performing Your Test

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.
- Process the collected specimen immediately after collection. 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.
- Use only the swab provided in the INDICAID™ COVID-19 Rapid Antigen At-Home Test Kit.



Check the expiration date on the outside of the product box.

Remove 1 swab, 1 test device pouch, and 1 buffer solution vial.

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

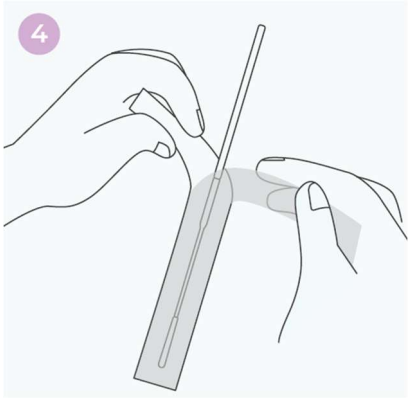
Make sure you have a timer (that can time 20 minutes). The test kit does not come with one.

Wash your hands thoroughly for at least 20 seconds before and after testing.

Remove entire buffer solution vial cap

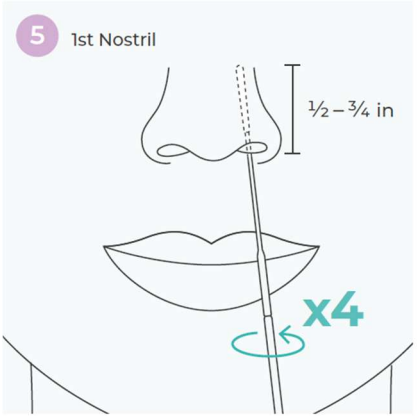
Twist off the entire cap (purple & white parts together) from the buffer solution vial. Place the vial and cap on a flat surface.

Remove nasal swab from its pouch



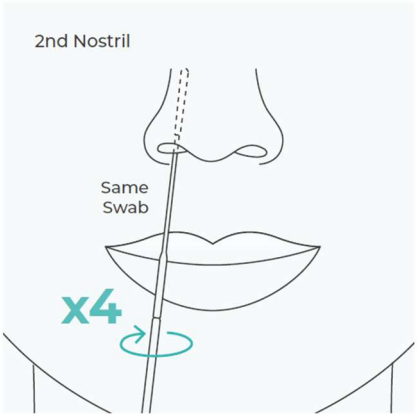
To keep the swab sterile, avoid touching the soft tip of the swab onto any surface. Only remove the swab from its pouch once the test is ready to be performed.

Collect nasal swab sample from both nostrils using the same swab



Gently insert the swab tip into one nostril (no more than ½ to ¾ of an inch). You do not need to go deep. Inserting the swab deeper than the recommended ½ to ¾ inches may cause harm. Refer to diagram.

Using firm pressure, slowly rotate the swab in a circular path against the inside wall of the nostril. Make **at least 4 big circles**. Take approximately 15 seconds to collect the specimen. Be

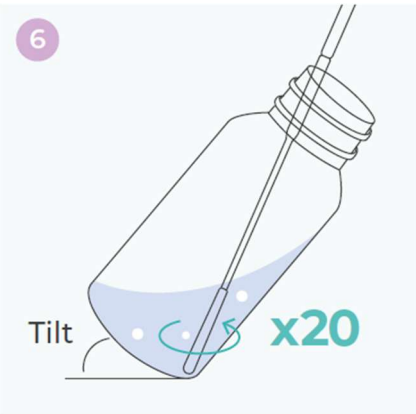


sure to collect any nasal drainage that may be present on the swab.

Repeat in the other nostril using the same swab.

With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person hold the child's head while swabbing.

Release sample into buffer solution vial



Immediately place the nasal swab into the buffer solution vial.

Tilt the vial to make sure that the swab tip (soft end) is thoroughly soaked and immersed in the buffer solution.

Twist the swab back and forth 20 times in the buffer solution. Before taking out, roll the swab tip against the inner wall of the vial to remove any excess solution. Properly dispose of the used swab in a trash receptacle.

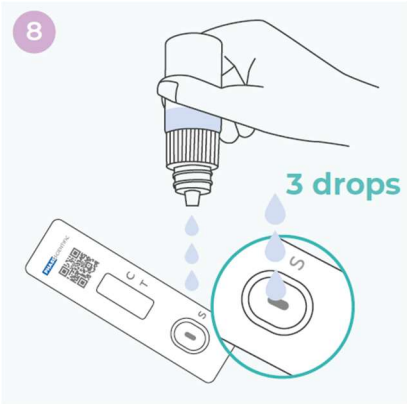
Note: Test samples immediately after collection, but no more than 5 minutes after specimen collection before placement into extraction buffer or up to 2 hours after placement into extraction buffer, if kept at room temperature.

Cap the vial and expose dropper tip

Tightly cap the buffer solution vial with the vial cap.

Remove the purple part of the cap from the vial to expose the dropper tip. Avoid touching the dropper tip with your finger.

Add buffer solution to the test device



Open the test device pouch and place the test device on a flat surface.

Locate the sample well (S) on the test device.

Slowly squeeze **3 drops** of the buffer solution into the sample well.

False negative results may occur if less than 3 drops are applied to the sample well.

Let test device sit for 20 minutes and read test result

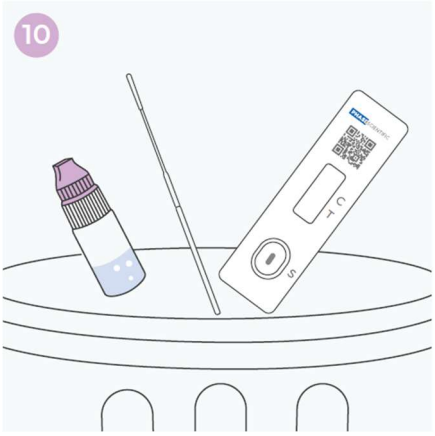
Start a timer for 20 minutes.

Leave the test device on a table or flat surface until the timer goes off.

Read your test results immediately at 20 minutes.

Note: Do NOT read the results before 20 minutes or if it has been longer than 25 minutes from when the vial solution has been added to the sample well, as the test may have an inaccurate outcome.

Dispose of used test kit materials



Dispose of all used test kit components and swab samples in a trash receptacle.

Do not flush or pour test liquids down the drain.

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

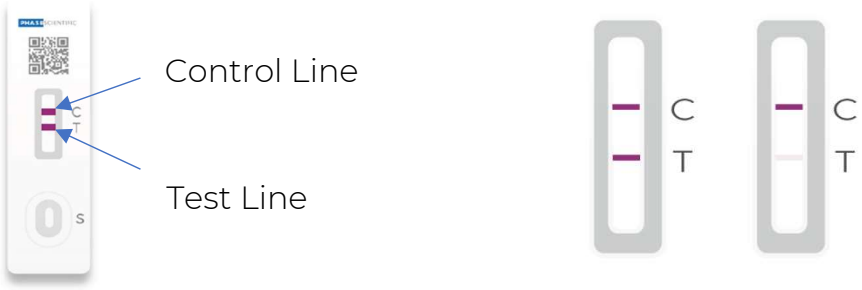
Positive Result

Two red-colored lines appear in the test window, one on the control line position (C) **and** the other on the test line position (T).

A positive test result is interpreted as protein antigen from the virus that causes COVID-19 was detected in the specimen. The individual is positive for COVID-19. Test results should be considered in association with the patient's history and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations).

You do not need to perform repeat testing if you have a positive result at any time.

Note: The test line (red line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the control line should not be compared to that of the test line for the interpretation of the test result. Any faint visible red test line should be interpreted as positive, when the control line (C) line is also present.



Positive

Negative Result

Only one red-colored line on the control line (C) position appears **and** no visible line on the test line position (T)

Negative

A negative result means that antigen from the virus that causes COVID-19 is not detected in the sample.

Negative results do not rule out SARS-CoV-2 infection. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed.

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

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

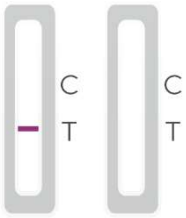
Note: A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.

Note: Additional confirmatory testing with a molecular test for negative results may be necessary for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as a

close contract with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also 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.

Invalid Result

If a red-colored line does not appear on the control line position (C) in 20 minutes, the test result is invalid. Re-test with a new INDICAID™ COVID-19 Rapid Antigen At-Home Test.



Invalid

Performance Characteristics

Clinical Performance

The clinical performance of the INDICAID™ COVID-19 Rapid Antigen At-Home Test was evaluated in an on-going prospective study performed at four (4) geographically diverse sites throughout the United States. Between December 2021 and January 2022, site operators sequentially enrolled 242 eligible subjects presenting with at least one symptom of COVID-19 within 6 days of symptom onset. Using the lay-user Instructions for Use provided in the test kit, individuals aged 14 years and older independently collected an anterior nasal swab specimen, conducted the INDICAID™ COVID-19 Rapid Antigen At-Home Test, interpreted, and reported their self-test result. For pediatric subjects between the ages of two (2) and 13 years, an accompanying adult (e.g., parent or legal guardian aged 18 years and older) was present to collect the anterior nasal swab specimen, conduct the INDICAID™ COVID-19 Rapid Antigen At-Home Test, interpret, and report the result for the subject. A high-sensitivity RT-PCR SARS-CoV-2 assay was used as a comparator method to test anterior nasal swab samples that were collected from each subject by a healthcare professional.

The INDICAID™ COVID-19 Rapid Antigen At-Home Test results were compared against the results of the RT-PCR comparator assay to calculate the positive percent agreement (PPA) and negative percent agreement (NPA).

When conducted by a lay-user, the INDICAID™ COVID-19 Rapid Antigen At-Home Test identified 81.7% (95% CI: 71.6% - 89.4%) of the subjects that were identified as SARS-CoV-2 positive by the comparator assay[2]. Additionally, INDICAID™ COVID-19 Rapid Antigen At-Home Test correctly identified 99.4% (95% CI: 96.6% - 100%) of SARS-CoV-2 negative subjects.

Table 1: INDICAID™ COVID-19 Rapid Antigen Test Performance Against Comparator Method (Within 6 Days Symptom Onset)

INDICAID™ COVID-19 Rapid Antigen Test	Comparator Method		
	Positive	Negative	Total
Positive	67	1	68
Negative	15	159	174
Total	82	160	242
PPA	81.7% (95% CI: 71.6% - 89.4%)		
NPA	99.4% (95% CI: 96.6% - 100%)		

This clinical performance data reflects the accuracy of the test when testing once. This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA, **which has shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results.**

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

Age (years)	Total	Comparator Positive	Prevalence	INDICAID™ Positive
2 to 13	23	6	26.1%	4
14 to 24	34	14	41.2%	14
25 to 64	150	54	36.0%	45
65+	34	8	23.5%	4

[2] The 82 patient samples that were identified as SARS-CoV-2 positive by the comparator assay were analyzed by sequencing to determine the prevalence of Omicron among the clinical study population. Of the 82 positive samples analyzed, 73 samples had sufficient RNA to determine variant identity by sequencing. Sixty-eight (68) of the 73 analyzable samples (93.2%) were identified as the Omicron (BA.1/BA.1.1) variant.

Table 4: Positive results by days since symptom onset

Days Since Symptom Onset	Cumulative Comparator Positive	Cumulative INDICAID™ Positive	PPA
1	13	10	76.9%
2	35	30	82.9%
3	52	43	80.8%
4	63	52	81.0%
5	74	61	81.1%
6	82	68	81.7%

Serial-Testing Clinical Performance

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 SARS-CoV-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 RT-PCR, 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 tests in study combined.

Days After 1st PCR Positive Test Result	Asymptomatic on 1st Day of Testing			Symptomatic on 1st Day of Testing		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/39 (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%)	N/A	4/9 (44.4%)	3/7 (42.9%)	N/A

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 with SARS-CoV-2.
2 Tests= two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests= three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Limit of Detection (Analytical Sensitivity)

The limit of detection (LoD) of the INDICAID™ COVID-19 Rapid Antigen At-Home Test was determined using serial dilutions of gamma-irradiated SARS-CoV-2 virus (Isolate USA-WA1/2020, NR-52287). Contrived samples were prepared by spiking the strain into pooled human nasal matrix from presumed negative donors. 50 µl of spiked sample preparation was added onto the swab and subsequently transferred to pre-filled buffer solution vial and tested as per the IFU. The preliminary LoD initially determined by testing a two-fold dilution series of 3

replicates per concentration was confirmed by testing in 20 replicates. The confirmed LoD for the INDICAID™ COVID-19 Rapid Antigen At-Home Test 2.8 X 10^3 $TCID_{50}$ /mL.

Cross-reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity and microbial interference studies were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in a clinical specimen for the nasal cavity. Each organism and virus (as indicated in table below) was tested in both the absence and presence of inactivated SAR-CoV2 (SARS-CoV-2 isolate USA-WA1/2020) at 3X LoD. All testing samples were prepared in pooled human nasal matrix from healthy donor. No cross reactivity or interference was observed at the concentration tested as shown in the table below.

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

Type	Potential Cross-reactant	Test Concentration
	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. Cross-reactivity with human coronavirus HKU1 cannot be completely 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

The INDICAID™ COVID-19 Rapid Antigen At-Home Test was tested up to 2.8 x 10^5 $TCID_{50}$/mL (1.4 x 10^4 $TCID_{50}$/swab) of gamma-irradiated SARS-CoV-2 (USA-WA1/2020) and no high-dose Hook Effect was observed.

Endogenous Interfering Substances

The interference was performed for the potentially interfering substances that may be present in the respiratory tract or might be artificially introduced onto the nasal swab in the home environment that may cross-react or interfere with the detection of SARS-CoV-2 by the INDICAID™ COVID-19 Rapid Antigen At-Home Test. The positive (3X LoD SARS-CoV-2) and negative samples were tested with the addition of potentially interfering substances. The performance of the INDICAID™

COVID-19 Rapid Antigen At-Home Test was not affected by any of the potentially interfering substances listed in the table below at the concentration tested.

Potential Interferent	Test Concentration	Test Result	
		(+) 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
NasalCrom (Cromolyn)	15% v/v	Positive	Negative
Nasacort (Triamcinolone)	5 % v/v	Positive	Negative
Neo-Synephrine (Phenylephrine HCl) (Spray)	15% v/v	Positive	Negative
Rhinocort (Budesonide)	5% v/v	Positive	Negative
Ricola (menthol)	1.5 mg/mL	Positive	Negative
Saline nasal spray	15% v/v	Positive	Negative
Sucrets (Dyclonine/Menthol)	1.5 mg/mL	Positive	Negative
Zanamivir	282 ng/mL	Positive	Negative
Zicam Cold Remedy (Galphimia glauca, Luffa)	5% v/v	Positive	Negative
Bleach (Sodium Hypochlorite)[1]	0.037% v/v	Positive	Negative
	1% v/v	Negative	Negative
Dish-washing Liquid (Sodium lauryl sulfate)	1% v/v	Positive	Negative
Hand sanitizer (ethyl alcohol)	1% v/v	Positive	Negative
Hand Soap (Benzalkonium chloride)	1% v/v	Positive	Negative
Laundry detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% v/v	Positive	Negative
Surface Sanitizer (Citric Acid)	1% v/v	Positive	Negative
	4.7% w/w	Positive	Negative

Potential Interferent	Test Concentration	Test Result	
		(+) SARS-CoV-2 (3x LoD)	(-) SARS-CoV-2
Vicks VapoRub (Camphor, Eucalyptus oil, Menthol)	2.6% w/w	Positive	Negative
	1.2% w/w	Positive	Negative

[1] Testing demonstrated false negative results at concentrations of 1% v/v.

Flex Studies

A robust use of the INDICAID™ COVID-19 Rapid Antigen At-Home Test was demonstrated by 9 flex studies as follows:

1) Non-level positioning of the test device
2) Varying the extraction buffer solution volume
3) Varying the swab rotation number
4) Sample volume variability
5) Result reading time variability
6) Temperature and humidity
7) Test device drop
8) Delay in sample extraction
9) Non-tilting of buffer solution vial during sample extraction

Usability Study

A usability study was conducted to evaluate the ability of representative lay users to follow the instructional steps provided in the INDICAID™ COVID-19 Rapid Antigen At-Home Test Quick Reference Guide (QRG) under expected use conditions, comprehend the potential set of test results, and understand the product labeling.

Thirty (30) representative test kit users (self-testers, caregiver-child, and proxy caregiver-adult pairs) were observed performing an INDICAID™ COVID-19 Rapid Antigen At-Home Test while following QRG, and other instructional materials, that accompany the kit. Participants were asked to collect a nasal swab sample to perform the test. They were also asked to interpret a mock test result and state the appropriate course of action based upon the test result. Participants additionally were provided with a written questionnaire to evaluate their understanding of the product labeling and to provide subjective feedback about the ease-of-use and perceived safety of the kit.

Successful completion of each study task performed by the subjects was determined by unassisted professional observation. Participants correctly performed 96.7% (667/690) of the steps/tasks and 96.7% (29/30) of the participants correctly interpreted the test results. 93.1% (27/29) of the participants provided a fully correct follow-up action response given their test result, while the remaining

6.9% (2/29) provided a partially correct response. For label comprehension questions, 94.4% (170/180) were answered correctly across all subjects.

Technical Support

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Symbols

	*In vitro* diagnostic medical device		Keep dry
	Consult Instructions for Use		Do not re-use
	Caution		Catalog number
	Temperature limit		Batch code
	Keep away from sunlight		Use-by date
	Contains sufficient for <n> tests		Manufacturer
	Sterilized using irradiation		Do not use if package is damaged and consult instructions for use

Manufacturer

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