LAY USER INSTRUCTIONS

REF P0038, P0039, P0040, P0041

INDICAID™ OTC

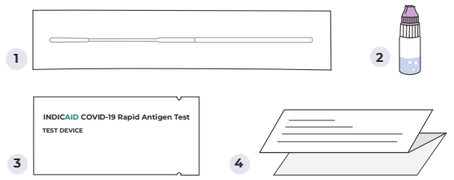
COVID-19 Rapid Antigen At-Home Test

FOR EMERGENCY USE AUTHORIZATION (EUA) ONLY IN VITRO DIAGNOSTIC USE ONLY

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

- An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
- For the most current information on COVID-19, please visit: www.cdc.gov/COVID19.

KIT CONTENTS



1. Individually wrapped sterile nasal swab
2. Single use buffer solution vial
3. Individually packaged single-use test device
4. Quick reference guide (see reverse side)
5. Lay user instructions (this document)

NOTE: This product comes in a 2-test, 4-test, 12-test, or 24-test format. The number of items supplied in the kit will vary depending on which kit was purchased.

A timer is required to perform the test and is not included in the test kit. Do not begin if you do not have at least 25 minutes available to focus on performing the test. Before you begin, wash your hands for at least 20 seconds and then dry your hands. Perform the test indoors, at room temperature on a clean, flat surface.

INTENDED USE

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

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 which is generally detectable in anterior nasal (nares) swabs 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.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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 measures such as isolating from other and wearing masks. 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. 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 physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The INDICAID™ COVID-19 Rapid Antigen At-Home Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The INDICAID™ COVID-19 Rapid Antigen At-Home 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.

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 (EUA).
- 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. §360bbb3(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 you have had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Leave test card sealed in its pouch until just before use. Once opened, the test card should be used within 2 hours.
- Do not touch swab tip.
- Use only the contents provided in the test kit.
- Test components are single use. Do not re-use.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If contact to the body occurs, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**
- Do not use the test on children under 2 years of age.
- Children aged 2 to 13 years of age should be tested by an adult.
- Wear a safety mask or other face covering when collecting specimen from a child or another individual.
- False negative test results may occur if a specimen is incorrectly collected or handled.
- 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 read test results 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.
- Do not use this test kit beyond its expiration date. For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

HAZARDOUS INGREDIENTS

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.

LIMITATIONS

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.

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 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.

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.

If the test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have 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.

FREQUENTLY ASKED QUESTIONS

Will this test hurt?

No. The nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

What is COVID-19?

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

What is serial testing?

Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Please see the Warnings, Precautions, and Safety Information section for the recommended testing frequency for individuals with and without symptoms of COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect results (see Warnings, Precautions, and Safety Information and Interpreting Your Results sections for more information).

Benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs visit: www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

What is the difference between an antigen and molecular test?

There are different kinds of tests for the virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the INDICAID™ COVID-19 Rapid Antigen At-Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

How accurate is this test?

Clinical studies have 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. The performance of the INDICAID™ COVID-19 Rapid Antigen At-Home Test was established in a prospective study using an EUA authorized molecular test as a comparator method (PPA 81.7% and NPA 99.4%). For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.indicaid.com.

What if I have a positive test result?

A positive result means that, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a negative test result?

A negative test result indicates that antigens from the virus that causes COVID-19 was not found in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does invalid test result mean?

If no control line shows up on the test, the result is invalid (even if any test line shows up). An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

STORAGE AND STABILITY

Store the INDICAID™ COVID-19 Rapid Antigen At-Home Test between 2-30°C (36-86°F) until use. Ensure all kit components are at room temperature before use. Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date. For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

SUPPORT

For questions, or to report a problem, please call +1 (877) 934-9344, or email care@indicaidusa.com or visit www.indicaid.com. Additional information is also available for you and your healthcare provider at www.indicaid.com. This user instructions, quick reference guide, fact sheet for healthcare provider and healthcare provider instructions for use are also available at www.indicaid.com.

The INDICAID™ COVID-19 Rapid Antigen At-Home Test Letter of Authorization, authorized fact sheets and authorized labeling are available on the FDA website and www.indicaid.com.

EXPLANATION OF SYMBOLS

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

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

QUICK REFERENCE GUIDE

INDICAID™ OTC

COVID-19 Rapid Antigen At-Home Test

REF P0038, P0039, P0040, P0041

IVD

Suitable for ages 2+ years
Must be 14+ to use kit unsupervised

HOW TO USE THIS TEST

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but 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 your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

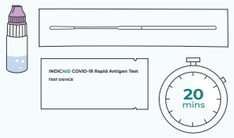
WHAT YOU NEED TO KNOW BEFORE YOU START

- This test aids in the clinical diagnosis of COVID-19, but it should not be the only guide to manage illness. Please consult a healthcare professional if your symptoms persist or worsen.
- This test kit is for testing for current infection only and cannot tell if you have had a COVID-19 infection in the past.
- You must follow the test directions carefully to get an accurate result. Read lay user instructions carefully before starting the test.
- Make sure you have enough time to complete the entire testing process. It takes approximately 25 minutes to complete the process once you begin.
- This kit should not be used on children under age 2. In children ages 2-13, the nasal swab sample must be collected and tested by an adult (18+ years old).
- Always wear a protective mask or other face-covering when collecting nasal swab samples from anyone, whether a child or an adult.

Swabbing the nostrils is critical for obtaining an accurate result. If you do not swab your nose, the test will produce a false negative result.

Performing Your Test

1



Note:
Your test kit box may contain more than one test kit

Gather your supplies

- Check the expiration date on the outside of the product box. For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests
- Remove 1 swab, 1 test device pouch, and 1 buffer solution vial.
- Make sure you have a timer (that can time 20 minutes). The test kit does not come with one.

2

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

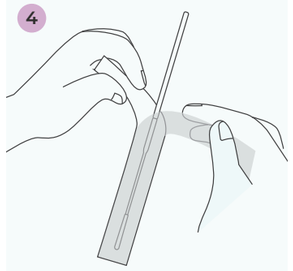
Check the buffer solution volume in the vial. If the vial is empty, DO NOT use and obtain a new buffer solution vial.

3

Remove entire buffer solution vial cap

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

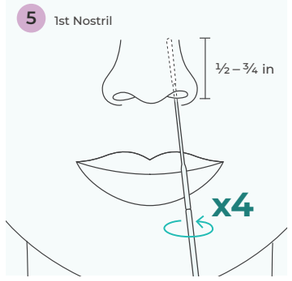
4

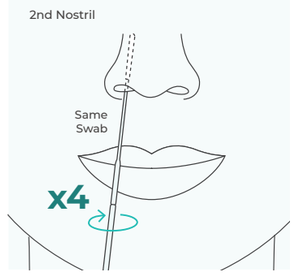


Remove nasal swab from its pouch

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

5

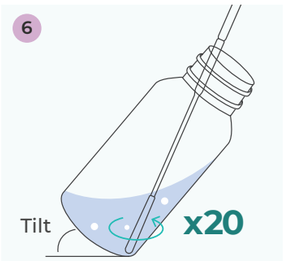




Collect nasal swab sample from both nostrils using same swab

- Gently insert the swab tip into one nostril **(no more than ½ to ¾ inch)**. You do not need to go deep. 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 second 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.

6

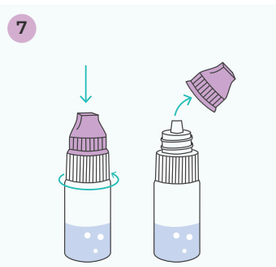


Release sample into buffer solution vial

- 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, press and 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.

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.

7



Cap the vial and expose dropper tip

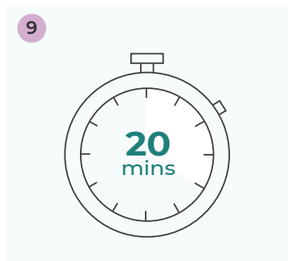
- Tightly cap the buffer solution vial with the vial cap.
- Remove the purple part of the cap from the vial to expose the dropper tip.
- Avoid touching the dropper tip with your finger.

8

Add buffer solution to 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.

9

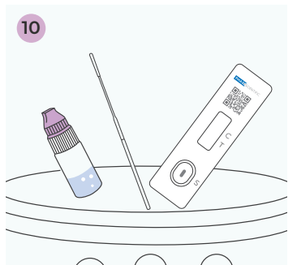


Let test device sit for 20 minutes and read test result

- 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.

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.

10



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.

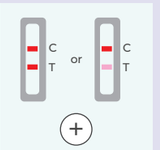
Interpreting Your Results

- 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.
- Read your results in a well-lit area.
- Look for lines next to the 'C' (Control) and the 'T' (Test) areas on the test device. Use the information below to interpret what you see.
- Report your test results to your healthcare provider to receive appropriate medical care.

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 TEST RESULT

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.



If a control (C) line and a test (T) line are visible, the test is positive. Any faint visible red test (T) line with the control line (C) should be read as positive. **You do not need to perform repeat testing if you have a positive result at any time.**

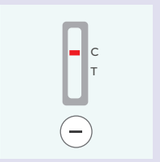
Look very closely! The color intensity in the "T" area can vary. Any faint line right next to the "T" should be considered positive.

Take these next steps

Please consult your healthcare provider to discuss your positive test result. You should self-isolate at home per CDC recommendations to stop spreading the virus to others.

NEGATIVE TEST RESULT

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. 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 higher chance of false negative results with antigen tests than with laboratory-based molecular tests such as PCR. This means that there is higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your healthcare provider.



If the control (C) line is visible, but the test (T) line is not visible, the test is negative

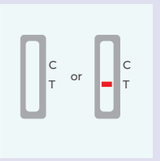
Take these next steps

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.**
- If you develop COVID-19 symptoms or your symptoms become severe, seek medical attention immediately.

Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

INVALID TEST RESULT



No red-colored line next to the "C" means the test is invalid. Re-test with a new swab and a new test device.

If there is no red line next to the "C", the result is invalid regardless of whether there is a red-colored line next to the "T".

Take these next steps

Collect a new nasal swab sample and repeat the test with a new INDICAID™ COVID-19 Rapid Antigen At-Home Test. If you develop COVID-19 symptoms or your symptoms become severe, seek medical attention immediately.

PI-0001 (D)