USER INSTRUCTIONS

REF P0038, P0039, P0040, P0041

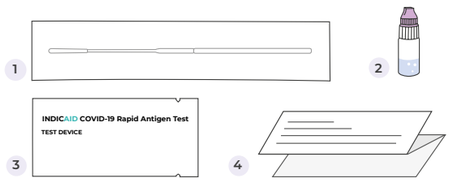
INDICAID® COVID-19 Rapid Antigen At-Home Test

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

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

- 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.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- 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.
- For more information on EUAs visit: www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatoryand-policy-framework/emergency-use-authorization.
- 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. User Instructions (this document)
6. Fact Sheet for Individuals

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 intended for the qualitative detection of SARS-CoV-2. This test is authorized for non-prescription home use with self-collected direct anterior Nasal (nares) swab samples from individuals 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also intended for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also 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, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 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. Antigen 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.

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.

For serial testing programs, 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 a 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.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 (LVID) 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 an adult lay user testing another person 2 years of age or older. The INDICAID® COVID-19 Rapid Antigen At-Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

WARNINGS PRECAUTIONS AND SAFETY INFORMATION

- 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.
- To ensure correct results, you must follow the instructions for use.
- Use only the contents provided in the test kit.
- Test components are single use. Do not re-use.
- Do not use this test kit beyond its expiration date.
- 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 copious amount of water. If irritation persist, 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.

HAZARDOUS INGREDIENTS

Reagent	Concentration	Link to the MSDS
Triton™ X-100	0.1 % v/v[1]	www.sigmaaldrich.com/US/en/sds/sial/x100
ProClin™ 300	0.045% v/v[1]	www.sigmaaldrich.com/US/en/sds/ sial/48914-u

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

SERIAL TESTING INFORMATION AND LIMITATIONS

If you have symptoms of COVID-19 that started within the last 6 days, you can use a single test.

Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional test to perform this serial (repeat) testing.

For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.

Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

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

If both your first and second tests re negative, you may not have COVID-19, however you should follow-up with your healthcare provider if you are at high risk for COVID-19.

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. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at lest 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

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 and Result Interpretation 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.

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, detects proteins from the virus. Antigen tests are very specific for the SARS-CoV-2 virus but are not as sensitive as molecular tests. This means that positive result is highly accurate, but negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular test. This means that there is a higher chance this test will give you negative result when you have COVID-19 than a molecular test would.

How accurate is this test?

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%). You can find further information by visiting indicaidusa.com. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

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 healthcare provider for medical advice about your positive result. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) medical history, and symptoms.

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. If you have symptoms, you likely do not have COVID-19. If you do not have symptoms and you receive a second negative result 24 to 48 hours after your first negative result, then you are likely not infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. 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. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you should 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 the test should be run again, using all new test components.

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 component 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.

SUPPORT

For questions, or to report a problem, please call +1 (877) 934-9344, or email care@indicaidusa.com or visit indicaidusa.com. Additional information is also available for you and your healthcare provider at indicaidusa.com. This User Instructions, Quick Reference Guide, Fact Sheet for Individuals, Fact Sheet for Health Care Provider and Health Care Provider Instructions for Use are also available at indicaidusa.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 indicaidusa.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 limitation	LOT	Batch code
	Keep away from sunlight		Use by
Σ	Sufficient for use		Manufacturer

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

INDICAID® OTC

QUICK REFERENCE GUIDE

INDICAID® COVID-19 Rapid Antigen At-Home Test

REF P0038, P0039, P0040, P0041

IVD

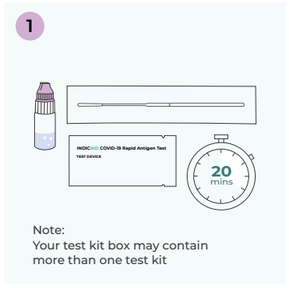
Suitable for ages 2+ years
Must be 14+ to use kit unsupervised

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.
- If you have symptoms of COVID-19, you can use a single test.
- If you do not have symptoms of COVID-19, you will need at least two tests per person.
- 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 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



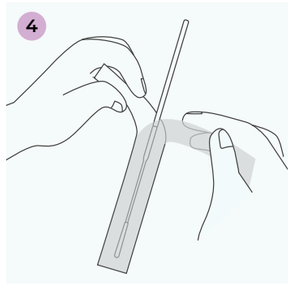
Gather your supplies

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

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

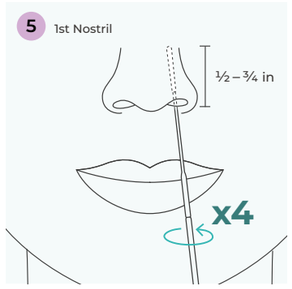
Remove entire Buffer Solution Vial cap

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



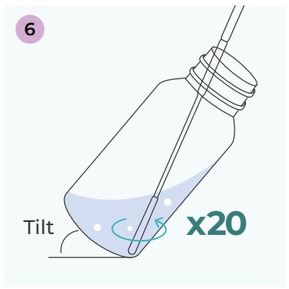
Remove Nasal Swab from its pouch

- 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.



Collect Nasal Swab sample from both nostrils using same swab

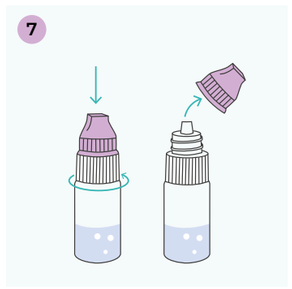
- Gently insert the swab tip into one nostril **(no more than ½ to ¾ inch)**. You do not need to go deep. Refer to diagram.
- Using firm pressure, slowly rotate the swab in a circular path against the inside wall of the nostril. Make **at least 4 big circles**. Take approximately 15 seconds to collect 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.



Release sample into Buffer Solution Vial

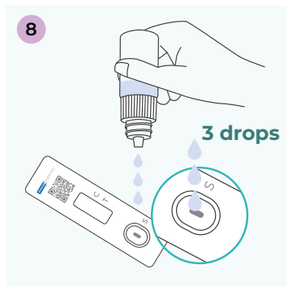
- Immediately place the Nasal Swab into the Buffer Solution Vial. **Tilt the vial to make sure that the swab tip (soft end) is thoroughly soaked and immersed in the Buffer Solution**.
- Twist the swab back and forth 20 times in the Buffer Solution.
- Before taking out, press and roll the swab tip against 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.



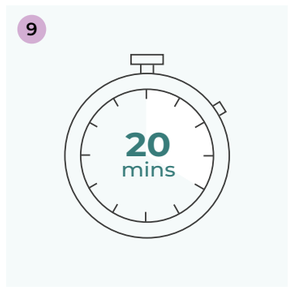
Cap the vial and expose dropper tip

- 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 Test Device

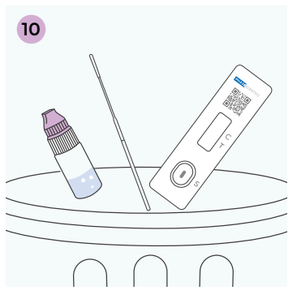
- Open the Test Device pouch and place the Test Device on a flat surface.
- Locate the sample well (S) on the Test Device.
- Slowly squeeze **3 drops** of the Buffer Solution into the sample well.
- False negative results may occur if less than 3 drops are applied to the sample well.



Let Test Device sit for 20 minutes and Read test results

- 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.



Dispose of used test kit materials

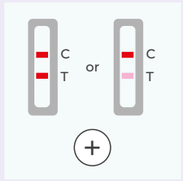
- Dispose of all used test kit components and swab samples in a trash receptacle.
- Do not flush or pour test liquids down the drain.

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 table below to interpret what you see.
- Report your test results to your healthcare provider to receive appropriate medical care.
- If you have symptoms of COVID-19, you can use a single test.
- If you do not have symptoms of COVID-19, you will need at least two tests per person.

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 the 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.

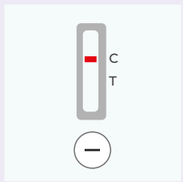
Look very closely! The color intensity in the "T" area can vary. Any faint line right next to the "T" should be considered positive.

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 from the specimen. A negative result does not rule out COVID-19. There is higher chance of false negative results with antigen tests than with laboratory-based molecular tests. 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 health care provider.

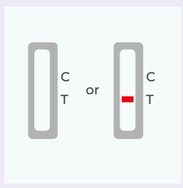


If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative

Take these next steps

If you develop COVID-19 symptoms or your symptoms become severe, seek medical attention immediately. If you have no symptoms OR if this is the first test in a serial testing program, a second test must be done between 24 and 48 hours after the first test.

INVALID TEST RESULT



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

INDICAID® OTC

CONTAINED IN THIS BOX

A timer is required but not provided.

SIMPLE TO USE

Refer to detailed instructions inside

Individually Wrapped Test Devices (2 Each)

Buffer Solution Vial (2 Each)

Individually Wrapped Swabs (2 Each)

User Instructions and Fact Sheet for Individuals

INDICAID® OTC

COVID-19 RAPID ANTIGEN AT-HOME TEST

The INDICAID® COVID-19 Rapid Antigen At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

PROTECT others PROTECT yourself

TEST WHEN...

- ☑ COVID-19 symptoms
- ☑ Self-quarantine
- ☑ Travel decisions
- ☑ School/Work decisions
- ☑ Protect others

RESULTS

C T — 2 lines — Positive Result

C T — 1 line — Negative Result

Refer to detailed results explanation inside

IMPORTANT

- One-time use only
- Read instructions inside before use
- For use with and without symptoms
- Contains 2 tests
- Keep away from sunlight
- Keep away from moisture
- Use device with caution
- Suitable for ages 2+ years. Must be 14+ to use kit unsupervised
- Store at 2°C – 30°C (35.6°F – 86°F)

REF P0038 IVD

PHASE SCIENTIFIC

PROTECT others PROTECT yourself

INDICAID® OTC

Quick and Easy

PB-001S Rev. C

INDICAID® OTC

FDA EMERGENCY USE AUTHORIZATION

2 TESTS

PROTECT others PROTECT yourself

COVID-19
RAPID ANTIGEN AT-HOME TEST

Quick · Easy · Results in 20 minutes

PHASE SCIENTIFIC

Lot

Exp

4 897114 730237

Manufacturer:
PHASE SCIENTIFIC INTERNATIONAL LTD.
32 & 33/F, Gravity, 29 Hing Yip Street
Kwun Tong, Kowloon, Hong Kong

indicaidusa.com +1 (877) 934-9344 care@indicaidusa.com

• In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an 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. §360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

• **For Emergency Use Authorization (EUA) only • For in vitro diagnostic use • Must be 2+ years to use this kit** • If you have symptoms of COVID-19, you can use a single test • If you do not have symptoms of COVID-19, you will need at least two tests per person • You may need to purchase additional tests to perform serial (repeat) testing • This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test • This test does NOT determine if you had COVID-19 in the past or if you have immunity.

CONTAINED IN THIS BOX

A timer is required but not provided.

SIMPLE TO USE

Refer to detailed instructions inside

INDICAID® OTC

COVID-19 RAPID ANTIGEN AT-HOME TEST

The INDICAID® COVID-19 Rapid Antigen At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

PROTECT others
PROTECT yourself

TEST WHEN...

- ☑ COVID-19 symptoms
- ☑ Self-quarantine
- ☑ Travel decisions
- ☑ School/Work decisions
- ☑ Protect others

RESULTS

2 lines Positive Result

1 line Negative Result

Refer to detailed results explanation inside

IMPORTANT

- One-time use only
- Read instructions inside before use
- For use with and without symptoms
- Contains 4 tests
- Keep away from sunlight
- Keep away from moisture
- Use device with caution
- Suitable for ages 2+ years. Must be 14+ to use kit unsupervised
- Store at 2°C – 30°C (35.6°F – 86°F)

REF P0039 IVD

PHASE SCIENTIFIC

INDICAID® OTC

Quick and Easy

PROTECT others
PROTECT yourself

INDICAID® OTC

FDA EMERGENCY USE AUTHORIZATION

4 TESTS

PROTECT others
PROTECT yourself

COVID-19
RAPID ANTIGEN AT-HOME TEST

Quick · Easy · Results in 20 minutes

PHASE SCIENTIFIC

Lot

Exp

4 897116 730268 >

PB-0016 Rev. B

Manufacturer:
PHASE SCIENTIFIC INTERNATIONAL LTD.
32 & 33/F, Gravity, 29 Hing Yip Street
Kwun Tong, Kowloon, Hong Kong

indicaidusa.com +1 (877) 934-9344 care@indicaidusa.com

• In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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. §360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

• **For Emergency Use Authorization (EUA) only • For in vitro diagnostic use • Must be 2+ years to use this kit** • If you have symptoms of COVID-19, you can use a single test • If you do not have symptoms of COVID-19, you will need at least two tests per person • You may need to purchase additional tests to perform serial (repeat) testing • This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test • This test does NOT determine if you had COVID-19 in the past or if you have immunity.

COVID-19
RAPID ANTIGEN AT-HOME TEST
Quick · Easy · Results in 20 minutes
PHASE SCIENTIFIC

INDICAID® OTC

FDA EMERGENCY USE AUTHORIZATION

12 TESTS

PROTECT others
PROTECT yourself

PB-007P Rev.B

INDICAID® OTC

COVID-19 RAPID ANTIGEN AT-HOME TEST

PROTECT others
PROTECT yourself

Lot
Exp

RESULTS

2 lines Positive Result

1 line Negative Result

Refer to detailed results explanation inside

IMPORTANT

- One-time use only
- Read instructions inside before use
- For use with and without symptoms
- Contains 12 tests
- Keep away from sunlight
- Keep away from moisture
- Use device with caution
- Suitable for ages 2+ years. Must be 14+ to use kit unsupervised
- Store at 2°C – 30°C (35.6°F – 86°F)

REF P0040 IVD

PHASE SCIENTIFIC

CONTAINED IN THIS BOX A timer is required but not provided.

- Individually Wrapped Test Devices (12 Each)
- Buffer Solution Vial (12 Each)
- Individually Wrapped Swabs (12 Each)
- User Instructions and Fact Sheet for Individuals

INDICAID® OTC

COVID-19 RAPID ANTIGEN AT-HOME TEST

TEST WHEN...

- ☑ COVID-19 symptoms
- ☑ Travel decisions
- ☑ Protect others
- ☑ Self-quarantine
- ☑ School/Work decisions

12 TESTS

PROTECT others
PROTECT yourself

The INDICAID® COVID-19 Rapid Antigen At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

SIMPLE TO USE Refer to detailed instructions inside

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Manufacturer:
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4 891716 730275 >

Quick and Easy

Results in 20 minutes

FDA EMERGENCY USE AUTHORIZATION

PHASE SCIENTIFIC

COVID-19 RAPID ANTIGEN AT-HOME TEST

INDICAID® OTC

24 TESTS

PROTECT others PROTECT yourself

INDICAID® OTC

COVID-19 RAPID ANTIGEN AT-HOME TEST

PROTECT others PROTECT yourself

Lot

Exp

RESULTS

2 lines	Positive Result
1 line	Negative Result

Refer to detailed results explanation inside

IMPORTANT

- One-time use only
- Read instructions inside before use
- For use with and without symptoms
- Contains 12 tests
- Keep away from sunlight
- Keep away from moisture
- Use device with caution
- Suitable for ages 2+ years. Must be 14+ to use kit unsupervised
- Store at 2°C – 30°C (35.6°F – 86°F)

REF P0041 IVD

PHASE SCIENTIFIC

• In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an 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. §360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

• For Emergency Use Authorization (EUA) only • For in vitro diagnostic use • Must be 2+ years to use this kit • If you have symptoms of COVID-19, you can use a single test • If you do not have symptoms of COVID-19, you will need at least two tests per person • You may need to purchase additional tests to perform serial (repeat) testing • This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test • This test does NOT determine if you had COVID-19 in the past or if you have immunity.

PB.0018 Rev. B

CONTAINED IN THIS BOX A timer is required but not provided.

Individually Wrapped Test Devices (24 Each)

Buffer Solution Vial (24 Each)

Individually Wrapped Swabs (24 Each)

User Instructions and Fact Sheet for Individuals

INDICAID® OTC

COVID-19 RAPID ANTIGEN AT-HOME TEST

TEST WHEN...

- ☑ COVID-19 symptoms
- ☑ Travel decisions
- ☑ Protect others
- ☑ Self-quarantine
- ☑ School/Work decisions

24 TESTS

PROTECT others PROTECT yourself

Manufacturer:
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The INDICAID® COVID-19 Rapid Antigen At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

SIMPLE TO USE Refer to detailed instructions inside