**INTENDED USE**
Do not begin if you do not have at least 25 minutes available to focus on the test. A timer is required to perform the test and is not included in the test kit purchased.

**FOR EMERGENCY USE AUTHORIZATION**

For emergency use authorization, this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of this test during the COVID-19 pandemic. The declaration was made by the 21st Century Cures Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated, or authorized fact sheets and authorized labeling are available on the FDA website and www.indicaid.com. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

In asymptomatic individuals and three days with at least 48 hours between tests, and for individuals without symptoms, testing (serial testing) may be performed. Negative results 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 confirmatory with a molecular test, such as a chemiluminescent immunoassay or a reverse transcription polymerase chain reaction (real-time PCR) test. If you have symptoms, a healthcare provider should follow-up with a molecular test to confirm the result. Both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

For more information on EUAs visit: www.fda.gov/emergency-preparedness-response-procurement/medicines-and-vaccines/emergency-use-authorizations-euas.

**LIMITATIONS**
There is a higher chance of false negative results with antigen tests than with laboratory-confirmed results. There is no loss of sensitivity or lack of specificity 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 under ideal conditions.

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. This test has not been established for all laboratories. It is anticipated to be reflective of the prevalent variants in circulation at the time of testing. Performance of the test may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

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**INDICATIONS**
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 (nasal) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nasal) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset if tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms, testing (serial testing) may be performed. Negative results may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

**FREQUENTLY ASKED QUESTIONS**

**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 wide range of symptoms, such as fever, cough, and difficulty breathing, but symptoms vary from mild to severe.

**Who should test?**
Individuals who test negative and continue to experience COVID-19 symptoms should consider testing again. Positive results should be reported to local health authorities in accordance with local, state, and federal requirements using appropriate reporting mechanisms as defined by the Laboratory in Vitro Diagnostics (LVDs) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

**How accurate is this test?**
Clinical studies have shown that antigen tests more accurately determine whether someone is infected with COVID-19 than they do to rule out infection. 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 (90% 87.1% and 99.4%). For more information on the performance of the test and how the performance may apply to you, please contact your healthcare provider.

**What is the difference between an antigen and molecular test?**
Antigen tests detect genetic material from the virus. Antibody tests, such as the INDICAID COVID-19 Rapid Antigen At-Home Test detect proteins from the virus. Due to the lover 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.

**Keep away from moisture**

**INDICAD™ COVID-19 Rapid Antigen At-Home Test**

**PHASE Scientific International Limited**
**VP, Building 22E, Phase 3, Hong Kong Science Park, Shatin, New Territories, Hong Kong**

**CONTACT INFORMATION**

For questions, or to report a problem, please call +1 (977) 954-3344, or email info@indicaid.com or visit www.indicaid.com. Additional information is available for you and your healthcare provider at www.indicaid.com. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

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VP, Building 22E, Phase 3, Hong Kong Science Park, Shatin, New Territories, Hong Kong

**EXPLANATION OF SYMBOLS**

In vitro diagnostic medical device
Consultations
card
Consultations
 accompany documents
Catalog number
Temperature limits
Batch code
Keep away from sunlight
Use-by date
Contains sufficient for n tests
Manufacturer
Performing Your Test

1. Release sample into buffer solution vial
   - Gently 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.

2. Cap the vial and expose dropper tip
   - Gently 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.

3. 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.
   - Gently add 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.

4. 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.

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 4-6 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 1 inch, and you may need to have a second person hold the child’s head while swabbing.

6. 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.

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 test kits 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 current infection only and cannot tell if you have had a COVID-19 infection in the past.
- You must follow the test directions 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 (≥8 years old).
- Always wear a protective mask or other face-covering when collecting nasal swab samples from anyone, whether a child or an adult.

In case of a negative test:
- False-negative results may occur if the test is not performed as directed. Always replace the nasal swab and test device pouch and ensure the test device cap is properly seated.
- False negative results may occur if the test kit is not used as directed or if the test device is not tested within the recommended time window (10 mins before placement into extraction buffer). The test kit is not intended for use outside of the product box. For dating for COVID-19 antigen tests, please see http://www.fda.gov/covid-tests/COVID-19.

In case of a positive test:
- A positive test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample and you are likely not infected. You may still have COVID-19, however you should follow-up with your healthcare provider.
- If you test positive, then you have a COVID-19 infection. You may still have COVID-19 and you may still be contagious. Your healthcare provider will work with you to determine the best care for you based on your test results along with medical history and your symptoms.

Interpreting Your Results
- Results should be considered in the context of an individual’s recent exposure, 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.

POSITIVE TEST RESULT
A positive test result means that the virus that causes COVID-19 was detected in your sample and you are 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 the best 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 (C) should be read as positive. You do not need to perform repeat testing if you have a positive result at any time.

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 a very small chance that this test can give a negative result even if 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.
EMERGENCY USE AUTHORIZATION

Quick and Easy

IMPORTANT

Positive Result

Negative Result

2 lines
1 line

Refer to detailed results explanation inside

RESULTS TEST WHEN...

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

COVID-19 RAPID ANTIGEN AT-HOME TEST

Quick • Easy • Results in 20 minutes

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
Determining a negative result requires multiple tests • 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.

OTC

User Instructions
Individually Wrapped Test Devices (2 Each)
Buffer Solution Vials (2 Each)
Individually Wrapped Swabs (2 Each)

CONTAINED IN THIS BOX

A timer is required but not provided.
SIMPLE TO USE

Refer to detailed instructions inside.

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 when tested at least twice over three days with at least 48 hours between tests, or from those 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.

One-time use only
Read instructions inside before use
For use with and without symptoms

Contains 2 tests
Use device with caution
Suitable for ages 2+ years
Valid for 30 days from manufacturing date (INDICAID™ 12°C – 25°C)

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

Manufacturer:
PHASE SCIENTIFIC INTERNATIONAL LTD.
1/F, Building 22E, Phase 3, Hong Kong Science Park,
Shatin, New Territories, Hong Kong

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

Project: COVID-19 Rapid Antigen Test
Description: US OTC Box (2rxn)
Document Number: PB-0015 (E)
Size: L203xW25xH65
Unit: MM
Paper: 100gm one side white cardboard
Color: 4C+0C
Finishing: Matt Lamination
Last Update: 18 Nov 2022

203 25 18

25 65.8

50 203

24.2
**Quick • Easy • Results in 20 minutes**

**COVID-19 RAPID ANTIGEN AT-HOME TEST**

*EMERGENCY USE AUTHORIZATION*

**FDA**

**4 TESTS**

**IMPORTANT**

Positive Result

2 lines

Negative Result

1 line

Refer to detailed results explanation inside

CT

CT

**RESULTS TEST WHEN...**

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

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- Must be 2+ years to use this kit

**Determining a negative result requires multiple tests**

- 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.

**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 when tested at least twice over three days with at least 48 hours between tests, or from those without symptoms or with epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.**

**User Instructions**

**Individually Wrapped Test Devices (4 Each)**

**Buffer Solution Vials (4 Each)**

**Individually Wrapped Swabs (4 Each)**

**CONTAINED IN THIS BOX**

- A timer is required but not provided.
- SIMPLE TO USE: Refer to detailed instructions inside.

**One-time use only**

**Read instructions inside before use**

**For use with and without symptoms**

**Store at 2°C – 30°C (35.6°F – 86°F)**

**Use device with caution**

**Suitable for ages 2+ years.**

**Must be 14+ to use kit unsupervised**

**Contains 4 tests**

**Keep away from sunlight**

**Keep away from moisture**

**PB-0016 (D)**

**PROTECT others**

**PROTECT yourself**

**PROTECT others**

**PROTECT yourself**

**PROTECT others**

**PROTECT yourself**

**OTC**

**indicaid.com**

**+1 (877) 934-9344**

**care@indicaidusa.com**

**20315 203 34.2**

**Project: COVID-19 Rapid Antigen Test**

**Description: US OTC Box (4x4)**

**Document Number: PB-0016 (D)**

**Size: L203xW35xH65**

**Unit: MM**

**Paper: 300gsm one side coat artboard**

**Color: 4C+0C**

**Finishing: Matt Lamination**

**Last Update: 18 Nov 2022**

For more information on expiration dating for COVID-19 antigen tests, please visit [http://www.fda.gov/covid-tests](http://www.fda.gov/covid-tests)
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 when tested at least twice over three days with at least 48 hours between tests, or from those 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.
Quick and Easy Results in 20 minutes

24 TESTS

IMPORTANT
Positive Result
Negative Result
2 lines
1 line

Refer to detailed results explanation inside

COVID-19 RAPID ANTIGEN AT-HOME TEST

Individually Wrapped Swabs (24 Each)
User InstructionsIndividually Wrapped Test Devices (24 Each)
Buffer Solution Vials (24 Each)

CONTAINED IN THIS BOX

A timer is required but not provided.

TEST WHEN...
COVID-19 symptoms
Self-quarantine
Travel decisions
School/Work decisions
Protect others

EMERGENCY USE AUTHORIZATION

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 when tested at least twice over three days with at least 48 hours between tests, or from those 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.

SIMPLE TO USE

Refer to detailed instructions inside.

• 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
• Determining a negative result requires multiple tests • 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.

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

One-time use only
Read instructions inside before use
For use with and without symptoms

2
Store at 2°C – 30°C (35.6°F – 86°F)
Use device with caution
Suitable for ages 2+ years. Must be 14+ to use kit unsupervised

2+
Contains 24 tests
Keep away from sunlight
Keep away from moisture

Manufacturer:
PHASE SCIENTIFIC INTERNATIONAL LTD.
1/F, Building 22E, Phase 3, Hong Kong Science Park, Shatin, New Territories, Hong Kong

PB-0018 (D)

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests