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 may result in inaccurate test results.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This test is intended for use by individuals aged 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 this test under §606 (c) (4) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §360b(b)(4), unless the declaration is terminated, or revoked sooner.

More information on EUA: www.fda.gov/medical-devices/emergency-authorized-devices

For more recent information on COVID-19, please visit: www.cdc.gov/covid19

INDICATIONS

This 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.

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 the course of disease. If you have symptoms 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. 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 (see reverse side) at least twice over the course of disease. 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, test results from the virus that causes COVID-19 may still be positive for up to 48 hours after you have symptoms. If both of your first and second tests are 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

What is the performance of the INDICAID® COVID-19 Rapid Antigen At-Home Test?

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 (IPRA 87% and NMA 99.4%), you can find further information by visiting indicaidusa.com. The performance of this test is still being evaluated with validated clinical 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 test result means that, it is very likely that you have COVID-19 because the virus that causes COVID-19 was found in your sample. You should to stay home for at least 24 hours before seeking medical advice from a healthcare provider for 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 were not detected. If you have symptoms, you likely do not have COVID-19. If you do not have symptoms you receive a second test within a 48-hour window after your first test, you may still be infected with COVID-19.

Storage and Stability

Store The INDICAID® COVID-19 Rapid Antigen At-Home Test between 2-30°C (36-86°F). The test components are stable at room temperature up to 30 days. Do not use beyond the expiration date.

Support

For questions, or to report a problem, please call 1 (877) 954-3344, or email care@indicaidusa.com or visit indicaidusa.com. Additional information is also available for you and your healthcare provider at: indicaidusa.com. For more information, use Instructions, Quick Reference Guide, Fact Sheet for Individuals, Fact Sheet for Healthcare 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

VO

In vitro-diagnostic medical device

Keep away from moisture

ROI

Caution—consult accompanying documents

Catalog number

Temperature limitation

Catch code

Keep away from sunlight

Sufficient for use

Manufacturer

PHASE Scientific International Limited 32 & 33, Gravity, 29 Hing Yip Street, Kowloon, Hong Kong
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 the test instructions 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.

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
- Twit 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 1/4 to 1/2 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 1/4 of an inch, and you may need to have a second person hold the child's head while swabbing.

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.

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.

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.

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 a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is higher risk of you getting a false negative. If you have symptoms of COVID-19 when you have COVID-19, you may test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath. If you test negative, but have symptoms of COVID-19, please consult your healthcare provider to discuss your positive test result.

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. Contact your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a 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.

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-ventilated 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.

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.

Invalid Test Result
If a Control (C) line is visible and the Test (T) line is not visible, the test is negative. 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.

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.

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.

Invalid Test Result
If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint line right next to the “T” should be read as positive.

Take these next steps
If you develop COVID-19 symptoms or your symptoms become severe, seek medical attention immediately. If you have symptoms of COVID-19 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.

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.
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.
**INDICAID® COVID-19 RAPID ANTIGEN AT-HOME TEST**

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

**RESULTS**
- Negative Result
  - 1 line

**IMPORTANT**
- One-time use only
- Refer to detailed instructions inside before use
- Protect from light
- Use device with caution
- Suitable for ages 2+ years
- Must be 14+ to use kit unsupervised

**CONTAINED IN THIS BOX**
- User Instructions and Fact Sheet for Individuals
- Individually Wrapped Test Devices (4 Each)
- Vial (Buffer Solution) (4 Each)
- Individually Wrapped Swabs (4 Each)

**Quick and Easy**
- COVID-19 RAPID ANTIGEN AT-HOME TEST
- Quick - Easy - Results in 20 minutes

**USER INSTRUCTIONS**

1. **Prepare Test Device**
   - Remove the test device from the packaging
   - Tear open the sachet and remove the test device

2. **Collect Nasal Swab Sample**
   - Instruct the user to collect a nasal swab sample
   - Use swab to collect a sample
   - Swab should be used within 6 days of symptom onset or 24 hours after symptom onset

3. **Apply Nucleic Acid Buffer Solution**
   - Remove the nucleic acid buffer solution vial from the packaging
   - Squeeze the swab to remove excess liquid
   - Insert swab into the solution and agitate for 30 seconds
   - Remove swab from solution and dry it

4. **Perform Test**
   - Insert the dry swab into the test area
   - Wait for 20 minutes
   - Observe the result

5. **INTERPRET RESULTS**
   - Negative Result: 1 line
   - Positive Result: 2 lines

**SAVE THE RESULTS **

- Test results are valid for 4 hours
- Result interpretation is based on the presence of 2 lines

**PROTECT YOURSELF AND OTHERS**

- Perform serial (repeat) testing
- Purchase additional tests as needed

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

- 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

**Am I eligible to use this rapid antigen 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
- 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.**
PROTECT others
PROTECT yourself

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

IMPORTANT
Contains 12 tests
Keep away from sunlight
Keep away from moisture

RESULTS
Positive Result
Negative Result
2 lines
1 line

Refer to detailed results explanation inside

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.

SIMPLE TO USE
Refer to detailed instructions inside

CONTAINED IN THIS BOX
Buffer Solution Vial (12 Each)
Individually Wrapped Test Devices (12 Each)
Individually Wrapped Swabs (12 Each)
User Instructions and Fact Sheet for Individuals

A timer is required but not provided.

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 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 to confirm your negative results.
This test detected COVID-19 at the time of your last exposure
The test did not detect if you had COVID-19 in the past or have immunity

Manufacturer:
PHASE SCIENTIFIC INTERNATIONAL LTD.
32 & 33/F, Gravity, 29 Hing Yip Street
Kwun Tong, Kowloon, Hong Kong
+1 (877) 934-9344
indicaidusa.com
care@indicaidusa.com
**INDICAID® COVID-19 RAPID ANTIGEN AT-HOME TEST**

**24 TESTS**

This INDICAID COVID-19 Rapid antigen 24-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in an anterior nasal swab 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.

**IMPORTANT**

- **Positive Result:** 2 lines
- **Negative Result:** 1 line

Refer to detailed results explanation inside.

**CONTAINED IN THIS BOX:**

- A timer is required but not provided.

**DETAILS**

- **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 14+ to use kit unsupervised
- Contains 12 tests
- Keep away from sunlight
- Keep away from moisture
- Suitable for ages 2+ years.

**TEST WHEN...**

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

**READ INSTRUCTIONS**

- 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
- Must be 14+ to use kit unsupervised
- 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.

**MANUFACTURER:**

PHASE SCIENTIFIC INTERNATIONAL LTD.
32 & 33/F, Gravity, 29 Hing Yip Street
Kwun Tong, Kowloon, Hong Kong
+1 (877) 934-9344
indicaidusa.com
care@indicaidusa.com