**INDICIAID COVID-19 Rapid Antigen At-Home Test**

**INTENDED USE**

The INDICIAID® COVID-19 Rapid Antigen At-Home Test is a lateral flow immunosay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in nasal swab specimens from individuals 2 years of age and older.

**INDICATIONS FOR USE**

- The INDICIAID® COVID-19 Rapid Antigen At-Home Test is intended for non-prescription use by adults and children 2 years of age and older at home or other non-clinical settings.
- This test is not intended for use on children under 2 years of age.
- Adults or children 12 years of age and older may be tested at home or in other non-clinical settings.
- The test is intended for use in adults and children 2 years of age and older at home or in other non-clinical settings.

**WARNING PRECAUTIONS AND SAFETY INFORMATION**

- **Leak test card seal in its pouch until just before use.**
- **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 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.**
- **Do not direct light or heat on the test strip.**
- **Do not use this test on individuals 2 years of age or younger.**
- **Do not use the test on children under 2 years of age.**
- **Children aged 2 to 12 years of age should be tested by an adult.**
- **Wear a 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.**
- **False negative test results may occur if a specimen is incorrectly collected or handled.**

**HAZARDOUS INGREDIENTS**

- **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 a 48-hour period, with at least 24 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 kit.

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 are present in your nasal swab sample. Additional testing may be necessary.

**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 your 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 transmitted between individuals while one is sick, but even before a person shows signs or symptoms of being sick (e.g., coughing, difficulty breathing, etc.).

**What is serial testing?**

Serial testing is when one person tests themselves multiple times for COVID-19 on the same day, such as 1 test every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing is appropriate for individuals with suspected COVID-19 infection who are negative on a single test but who are at high risk of subsequent COVID-19 infection. For individuals who are not at high risk of subsequent COVID-19 infection, serial testing is not recommended.

**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 others through 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 INDICIAID® COVID-19 Rapid Antigen At-Home Test, detect viral proteins. The virus antigen tests are very specific for the SARS-CoV-2 virus but are not as sensitive as molecular tests. This means that molecular tests are more 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. However, antigen tests can be performed more quickly and are suitable for rapid screening. These tests are highly sensitive and are used for outbreak detection and for serial screening. Performance may differ in multiple 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 notify your healthcare provider before leaving the EECA assistance for contact healthcare provider for further advice about your positive result. Your healthcare provider will work with you to determine what steps you need to take to ensure your health and the health of your family. See your healthcare provider for based on your test result(s), medical history, and symptoms.

**What if I have a negative test result?**

A negative test result indicates that the virus that causes COVID-19 is not present 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 test result that is also negative, then it is very likely that you are 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 negatives) in some people with COVID-19. The amount of COVID-19 in a sample may decrease the longer you have had COVID-19 and continue to experience COVID-19 symptoms. If symptoms of fever, cough, or a sore throat persist, 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 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 test components.

**STORAGE AND STABILITY**

Store the INDICIAID® 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 carton. Do not use beyond the expiration date.

**SUPPORT**

For questions, or to report a problem, please call 1-877-934-3344, or email care@indicaidusa.com or visit indicaidusa.com. Additional information is available for you and your healthcare provider at indicaidusa.com. User Instructions, Quick Reference Guide, Fact Sheet for Individuals, Fact Sheet for Healthcare Providers, and Health Care Provider Instructions for Instructions for Use are also available at.indicaidusa.com.

The INDICIAID® 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**

- **In vitro diagnostic medical device**
- **Keep away from moisture**
- **Consult Instructions for use**
- **Catalog number**
- **Do not use**
- **Sufficient for use**
- **Temperature limitation**
- **Use by**
- **Kowloon, Hong Kong**
- **Keep away from sunlight**
Performing Your Test

1. 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.

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

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 ¼ of an inch, and you may need to have a second person hold the child’s head while swabbing.

6. 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.

7. 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.

8. 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 your 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.
- Repetition of a true 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 consult your 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.

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 consult your 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.

NEGATIVE TEST RESULT

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in 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 spreading the virus to others 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.

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. If a Control (C) line is visible, and 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 test positive (your results are positive and you have symptoms of COVID-19), you must follow the test directions carefully to get an accurate result. Read Lay user instructions carefully before starting the test.

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.

INVALID TEST RESULT

No red-colored line next to the “C” means test is invalid. Test with new swab and new test device.

Take these next steps

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.
**Indications:** 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.

**User Instructions:**
1. **Prepare Swab:** Wipe the swab tip with the tip of the cap.
2. **Swab:** Use the swab to gently collect mucus from the nasal passageway.
3. **Place Swab:** Insert the swab tip into the buffer solution vial and gently stir until the swab is completely submerged.
4. **Remove Swab:** Carefully remove the swab from the buffer solution vial and gently squeeze the swab to release the sample into the buffer solution vial.
5. **Wait 20 minutes:** Place the buffer solution vial on its side and wait for 20 minutes to get the results.
6. **Interpret Results:**
   - **Positive Result:** 2 lines (one above and one below the control line) appear.
   - **Negative Result:** 1 line (below the control line) appears.

**Important:** Use device with caution. Suitable only for age 2 years and older.

**Results:**
- **Positive Result:** Contains 2 tests.
- **Negative Result:** Contains 1 test.

**Handling:**
- Store at 2°C – 30°C (35.6°F – 86°F).
- Do not freeze.
- Use device with caution.

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

**Contact:**
- **Phone:** +1 (877) 934-9344
- **Email:** care@indicaidusa.com

**Disclaimer:** 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.
**COVID-19 RAPID ANTIGEN AT-HOME TEST**

*Quick • Easy • Results in 20 minutes*

**EMERGENCY USE AUTHORIZATION**

**FDA**

**PROTECT**

**others**

**PROTECT**

**yourself**

**4 TESTS**

**One-time use only**

**Read instructions inside before use**

**For use with and without symptoms**

**IMPORTANT**

**Contains 4 tests**

**Keep away from sunlight**

**Keep away from moisture**

**Positive Result**

**2 lines**

**Negative Result**

**1 line**

**Refer to detailed results explanation inside**

**RESULTS TEST WHEN...**

**COVID-19 symptoms**

**Self-quarantine**

**Travel decisions**

**School/Work decisions**

**Protect others**

**Store at 2°C – 30°C**

(35.6°F – 86°F)

**Manufacturer**

PHASE SCIENTIFIC INTERNATIONAL LTD.

32 & 33/F, Gravity, 29 Hing Yip Street

Kwun Tong, Kowloon, Hong Kong

**Lot Exp**

PB-0016 Rev. B

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

indicaidusa.com

care@indicaidusa.com

**OTC**

**Quick and Easy**

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

EMERGENCY USE AUTHORIZATION
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
This test detects SARS-CoV-2 and is not diagnostic of any other virus or infection. 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

INDICAID® COVID-19 RAPID ANTIGEN AT-HOME TEST

COVID-19 symptoms
Self-quarantine
School/work decisions
Protect others

TEST WHEN...

Positive Result
Negative Result
2 lines
1 line

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

**Test when:**
- COVID-19 symptoms
- Self-quarantine

**Use Device with Caution:**
- Suitable for ages 2+ years.
- Must be 14+ to use kit unsupervised.
- Contains 12 tests.

**Important:**
- Positive result: 2 lines
- Negative result: 1 line
- Refer to detailed results explanation inside

**Individually Wrapped:**
- Swabs (24 Each)
- Test Devices (24 Each)
- Buffer Solution Vial (24 Each)

**User Instructions and Fact Sheet for Individuals:**
- Individually Wrapped
- A timer is required but not provided.

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

**Travel decisions / School/Work decisions / Protect others / Protect yourself:**
- For Emergency Use Authorization (EUA)
- 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.

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

**Lot / Exp:**
- PB-0018 Rev. B
- Lot contained in this box

**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