This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

- Anterior nasal (nares) swabs are collected from an individual aged 14 years and older. Children aged 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 by the Food and Drug Administration under 21 C.F.R. § 630.1(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- More information on EUA: www.fda.gov/emergency-preparedness-and-response/coronavirus-emergency-use-
authorizations-

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

INDICATIONS

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

- • Leve test card was sealed in its pouch until just before use. Once opened, the test should be performed 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 reuse.
- • 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 test kit and kit components away from children and pets before and after use. Do not allow anyone to touch 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 ingestion is likely, seek medical advice: https://www.poisonhelp.org or call 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 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 not used.
- • 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., bleach) may result in an incorrect result.

HAZARDOUS INGREDIENTS

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Triton X-100 0.1% w/v</th>
<th>Link to the MSDS</th>
<th>ProClin™ 300 0.045% w/v</th>
<th>Link to the MSDS</th>
</tr>
</thead>
</table>

- 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 period of 48 hours. 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 no later than 48 hours after your previous test result.

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 may be present in the respiratory secretions. 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 positive within 48 hours after your previous test result, then you may not be infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a false negative result that is incorrect (false negative) in some people with COVID-19. 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 (e.g., cough or fever) and continue to experience COVID-19 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.

What is 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 contacts and to 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, detect 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 protein tests are 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. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. If your test result is positive, this means that you have COVID-19. There is a lower chance of false negative results with antigen tests than with laboratory-based molecular tests. If your test result is positive, this means that you have COVID-19 even though you have negative result when you have COVID-19 from 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 COVID-19 rapid antigen test as a comparator method (IRA 87.1% and NIA 99.4%). You can find further information by visiting indicaidusa.com. The performance of this test is still being studied as it is evaluated against the 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 discuss the result with your healthcare provider for further advice about your positive result. Your healthcare provider will work with you to determine medical care 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 found in your sample. If you have symptoms, you likely do not have COVID-19. If you do not have any symptoms and you receive a second test result that is negative within 48 hours after your previous test result, then you may not be infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a false negative result that is incorrect (false negative) in some people with COVID-19. 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 (e.g., cough or fever) and continue to experience COVID-19 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 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). All materials in the kit are at room temperature or refrigerated until use. Kit contents are stable until the expiration date printed on the outer box. Do not use beyond the expiration date.

SUPPORT

For questions, or to report a problem, please call 1 (977) 934-3344, or email care@indicaidusa.com or visit indicaidusa.com. Additional information is also available for you and/or your healthcare provider at indicaidusa.com. Please see 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

- In vitro diagnostic medical device
- Keep away from moisture
- Do not reuse
- Catalog number
- Temperature limitation
- Keep away from sunlight
- Manufacture
- PHASE Scientific International Limited
- 32 & 33, Cagle, 29 Ming Yeip Street, Kowloon, Hong Kong
Performing Your Test

1. 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.

2. Wash your hands thoroughly for at least 20 seconds before and after testing.
3. 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.
   - Place vial and cap on a flat surface.

4. 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 ½ of an inch, and you may need to have a second person hold the child’s head while swabbing.

5. 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.

6. 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.

7. 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.

8. Interpreting Your Results
   - RESULTS
     - 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.

9. If you develop COVID-19 symptoms or your symptoms become severe, seek medical attention immediately. If you have symptoms-O9 if this is the first test in a symptom testing program, a second test must be done between 24 and 48 hours after the first test.

10. If there is no red line next to the “C” line, the result is invalid regardless of whether there is a red-colored line next to the “T” line. This means that the test kit has not worked properly. The test kit may need to be discarded and a new test kit should be used.

11. 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.

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

13. 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 there is a high chance that you may have COVID-19 even if you test negative. 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.

14. 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.

15. If you do not have symptoms of COVID-19, you will need at least two tests per person.

16. POSITIVE TEST RESULT
   - 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.

17. If you do not have symptoms of COVID-19, you will need at least two tests per person.

18. 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.

19. If the Control (C) line is not visible, the test is invalid.

20. 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.