INDICAID™ **QUICK REFERENCE GUIDE**

INDICAID™ COVID-19 Rapid Antigen Test

For Emergency Use Authorization (EUA) Only

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

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate complexity, high complexity, or waived tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
  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 the virus that causes 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 the authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**

INTENDED USE

The INDICAID™ COVID-19 Rapid Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptoms onset when tested at least twice over three days with at least 48 hours between tests or from individuals 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The INDICAID™ COVID-19 Rapid Antigen Test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in direct anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to fully determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are 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.

The INDICAID™ COVID-19 Rapid Antigen Test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The INDICAID™ COVID-19 Rapid Antigen Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer
2. Personal protective equipment
3. INDICAID™ COVID-19 Antigen Quality Control (Sold Separately)

MATERIALS PROVIDED IN KIT

1. 25 Individually wrapped test devices
2. 25 Buffer solution vials
3. 25 individually wrapped swabs
4. 1 IFU and quick reference guide

- **See Package Insert for complete instruction, warnings, precautions, limitations, storage & handling conditions, and Quality Control recommendations.**
- **For in vitro diagnostic use only.**
- **Specimens should be tested immediately after specimen collection. Do not test specimens after 2 hours of collection.**
- **All components in this test kit should remain sealed until ready for use.**
- **All components in this test kit are for one-time use only. Do not reuse.**
- **Store at 2-30°C. Do not freeze. Avoid direct sunlight.**
- **If buffer solution comes into contact with eyes and/or skin flush abundantly with water.**
- **Do not use the test kit after the expiration date.**

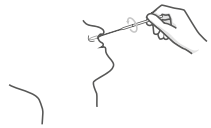
TEST PROCEDURE

Wear appropriate personal protective equipment and gloves when handling patient samples and running the test. Nasal swab specimens may be self-collected by the patient if collection procedure is observed by a healthcare professional.

01 Remove the swab and test device from their packaging. Place the test device on a horizontal (flat) surface for running the test.

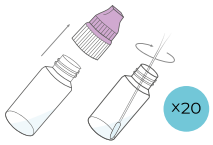
02 Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril.

Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall **at least 4 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.



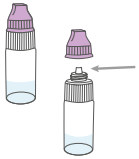
Repeat in the other nostril using the same swab.

03 **Check the buffer solution volume in the vial. If the vial is empty, DO NOT use and obtain a new buffer solution vial.**
The buffer solution vial cap is composed of two parts (purple and white).



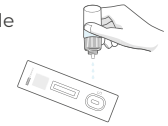
Remove the entire cap. Stir the swab into the buffer solution, **ensuring that the swab head is fully submerged by tilting the vial**. Twist the swab back and forth 20 times in the Buffer Solution. Roll the swab head against the inner wall of the vial to release the liquid from the swab, then discard the swab.

04 Close the entire cap tightly. **Immediately** perform steps 5 - 7.



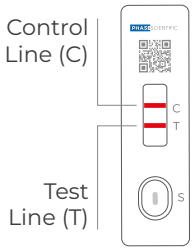
05 **Remove the purple top half of the cap** to expose the dropper tip.

06 Hold the vial vertically above the sample well (S). **Slowly squeeze and apply 3 drops** of the buffer solution into the sample well (S) of the test device.



07 **Read the test line (T) and control line (C) results promptly at 20 minutes**, and not earlier to ensure proper test performance. **Results after 25 minutes should not be used.**

INTERPRETATION OF THE TEST RESULTS



RESULT INTERPRETATION

- 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.
- Test results are interpreted visually, without the aid of instruments.
- Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Positive result:
The presence of both the red-colored control line (C) and colored test line (T) indicates the presence of SARS-CoV-2 antigen. The result suggests current SARS-CoV-2 infection. Samples with low levels of antigen may produce a faint test line. Any visible test is considered positive. **Repeat testing does not need to be performed if patients have a positive result at any time.**

Note: Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

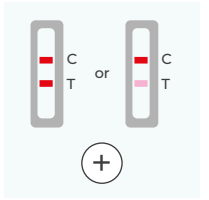
Negative result:
The presence of red-colored control line(C) and no visible test line (T) indicates a negative result. No SARS-CoV-2 antigen was detected.

Note: To increase the chance that the negative result for COVID-19 is accurate, you should:

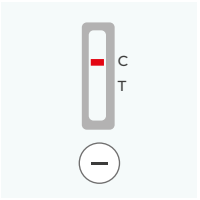
- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

Note: A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.
All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

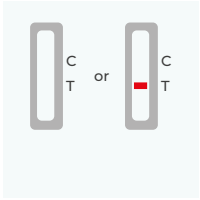
Invalid result:
If the red-colored control line (C) is not visible, DO NOT interpret the test result. The result is invalid regardless of the appearance of the test line. Collect a new nasal swab sample and repeat the assay with a new INDICAID™ COVID-19 Rapid Antigen Test.



Positive Result



Negative Result



Invalid Result

INDICAID™ COVID-19 Rapid Antigen Quality Control Kit is available separately from PHASE Scientific International, Ltd. We recommend that these external positive and negative controls are run once with every new kit lot, new shipment, and each new user.

External Control Test Procedure:

1. Remove a new swab & test device from their packaging. Place the test device on a horizontal (flat) surface for running the test.
2. Hold the external positive control vial vertically and remove the entire cap.
3. Dip the swab into the vial, making sure that the swab head is fully submerged in solution. Remove the swab from the vial.
4. Test the swab by performing steps 3 through 7 of the test procedure in this quick reference guide.
5. Repeat to test the external negative control.

PHASE Scientific International Limited
1/F, Building 22E, Phase 3, Hong Kong Science Park,
Shatin, New Territories, Hong Kong

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 limit	LOT	Batch code
	Keep away from sunlight		Use-by date
Σ	Sufficient for use		Manufacturer

For more information,
please visit www.indicaidusa.com

If you have questions, please contact customer service:
care@indicaidusa.com (US) +1 (877) 934-9344

PHASE SCIENTIFIC

PI-2110400QS (C) | Dec 2022 Edition
For in-vitro diagnostic use

PI-2110400QS (D)