INDICAID™ **QUICK REFERENCE GUIDE**

## INDICAID™ COVID-19 Rapid Antigen Test

For Emergency Use Authorization (EUA) Only

### 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 from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. Anterior nasal swab specimens may be collected by a healthcare provider (HCP) or self-collected (by individuals 18 years of age or older, under the supervision of an HCP). 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 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.

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

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swabs 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 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 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 positive results to the appropriate public health authorities.

Negative results should be treated as 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. For serial testing programs, additional confirmatory testing with a molecular test for negative results 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. Additional confirmatory testing with a molecular test for positive results may also 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 INDICAID™ COVID-19 Rapid Antigen Test is intended for use by trained clinical laboratory personnel and medical and healthcare personnel in Point of Care (POC) settings. The INDICAID™ COVID-19 Rapid Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

### 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

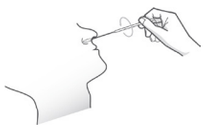
Wear appropriate personal protective equipment and gloves when handling patient samples and running the test. Nasal swab specimens may be self-collected by the patient if collection procedure is observed by a healthcare professional.

**01** Remove the Swab & 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.

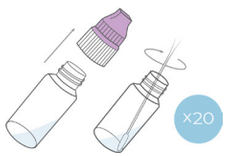
Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall **at least 4 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.

**Repeat in the other nostril using the same swab.**



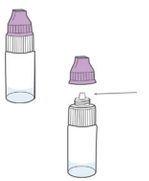
**03** The Buffer Solution Vial cap is composed of two parts (purple and white).

**Remove the entire cap**. Stir the swab into the Buffer Solution, **ensuring that the swab head is fully submerged by tilting the vial**.




**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.

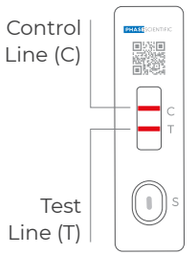


**06** Hold the vial vertically above the sample well (S). **Slowly squeeze and apply 3 drops** of the Buffer Solution into the sample well (S) of the Test Device.

**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.***


PI-2110400QS Rev B

## INTERPRETATION OF THE TEST RESULTS




**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.

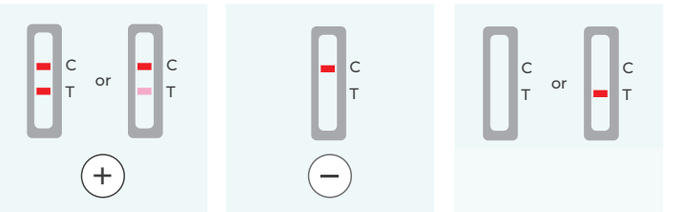
Note: Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

**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: Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

Note: For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, 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. Additional confirmatory testing with a molecular test for positive results may also 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.

**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.

**Disclaimers:**
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. In the USA, 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.

Manufactured By
PHASE Scientific International Limited
32 & 33F, Gravity, 29 Hing Yip St., Kwun Tong, Kowloon, Hong Kong

Caution, Consult accompanying documents

Temperature Limitation

Sufficient for Use

Keep away from sunlight

Keep away from moisture

Do not reuse

Consult Instructions for Use

IVD — In-Vitro Diagnostic Medical Device

REF — Catalog number

LOT — Batch code

Use by

Manufacturer

For more information,
please visit www.phasescientific.com

If you have questions, please contact Customer Service:
Indicaid@phasesci.com US +1 (657) 296-6106

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