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INDICAID™ COVID-19 Rapid Antigen Test

FDA EMERGENCY USE AUTHORIZED

The **INDICAID™ COVID-19 Rapid Antigen Test** is a point-of-care kit designed for the detection of SARS-CoV-2 antigens in direct nasal swab samples.

The test is intended for use by healthcare professionals in symptomatic individuals within 5 days after onset of symptoms.

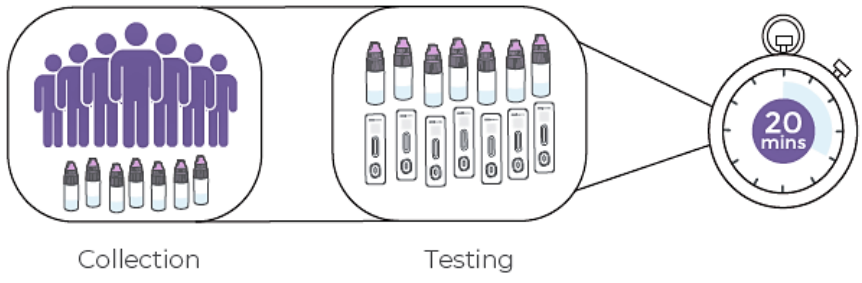
Product Advantages

- **Fast:** Results in 20 minutes
- **Convenient:** No equipment or training needed
- **Simple Sampling:** Self-collected shallow nasal samples
- **Batch Testing:** Easily collect and test multiple samples

Intuitive Workflow

Batch Testing

Intuitive design allows for the concurrent collection of a large number of samples followed by batch testing of individual samples within 2 hours.



Clinical Performance

In a prospective US clinical study, **INDICAID™** accurately identified 84% of those who were positive (PPA) and 97% of those who were negative (NPA) for SARS-CoV-2.

Product performance against variants of concern are evaluated on an ongoing basis.

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TECHNICAL BRIEF:

Detection of SARS-CoV-2 Genomic Variants with the INDICAID™ COVID-19 Rapid Antigen Test

The World Health Organization (WHO) has identified genetic variants of concern of SARS-CoV-2 for which there is evidence of increased transmissibility, more severe disease, significant reduction in neutralization by antibodies, reduced effectiveness of treatments or vaccines, or diagnostic detection failures. It is important that current SARS-CoV-2 diagnostic tests remain capable of detecting these emerging variants. This technical brief describes our ongoing evaluation into the performance of INDICAID™ COVID-19 Rapid Antigen Test with emerging SARS-CoV-2 variants.

Summary of Recombinant Nucleoprotein Testing Results

Recombinant SARS-CoV-2 nucleocapsid proteins (from Acro Biosystems, Delaware, USA) with mutations associated with individual SARS-CoV-2 variants of concern were diluted to an initial target concentration, and then tested on the INDICAID COVID-19 Rapid Antigen Test. Afterward, serial dilutions of each recombinant protein were also tested on the INDICAID COVID-19 test. Based on the results, the detection capability of the INDICAID COVID-19 Rapid Antigen Test is described below in Table 1.

Table 1. Recombinant proteins of SARS-CoV-2 Variants of Concern and INDICAID Test Performance

WHO Variants SARS-CoV-2	**PANGO** Lineage	**Recombinant N Protein Mutations**	**INDICAID™** Test Performance
Alpha	B.1.1.7	D3L, R203K, G204R, S235F	Not affected
Beta	B.1.351	T205I	Not affected
Gamma	P.1	P80R	Not affected
DELTA	B.1.617.2	D63G, R203M, D377Y, R385K	Not Affected
Delta Plus	AY.1 and AY.2	D63G, R203M, G215C, D377Y	Not affected

Summary of B.1.617.2 Variant Clinical Specimen Testing Results

In a separate study, 25 clinical remnant nasal specimens containing the B.1.617.2 (Delta) variant in viral transport media (from Orange County Public Health Laboratory) were tested with the INDICAID COVID-19 Rapid Antigen Test. The presence of SARS-CoV-2 was determined by RT-PCR with the Perkin Elmer nCoV Nucleic Acid Detection Kit. Whole genome sequencing was then conducted on an Illumina MiSeq, using the ARTIC v.3 protocol and Nextera DNA Flex Library Prep. The INDICAID Test detected 100% (25/25) of the B.1.617.2 specimens.

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Quick Reference Guide

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. 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 test 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. 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.

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

IMPORTANT:
- 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.

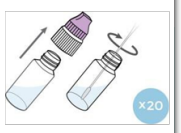
02 Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril.

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.**



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.

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Interpretation of the test results

Positive result:

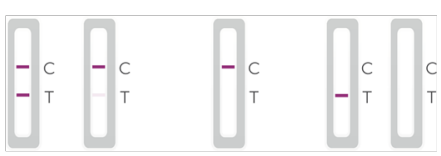
The presence of both the red-colored control line (C) and colored test line (T) indicates the presence of SARS-CoV-2 antigen. The result suggests current SARS-CoV-2 infection. Samples with low levels of antigen may produce a faint test line. Any visible test is considered positive.

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.

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.



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., inpatient 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
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