USER MANUAL

REF 2110500

INDICAID®

CE IVD

INDICAID® COVID-19 Rapid Antigen Test

INTENDED USE

The INDICAID® COVID-19 Rapid Antigen Test is a lateral flow immunoassay intended for the qualitative detection of antigens specific to SARS-CoV-2 in direct nasal and nasopharyngeal swab samples from individuals who are suspected of COVID-19 by their healthcare provider.

The INDICAID® COVID-19 Rapid Antigen Test is for use by medical professionals or trained operators.

PRINCIPLE

The INDICAID® COVID-19 Rapid Antigen Test is a lateral flow immunoassay that uses highly sensitive antibodies to detect SARS-CoV-2 antigens from nasal and nasopharyngeal swab samples. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a nitrocellulose membrane support as two distinct lines. The test line (T) region contains monoclonal anti-SARS-CoV-2 antibodies and the control line (C) region contains the control antibody. Monoclonal anti-SARS-CoV-2 antibodies conjugated with red latex microspheres are used to detect the SARS-CoV-2 antigen.

During the test, the patient sample swab is placed in a buffer solution vial. The buffer solution is then applied to the sample well of the test device. If SARS-CoV-2 antigen is present, it will bind to the antibody-latex microsphere conjugate forming an immunocomplex. The immunocomplex will then travel across the strip and bind to the SARS-CoV-2 antibodies at the test line (T), forming a visible red line to indicate detection of antigen. If SARS-CoV-2 antigens are not present, no color will appear at the test line (T).

Test results are interpreted at 20 minutes after application of the buffer solution to the test device. **Results should not be read after 25 minutes**.

The control line is used for procedural control and should appear red regardless of the test result to ensure the test is performing properly.

MATERIALS PROVIDED IN KIT

1. 25 Individually-Wrapped Test Devices
2. 25 Buffer Solution Vials
3. 25 Individually-Wrapped Swabs
4. 1 User Manual

Materials required but not provided:
Timer

STORAGE AND HANDLING

Store the test kit in a cool, dry place between 2-30°C (36-86°F). Keep away from light and moisture. Do not freeze.

Use the test kit at temperatures between 15-30°C (59-86°F). Do not use the test kit beyond the expiration date. Exposure to temperature out of the specified conditions may result in inaccurate results.

LIMITATIONS

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.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information by a medical professional is necessary to determine infection status. Positive results may also be due to present infection with non- SARS-CoV-2 coronavirus strains.

Do not reuse the test kit.

The test kit can only be used with nasal and nasopharyngeal swab samples. Using other samples may produce inaccurate results.

Test results are interpreted at 20 minutes after application of the buffer solution to the test device. **Do not interpret the result after 25 minutes.**

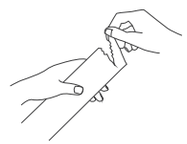
Please follow the user manual when testing.

Note: Avoid contact with eyes and skin. Flush abundantly with water if the reagent is spilled.

TEST PROCEDURE

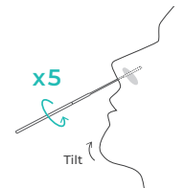
Wear appropriate personal protective equipment and gloves when handling patient samples and running the test.

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

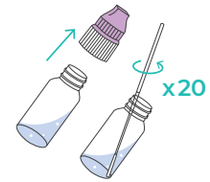


02 **For Nasal Swab Collection**
Tilt the patient's head back. Gently insert the swab about 2.5 cm (1 inch) into one of the nostrils (until a slight resistance is met). Rub the swab against the walls of the nostrils 5 times in a large circular path. Repeat with the other nostril using the same swab.

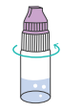
For Nasopharyngeal Swab Collection
Samples should be collected by medical professionals according to approved sampling procedures.



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 by twisting the swab back and forth 20 times. Ensure that the swab head is fully submerged 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 vial 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. Slowly squeeze and apply 3 drops of the buffer solution into the sample well of the test device.

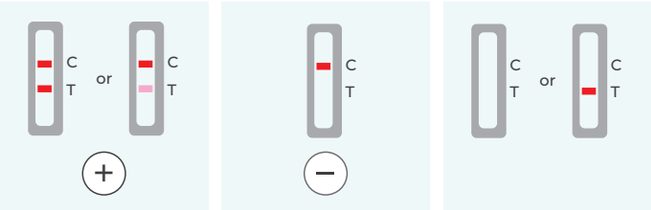
07 Read the test line (T) and control line (C) results promptly at 20 minutes, and not earlier to ensure proper test performance. Results after 25 minutes should not be used.

INTERPRETATION OF THE TEST RESULTS

Positive result:
The presence of both the control line (C) and 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 line is considered positive.

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

Invalid result:
If the 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 or nasopharyngeal swab sample and repeat the assay with a new INDICAID® COVID-19 Rapid Antigen Test.



Positive Result | Negative Result | Invalid Result

ANALYTICAL PERFORMANCE

The limit of detection (LoD) of the INDICAID® COVID-19 Rapid Antigen Test was determined by testing limiting dilutions of inactivated SARS-CoV-2 virus in pooled human nasal matrix from presumed negative donors. Each test concentration was inoculated onto kit-provided swabs and processed according to the test procedure. The LoD was determined by confirming the lowest detectable concentration of SARS-CoV-2 at which 95% of the 20 replicates analyzed resulted in a positive test. The INDICAID® COVID-19 Rapid Antigen Test LoD in nasal matrix was confirmed to be 140 $TCID_{50}$ per swab.

LIMIT OF DETECTION

Concentration ($TCID_{50}$/swab)	Number of Positives / Total	% Detected
140	20 / 20	100%

ANALYTICAL SPECIFICITY (CROSS-REACTIVITY)

Common respiratory pathogens were tested for cross-reactivity and microbial interference with the INDICAID® COVID-19 Rapid Antigen Test. No cross-reactivity or microbial interference was observed for the following bacteria, viruses, and yeast that were evaluated at the concentrations indicated: *Bordetella pertussis A639, Chlamydia. Pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, Streptococcus pneumoniae, Streptococcus pyrogenes, Staphylococcus aureus, Staphylococcus epidermidis* tested at 1.0 x 10^6 CFU/mL; Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Adenovirus, Influenza A and B, Rhinovirus, Parainfluenza Virus Type 1-4, Enterovirus Type 68, Respiratory Syncytial Virus Type A and B, and MERS-Coronavirus tested at 1.0 x 10^5 $TCID_{50}$/mL; Human Metapneumovirus tested at 1.6 x 10^4 $TCID_{50}$/mL; SARS-Coronavirus test samples with RT-PCR Ct value of 25-28; Candida albicans tested at 1.0 x 10^6 CFU/mL.

INTERFERENCE

14 substances including over-the-counter medications that may be found in respiratory specimens were evaluated for potential interference with the INDICAID® COVID-19 Rapid Antigen Test. No interference was observed for the following substances that were evaluated at the concentrations indicated:

Substance	Concentration	Substance	Concentration
Whole Blood	4% v/v	Zicam	5% v/v
Mucin	0.5% w/v	Homeopathic (Alkalol)	1:10 dilution
Chloraseptic (Menthol/Benzoco-caine)	1.5 mg/mL	Sore Throat Phenol Spray	15% v/v
Naso Gel (NeilMed)	5% v/v	Tobramycin	4 µg/mL
CVS Nasal Drops (Phenylephrine)	15% v/v	Mupirocin	10 mg/mL
Afrin (Oxymetazoline)	15% v/v	Fluticasone Propionate (Flonase)	5% v/v
CVS Nasal Spray (Cromolyn)	15% v/v	Tamiflu (Oseltamivir Phosphate)	5 mg/mL

N PROTEIN VARIANTS

Recombinant N protein from linage B.1.1.7 (Alpha) , linage B.1.351 (Beta), linage B.1.1.28 (Gamma) and linage B.1.2 variants were tested and found to be detectable by the INDICAID® COVID-19 Rapid Antigen Test.

CLINICAL PERFORMANCE

Patients suspected of COVID-19 infection, and at least 5 years of age, were enrolled and tested in a prospective study at a point-of-care U.S. clinical site. Test operators were non-laboratory healthcare professionals with no prior training using the INDICAID® COVID-19 Rapid Antigen Test. Two nasal swabs were collected from each patient—one for the INDICAID® COVID-19 Rapid Antigen Test and the other analyzed by an FDA Emergency Use Authorized RT-PCR assay as the comparator method for detection of SARS-CoV-2. Retrospective clinical samples with known SARS-CoV-2 status were also tested to supplement the clinical performance evaluation.

CLINICAL STUDY RESULTS

INDICAID® COVID-19 Rapid Antigen Test	Comparator Method (RT-PCR)		
	Positive	Negative	Total
Positive	91	12	103
Negative	9	278	287
Total	100	290	390
Positive Percent Agreement	91.0% (95% CI: 83.8% - 95.2%)		
Negative Percent Agreement	95.9% (95% CI: 92.9% - 97.6%)		
Overall Percent Agreement	94.6% (95% CI: 91.9% - 96.5%)		

QUALITY CONTROL

Each lot of INDICAID® COVID-19 Rapid Antigen Test is tested against predetermined specifications to ensure consistent product quality in accordance with PHASE Scientific's Quality Management System.

DISCLAIMERS

This kit is intended for *in vitro* diagnostic use only.

TECHNICAL SUPPORT

For technical support, contact us at cs@indicaid.com or +852 3700 8888.

For more information, please visit www.phasescientific.com

EXPLANATION OF SYMBOLS

CE registration
Consult instructions for use
Caution, consult accompanying documents
IVD — In vitro diagnostic medical device
Temperature limitation
REF — Catalog number
Sufficient for use
LOT — Batch code
Keep away from sunlight
Use by
Keep away from moisture
Manufacturer
Do not reuse
EC REP — European authorized representative

PHASESCIENTIFIC

PHASE Scientific International Limited
32 & 33F, Gravity, 29 Hing Yip Street,
Kwun Tong, Kowloon, Hong Kong

EC REP

Lotus NL B.V.
Koningin Julianaplein 10
1e Verd, 2595AA,
The Hague, The Netherlands

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