PHASE SCIENTIFIC

For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use only

For prescription use only

INDICAID™

COVID-19 Rapid Antigen Test

For Rapid Detection of SARS-CoV-2 Antigen

INSTRUCTIONS FOR USE

PHASE SCIENTIFIC

Contents

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.

Summary and Explanation of the Test

Coronaviruses are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as MERS and SARS-CoV. A novel coronavirus (SARS-CoV-2) was discovered in December 2019 and has resulted in

millions of confirmed human infections worldwide. COVID-19, the disease brought on by the virus, produces symptoms in infected patients that are similar to the other viral respiratory diseases including fever, cough, and shortness of breath. The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection.

The INDICAID™ COVID-19 Rapid Antigen Test is a non-invasive rapid point-of-care diagnostic test for the qualitative detection of SARS-CoV-2 antigen in respiratory specimens. Each INDICAID™ COVID-19 Rapid Antigen Test is single-use and can analyze one anterior nasal swab sample. The total time required to perform one test is approximately 20 minutes from clinical specimen collection to result.

Principles of the Procedure

The INDICAID™ COVID-19 Rapid Antigen Test is an immunochromatographic lateral flow assay that uses highly sensitive antibodies to detect antigen from SARS-CoV-2 in direct anterior nasal swab specimens from patients who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset. 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 polyclonal control antibodies. Polyclonal and monoclonal anti-SARS-CoV-2 antibodies conjugated with red-colored colloidal gold particles are used to detect the SARS-CoV-2 antigen.

During the test, the swab containing patient sample is placed and mixed in a Buffer Solution Vial. That 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-gold conjugate forming an immunocomplex. The immunocomplex will then travel across the strip via capillary action towards the test line. The immunocomplex will then bind to the anti-SARS-CoV-2 antibodies at the test line (T), forming a visible red-colored line to indicate detection of antigens. If SARS-CoV-2 antigens are not detected in the sample, no color will appear at the test line (T).

The control (C) line is used for procedural control and should appear regardless of the test result. The appearance of the control line (C) serves to ensure the test is performing properly and the test result is valid.

The INDICAID™ COVID-19 Rapid Antigen Test is validated for use from direct specimens testing without transport media.

Reagents and Materials Provided

Kit Component	Quantity	Description
Test Devices	25	Individually foil pouched test device containing one test strip in a plastic device cassette. Each strip has one control line and one test line.
Buffer Solution Vials	25	Vial with cap and integrated dispensing tip, containing 400 µL of buffer solution.
Nasal Swabs	25	Individually wrapped, sterile specimen collector.
Package Insert	1 Instructions for Use 1 Quick Reference Guide	Instructions for use and Quick Reference Guide

Chemical and Safety Information

The extraction buffer in the INDICAID™ COVID-19 Rapid Antigen Test Buffer Solution vials contain the following hazardous ingredients:

Reagents	Hazards	Link to MSDS
Triton™ X-100	• Harmful if swallowed. • Causes skin irritation. • Causes serious eye damage. • Very toxic to aquatic life with long lasting effects.	https://www.sigmaaldrich.com/US/en/sds/sial/x100
ProClin™ 300	• Harmful if swallowed or inhaled. • Causes severe skin burns and eye damage. • May cause an allergic skin reaction. • Very toxic to aquatic life with long lasting effects.	https://www.sigmaaldrich.com/US/en/sds/sial/48914-u

The extraction buffer in the INDICAID™ COVID-19 Rapid Antigen Test Buffer Solution vials contain hazardous ingredients as shown in the table above. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. In case the irritation persists, please seek medical advice at: https://www.poison.org/contact-us or 1-800-222-1222.

Materials Required but not Provided

- Timer
- External Positive and Negative Controls (sold separately) – P/N: 2110410/2110420
  - 250 µL single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives)
  - 250 µL single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives)
- Any necessary personal protective equipment (PPE)

Precautions

- For *in vitro* diagnostic use only.
- For prescription use only.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA 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.
- This product is only authorized 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 COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
- Do not use this kit beyond the use by date printed on the product label.
- Do not use if the Test Device package is damaged.
- All components in this test kit should remain sealed until ready for use. Immediately use after opening and removing the Test Device from the pouch.
- To obtain accurate results, the test must be performed as indicated in this Instructions for Use.
- Do not interpret the test result before 20 minutes or after 25 minutes, following application of the sample to the Test Device.
- All kit components are single use only. Do not re-use any kit components or mix components from different kit lots or different products.

- Do not store specimens in viral transport media for specimen storage.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Use appropriate precautions when collecting, handling, storing, and disposing of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Nitrile or latex gloves should be worn when performing this test.
- If Buffer Solution comes into contact with eyes and/or skin, flush abundantly with water.
- Handle all specimens as though they contain infectious agents. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- Test Devices used in a laminar flow hood or in areas with high air flow should be covered during test development to ensure proper sample flow.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at phasescientific.com.

Storage and Stability

- Store the test kit in a cool, dry place between 2-30°C (36-86°F). Do not freeze. Avoid direct sunlight.
- Kit contents are stable until the use by date printed on the product label and outer packaging. Do not use after the date indicated.
- All components in this test kit should remain sealed until ready for use.

Quality Control

Internal Quality Control:

The INDICAID™ COVID-19 Rapid Antigen Test Device contains an internal procedural control to ensure that the test is functioning properly. The control line (C) on the Test Device will appear as a red-colored line and should appear regardless of the test result. If the control line does not develop within 20 minutes, the test result is considered invalid and retesting should be performed with a newly collected sample, new Buffer Solution Vial, and a new Test Device.

External Quality Control:

The use of INDICAID™ COVID-19 Antigen Quality Control external positive and negative controls is recommended to ensure that the reagents and materials are working and that the test procedure is correctly performed. Positive and negative controls should be run once with every new lot, shipment, and each new user,

using the test procedure provided in this Instructions for Use. Contact PHASE Scientific Technical Support for External positive and negative controls that are available separately.

If either or both external control results are unexpected or invalid, repeat the external controls with a new Swab, Buffer Solution Vial and Test Device and if results continue to be unexpected or invalid, contact PHASE Scientific Technical Support at +1 (657) 296 6106 or indicaid@phasesci.com before testing patient specimens.

Specimen Collection, Handling, and Transport

The INDICAID™ COVID-19 Rapid Antigen Test should only be used with the swabs provided in the kit to collect direct nasal samples according to the procedures in these Instructions for Use. Specimens should be tested immediately after collection for best performance. Do not transport or store specimens for later testing. Inadequate specimen collection or improper handling, storage, and transport may lead to incorrect results. Do not test specimens 2 hours after collection.

Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Note:

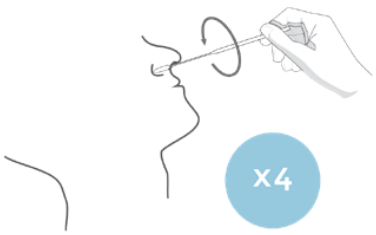
- If stored refrigerated, allow test components (Test Device and Buffer Solution Vial) to equilibrate to room temperature (15–30°C or 59-86°C) before starting the Test Procedure.
- Nasal swab specimens may be self-collected by the patient if the collection procedure is instructed and observed by a healthcare professional.
- Process the collected specimen immediately after collection.
- Use only the swab provided in the INDICAID™ COVID-19 Rapid Antigen Test Kit.
- Wear appropriate personal protective equipment and gloves when collecting and handling patient samples and when running the test.
- Inspect all test reagents and materials for damage prior to use. Do not use any test components that show evidence of damage.

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.

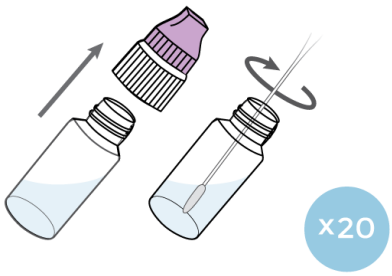
Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall **at least 4 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.

Repeat in the other nostril using the same swab.

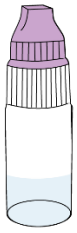


03 The Buffer Solution Vial cap is composed of two parts (purple and white). **Remove the entire cap.** Stir the swab into the Buffer Solution, **ensuring that the swab head is fully submerged by tilting the vial**.

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 vial cap tightly. **Immediately** proceed to the Test Procedures to process the sample.



PHASE SCIENTIFIC

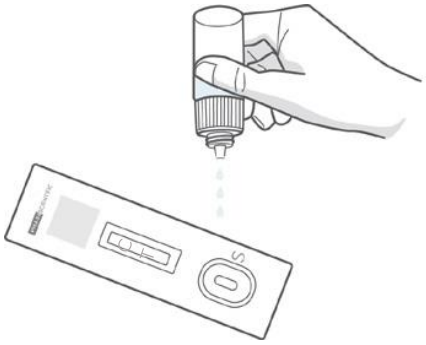
Test Procedure for Patient Swabs

Note:

- Perform the following Test Procedures immediately after the specimen has been collected in the Buffer Solution Vial.
- The Test Device should be placed on a horizontal (flat) surface when running the test. Do not perform testing with the Test Device in any other orientation.

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

02 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.



03 **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.

Result Interpretation

- Test results are interpreted visually, without the aid of instruments.

Positive Result

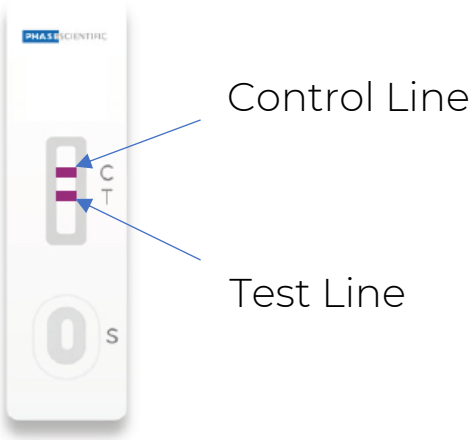
The presence of both the red-colored control line (C) **and** red-colored test line (T) indicates the presence of SARS-CoV-2 antigen. The result suggests current SARS-CoV-2 infection. Samples with low levels of antigen may produce a faint test line. Any visible test line is considered positive.

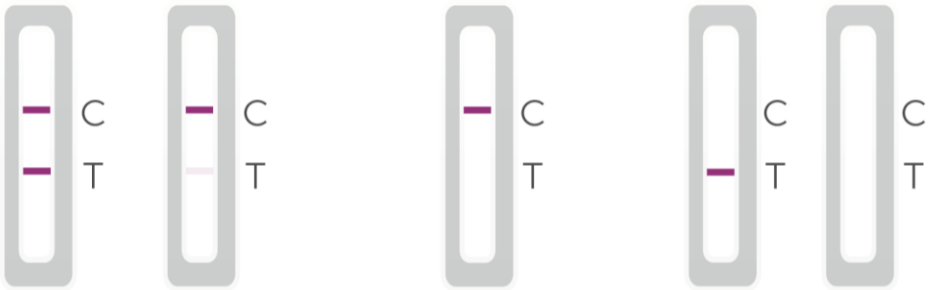
Negative Result

The presence of the 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.





External Quality Control Test Procedure

Please refer to the complete INDICAID™ COVID-19 Antigen Quality Controls Instructions For Use.

01 Remove a new Swab and Test Device from their packaging. Place the Test Device on a horizontal (flat) surface for running the test.

02 Hold a new INDICAID™ COVID-19 Antigen Positive Control Vial vertically and open the cap.

03 Dip the new Swab into the Positive Control Vial, making sure that the Swab head is fully submerged in the solution. Roll the Swab head around in the solution to ensure the swab is wetted. Remove the Swab from the Vial.

04 Test the Swab immediately performing the same steps as described in section "Test Procedure for Patient Swabs" above.

05 Repeat all the above steps to test the INDICAID™ COVID-19 Antigen Negative Control Vial.

Limitations

- The test is designed for use with nasal swab samples only. Performance has not been established for use with other specimen types. Other specimen types have not been evaluated and should not be used with this assay.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- A negative test result may occur if the level of SARS-CoV-2 antigen in a sample is below the detection limit of the test.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- 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 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 is necessary to determine infection status. Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.
- Positive results do not rule out co-infections with other pathogens. Test results are not intended to rule out or diagnose other non-SARS viral or bacterial infections.
- The Test Device, Buffer Solution Vial, and Swab should not be re-used (single use only).

- This test detects both viable (live) and non-viable SARS-CoV-2 virus. Test performance depends on the amount of SARS-CoV-2 antigen in the sample and may or may not correlate with viral culture results performed on the same sample.
- Test performance is dependent upon proper specimen collection, handling, storage, and preparation. Failure to follow proper procedures may produce inaccurate results.
- Failure to follow these Instructions for Use may adversely affect test performance and/or invalidate the test result.
- Specimens should be tested immediately after specimen collection. Do not test specimens after 2 hours of collection.
- False negative results may occur if insufficient Buffer Solution is applied to the Test Device (e.g. less than 3 drops).
- False negative results may occur if the Swab is not twisted 20 times in the Buffer Solution Vial. False negative results may occur if the Swab head is not rolled against the inner wall of the Buffer Solution Vial to release as much liquid from the Swab as possible.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g. PCR testing) should be considered.
- The clinical performance of this test has not been evaluated in patients without signs and symptoms of respiratory infection or other reasons to suspect COVID-19 infection.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February and March 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Conditions of Authorization for Laboratory and Patient Care Settings

The INDICAID™ COVID-19 Rapid Antigen Test Letter of Authorization along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:
https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

However, to assist with clinical laboratories using the INDICAID™ COVID-19 Rapid Antigen Test, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and PHASE Scientific International, LTD (via email: indicaid@phasesci.com, or via phone at Technical Service: +1-657-296-6106) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal

[1] The letter of authorization refers 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." as "authorized laboratories."

protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

- PHASE Scientific International, LTD, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Performance Characteristics

Clinical Performance and Point-of-Care Use

The clinical performance of the INDICAID™ COVID-19 Rapid Antigen Test was evaluated in a prospective study performed at a COVID-19 Community Testing Center in San Fernando, CA, U.S. Testing was performed by a total of five healthcare professionals (HCP) with no laboratory experience, representing the intended users at the point-of care. The operators had no prior training with the INDICAID™ COVID-19 Rapid Antigen Test and only had the Quick Reference Guide for instruction on how to perform the test.

A total of 270 patients presenting with one or more symptoms typical of COVID-19 infection within five days of symptom onset were sequentially enrolled. Each patient provided one self-collected nasal swab to perform the INDICAID™ COVID-19 Rapid Antigen Test, one HCP-collected nasal swab to perform the INDICAID™ COVID-19 Rapid Antigen Test and one HCP-collected nasal swab to perform the comparator molecular test. For the self-collected sample, the HCP provided specimen collection instructions according to the Quick Reference Guide and observed the specimen collection by the patient. The order of the second and third HCP-collected samples was randomized for testing with the investigational antigen test and an FDA EUA molecular comparator method to ensure that bias was not introduced due to unequal distribution of viral material. The self-collected and HCP-collected nasal swab samples for the INDICAID™ antigen test were immediately tested after collection while the nasal swab sample for comparator analysis was eluted in viral transport media and shipped to the comparator testing laboratory.

The INDICAID™ COVID-19 Rapid Antigen Test results for the self-collected and HCP-collected samples were compared against the results of the FDA EUA molecular comparator assay to calculate the positive percent agreement (PPA), negative percent agreement (NPA), and overall percent agreement (OPA). One specimen that was lost during handling and one specimen that was deemed quantity not sufficient for comparator testing were excluded from the analysis, bringing the total number patient samples analyzed to 268.

Table 1: INDICAID™ COVID-19 Rapid Antigen Test Performance Against Comparator Method (HCP-Collected Sample)

INDICAID™ COVID-19 Rapid Antigen Test	Comparator Method		
	Positive	Negative	Total
Positive	27	7	34
Negative	5	183	188
Total	32	190	222
PPA	84.4% (95% CI: 68.2% - 93.1%)		
NPA	96.3% (95% CI: 92.6% - 98.2%)		

Table 2: INDICAID™ COVID-19 Rapid Antigen Test Performance Against Comparator Method (Self-Collected Sample)

INDICAID™ COVID-19 Rapid Antigen Test	Comparator Method		
	Positive	Negative	Total
Positive	27	6	33
Negative	5	184	189
Total	32	190	222
PPA	84.4% (95% CI: 68.2% - 93.1%)		
NPA	96.8% (95% CI: 93.3% - 98.5%)		

Table 3: Positive results by age (years) of patient

Age (years)	Total*	Comparator Positive	Prevalence	INDICAID™ Positive
5 to 20	39	10	25.6%	10
21 to 40	88	7	8.0%	5
41 to 60	77	13	16.9%	10
60+	17	2	11.8%	2

*Age information not provided for 1 patient out of 222

Table 4: Positive results by days since symptom onset

Days Since Symptom Onset	Cumulative Comparator Positive	Cumulative INDICAID™ Positive	PPA
1	6	6	100.0%
2	13	12	92.3%
3	26	22	84.6%
4	30	25	83.3%
5	32	27	84.4%

Contrived samples near the test's limit of detection (2xLoD) and simulated negative matrix were also performed by the same HCP operators who performed the clinical POC evaluation study at the same site. The contrived samples were blinded to the HCP operators.

Table 5: INDICAID™ COVID-19 Rapid Antigen Test (near cut-off) Performance

Contrived Sample	Number of Tests Interpreted Correctly/Total	% Concordance w/ Expected Result
2xLoD (near cut-off)	11/12	91.7%
Negative matrix	12/12	100%

Limit of Detection (Analytical Sensitivity)

The INDICAID™ COVID-19 Rapid Antigen Test limit of detection (LoD) was determined by testing limiting dilutions of gamma-irradiated SARS-CoV-2 virus (Isolate USA-WA1/2020, NR-52287) 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.

INDICAID™ COVID-19 Rapid Antigen Test Limit of Detection

SARS-CoV-2 Concentration			Number of Positives/Total	% Detected
$TCID_{50}$/mL	cp/mL	$TCID_{50}$/swab		
2.8×10^3	1.75×10^6	1.4×10^2	20/20	100%

Cross-reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity and microbial interference of common respiratory pathogens with the INDICAID™ COVID-19 Rapid Antigen Test was evaluated by testing the panel of microorganisms at the concentration presented in the table below. For cross-reactivity testing, each microorganism was prepared in pooled human nasal matrix from healthy donors in absence of SARS-CoV-2 and tested in triplicate. For microbial interference testing, microorganisms were tested individually or in a pool of 2 to 4 organisms per pool in the presence of irradiated SARS-CoV-2 (3x LoD, 4.2×10^2 $TCID_{50}$/swab) and tested in triplicate. No cross-reactivity or microbial interference was observed for the following organisms when tested at the concentration listed.

Type	Potential Cross-reactant	Test Concentration
Bacteria	*Bordetella pertussis A639*	1.0 x 10^6 CFU/mL
	Chlamydia Pneumoniae	1.0 x 10^6 IFU/mL
	Haemophilus influenzae	1.0 x 10^6 CFU/mL
	Legionella pneumophila	1.0 x 10^6 CFU/mL
	Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL
	Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
	Streptococcus pyrogenes	1.0 x 10^6 CFU/mL
	Staphylococcus aureus	1.0 x 10^6 CFU/mL
	Staphylococcus epidermidis	1.0 x 10^6 CFU/mL
Virus	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL
	Adenovirus	1.0 x 10^5 $TCID_{50}$/mL
	Human Metapneumovirus (hMPV)	1.0 x 10^5 $TCID_{50}$/mL
	Influenza A	1.0 x 10^5 $TCID_{50}$/mL
	Influenza B	1.0 x 10^5 $TCID_{50}$/mL
	Rhinovirus	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 1	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 2	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 3	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Virus Type 4	1.0 x 10^5 $TCID_{50}$/mL
	Enterovirus Type 68	1.0 x 10^5 $TCID_{50}$/mL
	Respiratory Syncytial Virus Type A	1.0 x 10^5 $TCID_{50}$/mL
	Respiratory Syncytial Virus Type B	1.0 x 10^5 $TCID_{50}$/mL
	MERS-Coronavirus	1.0 x 10^5 $TCID_{50}$/mL
Yeast	Candida albicans	1.0 x 10^6 CFU/mL
Other	Pooled human nasal wash	100%

In silico analysis was performed using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) to estimate the likelihood of cross-reactivity with microorganisms not available for wet-testing. The degree of protein sequence homology was determined between the SARS-CoV-2 nucleocapsid protein antigen and the following microorganisms:

- Human Coronavirus HKU1: Sequence homology between SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1 nucleocapsid protein is

relatively low at 36.7% across 82.0% of sequences, but cross-reactivity cannot be ruled out.

- *Mycobacterium tuberculosis*: No protein sequence homology was found between the SARS-CoV-2 nucleocapsid protein and *Mycobacterium tuberculosis* total protein (5925 sequences). Homology-based cross-reactivity cannot be ruled out.
- *Pneumocystis jirovecii* (PJP): No protein sequence homology was found between the SARS-CoV-2 nucleocapsid protein and *PJP* total protein (3762 sequences). Homology-based cross-reactivity cannot be ruled out.
- SARS Coronavirus: Sequence homology between SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus nucleocapsid protein was found to be 90.5% with 100% query sequence coverage. Cross-reactivity with SARS Coronavirus cannot be ruled out.

High Dose Hook Effect

A high-dose Hook Effect Study was performed to evaluate whether a false negative test result occurs when very high levels of target is present in a sample. The INDICAID™ COVID-19 Rapid Antigen Test was evaluated using increasing concentration of inactivated SARS-CoV-2 virus in negative clinical matrix (pooled human nasal fluid in PBS). A total of 5 concentrations starting from 2.8×10^1 $TCID_{50}$/mL (1.4 $TCID_{50}$/swab) up to a concentration of 2.8×10^5 $TCID_{50}$/mL (1.4×10^4 $TCID_{50}$/swab) and a blank (negative) sample were tested. Each concentration was tested in triplicate. No high-dose Hook Effect was observed up to 2.8×10^5 $TCID_{50}$/mL (1.4×10^4 $TCID_{50}$/swab) of gamma-irradiated SARS-CoV-2 virus with the INDICAID™ COVID-19 Rapid Antigen Test.

Endogenous Interfering Substances

Fourteen (14) substances including over-the-counter medications that may be found in respiratory specimens of patients who are symptomatic for respiratory illness were evaluated for potential interference with the INDICAID™ COVID-19 Rapid Antigen Test. Test samples containing the endogenous substances at the listed concentrations all produced the expected positive and negative test line results in the presence and absence of 3x LoD inactivated SARS-CoV-2 virus, respectively.

		Test Result	
Potential Interferent	Test Concentration	(+) SARS-CoV-2 (3x LoD)	(-) SARS-CoV-2
Whole Blood	4%	Positive	Negative
Mucin	0.5%	Positive	Negative

Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Positive	Negative
Naso GEL (NeilMed)	5% v/v	Positive	Negative
CVS Nasal Drops (Phenylephrine)	15% v/v	Positive	Negative
Afrin (Oxymetazoline)	15% v/v	Positive	Negative
CVS Nasal Spray (Cromolyn)	15% v/v	Positive	Negative
Zicam	5% v/v	Positive	Negative
Homeopathic (Alkalol)	1:10 dilution	Positive	Negative
Sore Throat Phenol Spray	15% v/v	Positive	Negative
Tobramycin	4 µg/mL	Positive	Negative
Mupirocin	10 mg/mL	Positive	Negative
Fluticasone Propionate (Flonase)	5% v/v	Positive	Negative
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	Positive	Negative

Technical Support

For more information, questions, or support, please visit www.phasescientific.com, or contact us at:

Telephone: +1 (657) 296 6106 email: indicaid@phasesci.com

Symbols

For prescription use only

In vitro diagnostic medical device


Consult Instructions for Use


Caution—consult accompanying documents

Temperature limitation


Keep away from sunlight


Sufficient for use


Keep away from moisture


Do not reuse

Catalog number

Batch code


Use by


Manufacturer