INDICAID®

USER MANUAL

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 an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 antigen 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 colloidal gold particles are used to detect the SARS-CoV-2 antigen.

During the test, the patient sample swab is placed 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 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. 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 kits at temperatures between 15-30°C (59-86°F). Do not use the test kits beyond the expiration date. Exposure to temperature outside 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, such as SARS-CoV.

Do not reuse the Test Device.

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:
For in vitro diagnostic use. Avoid contact with eyes and skin. Flush abundantly with water if the reagent is spilled.

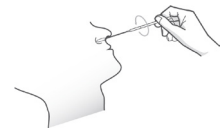
Test Procedure

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

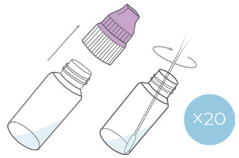
01 Remove the Swab and Test Device from their packaging. Place the Test Device on a clean horizontal surface for running the test.

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

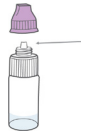


03 The Buffer Solution Vial cap is composed of two parts (purple and white). Remove the entire cap. Stir the swab into the Buffer Solution by twisting the swab back and forth 20 times. Ensure that the swab head is fully submerged in the Buffer Solution. Roll the swab head against the inner wall of the vial to release the liquid from the swab, then discard the swab.

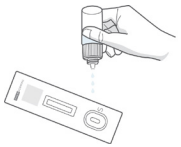


04 Close the entire vial cap tightly. Immediately perform Steps 5-7.

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.

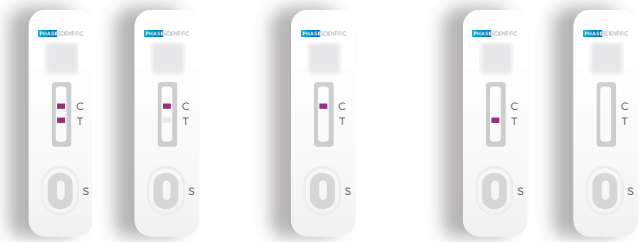
PI-211020OENG | IC04PI2053 | Ver A

Interpretation of the test results

1. **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.

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

3. **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

INDICAID® COVID-19 Rapid Antigen Test limit of detection (LoD) 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 TCID50 per swab.

INDICAID® COVID-19 Rapid Antigen Test Limit of Detection

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

Clinical Performance

The clinical performance of the INDICAID® COVID-19 Rapid Antigen Test was evaluated by testing 50 positive and 50 negative SARS-CoV-2 retrospective clinical specimens from unique donors that were previously confirmed by a molecular test. The 100 clinical specimens were nasopharyngeal swab samples eluted in saline. Testing was performed at one investigational site by two untrained operators who were blinded to the RT-PCR results of the samples. The samples were first randomized, then each sample eluate was inoculated onto kit-provided swabs and processed as instructed in test procedure. The INDICAID® COVID-19 Rapid Antigen Test correctly detected 48 / 50 positive samples and demonstrated no false positives for the negative samples.

INDICAID® COVID-19 Rapid Antigen Test	Comparator Method		
	Positive	Negative	Total
Positive	48	0	48
Negative	2	50	52
Total	50	50	100
Positive Percentage Agreement (PPA)	96% (95% CI: 86.3% - 99.5%)		
Negative Percentage Agreement (NPA)	100% (95% CI: 92.9% - 100%)		

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.
We reserve the right to change, alter or modify any product to enhance its performance and design.

Technical Support

For technical support, contact us at indicaid@phasesci.com or +852 9135 2570.

Manufactured By

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

EC REP

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

For more information, please visit www.phasescientific.com.

IC04PI2053 | PI-2110200ENG | Rev A | Nov 2020 Edition |

CE Registration

Caution, Consult accompanying documents

2°C 30°C 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

PHASE SCIENTIFIC

PI-2110200ENG | IC04PI2053 | Ver A