INDICAID QUICK START GUIDE

COVID-19 RAPID ANTIGEN TEST Ref # 2120100

CE IVD

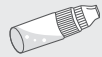
INTENDED USE

INDICAID® COVID-19 Rapid Antigen Test is an in vitro diagnostic test for determining the presence of SARS-CoV-2 antigens in direct nasal swab samples.

PRINCIPLE

Antigen is generally detectable in upper respiratory tract during the early phase of infection. Antigens are present on the SARS-CoV-2 virus, and can be used as markers for disease exposure.

CONTAINED IN THIS BOX

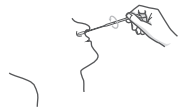
1 individually-wrapped test device	1 vial of buffer solution	1 individually wrapped swab	1 quick start guide
			

HOW TO USE

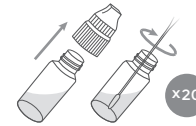
Follow these instructions closely to achieve the best results:

01 Remove the swab and test device from their packaging.

02 Tilt your head back. Gently insert the swab about 1 inch into one of your nostrils. Rub the swab against the walls of one of your nostrils 5 times in a large circular path. Repeat with your other nostril.

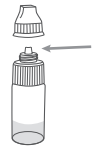


03 The Buffer Solution Vial cap is composed of two parts. Remove the entire cap. Stir the swab into the buffer solution by twisting the swab back and forth 20 times. Ensure that the swab tip is fully submerged in the solution.

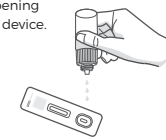


04 Close the entire vial cap tightly. Immediately perform Steps 5-7.

05 Remove the top half of the vial cap to expose the dropper tip.



06 Hold the vial vertically. Squeeze and drip 3 drops of the solution into the circular opening of the test device.



07 Leave for 20 minutes and read the results. Do not read after 25 minutes. Refer to "Interpreting Your Results" section below.

INTERPRETING YOUR RESULTS:

	INDICATOR	RESULT	INTERPRETATION
	A line appears in regions (C) and (T)	Positive	The presence of both the control line (C) and line (T) indicates the presence of SARS-CoV-2 antigens. The result suggests current COVID-19 infection.
	A line appears in the region (C)	Negative	The presence of only the control line (C) and not the line (T) indicates no detection of SARS-CoV-2 antigens.
	No line appears in the region (C)	Invalid	If the control line (C) does not appear, the result is invalid, regardless whether the line (T) is present. Repeat the test with a new test device.

NOTE: The indicator lines could be faint. Any line, even if faint, should be interpreted as a line. Do not compare the color intensity of each indicator line to another.

IMPORTANT

- For in vitro diagnostic use
- User should not make any decision of medical relevance without first consulting his/her health care provider
- All components in this test kit should remain sealed until ready for use
- The test must be performed between 18-25˚C
- 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
- Do not swallow or inhale
- Avoid contact with your eyes. If contact occurs, flush with water immediately and seek medical help
- Do not use the test kit after the expiration date

LIMITATIONS

- The test is designed for using nasal swab samples.
- Negative results do not rule out COVID-19 infection, especially if you have been in contact with the virus. Follow-up molecular testing should be considered to rule out infection.
- Positive results may be due to present infection with non SARS-CoV-2 coronavirus strains, such as SARS-CoV.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude COVID-19 infection.
- If you have questions about your results, please contact Customer Service at +852-3892-7200 or indicaid@phasesci.com.

I ACCIDENTALLY SPILLED THE TEST SOLUTION. IS IT HARMFUL?

If the test solution has been spilled, flush abundantly with water upon disposal.

Avoid having the test solution come into contact with your eyes, skin and mouth. If contact occurs with the eyes, flush with water immediately and seek medical help. If contact occurs with your skin, wash the area with soap and rinse with water.

Do not ingest or inhale the test solution. If accidental ingestion occurs, please seek medical help immediately.

HOW FAR SHOULD I INSERT THE SWAB INTO MY NOSTRILS?

Inserting the swab 1 inch into your nostril should be far enough to collect samples for this test. You can stop pushing the swab when you feel a slight resistance and proceed to collecting your sample. Samples should be collected gently.

WHAT DO I DO WITH THE TEST UNIT AFTER READING THE RESULTS?

After recording your results, carefully wrap all product components and dispose by throwing it into the garbage just like any household trash. Wash your hands thoroughly after handling and disposing the components.

HOW DOES THE TEST WORK?

This test is designed to detect the presence of SARS-CoV-2 antigens from nasal swab samples. Antigens are present on the SARS-CoV-2 virus, and can be used as markers for disease exposure.

WHAT IF I TESTED NEGATIVE?

Rapid antigen tests can only detect the presence of antigens at the time of the test. A false negative result may be produced when the level of antigen in the sample is below the detection limit of the test, the sample is collected improperly, or when the test was performed incorrectly. If you had contact with a known or suspected COVID-19 cases, as a best practice, performing the test at least once every week is recommended.

WHAT IF I TESTED POSITIVE?

If you tested positive for COVID-19 antigens, we recommend contacting your local health authorities to organize a follow-up molecular diagnostics test for diagnosis.

HOW ACCURATE IS THE TEST?

The INDICAID® COVID-19 Rapid Antigen Test has been clinically validated reach a high detection accuracy, reaching a relative detection specificity of 99% and a relative detection sensitivity of 96%.

In our clinical study, the INDICAID® COVID-19 Rapid Antigen Test device was tested on clinical specimens from 50 healthy persons and 50 identified COVID-19 patients, using PCR as the reference method. The results are summarized as below.

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%)		

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