


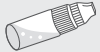


INTENDED USE

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 instruction sheet 
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HOW TO USE

Follow these instructions closely to achieve the best results:

Remove the swab and test device from their packaging.



Tilt your head back. Gently insert the swab about 1 inch into one of your nostrils. Twist for 5 seconds. Repeat with your other nostril.



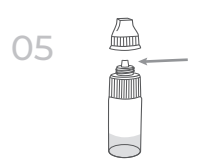
The Buffer Solution Vial cap is composed of two parts. Remove the entire cap. Stir the swab into the buffer solution by twisting the swab back and forth 20 times. Ensure that the swab tip is fully submerged in the solution.



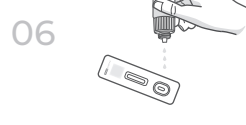
Close the entire vial cap tightly. Immediately perform Steps 5-7.



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






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



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
	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.
	Negative	The presence of only the control line (C) and not the line (T) indicates no detection of SARS-CoV-2 antigens.
	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.

FREQUENTLY ASKED QUESTIONS (FAQs)

I ACCIDENTALLY SPILLED THE TEST SOLUTION. IS IT HARMFUL?

If the test solutions have been spilled, flush abundantly with water upon disposal.

Avoid having the test solutions 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 solutions. 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 and seal 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.

產品用途

妥析® COVID-19 快速抗原測試試劑盒是一款體外診斷測試工具，用於檢測人體鼻咽拭子中的SARS-CoV-2抗原。

檢測原理


抗原通常在感染早期就可以在上呼吸道中被檢測出來。抗原存在於SARS-CoV-2病毒上，可作為檢測體內病毒的指標。

本盒內配有			
1 支獨立包裝的測試棒	1 瓶測試溶液	1 支獨立包裝的棉棒	1 份說明書


如何使用

如欲獲得最佳效果，請小心遵備本說明書指示：


打開包裝，取出棉棒和測試棒。

01 

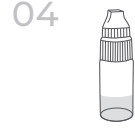
把頭向後傾，輕輕地把棉棒伸進鼻孔(約一寸深)，在內打圈約5秒。在另一側鼻孔裡重複步驟。

02 

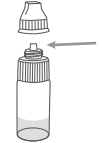
裝有測試溶液的小瓶的蓋子分為兩部分，分別是上半部及整個蓋子。扭開小瓶的整個蓋子，然後把棉棒浸在測試溶液中，來回轉動棉棒20次。轉動時須確保棉棒頂端完全浸泡在溶液中。

03 

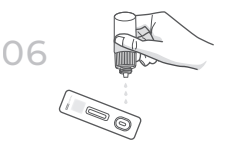
把蓋子扭緊。立即進行下一個步驟。

04 


然後扭開蓋子上半部分，露出滴頭。

05 

把小瓶垂直置於測試棒上的圓形開口上方，擠出3滴瓶內溶液到開口裡。

06 

置於室溫20分鐘後(不可多於25分鐘)查看檢測結果。請細閱以下「如何解讀您的結果」部分。

07 

如何解讀您的結果:

指示線	結果	解釋
 在(C)和(T)區內顯示一條線	陽性	此結果顯示在樣本中檢測到 SARS-CoV-2 抗原，說明您現正受到 COVID-19 感染。
 在(C)區內顯示一條線	陰性	在血液中沒有檢測到 SARS-CoV-2 抗原。
 在(C)區內沒有顯示一條線	無效	本測試無效。請使用新的測試棒再試一次。

注意: 指示線有時會顯得模糊，但仍然應視作指示線進行結果解讀；指示線的顏色強度不一致是正常情況，進行結果解讀時毋須比較兩者顏色強度。

重要事項

- 本試劑盒只供體外診斷之用
- 請勿在未事先諮詢醫護人員的情況下，做出任何與醫學相關的決定
- 本試劑盒內含有的所有部件應保持密封直至使用為止
- 測試必須在18-25°C環境內進行
- 所有部件僅為一次性使用，不能重複使用
- 本試劑盒應儲存於溫度2-30°C之間。避免陽光直接照射
- 不要吞嚥或吸入本測試劑盒內任何部件
- 避免接觸眼睛。如發生意外接觸，請及時用清水沖洗並向醫護人員求助
- 請勿使用過期試劑盒

產品局限性

- 本測試套裝只為檢測人體鼻咽拭子而設
- 由於陰性結果不能排除COVID-19感染的可能，您應該考慮進行後續的分子檢測以排除感染的可能；特別是當您曾經與病毒接觸。
- 陽性結果也可能是由於過去或現在感染了非SARS-CoV-2的冠狀病毒，例如 SARS-CoV。
- 抗原測試的結果不應用作診斷COVID-19感染的唯一依據。
- 如果您對結果存有疑問，請致電+852-3892-7200或電郵至 indicaid@phasesci.com 與我們的客戶服務部聯絡。

常見問題 (FAQs)

我意外倒翻了溶液，是否有害？

請在處理好倒翻的溶液後，使用大量清水充分清洗受影響的地方。

請避免眼睛、皮膚或口腔接觸溶液。如果溶液接觸了眼睛，請立即用清水沖洗並向醫護人員求助。如果接觸了皮膚，用肥皂洗淨該部位後再用清水沖洗即可。

切勿吞嚥或吸入溶液。如意外吞食了溶液，請立即求醫。

在採集鼻咽拭子時，我應該把棉棒插得有多深？

把棉棒伸進鼻孔內一寸已經足夠。如果您在把棉棒伸入鼻孔的過程中感到輕微阻力，則毋需繼續把棉棒伸進去，並可以進行下一步。切勿過於用力，以免造成傷害。

讀完檢測結果後，如何處理用過的測試棒及其他部件？

請先記錄您的檢測結果，然後把測試棒及其他部件包起密封，再跟普通家庭垃圾一起丟棄在垃圾桶裏。處理完畢後切記洗手。

試劑盒的運作原理是什麼？

抗原存在於病毒上，如果檢測出體內有SARS-CoV-2抗原，則表示體內有SARS-CoV-2病毒，反之亦然，因此抗原可作為檢測體內病毒的指標。抗原通常在感染早期已經可以在上呼吸道中被檢測出來。

如果測試結果顯示為陰性，我應該做什麼？

快速抗原測試只能指出測試當下樣本中是否含有抗原。抗原數量比檢出下限低、樣本採集過程出錯、檢測操作過程出錯均有可能導致假陰性結果。如果您曾經與COVID-19疑似或確診病例接觸，建議至少每週測試一次以確保沒有受到感染。

如果測試結果顯示為陽性，我應該做什麼？

請立即與當地衛生部門聯絡，以安排後續的分子診斷測試進行確認。