

Indicaid rapid antigen test instruction guide 妥析快速檢測用法

Please watch our YOUTUBE link and read the INSTRUCTION FOR USE before use.

參前，請先參照 YOUTUBE 影片教學及 使用說明。

- Youtube link:

<https://www.youtube.com/watch?v=AcHE11bi9Os>

- Enclosed please find the instruction for use.

請參閱附件使用說明。

Should you have any enquiry, please do not hesitate to contact our Customer Service Department at +852 3700 8888 from Monday to Sunday, 8am – 8pm





如有任何疑問，請於星期一至日，早上 8 時至晚上 8 時，致電我司客戶服務熱線 +852 3700 8888 查詢。

INTENDED USE

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

PRINCIPLE

During COVID-19 infection, the virus SARS-CoV-2 is found in the upper respiratory tract. SARS-CoV-2 antigens are substances of the virus that serve 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

Remove the test device and swab from their packaging.



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



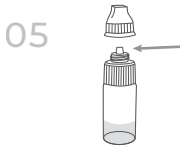
The buffer solution vial cap is composed of two parts. Remove the entire cap. Stir the swab into the buffer solution by twisting the swab back and forth **20 times**. Slightly tilt the vial to ensure the swab tip is fully submerged in the solution.



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 the 'Interpreting Your Results' section below.



*Watch the how-to-use video by scanning the QR code.



INTERPRETING YOUR RESULTS:

INDICATOR	RESULTS	INTERPRETATION
	Positive	This result indicates the presence of SARS-CoV-2 antigen in the sample. This result indicates the presence of SARS-CoV-2 antigen in the sample. Please call PHASE Scientific's customer service hotline at +852-3700-8888 for a consultation.
	Negative	This result indicates no SARS-CoV-2 antigen is detected in the sample. Regular testing (at least once every week) is recommended. If you have been in contact with a known or suspected COVID-19 case, we recommend that you arrange a PCR test to confirm your negative result.
	Invalid	There was an issue with the specimen collection or the test processing. Repeat the test with a new test kit.

IMPORTANT

- For in vitro diagnostic use
- User should not make any decision of medical relevance without first consulting their health care provider
- All components in this test kit should remain sealed until ready for use
- The test must be performed between 15-30°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
- Samples with low levels of antigen may give a faint test line. Any visible pink/purple colored line is positive, do not compare the color intensity of each indicator line to another
- Handle all specimens as if they are potentially infectious
- If you have questions about your results, please contact Customer Service at **+852-3700-8888** or **cs@indicaid.com**

LIMITATIONS

- The test is designed for using direct nasal swab sample.
- Negative results do not rule out COVID-19 infection, especially if you have been in contact with the virus. A follow-up PCR test should be considered to rule out infection
- Positive results may be due to current 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
- Users under the age of 18 should use this test under adult supervision

I ACCIDENTALLY SPILLED THE BUFFER SOLUTION. IS IT HARMFUL?

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

Avoid having the buffer 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 buffer solution. If accidental ingestion occurs, please seek medical help immediately.

HOW DEEP SHOULD I INSERT THE SWAB INTO MY NOSTRILS?

Inserting the swab 1 inch into the nostril should be deep enough to collect samples for this test. Once you feel a slight resistance, proceed to gently collect your sample. Check the swab after collection to ensure the tip is covered in nasal secretion.

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

The buffer solution in this test kit contains reagents that reduce virus infectivity, lowering the risk of further infection. After completing the test and recording your results, carefully wrap all product components and dispose them into the garbage just like any other household trash. Wash your hands thoroughly with soap and water after handling the components.

HOW ACCURATE IS THE TEST?

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

The INDICAID® COVID-19 Rapid Antigen Test device was tested on clinical specimens from 50 healthy individuals and 50 COVID-19 patients identified by PCR test. 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%)		



About the INDICAID® Mobile APP

The INDICAID® Mobile APP is a digital health pass that can interpret and record test results when used with the INDICAID® COVID-19 Rapid Antigen Test. It also provides users with clear step-by-step instructions throughout the process to ensure effective testing and accurate results.

User Instructions

- (1) Download the mobile APP > (2) Create your account > (3) Select start self-test > (4) Scan the QR code on the test device packaging > (5) Follow the instructions to complete the test > (6) Scan the test results after 20 minutes > (7) Check your result QR code and test record.

Scan to download the INDICAID® mobile APP





產品用途

INDICAID® 妥析® 新冠病毒快速抗原檢測測試劑盒是一款體外診斷測試工具，用於檢測人體鼻拭子中的新冠病毒 (SARS-CoV-2) 抗原。

檢測原理

新冠病毒感染期間，SARS-CoV-2 病毒可以在上呼吸道中被檢測出來。SARS-CoV-2 抗原存在於病毒中，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 支獨立包裝的採樣棒	1 份產品使用說明

如何使用

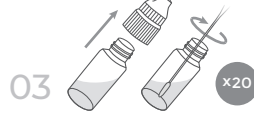
打開包裝，取出測試棒和採樣棒。



把頭向後傾，輕輕地把採樣棒伸進鼻孔（約一吋深），沿鼻孔內壁在內**至少打5個大圈**。在另一側鼻孔裡重複同樣的步驟。



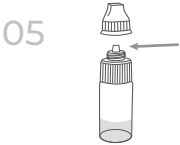
測試溶液小瓶的蓋子分為兩部分，分別是上半部及整個蓋子。扭開小瓶的整個蓋子，然後把採樣棒浸在測試溶液中來回轉動**20次**。轉動時須確保採樣棒頂端完全浸泡在溶液中。



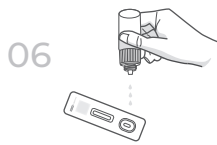
扭緊蓋子。立即進行5-7的步驟。



扭開小瓶的蓋子的上半部分，露出滴頭。



把小瓶垂直置於測試棒上的圓形開口上方，擠出3滴溶液到開口裏。



置於室溫**20分鐘後**（不可多於**25分鐘**）查看檢測結果。請仔細閱讀以下「如何解讀檢測結果」部分。



*掃描二維碼以觀看使用視頻



如何解讀檢測結果：

指示線	結果	解釋
在 (C) 和 (T) 區內分別顯示一條線	陽性	結果顯示樣本中檢測到 SARS-CoV-2 抗原。請致電生產商相連生物科技的客戶服務熱線： +852-3700-8888 進行相關諮詢。我們可免費為您提供進一步核酸檢測服務。
只在 (C) 區內顯示一條線	陰性	結果顯示樣本中未檢測到 SARS-CoV-2 抗原。建議您定期進行檢測（每星期一次），如果您曾經與疑似或確診新冠病毒病例接觸，我們建議您進行一次核酸檢測確定您的結果。
在 (C) 區內沒有顯示一條線	無效	樣本採樣過程或測試處理中出現了問題，請使用新的試劑盒再檢測一次。

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
- 進行測試前，本試劑盒內的所有部件應保持密封
- 測試必須在15-30°C環境內進行
- 所有部件僅為一次性使用，不可重複使用
- 本試劑盒應儲存於溫度2-30°C之間。避免陽光直接照射
- 不可吞嚥或吸入本試劑盒內任何部件
- 避免接觸眼睛。如發生意外接觸，請立即用清水沖洗並向醫護人員求助
- 請勿使用過期試劑盒
- 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條條的顏色強度
- 所有樣本均有傳染性風險，請謹慎處理
- 如果您對結果存有疑問，請致電**+852-3700-8888**或電郵至**cs@indicaid.com**與我們的客戶服務人員聯絡

產品局限性

- 本試劑盒用於檢測人體鼻拭子樣本
- 陰性結果不能完全排除新冠病毒感染的可能，如果您曾經處於有可能感染新冠病毒的環境，您應當考慮做進一步的核酸檢測
- 陽性結果也可能是由於感染了非 SARS-CoV-2 的其他冠狀病毒所引起，例如 SARS-CoV
- 本抗原測試的結果不應用作診斷新冠病毒感染的唯一依據
- 18歲以下的用戶家在成人的全程監督下進行本測試

我意外倒翻了溶液，是否有毒？

若不慎倒翻溶液，請立即使用大量清水充分清洗受影響的地方。

請避免眼睛、皮膚或口部接觸溶液。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。如皮膚沾到溶液，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。

在採集鼻拭子樣本時，我應該把採樣棒插入多深？

把採樣棒伸進鼻孔內一吋即可。如果您在把採樣棒伸入鼻孔的過程中感到輕微阻力，則繼續輕輕地收集樣本。收集樣本後，檢查採樣棒以確保其頂端被鼻腔分泌物覆蓋。

讀完檢測結果後，如何處理用過的測試棒及其他部件？

本產品的測試溶液能夠減低鼻拭子樣本中病毒的傳播能力，不會造成進一步感染。完成測試後，請先記錄您的檢測結果，然後把測試棒及其他部件包好，再用處理普通家庭垃圾的方式丟棄在垃圾桶裏。處理完畢後切記洗手。

此產品的結果準確嗎？

本產品經臨床驗證，其整體檢測特異度和靈敏度分別高達99%和96%，證明檢測結果準確度非常高。

在我們的臨床研究中，我們使用INDICAID® 妥析® 新冠病毒快速抗原檢測測試劑盒，對50個健康的樣本 and 50個核酸檢測中被診斷為新冠病毒陽性的患者樣本進行測試，結果如下：

INDICAID® 妥析® 新冠病毒快速抗原檢測	檢測方法結果對比		
	陽性	陰性	總數
陽性	48	0	48
陰性	2	50	52
總數	50	50	100
靈敏度	96% (95% CI: 86.3% - 99.5%)		
特異度	100% (95% CI: 92.9% - 100%)		



關於INDICAID® 手機應用程式

掃描下載INDICAID®
手機應用程式

INDICAID® 手機應用程式提供數碼健康管理服務，配合INDICAID® 妥析® 新冠病毒快速抗原檢測測試劑盒同時使用，能夠方便紀錄和管理檢測結果。測試過程中會提供清晰的使用說明，確保有效的結果管理。

使用步驟

- (1) 下載手機應用程式 > (2) 註冊帳戶 > (3) 點擊開始個人測試 > (4) 掃描測試棒包裝上的二維碼 > (5) 按照應用程序的使用步驟進行測試 > (6) 20分鐘後掃描檢測結果 > (7) 查看您的結果二維碼及檢測記錄。

