INDICAID® INSTRUCTION GUIDE

COVID-19 RAPID ANTIGEN TEST Ref # 2120300

CE IVD

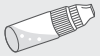
INTENDED USE

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 or nasopharyngeal swab sample.

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

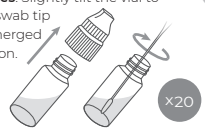
1 individually-wrapped test device	1 vial of buffer solution	1 individually-wrapped swab	1 instruction guide
			

HOW TO USE

01 Remove the test device and swab 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 wall of one of your nostrils **at least 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**. Slightly tilt the vial to ensure 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 the "Interpreting Your Results" section below.

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

INTERPRETING YOUR RESULTS:

	INDICATOR	RESULTS	INTERPRETATION
	A line appears in regions (C) and (T)	Positive	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.
	A line appears in the region (C)	Negative	This results 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.
	No line appears in the region (C)	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
- 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 or nasopharyngeal 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
- Results from antigen testing should not be used as the sole basis to diagnose or exclude COVID-19 infection

FREQUENTLY ASKED QUESTIONS (FAQs)

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 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?

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?

In the first study using retrospective nasopharyngeal swab specimens, 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% for nasopharyngeal swab sample (Table A). In the second study using prospective nasal and retrospective nasopharyngeal swab specimens, the relative detection specificity and sensitivity reach >95% and 91% respectively (Table B).

Table A (Study #1 with retrospective nasopharyngeal swab specimens)

INDICAID® COVID-19 Rapid Antigen Test	Comparator Method (RT-qPCR)		
	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%)		

Table B (Study #2 with prospective nasal and retrospective nasopharyngeal swab specimens)

INDICAID® COVID-19 Rapid Antigen Test	Comparator Method (RT-qPCR)		
	Positive	Negative	Total
Positive	91	12	103
Negative	9	278	287
Total	100	290	390
Positive Percentage Agreement (PPA)	91% (95% CI: 83.8% - 95.2%)		
Negative Percentage Agreement (NPA)	96% (95% CI: 92.9% - 97.6%)		

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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

INDICAID.COM

MANUFACTURER
PHASE Scientific International Limited
32 & 33/F, Gravity, 29 Hing Yip Street,
Kwun Tong, Kowloon, Hong Kong

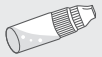
INDICAID® 妥析® 使用說明

新冠病毒快速抗原測試
Ref # 2120300

產品用途
INDICAID® 妥析® 新冠病毒快速抗原檢測試劑盒是一款體外診斷測試工具，用於檢測人體鼻拭子或鼻咽拭子中的新冠病毒 (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 份使用說明
			

如何使用

打開包裝，取出測試棒和採樣棒。

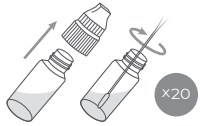
01

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。

02

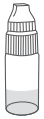
測試溶液小瓶的蓋子分為兩部分，分別是上半部及整個蓋子。扭開小瓶的整個蓋子，然後把採樣棒浸在測試溶液中來回轉動**20次**。轉動時須確保採樣棒頂端完全浸泡在溶液中。

03



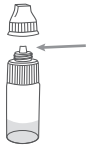
扭緊蓋子。立即進行5-7的步驟。

04



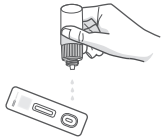
扭開小瓶的蓋子的上半部分，露出滴頭。

05



把小瓶垂直置於測試棒上的圓形開口上方，擠出3滴溶液到開口裏。

06



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。

07

*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。請致電生產商相達生物科技的客户服務熱線:**+852-3700-8888** 進行相關諮詢。
	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線條的顏色強度
- 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或鼻咽拭子樣本
- 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致
- 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

常見問題 (FAQs)

我意外倒翻了溶液，是否有害？

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？

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？

在第一項INDICAID®妥析®新冠病毒快速抗原檢測試劑盒臨床研究中，研究人員用回溯性鼻咽拭子樣本測試產品的檢測準確度。實驗結果顯示產品的相對特異度>99%，而相對靈敏度亦高達96% (表A)。於第二項INDICAID®妥析®新冠病毒快速抗原檢測試劑盒臨床研究中，研究人員以前瞻性鼻拭子及回溯性鼻咽拭子作為實驗樣本試驗產品的檢測準確度，實驗結果顯示產品的相對特異度大於95%，而相對靈敏度則有91% (表B)。

表A (臨床研究 #1 回溯性鼻咽拭子樣本)

INDICAID®妥析® 新冠病毒快速抗原檢測	比對RT-qPCR結果		
	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%)		

表B (臨床研究 #2 前瞻性鼻拭子及回溯性鼻咽拭子樣本)

INDICAID®妥析® 新冠病毒快速抗原檢測	比對RT-qPCR結果		
	陽性	陰性	總數
陽性	91	12	103
陰性	9	278	287
總數	100	290	390
靈敏度	91% (95% CI: 83.8% - 95.2%)		
特異度	96% (95% CI: 92.9% - 97.6%)		

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關於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) 註冊賬戶 > (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。

掃描下載INDICAID® 手機應用程式

PI-2120300IG1 | Rev B | 僅供體外診斷之用 |

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