USER INSTRUCTIONS

INDICAID™

RESPIRATORY 5-in-1 Rapid Antigen Test

SARS-CoV-2 • Influenza A&B • RSV • ADV

REF P0150

IVD

Suitable for ages 2+ years
Must be ages 14+ to use kit unsupervised
For in vitro diagnostic use only

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

INTENDED USE

INDICAID™ RESPIRATORY 5-IN-1 RAPID ANTIGEN TEST (SARS-CoV-2·Influenza A&B·RSV·ADV) is an in vitro diagnostic test for determining the presence of SARS-CoV-2, influenza A (flu A), influenza B (flu B), respiratory syncytial virus (RSV) and/or adenovirus (ADV) antigens in anterior nasal swab samples. This test is intended for self-collected anterior nasal swab from individuals over 14 years old or adult collected anterior nasal swab from individuals aged 2 years or older with symptoms of respiratory infections within the first 7 days of symptom onset.

Results are for the identification of SARS-CoV-2, influenza A, influenza B, RSV and/or ADV antigens. Antigens are generally detectable in anterior nasal swabs during the acute phase of infection and are parts of the virus that can serve as markers for disease exposure.

CONTAINED IN THIS BOX

1x Individually-Wrapped Test Device, Buffer Solution Vial, Individually-Wrapped Swab, User Instructions

WARNINGS PRECAUTIONS AND SAFETY INFORMATION

- ✓ Children aged 2 to 13 years should be tested by an adult.
- ✓ Use only the contents provided in the test kit.
- ✓ Keep test kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth.
- ✓ Leave test device sealed in its pouch until just before use. Once opened, the test device should be used within 1 hour.
- ✓ Store at 2 - 30°C. Do not freeze. Avoid direct sunlight.
- ✓ Wear a face mask or other face covering while collecting sample from a child or an adult.
- ✓ The reagent solution contains hazardous chemicals. If contact to the body occurs, flush with copious amount of water. If irritation persist, seek medical advice.
- ✓ Keep foreign substances and household cleaning products away from the test device during the testing process. Contact with foreign substances and household cleaning products (e.g., 1% bleach) may result in an incorrect test result.
- ✗ Do not touch the swab tip.
- ✗ Do not reuse. Test components are for single-use.
- ✗ Do not use test kit beyond its printed expiration date.
- ✗ Do not use if any of the test kit content or packaging is damaged or opened.
- ✗ Do not ingest any kit components.
- ✗ Do not use the test on children under 2 years of age.

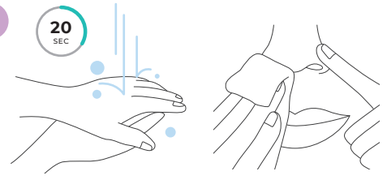
Get help here:
please contact Customer Service at +852 3700 8888 or email to cs@indicaid.com

Performing Your Test

1

Check the expiration date on the outside of the product box.

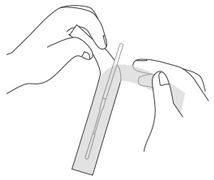
2



Wash your hands thoroughly for at least 20 seconds before and after testing.

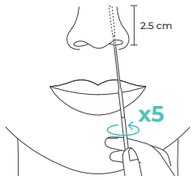
Before sampling, please clear any mucus or discharge from your nostrils.

3



Remove the test device and swab from their packaging.

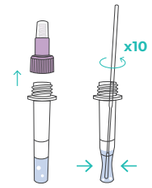
4



Tilt your head back. Gently insert the swab about **2.5 cm** 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 **using the same swab**.

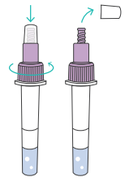
If you swab your nose incorrectly, the test will produce a false negative result.

5



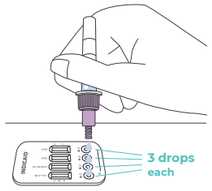
The buffer solution vial cap is composed of two parts. Remove the entire cap. Immediately place the nasal swab into the buffer solution vial. **Press and roll** the swab tip against the inner wall of the vial 10 times and squeeze the sides of the vial towards the swab tip to remove excess solution.

6



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

7



Place the test device on a flat surface. Hold the vial vertically. Slowly squeeze **3 drops** of the solution into the sample well.

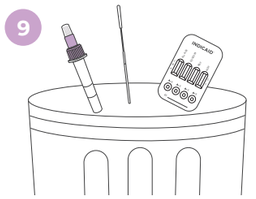
Make sure to squeese **3 drops** of the solution into **each of the sample wells**. Inaccurate results may occur if **less than 3 drops** are applied to each well.

8

Leave for **15 minutes** and read the results. Do not read after 20 minutes. Refer to the "Interpreting Your Results" section below.

Make sure the test device is placed on a horizontal (flat) surface while running the test/ until the timer ends.

9



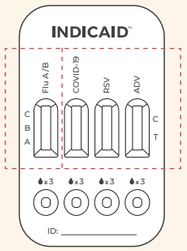
Dispose of all used test kit supplies and swab samples in a trash receptacle.

LIMITATIONS OF THE TEST

- Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease.
- Negative results do not rule out SARS-CoV-2, influenza A, influenza B, RSV and/or ADV infections, especially if you have been in contact with the viruses(es). A follow-up PCR test should be considered to rule out infection.
- False negative result may occur if the level of antigen in the sample is below the test limit or the test procedure is not carried out properly.
- Results from this test should not be used as the sole basis to diagnose or exclude SARS-CoV-2, influenza A, influenza B, RSV and/or ADV infections. User should not take any decision of medical relevance without first consulting healthcare professional.
- This test kit can test for current infection only and cannot tell if you have had SARS-CoV-2, influenza A, influenza B, RSV and/or ADV infection in the past.
- A negative test result may occur if virus has mutated at the specific antigen region recognized by this test.

Interpreting Your Results

This test has 4 result windows, each showing test results for different respiratory viruses:



FLU A/B: influenza A / influenza B

Look for the lines next to the 'C' (Control), 'A' (Flu A), and 'B' (Flu B). Use the information on the right to interpret the lines.

COVID-19: SARS-CoV-2
RSV: respiratory syncytial virus
ADV: adenoviruses

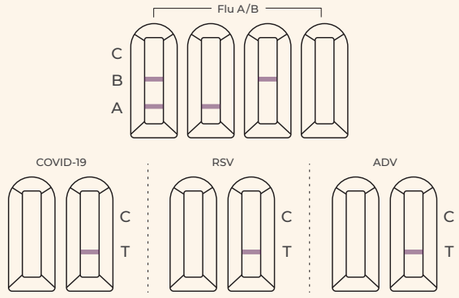
Look for the lines next to the 'C' (Control) and 'T' (Test). Use the information on the right to interpret the lines.

- **Look closely!** Lines can vary in color and may appear very faint!
- **Make sure there is a line next to the 'C'!** Your result is INVALID if there is no 'C' line.

INVALID TEST RESULT

No 'C' Line

STOP **If no 'C' line is seen, the test result is INVALID** even if you see 'A', 'B', or 'T' line(s).

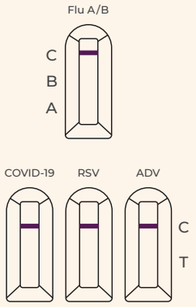


Take these next steps:

- Collect a new nasal swab sample and repeat the test with a new INDICAID™ RESPIRATORY 5-IN-1 RAPID ANTIGEN TEST.
- If you develop SARS-CoV-2, influenza A, influenza B, RSV, and/or ADV symptoms or your symptoms become severe, seek medical attention immediately.

NEGATIVE TEST RESULT

'C' Line Only



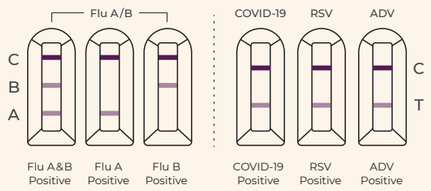
Take these next steps:

- If you develop SARS-CoV-2, influenza A, influenza B, RSV, and/or ADV symptoms or your symptoms become severe, seek medical attention immediately.

POSITIVE TEST RESULT

'C' Line AND any 'A', 'B', or 'T' Line

Look very closely! Even a very faint line next to the 'A', 'B', or 'T' should be considered positive if there is also a 'C' line.



Take these next steps:

- Consult your healthcare provider to discuss your positive test result.

Understanding Your Results

What an invalid result means: The test could not tell whether or not you have SARS-CoV-2, influenza A, influenza B, RSV, and/or ADV. The test needs to be repeated with a new kit and freshly collected anterior nasal swab sample.

What a negative result means: The SARS-CoV-2, influenza A, influenza B, RSV, and/or ADV virus(es) were not detected in the sample. A negative result does not rule out SARS-CoV-2, influenza A, influenza B, RSV and/or ADV virus(es) infection. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have SARS-CoV-2, influenza A, influenza B, RSV and/or ADV. If you tested negative and continue to experience SARS-CoV-2, influenza A, influenza B, RSV, and/or ADV-like symptoms of fever, cough and/or shortness of breath, you should seek follow-up care with your healthcare provider.

What a positive result means: The SARS-CoV-2, influenza A, influenza B, RSV, and/or ADV virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. You are advised to consult your healthcare provider on the interpretation of your test results, and your treatment options based on your medical history and symptoms.

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www.indicaid.com

PI-0096 (A)

使用說明書

INDICAID™ 妥析™

呼吸道病毒5合1
快速抗原檢測試劑盒

新冠病毒・甲型及乙型流感病毒・
呼吸道合胞病毒・呼吸道腺病毒

REF P0150

IVD

適合2歲或以上人士使用
使用者必須年滿14歲方能在無人監督的情況下使用測試套裝
僅供體外診斷使用

在進行測試前，請仔細閱讀使用說明書。不遵循指示可能會產生不準確的測試結果。

預期用途

INDICAID™妥析™呼吸道病毒5合1快速抗原檢測試劑盒(新冠病毒・甲型及乙型流感病毒・呼吸道合胞病毒・呼吸道腺病毒)是一款體外診斷測試試劑，用於檢測前鼻拭子中的新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒抗原。此測試適用於在7天內已出現病徵人士。14歲或以上的人士可自行在前鼻腔採樣，兩歲以上的人士需由成年人協助在前鼻腔採樣。測試結果用於識別新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒抗原。新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒感染期間，其抗原可以在上呼吸道中被檢測出來。抗原是病毒的一部分，並可作為接觸過病毒的指標。

盒內包括

1x 獨立包裝測試卡、測試溶液瓶、獨立包裝採樣棒、使用說明書

注意事項及安全資訊

- ✓ 2至13歲的兒童須由成年人協助測試。
- ✓ 只可使用試劑盒中提供的物品進行測試。
- ✓ 在使用前後，請將試劑盒和所有檢測組件放在兒童和寵物接觸不到的地方。請避免皮膚、眼睛、鼻子或口部接觸試劑盒及檢測部件。
- ✓ 測試前測試卡應保持密封。測試卡一經打開，須在1小時內使用。
- ✓ 本試劑盒應儲存於溫度2-30°C之間。請勿冷藏。
- ✓ 為兒童或其他人士採集樣本時，請佩戴口罩或面罩。
- ✓ 試劑溶液含有有害化學物質，一旦溶液與身體接觸，請使用大量清水沖洗。如刺激感持續，請尋求醫護人員協助。
- ✓ 測試期間，請將其他物件和家用清潔產品放置在遠離測試的地方。如接觸其他物件和家用清潔產品(例如1%漂白水)，可能會令測試結果不準確。
- ✗ 請勿觸摸採樣棒頂端。
- ✗ 不可重複使用，所有測試部件為一次性使用。
- ✗ 請勿使用過期試劑盒。
- ✗ 請勿使用任何包裝出現損壞或已被打開的測試部件。
- ✗ 避免陽光直接照射。請勿吞服任何檢測部件。
- ✗ 請勿為2歲以下兒童進行本測試。

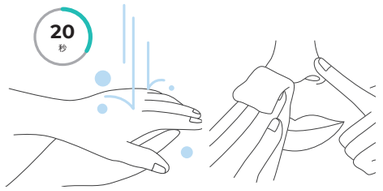
聯絡我們:
如需要協助，請致電+852 3700 8888或電郵至cs@indicaid.com與我們聯絡

進行測試

1

檢查產品包裝盒上的**有效日期**。

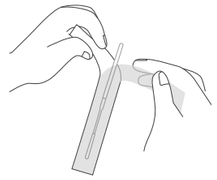
2



於測試前後徹底洗淨雙手最少20秒。

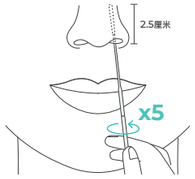
請於採樣前清潔鼻孔，確保沒有多餘鼻涕或鼻垢。

3



打開包裝，取出測試卡和採樣棒。

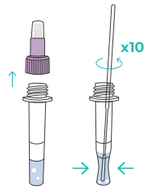
4



把頭向後傾，輕輕地把採樣棒伸進鼻孔(**約2.5厘米深**)，沿鼻孔內壁至少打**5個大圈**。在另一側鼻孔裏使用同一支採樣棒重複同樣的步驟。

若你於鼻孔採樣方式不正確，測試將產生假陰性結果。

5

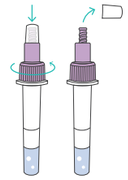


測試溶液瓶蓋分為兩部分，分別是上半部及整個蓋子。

扭開整個瓶蓋，立刻將採樣棒放進測試溶液瓶內，緊靠內壁大力轉動擠壓採樣棒頂端**10次**。

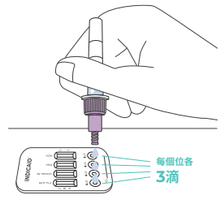
然後用手**按壓溶液瓶**，令其內壁擠壓採樣棒頂端，使溶液盡可能留在瓶中。

6



扭緊整個瓶蓋。然後扭開小瓶蓋子的上半部分，露出滴頭。

7



測試卡需放置於水平(平坦)的表面上。把小瓶垂直置於測試卡上的，於**每個圓形開口**上方擠出**3滴**溶液到開口裏。滴出少於3滴溶液於圓形開口可能會出現假陰性結果。

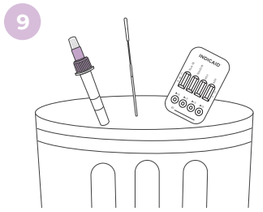
需於**每個圓形開口**滴**3滴**溶液。滴出**少於3滴**溶液於橢圓形開口可能會出現假陰性結果。

8

置於室溫**15分鐘**後(不可多於20分鐘)查看檢測結果。請仔細閱讀下方的「結果解讀」部分。

測試卡必須放置於水平(平坦)的表面上直至完成檢測。

9



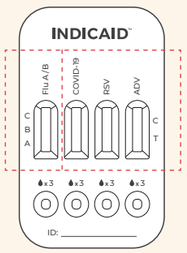
將所有用過的測試組件和採樣樣本丟棄到垃圾桶內。

產品局限性

- 陽性結果不排除是因細菌感染或與其他病毒的共同感染而造成，同時檢測到的病原體亦可能並非致病的確切原因。
- 陰性結果並不能排除感染新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒的可能性，尤其當你曾處於有可能感染病毒的環境，你應當考慮做進一步的核酸檢測。
- 如果採集樣本的抗原量低於檢測限或樣本採集不當，可能會出現假陰性結果。
- 本抗原測試的結果不應用作診斷感染新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒的唯一依據。
- 使用者不應在未事先諮詢醫護人員的情況下做出任何與醫療相關的決定。
- 本測試套裝僅用於測試現時的感染情況，且無法判斷你過去曾否感染過新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒。
- 若病毒變異位於此測試的抗原識別區，則可能會出現陰性測試結果。

結果解讀

測試卡有4個測試窗口，分別顯示不同病毒的測試結果:



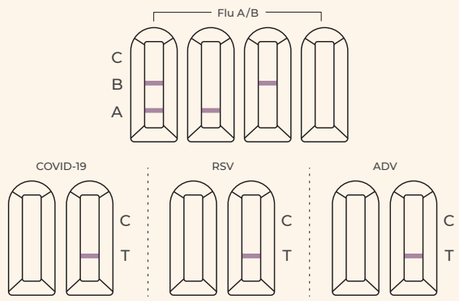
FLU A/B:
甲型/乙型流感病毒
尋找測試卡上 'C' (對照)、'A' (甲型流感)、'B' (乙型流感)旁邊的指示線。
請使用右表解讀所看到的結果。

COVID-19: 新冠病毒
RSV: 呼吸道合胞病毒
ADV: 呼吸道腺病毒
尋找測試卡上 'C' (對照)、'T' (測試)旁邊的指示線。
請使用右表解讀所看到的結果。

- **請細心留意!** 指示線的顏色深淺度可能會有差異或顯得很微弱!
- **請確保** 'C' 旁邊有出現指示線!若在 'C' 旁沒有出現任何線，表示測試無效。

無效測試結果
沒有 'C' 線

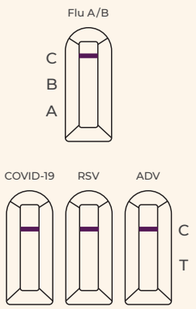
若 'C' 旁邊沒有指示線，則無論 'A'、'B'，或 'T' 旁是否有指示線，結果均屬**無效**。



後續步驟:

- 請用新的INDICAID™妥析™呼吸道病毒5合1快速抗原檢測試劑盒重新採樣及測試。
- 若你出新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒徵狀或徵狀變得嚴重，請立即求醫。

陰性測試結果
只有 'C' 線

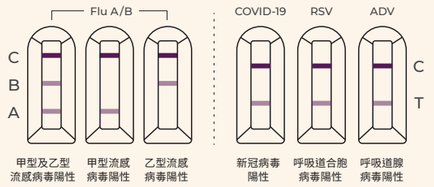


後續步驟:

- 若你出新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒徵狀或徵狀變得嚴重，請立即求醫。

陽性測試結果
'C' 線及任何一條 'A'、'B' 或 'T' 線

請細心留意! 若能見到 'C' 線，而 'A'，'B' 或 'T' 旁出現的任何微弱線均被視為陽性結果。



後續步驟:

- 請向你的醫療服務提供者查詢，以討論你的陽性測試結果。

檢測結果解釋

無效測試結果表示: 本測試無法測定你是否感染新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒的可能性。假如測試無效，你應使用新的採樣棒以採集新的鼻腔樣本再次進行測試。

陰性測試結果表示: 本測試未有在您的樣本中檢測出能引發新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒抗原。陰性測試結果並不能排除感染新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒的可能性。

陽性測試結果表示: 本測試從你的樣本中檢測出能引發新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒的病毒，你很可能已感染了相應的病毒並且具有傳染性。請立即聯絡你的家庭醫生，並根據你的測試結果及病史、病徵為你安排合適的護理。

與在實驗室進行的核酸檢測相比，抗原測試出現假陰性結果的機會較高。因此當你感染新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒時，你在抗原測試中得到陰性結果的機會比核酸檢測為高。如果你的檢測結果呈陰性，但持續出現與新冠病毒、甲型及乙型流感病毒、呼吸道合胞病毒和呼吸道腺病毒類似的病徵(如發燒、咳嗽及/或呼吸急促)，你應向醫護人員尋求跟進護理。

相達生物科技國際有限公司
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