CN LABNOVATION

SARS-CoV-2 抗原快速檢測試劑盒

(免疫層析法)

個人自測使用

使用說明

產品介紹

2019 年 12 月，中國武漢報導了由冠狀病毒 (SARS-CoV-2) 引起的新型呼吸道疾病 (COVID-19)， 據世界衛生組織稱，大多數感染 SARS-CoV-2 的人患有 輕中度呼吸系統疾病，發熱、咳嗽無需治療即可痊癒。 然而，免疫系統較弱的人，如老年人或既往疾病（如心血管疾病、糖尿病、慢性呼吸系統疾病、癌症等）的人，更有可能患上可導致感染者死亡的嚴重疾病。

該快速檢測試劑盒旨在定性檢測疑似 COVID-19 患者的人前鼻分泌物的 SARS-CoV-2 病毒核衣殼抗原。 抗原檢測陽性結果可用於疑似感染患者的早期隔離，但不能作為SARS-CoV-2感染的診斷依據。 陰性結果不排除 SARS-CoV-2 感染，不應作為治療的唯一依據。 對抗原檢測結果為陽性或陰性的疑似人群，應進一步進行核酸檢測.

該試劑盒是一種免疫層析法，利用雙抗體夾心法檢測樣品中的 SARS-CoV-2核衣殼抗原。 如果樣品中存在病毒抗原，它會與相應的膠體金抗體結合。 這種複合物跨膜“遷移”並與測試線 (T) 處的單克隆抗體結合。 這會創建一條可見的紅線，表示陽性結果。 但是，如果樣品不含任何抗原，則無法形成複合物，因此在測試線 (T) 中不會形成紅色線條。 無論樣品是否含有抗原，在質控線 (C) 中都會形成一條紅色線。

主測試套裝包括

- 1 個檢測裝置
- 1 個帶有預裝樣品提取液的樣品管
- 1 個收集鼻拭子樣本
- 1 個試管架（在外盒上）
- 1份使用說明書

額外需要的材料:

1 個計時器

儲存以及保質期

在測試之前，請將試劑盒和其他測試準備材料放在室溫（15℃至 27℃）中。將所有材料放在乾淨、乾燥、平坦的平面上。

檢測結果評估

讀取測試結果時，只需確定控制 (C) 位置是否存在一條線。 控制線 (C) 的強弱無關緊要.

性能特徵

1. 靈敏度和特異性

來自臨床研究的所有樣本的分析結果:

SARS-CoV-2抗原快速檢測	RT-PCR		總數
	陽性	陰性	
陽性	306	0	306
陰性	8	650	658
總數	314	650	964

靈敏度: 97.45% (95.04%-98.89%) *
特異性: 100% (99.43%-100%) *
總相符性: 99.17% (98.37%-99.64%) *
*95 %置信區間

2. 檢測線

LOD 濃度	30 $TCID_{50}$/mL

3. 交叉反應

與人冠狀病毒 229E、人冠狀病毒 OC43、人冠狀病毒 NL63、腺病毒、人偏肺病毒、副流感病毒 1、副流感病毒 2、副流感病毒 3、副流感病毒 4、甲型流感、B 型流感、腸道病毒、呼吸道合胞病毒、鼻病毒、 冠狀病毒、MERS 冠狀病毒、流感嗜血桿菌、肺炎鏈球菌、化膿性鏈球菌、白色念珠菌、百日咳博多特菌、肺炎支原體、肺炎衣原體、嗜肺軍團菌等無交叉反應。

4. 干擾成分

樣本中常見的干擾物質，如血液、粘蛋白、膿液等，對檢測結果無影響。

警告和重要資訊

- 本試劑盒為定性檢測，無法確定抗原的準確含量。
- 該測試僅供體外使用。
- 不得內服。避免樣品緩衝液接觸皮膚和眼睛。
- 避免陽光照射，不要凍結。儲存在 2° C 至 30° C 之間的干燥處。請勿在包裝上印刷的有效期後使用。
- 放在兒童接觸不到的地方。任何 16 歲以下的兒童都不應在沒有父母指導或專業幫助的情況下進行測試。
- 不遵循確切的說明會影響測試結果。最終診斷必須由醫生確認。
- 如果包裝損壞，請勿進行測試。不要使用損壞的測試組件。
- 所有測試組件僅用於此測試。不要重複使用測試或測試組件。
- 測試應在打開鋁箔袋後立即或一小時內進行（15-30° C，濕度<60%）。
- 樣本採集後儘快處理樣本。如果不能立即進行測試，樣品應密封保存，2~8℃保存8小時，-20℃以下保存1個月。不建議長期存放。
- 視力不佳、色盲或光線不足可能會影響您正確解讀測試的能力。
- 處置 根據適用的當地法規，可以將測試套件與普通生活垃圾一起處置。
- 陰性結果不排除感染 SARS-CoV-2 感染。因此，該試驗不應作為臨床診斷的唯一參考。結果必須由 PCR 確認。
- 使用後，用水徹底沖洗雙手，或在接觸緩衝溶液的情況下用水徹底沖洗受影響的身體部位。
- 如果症狀持續存在：尋求醫療建議。

參考文獻

1.) Nanshan Chen*, Min Zhou*, Xuan Dong*, Jieming Qu*,Fengyun Gong, Yang Han, Yang Qiu, Jingli Wang, Ying Liu,Yuan Wei, Jia'an Xia, Ting Yu, Xinxin Zhang, Li Zhang Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. LANCET. January 29, 2020.

2.) World Health Organization (Coronavirus disease 2019) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it(Zugriff am 27.03.2020)

3.) World Health Organization (Coronavirus disease 2019) https://www.who.int/health-topics/coronavirus# tab=tab_1 (Zugriff am 27.03.2020)

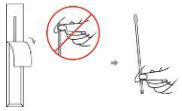
分步使用說明

選擇一個可以不受干擾地靜坐 20 分鐘的位置進行此測試。
進行測試前，讓測試盒和測試組件在室溫（10℃至 30℃）下放置。
☒在開始進行測試之前，請先洗手並擦乾。
☒請檢查印在盒子上的有效期不要超過有效期。
將所有提供的材料放在乾淨、乾燥和平坦的表面上。

☒取出裝有樣品提取緩衝液的樣品管，取下樣品管的密封膜。 然後將試管放入試管架中（試管架為外盒，見下圖。）

☒打開密封袋並取出測試盒。 將其正面朝上放在乾淨、乾燥且平坦的表面上。

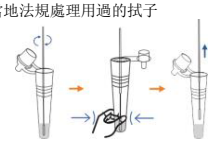
☒從容器中取出拭子，小心不要接觸柔軟的一端，即吸水尖端。.



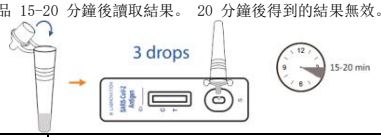
☒輕輕地將拭子的整個吸水尖端（約 1.5 厘米）插入您的鼻孔。 慢慢地將拭子繞著鼻孔內壁旋轉 5 次或更多次。 一定要收集拭子上可能存在的任何鼻腔引流物。 輕輕取出拭子。 使用相同的拭子在另一個鼻孔中重複步驟，然後慢慢取出拭子。

注意：如果在取樣過程中拭子棒斷裂採集，用新拭子重複採集樣本.

☒將拭子插入裝有預填充提取緩衝液的樣品管中。 充分混合併通過將管壁壓在拭子上來擠壓拭子 10-15 次.
取出時，將拭子前端靠在試管的內壁上滾動。 嘗試釋放盡可能多的液體。 根據適用的當地法規處理用過的拭子



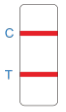
☒關閉樣品管的蓋子。
將 3 滴混合溶液垂直添加到測試盒的樣品孔 (S) 中。
添加樣品 15-20 分鐘後讀取結果。 20 分鐘後得到的結果無效。



⚠	放在兒童接觸不到的地方。 任何 18 歲以下的孩子都不應在沒有父母指導或專業說明的情況下進行測試。
☣	標本處理不當會導致生物感染。 避免直接接觸試劑或廢物。

檢測結果說明

陽性

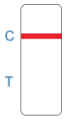


陽性

卡上出現兩條彩色帶。
一個條帶出現在控制區域 (C) 中，另一個條帶出現在檢測結果意味著您的樣本中可檢測到 SARS-CoV-2 抗原。 這些抗原的檢測表明感染新型冠狀病毒的可能性很高。

如果檢測結果呈陽性:
-目前懷疑感染了 COVID-19.
-立即聯繫醫生/家庭醫生或當地公共衛生部門
-遵守當地的自我隔離指南
-進行 PCR 確認測試
***注：線條粗細無關緊要;**
測試線 (T) 中的任何微紅色都應視為陽性結果。 陽性檢測結果必須通過PCR確認.

陰性

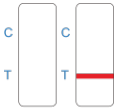


陰性

在控制區域 (C) 中僅出現一個彩色條帶。在測試區域 (T) 中沒有出現明顯的彩色條帶。 測試結果表明存在樣本中沒有或太少 SARS-CoV-2 抗原，目前可能沒有感染新型冠狀病毒。

如果檢測結果為陰性
-繼續遵守有關與他人接觸和保護措施的所有適用規則.
-即使檢測結果為陰性，仍可能存在感染。
-如有懷疑，請在 1 - 2 天后重複測試，因為無法在感染的所有階段準確檢測到冠狀病毒。
***注意：假陰性結果可能來自不正確的採樣、不正確的測試執行或樣本中的病毒不足。**

無效



無效

如果結果窗口中沒有控制線 (C) 或只有測試線 (T)，則測試未正確運行，結果無效。.

如果測試結果無效
-可能由不正確的測試性能引起
-重複測試
-如果檢測結果仍然無效，請聯繫醫生或 COVID-19 檢測中心。
***注意：請務必仔細按照測試說明進行操作。 您應該使用新樣品和新測試再次測試。**

廢棄處理

處置 根據適用的當地法規，可以將測試套件與普通生活垃圾一起處置。
***注意：完成所有步驟後，洗手或使用洗手液。**

香港代理

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製造商

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CE 1434 EC REP MedNet EC-REP GmbH Borkstrasse 10,48163 Muenster,Germany

Hotline: +49 251 3226669

符號說明

Manufacturer	LOT Batch number (see imprint on package)
Consult instruction for use	2 for single use
Contains sufficient for 1 tests	Store at 2°C - 30°C Do not freeze.
REF Order number	IVD In vitro diagnostic medical device (for external use)
Expire date (see imprint on package)	Keep dry
manufacturing date	STERILE R Sterilization by irradiation

Ref Ver. 1.0
2021-12-30

EN LABNOVATION

SARS-CoV-2 Antigen Rapid Test Kit

(Immunochromatography)

Self-testing

INSTRUCTION FOR USE

INTRODUCTION

In December 2019, the novel respiratory disease (COVID-19) caused by the coronavirus (SARS-CoV-2) was reported in Wuhan, China.1,2 According to WHO, most of the people infected with SARS-CoV-2 have mild to moderate respiratory diseases, fever, cough and recover without treatment. However, people with weak immune systems, such as the elderly or people with previous illnesses (e.g., cardiovascular disease, diabetes, chronic respiratory diseases, cancer, etc.) are more likely to develop a serious illness that can lead to the death of the infected person.[3]

This rapid test kit is intended for the qualitative detection of SARS-CoV-2 viral nucleocapsid antigens from human anterior nasal of secretion from individuals suspected of COVID-19. Positive result of the antigen test can be used for early isolation of patients with suspected infection, but it cannot be used as diagnosis basis of SARS-CoV-2 infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment. Further nucleic acid detection should be carried out for suspected population whose antigen test result is positive or negative.

This kit is an immunochromatography assay which detects SARS-CoV-2 nucleocapsid antigen in the samples with the help of the double antibody sandwich method. If there is virus antigen presence in the sample, it binds with the corresponding colloidal gold antibody. This complex "migrates" across the membrane and binds to the monoclonal antibody at the Test line (T). This creates a visible red line, which indicates a positive result. However, if the sample does not contain any antigen, then the complex cannot be formed and thus no reddish line forms in the Test line (T). Regardless of whether the sample contains antigen or not, a reddish line forms in the Control line (C).

KIT COMPONENTS

- 1 Test cassette
- 1 Sample tube with prefilled sample extraction buffer
- 1 Swab
- 1 Tube stand (in the outer box)
- 1 Instruction for use

Additionally required materials:

1 Timer

STORAGE & SHELF LIFE

The product should be stored at 2-30°C, and its shelf life is 24 months. The test cassette and sample extraction buffer should be used immediately after opening.

EVALUATION OF TEST RESULTS

To read the test results simply determine whether a line is present or absent at the Control (C) position. It does not matter how strong or weak a Control line (C) is.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

Analytical results for all samples from clinical studies:

SARS-CoV-2 Antigen Rapid Test	RT-PCR		TOTAL
	Positive	Negative	
Positive	306	0	306
Negative	8	650	658
TOTAL	314	650	964

Sensitivity: ＞ 95%*
Specificity: ＞99 %*
Total accuracy: ＞98% *
*95 % Confidence Interval.

2. Limit of detection

LOD concentration	30 $TCID_{50}$/mL

3. Cross-reactivity

With human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, adenovirus, human metapneumovirus, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, influenza A, type B Influenza, enterovirus, respiratory syncytial virus, rhinovirus, SARS coronavirus, MERS coronavirus, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumonia, pneumonia Chlamydia, Legionella pneumophila, etc. have no cross reaction.

4. Interfering

Common interfering substances in the sample, such as blood, mucin, and pus, have no effect on the test results.

WARNINGS AND IMPORTAN INFORMATION

- This kit is a qualitative detection, which cannot determine the exact content of antigen.
- The test is intended for use outside the body only.
- Not to be taken internally. Avoid sample buffer contact with skin and eyes.
- Protect from sunlight, do not freeze. Store in a dry place between 2°C and 30°C. Do not use after the expiration date printed on the package.
- Keep out of the reach of children. Any child under age 16 shouldn't perform the test without parental guidance, or professional aid.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by a physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components.
- The test should be carried out immediately or within one hour after opening the foil pouch (15-30°C, humidity <60%).
- Samples be processed as soon as possible after sample collection. If the test cannot be performed immediately, the sample should be stored in a sealed state, stored at 2~8°C for 8 hours, and stored below -20°C for 1 month. Long-term storage is not recommended.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- DISPOSAL The test kit can be disposed of with normal household waste in accordance with applicable local regulations.
- A negative result does not rule out the infection of a SARS-CoV-2 infection. Therefore, the test should not be used as the only reference for the clinical diagnosis. The result must be confirmed by the PCR.
- After use, rinse hands or, in case of contact with the buffer solution, the affected body parts thoroughly with water.
- If symptoms persist: Seek medical advice.

LITERATURE

1.) Nanshan Chen*, Min Zhou*, Xuan Dong*, Jieming Qu*,Fengyun Gong, Yang Han, Yang Qiu, Jingli Wang, Ying Liu,Yuan Wei, Jia'an Xia, Ting Yu, Xinxin Zhang, Li Zhang Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. LANCET. January 29, 2020.

2.) World Health Organization (Coronavirus disease 2019) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it(Zugriff am 27.03.2020)

3.) World Health Organization (Coronavirus disease 2019) https://www.who.int/health-topics/coronavirus# tab=tab_1 (Zugriff am 27.03.2020)

STEP-BY-STEP INSTRUCTION

Choose a location to do this test where it can sit UNDISTURBED for 20 minutes.

Let test cassette and test components stand at a room temperature (10℃ to 30℃) before performing the test.

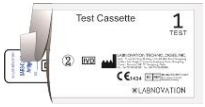
❶Wash and dry hands before you begin to perform the test.

❷Please check the expiration date printed on the BOX Do not use it beyond the expiration date.

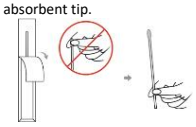
Lay all the supplied materials on a clean, dry and flat surface.

❸ Take sample tube with sample extraction buffer and remove the sealed film of the sample tube. Then place the tube in the tube stand (The tube stand is the outer box, see below.)

❹ Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.



❺Remove the swab from the container, being careful NOT to touch the soft end, which is the absorbent tip.

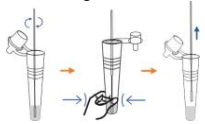


❻ Gently, insert the entire absorbent tip of the swab (around 1.5 cm) into your nostril. Slowly, rotate the swab in a circular against the inside walls of your nostril 5 times or more. Be sure to collect any nasal drainage that maybe present on the swab. Gently remove the swab. Use the same swab to repeat steps in the other nostril and slowly, take out the swab.

CAUTION: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

❼Insert the swab into the sample tube with prefilled extraction buffer. Mix well and squeeze the swab 10-15 times by compressing the w alls of the tube against the swab.

Roll the swab head against the inner wall of the tubes as you remove it. Try to release as much liquid as possible. Dispose of the used swab in accordance with applicable local regulations.



❽ Close the cap of the sample tube.

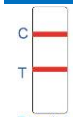
Add 3 full drops of the mixed solution vertically into the sample well (S) of the test cassette.

Read the result 15-20 minutes after adding the sample. Result got after 20 minutes is invalid.

⚠	Keep out of the reach of children. Any child under age 16 shouldn't perform the test without parental guidance, or professional aid.
☣	Improper handling of specimen can lead to biological infections. Avoid any direct contact with reagents or wastes.

INTERPRETATION OF RESULTS

Positive



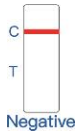
Two colored bands appear on the membrane.
One band appears in the control region **(C)** and another band appears in the test region **(T)**.
The test result means that SARS-CoV-2 antigen is detectable in your sample. The detection of these antigens indicate with a high probability of infection with the novel coronavirus.

In case of a positive test result:

- There is currently a suspicion of a COVID-19 infection.
- Immediately contact a doctor/family physician or the local public health department
- follow local guidelines for self-isolation
- have a PCR confirmatory test performed

***Note:** The thickness of the line is insignificant;
Any reddish color in the Test line (T) should be considered a positive result. The positive test result must be confirmed by PCR.

Negative



Only one colored band appears, in the control region **(C)**.
No apparent colored band appears in the test region **(T).**
The test result indicates that there is no or too little SARS-CoV-2 Antigen in the sample and at the current time there is probably no infection with the novel coronavirus.

If the test result is negative

- Continue to follow all applicable rules regarding contact with others and protective measures.
- Even if the test is negative, an infection may still be present.
- In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be detected accurately in all phases of an infection.

***Note:** False negative results can be from incorrect sampling, incorrect execution of the test, or insufficient virus in the sample.

Invalid

If there is no Control line **(C)** or only a Test line **(T)** in the result window, the test did not run correctly and the results are not valid.

In case of an invalid test result

- Possibly caused by incorrect test performance
- Repeat the test
- If test results remain invalid, contact a doctor or a COVID-19 testing centre.

***Note:** It is important that you carefully follow the instructions for the test. You should test again with a new sample and a new test.

DISPOSE USED TEST

DISPOSAL The test kit can be disposed of with normal household waste in accordance with applicable local regulations.

***Note:** After completing all steps, wash hands or use hand sanitizer.

MANUFACTURER

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INSTRUCTIONS OF SYMBOL

Manufacturer	LOT Batch number (see imprint on package)
Consult instruction for use	2 for single use
Contains sufficient for 1 tests	Store at 2°C - 30°C Do not freeze.
REF Order number	IVD In vitro diagnostic medical device (for external use)
Expire date (see imprint on package)	Keep dry
manufacturing date	STERILE R Sterilization by irradiation

Ref Ver.1.0
2021-12-30