SARS-CoV-2 Antigen Rapid Detection Kit
Instructions for Use

INTENDED USE

CAS-Envision SARS-CoV-2 Antigen Rapid Detection Kit is a colloidal gold immuno-chromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal vestibule swab or oral cavity and saliva swab specimen.
The test provides preliminary test results but cannot be used as the sole basis for treatment or other management decision. Positive results indicate the presence of viral antigens, but do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 infection. The results should be considered in the context of a personal recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay.

SUMMARY

Coronavirus is a large virus family, known to cause colds and more serious diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The new coronavirus is a new strain of coronavirus that has never been found in humans before. The International Committee on Classification of Viruses named the 2019 new coronavirus SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2), and the disease caused by it was named COVID-19 by the WHO.
The main transmission routes of SARS-CoV-2 are respiratory droplets and contact transmission. The transmission routes of Relative sensitivityaerosol and feces-oral still need to be further clarified.People infected with SARS-CoV-2 will have a range of symptoms, main symptoms include fever, fatigue and dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia and diarrhea were found. Some will develop pneumonia, and some will be more serious or even death. The fatality rate of the virus is about 2% to 4%, but this is a very early percentage and may change as more information becomes available. At the same time, this does not mean that it is not serious.

PRINCIPLE

CAS-Envision SARS-CoV-2 Antigen Rapid Detection Kit (Lateral Flow Method) is based on the principle of Immunochromatography sandwich for determination of SARS-CoV-2 antigen extracted from the nasal vestibule swab or oral cavity and saliva swab specimen.
After adding the extracted specimen into the test cartridges,the specimen will move along the nitrocellulose membrane to the end of the absorbent paper by capillary action. When the SARS-CoV-2 antigen level in the specimen reaches or exceeds the target threshold, the line T(Test Region) will be colored (pre-embedded with SARS-CoV-2 N protein monoclonal antibody),which indicates a positive result. another visible colored band may appear at the line C (Control Region), indicating that the test has been performed correctly. When the SARS-CoV-2 antigen level in the specimen is zero or below the target threshold, the T line is not colored , this indicates a negative result.

WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only;
2. Please follow the correct process for specimen collection and testing to avoid false or invalid results;
3. Do not reuse any kit components;
4. Please check the packaging before use. If it is damaged, poorly sealed or has expired, please do not use it;
5. Do not touch the reaction area of the test strip;
6. All specimens and used kits should be considered as a risk of infection;
7. After use, please dispose of the used test kit as biohazardous waste according to local requirements.

MATERIALS PROVIDED

	Kit size	1T/kits	5T/kits	25T/kits
Components	Foil bag (Contains 1 test cartridge and 1 desiccant pouch)	1	5	25
	Extraction tube with prefilled buffer	1	5	25
	Sterile swab	1	5	25
	Biohazard bag	1	5	25
	Instructions for Use	1	1	1
	QC card	/	1	1

STORAGE AND STABILITY

1. Store at 2~30℃;
2. The test cartridge should be used within 1 hour after taking out from the foiled pouch;
3. Keep away from sunlight, moisture and heat;
4. The product batch number, production and expiry date are printed on the outer packaging box. Under the correct storage conditions, the items in the kit are stable until the expiration date.

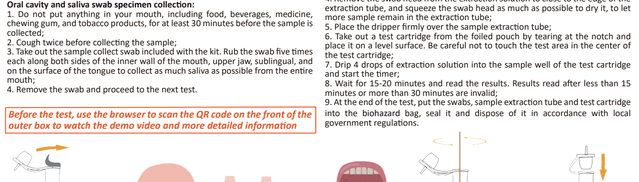
CAUTION BEFORE TEST

1. The test should be operated at room temperature (15-30℃).
2. Please read the instructions for use carefully before performing the test.
3. Do not read results after 30 minutes.

SPECIMEN COLLECTION

Specimens collection may significantly affect the test result. Specimens should be collected carefully follow the following methods or infection control procedures.
Choose one of the following two ways to collect specimens as required.
Nasal vestibule swab specimen collection:
1. Take out the sample collect swab included with the kit and carefully insert it into your nostrils 2-4cm until resistance is encountered;
2. Roll the swab against the nasal mucosa and wipe it back and forth 5 times to ensure adequate sample is collected;
3. Using the same swab to collect the sample from the other nostril with the same way;
4. Remove the swab and proceed to the next test.
Oral cavity and saliva swab specimen collection:
1. Do not put anything in your mouth, including food, beverages, medicine, chewing gum, and tobacco products, for at least 30 minutes before the sample is collected;
2. Cough twice before collecting the sample;
3. Take out the sample collect swab included with the kit. Rub the swab five times each along both sides of the inner wall of the mouth, upper jaw, sublingual, and on the surface of the tongue to collect as much saliva as possible from the entire mouth;
4. Remove the swab and proceed to the next test.

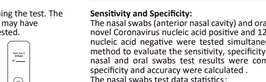
Before the test, use the browser to scan the QR code on the front of the outer box to watch the demo video and more detailed information



TEST PROCEDURE

1. Take out the extraction tubes(with prefilled buffer)of the tested quantity and place them on a suitable test tube rack with the opening facing up, tear off the aluminum film;
2. Put the collected sample swab into the extraction tube, press the swab head firmly on the tube wall, and rotate the swab at least 5 times to release the antigen from the swab head into the extraction solution;
3. Keep down the swab in the extraction tube and let it stand for 1 minute;
4. Remove the swab head from the extraction solution to close to the edge of the extraction tube, and squeeze the swab head as much as possible to dry it, to let more sample remain in the extraction tube;
5. Place the dripper firmly over the sample extraction tube;
6. Take out a test cartridge from the foiled pouch by tearing at the notch and place it on a level surface. Be careful not to touch the test area in the center of the test cartridge;
7. Drip 4 drops of extraction solution into the sample well of the test cartridge and start the timer;
8. Wait for 15-20 minutes and read the results. Results read after less than 15 minutes or more than 30 minutes are invalid;
9. At the end of the test, put the swabs, sample extraction tube and test cartridge into the biohazard bag, seal it and dispose of it in accordance with local government regulations.

RESULT INTERPRETATION



Positive Result
Colored bands appear at both test line (T) and control line (C) showing as following picture. It indicates a positive result for the SARS-CoV-2 antigen in the specimen.
Negative Result
Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antigen is zero or below the detection limit of the test.
Invalid Result
No visible colored band appear at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

REPORTING OF RESULTS

Positive Test:
Positive for the presence of SARS-CoV-2 antigen. Positive results indicate the presence of viral antigens, you have a very high probability of contracting SARS-CoV-2. But clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. You must immediately take the necessary quarantine measures and go to the local hospital for further diagnosis.

Negative Test:
Negative results are presumptive. You have a low probability of contracting SARS-CoV-2. But negative test results do not preclude infection. If you still suspect that you or your family members are infected with SARS-CoV-2, you can go to the local medical institution for further testing by molecular nucleic acid testing.

Invalid Test:
The invalid result indicates that this test is invalid. Please read the instruction carefully again and repeat the test. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.If repeated test results are still invalid, consult the kit seller.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient liquid volume, adequate membrane wicking and correct procedural technique.

PERFORMANCE VERIFICATION

Sensitivity and Specificity:
The nasal swabs (anterior nasal cavity) and oral saliva swabs of 118 patients with novel Coronavirus nucleic acid positive and 127 subjects with novel Coronavirus nucleic acid negative were tested simultaneously using the product and PCR method to evaluate the sensitivity, specificity and accuracy of the product; The nasal and oral swabs test results were compared with PCR, the sensitivity, specificity and accuracy were calculated .
The nasal swabs test data statistics：

Relative sensitivity	97.5%	115/118
Relative specificity	99.2%	126/127
Accuracy	98.4%	241/245

The oral saliva swabs test data statistics：

Relative sensitivity	95.8%	113/118
Relative specificity	98.4%	125/127
Accuracy	97.1%	238/245

Minimum detection limit:
Comparison test with The PCR kits，the LOD range finding was located as: 1:10000 titer of the contrived sampl(the Ct value = 34), which the three repeated tests result was 100% +(F). When 1:100000 titer of the contrived sample , the Ct value of 36.227 at which the result was +(F) and 67.7%. So ct value of 34 was confirmed as the LOD in nasal swabs sample.

Cross-reactivity:
Professional test, there is no cross-reaction between the pathogen samples listed in the table below and SARS-CoV-2 Antigen Rapid Detection Kit.

S.N.	Potential Cross Reactant	Concentration Tested	Cross Reactivity (Yse/ No)
1	Human coronavirus 299E	10 ug/mL	NO
2	Human coronavirus OC43	10 ug/mL	NO
3	Human coronavirus NL63	10 ug/mL	NO
4	Human coronavirus HKU1	10 ug/mL	NO
5	Human metapneumovirus	10 ug/mL	NO
6	Human parainfluenza virus 1	10 ug/mL	NO
7	Human parainfluenza virus 2	10 ug/mL	NO
8	Human parainfluenza virus 3	10 ug/mL	NO
9	Human parainfluenza virus 4	10 ug/mL	NO
10	MERS	10 ug/mL	NO

Interference:
Professional test, there is no interference between the pathogen samples listed in the table below and SARS-CoV-2 Antigen Rapid Detection Kit.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yse/ No)
1	Mycoplasma pneumoniae	50 ug/mL	NO
2	Avian Influenza(H7N9, H5N1)	5 ug/mL	NO
3	Influenza A(H1N1, H3N2)	5 ug/mL	NO
4	Influenza B	5 ug/mL	NO
5	Respiratory syncytial virus	50 ug/mL	NO
6	Staphylococcus aureus	10 ug/mL	NO
7	Epstein-Barr virus	30 ug/mL	NO
8	Mumps virus	10 ug/mL	NO
9	Varicella-zoster virus	10 ug/mL	NO
10	Bordetella pertussis	10 ug/mL	NO
11	Chlamydia pneumoniae	10 ug/mL	NO
12	Haemophilus influenza	10 ug/mL	NO
13	Legionella pneumophila	10 ug/mL	NO
14	Streptococcus pneumoniae	10 ug/mL	NO
15	Streptococcus pyogenes	10 ug/mL	NO
16	Mycobacterium tuberculosis	10 ug/mL	NO
17	Candida albicans	10 ug/mL	NO
18	Adenovirus	5 ug/mL	NO
19	Rhinovirus	10 ug/mL	NO
20	Enterovirus	10 ug/mL	NO
21	Normal nasal flush fluid	/	NO

Stability:
The three batches of products after 150 days of 37℃ thermal stability test, only in the 25pg/ml detection line and below appeared large fluctuations, other quality control concentration and negative performance are still stable, there is no obvious change, do es not affect the normal use of the product.According to the stability test data, the shelf life of the kit is more than 18 months.

LIMITATIONS OF PROCEDURE

1. This product can only be used to detect the N antigen of the SARS-CoV-2 in human nasal vestibule swab or oral cavity and saliva swab.
2. Positive test results do not rule out co-infections with other pathogens. Anegative test result does not rule out the possibility of infection with SARS-CoV-2.
3. Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-qPCR SARS-CoV-2 assay.
4. Using other non-provided consumables, such as swabs, extracts, etc., may cause false negative results.
5. Please follow the standard procedure. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.

HOOK EFFECT

Within the titer range of clinically positive samples of SARS-CoV-2 antigens, there is no hook effect in the test results of this product.

INDEX OF SYMBOL

IVD	*In Vitro* Diagnostic Use		See Instruction for Use
Σ	Tests per Kit		Manufacturing Date
LOT	Batch Number	EC REP	Authorized Representative
	Manufacturer		Do not reuse
	Expiry Date		Keep away from Sunlight
	Keep Dry	REF	Catalog #
2℃ 30℃	Store between 2~30℃		This Side Up

GENERAL INFORMATION

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EC REP
Riomavis S.L.
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新冠抗原(SARS-CoV-2)快速檢測試劑盒 使用說明書

預期用途

中科先見新冠抗原(SARS-CoV-2)快速檢測試劑盒(膠體金法)是一種基於膠體金免疫層析技術，用於定性檢測人鼻前庭拭子或口腔唾液拭子標本中新型冠狀病毒核衣殼抗原。
該檢測提供初步檢測結果，但不能作爲治療或其他管理決策的唯一依據。陽性結果提示存在病毒抗原，但不排除細菌感染或與其他病毒合併感染。陰性結果不排除新型冠狀病毒感染。應在個人近期接觸、病史以及是否有與新型冠狀病毒感染的肺炎相符的臨牀體徵和症狀的背景下考慮這些結果，並通過分子檢測得到證實。

產品介紹

冠狀病毒是一個大的病毒家族，已知會導致感冒和更嚴重的疾病，如中東呼吸綜合徵(MERS)和嚴重急性呼吸綜合徵(SARS)。新型冠狀病毒是一種從未在人類中發現的新型冠狀病毒。國際病毒分類委員會將2019年新型冠狀病毒SARS-CoV-2 (Severe Acute Respiratory Syndrome coronavirus)命名，由其引發的疾病被世界衛生組織命名爲COVID-19。
新型冠狀病毒的主要傳播途徑是空氣傳播和接觸傳播。相對少見的氣溶膠和糞口傳播途徑仍需進一步明確。感染新型冠狀病毒的人會出現一系列症狀，主要症狀包括髮燒、乏力和乾咳。少數病例出現鼻塞、流涕、咽痛、肌痛和腹瀉。患者會患上肺炎，有些人會較爲嚴重，甚至死亡。該病毒的致死率約爲2%至 4%，但這是一個非常早期的百分比，隨着獲得更多信息，可能會發生變化，這並不意味着它不嚴重。

检测原理

中科先見新冠抗原(SARS-CoV-2)快速檢測試劑盒(膠體金法)是基於免疫色譜夾層法原理，用於鼻前庭拭子或口咽拭子樣本中提取的新型冠狀病毒抗原。
將提取的樣品加入檢測卡後，樣品將因毛細管作用沿硝化纖維素膜移動到吸收端。當標本中的新型冠狀病毒抗原水平達到或超過目標閾值時，T線（檢測線）
將着色，表明檢測結果爲陽性。C線（質控線）出現另一個可見色帶，表明測試已正確進行。當標本中的新型冠狀病毒抗原水平爲零或低於目標閾值時，T線不染色，這表示檢測結果爲陰性。

警告和注意

1、本試劑盒僅供體外診斷使用;
2、請按照正確的流程進行標本採集和檢測，避免出現錯誤或無效的結果;
3、不要重複使用任何試劑盒組件;
4、使用前請檢查包裝。如損壞、密封不良或過期，請不要使用;
5、不要觸摸測試條的反應區域;
6、所有樣本和使用後的試劑盒均應被視爲有潛在感染風險。
7、使用後，請按照當地要求將使用過的檢測試劑盒作爲有害生物廢物處理。

試劑盒組成

	試劑盒尺寸	1人份	5人份	25人份
內容物	鋁箔袋（含1個檢測卡和一包乾燥劑）	1	5	25
	提取管（含樣本提取液）	1	5	25
	無菌拭子	1	5	25
	生物危害袋	1	5	25
	說明書	1	1	1
	合格證	/	1	1

存儲和穩定性

1、儲存於2～30℃;
2、測試盒從密封鋁箔袋中取出後，應在1小時內完成檢測;
3、避免陽光直射、潮溼環境和熱源;
4、外包裝盒上印有產品批號、生產和有效期。在正確的儲存條件下，試劑盒中的物品在保質期內是穩定的。

檢測前注意

1、試驗應在室溫(15-30℃)下進行。
2、請在進行測試前仔細閱讀使用說明。
3、請勿在30分鐘後閱讀結果。

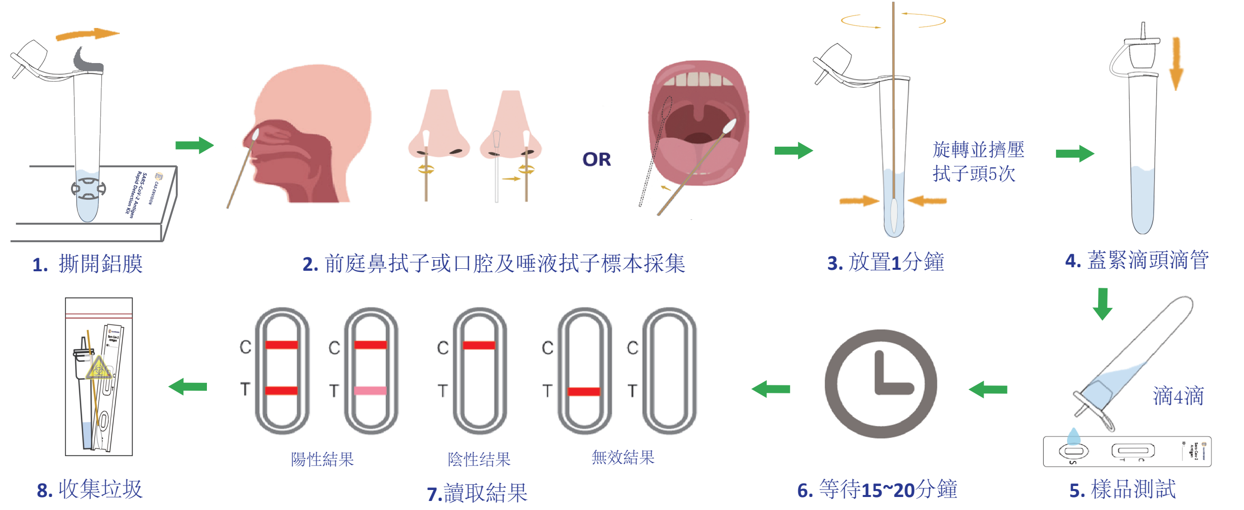
樣本採集

樣本採集可能對檢測結果有較大影響，應按照以下方法仔細收集標本。可根據需要選擇以下兩種採集方式中的一種。
鼻前庭拭子標本採集:
1、取出試劑盒附帶的樣品採集拭子，小心地將其插入鼻孔2-4cm，直到遇到阻力。
2、將拭子在鼻粘膜上滾動，來回擦拭5次，以確保收集到足夠的樣本。
3、用同一根拭子以相同的方法從另一個鼻孔採集樣本。
4、取出拭子，進行下一個測試。
口腔及唾液拭子標本採集:
1、在採樣前30分鐘，不要將任何東西放入嘴裏，包括食物飲料、藥物、口香糖和菸草製品。
2、採樣前咳嗽兩次。
3、取出試劑盒附帶的樣品採集拭子。用拭子頭沿口腔內壁、上頜、舌下及舌頭表面各擦五次，以儘可能多地收集整個口腔的唾液樣本。
4、取出拭子，進行下一個測試。

測試前，請使用瀏覽器掃描外盒正面的二維碼，觀看演示視頻和更詳細的信息

檢測流程

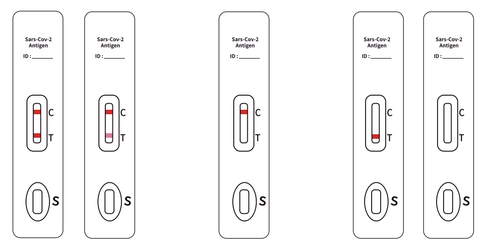
1、取出提取管(帶預充緩衝液)，將其置於外盒的孔中，開口朝上，撕開鋁膜。
2、將採集好的樣本拭子插入樣本提取管中，使樣本提取液浸沒過拭子頭，擠壓並攪拌拭子頭至少5次，使拭子中的抗原釋放到提取液中。
3.將拭子留在提取管中，靜置1分鐘。
4、將拭子頭抽出液體至接近樣本提取管口處，儘量擠壓拭子頭將其擠幹，使更多的樣本留在提取管內。之後將拭子丟棄至垃圾回收自封袋中。
5、將滴頭套緊在樣本提取管上。
6、撕下鋁膜袋，取出檢測卡，放置在水平桌面上。小心不要觸碰檢測卡中心的測試區域。
7、將4滴樣本提取液滴入測試卡的樣品孔中，啓動計時器。
8、等待15-20分鐘，然後讀取結果。不足15分鐘或超過30分鐘後讀取的結果是無效的。
9、測試結束後，將樣本提取管和檢測卡丟棄至垃圾回收自封袋中，封口後按照當地法律要求丟棄處理。



新冠抗原(SARS-CoV-2)快速檢測試劑盒

結果判讀

陽性結果:
檢測線(T)和質控線(C)都出現了彩色條帶，表示檢測樣本中新型冠狀病毒抗原呈陽性。
陰性結果:
彩色條帶只出現在質控線(C)處。表示檢測樣本中新型冠狀病毒抗原爲零或低於檢出限。
無效結果:
檢測結束後，質控線(C)處沒有可見的彩色帶。可能沒有正確地遵循檢測操作要求，或者試劑盒可能已經過期。建議對樣品進行復試。



陽性結果 陰性結果 無效結果

檢測結果的解釋

陽性結果:
新型冠狀病毒抗原檢測陽性結果表明樣本中存在病毒抗原，你已感染新型冠狀病毒的可能性非常高，但仍需要了解接觸史等其他診斷信息。陽性結果不排除細菌感染或與其他病毒合併感染。所檢測到的病原體可能不是疾病的唯一原因。您必須立即採取必要的隔離措施，併到當地醫院進行進一步診斷。
陰性結果:
陰性結果是假定的。你感染新型冠狀病毒的概率很低。但陰性結果並不排除感染。如果您仍然懷疑自己或家人感染了新型冠狀病毒，可以到當地醫療機構進行分子核酸檢測。
無效結果:
無效結果表明該次測試無效。請仔細閱讀說明，並重複測試。操作方法不正確或產品過期是檢測失效的最可能原因。如果重複檢測結果仍然無效，請聯繫試劑盒銷售商。

質量控制

測試中包含一個程序控制。出現在控制區域(C)中的有色線被認爲是內部過程控制。它確認了足夠的液體量，足夠的膜吸溼和正確的操作技術。

性能驗證

敏感性和特異性:
對118例新型冠狀病毒核酸陽性患者和127例新型冠狀病毒核酸陰性患者的鼻前庭拭子和口腔唾液拭子採用產物法和PCR法同時檢測，評價其敏感性。將鼻拭子、口腔拭子檢測結果與PCR檢測結果進行比較，計算敏感性、特異性和準確性。

鼻前庭拭子數據統計:

靈敏度	97.5%	115/118
特異性	99.2%	126/127
準確性	98.4%	241/245

口腔唾液拭子數據統計:

靈敏度	95.8%	113/118
特異性	98.4%	125/127
準確性	97.1%	238/245

最低檢測限:
使用PCR試劑盒進行比較測試，發現當樣品的滴度爲1：10000（Ct值爲34）時，三個重複測試結果爲100%陽性相符。滴度爲1：100000（Ct值爲36.227）時，三個重複測試結果67.7%陽性相符。因此，病毒樣本滴度1：100000確認爲產品的最低檢測限。

交叉反應:
經專業測試，下表所列病原體樣品與本產品之間沒有交叉反應。

序號	潛在的交叉反應物	測試濃度	交叉反應 (有/無)
1	冠狀病毒229E型	10 ug/mL	無
2	冠狀病毒OC43型	10 ug/mL	無
3	冠狀病毒NL63型	10 ug/mL	無
4	冠狀病毒HKU1型	10 ug/mL	無
5	人偏肺病毒	10 ug/mL	無
6	人副流感病毒I型	10 ug/mL	無
7	人副流感病毒II型	10 ug/mL	無
8	人副流感病毒III型	10 ug/mL	無
9	人副流感病毒IV型	10 ug/mL	無
10	中東呼吸綜合徵冠狀病毒	10 ug/mL	無

干擾反應:
經專業測試，下表所列病原體樣品與本產品之間沒有干擾反應。

	潛在的干擾物	測試濃度	干擾反應 (有/無)
1	肺炎支原體	50 ug/mL	無
2	禽流感病毒（H7N9，H5N1）	5 ug/mL	無
3	甲型流感病毒（H1N1，H3N2	5 ug/mL	無
4	）	5 ug/mL	無
5	乙型流感病毒	50 ug/mL	無
6	呼吸道合胞病毒	10 ug/mL	無
7	金黃色葡萄球菌	30 ug/mL	無
8	EB病毒	10 ug/mL	無
9	腮腺炎病毒	10 ug/mL	無
10	水痘帶狀皰疹病毒	10 ug/mL	無
11	百日咳桿菌	10 ug/mL	無
12	肺炎衣原體	10 ug/mL	無
13	流感嗜血桿菌	10 ug/mL	無
14	嗜肺軍團菌	10 ug/mL	無
15	肺炎鏈球菌	10 ug/mL	無
16	釀膿鏈球菌	10 ug/mL	無
17	結核分枝桿菌	10 ug/mL	無
18	白色念珠菌	5 ug/mL	無
19	呼吸道腺病毒	10 ug/mL	無
20	鼻病毒	10 ug/mL	無
21	腸道病毒	/	無

穩定性:
三批產品經過150天37℃熱穩定性試驗後，僅在25pg/ml及以下的檢測線出現較大的波動，其他質量控制濃度和陰性性能仍穩定，沒有明顯變化，不影響穩定性，因此認爲該試劑盒的保質期超過一年半。

檢測的侷限性

1、該產品僅可用於檢測人鼻前腔拭子或口腔唾液拭子中的新型冠狀病毒的N抗原;
2、陽性結果不排除與其他病原體合併感染。陰性結果不排除感染新型冠狀病毒的可能性。
3、與核酸檢測相比，已證明在症狀發作的前五天測試的敏感性降低;
4、使用其他未提供的物品，例如拭子，提取液等，可能導致錯誤的結果;
5、請遵循標準操作步驟進行操作。樣品採集不當、樣品存儲不當或試劑反覆凍融會影響測試結果。

鉤狀效應

新型冠狀病毒抗原臨牀陽性樣品的滴度範圍內，該產品的檢測結果無鉤狀效應。

符號及含義

IVD	用於體外診斷		詳見使用說明書
	測試/盒		生產日期
LOT	批號	EC REP	授權代表
	製造商		禁止重複使用
	有效期		保持陰涼
	保持乾燥	REF	目錄
2°C 30°C	儲存於2-30℃		此面朝上

一般信息

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