Glallergen

Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal Gold Immunochromatography)

- Nasal

English

【PRODUCT NAME】

Common name: Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal Gold Immunochromatography)

【SPECIFICATIONS】

1 Test/Kit, 5 Tests/Kit, 20 Tests/Kit

【ITENDED USE】

The COVID-19 Antigen Rapid Test Kit is intended for in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab from individuals who are suspected of COVID-19.

The novel coronaviruses (SARS-CoV-2) belong to the β genus. COVID-19 is an acute respiratory infectious disease. Based on the current epidemiological investigation, the incubation period is 1 to 14 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Positive results indicate the presence of viral antigens, 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. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, a confirmed with a molecular assay, if necessary, for patient management.

【PRINCIPLE】

The COVID-19 Antigen Rapid Test Kit is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. The test uses SARS-CoV-2 antibody (test line T) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. The burgundy-colored conjugate pad contains colloidal gold conjugated to anti- SARS-CoV-2 antibody conjugated with colloid gold (SARS-CoV-2 conjugates) and mouse IgG-gold conjugates. During the test, SARS-CoV-2 antigen in the specimen interacts with SARS-CoV-2 antibody conjugated with color microparticles making antigen-antibody labeled complex. This complex migrates on the membrance via capillary action until the test line, where it will be captured by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody. A colored test line (T) would be visible in the result window if COVID-19 antigens are present in the specimen. Absence of the T line suggests a negative result. The control line (C) is used for procedural control and should always appear if the test procedure is performed properly.

【MATERIALS PROVIDED】

NO.	Composition	For 1 Test/Kit	For 5 Tests/Kit	For 20 Tests/Kit
1	2019-nCoV Antigen Detection Card (sealed foil pouch)	1	5	20
2	Sample extraction buffer	1	5	20
3	Sterile swab	1	5	20
4	Tube stand	-	1	1

Note: 1. Reagents from different batches cannot be mixed use.

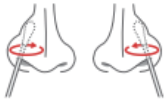
【STORAGE AND STABILITY】

1. The storage condition of this kit is 2-30℃ in a dry and dark place. The shelf life is 24 months.
2. Once open the pouch, the test should be used within one hour.
3. The LOT at the expiration date were printed on the labeling.

【SPECIMEN 】

Nasal swab specimen collection

Take the swab out of the package and carefully insert it into the nasal cavity 1.5cm until you feel a slight resistance. If you feel strong resistance or pain, do not insert the swab deeper. Under moderate pressure, move the swab in a circular motion along the inner wall of the nose for at least 15 seconds (approximately 4-6 times) to collect as many cells and mucus as possible. Repeat the sample with the same swab in the other nostril.



Sample transport and storage

The virus sampling solution or the sample extraction solution provided by this kit should be used for processing as soon as possible after specimen collection. If it cannot be processed immediately, the specimen should be stored in a dry, sterilized and strictly sealed plastic tube immediately. It can be stored for 8 hours at 2℃~8℃ or -70℃ can be stored for a long time.

【TEST PROCEDURE】

1. Preparation

Allow the test devices, reagents to equilibrate to room temperature (15-30℃) prior to testing.

2. Extraction

a) Tear off the sealing film of the extraction tube.

b) Insert the sampled swab into the solution in the sample extraction tube, rotate it close to the inner wall of the test tube about 10 times, Leave the swab in extraction buffer for 1 minute.

c) Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

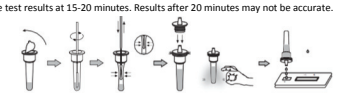
d) Install the cap onto the sample extraction tube tightly.

3. Test

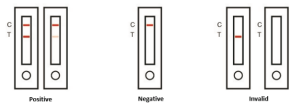
a) Open the pouch and remove the card. Place the card on a flat and level surface.

b) Add 4 drops (about 100μl) of the processed sample extract to the sample hole of the test card.

c) Read the test results at 15-20 minutes. Results after 20 minutes may not be accurate.



【INTERPRETATION OF RESULTS】



Positive

If two colored bands appear with one colored band in the Control Zone (C) and another in the Test Zone (T) within 15-20 minutes, the test result is positive. No matter how faint the colored band is in the Test Zone (T), the result should be considered as positive.

Negative

If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative.

Invalid

If no color line appears in the control area (C) within 15-20 minutes, the test is invalid.

【LIMITATIONS】

1. This product is only used to test the secretions of individual nasal swabs.
2. The accuracy depends on the sample collection process. Improper sample collection, storage, repeatedly frozen and thawed will affect the result.
3. The result of this product is for clinical reference only, and should not be used as the only basis for clinical diagnosis and treatment. The information of patient's symptoms, signs, history, other tests (especially pathogenic tests), treatment response and epidemiology are necessary to comprehensive consideration.
4. The presence of drugs in the samples such as high concentrations of nasal sprays will interfere with the results. If the result is suspicious, please retest.
5. Weak positive samples that have been heat-inactivated and treated with guanidine salt may cause false negative results.
6. The possibility of false negative results:

a) Improper operation procedures (sample collection, transfer, storage, processing, etc.) or the virus in the sample is below the detection limits.

b) Possible subtypes (mutant strains).

c) The antigen that are detected are not present during the stage of disease in which a sample is collected.

【PERFORMANCE CHARACTERISTICS】

1. When testing with enterprise references, meet the following standards:

1) Negative references compliance rate: Use the enterprise negative references for testing, and the negative references should be detected at least 20/20 (-/-).

2) Positive references compliance rate: Use the enterprise positive references for testing, and the positive references should be detected at least 5/5 (+/+).

3) Sensitivity references: Each detection item is tested with the corresponding minimum detection limit quality control serum. L1 and L2 results should be positive, and L3 should be negative.

4) Repeatability: Use enterprise precision references for testing, and the test results of repeatable references should be consistent.

2. Limit of detection

The study used cultured SARS-CoV-2 virus, which is β-propiolactone and heat inactivated and spiked into sample extract buffer. The limit of detection is 9.65 $TCID_{50}$/ml.

3. High-dose Hook effect

The Novel Coronavirus (2019-nCoV) Antigen Test Kit was tested up to 7×10^5 $TCID_{50}$/ml of inactivated SARS-CoV-2 and no high-dose hook effect was observed.

4. Cross reactivity

Cross reactivity was evaluated by testing 56 commensal and pathogenic microorganisms that may be present in the throat. Each of the organisms and virus were tested in the absence or presence of heat inactivated SARS-CoV-2 virus (265 $TCID_{50}$/ml), no cross-reactivity was seen.

No.	Crossing reacting substance	Strain	Concentration of cross-reacting substance	Result	
				Absence of SARS-CoV-2	Presence of SARS-CoV-2
1	Human Coronavirus	HKU1	2×10^5 $TCID_{50}$/mL	-	+
2		229E	2×10^5 $TCID_{50}$/mL	-	+
3		OC43	2×10^5 $TCID_{50}$/mL	-	+
4		NL63	2×10^5 $TCID_{50}$/mL	-	+
5		SARS	2×10^5 $TCID_{50}$/mL	-	+
6		MERS	2×10^5 $TCID_{50}$/mL	-	+
7	Adenovirus	Type 1	2×10^5 $TCID_{50}$/mL	-	+
8		Type 2	2×10^5 $TCID_{50}$/mL	-	+
9		Type 3	2×10^5 $TCID_{50}$/mL	-	+
10		Type 4	2×10^5 $TCID_{50}$/mL	-	+
11		Type 5	2×10^5 $TCID_{50}$/mL	-	+
12		Type 7	2×10^5 $TCID_{50}$/mL	-	+
13		Type 55	2×10^5 $TCID_{50}$/mL	-	+
14	Human Metapneumovirus (hMPV)	hMPV 3 Type B1/Peru2-2002	2×10^5 $TCID_{50}$/mL	-	+
15		hMPV 16 Type A1/IA10-2003	2×10^5 $TCID_{50}$/mL	-	+
16	Parainfluenza virus	Type 1	2×10^5 $TCID_{50}$/mL	-	+
17		Type 2	2×10^5 $TCID_{50}$/mL	-	+
18		Type 3	2×10^5 $TCID_{50}$/mL	-	+
19		Type 4A	2×10^5 $TCID_{50}$/mL	-	+
20	Influenza A	H1N1	2×10^5 $TCID_{50}$/mL	-	+
21		H3N2	2×10^5 $TCID_{50}$/mL	-	+
22		H5N1	2×10^5 $TCID_{50}$/mL	-	+
23		H7N9	2×10^5 $TCID_{50}$/mL	-	+
24	Influenza B	Yamagata	2×10^5 $TCID_{50}$/mL	-	+
25		Victoria	2×10^5 $TCID_{50}$/mL	-	+
26	Enterovirus	Type 68	2×10^5 $TCID_{50}$/mL	-	+
27		09/2014 isolate 4	2×10^5 $TCID_{50}$/mL	-	+
28	Respiratory syncytial virus	Type A	2×10^5 $TCID_{50}$/mL	-	+
29		Type B	2×10^5 $TCID_{50}$/mL	-	+
30	Rhinovirus	A16	2×10^5 $TCID_{50}$/mL	-	+
31		Type B42	2×10^5 $TCID_{50}$/mL	-	+
32	Chlamydia pneumoniae	TWAR strain TW-183	5×10^6 CFU/mL	-	+
33	Haemophilus influenzae	NCTC 4560	5×10^6 CFU/mL	-	+
34	Legionella pneumophila	Bloomington-2	5×10^6 CFU/mL	-	+
35		Los Angeles-1	5×10^6 CFU/mL	-	+
36		82A3105	5×10^6 CFU/mL	-	+
37	Mycobacterium tuberculosis	K	5×10^6 CFU/mL	-	+
38		Erdman	5×10^6 CFU/mL	-	+
39		HN878	5×10^6 CFU/mL	-	+
40		CDC1551	5×10^6 CFU/mL	-	+
41		H37Rv	5×10^6 CFU/mL	-	+
42	Streptococcus pneumonia	4752-98[Maryland(D1)6B-17]	5×10^6 CFU/mL	-	+
43		178[Poland 23F-16]	5×10^6 CFU/mL	-	+
44		262[CIP 104340]	5×10^6 CFU/mL	-	+
45		Slovakia 14-10[29055]	5×10^6 CFU/mL	-	+
46	Streptococcus pyrogens	Typing strain T1[NCIB11841, SF 130]	5×10^6 CFU/mL	-	+
47	Bordetella pertussis	NCCP 13671	5×10^6 CFU/mL	-	+
48	Mycoplasma pneumoniae	Mutant 22	5×10^6 CFU/mL	-	+
49		FH strain of Eaton Agent [NCTC 10119]	5×10^6 CFU/mL	-	+
50		M129-B7	5×10^6 CFU/mL	-	+
51	Pneumocystis jirovecii (PJP)	N/A	N/A	-	+
52	Pooled human nasal wash		N/A	-	+
53	Candida albicans	3147	5×10^6 CFU/mL	-	+
54	Pseudomonas aeruginosa	R. Hugh 813	5×10^6 CFU/mL	-	+
55	Staphylococcus epidermidis	FDA strain PCI 1200	5×10^6 CFU/mL	-	+
56	Streptococcus salivarius	S21B [IFO 13956]	5×10^6 CFU/mL	-	+

5. Interference

There was no interference for potential interfering substances listed below.

1) Exogenous factor

No	Exogenous factor	Interfering substance	Test conc
1	Nasal sprays or drops	Phenylephrine	128μg/ml
2		Oxymetazoline	128μg/ml
3		Saline Nasal Spray 10%	10%(V/V)
4	Nasal corticosteroids	Dexamethasone	2μg/ml
5		Flunisolide	0.2μg/ml
6		Triamcinolone acetonide	0.2μg/ml
7		Mometasone	0.5μg/ml
8	Throat lozenges	Strepsils (flurbiprofen 8.75mg)	5%（w/v,50mg/ml)
9		Throat candy	5%（w/v,50mg/ml)
10	Oral anesthetic	Anbesol (Benzocaine 20%)	5%(V/V)
11	Anti-viral drugs	α-Interferon-2b	0.01μg/ml
12		Zanamivir（influenza)	2μg/ml
13		Ribavirin（HCV)	0.2μg/ml
14		Oseltamivir（influenza)	2μg/ml
15		Peramivir（influenza)	60μg/ml
16		Lopinavir（HIV)	80μg/ml
17		Ritonavir	20μg/ml
18		Arbidol（influenza)	40μg/ml
19	Antibiotic	Levofloxacin Tablets	40μg/ml
20		Azithromycin	200μg/ml
21		Ceftriaxone	800μg/ml
22		Meropenem	100μg/ml
23	Antibacterial systemic	Tobramycin	128μg/ml
24	Other	Mucin: bovine submaxillary gland, type	100μg/ml
25		Biotin	100μg/ml
26	antihistamine drug	Diphenhydramine Hydrochloride	2μg/ml
27		Loratadine	40μg/ml

2) Endogenous factor

No	Exogenous factor	Interfering substance	Test conc
1	Autoimmune disease	Human anti-mouse antibody, HAMA	800ng/ml
2	Serum protein	Whole Blood(human), EDTA, anticoagulated	10%(w/w)

6. Clinical performance

Nasal swab specimen

To estimate the clinical performance between the Novel Coronavirus (2019-nCoV) Antigen Test Kit and the RT-PCR comparator, 210 samples were collected. The result is below:

COVID-19 Antigen	RT-PCR		Total
	Positive	Negative	
Positive	102	1	103
Negative	6	101	107
Total	108	102	210

Sensitivity (PPA)=94.44% (102/108), (95%CI:90.12%-98.76%)
Specificity (NPA)=99.02% (101/102), (95%CI: 97.11%-100%)
Total consistency=96.67% (203/210), (95%CI:94.24%-99.09%)

【WARNINGS AND PRECAUTIONS】

1. For in vitro diagnostic use only.
2. Please read the instruction manual carefully and strictly follow the methods and steps to perform the test.
3. This product is a qualitative detection; results cannot be used as a quantitative basis.
4. Do not use beyond the expiration date.
5. Test is for single use only. Do not re-use under any circumstances.
6. Due to the different sample titer, the red test line will show different shades of color, which are all represented positive results. The test line color shades are not applicable for determining the level of antigen titer in the sample.
7. Cold temperature preserved sample should be equilibrated to room temperature and mix thoroughly before testing.
8. Pay attention to safety measures during operation, such as protective clothing and gloves.

【INDEX OF SYMBOLS】

	Keep dry		Keep away from sunlight	IVD	In vitro diagnostic use
	Manufacturer	EC REP	Authorized representative		Date of manufacture
LOT	Batch number	2℃ ~30℃	Store between 2-30°C		Expiry Date
	Do not use if package is damaged		See instructions for use	REF	Catalogue number
	Do not re-use	Σ	Contains sufficient for <n> tests	CE	CE mark

【BASIC INFORMATION】

Glallergen CO., Ltd.
Address: North side of the third floor of No. 6 factory building, No. 1 Xinxing Road, Wuqing Development Zone, Tianjin
Contact: 86-22-82939117

EC REP
Osmunda Medical Technology Service GmbH
Address: Treskowallee 108, 10318 Berlin, Germany
Contact: 0049-30-81865123

Version 1.0 Date:1. December 2021

Glallergen

新型冠狀病毒（2019-nCoV）抗原檢測試劑盒

CE

（膠體金免疫層析法）說明書

【產品名稱】

通用名稱：新型冠狀病毒（2019-nCoV）抗原檢測試劑盒（膠體金免疫層析法）

【規格】

REF 600010

1 人份/盒，5 人份/盒，20 人份/盒。

【預期用途】

本試劑盒適用於體外定性檢測人前鼻拭子樣本中的新型冠狀病毒（2019-nCoV）抗原含量，判定患者是否感染新型冠狀病毒（2019-nCoV）。

新型冠狀病毒屬於 β 屬的冠狀病毒。新型冠狀病毒肺炎是急性呼吸道傳染病，人群普遍易感。目前所見傳染源主要是新型冠狀病毒感染的患者，無症狀感染者也可能成為傳染源。基於目前的流行病學調查，潛伏期 1-14 天，多為 3-7 天。以發熱、乾咳、乏力為主要表現。少數患者伴有鼻塞、流涕、咽痛、肌痛和腹瀉等症狀。陽性結果表明存在病毒抗原，但需要與患者病史和其他診斷資訊的臨床相關性來確定是否感染。 陽性結果不排除細菌感染或與其他病毒合併感染。 陰性結果不排除 2019-nCoV 感染，不應作為治療或患者管理決策（包括感染控制決策）的唯一依據。 應在患者近期接觸史、病史以及是否存在與 COVID-19 一致的臨床體征和症狀的背景下考慮陰性結果，如有必要，為患者進行分子檢測確認。

【檢驗原理】

COVID-19 抗原快速檢測試劑盒是基於雙抗體夾心技術原理的側向流免疫層析技術，在硝酸纖維素膜的檢測區包被有 2019-nCoV 抗體（測試線 T）和羊抗鼠 IgG（質控線 C）。結合墊含有與膠體金偶聯的抗 2019-nCoV 抗體（2019-nCoV 偶聯物）和小鼠 IgG-金偶聯物。檢測過程中，若待檢樣本中含有新型冠狀病毒（2019-nCoV）抗原，樣本中的 2019-nCoV 抗原與 2019-nCoV 抗體相互作用，形成抗原抗體複合物。由於層析作用，複合物沿著膜移動，在被檢測區將會被預包被的抗 2019-nCoV 單克隆抗體捕獲，在檢測區將顯示彩色測試線 (T)。游離的膠體金標記物繼續向前遷移，與質控區包被的羊抗鼠 IgG 結合，在質控區形成一條肉眼可見的條帶（質控線）。若待檢樣本中不含新型冠狀病毒（2019-nCoV）抗原，則不出現檢測線，僅出現質控線。

【主要組成成分】

序號	組成成分	規格		
		1 人份/盒	5 份/盒	20 人份/盒
1	2019-nCoV 抗原檢測卡	1	5	20
2	樣品提取液	1	5	20
3	拭子	1	5	20
4	管架	-	1	1

注：不同批號試劑中各組分不可混用。

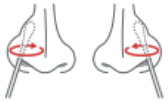
【儲存條件及有效期】

1. 本試劑盒儲存條件為 2℃～30℃乾燥、避光處保存，有效期 24 個月。
2. 一般情況下，試劑開封後應儘快使用。
3. 生產日期及失效日期見標籤。

【樣本】

前鼻拭子樣本收集

從包裝中取出拭子，小心地插入鼻腔 1.5 釐米，直到感覺到輕微的阻力。 如果您感到強烈的阻力或疼痛，請勿將拭子插入更深。在適度壓力下，沿鼻子內壁以圓周運動移動拭子至少 15 秒，以收集盡可能多的細胞和粘液。 在另一個鼻孔中用相同的拭子重複樣本。



樣本運輸和儲存

標本採集後應儘快使用本試劑盒提供的病毒採樣液或樣品提取液進行處理。 如不能立即處理，應立即將標本保存在乾燥、滅菌並嚴格密封的塑膠管中。 2℃~8℃可存放 8 小時，-70℃可長期存放。

【檢驗方法】

1. 準備

將待測樣本及所需試劑從儲存條件下取出，平衡至室溫(15-30℃)。

2. 提取

a) 撕掉提取管上的封口；

b) 將取樣的拭子插入樣品提取管中的溶液中，靠近試管內壁旋轉 10 次左右，靜置 1 分鐘，使樣品盡可能溶解在溶液中。

c) 在擠壓管子的側面以從拭子中提取液體的同時取出拭子。

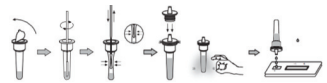
d) 用蓋子蓋住提取管。

3. 檢測

a）從包裝袋中取出試劑卡，平放於乾燥平面上；

b）將 4 滴（約 100μl）處理後的樣本提取物加入檢測卡的採樣孔；

c）15~20 分鐘判讀結果；20 分鐘後結果無效。



【檢驗結果的解釋】

1.陽性結果：出現兩條紅色/粉紅色條帶，質控線（C）和 COVID-19 抗原檢測線（T）。

2.陰性結果：僅出現一條質控線（C）。

3.無效結果：不出現質控線或出現一條檢測線，表明測試無效，需重新對樣本進行檢測。

【檢驗方法的局限性】

1. 本產品只用於個體前鼻拭子的測試。
2. 測試結果準確度取決於樣品採集過程。 樣本採集、儲存不當、反復凍融都會影響結果。
3. 本產品檢測結果僅供臨床參考，不應作為臨床診治的唯一依據，對患者的臨床管理應結合其症狀、體征、病史、其他實驗室檢查（尤其是病原學檢測）、治療反應及流行病學資訊綜合考慮。
4. 樣本中如果存在藥物，例如高濃度的鼻腔噴霧劑，則會干擾結果。如果結果可疑，請重新測試。
5. 經過熱滅活或胍鹽處理的弱陽性樣本可能會導致假陰性結果。
6. 假陰性結果存在下列可能：

1）操作程式不當（樣本採集、轉移、儲存、處理等）或樣本中的病毒低於檢出限；

2）病毒可能突變；

3）檢測到的抗原在收集樣本的疾病階段不存在。

【產品性能指標】

1. 使用企業參考品進行檢測時，需滿足以下標準：

1）陰性參考品符合率：陰性參考品符合率均應不低於 20/20(-/-)。

2）陽性參考品符合率：陽性參考品符合率均應為 5/5 (+ / +)。

3）靈敏度： L1、L2 應為陽性，L3 應為陰性。

4）重複性：結果應均為陽性且顯色度均一。

2. 檢出限

試驗中使用培養的 2019-nCoV 病毒（β-丙內酯），經過加熱滅活並加入樣品提取緩衝液中。 檢測限為 9.65 $TCID_{50}$/ml。

3. 高劑量鉤狀效應

對滅活的 2019-nCoV 進行了高達 7×10^5 $TCID_{50}$/ml 的檢測，未觀察到高劑量鉤狀效應。

4. 交叉反應

通過檢測可能存在於喉嚨中的 56 種共生微生物和病原微生物來評估交叉反應。 在不存在或存在熱滅活的 2019-nCoV 病毒 (265$TCID_{50}$/ml) 的情況下對每種生物體和病毒進行了檢測，未發現交叉反應。

序號	交叉反應物	品種	交叉反應物的濃度	結果	
				不存在 2019-nCoV	存在 2019-nCoV
1	人冠狀病毒	HKU1	2×10^5 $TCID_{50}$/mL	-	+
2		229E	2×10^5 $TCID_{50}$/mL	-	+
3		OC43	2×10^5 $TCID_{50}$/mL	-	+
4		NL63	2×10^5 $TCID_{50}$/mL	-	+
5		SARS	2×10^5 $TCID_{50}$/mL	-	+
6		MERS	2×10^5 $TCID_{50}$/mL	-	+
7	腺病毒	Type 1	2×10^5 $TCID_{50}$/mL	-	+
8		Type 2	2×10^5 $TCID_{50}$/mL	-	+
9		Type 3	2×10^5 $TCID_{50}$/mL	-	+
10		Type 4	2×10^5 $TCID_{50}$/mL	-	+
11		Type 5	2×10^5 $TCID_{50}$/mL	-	+
12		Type 7	2×10^5 $TCID_{50}$/mL	-	+
13		Type 55	2×10^5 $TCID_{50}$/mL	-	+
14	人偏肺病毒(hMPV)	hMPV 3 Type B1/Peru2-2002	2×10^5 $TCID_{50}$/mL	-	+
15		hMPV 16 Type A1/IA10-2003	2×10^5 $TCID_{50}$/mL	-	+
16	副流感病毒	Type 1	2×10^5 $TCID_{50}$/mL	-	+
17		Type 2	2×10^5 $TCID_{50}$/mL	-	+
18		Type 3	2×10^5 $TCID_{50}$/mL	-	+
19		Type 4A	2×10^5 $TCID_{50}$/mL	-	+
20	流感病毒 A	H1N1	2×10^5 $TCID_{50}$/mL	-	+
21		H3N2	2×10^5 $TCID_{50}$/mL	-	+
22		H5N1	2×10^5 $TCID_{50}$/mL	-	+
23		H7N9	2×10^5 $TCID_{50}$/mL	-	+
24	流感病毒 B	Yamagata	2×10^5 $TCID_{50}$/mL	-	+
25		Victoria	2×10^5 $TCID_{50}$/mL	-	+
26	腸道病毒	Type 68	2×10^5 $TCID_{50}$/mL	-	+
27		09/2014 isolate 4	2×10^5 $TCID_{50}$/mL	-	+
28	呼吸道合胞病毒	Type A	2×10^5 $TCID_{50}$/mL	-	+
29		Type B	2×10^5 $TCID_{50}$/mL	-	+
30	鼻病毒	A16	2×10^5 $TCID_{50}$/mL	-	+
31		Type B42	2×10^5 $TCID_{50}$/mL	-	+
32	肺炎衣原體	TWAR strain TW-183	5×10^6 CFU/mL	-	+
33	嗜血桿菌流感病毒	NCTC 4560	5×10^6 CFU/mL	-	+
34	嗜肺軍團菌	Bloomington-2	5×10^6 CFU/mL	-	+
35		Los Angeles-1	5×10^6 CFU/mL	-	+
36		82A3105	5×10^6 CFU/mL	-	+
37	結核分枝桿菌	K	5×10^6 CFU/mL	-	+
38		Erdman	5×10^6 CFU/mL	-	+
39		HN878	5×10^6 CFU/mL	-	+
40		CDC1551	5×10^6 CFU/mL	-	+
41		H37Rv	5×10^6 CFU/mL	-	+
42	肺炎鏈球菌	4752-98[Maryland(D1)6B-17]	5×10^6 CFU/mL	-	+
43		178[Poland 23F-16]	5×10^6 CFU/mL	-	+
44		262[CIP 104340]	5×10^6 CFU/mL	-	+
45		Slovakia 14-10[29055]	5×10^6 CFU/mL	-	+
46	化膿性鏈球菌	Typing strain T1[NCIB11841, SF 130]	5×10^6 CFU/mL	-	+
47	百日咳博多特氏菌	NCCP 13671	5×10^6 CFU/mL	-	+
48	肺炎支原體	Mutant 22	5×10^6 CFU/mL	-	+
49		FH strain of Eaton Agent [NCTC 10119]	5×10^6 CFU/mL	-	+
50		M129-B7	5×10^6 CFU/mL	-	+
51	肺孢子菌肺炎(PJP)	N/A	N/A	-	+
52	混合鼻炎沖洗劑		N/A	-	+
53	白色念珠菌	3147	5×10^6 CFU/mL	-	+
54	銅綠假單胞菌	R. Hugh 813	5×10^6 CFU/mL	-	+
55	表皮葡萄球菌	FDA strain PCI 1200	5×10^6 CFU/mL	-	+
56	唾液鏈球菌	S21B [IFO 13956]	5×10^6 CFU/mL	-	+

5. 干擾物質

下面列出的潛在干擾物質對本產品的檢測結果無影響。

1）外源性

序號	外源性	干擾物質	檢測濃度
1	鼻腔噴霧劑或滴劑	去氧腎上腺素	128ug/ml
2		羥甲唑啉	128ug/ml
3		生理鹽水噴鼻劑 10%	10%(V/V)
4	鼻用皮質類固醇	地塞米松	2ug/ml
5		氟尼縮松	0.2ug/ml
6		曲安奈德	0.2ug/ml
7		莫米松	0.5ug/ml
8	潤喉糖	氯比洛芬 8.75mg	5%（w/v,50mg/ml）
9		喉糖	5%（w/v,50mg/ml）
10	口服麻醉劑	苯佐卡因 20%	5%(V/V)
11	抗病毒藥物	α-干擾素-2b	0.01ug/ml
12		紮那米韋（流感）	2ug/ml
13		利巴韋林（HCV）	0.2ug/ml
14		奧司他韋（流感）	2ug/ml
15		帕拉米韋（流感）	60ug/ml
16		洛匹那韋（HIV）	80ug/ml
17		利托那韋	20ug/ml
18		阿比朵爾（流感）	40ug/ml
19	抗生素	左氧氟沙星片	40ug/ml
20		阿奇黴素	200ug/ml
21		頭孢曲松	800ug/ml
22		美羅培南	100ug/ml
23	全身抗菌藥物	妥布黴素	128ug/ml
24	其它	粘蛋白：牛頜下腺	100ug/ml
25		生物素	100ug/ml
26	抗組胺藥物	鹽酸苯海拉明	2ug/ml
27		氯雷他定	40ug/ml

2）內源性

序號	內源性	干擾物質	檢測濃度
1	自身免疫性疾病	人抗鼠抗體, HAMA	800ng/ml
2	血清蛋白	EDTA 抗凝的全血（人）	10%(w/w)

6. 臨床性能

臨床上收集了 210 個樣本，對比評估新型冠狀病毒 (2019-nCoV) 抗原檢測試劑盒和 RT-PCR 對比試劑盒之間的臨床性能，結果如下：

COVID-19 抗原	RT-PCR		總
	陽性	陰性	
陽性	102	1	103
陰性	6	101	107
總	108	102	210

靈敏性（PPA）：94.44% (102/108)，(95%CI:90.12%-98.76%)
特異性（NPA）：99.02% (101/102)，(95%CI: 97.11%-100%)
總一致性：96.67% (203/210)，(95%CI:94.24%-99.09%)

【注意事項】

1. 本試劑盒僅用於體外診斷。
2. 操作前應仔細閱讀說明書，嚴格按照說明書所規定的方法、步驟進行試驗操作。
3. 本產品為定性檢測，所得結果不可作為定量的依據。
4. 應使用在有效期內的試劑進行檢測。
5. 測試僅供一次性使用。 在任何情況下都不要重複使用。
6. 由於樣本滴度不同，檢測線的紅色線條會顯示出不同深淺的顏色，均表示陽性結果。檢測線顏色的深淺不能作為判定樣本中抗體滴度高低的依據。
7. 低溫保存的樣本應平衡至室溫並充分混勻後再進行檢測。
8. 操作時注意安全措施，如手套。

【標識的解釋】

	乾燥		避光
	生產企業	EC REP	歐洲授權代表
	生產日期		此日期前使用
LOT	批號		溫度限制
	包裝如破損，請勿使用		查閱使用說明
REF	編號	IVD	體外診斷試劑
	請勿重複使用	CE	CE 標誌
	含 <n> 人份		

【基本資訊】

註冊人/生產企業名稱：格林生物醫藥科技（天津）有限公司
住所：天津市武清開發區新興路 1 號 6 號廠房三層北側
聯繫方式：022-82939117
售後服務單位名稱：格林生物醫藥科技（天津）有限公司
聯繫方式：022-82939117
生產位址：天津市武清開發區新興路 1 號 6 號廠房三層北側