REF RNS92048B　新型冠狀病毒抗原檢測試劑盒鼻咽 TC
使用說明

產品名稱：新型冠狀病毒抗原檢測試劑盒鼻咽
製造商：深圳容金科技有限公司
COVID-19 抗原測試旨在供熟悉進行快速抗原測試的醫療保健專業人員或訓練有素的操作員使用。
本試劑盒為定性檢測，僅用於體外輔助診斷。

預期用途

新型冠狀病毒抗原檢測試劑盒鼻咽是一種體外診斷快速檢測試劑盒，用於使用免疫色譜法定性檢測人鼻咽、口咽拭子和鼻拭子樣本中的新型冠狀病毒核衣殼抗原。
陽性檢測結果表明存在病毒抗原，但需要進一步的臨床評估以確定感染狀態。 細菌感染或與其他病毒共同感染也可產生陽性結果。
陰性檢測結果並不能完全排除 COVID-19，應在存在臨床體徵和症狀的情況下考慮。
測試必須由醫療專業人員進行。

概括

COVID-19 是一種由新型冠狀病毒 SARS-CoV-2 引起的急性呼吸道傳染病。 新型冠狀病毒SARS-CoV-2屬於β屬，是一種有包膜的非分段RNA病毒。 目前，新型冠狀病毒感染的患者是主要傳染源，但無症狀感染者也可能成為傳染源。 根據目前的流行病學研究，潛伏期為 1 至 14 天，大多數情況下為 3 至 7 天。 主要表現為發熱、嗅覺和味覺喪失、全身乏力、乾咳。 在某些情況下，會出現流鼻涕、呼吸急促、肌肉疼痛和腹瀉。

原理

新型冠狀病毒抗原檢測試劑盒鼻咽是一種免疫層析膜測定法，它使用高度敏感的單克隆抗體來定性確定鼻咽拭子中 SARS-CoV-2 的核衣殼蛋白（N-Protein）抗原的存在。 當樣品滴入樣品孔時，樣品中的 SARS-CoV-2 抗原與針對 SARS-CoV-2 核衣殼蛋白的膠體金標記單克隆抗體結合。 這種複合物通過毛細作用在膜上遷移到測試區域 (T)，在那裡它被小鼠單克隆抗 SARS-CoV-2 捕獲。 如果樣本中存在 SARS-CoV-2 抗原，則 T 線中會出現一條彩色測試線。 作為程序控制，如果測試執行正確，控制區域 (C) 中始終會出現一條彩色線。

試劑

試劑膜含有與新型冠狀病毒單克隆抗體偶聯的膠體金； 反應膜含有新型冠狀病毒二抗和小鼠球蛋白多克隆抗體，這些抗體預先固定在膜上。

注意事項

- 僅用於體外診斷。
- 過期後請勿使用。
- 在打開使用之前，確保裝有測試裝置的箔袋沒有損壞。
- 在室溫 15 至 30°C 下進行測試。
- 懸掛樣品時戴上手套，避免接觸試劑膜和样品窗。
- 所有樣品和使用過的附件都應按照當地法規視為具有傳染性並丟棄。
- 避免使用帶血的樣本。

儲存和穩定性

將新型冠狀病毒抗原檢測試劑盒鼻咽儲存在室溫下或冷藏 (4-30°C)。 不要凍結。 所有試劑在其外包裝和緩衝液瓶上標明的失效日期之前都是穩定的。

標本採集和製備

1.標本採集：
應使用套件隨附的收集工具收集拭子樣本。 請按照以下詳細說明進行操作。 此測試不應使用其他收集工具。可以使用在一天中的任何時間收集的鼻咽拭子。
2.標本準備：
採集拭子樣本時，按照說明用試劑盒提供的緩衝液製備樣本。

組件

•新冠抗原測試卡　•無菌拭子　•樣品提取管　•使用說明

使用說明

測試前讓測試裝置、樣品、樣品提取緩衝液平衡至室溫 (15-30°C)。 在收集口咽拭子之前至少 10 分鐘內不要將任何東西放入口中，包括食物、飲料、口香糖、煙草、水和口腔清潔產品。

鼻咽拭子標本採集：


1.從包裝中取出棉籤。

2.將患者的頭部向後傾斜約 70°。


3. 將拭子平行於上顎插入鼻孔（不向上），直到遇到阻力或與患者耳朵到鼻孔的距離相等，表明接觸到鼻咽部。 （拭子的深度應等於從鼻孔到耳朵外開口的距離。）輕輕揉搓並滾動拭子。 將拭子留在原處幾秒鐘以吸收分泌物。

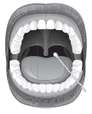

4.旋轉時慢慢取出拭子。 可以使用同一拭子從兩側採集樣本，但如果拭子的尖端被第一次採集的液體浸透，則無需從兩側採集樣本。 如果隔膜偏斜或堵塞導致難以從一個鼻孔獲取標本，請使用相同的拭子從另一個鼻孔獲取標本。

鼻拭子標本採集：


1. 輕輕旋轉棉籤，將拭子插入鼻孔約 2.5 厘米（1 英寸），直到鼻甲處遇到阻力。


2. 將拭子靠在鼻壁上旋轉數次，然後使用同一拭子在其他鼻孔重複。

口咽拭子標本採集：

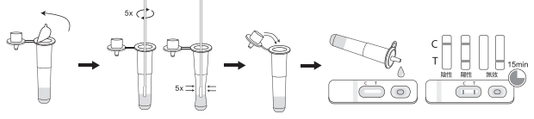

將拭子插入後咽和扁桃體區域。 用拭子擦拭扁桃體柱和口咽後部，避免接觸舌頭、牙齒和牙齦。

標本運輸和儲存：

不要將拭子放回原始棉籤包裝中。 應盡快處理新採集的標本，但不得遲於標本採集後一小時。 採集的標本可在2-8℃保存不超過24小時； 70℃長期保存，但避免反複凍融循環。

測試程序：

1.從樣品提取管上撕下鋁箔密封。
2.將取樣的拭子浸入樣本提取管中，使樣本提取緩衝液完全滲入拭子，旋轉並擠壓拭子5次，取出並丟棄拭子。
3. 將管蓋牢固地插入樣品提取管上。輕輕搖動提取管約 5 秒鐘，以確保樣品與提取緩衝液充分混合。
4.將2-3滴混合樣品垂直倒入測試卡中，啟動定時器。 在 15 分鐘時讀取結果。 不要在 20 分鐘後解釋結果。
**在 15 分鐘時讀取結果。 20 分鐘後的結果是無效的。



(1)　(2)　(3)　(4)

(請參考上圖)

陽性：出現兩條紅線。 控制區域 (C) 中出現一條紅線，測試區域 (T) 中出現一條紅線。 顏色的深淺可能會有所不同，但是只要有微弱的線條，就應該認為它是陽性的。
陰性：控制區域（C）中僅出現一條紅線，而測試區域（T）中沒有紅線。 陰性結果表明樣本中沒有新型冠狀病毒顆粒或病毒顆粒數量低於可檢測範圍。
無效：控制區域 (C) 中沒有出現紅線。 即使測試區域（T）上有一條線，測試也是無效的。 樣品量不足或程序技術不正確是控制線故障的最可能原因。 查看測試程序並使用新的測試設備重複測試。 如果問題仍然存在，請立即停止使用該測試套件並聯繫您當地的經銷商。

限制

• 新型冠狀病毒抗原檢測試劑盒鼻咽是一種用於定性檢測的急性期篩查試驗。採集的樣本可能含有低於試劑靈敏度閾值的抗原濃度，因此陰性檢測結果不能排除感染新型冠狀病毒。
• 新型冠狀病毒抗原檢測試劑盒鼻咽可檢測有活力和無活力的新型冠狀病毒抗原。測試性能取決於樣品中的抗原負荷，可能與對同一樣品進行的細胞培養無關。陽性測試並不排除可能存在其他病原體的可能性，因此，必須將結果與所有其他可用的臨床和實驗室信息進行比較才能做出準確的診斷。
• 如果樣本中提取的抗原水平低於檢測的靈敏度或獲得的樣本質量較差，則可能會出現陰性檢測結果。該檢測的性能尚未確定用於監測新型冠狀病毒的抗病毒治療。
• 陽性檢測結果不排除與其他病原體合併感染。
• 陰性檢測結果不用於判定除 SARS-Cov-2 以外的其他冠狀病毒感染。
• 與成人相比，兒童傳播病毒的時間往往更長，這可能會導致成人和兒童之間的敏感性差異。
• 如果標本中的抗原濃度低於檢測限或標本採集或運輸不當，可能會出現陰性結果，因此陰性檢測結果並不能消除感染SARS-Cov-2的可能性，並應通過病毒培養或 PCR 確認。

性能特點

臨床評估

在測試樣本中，有 105 例陽性和 155 例經 RT-PCR 證實為陰性 進行了臨床評估，以比較從新型冠狀病毒、新型冠狀病毒抗原檢測試劑盒鼻咽和 PCR 獲得的結果。 結果總結如下：

新型冠狀病毒抗原檢測試劑盒鼻咽 與 PCR

檢測方法		新型冠狀病毒核酸檢測試劑盒 (RT-PCR)		總結果
新型冠狀病毒抗原檢測試劑盒鼻咽鼻咽採樣	結果	陽性	陰性	
	陽性	100	3	103
	陰性	5	152	157
總結果		105	155	260

臨床敏感性 = 100/105= 95.23 %　(95%CI:85.56%-98.28%)
臨床特異性=152/155=98.71%　(95%CI:86.75%-99.42%)
準確性：(100+153)/ (100+2+5+153) *100%=97.31%

檢測方法		新型冠狀病毒核酸檢測試劑盒 (RT-PCR)		總結果
新型冠狀病毒抗原檢測試劑盒鼻咽口腔採樣	結果	陽性	陰性	
	陽性	101	3	104
	陰性	4	152	156
總結果		105	155	260

臨床敏感性 = 101/105= 96.19 %　(95%CI:85.25%-98.46%)
臨床特異性=152/155=98.06%　(95%CI:85.32%-99.65%)
準確性：(101+152)/ (101+3+4+152) *100%=97.31%

檢測限 (LoD)

新冠測試	REAGEN				
單位	$TCID_{50}$/mL				
濃度	$5.0X10^2$	$4.0X10^2$	$3.0X\ 10^2$	$2.0X10^2$	$1.0X10^2$
接近截止的 20 個重複的調用率	100(20/20)	100(20/20)	100(20/20)	100(20/20)	25(5/20)
每個病毒株的檢測限 (LoD)	$2.0\ X\ 10^2$ $TCID_{50}$/mL				

交叉反應

檢測結果低於下表中相應物質的濃度，對本試劑的陰性和陽性檢測結果沒有影響，不存在交叉反應。

類別	病原體名稱	濃度
新冠肺炎	新冠肺炎 HKU1	1.0 x 10^6copies/mL
	新冠肺炎 OC43	1.0 x 10^6copies/mL
	新冠肺炎 229E	1.0 x 10^6copies/mL
	新冠肺炎 NL63	1.0 x 10^6copies/mL
腺病毒	類型 1	1.0 x 10^6copies/mL
	類型 2	1.0 x 10^6copies/mL
	類型 3	1.0 x 10^6copies/mL
	類型 4	1.0 x 10^6copies/mL
	類型 5	1.0 x 10^6copies/mL
	類型 7	1.0 x 10^6copies/mL
	類型 55	1.0 x 10^6copies/mL
甲型流感	新型甲型 H1N1 流感病毒	1.0 x 10^6copies/mL
	H5N1	1.0 x 10^6copies/mL
	H3N2	1.0 x 10^6copies/mL
	H7N9	1.0 x 10^6copies/mL
	季節性 H1N1 流感病毒	1.0 x 10^6copies/mL
乙型流感	Yamagata	1.0 x 10^6copies/mL
	Victoria	1.0 x 10^6copies/mL
呼吸道病毒	Parainfluenza virus type 1	1.0 x 10^6copies/mL
	Parainfluenza virus type 2	1.0 x 10^6copies/mL
	Parainfluenza virus type 3	1.0 x 10^6copies/mL
病毒性肺炎	Respiratory syncytial virus type A	1.0 x 10^6copies/mL
	Respiratory syncytial virus type B	1.0 x 10^6copies/mL
	鼻病毒 A	1.0 x 10^6copies/mL
	鼻病毒 B	1.0 x 10^6copies/mL
	鼻病毒 C	1.0 x 10^6copies/mL
偏肺病毒	Human metapneumovirus	1.0 x 10^6copies/mL
腸道病毒	腸道病毒 A	1.0 x 10^6copies/mL
	腸道病毒 B	1.0 x 10^6copies/mL
	腸道病毒 C	1.0 x 10^6copies/mL
	腸道病毒 D	1.0 x 10^6copies/mL
嗜淋巴細胞病毒	EB virus	1.0 x 10^6copies/mL
麻疹病毒	Measles virus	1.0 x 10^6copies/mL
鉅細胞病毒	Human cytomegalovirus	1.0 x 10^6copies/mL
輪狀病毒	Rotavirus	1.0 x 10^6copies/mL
諾如病毒	Norovirus	1.0 x 10^6copies/mL
腮腺炎病毒	Mumps virus	1.0 x 10^6copies/mL
皰疹病毒	Herpes zoster virus	1.0 x 10^6copies/mL
支原體	Mycoplasma pneumoniae	1.0 x 10^6CFU/mL

干擾物質反應

使用新型冠狀病毒抗原檢測試劑盒鼻咽進行測試時，設備試劑與下表中列出的可能產生的潛在干擾物質之間沒有乾擾。

名稱	濃度	名稱	濃度
黏蛋白	120mg/dL	阿奇黴素	2mg/mL
人体的血	20% (v/v)	妥布黴素	1.2mg/mL
去氧腎上腺素	4mg/mL	組胺 二鹽酸鹽	10 mg/mL
羥甲唑啉	4mg/mL	洛匹那韋	1000mg/mL
氯化鈉	40mg/mL	利托那韋	120mg/mL
倍氯米松	40mg/mL	阿比朵爾	1400ng/mL
地塞米松	40mg/mL	頭孢曲松	80μg/mL
氟尼縮鬆	40μg/mL	美羅培南	400mg/mL
曲安奈德	4mg/mL	帕拉米韋	2mg/mL
布地奈德	4mg/mL	干擾素-α	1600IU/mL
莫米松	4mg/mL	利巴韋林	20mg/mL
氟替卡松	4mg/mL	奧司他韋	120ng/mL
扎那米韋	40mg/mL	左氧氟沙星	20μg/mL

符號			
符號	意義	符號	意義
IVD	體外診斷醫療器械		儲存溫度限制
	製造商	EC REP	歐洲的授權代表
	生產日期		有效期
	不能重複使用		參考使用說明
LOT	批號	CE	符合 EC 指令 98/79/EC 的要求

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REF RNS92048B

SARS-CoV-2 Antigen IVD Kit SWAB
Instructions for use

EN

Prodct name: SARS-CoV-2 antigen IVD kit SWAB
Manufacturer: Shenzhen Reagent Technology Co.,Ltd.
The COVID-19 Antigen test is intended for use by healthcare professionals or trained operators who are familiar with performing rapid antigen tests.
This kit is a qualitative test and is only for in vitro auxiliary diagnosis.

INTENDED USE

The SARS-CoV-2 Antigen IVD Kit SWAB is an in vitro diagnostic rapid test for the qualitative detection of novel coronavirus nucleocapsid antigens in human nasopharyngeal, oropharyngeal swab and nasal swab samples using an immunochromatographic method.
Positive test results suggest the presence of viral antigens, but further clinical evaluation is needed to determine infection status. Bacterial infection or co-infection with other viruses can also produce positive results.
Negative test results do not completely rule out COVID-19 and should be considered in the context of the presence of clinical signs and symptoms.
The test must be carried out by medical professionals.

SUMMARY

COVID-19 is an acute respiratory infectious disease caused by the novel coronavirus SARS-CoV-2. The novel coronavirus SARS-CoV-2 belongs to the β genus, which is an enveloped, non-segmented RNA virus. Currently, the patients infected with the novel coronavirus are the main source of infection, but asymptomatic infected people can also be a source of infection. Based on current epidemiological studies, the incubation period is 1 to 14 days, in most cases 3 to 7 days. The main manifestations are fever, loss of smell and taste, malaise and fatigue, and dry cough. In some cases, there is a runny nose, shortness of breath, muscle pain, and diarrhea.

PRINCIPLE

SARS-CoV-2 Antigen IVD Kit SWAB is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to qualitatively determine the presence of nucleocapsid protein (N-Protein) antigen from SARS-CoV-2 in direct nasopharyngeal swab. When the sample is dropped into the sample well, SARS-CoV-2 antigens in the sample are bound by colloidal gold-labeled monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2. This complex migrates on the membrane via capillary action to the test region (T), where it is captured by the mouse monoclonal anti-SARS-CoV-2. If the SARS-CoV-2 antigens are present in the sample, a colored test line becomes visible in the T line. To serve as a procedural control, a colored line always appears in the control region (C), if the test has performed properly.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus,and the polyclonal antibodies against the mouse globulin, which are pre- immobilized on the membrane.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store The SARS-CoV-2 antigen IVD kit SWAB at room temperature or refrigerated (4-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

SPECIMEN COLLECTION AND PREPARATION

1.Specimen collection:
The swab sample should be collected using the collection tools provided with the kit. Follow the instructions detailed below. No other collection tool should be used with this test. The swab collected at any time of the day can be used.
2.Specimen preparation:
When the swab sample is collected, follow the direction to prepare the specimen with buffer provided with the kit.

COMPONENTS

•SARS-Cov-2 Test Card •Sterile Swab •Sample Extraction Tube •Instruction for use

DIRECTIONS FOR USE

Allow the test device, specimen, sample extraction buffer to equilibrate to room temperature (15- 30°C) prior to testing. Do not place anything in the mouth including food, drink, gum, tobacco, water and mouth cleaning products for at least 10 minutes prior to collection of oropharyngeal swab.

Nasopharyngeal Swab Specimen Collection :

1.Remove the swab from the package.

2.Tilt patient's head back about 70°.

3.Insert the swab through the nostril parallel to the palate(not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. (Swab should reach depth equal to distance from nostrils to outer opening of the ear.) Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions.

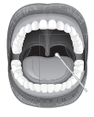
4.Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the tip of swab is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Nasal Swab Specimen Collection :

1.While gently rotating the swab, insert swab about 2.5 cm(1 inch) into nostril until resistance is met at turbinates.

2.Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

Oropharyngeal Swab Specimen Collection :



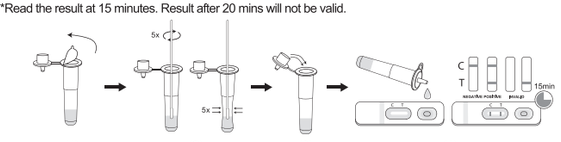
Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

Specimen Transport and Storage :

Do not return the swab to the original swab packaging. Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8 ℃ for no more than 24 hours; Store at-70 ℃ for a long time, but avoid repeated freeze-thaw cycles.

Testing Procedure :

1.Peel off the aluminum foil seal from a sample extraction tube.
2.Immerse the sampled swab into the sample extraction tube to make the sample extraction buffer completely penetrate the swab, rotate and squeeze the swab 5 times, take out and discard the swab.
3.Insert the tube cap firmly on the sample extraction tube.Gently shake the extraction tube for about 5 seconds to make sure sample mix well with extraction buffer.
4.Transfer 2-3 drops of mixed sample into the test card vertically, start the timer. Read the result at 15 minutes. Don't interpret the result after 20 minutes.
**Read the result at 15 minutes. Result after 20 mins will not be valid.



(Please refer to the illustration above)

POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.
NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Novel coroinavirus particles in the sample or the number of viral particles is below the detectable range.
INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

•The SARS-CoV-2 antigen IVD kit SWAB is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.
•The Novel Coronavirus SARS-CoV-2 antigen IVD kit SWAB detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present, therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
•A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if poor quality specimen is obtained.Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
•Positive test results do not rule out co-infections with other pathogens.
•Negative test results are not intended to rule in other coronavirus infection except the SARS- Cov-2.
•Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
•A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Under in the test sample, there are 105 positive and 155 negative confirmed by RT-PCR A clinical evaluation was carried out to compare the results obtained from Novel Coronavirus, SARS-CoV-2 Antigen IVD Kit SWAB and PCR. The results have been summarized below:

Table: SARS CoV-2 antigen IVD kit SWAB vs PCR

Method		COVID-19 Nucleic Acid Test Kit (RT-PCR)		Total Results
The SARS-CoV-2 antigen IVD kit SWAB Nasopharyngeal	Results	Positive	Negative	
	Positive	100	2	102
	Negative	5	153	158
Total Results		105	155	260

Clinical sensitivity = 100/105= 95.23 % （95%CI:85.56%-98.28%）
Clinical specificity =152/155=98.71% （95%CI:86.75%-99.42%）
Accuracy: (100+153)/ (100+2+5+153) *100%=97.31%

Method		COVID-19 Nucleic Acid Test Kit (RT-PCR)		Total Results
The SARS-CoV-2 antigen IVD kit SWAB Oropharyngeal	Results	Positive	Negative	
	Positive	101	3	104
	Negative	4	152	156
Total Results		105	155	260

Clinical sensitivity = 101/105= 96.19 % （95%CI:85.25%-98.46%）
Clinical specificity =152/155=98.06% （95%CI:85.32%-99.65%）
Accuracy: (101+152)/ (101+3+4+152) *100%=97.31%

Limit of detection (LoD)

COVID-19 Strain Tested	REAGEN				
Unit	$TCID_{50}$/mL				
Concentration	$5.0X10^2$	$4.0X10^2$	$3.0X\ 10^2$	$2.0X10^2$	1.0 X 10^2
Call rates of 20 replicates near cut-off	100(20/20)	100(20/20)	100(20/20)	100(20/20)	25(5/20)
Limit of detection (LoD) per Virus Strain	2.0 X 10^2 $TCID_{50}$/mL				

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Species	Name of pathogen	Concentration
Coronavirus	Coronavirus HKU1	1.0 x 10^6copies/mL
	Coronavirus OC43	1.0 x 10^6copies/mL
	Coronavirus 229E	1.0 x 10^6copies/mL
	Coronavirus NL63	1.0 x 10^6copies/mL
Adenovirus	Type 1	1.0 x 10^6copies/mL
	Type 2	1.0 x 10^6copies/mL
	Type 3	1.0 x 10^6copies/mL
	Type 4	1.0 x 10^6copies/mL
	Type 5	1.0 x 10^6copies/mL
	Type 7	1.0 x 10^6copies/mL
	Type 55	1.0 x 10^6copies/mL
Influenza A	Novel Influenza A (H1N1) Virus	1.0 x 10^6copies/mL
	H5N1	1.0 x 10^6copies/mL
	H3N2	1.0 x 10^6copies/mL
	H7N9	1.0 x 10^6copies/mL
	Seasonal H1N1 influenza virus	1.0 x 10^6copies/mL
Influenza B	Yamagata	1.0 x 10^6copies/mL
	Victoria	1.0 x 10^6copies/mL
Respiratory virus	Parainfluenza virus type 1	1.0 x 10^6copies/mL
	Parainfluenza virus type 2	1.0 x 10^6copies/mL
	Parainfluenza virus type 3	1.0 x 10^6copies/mL
Pneumonia virus	Respiratory syncytial virus type A	1.0 x 10^6copies/mL
	Respiratory syncytial virus type B	1.0 x 10^6copies/mL
Rhinovirus	Rhinovirus A	1.0 x 10^6copies/mL
	Rhinovirus B	1.0 x 10^6copies/mL
	Rhinovirus C	1.0 x 10^6copies/mL
Metapneumovirus	Human metapneumovirus	1.0 x 10^6copies/mL
Enterovirus	Enterovirus A	1.0 x 10^6copies/mL
	Enterovirus B	1.0 x 10^6copies/mL
	Enterovirus C	1.0 x 10^6copies/mL
	Enterovirus D	1.0 x 10^6copies/mL
Lymphophilic viruses	EB virus	1.0 x 10^6copies/mL
Measles virus	Measles virus	1.0 x 10^6copies/mL
Cytomegalovirus	Human cytomegalovirus	1.0 x 10^6copies/mL
Rotavirus	Rotavirus	1.0 x 10^6copies/mL
Norovirus	Norovirus	1.0 x 10^6copies/mL
Mumps virus	Mumps virus	1.0 x 10^6copies/mL
Herpes virus	Herpes zoster virus	1.0 x 10^6copies/mL
Mycoplasma	Mycoplasma pneumoniae	1.0 x 10^6CFU/mL

Interfering Substances Reaction

When tested using the SARS-CoV-2 antigen IVD kit SWAB, there was no interference between the device reagents and the Potential interference substances listed in below table that would create.
false positive or negative results for SARS- Cov-2 antigen.

Substance	Concentration	Substance	Concentration
Mucin	120mg/dL	Azithromycin	2mg/mL
Human Blood	20% (v/v)	Tobramycin	1.2mg/mL
Phenylephrine	4mg/mL	Histamine Dihydrochloride	10 mg/mL
Oxymetazoline	4mg/mL	Lopinavir	1000mg/mL
Sodium Chloride	40mg/mL	Ritonavir	120mg/mL
Beclomethasone	40mg/mL	Arbidol	1400ng/mL
Dexamethasone	40mg/mL	Ceftriaxone	80μg/mL
Flunisolide	40μg/mL	Meropenem	400mg/mL
Triamcinolone Acetonide	4mg/mL	Peramivir	2mg/mL
Budesonide	4mg/mL	Interferon-α	1600IU/mL
Mometasone	4mg/mL	Ribavirin	20mg/mL
Fluticasone	4mg/mL	Oseltamivir	120ng/mL
Zanamivir	40mg/mL	Levofloxacin	20μg/mL

SIMBOLO

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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CE

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