watmind

SARS-CoV-2 Antigen Rapid Test

Offers the Best Protection for Your Staff and Your Enterprise

Can accurately detect Omicron and Delta viruses

✓ Reasonably Priced ✓ High Accuracy

✓ Approved by European Commission ✓ CE Certified

✓ Nasal Sample Collection ✓ Sample Disposal Bag Included

Germany's Most Authoritative
Testing Institute
Paul Ehrlich Institute
Latest Test Result

Cq ⩽ 25 Sensitivity 100%
Cq 25-30 Sensitivity 95.7%

Scored Top Spots in Overall Sensitivity
Outstanding Results for Accuracy
Widely Used by German Enterprises

Hong Kong Distribution Agent:
Prunus Jade Creation Limited (Established in 2016)
www.jademedicals.com
Telephone: 5508-1331

watmind

新冠病毒快速測試

給您的員工和企業最好的保障

能準確檢測Omicron及Delta病毒

✓價錢合理 ✓準確度高 ✓歐盟認可 ✓CE

✓鼻拭子取樣 ✓內備樣品棄置袋方便安全

德國最權威檢測所
Paul Ehrlich Institute
最新測驗結果

Cq≤25 敏感度 100%
Cq 25-30 敏感度 95.7%
總敏感度前10名
成績斐然
德國巨企廣泛使用

香港代理:
Prunus Jade Creation Limited (成立於 2016 年)
www.jademedicals.com
電話: 5508-1331


warmind
SARS-CoV-2 Ag Self-test Kit (Nasal Swab)
IVD
CE 1434
1 test/box
www.warmind.com
BIOHAZARD
SPECIMEN BAG
SARS-CoV-2 Ag Self-test Kit
(Nasal Swab)
Instructions for Use (IFU)
REF LFA0401-1AE, LFA0401-5AE, LFA0401-25AE
For lay use
For in vitro diagnostic use only
For use with nasal swab
English
CE 1434
SARS-CoV-2 Ag

CERTIFICATE

EC Certificate No. 1434-IVDD-526/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Shenzhen Watmind Medical Co., Ltd
Kengzi Subdistrict, Pingshan District No.16-1, 8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzi Subdistrict, Pingshan District, 518118, Shenzhen, China

in vitro diagnostic medical devices
for self-testing

The list of medical devices covered by this certificate is provided in the Annex 1

In terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 29.12.2021 to 27.05.2025

The date of issue of the Certificate: 29.12.2021

The date of the first issue of the Certificate: 29.12.2021

CE 1434

Issued under the Contract No. MD-67/2021
Application No: 135/2021
Certificate bears the qualified signature.
Warsaw, 29/12/2021
Module A1
FBM-30-E_10

President
Aleksandra Kostrzewa

Digitally signed by Aleksandra Kostrzewa

President

SARS-CoV-2 Ag Self-test Kit (Nasal Swab) Instructions for Use (IFU)

wanmind

English

REF LFA0401-1AE, LFA0401-5AE, LFA0401-25AE

CE 1434

For lay use
For in vitro diagnostic use only
For use with nasal swab

This instruction for use (IFU) must be read carefully prior to use. Instruction for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

INTENDED USE

This kit is used for in vitro qualitative detection of Nucleocapsid (N) Protein antigen from SARS-CoV-2 in human nasal swab samples.
This kit is authorized for lay use with self-collected observed direct nasal swab samples from individuals aged 15 years or older or adult collected nasal swab samples from individuals aged four years or older.
Results are for the identification of SARS-CoV-2 Nucleocapsid Protein antigen. Antigen is generally detectable in nasal swab during the acute phase of infection. 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. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive and confirmation with a molecular assay. Negative results cannot exclude SARS-CoV-2 infection and should not be used as the sole basis for patient management 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.
Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally.
The SARS-CoV-2 Ag Test Kit is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from nasal swab, without viral transport media. The Kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLE OF THE PROCEDURE

The SARS-CoV-2 Ag Test Kit is a lateral flow immunoassay for the qualitative determination of Nucleocapsid Protein of SARS-CoV-2 virus in human nasal swab samples.
SARS-CoV-2 antibody is immobilized in the test region on nitrocellulose membrane. If the specimen contains SARS-CoV-2 antigen, during the assay specimen is allowed to react with the colored conjugate (SARS-CoV-2 antibody-colloidal gold conjugate); the mixture then migrates chromatographically on the membrane by the capillary action. An SARS-CoV-2 positive specimen produces a distinct color band in the test region, formed by the specific antibody antigen colored conjugate complex "(Au-SARS-CoV-2-Ab)-(SARS-CoV-2-Ag)- (SARS-CoV-2-Ab)". Absence of this colored band in the test region suggests a negative result. A colored band always appears in the control region serving as procedural control regardless of the specimen contains SARS-CoV-2 or not.

REAGENTS AND MATERIALS

Materials provided

Specification / Components	LFA0401-1AE 1 Test/kit, 1 test/carton	LFA0401-5AE 5 Tests/kit, 5 components/carton	LFA0401-25AE 25 Tests/kit, 25 components/carton
Test card with desiccant in a sealed foil pouch	1	5	25
Sample extraction solution	1	5	25
Disposable Sterile Swab (CE mark)	1	5	25
Dropper	1	5	25
Tube	1	5	25
Biohazard waste bag	1	5	25
Instruction for use	1	1	1

Materials required but not provided
• Clock, timer or stopwatch

PRECAUTIONS

1. For in vitro diagnostic use.
2. This product has been authorized only for the detection of nucleocapsid protein from SARS-CoV-2, not for any other viruses or pathogens.
3. Proper sample collection and handling are essential for correct results.
4. Do not touch swab tip when handling the swab sample.
5. Leave test card sealed in foil pouch until just before use. Do not use if pouch is damaged or open.
6. Do not use kit past its expiration date.
7. Do not mix test card and sample extraction solution from different kit lots.
8. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.

STORAGE AND STABILITY

Kits should be stored in 2℃–30℃, valid for 18 months, forbidden to store under 2℃ and avoid using expired products.
Manufacture date (MFD) and Expiry date (EXP): marked on the label.

TEST PROCEDURE

Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.
Before performing the test, you must read the instruction manual of the product completely, and please balance the test cards and sample extraction solution to room temperature (15℃–30℃) before the test. Do not perform the test until the reagent was equilibrated to room temperature (15℃–30℃) , so as to avoid affecting the accuracy of the experimental results.

Wash Your Hands before Testing
Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.

1. Open your test kit and you should have:

REF						
LFA0401-1AE	1	1	1	1	1	1
LFA0401-5AE	5	5	5	5	5	5
LFA0401-25AE	25	25	25	25	25	25

2. Open Pouch and place the card on a clean, dry, flat surface.
NOTE: Do not touch any parts on inside of the card.

3. Open the sample extraction solution sealed vial.

4. Drop all the liquid into the tube.

5. Open Swab.
Open swab package and take the swab out.
NOTE: Keep fingers away from swab end.

6. Sample Collection Process.
Do not use nasal spray within 10 minutes before collecting nasal swab.
Carefully insert the entire absorbent tip of the swab into the nostrils (about 1.5–2 cm). Firmly sample the nasal wall by rotating the swab in a circular path five times against the nasal wall. Slowly remove swab from the nostril. (This step should take approximately 15 seconds, ensuring to collect mucous and cells).
Repeat the same process with the same swab in the other nostril.

Note: Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for less than15 seconds is not a proper technique and may result in an insufficient sample.

7. Elution of samples from swab.
Place the swab into the sample tube and then completely immerse the swab head in the sample. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) and squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the sample extraction buffer.

8. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.

9. Discard the swab, cover the drip head and toggle tube for 5-6 times.

10. Dispense 100μL (2drops) of the specimen into the sample well ("S" well) on the card.

11. Wait 15 minutes.
NOTE: Do not disturb card during this time. False results can occur if the card is disturbed/moved or test results are read before 15 minutes.

12.Interpret the test results at 15–20 minutes.
Do not interpret the results after 20 minutes.

INTERPRETATION OF TEST RESULTS

There are three types of results possible.

1. Positive
Both red/purplish test band (T) and red/purplish control band (C) appear in window.

Note: The red/purplish band in the test area (T) can show the color depth. However, within the specified observation time, regardless of the color of the ribbon, even a very weak ribbon should be judged as a positive result.

In case of a positive test result:
- COVID-19 infection is currently suspected.
- Immediately contact physician/family physician or local health department.
- Follow local guidelines for self-isolation.
- Have a PCR confirmatory test performed.

2. Negative
Only the red/purplish control band (C) appears in window. The absence of a test band (T) indicates a negative result.

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

2. Invalid

There should always be a red/purplish control band (C) in the control region regardless of test result. If control band (C) is not seen, it indicates that the incorrect operation process or the kit has deteriorated or damaged.

Invalid

In case of an invalid test result:
- Possibly caused by incorrect test performance.
- Repeat the test.
- If test results remain invalid, contact a physician or COVID-19 testing center.

Handling instructions/Actions after the test result

1.The following reasons may cause false negative results:
1)Inappropriate sample collection, using other non-matching solution, sample transfer time it too long (more than half an hour), the volume of solution added when eluted the swab are too much, non- standardized elution operation, low virus titer in the sample, these may all lead to false negative results.
2)Mutations in viral genes may lead to changes in antigen epitope, leading to false negative results.
2.Analysis the possibility of false positive results:
1) Inappropriate sample collection, using other non-matching solutions, non-standardized elution operation, these may all lead to false positive results.
2) Cross-contamination of samples may lead to false positive results.
3) False negative result from nucleic acid.
3.Analysis the possibility of invalid result:
1) If the sample volume is not enough, the chromatography cannot be carried out successfully.
2) The test card would invalid if the package was broken. The packaging status must be carefully checked before use.

DISPOSE IN TRASH

After test is completed, all used test components should put in biohazard waste bag and seal it. The trash must be disposed of in your household waste or in accordance with local disposal regulations.

Wash Your Hands after Testing

After completing all test steps, wash your hands or use hand sanitizer.

LIMITATIONS

1.The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
2.Due to the limitation of the detection method, the negative result cannot exclude the possibility of infection. The positive result should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms and further diagnosis methods.
3.Positive test results do not rule out co-infections with other pathogens.
4.False negative results are more likely after 8 days or more of symptoms.
5.Negative results, from patients with symptom onset beyond 7 days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
6.This reagent can only qualitatively detect SARS-CoV-2 antigens in human nasal swab samples. It cannot determine the certain antigen content in the samples.
7.The accuracy of the test depends on the sample collection process. Improper sample collection will affect the test results.

8.False negative results may occur if swabs are stored in their paper sheath after specimen collection.
9.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
10.A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
11.Cross reactions maybe exist due to the N protein in SARS has a high homology with the new coronavirus (SARS-CoV-2). However, the interpretation of the results is not affected during seasons without SARS infection.

PERFORMANCE CHARACTERISTIC

1. Analytical Performance

1.1. Limit of detection

This kit was confirmed to detect 1.0×102 TCID50/mL of SARS-CoV-2 which was isolated from USA-WA1/2020, Gamma-Irradiated.

1.2. Cross reactivity

The following viruses and other Microorganism have no effect on the test results.

	Potential Cross-Reactant	Test Concentration	Test Result
Virus	Respiratory Syncytial Virus A	1.0×10^6 PFU/mL	No cross reaction
	Respiratory Syncytial Virus B	1.0×10^5 TCID$_{50}$/mL	No cross reaction
	Measles Virus	1.0×10^5 TCID$_{50}$/mL	No cross
	Adenovirus Type 3	1.0×10^5 TCID$_{50}$/mL	No cross
	Adenovirus Type 7	1.0×10^5 TCID$_{50}$/mL	No cross
	Human cytomegalovirus	1.0×10^5 TCID$_{50}$/mL	No cross
	Varicella-zoster virus	1.0×10^5 TCID$_{50}$/mL	No cross
	Human coronavirus OC43	1.0×10^5 TCID$_{50}$/mL	No cross reaction
	Human coronavirus 229E	1.0×10^5 TCID$_{50}$/mL	No cross reaction
	Rotavirus	1.0×10^5 TCID$_{50}$/mL	No cross
	Influenza B	1.0×10^5 TCID$_{50}$/mL	No cross
	Influenza A	1.0×10^5 TCID$_{50}$/mL	No cross
	Mycoplasma pneumonia	1.0×10^5 TCID$_{50}$/mL	No cross
	Epstein Barr Virus	1.0×10^5 TCID$_{50}$/mL	No cross
	MERS-CoV	1.0×10^5 TCID$_{50}$/mL	No cross
	HCoV-HKU1	1.0×10^5 TCID$_{50}$/mL	No cross
	Coronavirus 229E	1.0×10^5 TCID$_{50}$/mL	No cross
Other Microorganism	Staphylococcus aureus	1.0×10^6CFU/mL	No cross reaction
	Streptococcus pneumoniae	1.0×10^6CFU/mL	No cross reaction

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for SARS-coronavirus. SARS-coronavirus shows 90.51% homology across 100% of the nucleocapsid sequence. Therefore, cross-reactivity is highly likely.

1.3. Interfering Substances

The following interfering substances have no effect on the test results.

Substance	Active Ingredient	Concentration	Test Result
Hemoglobin	Blood	1.0% (v/v)	No interference
Nasal Spray	Oxymetazoline	15 % (v/v)	No interference
Sore Throat Nasal Spray	Phenol	10 % (v/v)	No interference
Throat Lozenge	Benzocaine, Menthol	0.15% (w/v)	No interference
Anti-viral Drug	Ribavirin	12.9 mg/mL	No interference
Antibacterial, Systemic	Tobramycin	4 mg/mL	No interference

1.4. High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.0 x 105 TCID50/mL of heat inactivated SARS-CoV-2 virus.

2. Clinical study

The clinical evaluation was performed to compare the results obtained with the SARS-CoV-2 Ag Test Kit and a comparative reverse transcriptase polymerase chain reaction test (Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit(PCR-Fluorescence Probing) manufactured by Sansure Biotech Inc). Among patients, there are 162 positive and 205 negative samples by RT-PCR confirmed. The presentation of the results of the SARS-CoV-2 Ag Test Kit is as follows:

CT value	Number of samples	2019-nCoV RT-PCR Results	SARS-CoV-2 antigen test result as compared to RT-PCR
≤30	99	positive	95.06% (94/99) (95% CI: 89.0%-97.98%)
>30	172	positive	72.67% (125/172) (95% CI: 65.54%-78.85%)
N/A	205	negative	98.54% (202/205) (95% CI: 96.01%-99.57%)

Days	Number of samples	2019-nCoV RT-PCR Results	SARS-CoV-2 antigen test result as compared to RT-PCR
≤7	166	positive	95.18% (158/166) (95% CI: 90.49%-97.67%)
>7	171	positive	82.46% (141/171) (95% CI: 76.38%-87.34%)
N/A	29	positive	75.86% (22/29) (95% CI: 57.96%-88.23%)

Sensitivity: 86.96% 95%CI: 80.65%-91.52% for CT values ≤36.
Sensitivity: 91.51% 95%CI: 86.65%-95.07% for onset of symptoms within 7 days.
Specificity: 99.02% 95%CI: 96.51%-99.73%

3. Human Factors Study

Wantmed conducted a human factor's study to evaluate whether home user patients or caregivers (lay user) could perform the test and accurately interpret test results from the SARS-COV-2 Ag Card.
In this study, a total of 50 lay users, age 18 and older with either good or corrected vision (farsean-sighted or wear bifocals) participated in a 30-minute session including an introduction, a product overview, and simulated use cases of SARS-COV-2 Ag Test Kit result interpretation. Participants were asked to read and interpret a panel of 7 different SARS-COV-2 Ag Card test results, including high positive, low positive, negative and invalid.
46/50 participants described the process of reading and interpreting the test card results as being easy. However, 4/50 of the participants commented that it was difficult to see some of the fainter line conditions.
A total of 350 trials were recorded in this study. Participants were able to perceive and interpret the results correctly for 327 trials, or 93.4% of the time. Positive results with stronger intensity lines were easier to read than the positive lines with less intensity.
After the human factor evaluation, participants were asked for their overall impressions of the instructional materials they were provided. Nearly all participants (49/50) thought the instructions were straightforward and easy to understand and follow.

4. Usability Study

Wantmed conducted a study to evaluate whether a home user can read the instructions and successfully perform the test steps for the SARS-COV-2 Ag Card test, including swab collection at home, and correctly interpreting the results.
200 home users, including individuals (n=100) and caregivers (n=100), participated in the study. Each individual or caregiver pair participated in a 30-minute session with an instructor. The usability evaluation session included one simulated use of the SARS-CoV-2 Ag Test Kit.
98.0% (196 out of 200) home users produced a valid result (all negative) and 4 participants produced an invalid result. (The causes of the invalid tests were insufficient amount of reagent added, and damage to the test strip). 196 out of 200 participants interpreted their test result correctly and 4 participants interpreted their result incorrectly (where they perceived a faint line in the sample window (as positive) when there was none (all results were verified by the study moderator).

The individual home use group completed 98.3% (2259/2300) of the total tasks/steps correctly. The caregiver home user group completed 97.6% (2245/2300) of the total tasks/steps correctly. The most common use errors observed during critical tasks included incorrectly swabs collection and contacting the test strip with the hands or with the surface.
98.5% (197 out of 200) of the home (individual and caregiver) participants had positive impressions of the SARS-CoV-2 Ag Test Kit. The test was perceived as being easy to use.

SYMBOLS

IVD	For In Vitro Diagnostic Use	REF	This symbol indicates the product's catalog number
	This symbol indicates that the product should be kept away from sunlight		This symbol indicates the product's Manufacturer
	This symbol indicates the product's Manufacturing Date		This symbol indicates that the productshould be Stored between 2 – 30°C
	This symbol indicates the product's Expiry Date		This symbol indicates that the product is for single use only. It is norm be re-used.
	This symbol indicates that you should consult the instructions for use	LOT	This symbol indicates the product's Batch Number
	This symbol indicates that the product should be kept dry	EC REP	EU Authorized Representative
CE 1434	CE Mark		

SARS-CoV-2 Ag Self-test Kit (Nasal Swab)

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CE 1434

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Swab

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CE 0197

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Date of Approval and Amendment of IFU: 2021-12-25

新型冠狀病毒（SARS-CoV-2）抗原自測試劑盒（鼻腔）使用說明書（IFU）

warmnd

中文繁体

REF LFA0401-1Ae, LFA0401-5Ae, LFA0401-25Ae

自測用
僅用於體外診斷
用於鼻腔標本

CE 1434

使用前必須仔細閱讀使用說明書（IFU），並嚴格按照說明書操作。如果不遵循使用說明，則不能保證測試結果的可靠性。

預期用途

該試劑盒用於人鼻腔拭子樣本中 SARS-CoV-2 抗原核衣殼蛋白（N 蛋白）的體外定性檢測。

本試劑盒經授權可用於 15 歲或以上的個人或 4 歲及以上由成年人收集的人鼻腔樣本的檢測。

檢測結果為 SARS-CoV-2 核衣殼蛋白抗原的鑒定提供了依據。在感染的急性期，抗原一般可在鼻腔拭子中檢測到。陽性結果表明存在病毒抗原，但需要進一步分析患者的臨床病史和其他診斷資訊，以確定患者的感染狀況。陽性結果不排除細菌感染或與其他病毒合併感染。所發現的病原體可能不是疾病的病因。

陰性結果可以作為分子檢測方法的進一步確認。陰性結果不能排除 SARS-CoV-2 感染，也不應作為患者管理決策的唯一標準。陰性結果應根據患者的最近接觸情況、病史和存在與 COVID-19 一致的臨床體徵和症狀來考慮。

檢測結果呈陰性的病人，如持續出現 COVID- 樣症狀或症狀加劇，應諮詢醫療保健提供者進一步的醫療建議。

概述

冠狀病毒是導致動物或人類疾病的一大類病毒家族。SARS-CoV-2 是一種 β 屬包膜單鏈 RNA 病毒。該病毒可導致輕微到嚴重的呼吸道疾病，並已在全球蔓延。

SARS-CoV-2 抗原檢測試劑盒採用快速側向免疫層析方法，直接從鼻腔中 SARS-CoV-2 抗原進行檢測，無需病毒增殖分離。該試劑盒用於進行 SARS-CoV-2 檢測研究的研究部分。

檢測原理

SARS-CoV-2 抗原檢測試劑盒用於人鼻腔樣本中 SARS-CoV-2 抗原核衣殼蛋白（N 蛋白）的定性檢測。

將 SARS-CoV-2 抗體包被在檢測區中的硝酸纖維素膜上。如果測試樣本含有 SARS-CoV-2 抗原，在測試過程中，初標色複合物（SARS-CoV-2 抗體 - 膠體金複合物）會與樣本中的 SARS-CoV-2 抗原發生反應，複合物通過毛細管作用在膜上進行色譜遷移。陽性樣本在測試區域會產生明顯的色帶，這是由抗原性抗體抗原夾心複合物 "(Au-SARS-CoV-2-Ab)-(SARS-CoV-2-Ag)-(SARS-CoV-2-Ab)" 形成的。在檢測區（T）沒有出現這條色帶表明結果為陰性，無論樣本是否含有 SARS-CoV-2 抗原，控制區（C）均應顯色。

提供的試劑和材料

主要組成成分

組成 \ 規格	LFA0401-1Ae 數量	LFA0401-5Ae 數量	LFA0401-25Ae 數量
含有乾燥劑的密封測試卡	1	5	25
樣本提取液	1	5	25
一次性無菌拭子(CE 0197)	1	5	25
滴管	1	5	25
滴頭	1	5	25
生物安全袋	1	5	25
說明書	1	1	1

需要但未提供的材料
- 時鐘、計時器或碼錶

注意事項

1. 僅供體外診斷。
2. 本產品僅限於定性檢測 SARS-CoV-2 的核衣殼蛋白，不用於檢測任何其他病毒或病原體。
3. 正確的樣品收集和處理是獲得正確結果的必要條件。
4. 處理拭子樣本時，不要觸碰拭子尖頭。
5. 在使用前檢測試劑卡密封包裝是否完整，如果包裝損壞或打開，請不要使用。
6. 不要使用過期的試劑盒。
7. 不要將不同試劑盒批次的測試卡和樣品提取液混合。
8. 所有套件元件都是一次性使用的產品。不要將多個樣本一起使用。不要重複使用使用過的測試卡。

儲存條件和效期

試劑盒應在 2° C ~ 30° C 下儲存於避光乾燥處保存，有效期為 18 個月。禁止在 2° C 下保存，避免使用過期的產品。

生產日期（MFD）和有效期（EXP）見包裝標籤。

檢測流程

在準備測試前不要打開包裝袋，應該在 1 小時內在低濕度環境（RH ≤ 70%）下進行一次性測試。

測試前必須先閱讀本產品說明書，測試前應使測試卡和樣品提取液平衡至室溫（18℃ ~26℃），不要只在試劑平衡到室溫（18℃ ~26℃）時才進行測試，以免影響檢測結果的準確性。

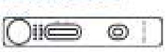
測試前清洗雙手

開始測試前用肥皂和清水徹底洗手，確保開始測試時手是乾淨的。

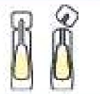
1. 打開試劑盒，其中應含有：

REF						
LFA0401-1Ae	1	1	1	1	1	1
LFA0401-5Ae	5	5	5	5	5	5
LFA0401-25Ae	25	25	25	25	25	25

2. 拆開鋁箔袋並將試劑卡放在乾淨、乾燥、平整的檯面上。
注意：不要觸碰試劑卡內部任何部位。



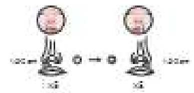
3. 打開樣本提取液密封條。



4. 將所有液體倒入滴管。

5. 打開拭子的包裝
打開拭子的包裝並取出拭子
注意：手指不要觸碰拭子尖端

6. 樣本採集過程
在收集鼻拭子前 30 分鐘內不要使用鼻噴霧劑。
①小心將棉簽的拭子頭放進鼻入鼻腔（大約 1.5~2cm），將棉簽沿著鼻腔內壁旋轉 5 次，緩慢將棉簽從鼻孔中取出（請回憶最大的區域 15 秒，然後收集足夠的鼻腔細胞）。
②使用同樣的拭子在另一個鼻孔重複同樣的過程。
注意：把塑拭棉棒保在鼻子內壁的一邊至少上旋轉或讓棉簽在鼻子內停留至少 15 秒鐘的採樣不當，可能導致樣品不足。



7. 將樣本從拭子上洗脫
將拭子放入裝有提取液的管中，然後將拭子頭完全浸入管中，將拭子沿著管壁旋轉至少 10 次（浸入提取液中），充分混合液體，並用手擠壓試管 5 次，以確保將拭子上的樣本完全洗脫到樣本提取液中。

8. 沿著管子內壁折斷拭子頭，使破碎部分都留在管子裡。

9. 丟棄拭子，蓋上滴頭，搖晃管 5-6 次。

10. 將 100µL(3 滴) 的樣品滴入卡片上的樣孔中。

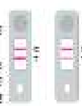
11. 等待 15 分鐘
注意：等待時間不要觸碰試劑卡，在 15 分鐘讀數之前，當觸碰 / 移動測試卡可能導致假陽性結果的發生。

12. 在 15-20 分鐘讀取測試結果，
不要讀取超過 20 分鐘後的測試結果。

檢驗結果的解釋

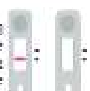
有三種可能的測試結果。

1. 陽性
在檢測視窗中，檢測區（T）和控制區（C）均出現紅色 / 紫色條帶
注意：測試區域（T）的紅色 / 紫色條帶可以顯示色彩深淺，但在規定的觀測時間內，無論色帶的顏色如何，即使色帶很弱，也應判定為陽性結果。
如果檢測結果為陽性：
- 目前懷疑是 COVID-19 感染。
- 立即聯繫醫生 / 家庭醫生或當地衛生部門。
- 遵守當地的自我隔離規則。
- 進行 PCR 確認試驗。



2. 陰性
在檢測視窗中，僅控制區（C）出現紅色 / 紫色條帶，沒有測試帶（T）表示結果為陰性。
如果出現陰性結果：
- 繼續遵守所有關於與他人接觸和保護措施的適用規則。
- 即使檢測結果呈陰性，當前也有可能存在感染。
- 如有懷疑，應在 1-2 天後重複檢測，因為新冠病毒不可能在感染的所有階段都被準確檢測到。

3. 無效
無論測試結果如何，在控制區域都應該有一個紅色 / 紫色的控制帶（C）。如果沒有看到控制帶（C），則表明操作過程不正確或試劑損壞。在這種情況下，請仔細閱讀說明並使用新的測試卡進行測試。如果問題仍然存在，請與當地供應商聯繫。
如果測試結果無效：
- 可能是測試操作不正確引起的
- 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。



1. 以下原因可能會導致假陽性結果：
1) 樣本採集不當，使用先前未開封的液體，樣本輸送錯誤過長（超過半小時），洗脫液加入的液滴量誤差大，洗脫操作不規范，樣本中的病毒抗原，這些都可能導致假陽性結果。
2) 病毒突變或其可能導致抗原表位改變，導致假陽性結果。
2. 假陰性結果的可能性分析：
1) 樣本採集不當，使用先前未開封的液體，洗脫操作不規范，這些都可能導致假陰性結果。
2) 樣品交叉污染可能導致假陽性結果。
3) 檢驗檢測結果假陰性。
3. 無效結果的可能性分析：
1) 如果樣本量不夠，層析過程不能成功進行。
2) 如果包裝破損，測試卡無效。使用前必須仔細檢查包裝狀況。

垃圾處理

測試完成後，所有使用過的測試部件應放入生物安全廢物袋中，並與家庭垃圾一起按照當地法規處理。

測試後清洗雙手

在完成所有測試步驟後，使用肥皂和清水洗手。

檢測方法的局限性

1. 本產品的檢測結果不能作為確診的依據，僅供臨床參考，應根據 RT-PCR 結果、臨床症狀、流行情況和進一步的臨床資料作出判斷。
2. 由於檢測方法的局限性，陰性結果不能排除感染的可能性，陽性結果不應被視為確診，判斷應結合臨床症狀和進一步診斷方法。
3. 陽性檢測結果不排除與其他病原體合併感染。
4. 當症狀出現 5 天或以上，檢測結果可能會出現假陰性。
5. 如果症狀發作超過 7 天的患者，陰性結果應作為推測的和分子檢測的確認，如有必要，可進行患者管理。
6. 該試劑只能定性檢測人體鼻腔樣本中的 SARS-CoV-2 抗原，它不能確定樣品中抗原的含量。
7. 測試的準確性取決於樣品採集過程，樣品採集不當會影響檢測結果。
8. 如果樣本採集後僅在拭子中放在保存中，可能會出現假陰性結果。
9. 陰性檢測結果不能用於排除其他非 sars 病毒或細菌感染。
10. 如果樣本中的抗原水平低於檢測限，則可能出現陰性檢測結果。
11. SARS 的 N 蛋白與新型冠狀病毒 (SARS- cov -2) 具有高度同源性，可能存在交叉反應，然而，在沒有 SARS 爆發的季節，對結果的解釋不會受到影響。

產品性能指標

1. 分析性能
1.1. 檢出限
經試驗證明，本試劑盒可檢測出經 USA-WA1/2020（Gamma-irradiated）分離出的 SARS-CoV-2 病毒 1.5×10^2 TCID50/mL。
1.2. 交叉反應
以下病原及其他物質對檢測結果無影響。

潛在交叉反應物		檢測濃度	檢測結果
病毒	呼吸道合胞病毒 A	1.0×10^5 PFU/mL	無交叉反應
	呼吸道合胞病毒 B	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	鼻病毒	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	腺病毒 3 型	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	腺病毒 7 型	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	人類巨細胞病毒	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	水痘－帶狀皰疹病毒	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	人類冠狀病毒 OC43	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	人類冠狀病毒 229E	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	麻疹病毒	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	流感病毒 B	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	流感病毒 A	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	支原體肺炎	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	EB 病毒	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	中東呼吸綜合征冠狀病毒	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	人冠狀病毒 HKU1	1.0×10^5 $TCID_{50}$/mL	無交叉反應
	冠狀病毒 NL63	1.0×10^5 $TCID_{50}$/mL	無交叉反應
其他微生物	金黃色葡萄球菌	1.0×10^6CFU/mL	無交叉反應
	肺炎鏈球菌	1.0×10^6CFU/mL	無交叉反應

利用美國國家生物技術資訊中心管理的 BLASTPs 工具對 SARS-冠狀病毒進行了內部分析。SARS- 冠狀病毒核衣殼蛋白中同源性為 90.52%，這時可能存在交叉反應。
1.3. 干擾物質
以下干擾物質對檢測結果無影響。

干擾物	活性成分	濃度	檢測結果
內源性	黏蛋白	2.0 % w/v	無干擾
噴鼻劑	鹽酸羥甲唑啉	12 % v/v	無干擾
鼻腔噴霧劑	苯酚	15 % v/v	無干擾
順勢療法	高山牛蒡，葡萄糖	0.15% w/v	無干擾
抗病毒藥物	利巴韋林	12.9 mg/mL	無干擾
抗菌藥物	妥布黴素	4.0 µg/mL	無干擾

1.4. 高劑量 HOOK 效應
當使用濃度高達 1.6×10^7 TCID50/mL 的滅活 SARS-CoV-2 病毒時，未觀察到高劑量鉤狀效應。

2. 臨床性能
臨床評價結果通過將 SARS-CoV-2 抗原檢測試劑盒與實時熒光聚合酶鏈反應檢測試劑盒（醫療器械技術公司生產的新型冠狀病毒 (2019-nCoV) 核酸診斷試劑盒 (PCR - 熒光探針法)）相比，經 RT-PCR 檢測，樣本中陽性 152 例，陰性 205 例。
根據不同的 CT 值 SARS-CoV-2 抗原檢測試劑盒臨床檢測結果如下：

CT 值	樣本數量	2019-nCoV RT-PCR 結果	SARS-CoV-2 抗原檢測 RT-PCR 檢測結果
≤ 30	93	陽性	85/93=91.40% (95%CI:83.93%-95.58%)
≤ 36	152	陽性	132/152=86.84% (95%CI:80.55%-91.32%)
> 40	205	陰性	203/205=99.02% (95%CI:96.51%-99.73%)

天數	樣本數量	2019 nCoV RT-PCR 結果	SARS-CoV-2 抗原檢測 RT-PCR 檢測結果
≤ 7	106	陽性	97/106=91.51% (95%CI:84.65%-95.47%)
≤ 14	131	陽性	115/131=87.79% (95%CI:81.08%-92.34%)
> 14	21	陽性	17/21=80.95% (95%CI:60.00%-92.33%)

靈敏度：86.84% (95%CI:80.55%-91.32%)，當 CT 值 ≤ 36
靈敏度：91.51% (95%CI:84.65%-95.47%，當症狀在 7 天內
特異性：99.02% (95%CI:96.51%-99.73%)。

3. 人為因素研究
生產商的公司開展了人為因素研究，以評估家庭用戶非專業或經驗人員（非專業用戶）是否能進行檢測，並準確解讀 SARS-COV-2 抗原檢測試劑卡的檢測結果。
在這項研究中，共有 50 名 15 歲及以上視力良好或矯正視力（近視 / 近視或其他視力缺陷）的非專業用戶參加了 30 分鐘的會議，包括介紹，查看試劑說明以 SARS-COV-2 抗原檢測試劑盒結果解釋的使用說明。參與者被要求閱讀和解釋 7 種不同的 SARS-COV-2 抗原檢測卡檢測結果，包括強陽性、弱陽性、陰性和無效。46/50 的參與者認為閱讀和解釋測試結果的過程很容易，然而，有 4/50 的參與者表示，他們對弱的線條感到困惑。
本研究共記錄 350 個試驗。在 327 次試驗中，參與者能夠正確地讀取和解釋結果，即 93.4% 的準確。陰性與較弱的陽性結果比強陽性的陽性結果更容易解釋。
在人為因素評估後，參與者被要求提供他們對所提供的說明材料的總體印象。幾乎所有的參與者 (49/50) 認為說明是直接的、容易理解和遵循。

4. 可用性研究
生產商的公司開展了一項研究，評估家庭用戶是否能夠遵循說明書並正確執行 SARS-COV-2 抗原檢測試劑卡的測試步驟，包括在家中採集拭子，並正確解讀結果。
200 名家庭用戶，包括個人 (n=100) 和經驗人員 (n=100)，參與了這項研究，每個人或經驗人員都參加了 30 分鐘的培訓課程，可用性評估會議包括一次獨立使用 SARS-COV-2 抗原檢測試劑盒。
98.0%(200 人中的 196 人) 的家庭用戶得到了有效的結果（全部陰性），4 名參與者得到了無效的結果，（無效試驗的原因是添加液體量不足，滴錯操作）。200 名參與者中有 196 人正確地解釋了他們的測試結果，4 名參與者錯誤地解釋了他們的結果（他們認為在樣本視窗中有一條微弱的線（為陽性），而實際上沒有（所有的結果都被研究負責人驗證了））。
個人家庭使用者正確完成了 98.2%(2258/2300) 的每個步驟 / 步驟，家庭經驗使用者正確完成了 97.6%(2245/2300) 的每個步驟 / 步驟，在關鍵步驟中觀察到的最常見的使用錯誤是不正確的拭子收集和兩手或未按要求試驗。
98.5%(200 人中的 196 人) 的家庭（個人和經驗人員）對 SARS-COV-2 抗原檢測試劑盒有積極印象，認為測試說明易於理解使用。

標誌的解釋

IVD	體外診斷醫療	[i]	查閱使用說明書
REF	產品編號	LOT	批次代碼
⧗	有效期		生產日期
②	不得二次使用		溫度極限
	避免光照		保持乾燥
	製造商	EC REP	歐盟授權代表
	腐蝕性	!	警告
	環境危害		

新型冠狀病毒（SARS-CoV-2）抗原自測試劑盒（鼻腔）

深圳華通源微醫療科技有限公司
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CE 1434
EC REP
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拭子

江蘇德檀醫療科技有限公司
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CE 0197
EC REP
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

說明書核准及修改日期：2021-12-25

掃描二維碼以觀看操作說明影片

SARS-CoV-2 Ag Self-test Kit (Nasal Swab) Instructions for Use (IFU)

wantmind

English

REF LFA6401-1AE, LFA6401-5AE, LFA6401-25AE

CE 1434

For lay use
For in vitro diagnostic use only
For use with nasal swab

This instruction for use (IFU) must be read carefully prior to use. Instruction for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

INTENDED USE

This kit is used for in vitro qualitative detection of Nucleocapsid (N) Protein antigen from SARS-CoV-2 in human nasal swab samples.
This kit is authorized for lay use with self-collected observed direct nasal swab samples from individuals aged 15 years or older or adult collected nasal swab samples from individuals aged four years or older.
Results are for the identification of SARS-CoV-2 Nucleocapsid Protein antigen. Antigen is generally detectable in nasal swab during the acute phase of infection. 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. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive and confirmation with a molecular assay. Negative results cannot exclude SARS-CoV-2 infection and should not be used as the sole basis for patient management 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.
Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally.
The SARS-CoV-2 Ag Test Kit is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from nasal swab, without viral transport media. The Kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLE OF THE PROCEDURE

The SARS-CoV-2 Ag Test Kit is a lateral flow immunoassay for the qualitative determination of Nucleocapsid Protein of SARS-CoV-2 virus in human nasal swab samples.
SARS-CoV-2 antibody is immobilized in the test region on nitrocellulose membrane. If the specimen contains SARS-CoV-2 antigen, during the assay specimen is allowed to react with the colored conjugate (SARS-CoV-2 antibody-colloidal gold conjugate); the mixture then migrates chromatographically on the membrane by the capillary action. As SARS-CoV-2 positive specimen produces a distinct color band in the test region, formed by the specific antibody antigen colored conjugate complex: "(Au-SARS-CoV-2-Ab)-(SARS-CoV-2-Ag)- (SARS-CoV-2-Ab)". Absence of the colored band in the test region suggests a negative result. A colored band always appears in the control region serving as procedural control regardless of the specimen contains SARS-CoV-2 or not.

REAGENTS AND MATERIALS

Materials provided

Specification / Ingredients	LFA6401-1AE 1 Test/box Components	LFA6401-5AE 5 Tests/box Components	LFA6401-25AE 25 Tests/box Components
Test card with desiccant in a sealed foil pouch	1	5	25
Sample extraction solution	1	5	25
Disposable Sterile Swab (CE 0197)	1	5	25
Dropper	1	5	25
Tube	1	5	25
Biohazard waste bag	1	5	25
Instruction for use	1	1	1

Materials required but not provided

- Clock, timer or stopwatch

PRECAUTIONS

1. For in vitro diagnostic use.
2. This product has been authorized only for the detection of nucleocapsid protein from SARS-CoV-2, not for any other viruses or pathogens.
3. Proper sample collection and handling are essential for correct results.
4. Do not touch swab tip when handling the swab sample.
5. Leave test card sealed in foil pouch until just before use. Do not use if pouch is damaged or open.
6. Do not use kit past its expiration date.
7. Do not mix test card and sample extraction solution from different kit lots.
8. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.

STORAGE AND STABILITY

Kits should be stored in 2℃–30℃, valid for 18 months, forbidden to store under 2℃ and avoid using expired products.
Manufacture date (MFD) and Expiry date (EXP) marked on the label.

TEST PROCEDURE

Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.
Before performing the test, you must read the instruction manual of this product completely, and please balance the test cards and sample extraction solution to room temperature (18℃–26℃) before the test. Do not perform the test until the reagent was equilibrated to room temperature (18℃–26℃), so as to avoid affecting the accuracy of the experimental results.

Wash Your Hands before Testing
Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.

1. Open your test kit and you should have:

REF	–					
LFA6401-1AE	1	1	1	1	1	1
LFA6401-5AE	5	5	5	5	5	5
LFA6401-25AE	25	25	25	25	25	25

1. Open Pouch and place the card on a clean, dry, flat surface.
NOTE: Do not touch any parts on inside of the card.

2. Open the sample extraction solution sealed vial.

4.Drop all the liquid into the tube.

5. Open Swab.
Open swab package and take the swab out.
NOTE: Keep fingers away from swab end.

6. Sample Collection Process.
Do not use nasal spray within 30 minutes before collecting nasal swab.
① Carefully insert the entire absorbent tip of the swab into the nostril (about 1.5–2 cm). Firmly sample the nasal wall by rotating the swab in a circular path five times against the nasal wall. Slowly remove swab from the nostril. (This step should take approximately 15 seconds, ensuring to collect mucous and cells).
② Repeat the same process with the same swab in the other nostril.
Note: Simply swirling the swab against one part of the inside of the nose or leaving the swab in the nose for less than10 seconds is not a proper technique and may result in an insufficient sample.

7. Elution of samples from swab.
Place the swab into the sample tube and then completely immerse the swab head in the sample. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) and squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the sample extraction buffer.

8. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.

9. Discard the swab, cover the drip head and waggle tube for 5-6 times.

10. Dispense 100μL (3drops) of the specimen into the sample well ("S" well) on the card.

11. Wait 15 minutes.
NOTE: Do not disturb card during this time. False results can occur if the card is disturbed moved or test results are read before 15 minutes.

12.Interpret the test results at 15–20 minutes.
Do not interpret the results after 20 minutes.

INTERPRETATION OF TEST RESULTS

There are three types of results possible.

1. Positive
Both red/purplish test band (T) and red/purplish control band (C) appear in window.
Note: The red/purplish band in the test area (T) can show the color depth. However, within the specified observation time, regardless of the color of the ribbon, even a very weak ribbon should be judged as a positive result.

In case of a positive test result:
- COVID-19 infection is currently suspected.
- Immediately contact physician/family physician or local health department.
- Follow local guidelines for self-isolation.
- Have a PCR confirmatory test performed.

2. Negative
Only the red/purplish control band (C) appears in window. The absence of a test band (T) indicates a negative result.

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

3. Invalid
There should always be a red/purplish control band (C) in the control region regardless of test result. If control band (C) is not seen, it indicates that the incorrect operation process or the kit has deteriorated or damaged.

In case of an invalid test result:
- Possibly caused by incorrect test performance
- Repeat the test
- If test results remain invalid, contact a physician or COVID-19 testing center.

Handling instructions/Actions after the test result

1. 1.The following reasons may cause false negative results:
   1)Inappropriate sample collection, using other non-matching solution, sample transfer time is too long (more than half an hour), the volume of solution added when eluted the swab are too much, non- standardized elution operation, low virus titer in the sample, these may all lead to false negative results.
   2)Mutations in viral genes may lead to changes in antigen epitope, leading to false negative results.
2. Analysis the possibility of false positive results:
   1) Inappropriate sample collection, using other non-matching solutions, non- standardized elution operation, these may all lead to false positive results.
   2) Cross-contamination of samples may lead to false positive results.
   3) False negative result from nucleic acid.
3. Analysis the possibility of invalid result:
   1) If the sample volume is not enough, the chromatography cannot be carried out successfully.
   2) The test card would invalid if the package was broken. The packaging status must be carefully checked before use.

DISPOSE IN TRASH

After test is completed, all used test components should put in biohazard waste bag and seal it. The trash must be disposed of in your household waste or in accordance with local disposal regulations.

Wash Your Hands after Testing
After completing all test steps, wash your hands or use hand sanitizer.

LIMITATIONS

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
2. Due to the limitation of the detection method, the negative result cannot exclude the possibility of infection. The positive result should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms and further diagnosis methods.
3. Positive test results do not rule out co-infections with other pathogens.
4. False negative results are more likely after 5 days or more of symptoms.
5. Negative results, from patients with symptom onset beyond 7 days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
6. The reagent can only qualitatively detect SARS-CoV-2 antigens in human nasal swab samples. It cannot determine the certain antigen content in the sample.
7. The accuracy of the test depends on the sample collection process. Improper sample collection will affect the test results.
8. False negative results may occur if results are stored in their paper sheath after specimen collection.
9. Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
10. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
11. Cross reactions may be exist due to the N protein in SARS-CoV-2 has a high homology with the new coronavirus (SARS-CoV-2). However, the interpretation of the results is not affected during seasons without SARS-CoV-2 infection.

PERFORMANCE CHARACTERISTIC

1. Analytical Performance
1.1. Limit of detection
This kit was confirmed to detect 1.5×10^{2} TCID50/mL of SARS-CoV-2 which was isolated from LISA-WA1/2020, Gamma-Imsidiase.
1.2. Cross reactivity
The following viruses and other Microorganism have no effect on the test results.

Potential Cross-Reactant		Test Concentration	Test Result
Virus	Respiratory Syncytial Virus A	1.0×10^{5} PFU/mL	No cross reaction
	Respiratory Syncytial Virus B	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Measles Virus	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Adenovirus Type 3	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Adenovirus Type 7	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Human cytomegalovirus	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Varicella-zoster virus	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Human coronavirus OC43	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Human coronavirus 229E	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Rotavirus	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Influenza B	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Influenza A	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Mycoplasma pneumoniae	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Epstein Barr Virus	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	MERS-CoV	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	HCoV-HKU1	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
	Coronavirus NL63	1.0×10^{5} $TCID_{50}$/mL	No cross reaction
Other Microorganism	Staphylococcus aureus	1.0×10^{6}CFU/mL	No cross reaction
	Streptococcus pneumoniae	1.0×10^{6}CFU/mL	No cross reaction

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for SARS-CoV-2-coronavirus. SARS-CoV-2 coronavirus shows 90.32% homology across 100% of the nucleocapsid sequence. Therefore, cross-reactivity is highly likely.
1.3. Interfering Substances
The following interfering substances have no effect on the test results.

Substance	Active Ingredient	Concentration	Test Result
Endogenous	Mucin	2.0 % w/v	No interference
Nasal Spray	Oxymetazoline	12 % v/v	No interference
Sore Throat Phenol Spray	Phenol	15 % v/v	No interference
Throat Lozenge	Benocaine, Menthol	0.15% w/v	No interference
Anti-viral Drug	Ribavirin	12.9 mg/mL	No interference
Antibacterial, Systemic	Tobramycin	4.0 ug/mL	No interference

1.4. High Dose Hook Effect
No high dose hook effect was observed when tested with up to a concentration of 1.0×10^{7} TCID50/mL of heat inactivated SARS-CoV-2 virus.

2. Clinical study
The clinical evaluation was performed to compare the results obtained with the SARS-CoV-2 Ag Test Kit and a comparative reverse transcriptase polymerase chain reaction test (Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit(PCR-Fluorescence Probing) manufactured by Sansure Biotech Inc). Among patients, there are 102 positive and 200 negative samples by RT-PCR confirmed. The presentation of the results of the SARS-CoV-2 Ag Test Kit is as follows:

CT value	Number of samples	2019 nCoV RT-PCR Results	SARS-CoV-2 antigen test result as compared to RT-PCR
≤30	93	positive	85.92%=91.60% (95%CI:83.93%-95.58%)
≤35	152	positive	132/152=86.84% (95%CI:80.55%-91.22%)
> 40	205	negative	203/205=99.02% (95%CI:96.51%-99.72%)

Days	Number of samples	2019 nCoV RT-PCR Results	SARS-CoV-2 antigen test result as compared to RT-PCR
≤7	188	positive	97/108=90.51% (95%CI:84.65%-95.47%)
≤14	121	positive	115/121=97.79% (95%CI:91.98%-99.94%)
> 14	21	positive	17/21=80.95% (95%CI:60.00%-92.32%)

Sensitivity: 86.84%(95%CI: 80.55%-91.22%)for CT values ≤35.
Sensitivity: 91.51%(95%CI:84.65%-95.47%)for onset of symptoms within 7 days.
Specificity: 99.02%(95%CI:96.51%-99.72%)

3. Human Factors Study
Wantmind conducted a human factor's study to evaluate whether home user patients or caregivers (lay user) could perform the test and accurately interpret test results from the SARS-CoV-2 Ag Card.
In this study, a total of 60 lay users, age 15 and older with either good or corrected vision (farsight-sighted or near bifocals) participated in a 20-minute session including an introduction, a product overview, and simulated use cases of SARS-CoV-2 Ag Test Kit result interpretation. Participants were asked to read and interpret a panel of 7 different SARS-CoV-2 Ag Card test results, including high positive, low positive, negative and invalid.
58/60 participants described the process of reading and interpreting the test card results as being easy. However, 6/60 of the participants commented that it was difficult to see some of the faintest line conditions.
A total of 420 trials were recorded in this study. Participants were able to perceive and interpret the results correctly for 397 trials, or 95.6% of the time. Positive results with stronger intensity lines were easier to read than the positive lines with less intensity.
After the human factor evaluation, participants were asked for their overall impressions of the instructional materials they were provided. Nearly all participants (58/60) thought the instructions were straightforward and easy to understand and follow.

4. Usability Study
Wantmind conducted a study to evaluate whether a home user can read the instructions and successfully perform the test steps for the SARS-CoV-2 Ag Card test, including swab collection at home, and correctly interpreting the results.
200 home users, including individuals (n=100) and caregivers (n=100), participated in the study. Each individual or caregiver pair participated in a 20-minute session with an instructor. The usability evaluation session included one simulated use of the SARS-CoV-2 Ag Test Kit.
99.5% (199 out of 200) home users produced a valid result (all negative) and 1 participants produced an invalid result. (The causes of the invalid tests were insufficient amount of reagent added, and damage to the test strip). 196 out 200 participants interpreted their test result correctly and 4 participants interpreted their result incorrectly (where they perceived a faint line in the sample window (as positive) when there was none (all results were verified by the study moderator).
The individual home user group completed 98.3% (2359/2400) of the total tasks steps correctly. The caregiver home user group completed 97.6% (2342/2400) of the total tasks steps correctly. The most common use errors observed during critical tasks included incorrectly swabs collection and contacting the test strip with the hands or with the surface.
99.5% (197 out of 200) of the home (individual and caregiver) participants had positive impressions of the SARS-CoV-2 Ag Test Kit. The test was perceived as being easy to use.

SYMBOLS

IVD	For In Vitro Diagnostic Use		Instructions for use
REF	The product's catalog number	LOT	Product's Batch Number
	The product's Expiry Date		Manufacturing Date
2	Not to be re-used.		Stored between 2-30℃
	The product should be kept away from sunlight		The product should be kept dry
	The product's Manufacturer	EC REP	EU Authorized Representative
	Corrosive		Warning
	Dangerous for the environment		

SARS-CoV-2 Ag Self-test Kit (Nasal Swab)

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