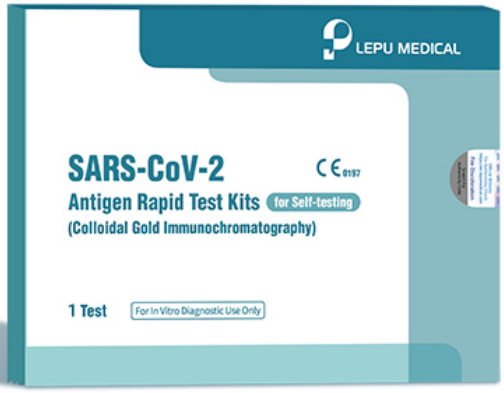
LEPU MEDICAL

NON-INVASIVE IVD FOR SELF-USE ONLY



SARS-CoV-2

CE 0197

Antigen Rapid Test Kits

(Colloidal Gold Immunochromatography)

FOR SELF-TESTING

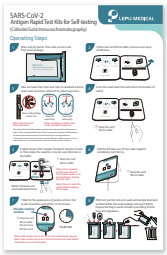
100% SENSITIVITY

100% SPECIFICITY

This product is a rapid, lateral flow immunoassay intended for the use of qualitative detection of SARS-CoV-2 nucleocapsid antigens from anterior nasal swabs that are self-collected by individuals aged 18 years or older. This test is intended for use on individuals with symptoms of other epidemiological reasons to suspect a COVID-19 infection. This product is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.

Product Features

Test card



Instruction card

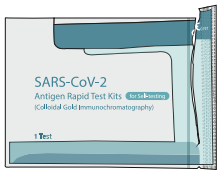
Swab

Buffer

- Non-invasive
- Easy to use
- No prescription needed
- Rapid, get result in 15 minutes
- Stable and high accuracy
- Inexpensive cost-effective

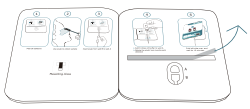
Operating Steps

1



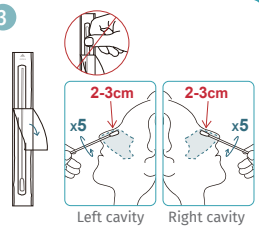
Wash and dry your hands before removing the package.

2



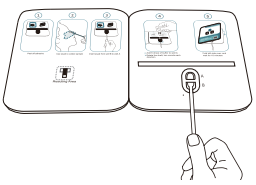
Place the test card on a flat surface, and remove the adhesive's cover-lay.

3



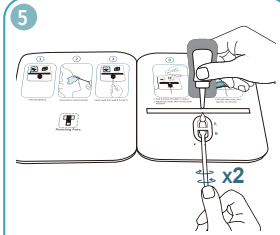
Take out the swabs from stick-end and insert swab fully into the nasal cavity (about 2-3cm for adults) and rotate 5 times for both sides to collect specimens.

4



Insert the swab head into well A from the bottom of well B on the test card.

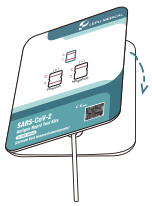
5



Add 6 drops of the Sample Treatment Solution to well A, then rotate the swab twice from different directions.

ⓘ Keep card flat on table

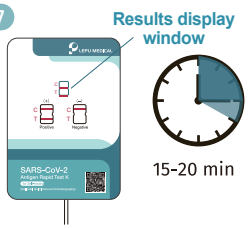
6



Fold the left side over to fit two sides together closely, and start timing.

ⓘ Keep card flat on table

7



Wait for the purple-red line to appear, and read the test results in 15-20 minutes.

ⓘ Do no move card

8

Once test is completed, put the test card, swab and sample treatment solution in the provided biohazard disposal bag, seal tightly and throw in your general household waste.

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LEPU MEDICAL

CE 0197 EN

SARS-CoV-2 Antigen Rapid Test Kits for Self testing (Colloidal Gold Immunochromatography)

For Self-Use Only
For In Vitro Diagnostic Use Only

【 Packing Specifications】

1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit, 50 tests/kit

No.	Catalogue number	Spec.
1	CG3601	1 test/kit
2	CG3605	5 tests/kit
3	CG3610	10 tests/kit
4	CG3625	25 tests/kit
5	CG3650	50 tests/kit

[Product Name]

SARS-CoV-2 Antigen Rapid Test Kits for Self-testing (Colloidal Gold Immunochromatography)

【Intended Use】

This product is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2nucleocapsid antigens from anterior nasal swabs that are self-collected by an individual aged 18 years orolder or are collected by an adult from an individual younger than 18 years old. This test is intended for use in individuals with symptoms or other epidemiological reasons to suspect a COVID-19 infection.
This product is intended for self-use as an aid in the diagnosis of SARS-CoV-2 infection. Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen isgenerally detectable in anterior nasal swab specimens during the acute phase of infection. Positive resultsindicate the presence of viral antigens, but the clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterialinfection 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, if necessary,for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection andshould not be used as the sole basis for treatment or patient management decisions including infectioncontrol 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 upcare from their healthcare provider.

【Introduction 】

Coronavirus, as the broad family of viruses, is a single strand plus RNA virus with an envelope. The virusis known to cause major diseases such as cold, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is N protein (Nucleocapsid), which is a protein component inside the virus. It is relatively conservative among β-coronaviruses and iscommonly used as a diagnostic tool for coronavirus. As the key receptor for SARS-CoV-2 to enter cells,ACE2 is significant for the study of viral infection mechanisms.

[Principle]

The current test kit is based on specific antibody-antigen reaction and immunoassay technique. The test strip consists of gold marked pad (coated with gold-marked SARS-CoV-2 N protein mouse anti human monoclonal antibody), sample pad, NC membrane (paired SARS-CoV-2 N protein mouse anti human monoclonal antibody coated on the test line (T) and goat anti-mouse IgG polyclonal antibody coated on the quality control line (C) and absorbing paper.
During the test, the N protein in the specimen binds to the gold-marked SARS-CoV-2 N protein mouse anti human monoclonal antibody pre-coated on the gold marked pad, and the conjugate moves upward under the capillary effect, and then is trapped by N protein mouse anti human monoclonal antibody conjugate fixed in the Test Line (T). The higher the N protein content in the specimen, the more conjugates are trapped, and the darker the color of the Test Line (T). If there is no SARS-CoV-2 in the specimen or the virus content is below the detection limit, no color appears in the Test Line (T). A purple-red band will appear in the Control Line (C) regardless of whether there is a virus in the specimen. The purple-red band that appears in the Control Line (C) is the criteria for determining whether there is enough specimen and whether the chromatography process is normal.

[Main Components]

The product includes test cards, instruction for use, operation card, disposable sterile swabs and sample treatment solution. Each reagent kit contains 1 novel coronavirus (SARS-CoV-2) antigen test card and 1 bag of desiccant.

Disposable sterile swab information:
Nasal Swab could be provided based on customer's requirement.

Name	Application
Disposable sterile swab information	Nasal swab

CE 0123 MDD 93/42/EEC
Manufacturer 1: Zhejiang Gongdong Medical Technology Co., Ltd.Beicheng Industrial Area 318020 Huangyan China
CE 0197 MDD 93/42/EEC
Manufacturer 2: Jiangsu Changfeng Medical Industry Co., Ltd. Touqiao Town,Guangling District Yangzhou 225109 Jiangsu China

CE 0197 MDD 93/42/EEC
Manufacturer 3: Shenzhen KangDaAn Biological Technology Co., Ltd.Liuxiandong industrial zone,Xilistreet Nanshan district,Shenzhen 518055 Guangdong China

CE 0413 MDD 93/42/EEC
Manufacturer 4: Medico Technology Co., Ltd.Zhangbei Industrial Park, Longcheng Street, Longgangdistrict, Shenzhen, 518100 Guangdong, China

CE 0197 MDD 93/42/EEC
Manufacturer 5: Goodwood Medical Care Ltd. 1-2 Floor, 3-919, Yongzheng Street, Jinzhou District, Dalian 116100 Liaoning, China

Spec.	Test card	Instruction manual	Operation card	Sample treatment solution	Swabs	Plastic Biohazard disposal bag
1 test / kit	1 test	1	1	300μl×1	1 piece	1 piece
5 tests / kit	5 tests	1	1	300 μl×5	5 pieces	5 pieces
10 tests / kit	10 tests	1	1	300 μl×10	10 pieces	10 pieces
25 tests / kit	25 tests	1	1	300 μl×25	25 pieces	25 pieces
50 tests / kit	50 tests	1	1	300 μl×50	50 pieces	50 pieces

Test card consists of paper shell, test strip, sample well and adhesive tape. The test strip, sample well and adhesive tape are attached on the paper shell.
The test strip consists of gold marked pad (coated with gold-marked SARS-CoV-2 N protein mouse anti human monoclonal antibody), sample pad, NC membrane (paired SARS-CoV-2 N protein mouse anti human monoclonal antibody coated on the test line (T) and goat anti-mouse IgG polyclonal antibody coated on the quality control line (C)) and absorbing paper.
The main compositions of sample treatment solution include tris, tritonX-100, sodium caseinate.
Plastic Biohazard disposal bag is provided for sample disposal.

[General description]

The SARS-CoV-2 Antigen Rapid Test Kits for Self-testing (Colloidal Gold Immunochromatography)
contains 3 core elements for operation:
·Testcard: Test card which is book-shaped hinged test card board containing the test strip (for single use)
·Sample Treatment Solution: Bottle containing sample treatment solution (for single use)
·Nasal Swabs: Sterile swab (for single use)

1 Test Card

1 Sample Treatment Solution (buffer)

1 Swab

[Material required but not provided]

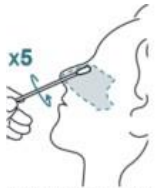
Clock or timer or stopwatch.
Hand soap and warm water, or hand sanitizer for cleaning your hands.

[Storage Conditions and Validity Period]

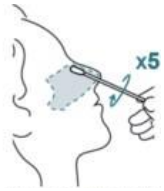
1. The test kit should be stored in a dry and dark place with temperature of 4-30℃, valid for 18 months.
2. The validity period of the test card is 1 hour after opening its inner package and it is suggested that the storage
temperature should be 4 ~ 30 ℃and the humidity should not exceed 70%.
3. The sample treatment solution should be used immediately after opening.
See package label for date of manufacture and expiration.

[Specimen Requirements]

This test kit is suitable for testing human anterior nasal swab specimens:
Specimen collection: During the collection process, relevant personnel should be well protected to avoid direct contact with the specimen. In case of accidental contact, timely disinfection should be carried out and necessary measures should be takenPengumpulan spesimen calitan hidung anterior:
Anterior nasal swab specimen collection: During sampling, the nasal swab head should be entirely inserted into the nasal cavity until you feel resistance (about 2-3cm), and gently rotated 5 times. When it was removed, specimen should be taken in the same way in the other nasal cavity to ensure the collection of enough specimens



Swab Left Nasal Cavity



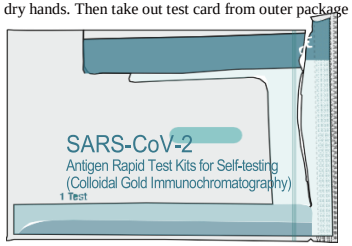
Swab Right Nasal Cavity

Specimen preservation: After the specimen are collected, please test immediately after sampling. Do not complete the test over 1 hour.

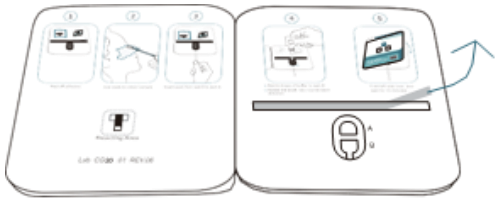
[Test Method]

Please read the instruction for use completely before performing any test, and use the reagents and specimens after returning to room temperature.

1. Wash and dry hands. Then take out test card from outer package

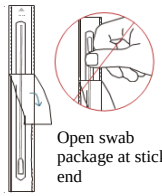


2. Place test card flat on table, remove cover-layer of adhesive



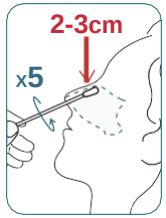
3. Take out swab from stick-end, refer to standard anterior nasal swab specimen collection to collect specimen: The nasal swab head should be entirely inserted into the nasal cavity until you feel resistance (about 2-3cm), and gently rotated 5 times. When it was removed, specimen should be taken in the same way in another nasal cavity to ensure the collection of enough specimens.

*The length of anterior nasal cavity of users may be different in different regions, 2~3cm is only for reference. It is recommended for user to insert swab until feel resistance.

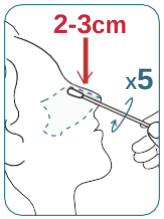


Open swab package at stick end

Note: Do not touch the swab head.



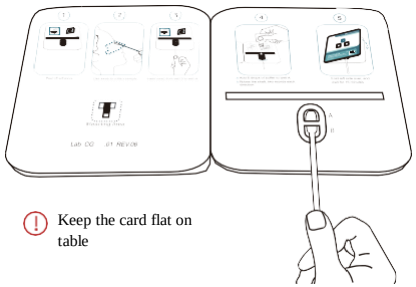
Swab left nasal cavity



Swab right nasal cavity

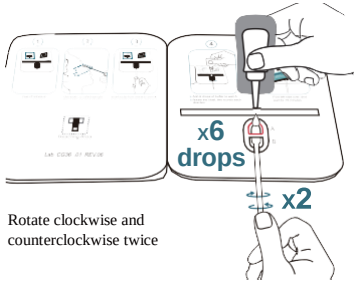
Note: Sampling in both nasal cavity sample is required.

4. Insert the swab head into well A from the bottom of well B



Keep the card flat on table

5. Add 6 drops of the Sample Treatment Solution to well A. Then rotate the swab for 2 rounds, each direction in the buffer.



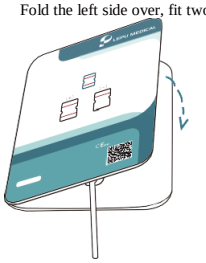
Keep the card flat on table

Note: False negative results may occur if the sample swab is not turned before closing the test card.

Rotate clockwise and counterclockwise twice

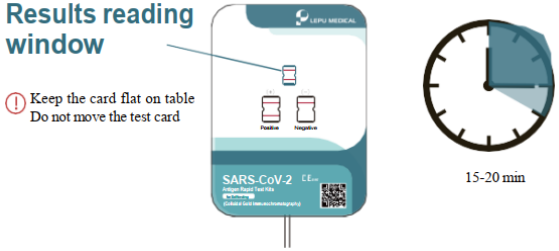
Note: Do not rotate the swab while dropping the sample

6. Fold the left side over, fit two sides together completely, start timing.



Keep the card flat on table

7. Wait for the appearance of purple-red line. Test results should be read within 15-20 minutes

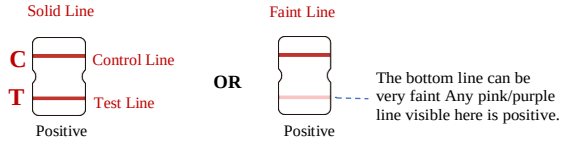


15-20 min

Note: False results can occur if the card is disturbed/moved.
Note: False results can occur if the test results are read before 15minutes or over 20 minutes

[Interpretation of Test Results]

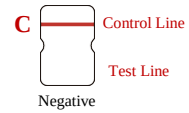
Positive (+): A purple-red band appears in the Control Line (C) and Test Line (T).



A positive test result means that you may have Corona Virus Disease 2019 (COVID-19).

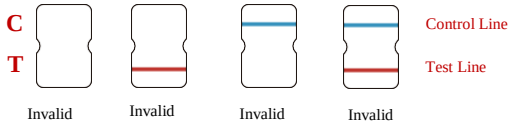
It is important to inform your healthcare professional of the results immediately. Your healthcare provider will work with you to further confirm the diagnosis of COVID-19 and determine how best to care for you based on your test result(s) along with your medical history, symptoms and other related medical tests. You should self-isolate to prevent spreading the virus to others.

Negative (-): Only the Control Line (C) shows a purple-red band. No purple-red band appears in the Test Line (T).



A negative test result means that proteins from SARS-CoV-2 which causes COVID-19 were not found in your sample.

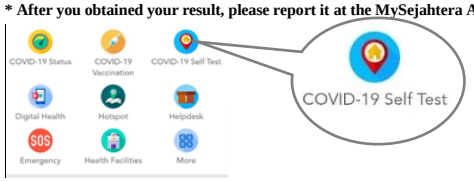
Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. If you develop symptoms, please consult your healthcare professional immediately.



Invalid: If "no purple-red band appears in Control Line (C) "and" a blue band appears in the Control Line (C)", it indicates that the operation process is incorrect or the test paper has been damaged.

In this case, please read the instruction manual carefully again and retest with a new test paper. If the problem persists, please stop using this batch of products immediately and contact your local supplier.

*** After you obtained your result, please report it at the MySejahtera App.**



[Instruction for disposal]

Once the test is completed, put the test card, swab and sample treatment solution in the provided biohazard disposal bag, seal it tightly and throw in your general household waste. Wash your hands thoroughly for 20 seconds using soap and warm water, or use hand sanitizer.

[Limitations of the testing method]

1. The test results of this product should be combined with other clinical information and comprehensively judged by physicians, and should not be used as the only criterion.
2. This product is only used to determine the novel coronavirus (SARS-CoV-2) antigen in the specimen.
3. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
4. False negative results may occur if a specimen is improperly collected or handled.
5. Invalid results may occur if inadequate sample treatment buffer is used (e.g., <6 drops). False negative results may occur if excessive sample treatment buffer is used (e.g., > 6 drops).
6. False negative results may occur if specimen swabs are not twirled within the test card.
7. False negative results may occur if swabs are stored in their paper sheath after specimen collection.
8. False negative results are more likely after seven days or more of symptoms.
9. This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
10. The performance of the SARS-CoV-2 Antigen Rapid Test Kits for Self-testing (Colloidal Gold Immunochromatography) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
11. The presence of high concentration mupirocin may interfere with the product and may cause false positive results
12. Positive test results do not rule out co-infections with other pathogens.
13. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
14. Negative results do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
15. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2

[Internal Quality Control]

The product has a Test Line (T) and a Control Line (C) on the surface of the test card. Neither the Test Line (T) nor the Control Line (C) is visible in the result window before applying a specimen. The control line is used for procedural control and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

[Product Performance Index]

1. Determination of the Limit of Detection

SARS-CoV-2 Antigen Rapid Test Kits limit of detection (LoD) was determined by evaluating different concentrations of inactivated SARS-CoV-2 Virus culture medium. Negative natural nasal swab specimens were eluted in 6 drops of sample treatment solution. 20 Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 Virus culture medium was diluted in this natural nasal swab matrix pool to generate virus dilutions for testing.

The testing was performed according to the test procedure, with the virus dilutions applied directly onto the Swab to prepare the contrived nasal swab samples. The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentra - tion at which at least 19 out of 20 replicates tested positive). Based on this test condition, the laboratory experiment data showed that the SARS-CoV-2 Antigen Rapid Test Kits forSelf-testing (Colloidal Gold Immunochromatography) LoD in natural nasal swab matrix was confirmed 200 TCID50/mL.

2. Analysis of Specificity

2.1 Cross-reaction: No cross-reactivity was seen with the following microorganisms when tested at the concentration presented in the table below

Potential Cross-Reactant	Test Concentration
Human coronavirus OC43	10^5TCID50/mL
Human coronavirus 229E	10^6TCID50/mL
Human coronavirus NL63	10^5TCID50/mL
Human coronavirus HKU1 recombinant N protein	50μg/mL
adenovirus	10^6TCID50/mL
Human metapneumovirus（hMPV）	10^6TCID50/mL
MERS coronavirus recombinant N protein	50μg/mL
Parainfluenza virus 1	10^7TCID50/mL
Parainfluenza virus 2	10^5TCID50/mL
Parainfluenza virus 3	10^6TCID50/mL
Parainfluenza virus 4	10^7TCID50/mL
Influenza A	10^6TCID50/mL
Influenza B	10^6TCID50/mL
Enterovirus（EV68）	10^7TCID50/mL
Respiratory syncytial virus	10^5TCID50/mL
Rhinovirus	10^6TCID50/mL
Measles virus	10^5TCID50/mL
Varicella zoster virus	10^5TCID50/mL
Haemophilus influenzae	10^7CFU/mL
Chlamydia pneumoniae	10^6CFU/mL
Legionella pneumophila	10^7CFU/mL
Mycobacterium tuberculosis	10^7CFU/mL
Streptococcus pneumoniae	10^7CFU/mL
Streptococcus pyogenes	10^7CFU/mL
Bordetella pertussis	10^7CFU/mL
Mycoplasma pneumoniae	10^8CFU/mL
Candida albicans	10^7CFU/mL
Staphylococcus epidermidis	10^7CFU/mL
Staphylococcus aureus	10^7CFU/mL
Pneumocystis giraldii	10^6CFU/mL
Staphylococcus salivarius	10^7CFU/mL
Combined human nasal Lotion	/

2.2 Interfering substances: No interference was seen with the following substances when tested at the concentration presented in the table below.

Potential Interfering substances	Test Concentration
Mucin	0.5%
Human whole blood	4%
HAMA	60 ng/mL
Biotin	1.2μg/mL
Benzocaine	2 mg/mL
Zanamivir	18μg/mL
Ribavirin	25μg/mL
Lopinavir	20μg/L
Ritonavir	18μg/mL
Acetylsalicylic acid	2 mg/dL
Ibuprofen	25 mg/dL
Tobramycin	16μg/mL
Phenylephrine	15%
Oxazole (nasal spray)	15%
Fluticasone	5%
Sodium chloride (containing preservatives)	10 mg/mL
Beclomethasone	2μg/mL
Budesonide	4ng/mL
Mometasone	2ng/mL
Strepsils (flurbiprofen 8.75mg)	5%
Throat candy (Mint)	5%
Naso GEL (NeilMed)	5%

3. Clinical Performance

The clinical performance study for SARS-CoV-2 Antigen Rapid Test Kit was conducted in Germany. A total of 222 clinical samples were used to perform the test. The positive and negative samples were all confirmed by PCR. The diagnostic sensitivity and diagnostic specificity of the product was 95.9% (90.8-98.2%) and 100% (96.3-100.0%) respectively.

Results with correlation to Ct value of the positive samples were shown in the table below.

Ct Value	Diagnostic sensitivity	95%CI
≤25	97.0 %	84.7-99.5%
≤30	96.2 %	88.3-98.7%
≤36	95.9 %	90.8- 98.2%

All the data above only represent the results of this clinical performance study in Germany

[Warnings and Precautions】

1. For in vitro diagnostic use only. The product can be used for self-testing.
2. Do not eat or smoke while handling specimens.
3. The temperature and humidity of the experimental environment should be avoided to be too high, the reaction temperature should be 15-30°C and the humidity should be below 70%.
4. The packaging bag contains desiccant, do not eat.
5. It is recommended to test in a well-lit environment.
6. Before testing, please wash hands or wear clean gloves.
7. Please do not use the test card with damaged card bag packaging, unclear marking or beyond the expiration date.
8. A test card should be used within 1 hour after it is taken out from the aluminum foil bag.
9. Users shall take samples according to the instruction manual. Inadequate or inappropriate sample collection may yield error results and retesting with a new test may be required. Particular attention needs to be paid to appropriate sample collection technique.
10. Remove the covering layer of double-sided adhesive to prevent liquid splashing before testing.
11. Do not drop the dilution buffer into the wrong well.
12. In the process of testing, the test card should be placed on a horizontal table, and it should not be moved.
13. If the buffer solution makes contact with the skin or eye, wash/ flush with a large volume of water. If skin irritation, rash or other abnormal reaction occurs, please get medical advice/attention.
14. Avoid splashing or aerosol formation of specimen and buffer.
15. All users have to read the instruction prior to performing a test.
16. Do not mix or interchange different specimens.
17. Do not mix reagent of different lots or those for other products.
18. To avoid contamination, do not touch the head of provided swab when opening the swab pouch.
19. To avoid cross-contamination, do not reuse the sterilized swabs for specimen collection.
20. Do not dilute the collected swab with any solution except for the provided extraction buffer.
21. Keep foreign substances away from the test during the testing process. Contact with foreign substances, specifically bleach, may result in an incorrect test result.
22. Nasal swabs are not recommended for anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
23. Patients with severe allergic rhinitis may have false positive results.
24. For patients with severe dry nasal mucosa, the sample volume may be insufficient due to the serious shortage of nasal secretions, resulting in inaccurate results.
25. Do not refrigerate or use after the expiration date (see packaging bag for expiration date).
26. Put all the used specimen, test card and other waste into the biohazard disposal bag and seal it tightly before it is thrown into the waste container.
27. It is suggested that the test should be performed in the company of people with normal vision for abnormal color vision users.

[Explanation of Symbols】

	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	DO NOT REUSE		USE-BY DATE
4℃ 30℃	TEMPERATURE LIMIT		DATE OF MANUFACTURER
	MANUFACTURER	LOT	BATCH CODE
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	CE 0197	CE MARK
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEANCOMMUNITY	REF	CATALOGUE NUMBER

[Basic Information]

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[Audiovisual Demonstration]

Please refer to outer box for QR CODE scan.