CE
IVD

COVID-19 Antigen Nasal fluid Test kit
Instruction for Use

For professional and in vitro diagnostic use only.

PRODUCT NAME

Commercial Name: COVID-19 Antigen Nasal fluid Test kit

PACKING SPECIFICATION

1 pcs/bag, 25 pcs/box

INTENDED USE

The product is used for the qualitative detection of SARS-CoV-2 infection.The entire detection process takes only 15-20 minutes, and the operation is simple and sensitive. No instrument required. It can be used for the screening of early infected patients and asymptomatic patients. This method is an effective supplement for nucleic acid detection.

PRINCIPLE

The detection of SARS-CoV-2 adopts the principle of double antibody sandwich method and colloidal gold immunochromatography to qualitatively detect SARS-CoV-2 antigen in human Nasal swabs, pharyngeal swabs,sputum,bronchoalveolar lavage fluid, etc., with two highly specific and highly sensitive SARS-CoV-2 N antigen monoclonal antibodies,wherein monoclonal antibody I is a capture antibody,fixed in the detection area on the NC membrane, monoclonal antibody II is a colloidal gold-labeled antibody,sprayed on the binding pad, and the NC membrane quality control area C is coated with goat anti-mouse IgG antibody. The double antibody sandwich method is used in the detection area,and the antigen-antibody reaction is used in the quality control area, combined with colloidal gold immunochromatography technology to detect the SARS-CoV-2 in the human body. During detection, the sample is chromatographed under the capillary effect. If the tested sample contains SARS-CoV-2, the gold-labeled SARS-CoV-2 N antigen monoclonal antibody II combines with SARS-CoV-2 to form a complex, and combines with the a SARS-CoV-2 N antigen monoclonal antibody I fixed at the detection line during the chromatography process,which will form the "Au-antibody II-N antigen- antibody I" sandwich, so that a purple band appears in the detection area (T); Otherwise, no magenta bands appear in the detection area (T). Regardless of whether there is a SARS-CoV-2 antigen in the sample, the complex will continue to be chromatographed up to the control area (C),and a purple band appears when reacting with the goat anti-mouse IgG antibody. The purple-red band presented in the control area (C) is a standard for judging whether the chromatographic process is normal, and also serves as an internal control standard for reagents.

MAIN COMPONENTS

SARS-CoV-2 Antigen Test Cassette (25 persons): Individually packaged in aluminum foil bags per person. The kit consists of a sample pad, a gold-labeled pad labeled with a gold-labeled mouse anti-human SARS-CoV-2 monoclonal antibody II, a nitrocellulose coated with a mouse anti-human SARS-CoV-2 monoclonal antibody I, and a goat anti-mouse IgG antibody.

It consists of plain film, absorbent paper, plastic backing and plastic template.

1. Virus extraction solution with tube (25pcs/box)
2. Instruction manual (1copy/box)
3. Nozzle with Filter: Tube tips to filter sample when delivered into devices. (25 pcs/box)
4. Sterile swab: Swabs for sample collection. (25pcs/box)

Note: The components in different batch kits are not interchangeable.

STORAGE

Storage conditions: The original package shall be stored in a dry place away from light at 2-30°C, and shall not be frozen.

The reagent shall be used as soon as possible within 1 hour after the unpacking of the aluminum foil bag; it is recommended to use the reagent as soon as possible when the ambient temperature is higher than 30°C or high humidity.

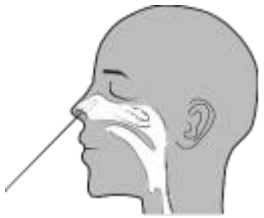
SPECIMEN COLLECTION

Nasal Swab

Use the nasal swab provided in the cassette.

1. Use a cotton swab to insert the left and right nostrils one by one.
2. Wipe the inner wall of the nostril and rotate the cotton swab 3-4 times in each of the left and right nostrils.
3. Make sure that there is liquid, and remove the cotton swab from the nostril.

Note: Use the same cotton swab to collect sample from both nostrils.



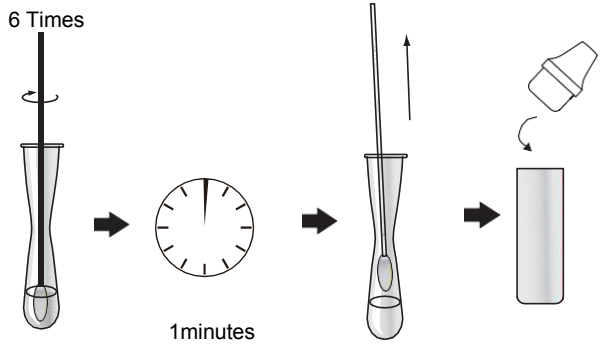
Nasopharyngeal swab

Use the nasopharyngeal swab supplied in the kit.

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx, that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. With draw the swab from the nasal cavity.

SAMPLE PREPARATION PROCEDURE

1. Insert the swab into the extraction tube of the extraction buffer.
2. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
3. Leave the swab in the extraction tube for 1 minute.
4. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.



TEST PROCEDURE

Allow the test Cassette test sample and buffer to equilibrate to room temperature (15-30°C or 59-86°F) prior to testing.

1. Remove test Cassette from the sealed pouch just prior to the testing and lay flat on workbench.
2. Insert a nozzle with filter into the sample extraction tube tightly.
3. Reverse the sample extraction tube, and add 3 drops (about 120 μL) of test sample by squeezing the extracted solution tube into the sample window.
4. Wait for colored line(s) to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.

INTERPRETATION OF RESULTS

1. POSITIVE:
   The presence of two lines as control line(C) and test line(T) within the result window indicates a positive result.
2. NEGATIVE:
   The presence of only control line (C) within the result window indicates a negative result.
3. INVALID:
   If the control line (C) is not visible within the result window after

performing the test, the result is considered invalid.Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NOTE:

1. ***The intensity of color in the test line region (T) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test line region(T) should be considered positive. Please note that this is a qualitative test only,and cannot determine the concentration of analytes in the specimen.***
2. ***Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.***

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative control sare sourced from a local competent authority and tested as a good laboratory practice,to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test.The Coronavirus Ag Rapid Test Cassette is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the Coronavirus Ag Rapid Test Cassette depends on antigen load and may not correlate with viral culture results performed on the same specimen.
2. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
6. Negative results should be treated as presumptive and confirmed with an authorized molecular assay, if necessary, for clinical management, including infection control.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Coronavirus Ag Rapid Test Cassette has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the Coronavirus Ag Rapid Test Cassette has a high overall relative accuracy.

Table 1: The Coronavirus Ag Rapid Test vs PCR

Method		PCR		Total Results
Coronavirus Ag Papid Test Cassette	Results	Positive	Negative	
	Positive	102	1	103
	Negative	2	150	152
Total Results		104	151	255

Relative Sensitivity=102/(102+2)*100.00%=98.08%

Relative Specificity=150/(1+150)*100.00%=99.34%

Accuracy=(150+102)/(102+2+1+150)*100.00%=98.82%

Cross reactivity

No cross-reactivity was observed with samples positive for the following pathogens: benign human coronaviruses (229E, OC43, NL63 & HKU1), influenza virus A & B, RSV A& B, Adenovirus, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila and parainfluenza virus(1-4).

Limit of detection

The limit of detection of the test is 500 TCID50 / mL (Median Tissue Culture Infectious dose) .

Interference study

All the samples shall yield Negative results. It indicates that the no positive or negative interference was demonstrated by load study in a matrix of nasopharyngeal secretions with the following substances: human blood (with anticoagulant EDTA),Mucin, antiviral drugs (Oseltamivir phosphate, ribavirin),Antibiotics (Levofloxacin, Azithromycin, Meropenem, Tobramycin), nasal sprays or drops (Phenylephrine, Oxymetazoline, nasal wash Alkalol, 0.9% NaCl), nasal corticosteroids (Beclomethasone, Hexadecadrol,Flunisolide, Triamcinolone, Budesonide, Fluticone, Mometasuticone).

INTERPRETATION OF SYMBOLS

Σ	Sufficient for tests		Use before the date
	Read the instruction		Storage temperature
IVD	in vitro Diagnostics		Do not reuse
LOT	Batch number	CE	Requirement on IVD
	Keep away from sunshine		Keep away from moisture
	Manufacturer	EC REP	Authorized Representative in European Community

Version No.: 1.0
Effective Date:24 months from date of manufacture

Form number: YY-QR-9.0-05-C0