FaStep®

COVID-19 Antigen Nasal Test Kit

1. INTENDED USE

The COVID-19 Antigen Nasal Test Kit is an in vitro immunoassay. The assay is for the direct and qualitative detection of SARS-CoV-2 viral nucleocapsid protein from nasal secretions fo the individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID- 19 infection. This test is authorized for home use with self-collected anterior nasal swab specimens directly from individuals. Children aged between 2 and 18 years old must be supervised or aided by an adult when carrying out the test. The COVID-19 Antigen Nasal Test Kit does not differentiate between SARS-CoV and SARS-CoV-2.

Test results should not be used as a sole basis for diagnosis but should always be interpreted by a physician in the clinical context.

2. PRINCIPLE

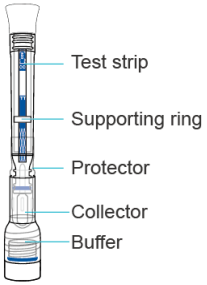
The COVID-19 Antigen Nasal Test Kit detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti-SARS-CoV-2 antibodies are immobilized at the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to colored particles are immobilized on the conjugated pad.

During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the sample pad, the target antigens will bind to anti-SARS-CoV-2 antibodies on the conjugate pad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 antibodies immobilized at the test region. Excess colored particles will be captured at the control region of the NC membrane.

The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

3. MATERIALS

- Individual packaged test



- Package insert
- Waste bag
- Desiccant

Materials Required but Not Provided

- Clock, timer, or stopwatch

4. TEST PROCEDURE

Prepare for the test

• The test should be used at room temperature.

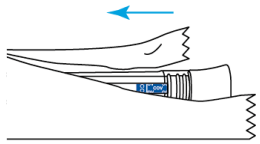
• Make sure that all packaging is intact. Do not use the test if the foil packaging is visibly damaged.

• Do not open the foil package until you are ready to perform the test. Use the test within 1 hour of opening.

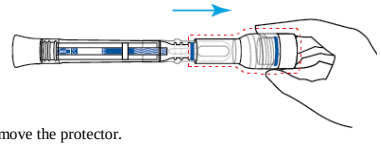
Test procedure

1. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

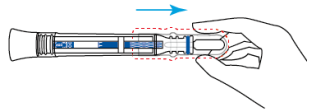
2. Remove the test device from its packing. For the best results, the assay should be performed within one hour.



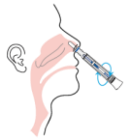
3. Take the test device out of the tube with extraction buffer.



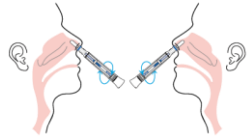
4. Remove the protector.



5. Gently insert the sample collector until resistance is met (about 1-2 cm into the nostril).

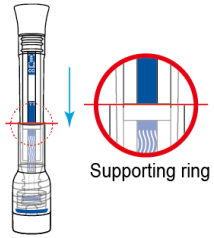


6. **Rotate the collector five times against the nasal wall and remove from the nostril. Repeat the sample collection procedure for the other nostril to ensure that sufficient specimen be collected from both nasal cavities.**

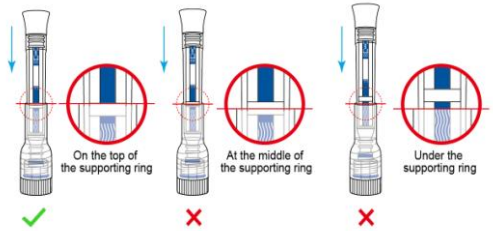


NOTE: 1). It is important to obtain as much secretion as possible.
2). This may feel uncomfortable. Do not insert the collector any deeper if you feel strong resistance.

7. Place the test device vertically into the extraction tube until the top edge of the extraction tube reach the top of the supporting ring.

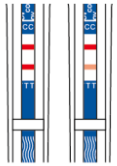


NOTE: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.



8. **Read the results at 15 minutes. Do not read the results at 30 minutes.**
9. When the test is finished, put the test you used into the waste bag provided . Dispose of the package with household waste.

5. RESULT INTERPRETATION



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C), and another band appears in the test region (T).

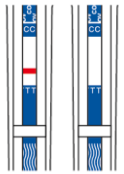
The intensity of the color in the test area (T) can vary. However, any shade in the test area should be considered positive. Note that this is a qualitative test only and the virus concentration in the sample cannot be determined.

If you get a positive result, it indicates a possible SARS-CoV-2 infection. A positive result also means you are at risk of infecting others, please contact a doctor, family doctor or local health department immediately for a confirmatory PCR test.

Note: Please follow local guidelines for self-isolation.

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

Negative results do not completely rule out SARS-CoV-2 infection. Please continue to comply with all applicable rules regarding contact with others and protective measures. An infection can also be present if the test is negative. In case of suspicion, repeat the tests after 1-2 days, as the coronavirus cannot be accurately detected in all phases of an infection.



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the test results remain invalid, contact a doctor or a COVID-19 test center.

NOTE:

1. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

6. PRECAUTIONS

1. Caution should be taken when inserting the sample collector into the nasal cavity.
2. Do not use kit or components beyond the expiration date.
3. Do not puncture the membrane in the extraction tube before testing.
4. Read the instructions for use before use. The instructions for use must be read carefully and followed.
5. The test components are packed in foil pouches to protect them from moisture during storage. Check each foil pouch before opening it. Do not use any component that has holes in the film or the pouch has not been completely sealed. Improper storage of test items or components can lead to incorrect results.
6. If samples and test components are not brought to room temperature before the test, the test sensitivity may be reduced. Incorrect or unsuitable sampling and storage can lead to false negative test results.
7. Avoid eye, skin and mucous membrane contact with the buffer. In the event of contact with buffer, rinse with plenty of water.
8. Do not use this test on anyone under 2 years of age.
9. Keep out of the reach of children. Small test components can pose a choking hazard.
10. Use only the supplied test components. Do not replace the buffer with any other liquid.
11. Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use.
12. Use a separate test for each person.
13. If you have a nose piercing, dab the other nostril. If pierced on both sides, remove the piercing on one side before wiping it off.
14. This test is for human use only.

7. QUALITY CONTROL

Internal Procedural Controls

The COVID-19 Antigen Nasal Test Kit has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the "C" region is present before reading the result.

8. LIMITATIONS OF THE TEST

1. The test is suitable for personal use and may only be used for the qualitative detection of the SARS-CoV-2 antigen.
2. As with all diagnostic tests, a clinical diagnosis must not be based on the results of a single test, but rather be made by the doctor after all clinical and laboratory results have been evaluated.
3. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may negatively affect and / or lead to incorrect results.
4. Negative results do not completely rule out an infection with SARS-CoV-2.

9. STORAGE AND STABILITY

- Store The COVID-19 Antigen Nasal Test Kit at 2~30℃when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on outer packaging and container

10. PERFORMANCE

Analytical Sensitivity (Limit of Detection):

The limit of detection was determined with a quantified SARS-CoV-2 virus and has been evaluated at $1x10^{2.4}TCID_{50}$/mL.

Clinical Evaluation:

A total of 616 clinical specimens were collected to verify the performance of COVID-19 Antigen Nasal Test Kit. There were 203 positive specimens and 413 negative specimens confirmed by RT-PCR. The results were summarized below:

Table: COVID-19 Antigen Nasal Test Kit vs. RT-PCR

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Nasal Test Kit	Positive	195	1	196
	Negative	8	412	420
Total		203	413	616

Relative Sensitivity: 96.1 % (92.4% ~ 98.0%)*

Relative Specificity: 99.8 % (98.6% ~ 100.0%)*

Overall Agreement: 98.5 % (97.2% ~ 99.2%)*

*95% Confidence Interval

Cross Reactivity:

Negative samples and low reactive samples spiked with each potentially cross-reacting microorganisms were tested, and the device presented no cross-reactivity or microbial interference with these microorganisms.

The following potentially cross-reacting microorganisms were examined:Adenovirus 1, MERS-coronavirus, *Bordetellaparapertussis,*Adenovirus 2, SARS-coronavirus, *Bordetella pertussis,*Adenovirus 3, Human metapneu- movirus, *Candida albicans,*Adenovirus 4, Influenza A (H1N1),pdm09 , *Chlamydia pneumoniae,*Adenovirus 5, Influenza A (H3N2), *Group C Streptococcus,*Adenovirus 7, Influenza B Victoria lineage, *Haemophilus influenza,*Adenovirus 55, Influenza B Yamagata lineage, *Legionella pneumophila,*Epstein-Barr virus , Norovirus, *Mycoplasma pneumoniae* Enterovirus EV70, Parainfluenza virus 1, *Mycobacterium tuberculosis* Enterovirus EV71, Parainfluenza virus 2, *Staphylococcus aureus* Enterovirus A16, Parainfluenza virus 3, *Staphylococcus epidermidis* Enterovirus A24, Parainfluenza virus 4, *Streptococcus agalactiae* Enterovirus B1, Respiratory syncytial virus A , *Streptococcus pneumoniae* Echovirus 6, Respiratory syncytial virus B , *Streptococcus pyogenes* HCoV-229E, Rhinovirus A30, HCoV-OC43, Rhinovirus B52, HCoV-NL63, ,

Interfering Substances:

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at listed below. None of them were found to affect test performance of The COVID-19 Antigen Nasal Test Kit.

Substance		
3 OTC nasal sprays	Dextromethorphan	Oxymetazoline
3 OTC mouthwashes	Diphenhydramine	Phenylephrine
3 OTC throat drops	Doxylamine succinate	Phenylpropanolamine
4-acetamidophenol	Flunisolide	Zanamivir
Acetylsalicylic acid	Guaiacol glyceryl ether	Adamantanamine
Albuterol	Mucin	Oseltamivir phosphate
Chlorpheniramine	Whole blood	Tobramycin
Dexamethasone	Mupirocin	Triamcinolone

11. LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
2. Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

12. GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

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