COVID-19 Antigen Nasal Test Kit

COV-S35002Pen

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 collected from symptomatic individuals suspected of COVID-19. The kit is in aid of diagnosis of COVID-19 and is to be used within 7 days of onset of symptoms.

The COVID-19 Antigen Nasal Test Kit is intended for use by trained healthcare professionals. For laboratory and point of care use. This assay is not intended for home testing (or self-testing).

Results are for the identification of SARS-CoV-2 viral nucleoprotein antigen. Antigen is generally detectable in nasal samples 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. Laboratories are required to report all positive results to the appropriate public health authority.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control 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, and confirmed with a molecular assay, if necessary for patient management.

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.

The nasal secretion collected by the intended user, is supposed to be mixed with the extraction buffer, which is individually packed in the kit.

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

Materials Provided

- 20 Individual packaged test
- 1 Package insert

Optional Materials

- External Negative and Positive control (Available upon request)

External Negative and Positive Control

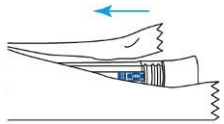
Negative control is lyophilized GCS and positive control is lyophilized SARS-CoV-2 NCP. Each control vial with 50 μL purified water. Insert the sample collector of device into the reconstituted control solution. Rotate the sample collector several times, ensuring that all solution sufficiently absorbed onto the sample collector. Store reconstituted controls at 4℃.

Materials Required but Not Provided

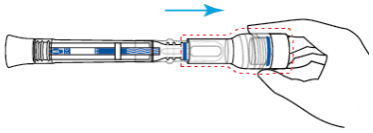
- Clock, timer, or stopwatch

4. TEST PROCEDURE

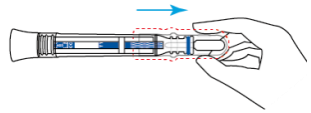
1. Bring devices, reagents and specimens and/or controls to room temperature (15~30℃) before use.
2. Remove the test device from its packing. Label the device with the patient's identification. For the best results, the assay should be performed within one hours.



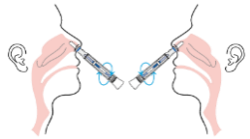
3. Take the test device out of the tube with extraction buffer.



4. Remove the protector.



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

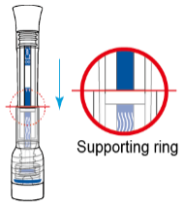


NOTE:

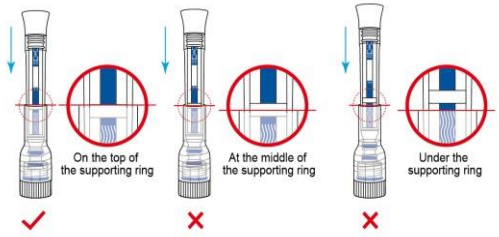
1). It is important to obtain as much secretion as possible.

2). This may feel uncomfortable. Do not insert the collector any deeper if you feel strong resistance. Children aged 2-15 years should be tested by an adult (18+ years old).

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

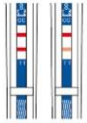


NOTE: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.



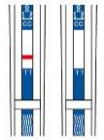
7. Read the results at 15 minutes.

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)

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



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 problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The color intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. 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.

6. PRECAUTIONS

1. For In Vitro Diagnostic Use Only.
2. Each device is for single use only and cannot be reused.
3. Caution should be taken when inserting the sample collector into the nasal cavity.
4. DO NOT ingest.
5. Do not use kit or components beyond the expiration date.
6. Do not puncture the membrane in the extraction tube before testing.
7. Read the instructions for use before use. The instructions for use must be read carefully and followed.
8. Do not test or components after their expiration date use.
9. The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
10. 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.
11. Do not use the kit when any component including test device, protector, extraction buffer, package insert is missing.
12. All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
13. Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
14. The buffer components include salts and surfactants, the preservative is sodium azide and water is the solvent. Avoid skin or eyes contact with buffer.
15. Avoid eye, skin and mucous membrane contact with the buffer. In the

event of contact with buffer, rinse with plenty of water.

16. Do not use this test on anyone under 2 years of age.
17. Keep out of the reach of children. Small test components can pose a choking hazard.
18. Use only the supplied test components. Do not replace the buffer with any other liquid.
19. Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use.
20. 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.
21. If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
22. Viral isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens are NOT recommended, except in a BSL3 laboratory using BSL3 work practices.
23. This test is for human use only.
24. There may be false negatives due to new unknown variants of SARS-Cov-2 prior to validation data available
25. COVID-19 Antigen Nasal Test Kit could detect SARS-CoV-2 variant alpha, beta, gamma, kappa and delta.

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.

External Positive and Negative Controls

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

8. LIMITATIONS OF THE TEST

1. The COVID-19 Antigen Nasal Test Kit is for professional in vitro diagnostic use, and should only be used for the qualitative detection of SARS-CoV-2 antigen. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. Both viable and nonviable SARS-CoV-2 viruses are detectable with The COVID-19 Antigen Nasal Test Kit.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
5. Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
6. Negative results do not preclude SARS-CoV-2 infection and should be confirmed via molecular assay.

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 their 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 $1x10^{2.4}TCID_{50}/mL$.

The limit of detection was also determined with recombinant SARS-CoV-2 nucleoprotein and has been evaluated at 370 pg/mL.

Clinical Evaluation:

A total of 508 clinical specimens were collected to verify the performance of COVID-19 Antigen Nasal Test Kit. There were 106 positive specimens from the individuals who were suspected of COVID-19 within 7 days of symptom and 402 negative clinical 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	104	1	105
	Negative	2	401	403
Total		106	402	508

Relative Sensitivity: 98.1 % (93.4% ~ 99.5%)*

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

Overall Agreement: 99.4 % (98.3% ~ 99.8%)*

*95% Confidence Interval

The table below shows the positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative COVID-19 Antigen Rapid Test Device Positive(+)	PPA	95%CI
0	5	5	100.0%	56.6%-100.0%
1	15	15	100.0%	79.6%-100.0%
2	28	28	100.0%	87.9%-100.0%
3	38	38	100.0%	90.8%-100.0%
4	50	49	98.0%	89.5%-99.6%
5	62	60	96.8%	89.0%-99.1%
6	69	67	97.1%	90.0%-99.2%
7	76	74	97.4	90.9%-99.3%
NA	106	104	98.1%	93.4%-99.5%

Cross Reactivity:

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the COVID-19 Antigen Nasal Test Kit.

Viruses	Con.	Viruses	Con.
Adenovirus 1	1.0×10^5 $TCID_{50}$/mL	HCoV-229E	1.0×10^5 $TCID_{50}$/mL
Adenovirus 2	1.0×10^5 $TCID_{50}$/mL	HCoV-OC43	1.0×10^5 $TCID_{50}$/mL
Adenovirus 3	1.0×10^5 $TCID_{50}$/mL	HCoV-NL63	1.0×10^5 $TCID_{50}$/mL
Adenovirus 4	1.0×10^5 $TCID_{50}$/mL	MERS-coronavirus	1.0×10^5 copies/mL
Adenovirus 5	1.0×10^5 $TCID_{50}$/mL	SARS-coronavirus	1.0×10^5 copies/mL
Adenovirus 7	1.0×10^5 $TCID_{50}$/mL	Human metapneumovirus	1.0×10^5 $TCID_{50}$/mL
Adenovirus 55	1.0×10^5 $TCID_{50}$/mL	Influenza A (H1N1)pdm09	1.0×10^5 $TCID_{50}$/mL
Epstein-Barr virus	5.0×10^5 copies/mL	Influenza A (H3N2)	1.0×10^5 $TCID_{50}$/mL
Enterovirus EV70	1.0×10^5 $TCID_{50}$/mL	Influenza B Victoria lineage	1.0×10^5 $TCID_{50}$/mL
Enterovirus EV71	1.0×10^5 $TCID_{50}$/mL	Influenza B Yamagata lineage	1.0×10^5 $TCID_{50}$/mL
Enterovirus A16	1.4×10^5 $TCID_{50}$/mL	Norovirus	1.0×10^5 copies/mL
Enterovirus A24	1.0×10^5 $TCID_{50}$/mL	Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL
Enterovirus B1	1.1×10^5 $TCID_{50}$/mL	Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL
Echovirus 6	1.0×10^5 $TCID_{50}$/mL	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL
Respiratory syncytial virus A	1.0×10^5 $TCID_{50}$/mL	Parainfluenza virus 4	1.0×10^5 $TCID_{50}$/mL
Respiratory syncytial virus B	1.0×10^5 $TCID_{50}$/mL	Rhinovirus B52	1.0×10^5 $TCID_{50}$/mL
Rhinovirus A30	1.0×10^5 $TCID_{50}$/mL	Human coronavirus HKU1	1.0×10^5 $TCID_{50}$/mL
Bacterium	**Con.**	**Bacterium**	**Con.**
Bordetella parapertussis	1.8×10^6 cfu/mL	*Mycobacterium tuberculosis*	6.32×10^6 cfu/mL
Bordetella pertussis	2.0×10^6 cfu/mL	*Staphylococcus aureus*	2.0×10^6 cfu/mL
Candida albicans	1.0×10^6 cfu/mL	*Staphylococcus epidermidis*	2.0×10^6 cfu/mL
Chlamydia pneumoniae	2.0×10^6 EB/ml	*Streptococcus agalactiae*	2.0×10^6 cfu/mL
Group C Streptococcus	2.0×10^6 cfu/mL	*Streptococcus pneumoniae*	2.0×10^6 cfu/mL
Haemophilus influenzae	1.0×10^6 cfu/mL	*Streptococcus pyogenes*	2.0×10^6 cfu/mL
Legionella pneumophila	2.0×10^6 cfu/mL	*Pseudomonas aeruginosa*	2.0×10^6 cfu/mL
Mycoplasma pneumoniae	2.0×10^6 cfu/mL	*Staphylococcus salivarius*	2.0×10^6 cfu/mL

In silico analysis:

For Pneumocystis jirovecii (PJP), blast results showed none homology exists between the SRAS-COV-2 nucleocapsid protein and Pneumocystis jirovecii (PJP).

Interfering Substances:

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

Substance	Con.	Substance	Con.
3 OTC nasal sprays	10%	Guaiacol glyceryl ether	20mg/mL
3 OTC mouthwashes	10%	Mucin	1%
3 OTC throat drops	10%	Whole blood	4%
4-acetamidophenol	10mg/mL	Mupirocin	250μg/mL
Acetylsalicylic acid	10mg/mL	Oxymetazoline	25μg/mL
Albuterol	10mg/mL	Phenylephrine	10 mg/mL
Chlorpheniramine	5 mg/mL	Phenylpropanolamine	1mg/mL
Dexamethasone	50μg/mL	Zanamivir	10mg/mL
Dextromethorphan	10μg/mL	Adamantanamine	500 ng/mL
Diphenhydramine	5 mg/mL	Oseltamivir phosphate	10mg/mL
Doxylamine succinate	1 mg/mL	Tobramycin	10mg/mL
Flunisolide	25μg/mL	Triamcinolone	14mg/mL

Precision:

The COVID-19 Antigen Nasal Test Kit demonstrates the expected test repeatability and reproducibility with three different lots at three different sites in 5 days by three difference operators.

Hook effect:

The study demonstrated that no false negatives occurred on virus level at $1\times10^{6.4}TCID_{50}/mL$ and recombinant SARS-CoV-2 nucleocapsid protein level at 1.48mg/mL.

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		

IVD

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