



EN
No. IFU-COVID-19Ag-NN01-01, Ver. A/3



COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

For professional use only

[Intended use]

This product is used for in vitro qualitative detection of the antigen of SARS-CoV-2 in human anterior nasal swab, nasopharyngeal (NP) swab, and oropharyngeal swab.

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main Manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[Test principle]

This kit uses the double antibody-sandwich method to detect SARS-CoV-2 antigens. When an appropriate amount of specimen is added to the specimen well (s) of the test device, the specimen will move forward along the test device. If the specimen contains an antigen, the antigen binds to mouse anti-SARS-CoV-2 N protein monoclonal antibody labeled with colloidal gold on the binding pad, and the immune complex forms a sandwich complex with another coated mouse anti-SARS-CoV-2 N protein monoclonal antibody which was coated on the test line, a visible colored line will show up, which indicates that the SARS-CoV-2 antigen is positive. The test device also contains a quality control line, regardless of whether there is a test line, the red quality control line should appear. If the quality control line does not appear, it indicates that the test result is invalid and need to do the test again.

[Warnings and Precautions]

1. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you may get inaccurate results.
2. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
3. Do not eat, drink, chew gum, smoke or vape for at least 30 minutes before collecting saliva.
4. Guard against moisture, do not open the foil bag before it is ready for testing. Do not use it if the foil bag is damaged or the test device is damp.
5. Please use it within the validity period.
6. Balance all reagents and specimens to room temperature (15 ~ 30 °C) before use.
7. Do not replace the components in this kit with components in other kits.
8. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
9. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.

10. The test methods and results must be interpreted in strict accordance with this instruction for use.
11. Negative results may occur if the SARS-CoV-2 antigen titer in the specimen falls below the minimum detection limit of this kit.
12. If the extraction reagent is individual packing and one piece per test device, the batch number, expiration date and other information cannot be marked separately due to the space is limited, but those information will be consistent with the corresponding test kit.
13. Both symptomatic and asymptomatic infections can be tested.
14. There is no reduction in sensitivity of the Deepblue Antigen test against the UK variant, Brazilian variant, Indian Delta variant or the South African variant.

[Materials and Components]

Materials provided

- 1) Sterilized Swab
- 2) Antigen Extraction Tube With Extraction Reagent
- 3) Test Device
- 4) Instruction
- 5) Tube Rack (For 25pcs/box only)

Materials required but not provided

Timer.

[Storage conditions & period of validity]

1. Store at 2°C~30°C, and it is valid for 24 months.
2. After the aluminum foil bag is unsealed, the test device should be used as soon as possible and within one hour.

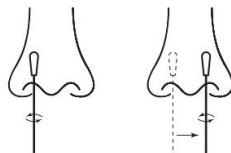
[Specimen Collection]

Option 1: Anterior nasal Swab Sample:

1. Let the patient's head relax naturally, take out the swab, hold the swab no more than 8cm away from the tip. Carefully insert the swab into the patient's nostril, the swab tip should be inserted up to 2-3 cm until resistance is met.



2. Roll the swab 5 times along the mucosa inside the nostril to ensure the mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure an adequate specimen is collected.



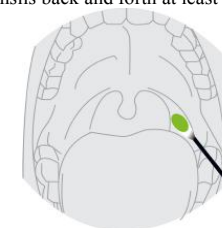
Option 2: Nasopharyngeal Swab Sample:

Let the patient's head relax naturally, carefully insert the swab in the patient's nostril. Swab over the surface of the posterior nasopharynx and rotate the swab several times. Use the same swab, take specimens from the other nostril in the same way.



Option 3: Oropharyngeal Swab Sample:

Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and gently wipe both sides of the patient's pharyngeal tonsils back and forth at least three times.



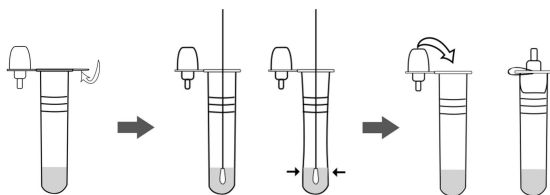
Gently cough before collection, concentrate your saliva in mouth (if there is sputum coughed up, please keep the sputum in the mouth), insert the soft tip of the swab into mouth and fully absorb it until the swab is full of saliva.

[Sample Transport and Storage]

After Swab specimens were collected, swab can be stored in extraction reagent provided with the kit. Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8°C for no more than 24 hours; Store at -70 °C for a long time, but avoid repeated freeze-thaw cycles.

[Specimen Preparation]

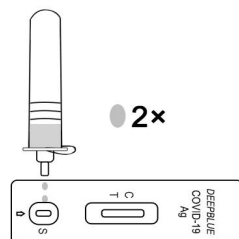
1. Tear off the sealing film on the antigen extraction tube.
2. Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4. Insert a dropper tip into the extraction tube tightly.



[Test Procedure]

Read the instructions carefully before use and allow test device, extraction reagent and specimens to equilibrate to room temperature prior to testing.

1. Open the package and take out the test device.
2. Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer.
3. Read results at 15 minutes. Do not read results after 30 minutes.

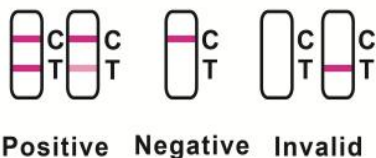


[Interpretation of test results]

Negative result: if there is only a quality control line C, the detection line T is colorless, indicating that SARS-CoV-2 antigen has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line T appear, indicating that SARS-CoV-2 antigen has been detected and the result is positive.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line T (as shown in the figure below), and the test shall be conducted again.



[Quality Control]

Program control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume. The kit does not provide control standards.

[Limitations of inspection methods]

1. This test kit is only used for in vitro diagnosis.

2. This test kit is only used to detect human anterior nasal, nasopharyngeal, oropharyngeal or saliva swab extracts. The results of other specimens may be wrong.

3. This test kit is only used for qualitative detection and cannot indicate the level of SARS-CoV-2 antigen in the specimen.

4. This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.

[Performance index]

1. Physical characters

1.1 Appearance: The test should be clean and complete, no burr, no damage and non-pollution. The shell of the test cassette should be flat, the upper and lower covers should be evenly closed, and there should be no obvious gap. The inner test strip should be firmly attached without wobble. The extraction reagent should be clear and free of foreign matter.

1.2 Size: the size of the inner strip should not be less than 2.5mm.

1.3 Liquid migration speed should not be less than 10mm/min.

2. **Minimum detection limit:** The minimum test limit reference products S1 should be negative, S2 and S3 should be positive.

NOTE: S1: Extraction Reagent for Antigen; S2: 0.1ng/ml of recombinant antigen S3: 1ng/ml of recombinant antigen

3. **Negative compliance rate:** 5 pieces of negative reference products of the test company shall be all negative, with a negative compliance rate of 100%.

4. **Positive compliance rate:** 5 pieces of positive reference products, each reference test one times and shall be all positive, with a positive compliance rate of 100%.

5. **Repeatability:** Test 1 piece of the enterprise positive reference, test it 10 times, the color should be consistent and all positive.

[Limit of detection, LOD]

Using the 320 TCID₅₀/mL concentration, the LOD was further refined using a 2-fold dilution series (four dilutions in total) of the gamma-irradiated SARS-CoV-2 virus made in pooled negative matrix. These dilutions were tested in triplicate. The lowest concentration at which all (3 out of 3 replicates) were positive was treated as the tentative LOD for the DeepBlue SARS-CoV-2 Ag Test. This TCID₅₀/mL was still 80.

SARS-CoV-2 tested (TCID ₅₀ /mL)	Test Result
320	3/3 positive
160	3/3 positive
80	3/3 positive
40	0/3 positive

[Cross-reactivity (Analytical Specificity)]

The cross-reactivity of the DeepBlue SARS-CoV-2 Ag Test is evaluated by testing a group of related pathogens, high-prevalence disease pathogens, and normal or pathogenic flora. The results prove that the product has no cross-reactivity.

Microorganism	Concentration	Cross-Reactivity (Yes/No)
Adenovirus 3	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Parainfluenza virus Type 2	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Human coronavirus NL63	9.87 x 10 ³ PFU/mL	No (3/3 negative)
MERS coronavirus(Pseudovirus, part of ORFlab+N gene)	7930 PFU/mL	No (2/2 negative)
Human coronavirus 229E	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Human coronavirus OC43	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Human Coronavirus HKU1	1 x 10 ⁵ PFU/mL	No (3/3 negative)
SARS-COV-2Pseudovirus (N full-length gene)	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Enterovirus	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Respiratory syncytial virus(A)	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Parainfluenza virus Type 3	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Parainfluenza virus Type 4a	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Influenza A H3N2 (Wisconsin/67/05)	8.82 x 10 ⁴ PFU/mL	No (3/3 negative)
Influenza A H1N1	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Influenza B (VICTORIA)	2.92 x 10 ⁴ PFU/mL	No (3/3 negative)
Rhinovirus(HRVA30)	4.17 x 10 ⁵ PFU/mL	No (3/3 negative)
Haemophilus influenzae	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Streptococcus pneumoniae	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Streptococcus pyogenes	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Candida albicans	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Bordetella pertussis	1 x 10 ⁶ CFU/mL	No (3/3 negative)



SARS-CoV-2 is present in a specimen with other microorganisms.

Mycoplasma pneumoniae	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Chlamydia pneumoniae	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Legionella pneumophila	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Mycobacterium tuberculosis	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Pneumocystis jirovecii	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Pseudomonas Aeruginosa	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Human Metapneumovirus (hMPV)	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Parainfluenza virus Type 1	1 x 10 ⁵ PFU/mL	No (3/3 negative)
Staphylococcus Epidermidis	1 x 10 ⁶ CFU/mL	No (3/3 negative)
Streptococcus Salivarius	1 x 10 ⁶ CFU/mL	No (3/3 negative)

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. For Human Coronavirus HKU1, homology exists between the SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1. BLAST results showed 30 sequence IDs, all nucleocapsid protein, showing homology. Sequence ID AGW27840.1 had the highest alignment score and was found to be 39.1% homologous across 76% of the sequences, this is relatively low but cross-reactivity cannot be fully ruled out. For SARS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus. BLAST results showed 68 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence ID AAR87518.1, had the highest alignment score isolated from a human patient and was found to be 90.76% homologous across 100% of the sequence. This is high and cross-reactivity is likely.

For MERS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and MERS-Coronavirus. BLAST results showed at least 114 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence IDs AHY61344.1 and AWH65950.1, had the highest alignment scores isolated from a human patient and were found to be 49.4% and 50.3% homologous across 88% of the sequence. Whilst this potentially represents moderate cross-reactivity testing of the MERS virus at 7930 PFU/mL showed no reactivity (see table above).

[Microbial Interference Studies]

Microbial interference in the DeepBlue SARS-CoV-2 Ag Test was evaluated by testing a panel of related pathogens, high prevalence disease agents and normal or pathogenic flora to demonstrate that false negatives do not occur when

Microorganism	Concentration	Interference (Yes/No)
Parainfluenza virus Type 1	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Parainfluenza virus Type 2	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Parainfluenza virus Type 3	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Parainfluenza virus Type 4a	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Adenovirus (e.g. C1 Ad. 71)	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Human Metapneumovirus (hMPV)	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Influenza A H3N2(Wisconsin/67/05)	8.82 x 10 ⁴ PFU/mL	No (3/3 positive)
Influenza A H1N1	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Haemophilus influenzae	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Streptococcus pneumoniae	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Streptococcus pyogenes	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Influenza B (Malaysia/2506/04)	2.92 x 10 ⁴ PFU/mL	No (19/20 positive)
Enterovirus	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Respiratory syncytial virus	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Rhinovirus	4.17 x 10 ⁵ PFU/mL	No (3/3 positive)
Chlamydia pneumoniae	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Legionella pneumophila	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Mycobacterium tuberculosis	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Pneumocystis jirovecii	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Pseudomonas Aeruginosa	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Candida albicans	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Pooled human nasal wash	14% v/v	No (3/3 positive)
Bordetella pertussis	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Mycoplasma pneumoniae	1 x 10 ⁶ CFU/mL	No (3/3 positive)

Staphylococcus Epidermidis	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Streptococcus Salivarius	1 x 10 ⁶ CFU/mL	No (3/3 positive)
Human coronavirus 229E	1 x 10 ⁵ PFU/mL	No (3/3 positive)
Human coronavirus OC43	1 x 10 ⁵ PFU/mL	No (19/20 positive)
Human coronavirus NL63	9.87 x 10 ³ PFU/mL	No (3/3 positive)
MERS coronavirus	7930 PFU/mL	No (3/3 positive)

[Endogenous Interference Studies]

A study was performed to demonstrate that potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications) do not cross-react or interfere with the detection of SARS-CoV-2 in the DeepBlue SARS-CoV-2 Ag Test.

Interfering Substance	Concentration	Interference (Yes/No)
Zicam Cold Remedy	5% v/v	No (3/3 Negative, 3/3 Positive)
Homeopathic (Alkalol)	10 % v/v	No (3/3 Negative, 3/3 Positive)
Sore Throat Phenol Spray	15% v/v	No (3/3 Negative, 3/3 Positive)
Blood (human)	5%	No (3/3 Negative, 3/3 Positive)
Mucin	5 mg/mL	No (3/3 Negative, 3/3 Positive)
Naso GEL (NeilMed)	5% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Drops (phenylephrine)	15% v/v	No (3/3 Negative, 3/3 Positive)
Afrin (Oxymetazoline)	15% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Spray (Cromolyn)	15% v/v	No (3/3 Negative, 3/3 Positive)
Tamiflu (Osetamivir phosphate)	500 mg/dL	No (3/3 Negative, 3/3 Positive)
Budenoside	0.00063 mg/dL	No (3/3 Negative, 3/3 Positive)
Biotin	0.35 mg/dL	No (3/3 Negative, 3/3 Positive)
Tobramycin	3.3 mg/dL	No (3/3 Negative, 3/3 Positive)



Mupirocin	0.15 mg/dL	No (3/3 Negative, 3/3 Positive)
Fluticasone	0.000126 mg/dL	No (5/5 Negative, 4/4 Positive)
Dextromethorphan	0.00156 mg/dL	No (19/20 Negative, 3/3 Positive)
Dexamethasone	1.2 mg/dL	No (3/3 Negative, 3/3 Positive)
Mucinex	5%	No (3/3 Negative, 3/3 Positive)
Methanol	150 mg/dL	No (19/20 Negative, 3/3 Positive)
Acetylsalicylic Acid	3 mg/dL	No (3/3 Negative, 3/3 Positive)
Diphenhydramine	0.0774 mg/dL	No (3/3 Negative, 3/3 Positive)
Benzocaine	150 mg/dL	No (3/3 Negative, 3/3 Positive)

[High Dose Hook Effect]

The serial increased concentrations of SARS-CoV-2 samples were tested with the COVID-19 (Sars-CoV-2) Antigen Test Kit (Colloidal gold) manufactured by the DeepBlue. No impact on test performance or hook effect at high concentrations was observed up to 1.4×10^5 TCID₅₀/mL of SARS-CoV-2 with the DeepBlue SARS-CoV-2 Ag Test.

Test Dilution	Concentration (TCID ₅₀ /mL)	Mean Signal (ADC Units)
1	0	495
2	62.5	26100.6
3	250	63013.8
4	1000	83451.8
5	1.4×10^5	86220

[Clinical Performance]

1..The overall study scale was 420 cases, 220 positive samples and 200 negative samples.

Statistics of test results of nasal swab samples:

Reference RT-PCR Assay					95% Wilson Score CI			
					LCI		UCI	
DEEP BLUE SARS-CoV-2 Ag Test		POS	NEG	TOTAL	PPA	98.64%	96.07%	99.53%
		217	0	217				
		3	200	203	NPA	100%	98.12%	100%
		220	200	420				

Sensitivity: 98.64% (95% CI: 96.07% - 99.53%)

Specificity: 100% (95% CI: 98.12% - 100%)

2..The overall study scale was 600 cases, 150 positive samples and 450 negative samples.

Statistics of test results of Nasopharyngeal/Oropharyngeal samples:

Reference RT-PCR Assay					95% Wilson-Score CI			
					LCI		UCI	
DEEP BLUE SARS-CoV-2 Ag Test		POS	NEG	TOTAL	PPA	98.67%	95.27%	99.63%
		148	0	148				
		2	450	452	NPA	>99.99%	99.15%	100%
		150	450	600				

Sensitivity: 98.67% (95% CI: 95.27% - 99.63%)

Specificity: >99.99% (95% CI: 99.15% - 100%)

PPA - Positive Percent Agreement (Sensitivity)

NPA - Negative Percent Agreement (Specificity)

CI - Confidence Interval

LCI - Lower Confidence Interval

UCI - Upper Confidence Interval



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[Index of CE Symbols]

	In vitro diagnostic medical device		Do not re-use
	Use-by date		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
	Temperature limit		Batch code
	Authorized representative in the European Community/ European Union		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use
	Date of manufacture		Biological risks
	CE Mark		Contains sufficient for <n> tests

Specification	REF
1 piece per box	COVAg1NNO1-1
2 pieces per box	COVAg1NNO1-2
5 pieces per box	COVAg1NNO1-5
10 pieces per box	COVAg1NNO1-10
25 pieces per box	COVAg1NNO1-25