Artron Laboratories Inc.

Catalog Number: A03-50-422S

COVID-19 Antigen Self Test

CE IVD

FOR HOME USE

PRODUCT NAME

Artron COVID-19 Antigen Self Test

SPECIMEN

Nasal Swab

INTENDED USE

Artron COVID-19 Antigen Home Test is a rapid and convenient lateral flow immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid protein from SARS-CoV-2. This test is for home use with self-collected anterior nasal (nares) swab specimens from individuals aged 14 years or older and who are suspected of COVID-19 within seven days of symptom onset and / or epidemiological criteria or adult collected nasal swab specimens from individuals aged 4 years or older who are suspected of COVID-19 within the first seven days of symptom onset and / or epidemiological criteria. The rapid test device is for home use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.

This assay provides preliminary test results. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and for patient management confirmation with a molecular assay, if necessary, may be performed. 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.

Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

Individuals who test positive should report the test results to relevant public health authorities.

The result of this test should not be the sole basis for the diagnosis and the test results should be confirmed by local government approved Real-Time Reverse Transcriptase (RT)-PCR Diagnostic assay.

SUMMARY AND PRINCIPLE OF THE ASSAY

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus strain that caused an outbreak of a novel coronavirus disease (COVID-19), which has subsequently affected countries and regions worldwide. Severe disease onset might result in death due to massive alveolar damage and progressive respiratory failure. On March 11, 2020, the World Health Organization (WHO) has declared the global outbreak of COVID-19 a pandemic associated with substantial morbidity and mortality.

Artron COVID-19 Antigen Home Test is an antigen-capture immunochromatographic assay, detecting presence of SARS-CoV-2 nucleocapsid protein in nasal swab specimens. SARS-CoV-2 specific antibody and a control antibody are immobilized onto a membrane support as two distinct lines-Test line(T) and Control line(C) and combined with colloidal gold- monoclonal antibody against SARS-CoV-2 antigen deposited on the conjugate pad to construct a test strip. When the swab sample migrates in the test strip, SARS-CoV-2 nucleocapsid protein bind to anti-SARS-CoV-2 nucleocapsid protein antibody-gold conjugate, forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip, forming a visible pink or purple line, indicating positive result. If SARS-CoV-2 are absent in the sample, no pink or purple line will appear in the test line, indicating a negative result.

To serve as an internal process control, a control band has been designed. This control line should always be seen after test is completed. Absence of a control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

- 1 Test cassette with desiccant in individual pouch
- 1 Extraction tube sealed with sample extraction buffer (300μL/tube)
- 1 Extraction tube cap
- 1 Sterilized nasal swab
- Test Instruction

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Latex gloves
- Clock or timer

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- The test is designed only for the detection of nasal swab specimens.
- This test is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- All kit components are single use items. Do not use with multiple specimens. Do not reuse the test cassette.
- Do not use if the pouch seal or the packaging is compromised.
- Do not use after the expiry date shown on the pouch.
- Do not mix and interchange different specimens.
- The swabs in the kit are approved for use with Artron COVID-19 Antigen home Test. Do not Use other swabs.
- Do not touch swab tip when handling the swab specimen.
- If the test is stored refrigerated, ensure that the test units are brought to room temperature (15-30°) at least 30mins before performing testing.
- Use the test device immediately after opening the pouch.
- INVALID RESULTS can occur when an insufficient drop of sample is added to the test cassette. To ensure delivery of adequate volume, hold vial vertically, ½ inch above the swab well, and add drops slowly.
- Wash hands thoroughly before and after finishing the testing.
- Dispose of kit components and patient samples in household trash.
- Keep out of children's reach.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water.

SPECIMEN COLLECTION AND PREPARATION

Note:

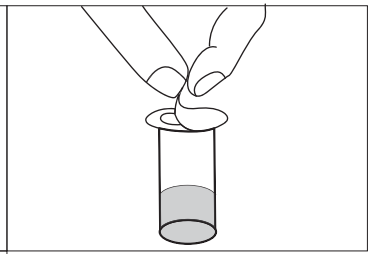
Before proceeding with sample collection and testing, please read the test instructions carefully, and operate strictly in accordance with the instructions.

Make sure that the test units are brought to room temperature (15-30°C) at least 30mins before performing testing.

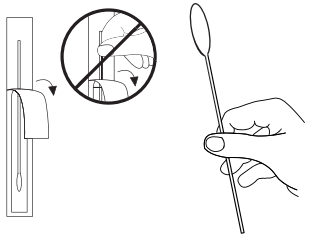
Wash or sanitize your hands. Make sure they are dry before starting.

Freshly collected specimens should be processed as soon as possible, but no later than 4 hours after the specimen collection.

1. Tear off the aluminum foil seal from the extraction tube.



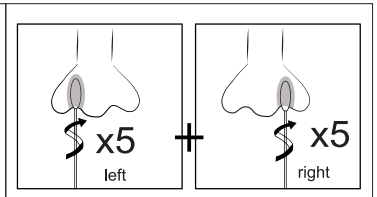
2. Remove a nasal swab at the stick end from the pouch.

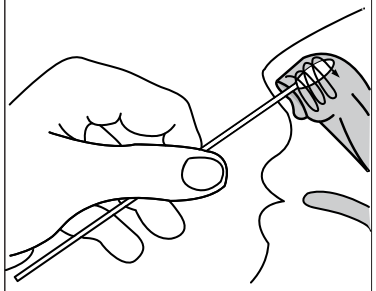


3. Gently insert the SWAB ½ - ¾ inch (1-1.5 cm) into the nostril, depending on the size of the person's nose. Firmly rub the SWAB in a circular motion around the inside wall of EACH NOSTRIL at least 5 times or more for at least 15 seconds. Be sure to rub BOTH nostrils with the SAME SWAB.

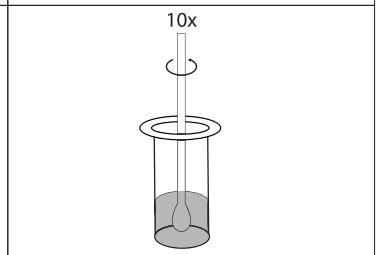
NOTE: If you are swabbing others, please wear a face mask.
With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

NOTE: Failure to swab properly may cause false negative results.

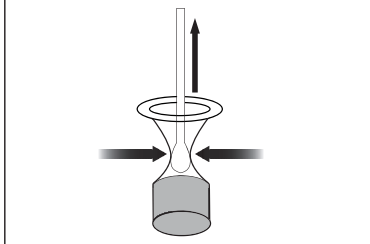




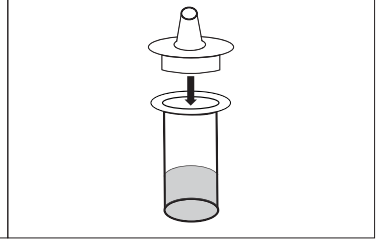
4. Immediately insert the swab in the extraction tube. Swirl the swab tip vigorously in the buffer fluid at least 10 times.



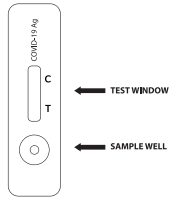
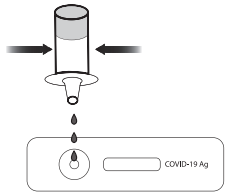
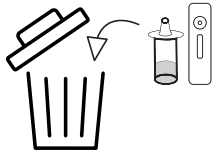
5. Remove the swab by rotating against the extraction tube while squeezing the sides of the tube to release the liquid from the swab. Dispose of the swab in the trash.



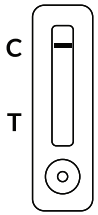
6. Close the extraction tube with the provided extraction tube cap and push firmly onto the tube.



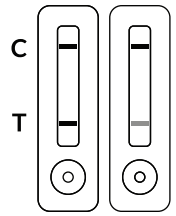
TEST PROCEDURES

A) Get the test cassette from the sealed pouch by tearing at the notch and place the cassette on a flat and dry surface. Do not touch the Test window.	
2. B) Hold the extraction tube vertically (not at an angle) above the sample well, slowly add 4 drops of the specimen without air bubbles into the sample well. DO NOT touch the card with the dropper tip while dispensing.	
C) Read and interpret the test result in 15-30 minutes. The test result should not be read and interpreted after 30 minutes. **Note:** False results can occur if the cassette is disturbed/moved, or test results are read before 15 minutes.	  DO NOT INTERPRET RESULTS AFTER 30 MINUTES.
D) All used test components should be disposed of in the household waste.	

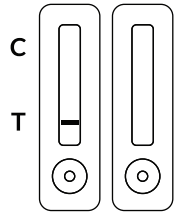
RESULT INTERPRETATION



Negative:
A clear pink or purple colored band appears only at the control region (C), indicating a negative result.
A negative test result for this test means that antigens from SARSCoV-2 were not present in the specimen above the limit of detection.
However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The amount of antigen in a sample may decrease as the duration of illness increases If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. It is important that you work with your healthcare provider to help you understand the next steps.



Positive:
A clear pink or purple control band (C) and a detectable test band (T) appears, indicating a positive result, which means antigens from SARS-CoV-2 have been detected.
A positive test result for COVID-19 indicates that the patient is very likely to be infected with the virus and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give you a positive test result that is wrong (false positive.) If you test positive with the Artron COVID-19 Antigen Home Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how to best care for you based on your test result along with your medical history, and your symptoms.
NOTE: THE BOTTOM TEST LINE MAY BE ALMOST INVISIBLE.



Invalid:
No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiry date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture, and heat.
- The test device is stable until the expiry date marked on the outer packaging and containers.
- Shelf life:18 month

LIMITATION

- The test is only intended for nasal swab specimens that are collected and tested directly, not for swab specimens stored in virus transport media.
- Failure to follow the Test Procedures may adversely affect test performance and/or invalidate the test result.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- False results may occur if specimens are tested past 4 hours of collection. Specimens should be tested as quickly as possible after specimen collection.
- False negative results may occur if inadequate specimen is added in the sample well (e.g., < 4 drops).
- False negative results may occur if specimen swabs are not twirled sufficiently in the sample extraction buffer.
- False negative results are more likely after eight days or more of symptoms. Negative results, from patients with symptom onset beyond seven days, should be confirmed with a molecular assay, if necessary, for patient management.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results do not rule-out other possible non-COVID-19 viral infections.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.
- This test only provides qualitative test result and does not provide information about the virus concentration in the sample.
- For mutant virus strains or virus strains from different regions, the detection ability of the detection reagent may be different, which may lead to false negative.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

PERFORMANCE CHARACTERISTICS

• Clinical Performance
To investigate the layman usability of Artron COVID-19 Antigen Home Test (Nasal Swab) in the home test use, 105 participants who had never previously used similar home test reagents, including 45 participants for prescription testing and another 60 participants randomly from healthy volunteers were recruited in the study. Under the observation and coaching of a clinical site staff member trained as a proctor, subjects self-collected nasal swab sample and performed the Artron COVID-19 Antigen Home test. Test results were interpreted and recorded by the subject or other home user and independently by the proctor. Parents of pediatric subjects under the age of 14 or legally authorized representatives of adult subjects unable to perform self-collection collected one nasal swab from the subject, performed Artron COVID-19 Antigen Home Test, then interpreted and recorded the result for the subject. A WHO Emergency Use Listing Real-Time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.
The 45 prescription testing participants in the study included 22 SARS-CoV-2 RT-PCR confirmed positives and 23 SARS-CoV-2 RT-PCR confirmed negatives; while all the other 60 healthy participants were confirmed negative with SARS-CoV-2 RT-PCR. Of the 22 positive cases, 10 were asymptomatic, 8 were 0-3 days after the onset of symptoms, and 4 were 7 days after the onset of symptoms; and 4 cases were with Ct value <20, 18 cases were with Ct value between 20-26. All the antigen test results from the 22 positive cases were interpreted as positive by the operators themselves when testing with Artron COVID-19 Antigen Home Test; the number of cases interpreted as a positive result was 100% consistent with the expected result. The other 84 antigen testing results from the 84 negative cases were all interpreted as negative by the operators; the number of cases interpreted as negative is 100% consistent with the expected result. All the results were consistent with the expected test results (100%). No invalid test results appeared.

Summary the layman study performance against the comparator method

Artron COVID-19 Antigen Home Test	Participants from prescription (RT-PCR confirmed)		Participants from OCT (RT-PCR confirmed)		Total
	Positive	Negative	Positive	Negative	
Positive	22	0	0	0	22
Negative	0	23	0	60	83
Subtotal	22	23	0	60	105
Performance with 95%CI	Sensitivity		Specificity		Overall Agreement
	100% (84.56-100.00)		100% (95.65-100.00)		100% (96.55- 100.00)

Summary of positive agreement related to Ct value

Original Ct value for N gene	Artron COVID-19 Antigen Home Test: Positivity Agreement	Original Ct value for N gene	Artron COVID-19 Antigen Home Test: Positivity Agreement with 95%CI
<20	4/4 (100%)	<30	22/22(100%) (84.56-100.00)
≥20, <30	18/18(100%)		
≥30	0/0	≥30	0/0

Summary of positive agreement related to days post onset

Days post onset of symptoms	Number of cases		Artron COVID-19 Antigen Home Test: Test Positivity Rate (with 95%CI)	
Asymptomatic	33		30/33(90.91%) (75.67- 98.08)	
0-3	32	64	32/32(100%) (90.00-100.00)	61/64(95.31%) (86.91-99.02)
4-7	32		29/32(90.62%) (74.98-98.02)	
>7	6		3/6(50%) (11.81-88.19)	

Due to the relatively small sample size for the home use ongoing laymen clinical study, at the time of the interim analysis, the Artron COVID-19 Antigen Home Test positive agreement established in this is estimated to be between 84.56% and 100% as reflected in the 95% Confidence Interval with Ct value <30. The positive rate from patient with days post onset of symptoms within 7 days with Ct value <30 or asymptomatic with Ct value <30 is estimated to be between 84.56% and 100% as reflected in the 95% Confidence Interval. This is consistent with the performance established in a separate multi-site clinical study, where the Artron COVID-19 Antigen Home Test was performed, and results were interpreted by test operators with no laboratory experience. In that study, Artron COVID-19 Antigen Home Test positive agreement was 96.77% (95%CI:90.86-99.33) with Ct value below 30. The positive agreement in patients with symptoms within 7 days is 95.31%(95%CI:86.91-99.02), the positive rate of over seven days was 50% (3/6). Therefore, negative results in patients with symptom onset greater than seven days should be interpreted with caution, as the sensitivity of the assay decreases over time. Please refer to Artron COVID-19 Antigen Home Test performance in a separate multi-site clinical study established with 330 nasal swabs collected from individual who were suspected of COVID-19 as below:

Summary of Artron COVID-19 Antigen Home Test performance against comparator method

Artron COVID-19 Antigen Home Test	RT-PCR		Subtotal
	Positive	Negative	
Positive	94	1	95
Negative	9	226	235
Subtotal	103	227	330
Performance 95% CI	Sensitivity	Specificity	Overall Agreement
	91.26% (84.06-95.93)	99.56% (97.57-99.99)	96.97% (94.50-98.54)
	PPV	NPV	
	98.95% (93.00- 99.85)	96.17% (93.08-97.91)	

Summary of positive agreement related to Ct Value

Original Ct value for N or ORF1ab gene	Artron COVID-19 Antigen Home Test: Test Positivity Rate	Original Ct value for N or ORF1ab gene	Artron COVID-19 Antigen Home Test: Test Positivity Rate: (95% CI)
<20	17/17 (100%)	<30	90/93(96.77%) (90.86-99.33)
≥20, <24	31/31 (100%)		
≥24, <27	24/24(100%)		
≥27, <30	18/21 (85.71%)		
≥30, <33	4/7 (57.14%)	≥30	4/10(40%) (12.16-73.76)
≥33	0/3 (0%)		

Summary of positive agreement related to days post onset

Days post onset of symptoms	Number of cases		Artron COVID-19 Antigen Home Test: Test Positivity Rate (with 95%CI)	
Asymptomatic	33		30/33(90.91%) (75.67- 98.08)	
0-3	32	64	32/32(100%) (90.00-100.00)	61/64(95.31%) (86.91-99.02)
4-7	32		29/32(90.62%) (74.98-98.02)	
>7	6		3/6(50%) (11.81-88.19)	

• Limit of Detection (LoD)-Analytical Sensitivity

The limit of detection (LoD) of Artron COVID-19 Antigen Home Test is 3.75×102 TCID50 /mL for live SARS-CoV-2 strain nCoV-SH01 P6, 1×103 TCID50 /mL for the heat inactivated SARS-CoV-2 strains nCoV-SH01 P6 and USA-WA1/2020.

• Cross Reactivity

None of the below mentioned related pathogens cross-reacted with Artron COVID-19 Antigen Home Test when the virus content>10^5PFU/mL and the bacterial content>10^6CFU/mL, nor did they interfere with the test results. The negative matrix prepared from pooled human nasal wash- representative of normal respiratory microbial flora and 20 negative nasal swab specimens from healthy volunteers were detected negative, indicating Artron COVID-19 Antigen home Test has good analytical specificity.

Potential cross-reactive pathogen	Concentration of the pathogen	SARS-CoV-2 virus (USA-WA1/2020) $TCID_{50}$/mL	
		0	3×10^3
Negative Matrix (Pooled human nasal wash)		(-)	N/A
Coronavirus OC43 (ATCC: VR-1558™)	1.6×10^5 $TCID_{50}$/mL	(-)	(+)
Coronavirus NL63	1.41×10^5 $TCID_{50}$/mL	(-)	(+)
Coronavirus 229E	1.41×10^5 $TCID_{50}$/mL	(-)	(+)
SARS Coronavirus (2003-00592 strain)	$>10^5$ $TCID_{50}$/mL	(-)	(+)
MERS Coronavirus (Florida/USA-2_Saudi Arabia_2014)	3.55×10^5 $TCID_{50}$/mL	(-)	(+)
H1N1 influenza virus (2009) (Canada/629/09 strain)	1.26×10^6 $TCID_{50}$/mL	(-)	(+)
H1N1 influenza virus (ATCC: VR-98™)	$1\times10^{7.5}$ $TCID_{50}$/mL	(-)	(+)
Seasonal H3N2 influenza virus (Brisbane/10/07 strain)	5.01×10^5 $TCID_{50}$/mL	(-)	(+)
Influenza B (Yamagata/16/88 strain)	$1\times10^{5.39}$ $TCID_{50}$/mL	(-)	(+)
Influenza B (Victoria/2/87 strain)	1.86×10^5 $TCID_{50}$/mL	(-)	(+)
Parainfluenza virus type 1 (ATCC: VR-94™)	1.6×10^7 $TCID_{50}$/mL	(-)	(+)
Parainfluenza virus type 2 (ATCC: VR-92™)	1.6×10^8 $TCID_{50}$/mL	(-)	(+)
Parainfluenza virus type 3 (ATCC: VR-93™)	1.6×10^6 $TCID_{50}$/mL	(-)	(+)
Parainfluenza virus type 4b (ATCC: VR-1377)	1.6×10^5 $TCID_{50}$/mL	(-)	(+)
Respiratory syncytial virus (ATCC: VR-1580™)	7.0×10^5 PFU/mL	(-)	(+)
Rhinovirus A (73) (ATCC: VR-1183™)	$5\times10^{5.5}$ $TCID_{50}$/mL	(-)	(+)
Rhinovirus B (B42)	1.05×10^6 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 1 (C)	2.57×10^8 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 2 (C)	1.15×10^7 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 3 (B)	3.8×10^6 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 4	$1\times10^{6.34}$ $TCID_{50}$/mL	(-)	(+)
Adenovirus type 5	$1\times10^{7.53}$ $TCID_{50}$/mL	(-)	(+)
Adenovirus type 7 (7A)	$1\times10^{5.15}$ $TCID_{50}$/mL	(-)	(+)
Enterovirus Group A (71)(2003)	$1\times10^{5.86}$ $TCID_{50}$/mL	(-)	(+)
Enterovirus group D (68)	1.6×10^6 $TCID_{50}$/mL	(-)	(+)
Epstein-Barr virus (B95-8)	2.70×10^8 cp/mL	(-)	(+)
Measles virus	$1\times10^{7.77}$ $TCID_{50}$/mL	(-)	(+)
Human cytomegalovirus	$1\times10^{5.62}$ $TCID_{50}$/mL	(-)	(+)
Rotavirus, WA strain	$1\times10^{7.06}$ $TCID_{50}$/mL	(-)	(+)
Mumps virus 1	$1\times10^{6.10}$ $TCID_{50}$/mL	(-)	(+)
Varicella-zoster virus (strain 82)	4.28×10^8 cp/mL	(-)	(+)
Metapneumovirus (Peru6-2003)	$>1\times10^6$ cp/mL	(-)	(+)
Mycoplasma pneumoniae (M129)	3.16×10^8 CCU/mL	(-)	(+)
Chlamydia pneumoniae (ATCC: VR-1435™)	1.44×10^8 IFU/mL	(-)	(+)
Haemophilus influenzae (ATCC: 49144™)	1×10^7 CFU/mL	(-)	(+)
Legionella (ATCC: 33152™)	1×10^7 CFU/mL	(-)	(+)
Mycobacterium tuberculosis (ATCC: 25177™)	1×10^7 CFU/mL	(-)	(+)
Streptococcus pyogenes (ATCC: 19615™)	1×10^7 CFU/mL	(-)	(+)
Streptococcus pneumoniae (ATCC:49619™)	1×10^7 CFU/mL	(-)	(+)
Staphylococcus epidermidis (PCI 1200, ATCC: 12228™)	1×10^7 CFU/mL	(-)	(+)
Staphylococcus aureus (ATCC: 12600™)	1×10^7 CFU/mL	(-)	(+)
Bordetella pertussis type 5 (ATCC: 9340-FZ™)	1×10^7 CFU/mL	(-)	(+)
Pneumocystis (W303-Pji strain)	5.12×10^8 CFU/mL	(-)	(+)
Candida albicans (ATCC: 44373)	1×10^7 CFU/mL	(-)	(+)
20 negative nasal swab specimens	N/A	(-)	N/A

• Endogenous/Exogenous Interference Study

There was no interference for potential interfering substances listed below.• Cross Reactivity

Interfering substances	Interfering substances Final concentration	SARS-COV-2 Virus ($TCID_{50}$/mL)	
		0	3×10^3
Endogenous interfering substances			
Mucin	2% W/V	(-)	(+)
Whole blood	4% W/V	(-)	(+)
OCT Nasal skin steroids			
Beclomethasone	0.5mg/ml	(-)	(+)
Dexamethasone	1mg/ml	(-)	(+)
Flunisolide	5mg/ml	(-)	(+)
Triamcinolone acetonide	1mg/ml	(-)	(+)
Budesonide	2mg/ml	(-)	(+)
Mometasone	2mg/ml	(-)	(+)
Fluticasone	1mg/ml	(-)	(+)
Naso GEL (NeiMed)	5%V/V	(-)	(+)
OTC Nasal drops or spray			
Phenylephrine	10% (V/V)	(-)	(+)
Oxymetazoline	10% (V/V)	(-)	(+)
Sodium chloride (with preservatives)	10% (V/V)	(-)	(+)
Menthol	1.5 mg/mL	(-)	(+)
Benzocaine	1.5 mg/mL	(-)	(+)
CVS Nasal Spray (Cromolyn)	15% V/V	(-)	(+)
Zicam	5% V/V	(-)	(+)
Homeopathic (Alkalol)	1:10	(-)	(+)
Sore Throat Phenol Spray	15% V/V	(-)	(+)
Anti-viral drugs			
alpha interferon	200,000IU/ml	(-)	(+)
Zanamivir	1mg/ml	(-)	(+)
Ribavirin	2mg/ml	(-)	(+)
Oseltamivir	12mg/ml	(-)	(+)
Peramivir	2mg/ml	(-)	(+)
Lopinavir	2mg/ml	(-)	(+)
Ritonavir	2mg/ml	(-)	(+)
Abidor	4mg/ml	(-)	(+)
Antibiotic drugs			
Levofloxacin	5mg/ml	(-)	(+)
Azithromycin	1mg/ml	(-)	(+)
Ceftriaxone	1mg/ml	(-)	(+)
Meropenem	2mg/ml	(-)	(+)
Mupirocin	10mg/ml	(-)	(+)
Systemic antibacterial drugs			
Tobramycin	1mg/ml	(-)	(+)
Allergic symptom relief medication			
Histamine Dihydrochloride	10mg/ml	(-)	(+)
Others			
Biotin	1mg/ml	(-)	(+)

• HOOK Effect

There was no hook effect at 9.55×10^6 $TCID_{50}$ /mL of SARS-CoV-2 strain USA-WA1/2020.

• Usability Study

The usability study was conducted to evaluate the test usability for the home users who will be supervised by a trained proctor through a virtual platform (the supervisor will only supervise the test and not couch and interfere with the testing). 105 subjects including 45 participants for prescription testing and another 60 participants randomly from healthy volunteers participated in the study. All the 45 participants from prescription tests completed the full test process from nasal swab specimen collection, testing and results interpretation at the clinical site, in person monitoring by the staff at the clinical site. 5 children were sampled and tested by their parents, while one adult was sampled and tested by her daughter. The other 60 participants conducted the tests at their own home and were remotely observed by visual monitoring during sample collection, test procedure and results interpretation. 8 children below 14 years were sampled and tested by their parents while 7 adults were sampled and tested by their legally authorized representatives to perform nasal swab collection and performed the Artron COVID-19 Antigen Home Test, followed by interpretation and recording of the result for the subject.

3/105(2.86%) participants encountered some difficulties in removing the sterile swabs from the pouch. During the sampling process, most of the participants experienced slight discomfort, mainly itching, and no one experienced pain or bleeding. The uncomfortable feeling was stronger for the participants who were sampled by another person than by themselves. The entire sampling process went smoothly and was completed within 1-2 minutes. 93 of 105 participants (88.58%) felt the sample collection was easy. However, 11/105 (10.48%) of participants felt difficult and 1/105(0.95%) of participant felt very difficult when sampling without proctor help.

In the process of sample preparation and testing, all participants followed the instructions or quick reference guide to operate the test step by step. 3/105(2.86%) of operators did not hold the sample extraction tube vertically during the process of dripping the sample, which caused the sample dripping to be difficult. 7/105(6.67%) operators quickly picked up the test device from the flat surface after dropping the sample then placed it back on the desktop. In all the detection processes, there was no contamination of the detection window, and there was no insufficient sample dripping. 94 of 105 participants (89.52%) felt the use of test procedure was easy. However, 10/105 (9.52%) of the participants felt difficult and 1/105(0.95%) of participant felt very difficult to conduct the testing without proctor help.

All the 105/105(100%) users produced a valid result and interpreted the test results independently and correctly. No invalid results were observed. 96 of the 105 participants (91.43%) felt the results interpretation was easy. However, 8/105 (9.52%) of the participants commented that it was difficult to see some of the faint bands and 1/105 (0.95%) felt very difficult.

Over 85% of the operators felt that the instruction of Artron COVID-19 Antigen Home Test and Quick Reference Guide was easy to understand and could be followed to complete the test (91/105 (86.67%) for IFU understanding and following, and 93/105 (88.57%) for Quick Reference Guide (QRF) understanding and following respectively).

REFERENCES

- Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim guidance. World Health Organization. 13 March 2020.
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- The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19). Chinese Center for Disease Control and Prevention. CCDC Weekly, 2(8):113-122, 2020.
- A novel coronavirus outbreak of global health concern. Wang C et al. Lancet, 395(10223):470- 473, 2020

INDEX OF SYMBOLS

	Do not reuse	LOT	Batch code
IVD	In vitro diagnostic medical device		Expire date
	Temperature limitation		Contains sufficient for <n> tests
	Caution	REF	Catalog number
	Manufacturer		Consult instruction for use
EC REP	European representative	CE	CE Mark

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