COVID-19 Antigen Home Test

Instruction for Use

Catalog Number: A03-50-422S1/A03-50-422S5/A03-50-422S25

Specimen: Nasal Swab

** Please read the instructions carefully before use*

INTENDED USE

Artron COVID-19 Antigen Home Test is a rapid lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in self-collected anterior nasal (nares) swab samples obtained from individuals aged 14 years or older or adult collected nasal swab specimens from individuals aged two years or older. This test is intended for individuals suspected of COVID-19 within the first seven days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. 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. Individuals who test positive should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.

Negative results 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 of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

The Artron COVID-19 Antigen Home Test rapid test device is intended for home use.

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

Test cassettes with desiccant in individual pouch (Material Number: A03-50-422S); 1device for 1pc/pack, 5 devices for 5 pcs/pack, 25 devices for 25 pcs/pack.

- Extraction tubes sealed with sample extraction buffer (300μL/tube, Material Number: A801-R350); 1 tube for 1pc/pack, 5 tubes for 5 pcs/pack, 25 tubes for 25 pcs/pack.
- Extraction tube caps; 1 cap for 1pc/pack, 5 caps for 5 pcs/pack, 25 caps for 25 pcs/pack.
- Sterilized nasal swabs; 1 nasal swab for 1pc/pack, 5 nasal swabs for 5 pcs/pack, 25 nasal swabs for 25 pcs/pack. (Sterile Method: EO; Manufacturer, Jiangsu Changfeng Medical Industry Co., Ltd, Certified by CE0197, Catalogue: CF 075-P 3 B; EC REP: Llins Service &Consulting GmbH)
- 1 Instructions for use (IFU).
- 1 Quick reference guide (QRG).

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Timer or Clock

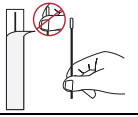
WARNINGS AND PRECAUTIONS

- 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.
- Complete the test within 1 hour after the reagent is opened.
- 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.
- Do not eat, drink, or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- 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 immediately. Specimens in Artron sample extraction buffer are stable for up to 4 hours at 2-8ºC or room temperature.

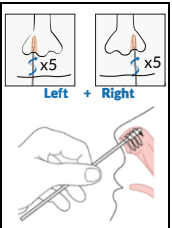
1. Tear off the aluminum foil seal from the extraction tube.		2. Remove a nasal swab at the stick end from the pouch.	

3. Gently insert the **SWAB ½ - ¾ inch (1.3-1.9 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**.

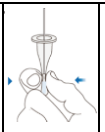
NOTE: If you are swabbing others, please wear a face mask.
With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

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

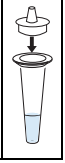


4. Immediately insert the swab in the extraction tube. Swirl the swab tip vigorously in the buffer fluid at least 10 times.

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.

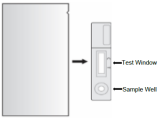


6. Close the extraction tube with the provided extraction tube cap and push firmly onto the tube.

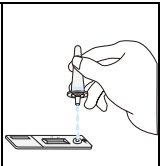


TEST PROCEDURES

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.



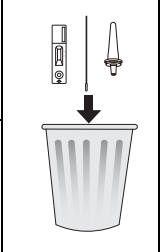
B) Hold the extraction tube **vertically** (not at an angle) above the sample well, slowly add 4 drops of the specimen without air bubbles into the sample well. DO NOT touch the card with the dropper tip while dispensing.



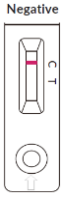
C) Read and interpret the test result in 15-30 minutes. The test result should not be read and interpreted after 30 minutes.
Note: False results can occur if the cassette is disturbed/moved, or test results are read before 15 minutes. If a test shows a negative result at the 15 minutes, it should not be discarded immediately as some positive results may develop later in the 15-30 min interval.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES.

D) All used test components should be disposed of in the household waste.



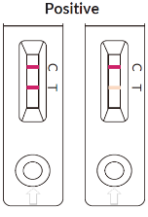
RESULT INTERPRETATION



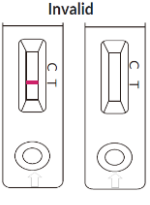
Negative:
A clear pink or purple colored band appears only at the control region (C), indicating a negative result.
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.



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.) You do not need to perform repeat testing if you have a positive result at any time. 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.



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.

These are the pictures of actual positive results. On the right, please note how faint the test band (bottom line) can get.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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.

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.
- Inadequate or inappropriate sample collection may yield false test results.
- 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.
- 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.
- Negative results, from asymptomatic patients suspected of SARS-CoV-2 exposure and patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- **Serial Testing Information and Limitations**:
  - Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
  - Symptomatic individuals that test negative should repeat testing twice at least 48-hours apart and three times at 48-hour intervals if they are asymptomatic.
  - The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the FDA.
  - All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

PERFORMANCE CHARACTERISTICS

- Clinical Performance
  - This clinical performance data reflects the accuracy of the test when testing once. This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

• Clinical performance of Artron COVID-19 Antigen Home Test

A total of 175 cases were recruited into clinical evaluation of Artron COVID-19 Antigen Home Test. Under the observation 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 FDA-EUA approved Real-Time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

All the 175 cases were confirmed with SARS- CoV-2 RT-PCR at the same timepoint, including 47 SARS-CoV-2 positives and 128 SARS- CoV-2 negatives. The age of recruited patients ranged from 2- 97 years, with the mean age of 39 years, including 68 males, 102 females and 3 subjects with unidentified gender information.

Among the 47 positive cases, 12 of the nasal swab samples were from asymptomatic patients, 35 were from patients with mild symptoms ranging from fever, headache, nasal congestion, diarrhea, loss of appetite, loss of taste and smell and other minor symptoms. There were 12 asymptomatic subjects, 12 subjects with 0-3 days post onset of symptoms, and 23 subjects with 4-7 days post onset.

Out of a total of 47 RT-PCR confirmed positive cases, Artron COVID-19 Antigen Home Test was able to correctly detect 47 specimens, with a sensitivity of 100% (95%CI: 92.5- 100.0); detected 16 cases out of 16 specimens which had median Ct value below 30 with a diagnostic sensitivity value of 100% (95%CI: 79.4- 100.0); detected 16 specimens out of 16 which had a median Ct value between ≥30, and <33 with a sensitivity of 100% (95%CI: 79.4- 100.0); detected 15 specimen with a median Ct value of ≥33 with a 100% (95%CI: 78.2- 100.0) sensitivity. Among the 47 positive cases, Artron COVID-19 Antigen Home Test identified 12 from 12 asymptomatic patients (100%, 95%CI: 73.5- 100.0), 12 from 12 samples with post onset 0-3 days (100%, 95%CI: 73.5- 100.0), 23 from 23 samples with post onset 4-7 days (100%, 95%CI: 85.2- 100.0). Artron COVID-19 Antigen Home Test was able to detect 125 negatives from 128 RT-PCR confirmed negative cases accurately, with a specificity of 97.7% (95%CI: 93.3% to 99.5%). The overall agreement was 98.3% (95%CI: 95.1- 99.7).

Summary of the clinical performance against SARS-CoV-2 Real-Time RT-PCR Test

Artron COVID-19 Antigen Home Test	RT-PCR Comparator Method		Total
	Positive	Negative	
Positive	47	3	50
Negative	0	125	125
Subtotal	47	128	175
Performance with 95%CI	Sensitivity (PPA)	Specificity (NPA)	Overall Agreement
	100% (92.5- 100.0)	97.7% (93.3- 99.5)	98.3% (95.1- 99.7)

Secondary RT-PCR assays were performed on the three samples that yielded discordant results. The additional testing with a FDA EUA molecular SARS-CoV-2 assay showed that two of the three false positive samples correctly tested as positive by the Artron COVID-19 Antigen Home Test.

Summary of positive agreement related to Ct value

Median Ct value for ORF1ab and/or S gene	Artron COVID-19 Antigen Home Test: Positivity Agreement with 95%CI
<30	16/16 (100%) (95%CI: 79.4- 100.0)
≥30, <33	16/16 (100%) (95%CI: 79.4- 100.0)
≥33	15/15 (100%) (95%CI: 78.2- 100.0)

Summary of positive agreement related to days post onset

Days post onset of symptoms	Number of cases	Artron COVID-19 Antigen Home Test: Positivity Agreement with 95%CI

Asymptomatic	12	12/12(100%) (73.5- 100.0)
0-3	12	12/12(100%) (73.5- 100.0)
4-7	23	23/23 (100%) (85.2- 100.0)

• Serial-testing clinical performance conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table below:

Table: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	**ASYMPTOMATIC ON FIRST DAY OF TESTING**			**SYMPTOMATIC ON FIRST DAY OF TESTING**		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	*9/97 (9.3%)*	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)

10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test= one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests= two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests= three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

- **Limit of Detection (LoD)-Analytical Sensitivity**

The limit of detection (LoD) of Artron COVID-19 Antigen Home Test is 1×10^3 TCID50 /mL.

- **Cross Reactivity**

None of the below related pathogens: Coronavirus OC43(ATCC: VR-1558™); Coronavirus NL63; Coronavirus 229E; Coronavirus HKU1; SARS Coronavirus (2003-00592 strain); MERS Coronavirus(Florida/USA-2_Saudi Arabia_2014); H1N1 influenza virus (2009) (Canada/629/09 strain); H1N1 influenza virus (ATCC:VR-98™);Seasonal H3N2 influenza virus (Brisbane/10/07 strain); Influenza B (Yamagata/16/88 strain); Influenza B (Victoria/2/87 strain); Parainfluenza virus type 1(ATCC: VR-94™); Parainfluenza virus type 2 (ATCC: VR-92™); Parainfluenza virus type 3(ATCC: VR-93™); Parainfluenza virus type 4b (ATCC: VR-1377); Respiratory syncytial virus (ATCC: VR-1580™); Rhinovirus A (73)(ATCC: VR-1183™); Rhinovirus B (B42); Adenovirus type 1 (C); Adenovirus type 2 (C); Adenovirus type 3 (B); Adenovirus type 4; Adenovirus type 5; Adenovirus type 7 (7A); Enterovirus Group A (71)(2003); Enterovirus group D (68); Epstein-Barr virus (B95-8); Measles virus; Human cytomegalovirus; Rotavirus, WA strain; Mumps virus 1; Varicella-zoster virus (strain 82); Metapneumovirus (Peru6-2003); Mycoplasma pneumoniae (M129); Chlamydia pneumoniae (ATCC: VR-1435™); Haemophilus influenzae (ATCC: 49144™); Legionella (ATCC: 33152™); Mycobacterium tuberculosis (ATCC: 25177™); Streptococcus pyogenes (ATCC: 19615™); Streptococcus pneumoniae (ATCC:49619™); Staphylococcus epidermidis(PCI 1200, ATCC: 12228™); Staphylococcus aureus (ATCC: 12600™); Bordetella pertussis type 5(ATCC: 9340-FZ™); Pneumocystis (W303-Pji strain); Candida albicans (ATCC: 44373) cross-reacted with Artron COVID-19 Antigen 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 nasopharyngeal swab specimens from healthy volunteers were detected negative, indicating Artron COVID-19 Antigen Test has good analytical specificity.

- **Endogenous/Exogenous Interference Study**

There was no interference for potential interfering substances listed below: Mucin (0.5% W/V), Whole blood (4%W/V), Beclomethasone (0.5mg/mL), Dexamethasone (1mg/mL), Flunisolide (5mg/mL), Triamcinolone acetonide(1mg/mL), Budesonide(2mg/mL), Mometasone(2mg/mL), Fluticasone(5%V/V), Naso GEL (NeiMed)(5%V/V), Phenylephrine (10%V/V), Oxymetazoline (10%V/V), Sodium chloride (with preservatives)(10% V/V), Menthol(1.5mg/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), alpha interferon (200,000IU/mL), Zanamivir (1mg/mL), Ribavirin (2mg/mL), Oseltamivir (5 mg/mL), Peramivir (2mg/mL), Lopinavir (2mg/mL), Ritonavir (2mg/mL), Abidor (4mg/mL), Levofloxacin (5mg/mL), Azithromycin (1mg/mL), Ceftriaxone (1mg/mL), Meropenem (2mg/mL), Mupirocin (10mg/mL), Tobramycin (4μg/mL), Histamine Dihydrochloride (10mg/mL), Biotin (1mg/mL), household detergent 1%(V/V), Lotion 1%(W/W), Soap 1%(W/W).

- **HOOK Effect**

There was no hook effect at 9.55×10^6 TCID50 /mL of SARS-CoV-2 strain USA-WA1/2020.

REFERENCES

- Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim guidance. World Health Organization. 13 March 2020.
- Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). World Health Organization. 16-24 February 2020.
- 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	Use by
Temperature limitation	Contains sufficient for < n > tests
Caution	REF Catalog number
Manufacturer	Consult instructions for use
EC REP Authorised representative in the European community	CE Mark

MANUFACTURER CONTACT INFORMATION

Artron Laboratories Inc.

3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

TEL: +1 604-415-9757
FAX: +1 604-415-9795
www.artronlab.com
info@artronlab.com

EC REP CE

MedNet EC-REP GmbH

Borkstrasse 10
48163 Muenster
Germany