COVID-19 Antigen Test

Instructions for Use

Format: Cassette

Specimen: Nasopharyngeal Swab

Catalog Number: A03-50-422

CE

* Please read the instructions carefully before use

INTENDED USE

Artron COVID-19 Antigen Test is a rapid and convenient lateral flow immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid protein from nasopharyngeal swab samples obtained from individuals suspected of COVID-19 by their healthcare provider within five to seven days of symptom onset or individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over 2 (or 3) days with at least 24 hours (and no more than 36 hours) between tests. The rapid test device is for professional 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 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. 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.

Artron COVID-19 Antigen Test may be used in any laboratory and non-laboratory environment that meets the requirements specified in the instructions for use and local regulation. This product is intended for use by healthcare professionals in clinical laboratories or Point of Care (POC) settings. 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 kit.

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 Test is an antigen-capture immunochromatographic assay, detecting presence of SARS-CoV-2 nucleocapsid protein in nasopharyngeal 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 was designed to indicate that the test is performed properly. 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

- 25 Test cassettes with desiccant in individual pouch
- Sample extraction buffer (2×6mL/bottle)
- 25 Extraction tubes
- 25 Extraction tube caps
- 25 Sterilized nasopharyngeal swabs
- 1 Tube rack
- 1 Instruction for use

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Personal protective equipment
- Timer
- Biohazard container

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- The test is designed only for the detection of nasopharyngeal swab specimens.
- This test is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration 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 Test Kit. Do not Use other swabs.
- If the test is stored refrigerated, ensure that the test units are brought to room temperature (15-30˚C) at least 30mins before performing testing.
- Immediately use after opening the test device in the pouch.
- Complete the test within 1 hour after the reagent is opened.
- In order to obtain accurate results, the test must follow this package insert.
- Wear personal protective equipment such as laboratory coats, disposable gloves and eye protection when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink, or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national, or regional regulations.
- Keep out of children's reach.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water.

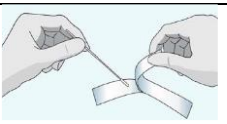
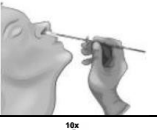
SPECIMEN COLLECTION AND PREPARATION

Note：

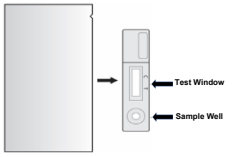
Before proceeding with sample collection and testing, please read the instruction carefully, and operate strictly in accordance with the instructions.

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.

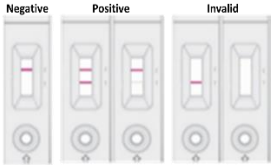
1. Put the extraction tube on the tube rack. Add sample extraction buffer into the extraction tube till to the Fill-line of the extraction tube (approximately 8 drops).	

2. Remove a nasopharyngeal swab from the pouch.	
3. Place the swab into one of the patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.	
4. Gently remove the swab from the nostril while rotating it.	
5. Insert the swab in the extraction tube. Swirl the swab tip vigorously in the buffer fluid at least 10 times.	
6. Remove the swab by rotating against the extraction tube while squeezing the sides of the tube to release the liquid from the swab. Properly discard the swab.	
7. 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, dry surface	
B) Hold the extraction tube vertically above the sample well, slowly add 5 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 20-30 minutes. The test result should not be read and interpreted after 30 minutes.	 DO NOT INTERPRET RESULTS AFTER 30 MINUTES.

RESULT INTERPRETATION



Negative:
A clear pink or purple colored band appears only at the control region (C), indicating a negative result.

Positive:
A clear pink or purple control band (C) and a detectable test band (T) appears, indicating a positive result.

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.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink or purple colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture, and heat.
- Shelf life:18 months.

LIMITATIONS

- The test is only intended for nasopharyngeal 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.
- The freshly collected specimens can be stably stored in the sample extraction buffer at room temperature up to 4 hours of collection.
- False negative results may occur if inadequate extraction buffer is used (e.g., <8 drops or 300µl) or inadequate specimen is added in the sample well (e.g., <5 drops or 150µl).
- False negative results may occur if specimen swabs are not twirled sufficiently in the sample extract buffer.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results do not rule-out possible other 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.
- Results from the test should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- This test only provides qualitative test result and cannot provide information about the virus concentration in the sample.
- The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.
- For mutant virus strains or virus strains from different regions, the detection ability of the device 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.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low SARS-CoV-2 activity when prevalence is moderate to low.
- Clinical studies in asymptomatic patients using serial testing are ongoing to establish clinical performance.
- The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications. Note that performance may differ in these populations.

PERFORMANCE CHARACTERISTICS

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

The limit of detection (LoD) of Artron COVID-19 Antigen Test is 1×10^3 $TCID_{50}$/mL.

- **Cross Reactivity**

None of the below related pathogens cross-reacted with Artron COVID-19 Antigen Test when the virus content>10^6PFU/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.

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 nasopharyngeal swab specimens	N/A	(-)	N/A

- **Endogenous/Exogenous Interference Study**

There was no interference for potential interfering substances listed below.

Interfering substances	**Interfering substances Final concentration**	**SARS-COV-2 Virus ($TCID_{50}$/mL)**	
		0	**3×10^3**
Endogenous interfering substances			
Mucin	0.5% 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	5% V/V	(-)	(+)
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	5 mg/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	4μg/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.

- **Clinical Performance**

A total of 812 nasopharyngeal swab specimens including 108 RT-PCR confirmed SARS-CoV-2 positive and 704 RT-PCR confirmed SARS-CoV-2 negative were sequentially enrolled and tested blindly from Nov 27, 2020-Apr 19, 2021, in Hemolab Clinic and Malibu Pathology. All the 108 RT-PCR positive specimens were collected from symptomatic patients with 75 patients from 0-3 days post onset of symptoms, 26 patients from 4-7 days post onset of symptoms and 7 patients from >7 days post onset of symptoms. Out of 108 positive symptomatic samples, Artron COVID-19 Antigen Test identified 105 positive cases. The diagnostic sensitivity of symptomatic patients was 97.22%(95%CI: 92.10 -99.42), the diagnostic specificity was 99.72% (95% CI: 98.98- 99.97). Overall agreement is 99.39%(98.57-99.80), the Positive Predictive Value for the symptomatic patients was 98.13% (92.93-99.53) whereas the Negative Predictive Value (NPV) was 99.58% (98.72- 99.86).

Clinical studies in asymptomatic patients using serial testing are ongoing to establish clinical performance. The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications. Note that performance may differ in these populations.

The performance of Artron COVID-19 Antigen Test against the comparator RT-PCR reagents

Artron COVID-19 Antigen Test	**RT-PCR**		**Total**
	Positive	**Negative**	
Positive	105	2	107
Negative	3	702	705
Total	108	704	812
Performance with 95% CI	**Sensitivity**	**Specificity**	**Overall Agreement**
	97.22% (92.10 -99.42)	99.72% (98.98 -99.97)	99.39% (98.57-99.80)

	Positive Predictive Value	Negative Predictive Value	
	98.13% (92.93-99.53)	99.58% (98.72- 99.86)	

Summary of positive rate related to Ct Value

Original Ct value for N gene	Artron COVID-19 Antigen Test: Test Positivity Rate with 95%CI	Original Ct value for N gene	Artron COVID-19 Antigen Test: Test Positivity Rate with 95% CI
<20	19/19(100%) (82.35-100.00)	**<30**	93/93(100%) (96.11-100.00)
≥20, <24	40/40 (100%) (91.19-100.00)		
≥24, <27	14/14 (100%) (76.84-100.00)		
≥27, <30	20/20 (100%) (83.16-100.00)		
≥30, <32	8/9 (88.89%) (51.75-99.72)	**≥30**	12/15(80.00%) (51.91-95.67)
≥32	4/6 (66.67%) (22.28-95.67)		

Summary of the positive rate related to days post onset

Days post onset of symptoms	Number of Cases	Artron COVID-19 Antigen Test: Test Positivity Rate with 95%CI
0-3	75	75/75(100%) (95.20-100.00)
4-7	26	25/26(96.15%) (80.36-99.90)
>7	7	5/7(71.43%) (29.04-96.33)

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INDEX OF SYMBOLS

	Do not reuse
IVD	In vitro diagnostic medical device
	Temperature limitation
	Caution
	Manufacturer
EC REP	Authorised representative in the European community
LOT	Batch code
	Use by
Σ n	Contains sufficient for < n > tests
REF	Catalog number
	Consult instructions for use
CE	CE Mark

MANUFACTURER CONTACT INFORMATION

Artron Laboratories Inc.

3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

Ph: +1 604-415-9757
Fax: +1 604-415-9795
www.artronlab.com
info@artronlab.com

EC REP

MedNet EC-REP
GmbH Borkstrasse 10
48163 Muenster
Germany