WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: Artron COVID-19 Antigen Test
Manufacturer: Artron Laboratories lnc
EUL Number: EUL 0585-168-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

Artron COVID-19 Antigen Test with product code A03-50-422, rest of world regulatory version manufactured by Artron Laboratories lnc, 3938 North Fraser Way, Burnaby V5J 5H6 Canada , was listed as eligible for WHO procurement on 11 August 2022.

Intended use

According to the claim of intended use from Artron Laboratories lnc, "*Artron COVID-19 Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.*
Artron COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasopharyngeal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results

do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories are required to report all positive results to the appropriate public health authorities.
Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection; and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.
Artron COVID-19 Antigen Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings. The product is intended as an aid to diagnosis of SARS-CoV-2 infection and only for use under the EUA/EUL/EU."

Specimen type that was validated: Nasopharngeal swab specimens.

Assay description

According to the claim of assay description from Artron Laboratories lnc, "*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) 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 the presence of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab samples. Nasopharyngeal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test.

This assay utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology for the detection of extracted antigen. SARS-CoV-2 monoclonal antibodies specifically against SARS-CoV-2 antigen are conjugated with colloidal gold, deposited on the conjugate pad, and immobilized on the Test Zone of the nitrocellulose membrane. When a sample is added, the gold-antibody conjugate is rehydrated and the SARS-CoV-2 antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone where they will be captured by immobilized antibodies, forming a visible pink line (Test band) indicative of a positive result. If SARS-CoV-2 antigen is absent in the sample, no pink line will appear in the Test Zone (T).

Artron COVID-19 Antigen Test is validated for use from direct specimens testing without transport media. Artron Covid-19 Antigen Test contains a built-in internal procedural control that is included in the test device. External control includes one positive and one negative control swabs used to demonstrate that the test device and test procedure perform properly."

Test kit contents

Component	Quantity
Test device (Single foil pouched test device containing one test cassette (one test strip encased in plastic cassette) and one desiccant.)	25
Extraction Buffer bottle (Each extraction buffer bottle contains a 6ml extraction buffer; each enough for 15 tests.)	2
Reagent Tube with Cap (A container to prepare reagents.)	25
Sterilized nasopharyngeal Swab	25
Package insert	1
External control (1 positive swab with heat-inactivated SARS-CoV-2 Virus 2* LoD, 1 negative swab.)	1

Items required but not provided

- Pipette
- Clock or timer.
- Latex gloves

Storage
The test kit should be stored at 2-30 °C.

Shelf-life upon manufacture
12 months (real-time stability studies are ongoing)

Warnings/limitations
Please refer to the attached instructions of use (IFU).

Product dossier assessment

Artron Laboratories Inc submitted a product dossier for the Artron COVID-19 Antigen Test as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (PQDx_0347)"*. The information (data and

documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL

As a requirement for listing, the manufacturer is required to:

1. Assess the traceability of the materials used in the validation of the product (including estimation of LoD) with the WHO International Standard when available.
2. Partake in an independent performance evaluation conducted by a laboratory commissioned by WHO. Any such performance evaluation testing will be performed using the protocol and technical criteria established by WHO.
3. Provide a supplementary clinical specificity study including at least 30 negative clinical specimens by 30 September 2022.
4. Provide the final real-time stability, including stability of external controls, in-use stability study reports by 30 April 2024, and interim stability reports at the time of EUL renewal if results at any of the testing time-points are outside the acceptance criteria or the planned shelf-life changes, it is a required of the manufacturer to notify WHO.

Risk-benefit assessment conclusion is acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Artron Laboratories lnc was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that sufficient information was provided by Artron Laboratories lnc to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen(PQDx_ 347)"*.

The quality management documentation assessment conclusion is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods, and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-prequalification activities are required to maintain the prequalification status:
1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"* (ISBN 978-92-4-001531-9).

Artron Laboratories Inc is also required to report complaints related to the product. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality, and performance monitoring activities are in place, which are in accordance with WHO guidance "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics."*[1]

Scope and duration of procurement eligibility

The Artron COVID-19 Antigen Test with product code A03-50-422 , manufactured by Artron Laboratories Inc, is considered eligible for WHO procurement for 12 months from the day of listing. The assay may detect the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, Artron Laboratories Inc must engage in post-market surveillance activities to ensure that the product meets safety, quality, and performance requirements, Artron Laboratories Inc must notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes made to the product.

[1] https://www.who.int/publications/i/item/9789240015319

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

Labelling

1. **Labels**
2. **Instructions for use**

1.0 Labels

1 TEST

Artron

COVID-19 Antigen Test

IVD For In Vitro Diagnostic use

Consult instructions for use

Do not reuse

Storge : 2°C ~ 30°C

Do not use after expiration date

REF Cat No. A03-50-422W

LOT Lot No.

Expiry Date

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

Control No.: AR420W Ver.1

L19.625 cm x W13.5 cm x H6.8 cm

- For POCT use
- For professional use only
- For In Vitro diagnostic use only
- Read instructions before performing the test
- Do not use the device after the expiry date or pouch is damaged
- Keep device out of reach of children
- Dispose of used materials as biological waste
- Store at 2~30ºC. Do not freeze
- Keep away from radiation, moisture and direct sun

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Artron

COVID - 19 Antigen Test

CAT Cat No. A03-50-422W

LOT Lot No.

Expiry Date

Inside the Box:

Test Cassettes x 25
Extraction Buffer Dropper Bottles x 2
Reagent Tubes with Caps x 25
Sterilized Nasopharyngeal Swabs x 25
Instruction For Use x 1
Positive Control Swab x 1
Negative Control Swab x 1
Quick Reference Guide x 1

25
Cassettes

Artron

Rapid Diagnostic Test

This product was manufactured in a plant whose Management System is certified as being in conformity with ISO13485

Made In Canada

Rapid Diagnostic Test

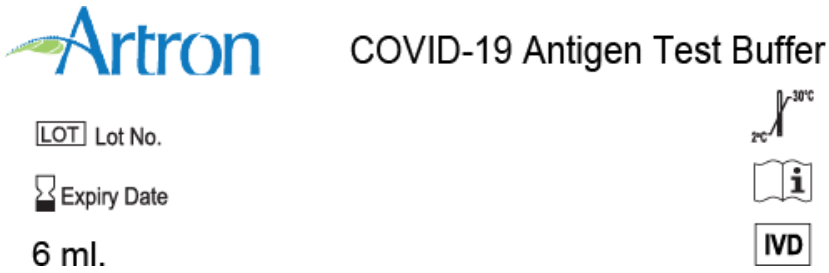
IVD

i

30°C

Artron

Buffer vial label



External Control label

-Positive Control:

Front Side:

Positive Control Swab CONTROL +
For Use with Artron COVID-19 Antigen Test Only

Back Side:

Product Code：
Lot #:
Expiry Date:

-Negative Control:

Front Side:

Negative Control Swab CONTROL -
For Use with Artron COVID-19 Antigen Test Only

Back Side:

Product Code：
Lot #:
Expiry Date:

2.0 Instructions for use (IFU)[2]

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

For use under the EUA/EUL/EU only
For *in vitro* diagnostic use only
For professional/POC use only

Artron COVID-19 Antigen Test

(Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen)
Instructions for Use

Format: Cassette

Specimen: Nasopharyngeal Swab

Catalog Number: A03-50-422W

* Please read the instructions carefully before use

Table of Contents

INTENDED USE

Artron COVID-19 Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

Artron COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasopharyngeal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection; and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

Artron COVID-19 Antigen Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings. The product is intended as an aid to diagnosis of SARS-CoV-2 infection and only for use under the EUA/EUL/EU

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) 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 the presence of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab samples. Nasopharyngeal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test.

This assay utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology for the detection of extracted antigen. SARS-CoV-2 monoclonal antibodies specifically against SARS-CoV-2 antigen are conjugated with colloidal gold, deposited on the conjugate pad, and immobilized on the Test Zone of the nitrocellulose membrane. When a sample is added, the gold-antibody conjugate is rehydrated and the SARS-CoV-2 antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone where they will be captured by immobilized antibodies, forming a visible pink line (Test band) indicative of a positive result. If SARS-CoV-2 antigen is absent in the sample, no pink line will appear in the Test Zone (T).

Artron COVID-19 Antigen Test is validated for use from direct specimens testing without transport media. Artron Covid-19 Antigen Test contains a built-in internal procedural control that is included in the test device. External control includes one positive and one negative control swabs used to demonstrate that the test device and test procedure perform properly.

PACKAGE CONTENTS

Name	Quantity (per kit)	Description
Test device	25 each	Single foil pouched test device containing one test cassette (one test strip encased in plastic cassette) and one desiccant.
Extraction Buffer Bottle	2 each	Each extraction buffer bottle contains a 6ml extraction buffer; each enough for 15 tests.
Reagent Tube with Cap	25 each	A container to prepare reagents.
Sterilized nasopharyngeal Swab	25 each	Single Sealed, for nasopharyngeal specimen collection.
Package insert	1 each	Instructions for use
External control	1 set	1 positive swab with heat-inactivated SARS-CoV-2 Virus 2* LoD, 1 negative swab.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Pipette
- Clock or timer.
- Latex gloves

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Immediately use after opening the test device in the pouch.
- In order to obtain accurate results, the test must follow this package insert.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasopharynx when collecting specimens.
- Do not interpret the test result before 20 minutes after starting the test.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is necessary, swabs can be placed into the extraction buffer for up to 48 hours at 2-8°C/ 36-46°F; or -20°C up to seven days.
- Specimens should not be stored dry.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.

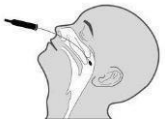
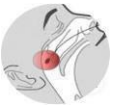
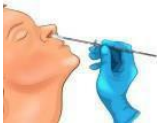
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Do not exchange buffer bottles from other lots.
- This test has been authorized only for the detection of proteins from SARS-CoV-2
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Nitrile or latex gloves should be worn when performing this test.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- 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.
- Dispose of all specimens and used device contents as biohazardous wastes in accordance with local, national, or regional regulations.
- Keep out of children's reach.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to the skin. Contact with acids produces a very toxic gas. If there is contact with skin or eye, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

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 Extraction Buffer bottle may be open and resealed for each assay. The Buffer cap should be firmly sealed between each use. The Extraction Buffer for Artron COVID-19 Antigen test is stable until the expiration date if kept at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture, and heat.

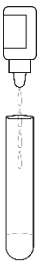
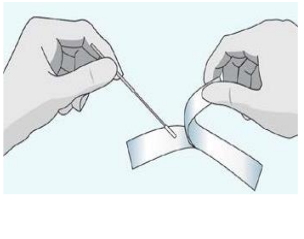
SPECIMEN COLLECTION PROCEDURE

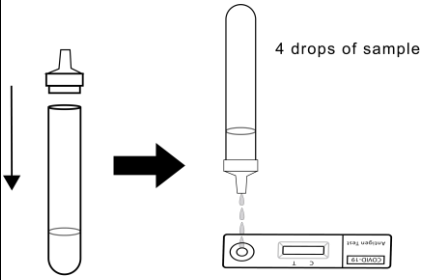
- Keep out of children's reach.
- Process the test sample immediately after collection.
- Use only provided swab for specimen collection.
- Collect the specimen wearing safety gloves to avoid contamination.
- Do not touch the tip (specimen collection area) of the swab.

 1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.	 2. Swab over the surface of the posterior nasopharynx. Slowly rotate 3-5 times the swab over the surface of the posterior.	 3. Withdraw the sterile swab from the nasal cavity.

TEST PROCEDURE

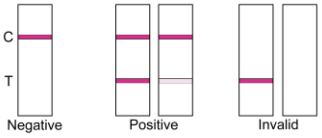
- Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30° C) prior to testing.
- Remove the COVID-19 Antigen test device from its foil pouch and put it on desk horizontally before testing.
- The COVID-19 Antigen kit IS INTENDED to be used only with a direct nasopharyngeal swab specimen.
- The COVID-19 Antigen kit IS NOT INTENDED for testing other liquid samples such as nasal wash or aspirate samples as results can be compromised by over dilution.
- Freshly collected extracted specimens must be placed into extraction buffer immediately. It is recommended to perform tests as soon as possible after specimen collection, if not, specimens can be stored for up to two hours at room temperature, or at 2-8°C/ 36-46°F for up to 48 hours, or at -20°C for up to 7days prior to testing. It is essential that correct specimen collection and preparation methods be followed.

A) Add 400ul extraction buffer (approximately 12 drops) into the reagent tube.	
B) a. For Negative and Positive Control Swab testing, prepare two reagent tubes with 400ul extraction buffer each, following Step A. Remove the negative control swab and the positive control swab from respective pouches. Insert the negative and positive swab into the separate reagent tubes prepared earlier for preparation of negative and positive control sample respectively. Follow Step C to Step E to perform the control testing.	
B) b. For freshly collected nasopharyngeal swab sample add Nasopharyngeal swab to the reagent tube with the extraction buffer prepared in Step A. Follow Step C to Step E to perform the testing.	
C) Vigorously rotate and twist the swab against the side of the tube at least 10 times.	
D) Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly.	

E) Apply the cap to the tubes with the specimen, and hold the tube vertically, add 4 drops of the specimen without air bubbles into the sample well. Start the timer immediately after adding four drops of the specimen into the sample well of the testing device. Read results at 20 minutes.	 Note: Do not interpret the result after 30 minutes.

RESULT INTERPRETATION

NOTE: The test results should be read under sufficient light where weak or faint test and control lines would be visible. The test results should be read and interpreted at 20 minutes after the sample application and the reading and interpretation of the results should not exceed 30 minutes. The test results should not be interpreted using any instruments.



Negative:
A pink colored band appears only at the control region (C), indicating no SARS-CoV-2 antigen was detected.

Positive:
A clear pink control band (C) and a detectable pink test band (T) appears, indicating SARS-CoV-2 antigen was detected.

Invalid:
If no visible band appears at the control region (C), the result is invalid. Repeat the test with a new test kit. If the test still fails, please contact the distributor with the lot number.

LIMITATIONS

- This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
- The contents of this kit are to be only used for the detection of SARS-CoV-2 antigen from nasopharyngeal swab specimens that are collected and tested directly (i.e. swabs that have NOT been placed in transport media such as VTM).
- Extracted specimens may be frozen at -20°C for up to 7 days, or up to 48 hours at 2-8°C/ 36-46°F. We did not test thaw cycles and will suggest that the thawed sample should not be frozen again.
- Testing must be conducted at room temperature (14-25°C).
- Humidity and temperature can adversely affect results.
- Results from the device should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- False-negative results may occur if the level of the target antigen in the specimen is below the detection limits of the device.

- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- Negative test results do not rule-out diseases caused by other bacterial or viral pathogens.
- The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- This test will indicate the presence of SARS-CoV-2 nucleocapsid protein antigen in the specimen from both viable and non-viable SARS-CoV-2 virus. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- This device has been evaluated for use with human specimen material only.
- Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak Sars-CoV-2 activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.

QUALITY CONTROL

Internal Quality Control: The *Artron* Antigen test contains a built-in internal procedural control that is included in the test device. A pink line appearing in the control region "C" is designed as an internal procedural control. The appearance of the procedural control line only indicates that sufficient flow has occurred. If the procedural control line does not appear in 20 minutes, the test is considered invalid, and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the distributor with the lot number. **External Quality Control**: External control is used to demonstrate that the test device and test procedure perform properly. It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided independently. Refer to "TEST PROCEDURE" in this IFU or the quick guide for the external control procedure.

PERFORMANCE CHARACTERISTICS

Clinical Performance

Clinical performance of the Artron COVID-19 Antigen Test was evaluated at three clinical sites, the patients presenting the COVID-19 like symptoms within seven (7) days of symptom onset at the study sites are enrolled. RT-PCR assay for the detection of SARS-CoV-2 from a NP swab is utilized as the comparator method for the study.

A total of 751 pair of NP swab specimens were tested. All of 164 positive cases were determined by RT-PCR, in which 151 positive results also detected by Artron COVID-19 Antigen Test; and all 587 negative cases determined by RT-PCR, negative results also were obtained by Artron COVID-19 Antigen Test.

The performance of the Artron COVID-19 Antigen as compared to the RT-PCR comparator method are presented in the table below:

		Artron COVID-19 Antigen Test		Total
		Positive	Negative	
RT-PCR	Positive	151	13	164
	Negative	0	587	587
Total		151	600	751
Positive Percent Agreement (PPA)		92.07% (95% CI 87.47% -96.67%)		
Negative Percent Agreement (NPA)		100% (95% CI 95 % -100%)		

Analytical Sensitivity: Limit of Detection (LoD)

The detection of limit (LoD) of Artron COVID-19 Antigen Test for SARS-CoV-2 strain nCoV-SH01 P6 live virus is 3.75×10^2 TCID50/mL, whereas for heat-inactivated virus the limit of detection is 1×10^3 TCID50/mL. For the inactivated virus strain USA-WA1/2020, the limit of detection is 1×10^3TCID50/mL. The final LoD was identified to be: 1.2×10^6 cp/ml.

Analytical Specificity: Cross-Reactivity and Microbial Interference

The potential cross-reactivity of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using Artron COVID-19 Antigen Test. Potential microbial interference was evaluated at approximately 3x LoD. A total of 26 pathogen were tested as listed below. At the concentrations of the potentially cross-reactive common organisms tested, no cross-reactivity with Artron COVID-19 Antigen Test was found. All samples with spiked heat-inactivated cell-culture derived SARS- CoV-2 virus strain showed positive with no microbial interference.

Pathogen to be tested with prepared concentration in the table below:

Pathogen	Type/Strain	Source	Final Conc.	
			Value	Unit
Coronavirus	229E	ATCC/live virus	1.60E+05	TCID50/ml
	OC43	ATCC/live virus	1.60E+04	TCID50/ml
	NL63	ZeptoMetrix	(1/10)22-25	Ct Value
SARS-coronavirus	N/A	ZeptoMetrix	N/A	N/A
MERS-coronavirus	Florida/USA-2_Saudi Arabia_2014	ZeptoMetrix	(1/10)22-25	Ct Value
Adenovirus	Type 1 (Species C)	ZeptoMetrix	1.00E+06	TCID50/ml
	Type 25 BP-1	ATCC/live virus	3.16E+04	TCID50/ml
	Type 26 BP-2	ATCC/live virus	1.00E+05	TCID50/ml
Human Metapneumovirus	Peru6-2003	ZeptoMetrix	(1/10)22-25	Ct Value
Influenza A virus	H1N1	ATCC/live virus	3.16E+05	CEID50/ml
	H3N2; A/Wisconsin/67/2005 (H3N2)	ATCC/live virus	2.30E+08	CEID50/ml
Influenza B virus	B/GL/1739/54	ATCC/live virus	5.00E+05	CEID50/ml
Enterovirus	Type 71; 2003 Isolate	ZeptoMetrix	1.25E+05	TCID50/mL
Respiratory syncytial virus	A2	ATCC/live virus	5.50E+06	PFU/ml
Rhinovirus	Type 73; 107E [V-181-001-021]	ATCC/live virus	1.00E+05	TCID50/ml
Chlamydia pneumoniae	J-21	ATCC/live virus	1.44E+07	IFU/ml
Haemophilus influenzae	AmMS 120	ATCC/live virus	1/10(>1.00E+04)	CFU/ml
Legionella pneumophila	Knoxville-1 [NCTC 11286]	ATCC/live virus	1/10(>1.00E+04)	CFU/ml
Mycobacterium tuberculosis	H37Ra	ATCC/live virus	1/10(>1.00E+04)	CFU/ml
Streptococcus pneumoniae	262 [CIP 104340]	ATCC/live virus	1/100(>1.00E+04)	CFU/ml
Streptococcus pyogenes	Bruno [CIP 104226]	ATCC/live virus	3.60E+05	CFU/ml
Bordetella pertussis	5 [17921]	ATCC/live virus	N/A	N/A
Mycoplasma pneumoniae	M129	ZeptoMetrix	1.50E+06	CCU/mL
Pneumocystis jirovecii	W303-Pji	ZeptoMetrix	5.00E+06	CFU/mL
Candida albicans	NIH 3172	ATCC/live virus	2.09E+06	CFU/ml
Pseudomonas aeruginosa	[CCEB 481, MDB strain BU 277, NCIB 8295, NCPPB 1965, NCTC 10332, NRRL B-771, R. Hugh 815]	ATCC/live virus	6.64E+05	CFU/ml
Staphylococcus epidermidis	FDA strain PCI 1200	ATCC/live virus	1.50E+05	CFU/ml
Streptococcus salivarius	K-12 [DSM 13084]	ATCC/live virus	1/100(>1.00E+04)	CFU/ml
Epstein-Barr virus	B95-8	ZeptoMetrix	1.00E+06	cp/mL
Cytomegalovirus	AD-169	ZeptoMetrix	5.00E+04	TCID50/mL
Pooled human nasal wash	N/A	Normal pooled human nasal wash from healthy employees	N/A	N/A

Endogenous Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the Artron COVID-19 Antigen Test, positive and negative samples were tested with the addition of potentially interfering substances. The SARS-CoV-2 target concentration in the positive samples was approximately 2x LoD. All 42 endogenous interfering substances tested and all produced expected results, demonstrating that Artron COVID-19 Antigen Test performance was not affected by any of the 50 potentially interfering substances listed below at the concentrations tested.

Potential interfering substances	Starting Concentration	Test Concentration
OTC Nasal Spray		
Afrin Nasal Spray (Oxymetazoline)	Oxymetazoline HCl 0.05%	10% (v/v)
hydraSense Nasal Spray	Not applicable	10% (v/v)
Healthguard Cromolyn Sodium Nasal Solution	5.2mg/metered spray	5% (v/v)
Sore Throat Phenol Spray	phenol 1.4% w/v	15% (v/v)
Flonase Allergy Relief Nasal Spray	Fluticasone Propionate ug/metered spray	5% (v/v)
Anti-inflammatory Medication		
Tylenol (Acetaminophen)	Acetaminophen 500mg/tablet	14 µg/mL
Ibuprofen	200mg/tablet	80 µg/mL
Triamcinolone	Pure; ≥99% (HPLC)	0.5 mg/mL
Antibiotic		
Mupirocin	Pure; ≥92% (HPLC)	20 µg/mL
Erythromycin	Pure	0.1 mg/mL
Ciprofloxacin	Pure; ≥98% (HPLC)	5 µg/mL
Tobramycin	Pure; ≥100% (TLC)	1.5 mg/mL
Antiviral Drug		
Zanamivir	Pure; ≥98% (HPLC)	60 µg/mL
Oseltamivir	Pure; ≥98% (HPLC)	60 ng/mL
Artemether	Pure; ≥98% (HPLC)	60 ng/mL
Doxycycline hyclate	Pure; ≥98% (HPLC)	9 µg/mL
Quinine	Pure; ≥98%	7 µg/mL
Lamivudine	Pure; 99.6% Ucrm	2.5 µg/mL
Ribavirin	Pure; ≥98% (TLC)	0.6 µg/mL
Tamiflu (Oseltamivir Phosphate)	30mg/capsule	5 mg/mL
Allergy Relief Medicine		
Chlorpheniramine maleate	Pure; 100.4% USP Ref. Standard	1.5 µg/mL

Flunisolide	Pure; ≥97%	0.25 mg/mL

Cromolyn Sodium Ophthalmic	Sodium Cromoglicate 2% w/v	20 mg/mL
Diphenhydramine HCl	Pure; ≥98% (HPLC)	0.2 µg/mL
CVS Nasal Drops (Phenylephrine)	Phenylephrine Hydrochloride 1.0%	15% (v/v)
Other		
Beclomethasone	Pure; ≥100% (HPLC)	2 mg/mL
Benzocaine	Pure; ≥99% (HPLC)	5 mg/mL
Budesonide	Pure; 98.3% Ucrm	2.4 ng/mL
Dexamethasone	Pure; ≥98% (HPLC)	1 µg/mL
Dextromethorphan HBr	Pure; 98.0-102.0% anhydrous basis	6 mg/ml
Guaiacol Glyceryl Ether (Guaifenesin)	Pure; ≥98% (GC)	40 mg/ml
Histamine Dihydrochloride	Pure; ≥99% (TLC)	0.013 µg/mL
Phenylpropanolamine HCl	1 mg/ml	0.3 µg/mL
Whole Blood	Not applicable	4%
Ricola Throat drop	Not applicable	15% (w/v)
Mucin	10mg/ml	100 ug/mL
Chloraseptic (Menthol/Benzocaine)	Menthol 10mg/Benzocaine 15mg per drop	1.5 mg/mL
Naso GEL (NeilMed)	Not applicable	5% (v/v)
Zicam	Zincum Gluconicum 1x/Zincum Aceticum 2x per drop	5% (v/v)
Homeopathic (Alkalol)	Not applicable	1:10 dilution
HAMA	Not applicable	1:10 dilution
Tobramycin	Pure; ≥100% (TLC)	1.5 mg/mL

High-dose Hook Effect

Artron COVID-19 Antigen Test was tested up to 5.01 x 10^7 $TCID_{50}$/ml of heat-inactivated SARSCoV-2 strain and no high-dose hook effect was observed.

TECHNICAL SUPPORT

For questions, or to report a problem, please contact TShelp@artronbioresearch.com.

REFERENCES

- Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim guidance. World Health Organization. March 13, 2020.
- Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). World Health Organization. February 16-24, 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 FOR 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

STERILE EO Ethylene Oxide Sterilization for Medical Devices

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Doc No. A03-50-422W **Version 07** **Revision: Jul. 2022**

Artron Laboratories Inc.

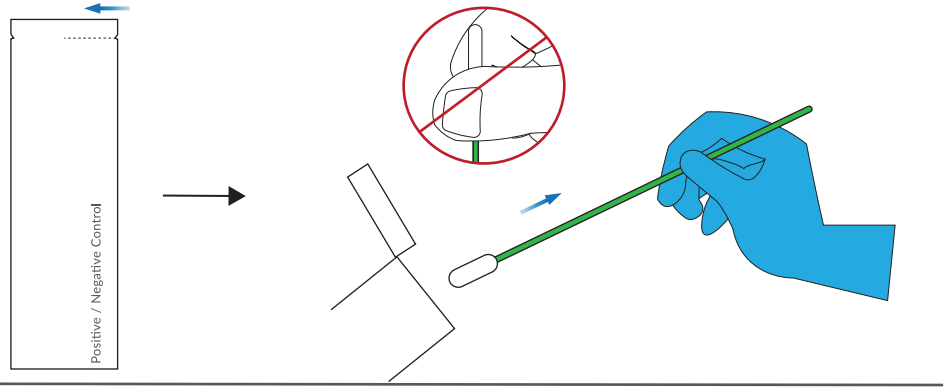
COVID-19 Antigen Test

Quick Reference Guide

1

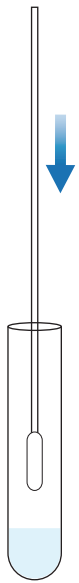
2

a.
For Positive /Negative Control testing



b.
For Specimen testing

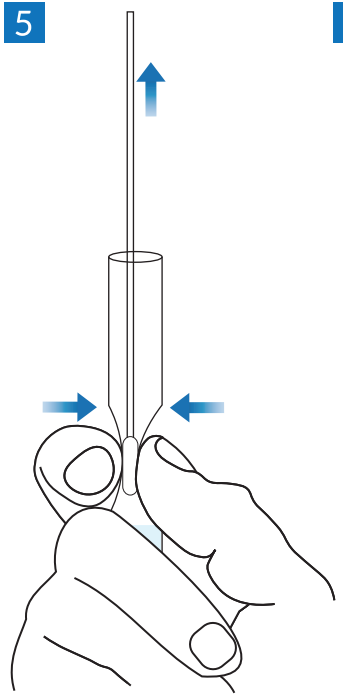
3



COVID-19 Antigen Test
Quick Reference Guide

4

5



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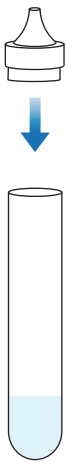

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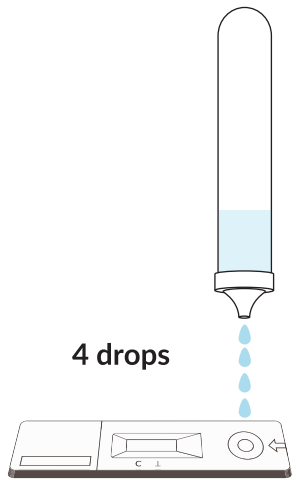
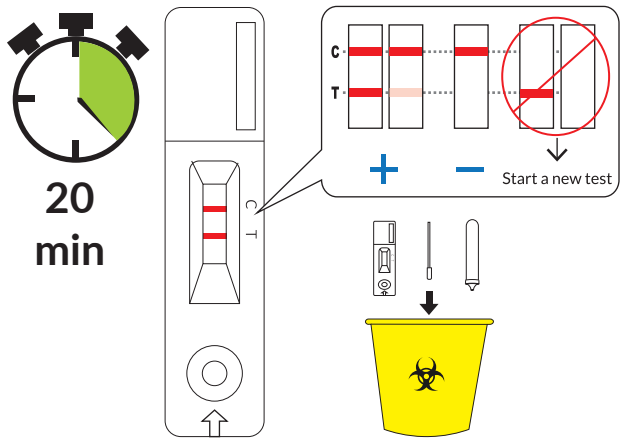


Results



Note: Do not interpret the result after 30 minutes.