RAPID

EASY

ACCURATE

COVID-19 Antigen Home Test

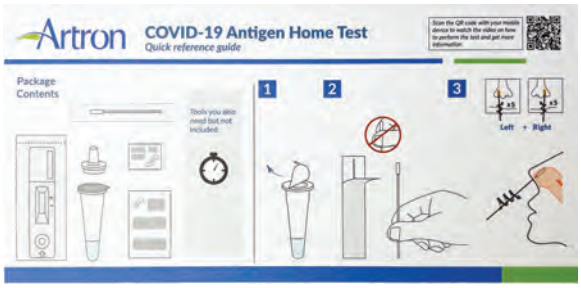
Artron Laboratories Inc.
3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

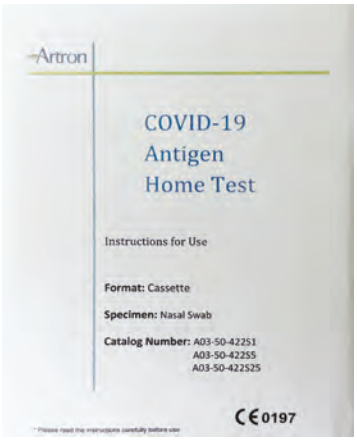
Ph: 604.415.9757
Fax: 604.415.9795
www.artronlab.com
info@artronlab.com

Artron

Product image of Artron COVID-19 Antigen Home Test

Components for 1 test/box





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COVID-19 Antigen Test Product Catalog

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	Product Name	Number of Tests	Number of Components									Certification
			A	B	C	D	E	F	G	H	I	
POCT	COVID-19 Antigen Test, Nasopharyngeal **A03-50-422PNP1**	1	1		1				1	1		HC & CE
	COVID-19 Antigen Test, Nasopharyngeal **A03-50-422PNP5**	5	5		5				5	1		
	COVID-19 Antigen Test, Nasopharyngeal **A03-50-422PNP25**	25	25		25	1			25	1		HC & CE
	COVID-19 Antigen Test, Nasal **A03-50-422PNS1**	1	1	1					1	1		HC & CE
	COVID-19 Antigen Test, Nasal **A03-50-422PNS5**	5	5	5					5	1		
	COVID-19 Antigen Test, Nasal **A03-50-422PNS25**	25	25	25		1			25	1		HC & CE
Home	COVID-19 Antigen Test, Nasal **A03-50-422 S1**	1	1	1			25	1	1	1		CE
	COVID-19 Antigen Test, Nasal **A03-50-422 S5**	5	5	5				1	5	1		CE
	COVID-19 Antigen Test, Nasal **A03-50-422 S25**	25	25	25				1	25	1		CE
Professional & POCT	COVID-19 Antigen Test **A03-50-422**	25	25		25		1			1	25	HC & CE

*HC stands for Health Canada Certification

Components

- A Test cassette with desiccant in individual pouch
- B Nasal swab
- C Nasopharyngeal swab
- D Tube rack
- E Sample extraction buffer (2*6 mL/bottle)
- F Quick reference guide
- G Extraction tube (pre-filled) and cap
- H Instruction for Use
- I Extraction tube (empty) and cap

COVID-19 Antigen Test Product Certification

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TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1272611-1

Organization: Artron Laboratories Inc.
3938 North Fraser Way, Burnaby, BC, V5J 5H6, Canada

Scope: Design and Development, Manufacture and Distribution of Urinalysis Reagent Strips and In-vitro Diagnostic Test Kits and Analyzers used in the Detection of Cardiac Markers, Cancer, Disease Status, Drugs of Abuse, Fertility Testing, Pregnancy Testing and Infectious Diseases Including Home Use, Near Patient In-vitro Diagnostic Devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190134455 110
Effective date: 2021-10-02
Expiry date: 2022-10-01
Issue date: 2021-09-30

TÜV Rheinland LGA Products GmbH Zertifizierstelle Gelle

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1272611-1

Manufacturer: Artron Laboratories Inc.
3938 North Fraser Way
Burnaby BC V5J 5H6
Canada

Products: Onestep Pregnancy Urine Tests for Self-testing, Onestep Ovulation Urine Tests for Self-testing, Onestep Follicle Stimulating Hormone Urine Tests for Self-testing and Male Fertility Sperm Tests for Self-testing, COVID-19 Antigen Home Test

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 190134455 110

Effective date: 2019-08-30

Expiry date: 2024-05-26

Issue date: 2021-11-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

COVID-19 Medical Device Authorization with Conditions for Importation or Sale Pursuant to Section 7 of the Interim Order

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19 avec conditions conformément à l'article 7 de l'Arrêté d'urgence

Authorization Reference Number :	327866	**Numéro de référence de l'autorisation**
Issue Date:	2021-10-20	**Date de délivrance:**
Amendment Date:	2021-12-09,	**Date de modification:**
Reason for Amendment	Significant Difference	**Raison de la modification**
Amendment Reference Number	337659	**Numéro de référence de la modification**

Device Class/Classe de l'instrument : 4

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurez de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument

ARTRON COVID-19 ANTIGEN TEST, ARTRON COVID-19 ANTIGEN TEST (NASOPHARYNGEAL), ARTRON COVID-19 ANTIGEN TEST (NASAL)

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

ARTRON LABORATORIES INC.
3938 NORTH FRASER WAY
BURNABY, BRITISH COLUMBIA
CANADA
V5J 5H6

David Boudreau, ing., Director General, Medical Devices Directorate
Directeur général, Direction des instruments médicaux

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

ARTRON COVID-19 ANTIGEN TEST

Device ID/No de l'instrument: 1035501
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
A03-50-422

ARTRON COVID-19 ANTIGEN TEST (NASOPHARYNGEAL)

Device ID/No de l'instrument: 1037225
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
A03-50-422PNP1
A03-50-422PNP25
A03-50-422PNP5

ARTRON COVID-19 ANTIGEN TEST (NASAL)

Device ID/No de l'instrument: 1037226
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
A03-50-422PNS1
A03-50-422PNS25
A03-50-422PNS5