The purpose of this fact sheet is to bring awareness to the recorded and observed harms that are associated with COVID-19 rapid antigen test kits. Currently, there is no proper disclosure of the known toxins in these tests; the risk of injuries, cancers, and death—as well as long-term health impacts—due to exposure to these toxic chemicals. Environmental impacts are also at the forefront of concern, as these chemicals impose significant impact on both land and water environments. Please read this information and pass it on, in order to draw attention to the threat of the components of COVID-19 rapid antigen tests.

On February 22, 2022, <u>COVID-19 rapid antigen test kits were sent home with school children</u>, from kindergarten to Grade 12. Rapid antigen tests were also widely dispersed at university settings.

On February 24, 2022, <u>Health Canada issued a warning regarding the use of COVID-19 rapid antigen tests</u>, specifically concerning the toxic ingredients sodium azide and ProClin-300. The issuing of this statement was reactionary, not precautionary. Schools continued to allow these tests to go home with children after this warning. Poison control calls continue to occur.

On March 23, 2022, COVID-19 rapid antigen test kits are now available to any individual aged 18+ from pharmacies, at no cost. Each test kit contains 5 tests and can be picked up every 28 days. Homes and communities across British Columbia are being unknowingly subjected to these biohazardous waste items, in unlimited quantities, without proper warnings or directives.

What follows are the details and facts related to serious concerns and harms associated with the widespread distribution of rapid antigen tests.

BCCDC approved manufacturer product inserts for COVID-19 rapid antigen tests:

- Artron Product Insert
- Abbot Product Insert
- BNTX Product Insert
- BD Veritor Product Insert
- **SD Biosensor** no inserts found; these tests are considered 'illegal' in the US yet considered 'approved' by Health Canada on the BCCDC website. No information exists on these tests.

1. COVID-19 Rapid antigen tests for medical professional and/or point of care (POC) use only

According to COVID-19 rapid antigen test kit product inserts, these medical products are **intended for use by healthcare professionals in clinical laboratory and/or 'Point of Care' (POC) settings only.** Precautions to be taken when utilizing these kits in a home setting have not been adequately provided to lay persons who may now be in possession of these rapid antigen tests, including the following:

- The use of personal protective equipment such as laboratory coats, disposable gloves and eye protection when running tests and handling specimens
- The safe disposal of test equipment, via biohazard collection

Artron, one of the main brands of test kits distributed within British Columbia, offers both a professional **and** an at-home version. At this time, the at-home self-tests are noted to be 'coming soon', and no specification is made on the BCCDC website stating that home-tests have been distributed. See below for these two product inserts:

- Artron At-Home Self-Test
- Artron Professional Test Catalog

*Refer to **page four** of the *Artron Professional Test Catalog* for the 'professional' or 'POCT' versus home-test ('Home') kit model numbers. Only 'POCT' and 'professional' tests are currently Health Canada certified (as indicated by HC in the catalog), **indicating that kits being utilized by the general public at home are not approved for personal use.**

^{**} See **REFERENCE** section below for more info on these five (5) tests

Specific warnings and instructions of note per product inserts:

_	
ARTR	ON
	Wear personal protective equipment such as laboratory coats, disposable gloves and eye protection when
	running each test and handling patient specimens.
	Do not eat, drink, or smoke in the area where the specimens or kits are being handled.
	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.
	Before proceeding with sample collection and testing, please read the instruction carefully, and operate strictly
	in accordance with the instructions.
ABBO	Т
Out of	15 warnings in the product insert for Abbott, two (2) serious warnings are highlighted:
	These instructions must be strictly followed by a trained healthcare professional to achieve accurate results . All users have to read the instruction prior to performing a test.

The Government of Canada confirms the inclusion of toxic ingredients in Abbott COVID-19 rapid antigen test kits. Refer to section 3 of dangerous material and section 6, 7, and 16 of Abbot's safety data sheet that codes sodium azide within the test kits as the following:

- H300: Fatal if swallowed.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.
- These tests cannot be thrown out in regular garbage. They must be treated as a biohazard.

☐ The buffer contains <0.1% sodium azide as a preservative which may be toxic if ingested.

BD VERITOR

٧£	KIIUK
	Other than the swabs used for specimen collection, kit components should not contact the patient.
	Specific training or guidance is recommended if operators are not experienced with specimen collection and
	handling procedures.
	Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are
	collected and evaluated.
	Dispose of used BD VeritorTM System test devices and reagents in accordance with federal, state and local
	requirements in an approved biohazard waste container.
	Do not flush reagents down the drain.

2. COVID-19 Rapid antigen test kit ingredients pose significant health concerns

COVID-19 rapid antigen tests include chemical constituents of concern within the extraction buffer and/or the nasal swab collection material. These include **sodium azide**, **ProClin-300**, **ethylene oxide**, **and an undisclosed bioluminescent material which is visible under ultraviolet lighting**. Furthermore, it is alarming that product manufacturers such as Artron, one of the largest rapid antigen test manufacturers/distributors in British Columbia, is not required to disclose the chemical components of their rapid test. The following are concerns associated with these rapid antigen test materials:

• **Sodium Azide:** found in the extraction buffer and/or nasal swabs of test kits; causes nausea, vomiting, skin burns and/or blistering, respiratory distress (including lung injury), convulsions, low blood pressure, and unknown long-term health effects such as cardiac and neural damage. Refer to CDC document 'Facts About Sodium Azide'.

According to the CDC, sodium azide is a rapidly acting, potentially deadly chemical that exists as an odorless white solid. When sodium azide is mixed with water or an acid, sodium azide changes rapidly to a toxic gas with a pungent (sharp) odor. It also changes into a toxic gas (hydrazoic acid) when it comes in contact with solid metals (for example, when it is poured into a drain pipe containing lead or copper). The odor of the gas may not be sharp enough, however, to give people sufficient warning of the danger.

- <u>ProClin-300</u>: allergic skin reactions, respiratory damage, poisoning if swallowed, and damage to aquatic life as detailed in FDA's document '<u>Phase Scientific COVID-19 Rapid Antigen Test</u>' and Sigma Aldrich '<u>ProClin-300 Safety Data Sheet</u>'.
- Ethylene Oxide (EO): test kits—which come into direct contact with the nasal cavity epithelium—clearly state that EO is a chemical constituent within the nasal swab. Ethylene oxide is classified as a toxic chemical, requiring proper handling and disposal protocols. EO is carcinogenic, as per documentation provided by the U.S. Environmental Protection Agency (EPA).

The U.S. Department of Health and Human Services generated a <u>Toxicological Profile for Ethylene Oxide</u> in 2020, detailing the following acute health concerns when exposed to ethylene oxide:

- O Acute inhalation exposure of workers to high levels of ethylene oxide has resulted in nausea, vomiting, neurological disorders, bronchitis, pulmonary edema, and emphysema.
- Dermal or ocular contact with solutions of ethylene oxide has caused irritation of the skin and eyes in humans.
- Tests involving acute exposure of animals have shown ethylene oxide to have high acute toxicity from inhalation exposures.
- <u>"Unknown ingredient causing the swabs to be bioluminescent"</u>: Nasal swabs also become bioluminescent when observed under UV light. The ingredient causing this chemical reaction is undisclosed on product inserts; therefore, rapid antigen test users are not receiving full informed consent when utilizing these medical supplies.

The bioluminescent ingredient may possibly be 'luciferase'. Below are primary examples:

- Yen Hsu, C. et al. (2013). Bioluminescence resonance energy transfer using luciferase-immobilized quantum dots for self-illuminated photodynamic therapy. *Biomaterials*. 34(4), 1204-1212.
- Azad et al. (2021). Luciferase-based biosensors in the era of the COVID-19 pandemic. American Chemical Society Nanoscience.

3. COVID-19 rapid antigen test kit ingredients pose significant environmental concerns

The aforementioned ingredients pose an environmental hazard and are classified as 'biohazardous waste'. Disposing of test kit components in the garbage is considered **illegal dumping.** COVID-19 rapid antigen test kits must be placed in biohazard containers and taken to a proper disposal facility, as per product insert instructions.

- <u>Disposal concerns:</u> local pharmacies (Shopper's Drug Mart and Pharmasave) have confirmed that there are no standardized protocols for the collection and disposal of rapid antigen tests within the community; thus, these test kits are currently being discarded via regular waste management systems. These rapid antigen kits pose a significant environmental harm through a compounding effect.
- The illegal dumping of rapid antigen test kits—classified as 'biohazard waste' directly on product inserts—needs to be halted immediately.

The BCCDC states the following information about all five (5) approved rapid antigen tests, see here. "All rapid antigen tests noted in this section have been approved for use by Health Canada. These kits are safe and effective for self-testing at home – be sure to read the package instructions carefully. As with many medications and athome care products, please note the following:

- These kits are to be handled and administered by adults
- Do not swallow the solutions, and avoid eye and skin contact

- Wash hands thoroughly after use
- Please keep the test components out of reach of children and animals
- Used tests and components can be safely disposed of in household garbage"

All of these above statements are correct **except** that **these tests CANNOT be thrown into household garbage**. Warnings from all other government sites state that used COVID-19 rapid antigen tests need to be taken to designated biohazardous waste facilities for proper disposal. Not only have used test kits been contaminated with human specimens, but they are also a source of potential environmental contamination by way of improper disposal of sodium azide, ethylene oxide, ProClin-300, and the undisclosed bioluminescent chemical constituent.

4. Limitations of COVID-19 rapid antigen test kits:

ARTRON package insert introduces concerns regarding the legitimacy of test result in the following situations:

- 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.
- The performance of this device **has not been assessed in a population vaccinated against COVID-19.** As of April 6, 2022, the <u>B.C. COVID-19 Pandemic Update</u> **states** that 87.5% of BC 5+ years of age received two doses of a COVID-19 vaccine.
- The performance of this test has **not yet been clinically validated for use in patients without signs and symptoms of respiratory illness.**

5. The Precautionary Principle: Understanding Ethics in Health & Environment

The following conversation demonstrates why COVID-19 rapid antigen test kits (and the harmful chemical components within them) should not be introduced into our healthcare system—and subsequently our environment—prior to adequate safety testing. The *Canadian Environmental Protection Act*, chapter 3 (1999) defined the Precautionary Principle as:

"The government's actions to protect the environment and health are guided by the precautionary principle, which states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (CEPA, 1999).

Source: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/guide-to-understanding/chapter-3.html

The Precautionary Principle —In Its Simplest Form:

"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some [cause-and-effect] relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the precautionary principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action." (Wingspread Statement, 1998)

"The Precautionary Principle is the basis for environmental law and plays an increasing role in developing environmental health policies."

"The Precautionary Principle encourages, and in some cases may require, transparency of the risk assessment process on health risk of chemicals both for public health and the environment. The best elements of a precautionary approach demand good science and challenge the scientific community to improve methods used for risk assessment."

Source: https://pubmed.ncbi.nlm.nih.gov/15968832

<u>Note:</u> The precautionary principle has clearly found its way into Canadian law and may impact future management decisions regarding environmental issues.

Supporting References: Precautionary Principle

- 1) <u>Hayes, A. W. (2005).</u> The precautionary principle. *Arh Hig Rada Toksikol*. Department of Environmental Health, Harvard School of Public Health, Boston, MA. 56(2):161-6.
- 2) <u>SEHN (1998).</u> The Science and Environmental Health Network. Wingspread Statement on the Precautionary Principle.

Mainstream Media: Highlighting the Concerns Associated with Rapid Antigen Tests

- 1) CTV: "At home testing for corona virus? Here's why you should keep pets away"
- 2) CTV: "Should you throw your used COVID-19 rapid test in the trash?"
- 3) Toronto City News: "How a Canadian Manufacturer of COVID rapid tests is working to meet the crushing demand"
- 4) News Nation: "Poison Control Issues Warning About Covid-19 Rapid Antigen Tests"

References

Primary Literature: Highlighting Safety Concerns of COVID-19 Rapid Antigen Tests

1) <u>Johnson-Arbor, K., Reid, N., & Smolinske, S. (2022).</u> Human toxicity from COVID-19 rapid home test kits. *The American journal of emergency medicine*, S0735-6757(22)00051

<u>Health Canada — Rapid Antigen Test Recall & Safety Alert:</u> https://recalls-rappels.canada.ca/en/alert-recall/rapid-antigen-test-kits-and-potential-exposure-hazardous-substances

Sodium Azide Toxicity:

- 1) CDC Sodium Azide Fact Sheet: https://emergency.cdc.gov/agent/sodiumazide/basics/facts.asp
- 2) 'Human Toxicity From COVID-19 Rapid Home Test Kits': https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8786400/
- 3) Harvard Lab Safety Guideline Sodium Azide: https://www.ehs.harvard.edu/sites/default/files/lab_safety_guideline_sodium_azide.pdf
- 4) Sodium Azide Hazardous Waste Material: https://www.vumc.org/safety/waste/p-listed-wastes
 - o Hazardous Waste No. P105
 - o Chemical Abstract No. 26628-22-8
- 5) National Library of Medicine Lab Chemical Safety Summary (LCSS): https://pubchem.ncbi.nlm.nih.gov/compound/33557#datasheet=LCSS
- 6) GHS Hazard Statements
 - o H300: Fatal if swallowed [Danger Acute toxicity, oral]
 - o H400: Very toxic to aquatic life [Warning Hazardous to the aquatic environment, acute hazard]
 - H410: Very toxic to aquatic life with long lasting effects [Warning Hazardous to the aquatic environment, long-term hazard]
- 7) National Library of Medicine Hazardous Substances Data
 - Bank: https://pubchem.ncbi.nlm.nih.gov/source/Hazardous%20Substances%20Data%20Bank%20(HSDB
- 8) Sodium Azide CEPA Schedule 7 Hazardous Waste and Hazardous Recyclable Material Chemicals: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/historical/regulations-other-instruments/draft-export-import-hazardous-waste-recyclable-material-regulations-revised/schedule-7.html

ProClin-300 Toxicity:

- 1) Sigma Aldrich *Proclin-300* Safety Data Sheet https://www.sigmaaldrich.com/CA/en/sds/sial/48914-u
- 2) FDA 'Phase Scientific COVID-19 Rapid Antigen Test'— https://www.fda.gov/media/151215/download

Ethylene Oxide Toxicity:

- 1) National Library of Medicine Lab Chemical Safety Summary (LCSS): https://pubchem.ncbi.nlm.nih.gov/compound/Ethylene-oxide#datasheet=LCSS
- 2) National Library of Medicine Hazardous Substances Data Bank: https://pubchem.ncbi.nlm.nih.gov/source/hsdb/170

- 3) National Institute of Health Ethylene Oxide, Laboratory Chemical Safety Summary (LCSS) DataSheet: https://pubchem.ncbi.nlm.nih.gov/compound/Ethylene-oxide
- 4) U.S. Environmental Protection Agency Ethylene Oxide: https://www.epa.gov/sites/default/files/2016-09/documents/ethylene-oxide.pdf
- 5) Government of Canada Canadian Environmental Protection Act List of Toxic Substances: https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/ethylene-oxide.html
- 6) U.S. Department of Health and Human Services *Toxicological Profile for Ethylene Oxide*: https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf

The five Health Canada-approved rapid antigen tests as listed on the BCCDC website, see below. Both the manufacturer 'Product Insert' and 'BCCDC Product Instructions' are included in this table:

Product Name	Sodium Azide a listed ingredient?	Product Insert Links	BCCDC Product Instructions
Abbott Panbio	Yes	https://manuals.plus/abbot/abbot-panbio-covid- 19-ag-rapid-test-device-instructions	http://www.bccdc.ca/health- info/diseases- conditions/covid-19/rapid- antigen-testing/rapid-testing- at-home#panbio
Artron (the product distributed to BC schools)	Undisclosed	https://genebiomedical.com/wp- content/uploads/2022/01/Artron-product-insert- Dec-2021.pdf	http://www.bccdc.ca/health- info/diseases- conditions/covid-19/rapid- antigen-testing/rapid-testing- at-home#Artron
BD Veritor	Yes	https://www.bd.com/documents/guides/directions- for-use/IDS_BD-Veritor-Plus-SARS-CoV-2- 500048916 DF EN.pdf	http://www.bccdc.ca/health- info/diseases- conditions/covid-19/rapid- antigen-testing/rapid-testing- at-home#Veritor
BTNX	Yes	https://www.btnx.com/files/COV-19C25/MSDS-I092%20COV-19C25%202.5_BTNX_En.pdf	http://www.bccdc.ca/health- info/diseases- conditions/covid-19/rapid- antigen-testing/rapid-testing- at-home#btnx
SD Biosensor*	Undisclosed	No insert found as this test is *NOT* FDA approved. SD Biosensor tests are considered 'illegal' in the US, but are considered 'approved' by Health Canada. See the FDA recall for SD Biosensor below.	http://www.bccdc.ca/health- info/diseases- conditions/covid-19/rapid- antigen-testing/rapid-testing- at-home#SDBiosensor

 $[*]FDA\ recall\ for\ SD\ Biosensor\ -\ \underline{https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sd-biosensor-issues-notification-voluntary-recall-standard-q-covid-19-ag-home-test\#recall-announcement$

2 Important Calls to Action:

- 1) Contact the <u>Ministry of Environment</u> to submit an <u>Environmental Pollution Report</u> for illegal waste disposal by phone, online or at local Conservation Officer Service district office:
 - Report All Poachers and Polluters: https://www2.gov.bc.ca/gov/content/environment/natural-resource-stewardship/natural-resource-stewardship/natural-resource-law-enforcement/conservation-officer-service/cos-rapp
 - Phone: 1-877-952-7277 (RAPP) / Online Submission: https://forms.gov.bc.ca/environment/rapp/
 - Contact Conservation Officer: https://www2.gov.bc.ca/gov/content/environment/natural-resource-stewardship/natural-resource-st
- 2) Review Government of Canada's *Toxic Substances List*. Research 'ethylene oxide' at this link:
- Toxic Substances List: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/toxic.html
- <u>Toxic Substances List Ethylene Oxide:</u> https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/ethylene-oxide.html