# Make Sure Your COVID-19 Tests Aren't Counterfeit August 12, 2022

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*This article is paraphrased from a Government of Canada public advisory that was published last week. Click <u>here</u> to read the original source.* 

Last Friday, Health Canada released a public advisory that counterfeit COVID-19 rapid antigen test (RAT) kits have been found in Ontario. Unlike the legitimate RAT kits, Health Canada has not evaluated these counterfeit kits for safety and effectiveness.

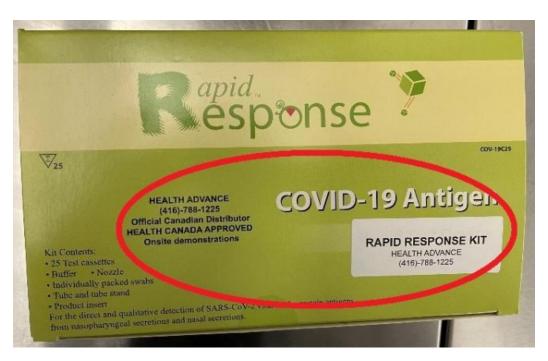
This article will explain how to tell if your RAT kits are legitimate, and what to do if you have a counterfeit test.

# Differences between the Legitimate Tests and the Counterfeit Tests

The packaging of these tests looks very similar to the approved Rapid Response COVID-19 rapid antigen tests by the company BTNX Inc. However, there are four big differences.

# Difference 1: The Top of the Box

Counterfeit:



The top of the box says "Health Advance", phone number, "Official Canadian Distributor", and "Health Canada Approved." Remember that these statements are not true.

### Legitimate:



The top of the box is sealed with a clear sticker with blue lettering that says "QC APPROVED".

#### **Difference 2: The Side of the Box** Counterfeit:



The company name and phone number appear on the side of the box is "Health Advance".

### Legitimate:



The company name and phone number appear on the side of the box is BTXN Inc.

**Difference 3: The Contents of the Box** <u>Counterfeit:</u>



Kits often have different types of testing equipment inside of them with different packaging.

## Legitimate:

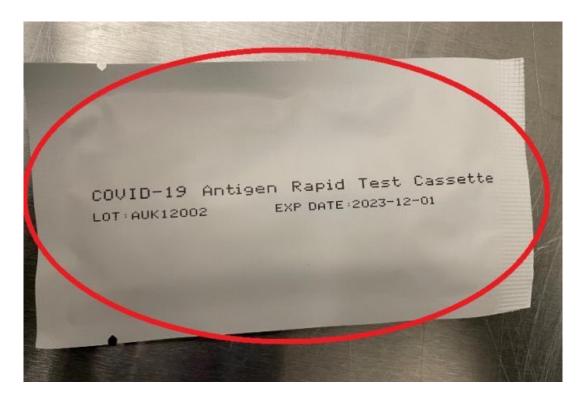


Shown here: test cassettes, tube stand, assay buffer, swabs, procedure card and package insert. Not shown here: extraction tubes and nozzle filters

The contents of legitimate RAT kits will not differ from test to test. There is one possible variation between kits: The liquid that you put into the tubes (called "assay buffers") may come in bottles (shown above) or 25 single-use vials (shown below).



**Difference 4: The Box & the Cassette Pouch** <u>Counterfeit:</u>



Cassette pouches are not green, and their expiry date and lot number may not match the box. Legitimate:

apic	L
M es	nonce
	Rapid Response COVID-19 Antigen Rapid Test Device
BINK bc. 570 Hood Road, Unit 23	LOT 12112418 2023-12-10
L3R 4G7, Catada	TWD For In-vitro Diagnostic Consult accompanied documents
E 12112418 2023-12-10 F6:2021-12-11	Store of 367-867 (2*C-30*C) (2) Do not reuse
	CE BTAX Inc.

Cassette pouches are green. The lot number and expiry date on the cassette pouch should match the lot number and expiry date on the box. Lot numbers start with the letter "I". In this picture, the lot number is I2112418.

## What To Do if You Have a Counterfeit Test

If you have a counterfeit test, do **not** use it! Instead, dispose of it in your household garbage.

You can report it to either Health Canada (click <u>here</u> to do that) or to BTNX Inc. by calling toll-free at 1-888-339-9964, or by email at <u>covid19@btnx.com</u> with the subject line "Suspected Counterfeit BTNX Tests."

## **Final Thoughts**

Apparently, the person who had purchased the 10,875 counterfeit COVID-19 tests (435 boxes of 25-pack RAT kits) bought them for personal use. The good news is that all of these tests from that shipment have been sent to Health Canada for inspection.

However, it's possible that there are counterfeit RAT kits circulating around Ontario from previous shipments. Counterfeit RAT kits haven't been found outside of Ontario.

Based on what we know so far, the issue appears to be limited to one manufacturer, Health Advance Inc., and one distributor, Healthful Plus. Health Advance Inc. appears to no longer be manufacturing medical devices. Also, Healthful Plus's website has been removed and the company appears to no longer be in operation.

Health Canada stated that it is "committed to protecting Canada's supply of licensed COVID-19 test kits and preventing counterfeit products from entering the Canadian supply chain, [and] it will continue to assess any potential counterfeit products it becomes aware of and to take compliance and enforcement action as needed, including informing consumers."

If you think you may be experiencing symptoms of COVID-19, take the self-assessment at <u>www.ontario.ca/coronavirus</u>. Follow all directions from your medical provider or your local health unit at the following phone numbers:

Telehealth Ontario: 1-866-797-0000 Toronto Public Health: 416-338-7600

Peel Public Health: 905-799-7700

Durham Region Health Department: 905-668-7711

York Region Public Health: 1-877-464-9675