

Since its first authorization, BTNX Inc. has continued the shelf-life evaluation studies for the **Rapid Response™ COVID-19 Antigen Rapid Test Cassette – At Home** to achieve an expiration of 24 months from the date of manufacture. These studies have been sent to Health Canada and we are pleased to announce that the shelf-life extension for up to 24 months from manufacture has been authorized to our Interim Order authorization **IO#342928**.

BTNX has a letter uploaded through the Ontario Health website:

<https://www.ontariohealth.ca/providing-health-care/clinical-resources-education/covid-19/health-system-response-resources>

If you have any questions about the shelf-life extension or inquiries related to the BTNX COVID-19 antigen tests, please reach out to us at covid19@btnx.com.

Following are the FAQs related to shelf-life and expiration dates of our COVID-19 related antigen tests:

Q: How is the expiration date determined for a BTNX COVID-19 diagnostic test?

A: The testing to determine this time period is called stability testing because it is confirming the time period over which the performance is expected to remain stable. There are different types of stability testing. The most accurate is real-time stability testing, where the manufacturer stores the tests at the recommended storage temperatures for the proposed shelf-life (with additional time to ensure the expiration date can be relied upon) and then evaluates its ability to perform accurately. For example, for a proposed 12-month shelf-life, the manufacturer would evaluate the performance after storing the test for 13 months.

Q: Why does the expiration date of the BTNX COVID-19 diagnostic test need to be extended?

A: Unfortunately, a vast amount of time is required to perform real-time stability testing on a product. The initial authorisation was with the studies available at the time. BTNX Inc. continued to perform the real-time stability testing until the full 24-month expiration date was achieved.

Q: Can the expiration date of any COVID-19 diagnostic test be extended?

A: Yes. Once the test manufacturer has more stability testing results, such as 12 or 18 months, the test manufacturer can contact Health Canada to request that Health Canada authorize a longer shelf-life. When a longer shelf-life is authorized, the expiration dates will be extended and the test manufacturer may send a notice to customers or make a public announcement to provide the new authorized expiration dates, so the customers know how long they can use the tests they already have.

Q: How do I know if the expiration date of my BTNX COVID-19 test has been extended? Where do I find the updated expiration date?

A: You can check the Expiration Date column of the [Health Canada page for List of authorized testing devices](#) to see the shelf-life for your BTNX COVID-19 test. And the new expiration dates for the respective lots can be found on the [Ontario Health COVID-19 Health System Response Materials](#).

Q: What format is the expiry date in?

A: The expiry date of the COVID-19 antigen test kits is in YYYY-MM-DD. For example, if the expiry date on the test kit is 2024-05-03, the expiry date is May 3rd, 2024.