September 26, 2022,

This letter is to inform regarding the extension of shelf-life expiration date for **Rapid Response™ COVID-19 Antigen Rapid Test Cassette – At Home** authorized under Health Canada Interim Order Authorization: **IO#342928**. As of July 19th 2022, Health Canada has authorized a shelf life to 24 months from the date of manufacture.

The table below provides information the affected product codes with their lots, their current short-dated expiration printed on the box and their new expiration date following this amendment:

Product code	Lot numbers	Manufacture Date	Expiration on box	New Expiration
COV-19CSHC2	COVN22030038	2022-03-10	2023-02-09	2024-03-09
COV-19CSHC2	COVN22030039	2022-03-10	2023-02-09	2024-03-09
COV-19CSHC2	COVN22030040	2022-03-10	2023-02-09	2024-03-09
COV-19CSHC2	COVN22030041	2022-03-10	2023-02-09	2024-03-09
COV-19CSHC5	COVN22030101, COVN22030102, COVN22030103, COVN22030104, COVN22030105, COVN22030106, COVN22030107, COVN22030108	2022-03-12	2023-02-11	2024-03-11
COV-19CSHC2	COVN22030042	2022-03-12	2023-02-11	2024-03-11
COV-19CSHC1	COVN22040034	2022-04-21	2023-03-20	2024-04-20
COV-19CSHC5	COVN22060001, COVN22060002, COVN22060003, COVN22060004, COVN22060005, COVN22060006, COVN22060007, COVN22060008, COVN22060009, COVN22060010, COVN22060011, COVN22060012, COVN22060013, COVN22060014, COVN22060015	2022-06-07	2023-05-06	2024-06-06
COV-19CSHC5	COVN22060016, COVN22060017	2022-06-08	2023-05-07	2024-06-07
COV-19CSHC5	COVN22060018, COVN22060019, COVN22060020, COVN22060021, COVN22060022, COVN22060023, COVN22060024, COVN22060025, COVN22060026, COVN22060027, COVN22060028, COVN22060029, COVN22060030, COVN22060031, COVN22060032	2022-06-08	2023-09-07	2024-06-07
COV-19CSHC5	COVN22060033, COVN22060034, COVN22060035, COVN22060036, COVN22060037	2022-06-14	2023-09-13	2024-06-13

722 Rosebank Rd, Pickering, Ontario, L1W 4B2 | Tel: (905) 944-9565 | Toll Free: 1-888-339-9964 | Fax: (905) 944-0406

Please retain this letter for future reference. Should you have any questions please reach out to covid19@btnx.com.

Sincerely,

BTNX Inc.

Health Canada Santé Canada

Medical Devices Directorate
11 Holland Avenue
Tower A, 2nd Floor
Address Locator: 3002A
Ottawa, Ontario
K1A 0K9

July 19th, 2022

Authorization Reference No.: 342928

Correspondence ID: 16917

KHASIM ALI KHAN
TECHNICAL OPERATIONS MANAGER
BTNX INC.
570 HOOD RD, UNITS #23, 21, 13, 6, 3 AND 5,
MARKHAM, ON
Canada, L3R 4G7
qara@btnx.com

Re: Authorization for Import or Sale with Conditions

Dear KHASIM ALI KHAN:

This letter is in reference to the above-noted authorization issued under Section 5 of the *Interim Order No. 3 Respecting the Importation and Sale of Medical Devices in relation to COVID-19* to BTNX INC. for the **RAPID RESPONSE COVID-19 ANTIGEN RAPID TEST CASSETTE - AT HOME**. On July 6th, 2022, conditions were placed on this authorization in accordance with Section 7 of the Interim Order. The information requested under this authorization has been revised.

Due to the nature of the expedited authorization process under the IO, which allows manufacturers to submit an abbreviated application to support the safety, effectiveness and quality of their device, Health Canada is imposing the following terms and conditions as a risk mitigation strategy to ensure evidence standards are not compromised. Therefore, in accordance with Section 7 of the Interim Order, the following terms and conditions are in effect:

This terms and conditions letter supersedes the previous terms and conditions imposed on the Authorization for Import or Sale with Conditions issued on July 6th, 2022 (IO 342928, Corr ID: 16777); however, the terms and conditions outlined in the aforementioned communication remain active as they are being brought forward:

The following terms and conditions are revised:

To be submitted by March 2023:

1. A shelf-life of 24 months is currently authorized based on available data. Provide the final report of the ongoing real-time stability study to fully support the shelf-life claim.

Your response may be submitted by e-mail to: hc.devicelicensing-homologationinstruments.sc@canada.ca, or sent by mail to the address above on a CD or DVD if it is too large to send by e-mail.

Responses to the above conditions should be include a copy of this letter. Responses to these conditions should not be submitted as part of any other regulatory correspondence (e.g. within an application for amendment to the IO). If you have previously received a letter with terms and conditions, please include the latest version of this letter.

Failure to supply this information may result in cancellation of this authorization under Section 8 of the Interim Order. If you have questions or require clarification, please email us within 10 business days from receipt of this letter, or before your first condition obligations are due, whichever comes first. If you do not bring forward any questions or concerns within the specified period, we will interpret that to mean that you understand the terms and conditions that have been imposed and that you are in a position to comply with our request.

Sincerely,

Christine Leckie
A/Executive Director
Medical Devices Evaluation Bureau
Medical Devices Directorate

CL/hg