



**\*\*\*\*\* Applicable to customers in the country of Canada only \*\*\*\*\***

December 7, 2021

As per Health Canada's list of medical devices for expanded use in relation to the COVID-19 pandemic<sup>1</sup>, the shelf life of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 (product numbers 256089 and 256082) has been extended to a total of 16 months in Canada. Please note that BD does not have any in-house data supporting this shelf-life extension to a total of 16 months. Health Canada obtained the required data from a study conducted by the National Microbiology Lab.

As this 16-month total shelf-life will not be incorporated into the product packaging, labelling, or instructions for use, please follow the below guide to determine the expiry date of your device based on the expiry date marked on the product:

<b>Which product number was received?</b>	256082	256089	
<b>What expiry date is marked on the product?</b>	Any	Expiry date in 2021	Expiry date in 2022
<b>What shelf life is marked on the product?</b>	6 months	6 months	12 months
<b>How can the Health Canada shelf life extension be calculated?</b>	Add 10 months to the marked expiry date	Add 10 months to the marked expiry date	Add 4 months to the marked expiry date
<b>Sample calculation</b>	Products with a marked expiry date of 2021-06-09 will have a new expiry date of 2022-04-09.	Products with a marked expiry date of 2021-06-09 will have a new expiry date of 2022-04-09.	Products with a marked expiry date of 2022-01-09 will have a new expiry date of 2022-05-09.

This letter applies only to customers located within Canada. For customers located in all other countries, the as-labeled dating for products 256082 and 256089 will apply.

Reference:

- 1) Health Canada - List of medical devices for expanded use in relation to the COVID-19 pandemic (<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/expanded-use.html>)

Kit Box				Included Test Device			
Kit Batch	Marked Expiry	BD Extension	Health Canada Extension	Device Batch	Marked Expiry	BD Extension	Health Canada Extension
<b>256089 - BD Veritor™ System for Rapid Detection of SARS-CoV-2</b>							
342239	4/16/2021	10/16/2021	2/16/2022	335260	4/16/2021	10/16/2021	2/16/2022
1010086	5/18/2021	9/18/2021	1/18/2022	1001309	5/18/2021	9/18/2021	1/18/2022
343900	5/20/2021	9/20/2021	1/20/2022	336490	5/20/2021	9/20/2021	1/20/2022
346215	5/22/2021	9/22/2021	1/22/2022	339023	5/26/2021	9/22/2021	1/22/2022
349155	5/26/2021	9/26/2021	1/26/2022	340765	5/26/2021	9/26/2021	1/26/2022
0365333	6/09/2021	12/09/2021	4/09/2022		6/09/2021	12/09/2021	4/09/2022
1003502	6/14/2021	12/14/2021	4/14/2022		6/14/2021	12/14/2021	4/14/2022
1007570	6/16/2021	12/16/2021	4/16/2022	364279	6/16/2021	12/16/2021	4/16/2022
1016642	6/25/2021	12/25/2021	4/25/2022	1006914	6/29/2021	12/25/2021	4/25/2022
1032077	7/6/2021	1/6/2022	5/6/2022	1015160	7/6/2021	1/6/2022	5/6/2022
1035279	7/6/2021	1/6/2022	5/6/2022	1022108	7/6/2021	1/6/2022	5/6/2022
1027050	7/7/2021	1/1/2022	5/5/2022	1018279	7/7/2021	1/1/2022	5/5/2022
1033798	7/7/2021	1/1/2022	5/5/2022	1021484	7/7/2021	1/1/2022	5/5/2022
1035122	7/7/2021	1/1/2022	5/5/2022	1022107	7/7/2021	1/1/2022	5/5/2022
1036924	7/10/2021	1/10/2022	5/10/2022	1024063	7/10/2021	1/10/2022	5/10/2022
1046484	7/10/2021	1/10/2022	5/10/2022	1032070	7/10/2021	1/10/2022	5/10/2022
1038934	7/12/2021	1/12/2022	5/12/2022	1026114	7/12/2021	1/12/2022	5/12/2022
1038689	7/13/2021	1/13/2022	5/13/2022	1026108	7/13/2021	1/13/2022	5/13/2022
1041056	7/15/2021	1/15/2022	5/15/2022	1026116	7/15/2021	1/15/2022	5/15/2022
1042874	7/15/2021	1/15/2022	5/15/2022	1026118	7/15/2021	1/15/2022	5/15/2022
1040092	7/16/2021	1/16/2022	5/16/2022	1026110	7/16/2021	1/16/2022	5/16/2022
1045248	7/16/2021	1/16/2022	5/16/2022	1029429	7/16/2021	1/16/2022	5/16/2022
1047008	7/19/2021	1/19/2022	5/19/2022	1032053	7/19/2021	1/19/2022	5/19/2022
1050033	7/19/2021	1/19/2022	5/19/2022	1039189	7/19/2021	1/19/2022	5/19/2022
1050036	7/19/2021	1/19/2022	5/19/2022	1039187	7/19/2021	1/19/2022	5/19/2022
1047060	7/20/2021	1/20/2022	5/20/2022	1033801	7/20/2021	1/20/2022	5/20/2022
1050617	7/20/2021	1/20/2022	5/20/2022	1033786	7/20/2021	1/20/2022	5/20/2022
1047054	7/21/2021	1/21/2022	5/21/2022	1033804	7/21/2021	1/21/2022	5/21/2022
1047064	7/21/2021	1/21/2022	5/21/2022	1033813	7/21/2021	1/21/2022	5/21/2022
1050591	7/21/2021	1/21/2022	5/21/2022	1033813	7/21/2021	1/21/2022	5/21/2022
1078956	1/27/2022	n/a*	5/27/2022	1046407	1/27/2022	n/a*	5/27/2022
1069690	1/30/2022	n/a*	5/30/2022	1048875	1/30/2022	n/a*	5/30/2022
1075845	1/30/2022	n/a*	5/30/2022	1048875	1/30/2022	n/a*	5/30/2022
1092578	2/3/2022	n/a*	6/3/2022	1082166	2/3/2022	n/a*	6/3/2022
1091111	2/4/2022	n/a*	6/4/2022	1084893	2/4/2022	n/a*	6/4/2022
1077985	2/5/2022	n/a*	6/5/2022	1054503	2/5/2022	n/a*	6/5/2022
1301007	9/24/2022	n/a*	1/24/2023	1290083	9/24/2022	n/a*	1/24/2023
<b>256082 - BD Veritor™ System for Rapid Detection of SARS-CoV-2</b>							
1248619	2/19/2022	8/21/2022	12/21/2022	1244655	2/19/2022	8/21/2022	12/21/2022
1256372	2/22/2022	8/24/2022	12/24/2022	1251895	2/22/2022	8/24/2022	12/24/2022
1255177	2/25/2022	8/27/2022	12/27/2022	1250917	2/25/2022	8/27/2022	12/27/2022

\*BD has extended the shelf life to a total of 12 months. This 12 month shelf life is marked on 256089 product manufactured after 1/21/2021. The 256082 product is marked with a six month shelf life.

Health Canada has independently issued a further expansion of shelf life to a total of 16 months. This extension will not be indicated on either product.



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

March 4, 2021

Authorization No.: 318420

**Extension of Shelf-Life**

To whom it may concern:

This letter is in reference to interim order authorization 318420 for the Bd Veritor System For Rapid Detection Of SARS-CoV-2.

On March 3, 2021, the Medical Devices Directorate approved an amendment to the authorization for this product, extending the shelf-life of the product from 6 months to 12 months.

This extension of the shelf-life applies to all BD Veritor System For Rapid Detection Of SARS-CoV-2 antigen tests that have been distributed in Canada to date, despite the stated expiry dates on those products. It applies to future distribution of the authorized tests as well.

Sincerely,

Roslynn Miller-Lee  
Executive Director  
Bureau of Evaluation  
Health Products and Food Branch