

## Extended shelf-life for rapid antigen tests

To all sites performing rapid antigen testing –

Please be aware of the following extensions for the shelf-life of **Abbott Panbio** and **BD Veritor** rapid antigen tests.

1. **Abbott Panbio**

*\*See below Health Canada authorization letters for Panbio Nasal (pg 2-3) and NP (pg 4-5) tests.*

On September 9, 2021, Health Canada authorized an amendment for a shelf-life extension from 12 to **24 months** for the COVID-19 Nasal and NP Version tests.

2. **BD Veritor**

*\*See below vendor letter (pg 6) and [link](#) to Health Canada authorization (found in table, 2021-10-08 authorization date).*

On October 18, 2021, Health Canada authorized a shelf-life extension of **16 months** (additional 4 months beyond the previous 12 month extension).

**Note:** refer to the expiry date that is printed on the outside of the BD Veritor rapid test kit boxes - internal components may indicate different dates.

Thank you for your ongoing efforts to support provincial antigen screening and please share this notice with teams as required.

Thank you,

**COVID-19 Provincial Laboratory Network**  
Ontario Health

## Abbott Panbio Covid-19 (Nasal Version) Amendment – Shelf life extension

### Abbott and the regulatory approval of Panbio Covid-19 Nasal test

- Abbott is an American company that holds 365 medical device licenses in Canada under 19 separate legal manufacturers.
- In the context of the pandemic, Abbott has 5 authorizations under the Interim Order for the following tests:
  - Abbott Realtime SARS-COV-2 PCR COVID test (March 25, 2020)
  - Abbott Architect (May 14, 2020)
  - Abbott Alinity (June 11, 2020)
  - Abbott ID Now (September 30, 2020)
  - Abbott Panbio COVID-19 AG Rapid Test Device (NP) (October 05, 2020)
- **On December 31, 2020, Health Canada issued an authorization under the Interim Order for the Abbott Panbio Covid-19 Nasal test.**
- **On June 08, 2021, Health Canada issued an amendment to the authorization under the Interim Order for the Abbott Panbio COVID-19 Nasal Test to include self-collected nasal swabs under the supervision of a health care provider and use of the test by trained operators.**
- **On September 09, 2021, Health Canada authorized an amendment for a shelf life extension from 12 to 24 months.**
  - **This amendment requires that the manufacturer continue to fulfil all previous conditions, as well as one additional condition specific to this amendment that is highlighted below.**
- **The IO authorization includes conditions** the manufacturer must fulfil to ensure a minimum standard of safety and reliability:
  - By November 25<sup>th</sup>, 2021**
    - An assessment of the UK and SA strains on the test and a plan to mitigate new risks or the following statement in the limitations section of the IFU “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.”
  - When available**
    - **Provide a report of the real time stability study at 24 months (adjusted)**

### The Abbott Panbio COVID-19 (Nasal Version) test

- The Abbott PanBio COVID-19 (Nasal Version) test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 antigen in laboratory and point-of-care settings by trained operators.

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- The test identifies the presence of SARS-CoV-2 nucleocapsid protein antigen in nasal swab samples collected by a health care professional or self collected under the supervision of a health care professional from individuals who are suspected of COVID-19 by their healthcare provider.
- The disposable test kit consists of :
  - Nasal swab
  - Testing cassette/testing device (pictured)
  - Extraction buffer
  - Extraction tubes and caps
  - Positive and negative control swabs
- The workflow includes filling the extraction tube with buffer fluid, sample collection, extraction of sample using the buffer, addition of sample to the testing device, and reading the results.
- The test operates on a single use basis, testing one individual in approximately 15 minutes
- Clinical trials provided by the manufacturer indicate a sensitivity of 91.4% and specificity of 99.8%.
- The approved shelf life is 24 months; however, it is subject to change depending on the submission of additional real-time stability data (see condition above).



### Intended use

- The Abbott Panbio COVID-19 test (nasal version) is intended for use in both laboratory and point of care settings by trained operators.
- The test is for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in nasal swab samples either collected by a healthcare professional or self collected under the supervision of a healthcare professional.
- Samples should be collected from individuals suspected of COVID-19 by their healthcare provider.

### Next steps

- Federal partners will be informed.

### Approved by

Tanya Ramsamy, Executive Director, on behalf of, David Boudreau, Director General  
Medical Devices Directorate

## Abbott Panbio Covid-19 (NP Version) Amendment – Shelf Life Extension

### Abbott and the regulatory approval of Panbio Covid-19 Version NP test

- Abbott is an American company that holds 365 medical device licenses in Canada under 19 separate legal manufacturers.
- In the context of the pandemic, Abbott has 5 authorizations under the Interim Order for the following tests:
  - Abbott Realtime SARS-COV-2 PCR COVID test (March 25, 2020)
  - Abbott Architect (May 14, 2020)
  - Abbott Alinity (June 11, 2020)
  - Abbott ID Now (September 30, 2020)
  - Abbott Panbio COVID-19 AG Rapid Test Device (nasal) (December 31, 2020)
- **On October 5, 2020 Health Canada issued an authorization under the Interim Order for the Abbott Panbio Covid-19 Version NP test.**
- **On September 9, 2021, Health Canada authorized an amendment for a shelf life extension from 12 to 24 months.**
  - This amendment requires that the manufacturer continue to fulfill all previous conditions, as well as one additional condition specific to this amendment that is highlighted below.
- The **IO authorization includes conditions** the manufacturer must fulfil to ensure a minimum standard of safety and reliability:
  - When available**
    - Provide a report of the real time stability study at 24 months (adjusted)
    - Provide the results of the reproducibility study
    - Provide the microbial interference study
    - Provide the results for the proposed sequencing and evaluation of clinical samples of the UK and SA variants sourced by Abbott’s Global Viral Surveillance Program

### The Abbott Panbio COVID-19 (NP Version) test

- The PanBio COVID-19 (NP Version) test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 antigen in laboratory and point-of-care settings.
- The test identifies the presence of SARS-CoV-2 nucleocapsid protein antigen in samples collected using either nasopharyngeal (NP) or nasal swabs in patients suspected of COVID-19 by their healthcare provider.
- The disposable test kit consists of :
  - Swab
  - Testing cassette/testing device (pictured)
  - Extraction buffer
  - Extraction tubes and caps
  - Positive and negative control swabs
- The workflow includes filling the extraction tube with buffer fluid, sample collection, extraction of sample using the buffer, addition of sample to the testing device, and reading the results.
- The test operates on a single use basis, testing one individual in approximately 15 minutes.



- Clinical trials provided by the manufacturer indicate a sensitivity of 91.4% and specificity of 99.8%.
- The approved shelf life is 24 months; however, it is subject to change depending on the submission of additional real-time stability data (see condition above).

#### **Intended use**

- The Abbott Panbio Covid-19 (NP Version) is intended for use in both laboratory and point of care settings by trained laboratory personnel or healthcare professionals.
- The test is for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in nasopharyngeal or nasal swab samples.
- Samples should be collected from individuals suspected of COVID-19 by their healthcare provider.

#### **Next steps**

- Federal partners will be informed.

#### **Approved by**

Tanya Ramsamy, Executive Director, on behalf of, David Boudreau, Director General  
Medical Devices Directorate



October 18, 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 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:

- If the expiry date printed on the product label is in 2021:
  - The date of manufacturing was 6 months prior to the printed expiry date.
  - The new expiry date will be 10 months after the date printed on the label.
  - *For example, products with a printed expiry date of 2021-06-09, now have a new expiry date of 2022-04-09.*
  
- If the expiry date printed on the product label is in 2022:
  - The date of manufacturing was 12 months prior to the printed expiry date.
  - The new expiry date will be 4 months after the date printed on the label.
  - *For example, products with a printed expiry date of 2022-01-09, now have a new expiry date of 2022-05-09.*

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>)