

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 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.