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Health Canada
Health Products and Food Branch
Medical Devices Directorate

September 09, 2021

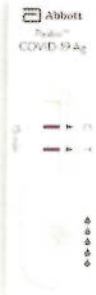
Abbott Panbio Covid-19 (Nasal Version) Amendment – Shelf life extension

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 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.
- 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 approximatively 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.