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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 **IO authorization includes conditions** the manufacturer must fulfil to ensure a minimum standard of safety and reliability:

    By November 25th, 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.

- 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.

Next steps

- Federal partners will be informed.

Approved by

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

Health Canada
Health Products and Food Branch
Medical Devices Directorate

September 09, 2021

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 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 Abott 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

COVID-19 Medical Device Authorization with Conditions for Importation or Sale Pursuant to Section 7 of the Interim Order

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19 avec conditions conformément à l'article 7 de l'Arrêté d'urgence

Authorization Reference Number :	324506	**Numéro de référence de l'autorisation**
Issue Date:	2020-12-31	**Date de délivrance:**
Amendment Date:	2021-06-08, 2021-09-09	**Date de modification:**
Reason for Amendment	Expanded Shelf Life to 24 months	**Raison de la modification**
Amendment Reference Number	335165	**Numéro de référence de la modification**

Device Class/Classe de l'instrument : 4

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurez de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument

PANBIO COVID-19 AG RAPID TEST DEVICE (NASAL)

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

ABBOTT RAPID DIAGNOSTICS JENA GMBH
ORLAWEG 1
JENA,
GERMANY
07743

David Boudreau, ing., Director General, Medical Devices Directorate
Directeur général, Direction des instruments médicaux

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

PANBIO COVID-19 AG RAPID TEST DEVICE (NASAL)

Device ID/No de l'instrument: 1027672
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
41FK11