Communication
COVID-19

DESTINATAIRES : Tous les membres du personnel et médecins du CISSS de Chaudière-Appalaches

DATE : 8 octobre 2021

OBJET : Prolongation de la durée de vie des tests rapides Panbio

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La présente est pour vous informer que Santé Canada a émis un amendement le 9 septembre dernier autorisant la prolongation de la durée de conservation des tests rapides Panbio d'une période initiale de 12 mois à une période de 24 mois.

Par conséquent, la date de péremption du produit est prolongée de 12 mois additionnels de l'information contenue actuellement sur ce dernier.

Par exemple, si la date d'expiration du produit en votre possession est le 30 octobre 2021, le produit viendra à péremption uniquement le 30 octobre 2022.

Cet avis affecte les tests rapides Panbio déployés dans les différents services pour le dépistage rapide des employés et il se distribue sous le code GRM 16800865.

Nous sollicitons votre aide pour procéder à l'affichage de cette note de service afin que tous les utilisateurs de ce produit puissent être informés.

Nous vous remercions de votre collaboration.

« Signature autorisée »

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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