**Health Canada**
Health Products and Food Branch
Medical Devices Directorate

October 06, 2020

# Abbott Alinity m SARS-CoV-2

## Abbott and the regulatory approval of Alinity m SARS-CoV-2 test

- Abbott has 15 separate legal manufacturers holding 260 medical device licences in Canada.
- In the context of the pandemic, Health Canada has already issued authorizations under the Interim Order for the following tests:
    - Abbott Realtime SARS-COV-2 PCR COVID test (March 25)
    - Abbott Architect (May 14)
    - Abbott Alinity (June 11)
    - Abbott ID Now (Sept 30)
    - Abbott PanBio (October 5)
- **On October 6, Health Canada issued an authorization under the Interim Order for the Abbott Alinity m SARS-CoV-2 test.**
- The **IO authorization includes conditions** the manufacturer must fulfil to maintain authorization. Applying conditions can help Health Canada expedite authorization without compromising patient safety. The Alinity m conditions include:
    - Provide the results of the wet testing performed with the Alinity m SARS-CoV-2 assay by January 20, 2021.
    - Provide the results of the shelf-life stability study for the Alinity m SARS-CoV-2 AMP kit and Alinity m SARS-CoV-2 CTRL kit by December 20, 2021.
- The Abbott Alinity m SARS-CoV-2 test also received an Emergency Use Authorization (EUA) in the US.

## The Alinity m SARS-CoV-2 test

- Alinity m is a molecular PCR test for use in laboratory settings, using nasopharyngeal and oropharyngeal swabs collected by a healthcare provider.
- The Alinity m SARS-CoV-2 assay is used with the Alinity m System. The Alinity m System is already licensed by Health Canada under licence 103666.
- Clinical evidence from the manufacturer indicates **100% sensitivity and 96.5% specificity**.

## Intended use

- The Alinity m SARS-CoV-2 assay (test) is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare provider.
- The test is intended for use in patients who are suspected of COVID-19 infection.
- The Alinity m SARS-CoV-2 AMP Kit is for laboratory use by qualified and trained clinical laboratory personnel. It is not intended for use by healthcare professionals.

## Next steps

- The list of authorized testing devices will be updated to include this authorization on October 6, 2020.
- Media lines and QP notes will be updated.
- Federal partners will be informed.