BD Veritor™ System for Rapid Detection of SARS-CoV-2 Expanded Use – Shelf Life

BD and the regulatory approval of the BD Veritor™ System for Rapid Detection of SARS-CoV-2
- BD (Becton, Dickinson and Company) is an American company that holds 216 medical device licences under 8 separate legal manufacturers. The test is manufactured in China.
- In the context of the pandemic, Health Canada already issued authorizations under the Interim Order for the following test:
  - BD SARS-CoV-2 Reagents For BD Max System (April 19, 2020)
  - BD Kit for Rapid Detection of SARS-CoV-2 (October 05, 2021)
- On October 9, 2020, Health Canada issued an authorization under the Interim Order for the BD Veritor™ System for Rapid Detection of SARS-CoV-2.
- On October 07, 2021, Health Canada authorized an Expansion of Use to the BD Veritor™ System for Rapid Detection of SARS-CoV-2 authorization for visually reading the test such that the analyzer is not required. The visual read cannot be used for serial testing in asymptomatic populations.
- On October 18, 2021, Health Canada authorized an Expansion of Use to the BD Veritor™ System for Rapid Detection of SARS-CoV-2 authorization for a shelf life extension from 12 to 16 months:
  - An accelerated stability study performed by the National Microbiology Laboratory was leveraged to support this expanded use.
  - As this was not requested by the manufacturer, the instructions for use and packaging will not be updated to reflect this change.
  - The 16 month shelf life will apply to both newly purchased BD Veritor System for Rapid Detection of SARS-CoV-2 testing devices, as well as previously purchased devices that have yet to be utilized:
    - If the expiry date printed on the label ends in 2021, then, the new expiry date is the expiry date printed on the label + 10 months.
    - If the expiry date printed on the label ends in 2022, then, the new expiry date is the expiry date printed on the label + 4 months.
- The expanded uses of the BD Veritor device can be found on: The list of medical devices for expanded use.

The BD Veritor™ System for Rapid Detection of SARS-CoV-2
- The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is a chromatographic immunoassay that is intended for the qualitative detection of SARS-CoV-2 antigen in point-of-care settings by trained healthcare professionals.
- The test identifies the presence of SARS-CoV-2 nucleocapsid protein antigen in nasal swab samples from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of symptom onset or from individuals without symptoms when tested twice over two or three days with at least 24 hours, and no more than 48 hours, between tests.
  - The visual read cannot be used for serial asymptomatic testing.
- The test kit contains enough reagents for 30 tests and consist of:
  - 30 single use testing cassettes
  - 30 reactions tubes with extraction buffer already dispensed into the tube
  - 30 nasal swabs
  - 1 positive and negative control set
- Additional materials that are not provided with the test kit:
  - BD Veritor analyzer (optional)
The workflow includes sample collection with the nasal swab, sample extraction from the nasal swab in the reaction tube, addition of the sample to the testing cassette, and either reading the result on the analyzer display screen OR visually reading the result directly from the testing cassette (no analyzer required). The visual read cannot be used for serial asymptomatic testing.

- 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 83.9% and specificity of 99.83% in symptomatic populations. Clinical performance has not been established for serial testing of asymptomatic populations.
- The approved shelf life is 16 months from the date of manufacture.

**Intended use**

- The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is intended for use in point-of-care settings by trained healthcare professionals.
- The test is for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in nasal swab samples collected by a healthcare professional.
- Samples should be collected from individuals suspected of COVID-19 by their healthcare provider within the first 5 days of symptom onset or from individuals without symptoms when tested twice over two or three days with at least 24 hours, and no more than 48 hours, between tests.
  - The visual read cannot be used for serial asymptomatic testing.

**Next steps**

- The list of medical devices for expanded use will be updated on October 18, 2021.
- Federal partners will be informed.

**Approved by**

David Boudreau, Director General
Medical Devices Directorate