Health Canada
Health Products and Food Branch
Medical Devices Directorate

October 18, 2021

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
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Medical Devices Directorate