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A	Executive Director, Medical Device Evaluation Bureau
	MDD
FROM	Jeffrey Skene
DE	Medical Device Directorate

Application Information

Information de soumission

Application ***Soumission***	**Name of device** ***Nom de l'homologation***		**Licence Number** ***No. de l'homologation***	**Risk Class** ***Classe de l'instrument***
318420	BD Veritor™ System for Rapid Detection of SARS-CoV-2 with the BD Veritor™ Plus Analyzer		N/A	4
Application Type ***Type de soumission***	**Licence Type** ***Type d'homologation***	**Manufacturer** ***Fabricant***		**Company ID** ***No. d'entreprise***
Application under IO	Test Kit	Becton Dickinson And Company		101281

Test Setting	Both Lab and POC

1 Background/*Antécédents*

The application for the BD Veritor™ System for Rapid Detection of SARS-CoV-2 with the BD Veritor™ Plus Analyzer was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. This Interim Order allows the Department to issue expedited authorization for sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians.

The information submitted is evaluated based on the Interim Order (IO) guidance document Applications for medical devices under the Interim Order for use in relation to COVID-19 (version 2020-09-16), Health Canada Testing devices for COVID-19: Antigen testing devices (version 2020-09-29), the FDA document Antigen Template for Manufacturers (version 2020-05-11), and the US CDC Interim Guidance for Rapid Antigen Testing for SARS-CoV-2 (updated 2020-08-16).

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 received a US FDA Emergency Use Authorization (EUA) on July 02, 2020. The US authorized users include trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures and individuals trained in point of care settings outside of a laboratory.

2 Intended Use

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is a chromatographic digital immunoassay intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid

antigens in nasal swabs from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. In the United States, testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

The BD Veritor System for Rapid Detection of SARS-CoV-2 is intended for use in point of care settings and operated by healthcare professionals or trained users specifically instructed in the use of the BD Veritor System and proper infection control procedures. In the United States, the BD Veritor System for Rapid Detection of SARS-CoV-2 is only for use under the Food and Drug Administration's Emergency Use Authorization. [IFU ref. 256082 version 2020-09]

3 Discussion/*Évaluation*

The information provided meets the minimum requirements to authorize the BD Veritor™ System for Rapid Detection of SARS-CoV-2 under the Interim Order.

The BD Veritor™ Plus Analyzer was licensed for sale in Canada on June 06, 2017 (Class 3 Licence No. 99263) for use with BD Veritor System Test Devices. The current BD Veritor System Test Devices include BD Veritor System FLU A+B (Licence No. 92066), BD Veritor System for Rapid Detection of Group A Strep (Licence No. 94554), BD Veritor System for Rapid Detection of Respiratory Syncytial Virus (RSV, Licence No.: 94839), and BD Veritor PLUS (Licence No. 99263).

The manufacturer holds a valid MDSAP Certificate. There are currently 470 active BD Veritor Analyzers in Canada and approximately 26,000 BD Veritor Plus Analyzers in the US.

The total workflow time for the test is a maximum of 20 minutes per sample. The BD Veritor Plus Analyzer has a limited use lifetime of 3500 tests.

Assay-specific studies including analytical sensitivity/limit of detection, cross-reactivity, microbial interference, hook-effect, cut-off, endogenous and exogenous Interferents, and precision

evaluation, including both repeatability and reproducibility, were provided. For the device robustness demonstration, the applicant cross-referred to a robustness study submitted for the BD Veritor FLU A/B assay (Licence No. 92066, application 210148), as it has identical technology and similar assay configuration to the SARS-CoV-2 assay. Based on the information submitted for the BD Veritor FLU A/B ASSAY (application 210148), the applicant's proposal to apply the BD Veritor FLU A/B assay robustness evaluation results to evaluation under Interim order of the BD Veritor System for detection of SARS-CoV-2 is deemed acceptable.

Results of the accelerated stability study were provided; real-time, in-use, and transport stability studies are ongoing.

To demonstrate performance of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 with clinical samples, the applicant submitted two internal studies that were conducted using 410 nasal swabs in total, collected by clinicians at 36 different point of care sites in the US. The samples were collected from symptomatic outpatients within 7 days after the symptoms onset and were suspected of having COVID19.

The results of two studies demonstrate sensitivity of 83.9% and 93.5%, and specificity of 100.0% and 99.3%, respectively.

With respect to the Point of Care study, the applicant cross-refers to the POC studies that have been performed for the BD Veritor Flu A+B assay that uses similar components of the assay and the test procedure are substantially similar the BD Veritor SARS CoV-2 assay; the only significant difference being the assay development time. A summary of the near-patient study for the Veritor Flu A/B assay was provided. The study was performed at multiple sites in the US and Japan. Based on the similar product POC study, the applicant made the following justification:

"The BD Veritor Flu A+B assay uses components and workflow steps substantially similar to the BD Veritor SARS CoV-2 assay; the only significant difference being the assay development time. The Flu A+B assay is interpreted ten minutes after sample addition, while SARS-CoV-2 is read at 15 minutes after sample addition." The submitted rationale is considered acceptable because the manipulation of the device and its components does not require special extensive training and special knowledge in addition to the health care professional training. No significant incidents or recalls were initiated in Canada and globally during this time.

Labelling meets the minimum requirements of the Regulations. The limitations section indicates the possibility of false-negative results, and states that negative results should be treated as presumptive and tested with an alternative molecular assay.

The assay is manufactured in the US (San Diego, CA) with the gradual design transfer to manufacturing locations in Suzhou, China and Holliston, MA USA.

Based on the scientific evidence available, it is reasonable that the test will be effective for the claimed intended use. In the current context related to COVID-19 pandemic, the risks related to the use of this assay are outweighed by the benefits that will be facilitated by the authorization for sale of this assay.

4 Recommendation

Authorization of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 with the BD Veritor™ Plus Analyzer under the Interim Order with the following conditions:

When available:

1. Provide completed real time and In-Use stability data for the BD Veritor™ System for Rapid Detection of SARS-Co assay reagent.

2. Provide completed shipping stability data for the assay.

Before importing or selling in Canada

3. Provide the final version of the submitted red-line IFU (IFU ref. 256082 version 2020-09) that incorporates all the changes identified in the red-line version.

4. Ensure that products contain the final IFU.

I concur / Je suis d'accord

Signed in Docubridge		*Signed in Docubridge*	
Jeffrey Skene	Date 2020-10-09	Rosslynn Miller-Lee Director/ Directrice Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date 2020-10-09