March 21, 2023

Michelle Bowerman
Director of Regulatory Affairs
Becton, Dickinson and Co.
7 Loveton Circle,
Sparks, MD 21152

Re: EUA201889/S005
Trade/Device Name: BD Veritor System for Rapid Detection of SARS-CoV-2
Dated: November 15, 2022
Received: November 15, 2022

Dear Michelle Bowerman:

This is to notify you that your request to update the authorized labeling of the BD Veritor System for Rapid Detection of SARS-CoV-2; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include results of additional reactivity studies, is granted. Upon review, we concur that the information submitted in EUA201889/S005 supports the requested updates for use with the BD Veritor System for Rapid Detection of SARS-CoV-2 and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the BD Veritor System for Rapid Detection of SARS-CoV-2 issued on March 31, 2021.

Sincerely yours,

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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health