July 23, 2020

Mary Ann Fiechtner
Senior Regulatory Affairs Specialist
Becton, Dickinson and Company
BD Integrated Diagnostic Solutions – Point of Care
10865 Road to the Cure, Suite 200
San Diego, CA 92064

Re: EUA201889/S001
Trade/Device Name: BD Veritor System for Rapid Detection of SARS-CoV-2
Dated: July 14, 2020
Received: July 15, 2020

Dear Ms. Fiechtner:

This is to notify you that your request to update the BD Veritor System for Rapid Detection of SARS-CoV-2 to; (1) allow use of the Puritan nasal sampling swab as one of the Specimen sampling swabs that is provided as part of the test kit, and (2) add Positive Predictive Value and Negative Predictive Value information to the clinical performance table in the Instructions for Use, is granted. Upon review, we concur that the data and information submitted in EUA201889/S001 supports the requested updates for use with the BD Veritor System for Rapid Detection of SARS-CoV-2. By submitting this amendment for review by the Food and Drug Administration (FDA), you have 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 July 2, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health