

April 9, 2021

Kristen Bankert, Ph.D.
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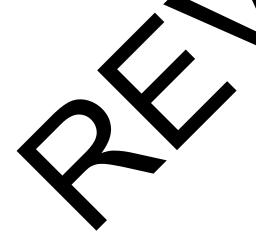
Re: EUA202975/S001 & S002

Trade/Device Name: BD SARS-CoV-2/Flu for BD MAX System

Dated: February 19, 2021 and March 10, 2021 Received: February 19, 2021 and March 10, 2021

Dear Dr. Bankert:

This is to notify you that your request to update the Instructions for I e (IFU) of the RS-CoV-2/Flu for BD MAX System to; (1) include use of anterior nasal swab specimens of cted distored in same, (2) include results of the FDA SARS-CoV-2 Reference Panel (reviewed under EUA202975) and (5) me some clarifications to Table 6, is granted. Upon review, we concur that the data and in n sul ted in EUA202975/S001 & S002 supports the requested updates for use with the BD SARS-CoV-2 u for BD m. FDA also concurs with updates made to the product information sheet (flyer) that is inclu d with each s ped product. In addition, FDA has updated the Fact Sheet for Healthcare Providers and Fact She for Patients to flect more recent authorizations. By submitting this EUA revision for review by the Food and Prug ministration DA), you have complied with the Conditions of Authorization stated in the letter authorizing f the BD SARS-CoV-2/Flu for BD MAX System issued on February 10, 2021.



acerely yours,

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