June 11, 2020

Kristen Bankert PhD,
Regulatory Affairs Specialist
Becton, Dickinson and Company
7 Loveton Circle, Sparks, MD 21152

Re: EUA200159/A001
Trade/Device Name: BD SARS-CoV-2 Reagents for BD MAX System
Dated: April 14 and May 8, 2020
Received: April 14, 2020

Dear Dr. Bankert:

This is to notify you that your request to update the Instructions for Use (IFU) of the BD SARS-CoV-2 Reagents for BD MAX System to; (1) update Intended Use to include mid-turbinate swab specimens and nasopharyngeal wash/ aspirate or nasal aspirates as additional specimen types, with the associated limitation, (2) update external control recommendations and the interpretation table, (3) update the inclusivity *in silico* data, (4) add data to support nasal swab specimens and remove the nasal swab limitation, (5) revise the color compensation setting of the User Defined Protocol (UDP), (6) update the materials provided section to include the extraction reagents as part of the BD SARS-CoV-2 Reagents for BD MAX System, and the associated update to the catalog number and outer box labeling, and (7) and make some minor clarifications and edits, is granted. We also concur with the revision to the External Control preparation white paper to add the Microbiologics Helix Elite Inactivated Standard Negative Cellularity Control (Inactivated Pellet) as an RNaseP Control and correct a dilution error identified for Microbiologics Helix Elite Synthetic Standard SARS-CoV-2 Synthetic RNA (N gene Targets) controls, along with some other minor clarifications and edits. Upon review, we concur that the data and information submitted in EUA200159/A001 supports the requested updates for use with the BD SARS-CoV-2 Reagents for BD MAX System, and we have also updated the Healthcare Provider and Patient Fact Sheets, accordingly. 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 SARS-CoV-2 Reagents for BD MAX System issued on April 8, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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