U.S. FOOD & DRUG ADMINISTRATION

May 29, 2020

Sherma Winston, M.S., RAC
Senior Manager, Regulatory Affairs
Becton, Dickinson & Company (BD)
7 Loveton Circle, Sparks, MD 21152

Re: EUA200098/A002
Trade/Device Name: BioGX SARS-CoV-2 Reagents for BD MAX System
Dated: April 16, 2020
Received: April 16, 2020

Dear Ms. Winston:

This is to notify you that your request to update the Instructions for Use (IFU) of the BioGX SARS-CoV-2 Reagents for BD MAX System to; (1) update Intended Use to include nasal, 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) and make some minor clarifications and edits, is granted. We also concur with the revision to the External Control preparation white paper to correct a dilution error identified for Microbiologics Heat 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 EUA200098/A002 supports the requested updates for use with the BioGX SARS-CoV-2 Reagents for BD MAX System, and we have also updated the Healthcare Provider and Patient Fact Sheets. 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 BioGX SARS-CoV-2 Reagents for BD MAX System issued on April 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