November 1, 2022

Christopher Hughes
Sr. Director, QRA
BioGX, Inc.
1500 1st Avenue N,
Birmingham, AL 35203

Re: EUA202863/S001 & S002
Trade/Device Name: BioGX Xfree COVID-19 Direct RT-PCR
Dated: October 20, 2021, and June 28, 2022
Received: October 20, 2021, and June 28, 2022

Dear Mr. Hughes:

This is to notify you that your request to update the authorized labeling of the BioGX Xfree COVID-19 Direct RT-PCR to; (1) address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (2) extended the reagent shelf-life to 15 months when stored at a temperature range of 2-8°C, and (3) add use of the BioGX pixl.16 platform, the Bio Molecular Systems Magnetic Induction Cycler (MIC), and the Applied Biosystems QuantStudio 5 Real Time PCR System, 384-well instruments as authorized real-time PCR platforms, is granted. Upon review, we concur that the data and information submitted in EUA202863/S001 & S002 supports the requested updates for use with the BioGX Xfree COVID-19 Direct RT-PCR. FDA have updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. By submitting this EUA revision 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 Xfree COVID-19 Direct RT-PCR issued on June 29, 2021, and the Viral Mutation Revision Letter issued on September 23, 2021.

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