January 21, 2022

Reeti Khare, Ph.D., D(ABMM)
Infectious Disease Laboratory Director
National Jewish Health
1400 Jackson St.
Denver, CO 80206

Re: EUA201863/S001
Trade/Device Name: SARS-CoV-2 MassArray Test
Dated: November 17, 2020
Received: November 18, 2020

Dear Dr. Khare:

This is to notify you that your request to update the EUA Summary for the SARS-CoV-2 MassArray Test to; (1) include data for FDA SARS-CoV-2 reference panel testing study, (2) add the Mastercycler Nexus Thermal Cycler real-time PCR instrument for use with the SARS-CoV-2 MassArray Test, (3) update the Limitations section to fulfill Conditions of Authorization related to the September 23, 2021 Viral Mutation Revision Letter, and (4) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA201863/S001 supports the requested updates for use with the SARS-CoV-2 MassArray Test. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 SARS-CoV-2 MassArray Test issued on September 29, 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

Enclosure[1]

[1] Technical Correction on January 28, 2022, to correct the printed date on the Letter Granting EUA Revision from January 21, 2021 to January 21, 2022 to be consistent with the date of signature.