February 1, 2022

Emi Zychlinsky, Ph.D.
Sr. Vice President, Quality and Regulatory
Fluidigm Corporation
2 Tower Place, Suite 2000
South San Francisco, CA 94080

Re: EUA201725/S005
Trade/Device Name: Advanta Dx SARS-CoV-2
Dated: November 3, 2021
Received: December 1, 2021

Dear Dr. Zychlinsky:

This is to notify you that your request to update the authorized labeling of the Advanta Dx SARS-CoV-2 to: (1) remove use of CDC's primers and probes manufactured by IDT for use with the Advanta Dx SARS-CoV-2, (2) update the inclusivity study data, (3) include use of Interpretive Software v1.0.1 with the Real-Time analysis software v4.7.1, Biomark Data Collection Software v4.7.1, and Juno System Software v3.14.1, and (4) include release of software version changes for new customers (Real-Time analysis software v4.8.1, Biomark Data Collection Software v4.8.1, Juno System Software v3.15.1, and Advanta DX SARS-CoV-2 Interpretive Software v2.0.1), is granted. Upon review, we concur that the data and information submitted in EUA201725/S005 supports the requested updates for use with the Advanta Dx SARS-CoV-2. 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 reissued letter authorizing the emergency use of the Advanta Dx SARS-CoV-2 issued on February 26, 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