January 8, 2021

Emi Zychlinsky, Ph.D.
Fluidigm Corporation
2 Tower Place, Suite 2000
South San Francisco, CA 94080

Re: EUA201725/S003
Trade/Device Name: Advanta Dx SARS-CoV-2 RT-PCR Assay
Dated: January 1, 2021
Received: January 1, 2021

Dear Mrs. Zychlinsky:

This is to notify you that your request to update the Instructions for Use (IFU) of the Advanta Dx SARS-CoV-2 RT-PCR Assay to; (1) add a new qualified manufacturer for the Advanta Dx SARS-CoV-2 RT-PCR Assay primers and probes; (2) clarify the interpretation of Positive Control, Negative Control and No Template Control results in the IFU and the Software Quick Reference Guide; and (3) minor updates to wording in the IFU and the Intended Use, is granted. Upon review, we concur that the information submitted in EUA201725/S003 supports the requested updates for use with the Advanta Dx SARS-CoV-2 RT-PCR Assay. 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 Advanta Dx SARS-CoV-2 RT-PCR Assay issued on November 5, 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