November 5, 2020

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

Re: EUA201725/S002
Trade/Device Name: Advanta Dx SARS-CoV-2 RT-PCR Assay
Dated: October 17, 2020
Received: October 19, 2020

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) update the Biomark Data Collection Software, the Real-Time PCR analysis software and the IFC Controller RX (RX Controller) system software to include the option for a manual Ct threshold adjustment, (2) include a procedure to manually adjust the fluorescence threshold for data analysis, (3) substitute the requirement of using sterile pipette tips with RNase/DNase free pipette tips, and (4) include minor updates to the IFU and the quick reference guide for the Advanta Dx SARS-CoV-2 RT-PCR Assay Interpretive Software, is granted. Upon review, we concur that the information submitted in EUA201725/S002 supports the requested updates for use with the Advanta Dx SARS-CoV-2 RT-PCR Assay. In addition, FDA has made updates to the Intended Use statement and IFU to reflect recent policy. 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 August 25, 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov