December 9, 2020

Aviva Jacobs, Ph.D.
Vice President, Product Development
DxTerity Diagnostics, Inc.
19500 S. Rancho Way, Suite 116
Rancho Dominguez, CA 90220

Re: EUA200379/S002
Trade/Device Name: DxTerity SARS-CoV-2 RT-PCR Test
Dated: December 1, 2020
Received: December 1, 2020

Dear Dr. Jacobs:

This is to notify you that your request to update the EUA Summary of the DxTerity SARS-CoV-2 RT-PCR Test to provide; (1) updated LoD study data and (2) data from the FDA reference panel, is granted. Upon review, we concur that the data and information submitted in EUA200379/S002 supports the requested updates for use with the DxTerity SARS-CoV-2 RT-PCR Test. 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 DxTerity SARS-CoV-2 RT-PCR Test issued on August 21, 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