March 29, 2021

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

Re: EUA202120/S003
Trade/Device Name: DxTerity SARS-CoV-2 RT PCR CE Test
Dated: February 18, 2021
Received: February 19, 2021

Dear Dr. Jacobs:

This is to notify you that your request to update the EUA Summary of the DxTerity SARS-CoV-2 RT PCR CE Test to include results of a post authorization clinical evaluation to further evaluate the negative percent agreement, is granted. Upon review, we concur that the information and data submitted in EUA202120/S003 supports the requested update to the authorized labeling of the DxTerity SARS-CoV-2 RT PCR CE Test. In addition, FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect 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 DxTerity SARS-CoV-2 RT PCR CE Test reissued on February 9, 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