February 8, 2021

Mohammad N. Qureshi, M.D, Ph.D.
President & Medical Director
QDx Pathology Services
46 Jackson Drive
Cranford, NJ 07016

Re: EUA200366/S003
Trade/Device Name: QDx SARS-CoV-2 Assay
Dated: February 3, 2021
Received: February , 2021

Dear Dr. Qureshi:

This is to notify you that your request to update the EUA Summary of the QDx SARS-CoV-2 Assay to include data for the winter stability study, is granted. Upon review, we concur that the data and information submitted in EUA200366/S003 supports the requested updates for use with the QDx SARS-CoV-2 Assay. In addition, FDA has updated the Intended Use statement to reflect recent authorizations and 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 QDx SARS-CoV-2 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