August 8, 2020

David Curley, COO
Trax Management Services Inc.
70 S. Sandusky St.,
Delaware, OH 43015

Re: EUA201916/S001
Trade/Device Name: PhoenixDx SARS-CoV-2 Multiplex
Dated: July 30, 2020
Received: July 30, 2020

Dear Mr. Curley:

This is to notify you that your request to update the Instructions for Use (IFU) of the PhoenixDx SARS-CoV-2 Multiplex to include two additional real-time PCR instruments, is granted. Upon review, we concur that the data and information submitted in EUA201916/S001 supports the requested updates for use with the PhoenixDx SARS-CoV-2 Multiplex. We have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. By submitting this EUA revision request 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 PhoenixDx SARS-CoV-2 Multiplex issued on July 14, 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