



November 20, 2020

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

Re: EUA201916/S002
Trade/Device Name: PhoenixDx SARS-CoV-2 Multiplex
Dated: October 24, 2020
Received: October 26, 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 use of the (1) Thermo Fisher QuantStudio 7 instrument and (2) use of the 384 well plate assay format to be run with the Thermo Fisher QuantStudio 7 and QuantStudio 5, is granted. Upon review, we concur that the data and information submitted in EUA201916/S002 supports the requested updates for use with the PhoenixDx SARS-CoV-2 Multiplex. In addition, FDA has updated the intended use 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 PhoenixDx SARS-CoV-2 Multiplex issued on July 13, 2020.

Sincerely yours,

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