August 8, 2020

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

Re: EUA200374/S003
Trade/Device Name: PhoenixDx 2019-nCoV
Dated: July 29, 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 2019-nCoV to; (1) correct the LoD data section, (2) add a definition for a missing result outcome to the result interpretation table, and (3) update the warning section per FDA request, is granted. Upon review, we concur that the data and information submitted in EUA200374/S003 supports the requested updates for use with the PhoenixDx 2019-nCoV. 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 2019-nCoV issued on April 20, 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