U.S. FOOD & DRUG ADMINISTRATION

May 11, 2020

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

Re: EUA200374/A001
Trade/Device Name: PhoenixDx 2019-nCoV
Dated: April 27, 2020
Received: April 27, 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) add two additional extractions methods - Qiagen QIAamp MiniElute Virus Spin kit and Roche High Pure Viral RNA Kit, (2) add two additional real-time PCR instruments - Qiagen Rotor-Gene Q and Applied Biosystems ABI 7500 Fast Real time PCR Dx, (3) modify the input volumes for the PCR reaction to reduce the extracted RNA content and the amount of reverse transcriptase and qPCR mastermix, and (4) include additional minor edits in the IFU for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200374/A001 supports the requested updates for use with the PhoenixDx 2019-nCoV. By submitting this amendment 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
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