



April 7, 2021

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

Re: EUA201916/S005
Trade/Device Name: PhoenixDx SARS-CoV-2 Multiplex
Dated: March 31, 2021
Received: April 1, 2021

Dear Mr. Curley:

This is to notify you that your request to update the PhoenixDx SARS-CoV-2 Multiplex to (1) update the formulation of the positive template control (TPC) and (2) update the instructions for use to add some additional clarifications, including in the results interpretation section, is granted. Upon review, we concur that the data and information submitted in EUA201916/S005 supports the requested updates for use with the PhoenixDx SARS-CoV-2 Multiplex. In addition, FDA have updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. 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