



July 30, 2020

James A. Hayward
Chairman, President & CEO
Applied DNA Sciences
50 Health Sciences Drive
Stony Brook, NY 11790

Re: EUA200474/A003
Trade/Device Name: Linea COVID-19 Assay Kit
Dated: July 15, 2020
Received: July 16, 2020

Dear Dr. Hayward:

This is to notify you that your request to update the Instructions for Use (IFU) of the Linea COVID-19 Assay Kit to include; (1) use of the Omega Bio-Tek Mag-Bind Viral RNA Xpress Kit on the Hamilton Company Microlab STARlet Liquid Handling System, (2) use of the Thermo Fisher Scientific (Applied Biosystems) QuantStudio 5 Real-Time PCR System equipped with QuantStudio Design and Analysis software v1.4, and (3) updates to the IFU to incorporate the additional, validated extraction method and real-time PCR instrument, is granted. Upon review, we concur that the data and information submitted in EUA200474/A003 supports the requested updates for use with the Linea COVID-19 Assay. 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 Linea COVID-19 Assay Kit issued on May 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