November 21, 2020

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

Re: EUA200474/S006
Trade/Device Name: Linea COVID-19 Assay Kit
Dated: August 5, 2020
Received: August 5, 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 the Applied Biosystems 7500 Fast Dx Real-Time PCR System (ABI 7500) as an additional PCR instrument is granted. Upon review, we concur that the data and information submitted in EUA200474/S006 supports the requested updates for use with the Linea COVID-19 Assay Kit. FDA has updated the Intended Use and 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 Linea COVID-19 Assay Kit issued on May 13, 2020.

Sincerely,

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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