July 21, 2021

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

Re: EUA200474/S009
Trade/Device Name: Linea COVID-19 Assay Kit
Dated: June 30, 2021
Received: June 30, 2021

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 results of the additional post-authorization study to further evaluate the analytical performance of your product using material representing SARS-CoV-2 sequence variant(s), completed to fulfill Condition of Authorization Q. of the May 11, 2021 letter of authorization, and add an associated limitation is granted. Upon review, we concur that the data and information submitted in EUA200474/S009 supports the requested updates for use with the Linea COVID-19 Assay Kit. In addition, Food and Drug Administration (FDA) have updated the webpage links in the Fact Sheet for Healthcare Providers to reflect more recent authorizations. By submitting this EUA revision for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Linea COVID-19 Assay Kit reissued on May 11, 2021.

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