



July 8, 2020

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

Re: EUA200474/A002
Trade/Device Name: Linea COVID-19 Assay Kit
Dated: June 21, 2020
Received: June 22, 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; (1) include use of the manual RNA extraction kit, Omega Bio-Tek Mag-Bind Viral RNA Xpress Kit, and (2) include minor edits in the IFU for clarification is granted. Upon review, we concur that the data and information submitted in EUA200474/A002 supports the requested updates for use with the Linea COVID-19 Assay Kit. FDA also requested minor updates to the "Intended Use", "Warnings and Precautions", and "Limitations" sections of the IFU to reflect language used in more recently issued Emergency Use Authorizations. FDA also updated the Healthcare Provider and Patient Fact Sheets accordingly. 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 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