April 20, 2022

Clay D. Shorrock, Esq.
Chief Legal Officer and Exec. Dir., Business Development
Applied DNA Sciences, Inc.
50 Health Sciences Drive
Stony Brook, NY 11790
Re: Revocation of EUA200474

Dear Mr. Shorrock:

This letter is in response to the request from Applied DNA Sciences, Inc., received on April 7, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Linea COVID-19 Assay Kit issued on May 13, 2020, re-issued on May 11, 2021, and amended on July 8, 2020, July 30, 2020, September 25, 2020, November 21, 2020, July 21, 2021, and September 23, 2021. Applied DNA Sciences, Inc. indicated that it is no longer distributing or utilizing the Linea COVID-19 Assay Kit. Applied DNA Sciences, Inc. has transitioned to the use of the Linea 2.0 COVID-19 Assay and other EUA-authorized tests.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Applied DNA Sciences, Inc. has notified FDA that it has decided to discontinue distribution of the Linea COVID-19 Assay Kit and requested FDA withdraw the EUA for the Linea COVID-19 Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200474 for the Linea COVID-19 Assay Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Linea COVID-19 Assay Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: James A. Hayward, Ph.D., Chairman, President & CEO, Applied DNA Sciences, Inc.