U.S. FOOD & DRUG ADMINISTRATION

February 7, 2022

Beth Hoover
Associate Director
LifeHope Labs
5009 Roswell Road
Sandy Springs, GA 30342
Re: Revocation of EUA200796

Dear Beth Hoover:

This letter is in response to a request from LifeHope Labs received via email on January 6, 2022, that the U.S. Food and Drug Administration (FDA) discontinue the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel for which an EUA was issued on June 29, 2020 and revised on September 23, 2021. LifeHope Labs confirmed that it is no longer using the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel, having transitioned to another FDA EUA-authorized test.

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 LifeHope Labs has notified FDA that it is no longer using the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel and requested FDA discontinue the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200796 for the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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