June 21, 2023

Aarthi Srinivasan
Regulatory Affairs
Verily Life Sciences
269 E Grand Ave.
South San Francisco, CA 94080

Re: Revocation of EUA202054

Dear Aarthi Srinivasan:

This letter is in response to the request from Verily Life Sciences, in an email received June 13, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Verily COVID-19 RT-PCR Test issued on September 8, 2020, reissued on December 18, 2020, March 30, 2021, and November 8, 2021, and revised on September 23, 2021 and November 15, 2022. Verily Life Sciences indicated that they are no longer distributing the Verily COVID-19 Nasal Swab Kits (authorized as part of the Verily COVID-19 RT-PCR Test) or offering testing services at the Verily Life Sciences laboratory using the Verily COVID-19 RT-PCR Test and requested that the EUA be withdrawn.

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 Verily Life Sciences has requested FDA withdraw the EUA for the Verily COVID-19 RT-PCR Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202054 for the Verily COVID-19 RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Verily COVID-19 RT-PCR Test 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,

_____

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration