August 18, 2023

Thiago Braga
Sr. Regulatory Affairs Specialist
Exact Sciences Laboratories
650 Forward Drive
Madison, WI 53711
Re: Revocation of EUA200367

Dear Thiago Braga:

This letter is in response to the request from Exact Sciences Laboratories, in a letter received via email August 1, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 (N gene detection) Test that was originally authorized under the March 31, 2020, Emergency Use Authorization (EUA) for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (High Complexity LDT Umbrella EUA) on May 22, 2020, and then issued an individual EUA on August 3, 2020, that was revised on August 28, 2020, and September 23, 2021. Exact Sciences Laboratories indicated that they have discontinued use of the SARS-CoV-2 (N gene detection) Test at Exact Sciences Laboratories, located at 650 Forward Drive, Madison, WI 53711 and 145 E. Badger Road Ste. 100, Madison, WI 53713, and requested that the EUA be withdrawn.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)© of the Act). Because Exact Sciences Laboratories has requested FDA withdraw the EUA for the SARS-CoV-2 (N gene detection) Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200367 for the SARS-CoV-2 (N gene detection) Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 (N gene detection) 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,

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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration