October 19, 2022

Susan Harrington, Ph.D.
Medical Director
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195
Re: Revocation of EUA200313

Dear Dr. Harrington:

This letter is in response to the request from Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute ("Cleveland Clinic"), received via email on October 7, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay issued on August 3, 2020, and amended on January 19, 2021, and September 23, 2021. Cleveland Clinic indicated that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future.

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 Cleveland Clinic has notified FDA that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future and requested FDA revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200313 for the Cleveland Clinic SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cleveland Clinic SARS-CoV-2 Assay 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration