January 16, 2024

Elizabeth Platt, EdD, MS
V.P., Regulatory & Clinical Affairs
Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Drive
Hercules, CA 94547

Re: Revocation of EUA202864

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories, Inc., in a letter dated January 7, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit issued on January 15, 2021, and amended on May 11, 2021, September 23, 2021, and October 25, 2022. Bio-Rad Laboratories, Inc. indicated that they have ceased United States (U.S.) distribution of the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit reagents remaining in distribution in the U.S.

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 Bio-Rad Laboratories, Inc. has requested that FDA revoke the EUA for the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202864 for the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Bio-Rad Reliance SARS-CoV-2 RT-PCR 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration