March 27, 2024

Elizabeth Platt, MLS(ASCP)$^{CM}$, CLS, ACRP-CP, CMDA, CQA, CSSGB, CMQ/OE, RAC (Devices, Global, US)
VP, Regulatory & Clinical Affairs
Bio-Rad Laboratories Inc.
4000 Alfred Nobel Drive
Hercules, CA 94547
**Re: Revocation of EUA200440**

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories Inc., in a letter dated March 16, 2024, that the U.S. Food and Drug Administration (FDA revoke the EUA for the Bio-Rad SARS-CoV-2 ddPCR Kit issued on May 1, 2020, reissued on September 18, 2020, and amended on December 9, 2020, September 23, 2021, and March 15, 2022. Bio-Rad Laboratories Inc. indicated that they have ceased United States distribution of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Bio-Rad SARS-CoV-2 ddPCR Kit reagents remaining in distribution in the United States.

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 SARS-CoV-2 ddPCR Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200440 for the Bio-Rad SARS-CoV-2 ddPCR Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Bio-Rad SARS-CoV-2 ddPCR 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