



April 14, 2022

Elizabeth Platt EdD, MS, MBA
Sr. Director, Regulatory & Clinical Affairs | Americas
Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Drive
Hercules, CA 92647
Re: Revocation of EUA202965

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories, Inc., received via email on March 17, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA, with an effective date of April 15, 2022, for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit issued on February 11, 2021, and amended on September 23, 2021. Bio-Rad Laboratories, Inc. ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit on March 2, 2022, and has discontinued this assay.

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 notified FDA that it has ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, has discontinued the assay, and requested FDA revoke the EUA for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, per your request, effective April 15, 2022, FDA hereby revokes EUA202965 for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, pursuant to section 564(g)(2)(C) of the Act. Effective as of April 15, 2022, the Reliance SARS-CoV-2/FluA/FluB 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,

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration