January 11, 2022

Linda Staswick
Regulatory Affairs Project Manager
Bio-Rad Laboratories
4000 Alfred Nobel Dr.
Hercules, CA 94547

Re: Revocation of EUA202689

Dear Linda Staswick:

This letter is in response to a request from Bio-Rad Laboratories, received December 20, 2021, that the U.S. Food and Drug Administration (FDA) revoke the BioPlex 2200 SARS-CoV-2 IgG – EUA202689 issued on July 1, 2021 and revised September 23, 2021. The BioPlex 2200 SARS-CoV-2 IgG Panel has not been commercialized by Bio-Rad 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 has notified FDA that Bio-Rad has not commercialized the authorized product in the U.S. and requested FDA revoke the BioPlex 2200 SARS-CoV-2 IgG – EUA202689, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202689 for the BioPlex 2200 SARS-CoV-2 IgG, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BioPlex 2200 SARS-CoV-2 IgG 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration