June 1, 2023

Ray Bandziulis, Ph.D.
Director of Regulatory Affairs
LGC, Biosearch Technologies
2905 Parameter Street
Middleton, WI 53562

Re: Revocation of EUA203030

Dear Dr. Bandziulis:

This letter is in response to the request from LGC, Biosearch Technologies, in an email received May 1, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test issued on April 15, 2021, and revised on September 23, 2021 and May 3, 2022. LGC, Biosearch Technologies indicated that they are no longer marketing the authorized product and requested that the EUA be revoked. FDA understands that, as of the date of this letter, there are no viable Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test 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 LGC, Biosearch Technologies has requested that FDA revoke the EUA for Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA203030 for the Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test 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