June 1, 2023

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

Re: Revocation of EUA210561

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 ultra-high-throughput End-Point RT-PCR Test issued on April 26, 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 customers will discontinue use of the Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test reagents.

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 FDA revoke the EUA for Biosearch Technologies SARS-CoV-2 ultra-high-throughput 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 EUA210561 for the Biosearch Technologies SARS-CoV-2 ultra-high-throughput 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 ultra-high-throughput 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