June 7, 2022

Yongjiang Daniel Li, Ph.D.
Associate Director, Molecular Biology Division
ScienCell Research Laboratories
1610 Faraday Avenue
Carlsbad, CA 92000
Re: Revocation of EUA200079

Dear Dr. Li:

This letter is in response to the request from ScienCell Research Laboratories ("ScienCell"), received on June 2, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit issued on April 3, 2020, and amended on June 5, 2020, September 22, 2020, and September 23, 2021. ScienCell indicated that it has decided to discontinue distribution of the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit and there is not any viable/non-expired product remaining in distribution.

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 ScienCell has notified FDA that it has decided to discontinue distribution of the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit and requested FDA revoke the EUA for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200079 for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration