December 10, 2021

James X. Li, Ph.D.
Chief Executive Officer
Cellex Inc.
76 TW Alexander Drive
Research Triangle Park, NC 27709

Re: Revocation of EUA200058

Dear Dr. Li,

This letter is in response to Cellex Inc.'s (Cellex's) request dated December 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA200058) for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test issued on April 1, 2020 and revised on June 12, 2020 and September 23, 2021. In its December 7 letter, Cellex requested withdrawal of the EUA effective December 10, 2021. FDA understands that the product is no longer being distributed.

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 Cellex requested that FDA withdraw the authorization and FDA understands the product is no longer being distributed, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200058 for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cellex q-SARS-CoV-2 IgG/IgM Rapid 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,

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