December 15, 2022

Janice Chen, PhD
Co-Founder & CTO
Mammoth Biosciences, Inc.
1000 Marina Blvd., Suite 600
Brisbane, CA 94005

Re: Revocation of EUA202365

Dear Dr. Chen:

This letter is in response to the request from Mammoth Biosciences, Inc., received via email on October 20, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 DETECTR Reagent Kit issued on August 31, 2020, and amended on July 7, 2021, and September 23, 2021. Mammoth Biosciences, Inc. indicated that there is no longer a viable market for this SARS-CoV-2 reagent kit and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there will no longer be any SARS-CoV-2 DETECTR Reagent Kits 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 Mammoth Biosciences, Inc. has requested FDA withdraw the EUA for the SARS-CoV-2 DETECTR Reagent Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202365 for the SARS-CoV-2 DETECTR Reagent Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 DETECTR Reagent 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Cc: Timothy Patno, Mammoth Biosciences, Inc.