November 30, 2022

Keyur P. Patel, Ph.D.
Medical Director, Molecular Diagnostics Laboratory
The University of Texas MD Anderson Cancer Center
6565 MD Anderson Blvd.
Houston, TX 77030

Re: Revocation of EUA200158

Dear Dr. Patel:

This letter is in response to the request from the University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory, received via email on November 18, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay issued on June 24, 2020, and amended on September 23, 2021 and November 29, 2021. The University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory discontinued testing with the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay as of October 31, 2022.

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 the University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory has requested FDA withdraw the EUA for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200158 for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay 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,

_____

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration