October 5, 2023

Donald C. Hall, Jr. Ph.D.
Director of Operations
Drexel Medicine Diagnostics
College of Medicine, Drexel University
245 N. 15th Street, Room 5108
Philadelphia, PA 19102

Re: Revocation of EUA220099

Dear Dr. Hall:

This letter is in response to the request from Drexel University College of Medicine, in an email received September 29, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, issued on April 28, 2023. Drexel University College of Medicine indicated that they have discontinued use of the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay at Drexel University, Drexel Medicine Diagnostics, located at 245 N. 15th Street, Room 5401, Philadelphia, PA 19102.

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 Drexel University College of Medicine has requested that FDA withdraw the EUA for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA220099 for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 DUCoM-PDL Modified Tetracore 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,

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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Technical Correction October 12, 2023: Edit to correct the date the EUA for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay was originally issued.