July 3, 2023

Charles Kolifrath
Associate Director, Regulatory Affairs, Genomics Platform
Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard
320 Charles Street
Cambridge, MA 02141

Re: Revocation of EUA210089

Dear Charles Kolifrath:

This letter is in response to the request from Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard, in an email received June 14, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) issued on March 5, 2021, reissued on May 13, 2021, and June 3, 2022, and revised on September 23, 2021. In addition, on June 15, 2021, FDA included the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) under Exhibit 1 of the April 20, 2021, pooling and serial testing amendment. Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard indicated that as of the date of this letter they are no longer distributing the CRSP Self-swab Kits (authorized as part of the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3)) or offering testing services at the Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard laboratory using the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) and requested voluntary revocation of the EUA.

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 Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard has requested voluntary revocation of the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3), FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210089 for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3), pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) 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