May 5, 2022

Chuck Kolifrath
Associate Director, Regulatory Affairs, Genomics Platform
Broad Institute of MIT and Harvard
320 Charles Street
Cambridge, MA 02141
Re: Revocation of EUA200147

Dear Mr. Kolifrath:

This letter is in response to the request from Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard ("Broad Institute of MIT and Harvard") received on April 4, 2022, 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 issued on July 8, 2020, re-issued on October 23, 2020, December 18, 2020, and June 10, 2021, and amended on August 30, 2020, and September 23, 2021. The Broad Institute of MIT and Harvard indicated that it is no longer conducting testing under this 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 the Broad Institute of MIT and Harvard has notified FDA that it has decided to discontinue use of the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay and requested FDA revoke the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200147 for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, 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 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

Cc: Niall J. Lennon, Ph.D., Institute Scientist and Sr. Director, Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard