



May 10, 2022

Brian Ciccariello
Quanterix Corporation
900 Middlesex Turnpike, Building One
Billerica, MA 01821

Re: Revocation of EUA202912

Dear Brian Ciccariello:

This letter is in response to a request from Quanterix Corporation, received May 5, 2022, and May 9, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the Simoa SARS-CoV-2 N Protein Antigen Test issued on January 5, 2021, and reissued on September 10, 2021, and December 21, 2021. FDA understands that Quanterix Corporation discontinued distribution of their Simoa SARS-CoV-2 N Protein Antigen Test and there are no viable (non-expired) tests remaining.

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 Quanterix Corporation has notified FDA that Quanterix Corporation has discontinued distribution of the authorized product and requested FDA withdraw the authorization of the Simoa SARS-CoV-2 N Protein Antigen Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202912 for the Simoa SARS-CoV-2 N Protein Antigen Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Simoa SARS-CoV-2 N Protein Antigen Test 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