

May 10, 2022

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

Re: Revocation of EUA201648

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 Semi-Quantitative SARS-CoV-2 IgG Antibody Test issued on December 23, 2020, and updated April 15, 2021, and September 23, 2021. FDA understands that Quanterix Corporation did not distribute their Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test in the US 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 did not distribute the authorized product in the US and requested FDA to withdraw the authorization of the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201648 for the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody 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

CC: Sarah O. Kalil, SK Consulting