February 22, 2024

Tara Viviani, RAC
Senior Director, Molecular Regulatory Affairs
Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727

Re: Revocation of EUA201881

Dear Tara Viviani:
This letter is in response to the request from Luminex Corporation, in a letter dated February 19, 2024, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the xMAP SARS-CoV-2 Multi-Antigen IgG Assay issued on July 16, 2020, and amended on September 23, 2021, and March 9, 2022. Luminex Corporation indicated that they have discontinued manufacture of the authorized product and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there are no viable xMAP SARS-CoV-2 Multi-Antigen IgG Assay reagents remaining in distribution in the United States.

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 Luminex Corporation has requested that FDA withdraw the EUA for the xMAP SARS-CoV-2 Multi-Antigen IgG Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201881 for the xMAP SARS-CoV-2 Multi-Antigen IgG Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the xMAP SARS-CoV-2 Multi-Antigen IgG 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

Cc: Jennifer Svoboda, Manager, Regulatory Affairs, Luminex Corporation