



August 3, 2023

Iman Sadreddin
Co-Founder, COO
Xtrava Health
3080 Olcott Street, Suite C201
Santa Clara, CA 95054

Re: Revocation of EUA210544

Dear Mr. Iman Sadreddin:

This letter is in response to the request from Xtrava Health, in an email received July 18, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SPERA COVID-19 Ag Test issued on October 12, 2021, revised on November 1, 2022, and reissued May 22, 2023. FDA understands that as of the date of this letter there are no SPERA COVID-19 Ag Test reagents 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 Xtrava Health has requested that FDA withdraw the EUA for the SPERA COVID-19 Ag Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210544 for the SPERA COVID-19 Ag Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SPERA COVID-19 Ag 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,

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration