

May 24, 2023

Melissa Bar Hoover, Ph.D., RAC
Senior Regulatory Affairs Manager
Becton, Dickinson and Company
7 Loveton Circle,
Sparks, MD 21152-0999

Re: Revocation of EUA220453

Dear Dr. Bar Hoover:

This letter is in response to the request from Becton, Dickinson and Company (“BD”), in a letter received May 22, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System issued on December 23, 2022. BD has decided not to manufacture or sell these kits moving forward and requested that the EUA be withdrawn. FDA understands that, as of the date of this letter, no VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System reagents were distributed 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 BD has requested that FDA withdraw the EUA for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA220453 for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System 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