June 15, 2023

Amanda Ker,
Regulatory Specialist
Becton, Dickinson and Co.
7 Loveton Circle
Sparks, MD 21152

Re: Revocation of EUA210417

Dear Amanda Ker:

This letter is in response to the request from Becton, Dickinson and Co ("BD"), in an email received May 30, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD Veritor At-Home COVID-19 Test issued on August 24, 2021, reissued on November 22, 2021 and revised on August 4, 2022, November 1, 2022 and February 21, 2023. BD indicated that they discontinued the sale the authorized product and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there are no viable BD Veritor At-Home COVID-19 Test 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 BD has requested FDA withdraw the EUA for the BD Veritor At-Home COVID-19 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210417 for the BD Veritor At-Home COVID-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BD Veritor At-Home COVID-19 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,

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