July 29, 2022

Melissa Barhoover
Senior Regulatory Affairs Manager
7 Loveton Circle
Sparks, Maryland 21152
Re: Revocation of EUA202975

Dear Melissa Barhoover:

This letter is in response to a request from Becton, Dickinson and Company (BD), received July 26, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD SARS-CoV-2/Flu for BD MAX System issued on February 10, 2021, and updated on April 09, 2021, and September 23, 2021. BD discontinued the sale of BD SARS-CoV-2/Flu for BD MAX System in the United States on July 01, 2022. The revocation is effective August 01, 2022.

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. Because BD notified FDA that BD has discontinued the sale of the BD SARS-CoV-2/Flu for BD MAX System, and requested FDA to withdraw the authorization of the BD SARS-CoV-2/Flu for BD MAX System, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, pursuant to section 564(g)(2)(C) of the Act, FDA revokes EUA202975.

Effective on August 01, 2022, the BD SARS-CoV-2/Flu for BD MAX System is no longer authorized for emergency use by FDA. FDA encourages BD to instruct laboratories to discontinue use of and discard any remaining inventory.

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