April 24, 2024

Kathy Barnecut, RAC
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company (BD)
7 Loveton Circle
Sparks, MD 21152
Re: Revocation of EUA220369

Dear Kathy Barnecut:

This letter is in response to the request from Becton Dickinson and Company, in a letter dated April 17, 2024, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD Respiratory Viral Panel for BD MAX System issued on February 3, 2023, and amended on July 28, 2023. Becton Dickinson and Company indicated that the last manufactured lot of EUA BD Respiratory Viral Panel for BD MAX System reagents (Catalog number: 445215) has expired and requested that the EUA be withdrawn. As of the date of this letter, Becton Dickinson and Company has fully transitioned to the BD Respiratory Viral Panel for BD MAX System product (Catalog number: 445373) that was cleared under K230956.

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 Becton Dickinson and Company has requested that FDA withdraw the EUA for the BD Respiratory Viral Panel 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 EUA220369 for the BD Respiratory Viral Panel for BD MAX System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BD Respiratory Viral Panel 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