December 8, 2021

Colton Muraira, J.D.
Staff Regulatory Affairs Specialist
Becton, Dickinson & Company (BD)
7 Loveton Circle
Sparks, MD 21152
Re: Revocation of EUA200098

Dear Colton Muraira:

This letter is in response to Becton, Dickinson & Company's (BD's) request received December 3, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200098) for the BioGX SARS-CoV-2 Reagents for BD MAX System issued on April 2, 2020, and amended on April 7, 2020, May 29, 2020, September 25, 2020 and September 23, 2021. BD indicated that to simplify and focus their BD MAX Portfolio, BD made the decision to discontinue the sale of the authorized product.

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 notified FDA that BD discontinued the sale of the authorized product and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200098 for the BioGX SARS-CoV-2 Reagents for BD MAX System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BioGX SARS-CoV-2 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,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration