February 14, 2023

Shakil Ahmed
Sr. Director, Regulatory Affairs and Quality Assurance
Twist Bioscience Corporation
681 Gateway Blvd.
South San Francisco, CA 94080

Re: Revocation of EUA202029

Dear Shakil Ahmed:

This letter is in response to the request from Twist Bioscience Corporation, received via email on January 27, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 NGS Assay issued on March 23, 2021, amended on June 25, 2021, and September 23, 2021, and reissued on July 28, 2022. Twist Bioscience Corporation indicated that they no longer plan to continue marketing the SARS-CoV-2 NGS Assay and requested that the EUA be withdrawn. FDA understands that no SARS-CoV-2 NGS Assay reagents associated with this EUA are available to the United States market.

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 Twist Bioscience Corporation has requested FDA withdraw the EUA for the SARS-CoV-2 NGS Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202029 for the SARS-CoV-2 NGS Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 NGS Assay 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