

December 17, 2021

Sophie Vernay  
Regulatory Affairs Manager  
BioMérieux SA  
376, Chemin de L'Orme  
Marcy L'Etoile, FR 69280  
**Re: Revocation of EUA200445**

Dear Ms. Vernay:

This letter is in response to BioMérieux SA's (BioMérieux's) request received December 10, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200445) for the SARS-COV-2 R-GENE issued on May 6, 2020 and amended on November 6, 2020 and September 23, 2021. BioMérieux indicated that due to the current public clinical needs being met by other EUA assays that are available on the market, BioMérieux has decided to no longer commercially support 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 BioMérieux has notified FDA that BioMérieux has decided to no longer commercially support the authorized product and requested 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 EUA200445 for the SARS-COV-2 R-GENE, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-COV-2 R-GENE 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