January 31, 2024

Laura Zani
Regulatory Affairs Specialist
bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Étoile, France

Re: Revocation of EUA201554

Dear Laura Zani:

This letter is in response to the request from bioMérieux SA in a letter dated January 22, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the VIDAS SARS-CoV-2 IgM kit issued on August 6, 2020, reissued on March 11, 2021, and amended on September 23, 2021. BioMérieux SA indicated that they will no longer commercially support the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable VIDAS SARS-CoV-2 IgM reagents remaining in distribution in the United States.

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 SA has requested that FDA revoke the EUA for the VIDAS SARS-CoV-2 IgM, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201554 for the VIDAS SARS-CoV-2 IgM, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VIDAS SARS-CoV-2 IgM 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