September 17, 2025

Catherine Corbin
Regulatory Affairs Specialist
GenMark Diagnostics, Inc.
5964 La Place Court
Carlsbad, CA 92008
Re: Revocation of EUA200021

Dear Catherine Corbin:

This letter is in response to the request from GenMark Diagnostics, Inc., an indirect, wholly owned subsidiary of Roche, in an email dated August 28, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the ePlex SARS-CoV-2 Test issued on March 19, 2020, and amended on August 18, 2020, and September 23, 2021. GenMark Diagnostics, Inc. indicated that they have discontinued manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there is no viable ePlex SARS-CoV-2 Test reagent 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 GenMark Diagnostics, Inc. has requested that FDA revoke the EUA for the ePlex SARS-CoV-2 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200021 for the ePlex SARS-CoV-2 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the ePlex SARS-CoV-2 Test 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration