July 3, 2025

Eveline Arnold, Ph.D.
Director, Regulatory Affairs
NeuMoDx Molecular, Inc., c/o QIAGEN Sciences, LLC
19300 Germantown Road
Germantown, MD 20874
Re: Revocation of EUA200073

Dear Dr. Arnold:

This letter is in response to QIAGEN's request on behalf of NeuMoDx Molecular, Inc., a QIAGEN Company, in a letter dated June 26, 2025, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the NeuMoDx SARS-CoV-2 Assay issued on March 30, 2020, revised and reissued on January 22, 2021, and amended on April 23, 2020, September 29, 2020, and September 23, 2021. QIAGEN has decided to discontinue the NeuMoDx Molecular, Inc. business on June 30, 2025. As of the date of this letter, no further EUA products will be marketed, all devices in the field have been discontinued, and there are no active customers in the U.S. for the NeuMoDx SARS-CoV-2 Assay.

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 QIAGEN, on behalf of NeuMoDx Molecular, Inc., has requested that FDA withdraw the EUA for the NeuMoDx SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200073 for the NeuMoDx SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the NeuMoDx SARS-CoV-2 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration