U.S. FOOD & DRUG ADMINISTRATION

May 24, 2023

Eveline Arnold, Ph.D.
Director, Regulatory Affairs
Clinical, Medical, and Regulatory Affairs (CMRA)
NeuMoDx Molecular, Inc., a QIAGEN Company
1250 Eisenhower Place
Ann Arbor, MI 48108

Re: Revocation of EUA202947

Dear Dr. Arnold:

This letter is in response to QIAGEN's request on behalf of NeuMoDx Molecular, Inc., a QIAGEN Company, in an email received May 11, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay issued on March 25, 2021, and revised on September 23, 2021. QIAGEN has decided to discontinue distribution of the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay in the United States and requested voluntary revocation of the EUA.

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 FDA revoke the EUA for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202947 for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage 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