April 3, 2025

Steve Back
Chief Operating Officer
Nuclein, LLC
8305 Cross Park Drive
Austin, TX 78754
Re: Revocation of EUA210603

Dear Steve Back:

This letter is in response to the request from Nuclein, LLC (following Nuclein, LLC's December 27, 2024, merger with, and assumption of responsibility for, the original EUA holder, Minute Molecular Diagnostics, Inc.), in a letter dated March 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the DASH SARS-CoV-2/S Test issued on March 15, 2022, and amended on July 28, 2022. Nuclein, LLC indicated that they have ceased manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable DASH SARS-CoV-2/S Test 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 Nuclein, LLC has requested that FDA revoke the EUA for the DASH SARS-CoV-2/S Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210603 for the DASH SARS-CoV-2/S Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the DASH SARS-CoV-2/S 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