April 2, 2025

Philip Adam, Ph.D., HCLD/CC(ABB)
MAWD Pathology Group, P.A.
Infectious Diseases Section Director
MAWD Laboratories
11070 Strang Line Rd.
Lenexa, KS 66215

Re: Revocation of EUA210691

Dear Dr. Adam:

This letter is in response to the request from MAWD Laboratories, in a letter received March 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR issued on October 13, 2023. MAWD Laboratories indicated that as of the date of this letter they have discontinued use of the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR test at MAWD Laboratories, located at 11070 Strang Line Rd., Lenexa, KS 66215.

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 MAWD Laboratories has requested that FDA revoke the EUA for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210691 for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR 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