January 8, 2025

Veronica Colinayo, Ph.D.
Staff Regulatory Affairs
Beckman Coulter, Inc.
250 S Kraemer Blvd,
Brea, CA 92821
Re: Revocation of EUA202631

Dear Dr. Colinayo:
This letter is in response to a notification from Beckman Coulter, Inc., in a letter dated November 22, 2024, of their intent to discontinue, as of January 1, 2025, distribution of the Access SARS-CoV-2 IgM that was issued an EUA on October 8, 2020, and amended on September 23, 2021, December 13, 2021, and February 7, 2022. Beckman Coulter, Inc. confirmed in an email dated December 10, 2024, in response to clarifying questions from FDA, that they would have ceased distribution of the authorized product effective January 1, 2025, and that they intended to have FDA revoke the EUA. FDA understands that as of the date of this letter there are no viable Access SARS-CoV-2 IgM 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 Beckman Coulter, Inc. has requested that FDA revoke the EUA for the Access SARS-CoV-2 IgM, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202631 for the Access SARS-CoV-2 IgM, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Access SARS-CoV-2 IgM 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