



May 22, 2024

Anita Targosz
Senior Director, Quality
Thermo Fisher Scientific
5823 Newton Drive
Carlsbad, CA, 92008
Re: Revocation of EUA200028

Dear Anita Targosz:

This letter is in response to the request from Mesa Biotech Inc. (a legal entity of Thermo Fisher Scientific), made by Thermo Fisher Scientific, Inc. on behalf of Mesa Biotech Inc. in a letter dated May 15, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Accula SARS-CoV-2 Test issued on March 23, 2020, amended on April 30, 2020 and August 30, 2020, reissued on January 7, 2021, amended on February 3, 2021 and September 23, 2021, and reissued on May 16, 2022, August 17, 2022 and March 15, 2023. Thermo Fisher Scientific Inc. indicated that they have discontinued commercialization and support 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 Accula SARS-CoV-2 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 Mesa Biotech Inc., through Thermo Fisher Scientific, Inc., has requested that FDA revoke the EUA for the Accula SARS-CoV-2 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200028 for the Accula SARS-CoV-2 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Accula SARS-CoV-2 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,

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration