February 14, 2022

Mohammad Kamal, MD
Omnipathology Solutions Medical Corporation
11 West Del Mar Blvd. Suite 203
Pasadena, CA 91105
Re: Revocation of EUA200170

Dear Dr. Kamal:

This letter is in response to requests from Omnipathology Solutions Medical Corporation received via email on February 7, 2022 and February 9, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the COVID-19 Assay by RT-PCR issued on June 17, 2020 and amended on December 28, 2020 and September 23, 2021. Omnipathology Solutions Medical Corporation confirmed that due to discontinuation of the commercial primer and probe products used in the Omni COVID-19 Assay by RT-PCR it has decided to discontinue use of this test but continue to offer COVID-19 testing using another FDA EUA-authorized test.

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 Omnipathology Solutions Medical Corporation has notified FDA that it is no longer using the Omni COVID-19 Assay by RT-PCR and requested FDA revoke the EUA for the Omni COVID-19 Assay 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 EUA200170 for the Omni COVID-19 Assay by RT-PCR, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Omni COVID-19 Assay 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration