



September 29, 2023

Kenneth Van Horn, PhD, D(ABMM)
Technical Director, Microbiology
Southern California Permanente Medical Group
Regional Reference Laboratories, Chino Hills
13000 Peyton Drive
Chino Hills, CA 91709

Re: Revocation of EUA203058

Dear Dr. Van Horn:

This letter is in response to the request from Southern California Permanente Medical Group, in a letter received May 11, 2023, that the U.S. Food and Drug Administration (FDA) terminate the EUA for the Kaiser Permanente High Throughput SARS-CoV-2 Assay, that includes the Kaiser Permanente Saliva Home Collection Kit, issued on April 19, 2021 and subsequently re-issued on September 21, 2021. Southern California Permanente Medical Group indicated that they have stopped distributing the Kaiser Permanente Saliva Home Collection Kit at the end of May 2023 and have also stopped receiving and processing the kits as of the date of this letter, and requested that the EUA be terminated.

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 Southern California Permanente Medical Group has requested that FDA terminate the EUA for the Kaiser Permanente High Throughput SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203058 for the Kaiser Permanente High Throughput SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Kaiser Permanente High Throughput SARS-CoV-2 Assay 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